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UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF CALIFORNIA

UNITED STATES OF AMERICA, *et al.*; *ex rel.* EVEREST PRINCIPALS, LLC,

Plaintiffs and Relator,

v.

ABBOTT LABORATORIES, INC. a/k/a ABBOTT LABORATORIES, ABBOTT CARDIOVASCULAR SYSTEMS INC., and ABBOTT VASCULAR INC.

Defendants.

Case No. 3:20-cv-0286-W-AGS

MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT OF DEFENDANTS' MOTION TO DISMISS FIRST AMENDED COMPLAINT

Date: October 18, 2021
Ctrm: 3C – Hon. Thomas J. Whelan

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INTRODUCTION

Abbott's groundbreaking MitraClip device treats patients suffering from mitral regurgitation, a life-threatening heart condition where the mitral valve fails to close properly, allowing blood to flow backwards in the heart. MitraClip and the minimally invasive procedure by which it is implanted in a beating heart pioneered a new field of non-surgical treatment so groundbreaking that a front-page *New York Times* article called MitraClip a "huge advance" that "sharply reduced deaths among patients with a grim prognosis."[1] Patients who previously had no good options now walk out of the hospital as soon as the morning after a short, non-surgical procedure. Since its introduction in 2013, MitraClip has saved, extended, and improved the lives of more than 100,000 patients worldwide.

When MitraClip was first approved, it was revolutionary. Even cardiologists had never seen anything like it and were unaware of its lifesaving benefits or how to identify good candidates for the treatment. To help its groundbreaking therapy reach patients, Abbott needed to educate cardiologists and other healthcare providers. Like virtually every medical device and pharmaceutical company, Abbott's educational and promotional efforts included speaker programs, conference participation, and business meetings, some of which were held in conjunction with a meal. These activities are not only routine, they are laudable—as physicians cannot use, or refer a patient to another doctor who can use, a device that they do not understand or in some cases even know about.

The original complaint—which Relator preemptively amended in the face of Abbott's Motion to Dismiss—sought to transform these everyday practices into a criminal "nationwide scheme" merely through pejorative labels such as "lavish" and "excessive," and bare legal conclusions such as "kickbacks." The First

[1] Gina Kolata, *Tiny Device Is a "Huge Advance" for Treatment of Severe Heart Failure*, N.Y. Times (Sept. 23, 2018), https://www.nytimes.com/2018/09/23/health/heart-failure-valve-repair-microclip.html.

Amended Complaint ("FAC") now adds pages of "facts" (*e.g.*, where meals occurred, their overall cost) but fails to fix the fundamental defects in Relator's claims. If Relator's pleading burden could be satisfied simply by providing rote details—such as publicly available payment data like that in Exhibit A to the FAC, or whether a lunch's attendees had soup or salad—every medical-device marketing program in the country could be transformed into an illegal kickback scheme. That is not the law. Stripped of fluff and conclusory labels, the FAC does not plausibly allege a criminal scheme. Instead, the allegations are perfectly consistent with ordinary educational activities about a novel, lifesaving treatment.

After investigating Relator's allegations, the federal government and 27 states declined to intervene in this case. *See* Dkt. No. 8. The Court should now dismiss the FAC in full, for failure to allege any violation of the federal False Claims Act ("FCA") or its state-law analogs.

FACTUAL BACKGROUND

I. Abbott's Innovative MitraClip Device

MitraClip is a revolutionary device that treats a debilitating, progressive, and potentially fatal condition known as mitral regurgitation, where the mitral valve of a patient's heart "fails to close tightly and thereby disrupts blood flow through the heart." FAC ¶ 58. Unlike risky open heart surgery, MitraClip utilizes a minimally invasive approach to repair the mitral valve in a beating heart. With a catheter, in a procedure known as Transcatheter Mitral Valve Repair ("TMVr"), the device is inserted through the femoral vein in the patient's leg. It is then guided into the heart's left ventricle, where the device grasps the two leaflets of the mitral valve, clipping them together to reduce the backflow of blood. Most MitraClip patients leave the hospital the day after their procedure.

The FDA approved MitraClip in 2013 for the treatment of degenerative (primary) mitral regurgitation, and in 2019 for the treatment of functional (secondary) mitral regurgitation. *See* FAC ¶ 62. When MitraClip was developed,

many cardiologists were unaware such a treatment existed, and others were skeptical of it. Today it has helped more than 100,000 patients worldwide, many of whom had no good alternative due to the risks of surgery.[2] In the United States, MitraClip remains the *only* FDA-approved transcatheter mitral valve repair alternative to surgery. Compl. ¶ 41.

To educate cardiologists and other healthcare providers about this novel treatment, Abbott provides clinical and safety information; information about patient screening, the burden on patients of mitral regurgitation, and the benefits of MitraClip; and other resources. Use of MitraClip in any particular patient occurs only with the approval of multiple independent decision makers involved in the patient's care. FAC ¶ 66. The patient must be a good candidate for the TMVr procedure, a cardiac surgeon and a cardiologist must choose to refer the patient for the procedure, the hospital where the procedure will occur must approve of the device's use, and the physician performing the procedure must decide to use the device and have the requisite expertise to do so.

For patients insured by government programs such as Medicare, physicians and hospitals may receive government reimbursement for uses of MitraClip that are reasonable and necessary—judgments made by multiple healthcare providers over whom Abbott has no control. *See* 42 U.S.C. § 1395y(a)(1). Relator does not allege a single unreasonable or unnecessary use of MitraClip. Nor does Relator allege that Abbott—which does not submit claims for reimbursement—had any involvement in claims submitted by physicians and hospitals.

II. Relator's First Amended Complaint

Relator is a Delaware LLC, formed for the apparent purpose of filing this

[2] Structural Heart Solutions, *MitraClip TMVr: The Leader in Transcatheter Mitral Valve Repair Technology*, https://www.structuralheartsolutions.com/us/structural-heart-products-solutions/mitral-valve-mitraclip/overview/#isi (last visited Sept. 16, 2021).

action while concealing the identity of the person behind it. Relator's sole member was an Abbott employee from August 2015 to April 2017. FAC ¶ 5. The original complaint was mostly boilerplate, and Abbott filed a motion to dismiss. *See* Dkt. Nos. 1, 30. Instead of opposing the Motion, Relator filed the FAC. *See* Dkt. Nos. 31, 35. Even with the added length of the FAC, factual material makes up a minority of the pleading, which does not begin to address *how* Abbott purportedly broke the law until page 52, and ends with an 80-page copy-and-paste exercise setting forth 31 substantively identical counts under the FCA and its state-law analogs (the "State FCAs").

The original complaint focused on the theory that Abbott provided "illegal kickbacks" to physicians and hospitals through "honoraria for sham speaker programs and events, free lavish meals, [and] cocktail parties" to induce physicians and hospitals to use MitraClip. Compl. ¶ 2; *see also id.* ¶¶ 44–79. The FAC adds a smorgasbord of theories: a purported "practice-building remuneration scheme" (FAC ¶¶ 86–90), an alleged partnership with doctors and hospitals through "clinical trials" that is never fully explained (*id.* ¶¶ 103–04), and supposedly improper "lobbying" of the Centers for Medicare and Medicaid Services ("CMS") (*id.* ¶¶ 111–15). But the FAC adds few, if any, facts that can support these theories.

The FAC does add "facts" such as details about purportedly improper meals, and publicly available claims and payment data for 28 physicians. *Id.* ¶ 84, Ex. A. But despite the continued liberal use of labels like "kickbacks," Relator never alleges with particularity any facts that connect these details in a way that plausibly alleges anything unlawful. Instead, Relator's implicit theory seems to be that if it can name the restaurant at which a meal occurred, or allege that Abbott has previously employed an implanting physician in any capacity, the Court can simply infer that a criminal act took place.

For all its added length, the FAC still fails to allege even a single actually false claim with particularity, as required by Rule 9(b). The FAC also fails to

allege how Abbott, which indisputably does not submit claims for reimbursement, caused any false claims to be presented. Nor does the FAC plead facts that support a plausible inference of any connection between Abbott's alleged wrongdoing and any supposedly false claims. Further, the FAC fails to plausibly allege with particularity any Anti-Kickback Statute violation. Nor does it clear the high bar set by the two scienter requirements Relator must meet. For each of these failures, the FAC should be dismissed with prejudice.

ARGUMENT

I. Legal Standards

A. The False Claims Act and the Anti-Kickback Statute

The FCA imposes liability on a person who "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval" to the federal government, "knowingly . . . causes to be made or use[d] a false record or statement material to a false or fraudulent claim" for federal payment, or "conspires to commit a violation [as described above]." 31 U.S.C. § 3729(a)(1). Not "an all-purpose antifraud statute," the FCA "attaches liability, not to the underlying fraudulent activity or to the government's wrongful payment, but to the claim for payment." *Universal Health Servs., Inc. v. U.S. ex rel. Escobar*, 136 S. Ct. 1989, 2003 (2016); *U.S. ex rel. Kelly v. Serco, Inc.*, 846 F.3d 325, 333 (9th Cir. 2017). To state an FCA claim, a relator must allege with particularity: "(1) a false statement or fraudulent course of conduct, (2) made with scienter, (3) that was material, causing (4) the government to pay out money or forfeit moneys due." *U.S. ex rel. Hendow v. Univ. of Phx.*, 461 F.3d 1166, 1174 (9th Cir. 2006).

A claim "resulting from" a violation of the federal Anti-Kickback Statute ("AKS") is a false claim for purposes of the FCA. 42 U.S.C. § 1320a-7b(g). To proceed on such a theory, the relator "must establish a connection between the alleged kickback scheme and actual false claims submitted to the government." *U.S. ex rel. Gough v. Eastwestproto, Inc.*, No. CV 14-465, 2018 WL 6929332, at *5

(C.D. Cal. Oct. 24, 2018). In particular, § 1320a-7b(g) "imposes a requirement of but-for causation"—i.e., that the alleged claim would not have occurred absent the alleged AKS violation. *Burrage v. United States*, 571 U.S. 204, 214 (2014) (construing the statutory phrase "results from"). Stating an AKS violation, in turn, requires pleading that the defendant (1) "knowingly and willfully" (2) offered or paid remuneration, (3) "to induce" the purchase or ordering of products or items for which payment may be made under a Federal healthcare program. 42 U.S.C. § 1320a-7b(b)(2)(B). The AKS, as a criminal statute, is construed narrowly. *See, e.g.*, *United States v. Harrell*, 530 F.3d 1051, 1058 n.3 (9th Cir. 2008).

B. Pleading standards

To survive a motion to dismiss, a complaint must allege "sufficient factual matter, accepted as true, to state a claim for relief that is plausible on its face." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quotation marks omitted). "[L]abels and conclusions"—such as "kickback" or "unlawful"—"will not do." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007). Nor is a court "bound to accept as true a legal conclusion couched as a factual allegation." *Id.*

Because an FCA claim alleges fraud, it must satisfy Rule 9(b)'s heightened pleading standards. Factual allegations must be stated with "particularity," including "the who, what, when, where, and how of the misconduct charged." *U.S. ex rel. Solis v. Millennium Pharms., Inc.*, 885 F.3d 623, 628–29 (9th Cir. 2018) (quoting *Ebeid ex rel. U.S. v. Lungwitz*, 616 F.3d 993, 998 (9th Cir. 2010)). Alleging a generalized scheme is insufficient. A relator must allege "particular details of a scheme to submit false claims paired with reliable indicia that lead to a strong inference that claims were actually submitted." *Ebeid*, 616 F.3d at 998–99.

II. Relator's FCA Claims Fail

A. Relator fails to allege the presentment of a false claim.

"[T]he [FCA] attaches liability" to the "claim for payment," *U.S. ex rel. Cafasso v. Gen. Dynamics C4 Sys., Inc.*, 637 F.3d 1047, 1055 (9th Cir. 2011), and

thus "[e]vidence of *an actual false claim* is 'the sine qua non of a False Claims Act violation.'" *U.S. ex rel. Aflatooni v. Kitsap Physicians Serv.*, 314 F.3d 995, 1002 (9th Cir. 2002) (emphasis added). Relator's original complaint did not allege that Abbott knowingly presented or caused to be presented any claim for payment, let alone assert facts setting out the basic who, what, and when of claims actually submitted. *See* Mot. to Dismiss at 9–12 (July 29, 2021). On this central point, the complaint was devoid of allegations giving rise to "a strong inference that [false] claims were actually submitted." *Ebeid*, 616 F.3d at 998–99.

Relator declined to oppose Abbott's Motion to Dismiss and amended the complaint instead—yet the FAC does nothing to cure these defects. Relator has, to be sure, larded the FAC with more instances of meals that purportedly took place with implanting and referring doctors, including the meals' cost and location. *See* FAC ¶ 84. The FAC also adds allegations about so-called "practice-building events," in which implanting doctors allegedly would increase their usage of MitraClip "in exchange" for Abbott hosting meals for referring doctors (purportedly so that those doctors would refer patients to the implanting doctors). *See id.* ¶¶ 79, 86–90, 96. In an attempt to support the conclusory legal assertion that supposed "practice building" events amounted to improper "kickbacks," the FAC attaches a one-page chart that claims to list Medicare reimbursement amounts that certain doctors received for performing procedures. *See* FAC Ex. A.

But for all their prolixity, these new allegations cannot fill the gap at the core of Relator's claims: Relator still fails to allege that Abbott knowingly presented or caused to be presented any actual false claim. To state an FCA claim, it is not enough merely to allege the details of meals, label them as illegal "practice building," and allege that doctors ultimately *received* reimbursements for this type of procedure. Relator must instead both identify false claims with particularity and *link* those claims to supposed kickbacks, by alleging with specificity that actual false claims were submitted as a result of the purportedly improper conduct. FCA

claims lacking such details must be dismissed, as numerous courts have held, including with kickback theories similar to what Relator alleges here.

In *U.S. ex rel. Solis v. Millennium Pharms., Inc.*, 445 F. Supp. 3d 786 (E.D. Cal. 2020), for example, the relator alleged that defendants "funnel[ed] millions of dollars in grants, [speaker] honoraria, and meals to physicians in order to induce [certain drug] prescriptions" in violation of the AKS. *Id.* at 791 (quotation marks omitted). The court dismissed the complaint because the relator "fail[ed] to identify even a single claim" submitted pursuant to the alleged scheme. *Id.* at 799–801 (citing *Solis*, 885 F.3d at 629 (affirming dismissal of complaint's earlier version due to relator's failure to "identify a single claim")). Similarly, in *U.S. ex rel. Dan Abrams Co. LLC v. Medtronic, Inc.*, No. CV15-01212, 2017 WL 4023092 (C.D. Cal. Sept. 11, 2017), the relator alleged a "kickback" scheme in which defendants supposedly paid for "food" and "arranged conferences and speaking events" to induce physicians "to purchase or use" certain medical devices. *Id.* at *11. The court dismissed the complaint because the relator did not allege that "a claim was submitted to a government health care program for payment" as a result of "the supposed inducements." *Id.*

So too here. The FAC "has failed to identify a single claim submitted pursuant to [an alleged] scheme," or to "provid[e] reliable indicia supporting a strong inference that such claims were submitted." *Solis*, 885 F.3d at 628–29; *see, e.g.*, *Ebeid*, 616 F.3d at 999.

Relator's generic allegations about providers *receiving* government reimbursement, while skirting the key element of presenting *false claims*, do not suffice. *See* FAC ¶¶ 92–96, 102. Exhibit A to the FAC purports to list Medicare reimbursements for procedures performed by various doctors. But Relator does not (and could not) allege that *all* of these procedures resulted from alleged kickbacks, much less make such a bold assertion with the requisite particularity. "[C]harts of publicly available information regarding Medicare and Medicaid

reimbursements"—such as Relator's Exhibit A—"do not remedy the disconnect between the alleged underlying conduct and any actual false claims for reimbursement." *Health Choice Grp., LLC v. Bayer Corp.*, No. 17-cv-126, 2018 WL 3637381, at *30, *49–50 (E.D. Tex. June 29, 2019), *report and recommendation adopted*, 2018 WL 3630042 (E.D. Tex. July 31, 2018). Top-line allegations of doctors receiving reimbursement—skipping the critical step of false claims being presented—are "perfectly consistent with conduct that is not wrongful," and thus "sto[p] short of the line between possibility and plausibility of entitlement to relief." *Twombly*, 550 U.S. at 557; *U.S. ex rel. Reilly v. Adventist Health*, No. 17-CV-00613, 2020 WL 2522114, at *8 (E.D. Cal. May 18, 2020).

Indeed, "[c]ourts have repeatedly held that merely pleading that a defendant performed a large number of procedures that allegedly included some false claims does not constitute reliable indicia of the submission of actual false claims." *U.S. ex rel. Dunlap v. Alaska Radiology Assocs., Inc.*, No. 14-CV-00143, 2017 WL 6048167, at *4 & n.38 (D. Alaska Mar. 31, 2017). For example, in *Dunlap*, the court granted a motion to dismiss, holding that alleging the use of medical "equipment on at least 6,000 procedures" was not enough to allege "actual false claims." *Id.* Likewise, in *U.S. ex rel. Grayson v. Genoa Healthcare*, No. C09-506Z, 2011 WL 2670079 (W.D. Wash. July 6, 2011), the court granted a motion to dismiss because an allegation that the defendant pharmacy "fill[ed] approximately 1,500–2,000 prescriptions for Medicare beneficiaries per month" was not sufficient to state a false claim. *Id.* at *2–3. And in *U.S. ex rel. Frazier v. IASIS Healthcare Corp.*, 812 F. Supp. 2d 1008 (D. Ariz. 2011), the court held that the allegation that a hospital performed over 400 surgeries a year was insufficient to allege a false claim. *Id.* at 1012, 1016–18. The court held that the relator's bare allegation—that a particular doctor "referred Medicare patients" to a specific hospital that then "submitted claims for Medicare patients referred by" that doctor—was "conclusiv[e]" and "pl[ed] no facts" to state an AKS-based FCA claim. *Id.* at 1016.

Relator's FAC has the same fundamental flaw and should be dismissed.

B. Relator fails to allege that Abbott induced any false claim.

Even if Relator had sufficiently alleged the submission of false claims by others, Relator has not adequately alleged that Abbott *induced* such claims. Accepting *arguendo* that its allegations about "patient-practice building events," "free meals," and "sham speaker program[s]" describe potential kickbacks (FAC ¶¶ 64–65)—they do not, *see infra* § II.C—the FAC fails to allege with plausibility and particularity that such events *actually resulted in* false claims. For all its appearance of heft, the FAC provides no "details linking the alleged scheme to any claim submitted to a federal healthcare program." *Solis*, 885 F.3d at 629.

For instance, Relator lists some meals that allegedly induced doctors to refer patients to implanting specialists, who would then supposedly use MitraClip and receive government payment. FAC ¶¶ 71, 84. But *none* of these allegations is paired with any specifics about referrals made, procedures done, or false claims submitted after—let alone "but for"—those purported inducements. Nor can fraudulent kickbacks simply be presumed. It defies common sense to conclude that a meal for a doctor as part of a business meeting—a routine industry practice—would be anything more than a "token gesture" of goodwill, much less that the meal constitutes criminal conduct. *Hart v. Publicis Touchpoint Sols., Inc.*, 821 F. App'x 557, 562–63 (6th Cir. 2020); *Jones-McNamara v. Holzer Health Sys.*, 630 F. App'x 394, 401–04 (6th Cir. 2015).

Courts routinely reject the FAC's implicit premise that meals are *per se* illegal. In *Hart*, for example, the court dismissed the "contention that 28 extra sandwiches . . . constituted a kickback intended to induce the doctors at Lansing Pediatrics to prescribe Quillivant more often." 821 F. App'x at 562–63. Similarly, in *Jones-McNamara*, the court, finding that a potential AKS claim was not "objectively reasonable" as a matter of law, emphasized that "[i]t cannot plausibly be suggested that one jacket valued at $23.50 . . . and occasional servings of

hotdogs and hamburgers . . . could induce a reasonable person to prefer one provider over another." 630 F. App'x at 401–04. And in *Solis*, the court held that the relator could not "sweepingly assert" that meals "necessarily . . . resulted in false claims when none have been identified." 445 F. Supp. 3d at 799–800. This principle has particular force here, where—as Relator previously alleged (Compl. ¶ 41)—MitraClip is the *only* FDA-approved transcatheter device for treating mitral regurgitation. Relator's across-the-board failure to specifically allege what happened *after* any meeting that included a meal, much less that false claims were submitted *as a result*, dooms the FAC.

Relator's single table of alleged MitraClip procedures cannot supply the missing link. FAC ¶ 96. A search of the FAC for each of the "referring physicians" listed in the chart yields no allegation in which any made a referral after a purported kickback.[3] Indeed, Relator never alleges *but-for causation*, i.e., that any claim for payment would not have resulted absent the alleged kickbacks. *See Burrage*, 571 U.S. at 214. Nor does Relator appear able to do so, since the TMVr procedure requires the approval of multiple independent parties (*infra* § II.C), and the FAC never alleges any instance where a TMVr procedure was not in the patient's best interests and medically necessary. Relator even fails to allege with specificity any "connection" between the purported kickback schemes and a false claim. *U.S. ex rel. Greenfield v. Medco Health Sols., Inc.*, 880 F.3d 89, 99–100 (3d Cir. 2018).

Relator cannot cure this deficiency by generically alleging that implanting doctors performed procedures on patients "from the referring physicians that Abbott targeted and provided inducements to make patient referrals[.]" FAC ¶ 91; *see also id.* ¶¶ 92, 94. Without connecting alleged inducements to actual referrals

[3] This omission is particularly telling given that Relator claims to have insight into purported referrals. *See* FAC ¶ 84(k), (l), (p), (u).

(let alone procedures and false claims), such a conclusory "kickback" claim fails to allege criminal wrongdoing, much less overcome the far more plausible explanation that Abbott hosted meetings that included meals to educate doctors.

Moreover, Relator also fails to allege "temporal proximity" between the events set forth in the FAC and specific false claims. *Id.*; *see U.S. ex rel. Sikkenga v. Regence Bluecross Blueshield of Utah*, 472 F.3d 702, 728 n.34 (10th Cir. 2006) (affirming dismissal of complaint that did not "tie any specific claim . . . to this series of events," because "a generalized daisy chain of causation does not meet the requirements of Rule 9(b)"), *abrogated on other grounds by Cochise Consultancy, Inc. v. U.S. ex rel. Hunt*, 139 S. Ct. 1507 (2019). For the small handful of "referring physicians" for whom the FAC appears to allege a meal provided by Abbott (*compare* ¶ 96, *with* ¶ 84(b), (k), (l), (p), (u)), the procedures had all been performed *before*—in some cases many months before—the purported meal occurred, and those procedures thus could not plausibly have been induced by the alleged meals. Although Relator alleges that *one* of those meals was a "reward" for a patient referral (¶ 84(b)), that conclusory, fact-free label carries no weight.

Other courts in this Circuit have dismissed complaints that took the same approach as Relator attempts here. In *U.S. ex rel. Dan Abrams Co. v. Medtronic, Inc.*, No. CV15-01212, 2018 WL 5266863 (C.D. Cal. June 7, 2018), the relator alleged that a medical device company used "dinners and conferences" to induce doctors to use certain spinal implant devices. The court dismissed the complaint because it "failed to allege a clear link between any alleged inducements and the false claims." *Id.* at *5–8. Similarly, in *Adventist Health*, the court dismissed the complaint because, although it alleged that "'tens of thousands' of referrals" were made "resulting in hundreds of millions of dollars in medical care over the past decade," it failed to "provide a single example of a referral *that took place at [defendant's] direction*." 2020 WL 2522114, at *8 (emphasis added); *see also U.S. ex rel. King v. Solvay Pharms., Inc.*, 871 F.3d 318, 332 (5th Cir. 2017) ("[I]t would

be speculation to infer that compensation for professional services legally rendered actually caused the physicians to prescribe Solvay's drugs to Medicaid patients."). For the same reasons, dismissal is equally warranted here.

C. Relator fails to plausibly allege causation with particularity.

Compounding the FAC's failure to allege the submission of any false claims, Relator also fails to properly plead that Abbott's alleged misconduct actually "cause[d] to be presented" a false claim for payment. *United States v. Mackby*, 261 F.3d 821, 827 (9th Cir. 2001). The defendant must have "knowingly *assisted in* causing the government to pay claims which were grounded in fraud[.]" *Id.* (emphasis in original).

Here, Relator has not plausibly alleged causation where Abbott's device "is currently the only FDA-approved TMVr device," as Relator previously alleged. Compl. ¶ 41. Although Relator removed that admission from the FAC (presumably in response to this argument), the FAC still does not dispute the fact. *See Royal Primo Corp. v. Whitewater West Indus., Ltd.*, No. 15-cv-4391, 2016 WL 1718196, at *3 (N.D. Cal. Apr. 29, 2016) ("[W]hen evaluating an amended complaint, the court may also consider the prior allegations as part of its context-specific inquiry based on its judicial experience and common sense to assess whether an amended complaint plausibly suggests an entitlement to relief") (quotation marks omitted). With no other FDA-approved options for this breakthrough technique, it is far more plausible that physicians' usage of, or referrals for, MitraClip reflects their independent medical judgment regarding the best treatment for their patients. Particularly given the lack of factual detail provided by the FAC, Relator's contrary theory is implausible. *See Eastwestproto, Inc.*, 2018 WL 6929332, at *7 (dismissing claim because "[r]elators have not alleged any facts to support their conclusory statement that any increase in calls cannot be attributable to market forces"); *U.S. ex rel. Suarez v. AbbVie, Inc.*, No. 15-C-8928, 2019 WL 4749967, at *10–12 (N.D. Ill. Sept. 30, 2019) (dismissing "kickback" allegations that "just as

easily allow for an inference that doctors prescribed Humira to government payor patients because they thought the drug was medically necessary"). The FAC's acknowledgment of a "growing population of cardiac patients" eligible for MitraClip also undermines causation. FAC ¶ 64. The existence of one or more "obvious alternative explanation[s]" for usage of Abbott's device precludes Relator from asking the Court to draw a plausible inference that improper kickbacks were the cause. *See Cafasso*, 637 F.3d at 1056–57.

Moreover, several independent actors—none of whom Relator accuses of any wrongdoing—must approve of MitraClip's use. Hospitals must order it, doctors must refer their patients for the TMVr procedure, and implanting doctors must then use MitraClip. *See* FAC ¶ 66. Indeed, as per the FDA label for the device, its use must be approved in advance "by a heart team, which includes a cardiac surgeon experienced in mitral valve surgery and a cardiologist experienced in mitral valve disease[.]"[4] Without particularized facts that suggest Abbott's alleged conduct compromised the independent medical judgments of all of these intervening actors, "[t]here are too many intervening events" for the allegations to plausibly state that Abbott's purported kickbacks caused the alleged false claims. *Hampton v. Steen*, No. 12-cv-00470, 2017 WL 11573592, at *7 (D. Or. Nov. 13, 2017); *see, e.g.*, *U.S. ex rel. Bane v. Breathe Easy Pulmonary Servs., Inc.*, 597 F. Supp. 2d 1280, 1291–92 (M.D. Fla. 2009) (requiring "strong and direct causal link" between defendant's actions and false claims). Despite knowing of this deficiency, Relator does nothing to cure it in the FAC—which, for example, still does not contain a single allegation regarding cardiac surgeons, for whom the decision to implant a MitraClip is a decision to forego performing surgery (*i.e.*, a decision against their own interests). Absent specific facts supporting causation, the FAC cannot make the leap from the

[4] *MitraClip NT Clip Delivery System* 4 (Mar. 4, 2019), https://www.accessdata.fda.gov/cdrh_docs/pdf10/P100009S028D.pdf (Section 1, Indication for Use).

alleged meals that were part of a business discussion—routine events that introduce doctors to the benefits of a medical device—to an inference of criminal misconduct.

Nor can Relator establish causation through the generic allegation that Abbott sought to boost sales. FAC ¶¶ 69–77, 81–83. As courts have held, there is nothing improper about tracking sales data or working to sell a product. *See, e.g.*, *United States v. Novartis Pharms. Corp.*, No. 13-CV-3700, 2020 WL 1436706, at *6 (S.D.N.Y. Mar. 24, 2020) (dismissing complaint alleging that drug company engaged in a "return-on-investment analysis" without "clearly alleg[ing] what actions, if any, [it] took on the basis of [such] analysis"). Relator's allegations—heavy on labels but light on facts—fail to tip the balance of plausibility in favor of a nefarious scheme as opposed to lawful education and marketing.

D. Relator fails to adequately allege illegal kickbacks.

Several independent grounds warrant dismissal before the Court needs to even reach the sufficiency of Relator's underlying allegations about "kickback" schemes. *See supra* § II.A–C. Like the original complaint, however, Relator also fails to allege specific facts to make out a plausible kickback scheme.

As discussed in Abbott's initial Motion to Dismiss, Relator's original complaint failed to assert specific facts to support alleged kickback schemes centering on purported "lavish meals" and honoraria for "sham speaker programs" provided to doctors and hospitals as inducements to increase MitraClip usage. *See* Mot. to Dismiss at 15–20. As the Motion to Dismiss made clear, the original complaint failed to provide "'the who, what, when, where, and how' of the misconduct charged," *Vess v. Ciba-Geigy Corp. USA*, 317 F.3d 1097, 1106 (9th Cir. 2003), instead just lobbing vague accusations of "free" or "lavish" meals.

Confronted with this absence of detail, Relator now pivots to a new theory that centers on a purported "practice-building remuneration scheme" (FAC ¶¶ 86–90). The FAC still alleges improper meals with implanting physicians and referral physicians—now with information about dates, locations, and costs, *id.* ¶ 84—but

also tacks on a few more kickback theories, stating that Abbott improperly induced doctors and hospitals through "clinical trials" (*id.* ¶¶ 103–04), "CMS lobbying" (*id.* ¶¶ 111–15), and "marketing events and consulting services" (*id.* ¶ 2). But none of these new theories adequately alleges improper kickbacks.

Relator's new allegations still lack the necessary particulars to state a kickback claim—such as specific facts supporting alleged improper "practice building," facts about meals that could show improper inducement, facts about whether the alleged speaker honoraria exceeded fair market value, and facts supporting kickbacks through "clinical trials" and "CMS lobbying." Nor does Relator allege any facts describing supposed free marketing or consulting services. At bottom, the FAC relies merely on generic labels, which fall far short of the particularity required to adequately allege a fraud-based claim of criminal misconduct. *See Druding v. Care Alts., Inc.*, 164 F. Supp. 3d 621, 633–34 (D.N.J. 2016) (dismissing complaint where relators' claims "fail to detail at least examples of what gifts, meals, and other perks were offered by whom, to whom, and when"); *Synovus Bank v. Okay Props., LLC*, No. 11-cv-330, 2012 WL 3745280, at *7 (W.D.N.C. Aug. 28, 2012).

1. No facts support a "practice-building remuneration scheme."

Under this theory, Abbott allegedly "identifie[d] and develop[ed] partnerships with targeted implanting physicians and hospitals, providing them with illegal remuneration in exchange for using the MC Device for TMVR procedures." FAC ¶ 79. The "illegal remuneration," Relator asserts, took the form of "helping [implanting physicians] to build their practices." *Id.* ¶ 86.

But Relator's "practice building" allegations are too vague to satisfy Rule 9(b). Merely stating that Abbott sought to "***build business***" does not suffice (nor does italicizing the phrase in bold magically make the conduct unlawful). FAC ¶ 70; *see also id.* ¶ 64. Stripped of conclusory labels, the facts alleged—Abbott hosting programs for doctors to discuss MitraClip's benefits—show nothing more

than routine educational activity "perfectly consistent with [lawful] conduct" to inform doctors about a novel medical device that has proven to better patients' lives. *Adventist Health*, 2020 WL 2522114, at *8.

The FAC also never actually explains what it means by "practice building," instead just suggesting that any conduct to which Relator assigns that label is *per se* unlawful. But the sources Relator cites to suggest "practice building" is improper—an assortment of articles and past FCA settlements—do not paint with so broad a brush. Rather, they focus narrowly on how the AKS can be violated with "free advertising assistance," "educational grants," "subsidie[s] [for] the cost of electronic medical records," and the like, in return for using a manufacturer's device. FAC ¶ 85; *see, e.g.*, DeLaurentis, Hooker and DePrince, *Anti-Kickback Statute Enforcement Year in Review and Outlook for 2021* (Mar. 25, 2021). Those practices are not alleged and, in fact, have nothing to do with the facts alleged here.

Relator instead asserts in conclusory fashion that Abbott illegally facilitated referrals to implanting physicians "*in exchange* for [their] performing the TMVr procedure with MC devices." FAC ¶ 86 (emphasis added). Missing from the FAC, however, are any "concrete details" plausibly supporting a claim of an improper *exchange*.[5] *Novartis*, 2020 WL 1436706, at *5. Indeed, beyond generalized assertions, there is not even an allegation of any specific referral made, procedure done, or false claim submitted after the purported "practice building" events took place. *See supra* § II.B; *Health Choice Grp.*, 2018 WL 3637381, at *50 (dismissing complaint where "Relators do not allege any specific instance in which one of the Covered Products was prescribed or a claim was submitted as a result of the three schemes"). The absence of such concrete facts is fatal to the FAC.

The "practice-building" allegations regarding supposed inducements to

[5] Elsewhere in the FAC, Relator describes meals that were allegedly provided "in exchange for *potential* patient referrals"—admitting that Relator does not know whether any referrals resulted. FAC ¶¶ 71–72 (emphasis added).

hospitals are even thinner. Relator alleges that Abbott "paid hundreds of thousands of dollars to implanting hospitals in the form of consulting fees, free meals, space rental, and facility fees." FAC ¶ 97. Whereas the original complaint made this same allegation "[u]pon information and belief" (Compl. ¶ 67)—without providing the belief's factual basis, as is required, *see Eastwestproto, Inc.*, 2018 WL 6929332, at *5—the FAC simply removes the "information and belief" caveat. That strategic excision does not save the theory from dismissal. The FAC still fails to allege even the most basic facts about these "consulting fees, free meals, space rental, and facility fees," such as when they occurred, the amounts, or even *which hospitals* participated in the supposed scheme.

Instead, the FAC offers a conclusory claim that "hospital administrators" were invited to a "lavish 2017 TMVr Summit" (FAC ¶ 98) and a lengthy description of marketing materials for hospitals (*id.* ¶ 100). But labeling an event as "lavish" is conclusory, and describing marketing materials does not come close to even suggesting an illegal kickback. *See Hanlester Network v. Shalala*, 51 F.3d 1390, 1398 (9th Cir. 1995) ("mere encouragement" to use a product is not improper); *U.S. ex rel. Fontanive v. Caris Life Scis., Inc.*, No. 10-CV-02237, 2013 WL 11579021, at *11–12 (N.D. Tex. Oct. 23, 2013) (dismissing complaint that defendant paid kickbacks by hosting a "P4 Summit Meeting" and offering "meals" and "luxury hotel accommodations," where the "conclusory allegation[s]" "do not reliably indicate that any physicians were actually induced to refer Medicare patients for [defendant's] services"). And in all events, the FAC provides no particularized allegation about who attended the summit or what even took place there. Rule 9(b) requires far more.

In connection with its deficient practice-building claims, the FAC also alleges that referring physicians were improperly induced to refer their patients to implanting physicians through "lavish meals," and that implanting physicians were improperly induced to use MitraClip through honoraria payments for speaker

programs. *See* FAC ¶¶ 84, 90. But these allegations fail too. With respect to the meal allegations, the FAC now alleges a string of meals along with their total cost—yet tellingly never alleges how many people attended those meals. *See id.* ¶ 84. A meal for two that costs $700 is not the same as a meal for a group of twenty. By omitting this information (which Relator appears to have access to), the FAC's labels of "lavish meals" fail to overcome the far more plausible explanation that Abbott hosted routine educational programs about MitraClip for groups of doctors that included meals. The façade of specificity created by extraneous details, such as restaurant names and items ordered, does not remedy this fatal omission.

With respect to the allegations about speaker programs, the FAC is even weaker. At these programs, doctors experienced with MitraClip would be paid to speak to other doctors to educate them about how the device worked and the benefits it offered. Speaker programs are commonplace in medicine, and alleging that honoraria payments were illegal kickbacks requires providing concrete details to support that inference. *Novartis*, 2020 WL 1436706, at *5.

For one thing, a complaint must provide specificity about the programs themselves, such as the "names of the speaker and the audience members" or "the content of the speakers' presentations." *Id.* (dismissing complaint for lacking such specificity). For another, a complaint must adequately allege that any payments to speakers exceeded what would have been fair market value for their time and services—as is necessary to allege that the payments were illegal "remuneration" under the AKS. *See, e.g.*, *Adventist Health*, 2020 WL 2522114, at *7 (dismissing complaint for failing to allege "market rates"); *Eastwestproto, Inc.*, 2018 WL 6929332, at *8 (dismissing complaint "because no comparative . . . rates are alleged"); *United States v. Ctr. for Diagnostic Imaging, Inc.*, 787 F. Supp. 2d 1213, 1223 (W.D. Wash. 2011) (dismissing complaint because "fair market value" and thus "remuneration" was not alleged).

Here, like the original complaint, the FAC is devoid of facts that could meet these requirements. Relator instead merely alleges that three implanting doctors (Drs. M.P., H.N., and A.P.) "received several thousand dollars" in the form of "speaker program honoraria and lavish meals," FAC ¶¶ 90, 92, 94—exactly what Relator alleged originally "upon information and belief" (Compl. ¶ 57), but now without that qualifier. This deletion cannot sustain Relator's theory when Relator still has not alleged how these amounts exceeded fair market value. *See Eastwestproto, Inc.*, 2018 WL 6929332, at *5.

Similarly, with respect to an alleged October 2016 speaker program for which a Dr. R.G. was purportedly paid $2500 to speak to "a group of family practice physicians" in San Diego, FAC ¶¶ 107–08, Relator never alleges that this fee exceeded fair market value. *See, e.g.*, *U.S. ex rel. Brown v. Celgene Corp.*, 226 F. Supp. 3d 1032, 1053–55 (C.D. Cal. 2016) (rejecting AKS-based FCA claims where there was no showing that "Celgene's payments [for speaker programs] were excessive compared to the honoraria provided by other physician speaker programs"). Without such an allegation, one cannot leap to the conclusion that this payment constituted an illegal kickback. Nor is it sufficient for Relator to assert that Dr. R.G.'s speaker presentation was "non-educational" or "non-substantive"—without providing particularized facts that plausibly support those labels. FAC ¶ 125. Relator's liberal use of the label "sham" when referring to Abbott's speaker programs is simply a "legal conclusion" masquerading as fact—not a substitute for the "concrete details" Rule 9(b) requires. *Twombly*, 550 U.S. at 555; *Novartis*, 2020 WL 1436706, at *5.

2. No facts support a scheme using "clinical trials."

The FAC also adds a theory that Abbott used "clinical trials" to "promote [MitraClip] through partner physicians" and hospitals and "to secure the physicians' loyalty," "promis[ing] physicians who were implanting [MitraClip] that they would be part of future clinical trials[.]" FAC ¶¶ 103–04. But the FAC offers

no details to support these far-fetched allegations. Nowhere does the FAC allege what kinds of clinical trials were being conducted, which doctors and hospitals received or were promised clinical trials, who from Abbott discussed clinical trials with doctors or hospitals, or how these clinical trials served as inducements. Clinical trials are commonplace and critical to the development of novel medical devices, and Relator offers no facts to plausibly show that trials were used to "bribe" doctors. The Court should reject this undeveloped theory, which lacks any particularized facts about the basic "'who, what, when, where, and how' of the misconduct charged." *Vess*, 317 F.3d at 1106.

3. No facts support a scheme involving "CMS lobbying."

Grasping now at straws, Relator ventures another form of inducement, alleging that it was improper for Abbott to purportedly work with doctors to seek "increase[d] coverage" for MitraClip from CMS. *See* FAC ¶ 111. But Relator never explains how Abbott's efforts to expand coverage served to improperly induce physicians to use MitraClip. Nor does Relator even specify which doctors or hospitals increased their use of MitraClip or submitted false claims as a result of purported "CMS lobbying." *Id*. Without any particularity, Relator's vague contentions that lobbying provided the basis for improper inducements remain patently implausible. Stripped of accusatory labels (and overlooking *arguendo* the lack of particularized facts), what Relator demeans as a criminal scheme—advocacy efforts to expand healthcare coverage of a groundbreaking medical device—is in fact exactly the sort of petitioning activity squarely protected by the First Amendment. *See, e.g.*, *Holley v. Sea Farms of Norway, Inc.*, 920 F.2d 936, 1990 WL 200237, at *1 (9th Cir. Dec. 7 1990) ("The Supreme Court has stated that individuals may lobby or make other focused efforts to obtain administrative results as an exercise of their first amendment rights.") (citing *Allied Tube & Conduit Corp. v. Indian Head, Inc.*, 486 U.S. 492, 499 (1988)).

E. Relator fails to plausibly allege scienter.

The FAC also fails to satisfy the "rigorous" requirements for alleging scienter. *Escobar*, 136 S. Ct. at 2002. "Although Rule 9(b) allows plaintiffs to allege scienter generally, scienter must still be pled with plausibility under Rule 8(a)." *Adomitis ex rel. U.S. v. San Bernardino Mountains Cmty. Hosp. Dist.*, 816 F. App'x 64, 66 (9th Cir. 2020) (citation omitted). And because Relator is using a purported AKS violation as a predicate for the alleged FCA violation, Relator must satisfy *both* statutes' scienter requirements. The FAC's allegations satisfy neither.

1. Relator does not allege scienter under the Anti-Kickback Statute.

Liability under the AKS requires that a party *knowingly and willfully* paid remuneration to induce another individual to use a medical device that may result in disbursement of federal healthcare funds. 42 U.S.C. § 1320a-7b(b)(2). Congress added this *mens rea* requirement to address concerns "that criminal penalties may be imposed under current law to an individual whose conduct, while improper, was inadvertent." H.R. Rep. No. 96-1167, at 59 (1980), *as reprinted in* 1980 U.S.C.C.A.N. 5526, 5572. This heightened scienter requirement puts the burden on a plaintiff to plead and prove the defendant's knowledge that it acted unlawfully. *Hanlester Network*, 51 F.3d at 1400. Indeed, the Supreme Court has held that, "[a]s a general matter, when used in the criminal context, a 'willful' act is one undertaken with a 'bad purpose.' In other words, in order to establish a 'willful' violation of a statute, 'the [plaintiff] must prove that the defendant acted with knowledge that his conduct was unlawful.'" *Bryan v. United States*, 524 U.S. 184, 191–92 (1998) (quoting *Ratzlaf v. United States*, 510 U.S. 135, 137 (1994)).

Relator's allegations fail this standard, because any inference of criminal intent based on the FAC's threadbare allegations would be an enormous leap. Stripped of conclusory labels, the FAC's factual assertions make it equally plausible (indeed more plausible) that Abbott worked to educate doctors in order to promote and gain acceptance of a new, groundbreaking treatment, not to execute

some criminal kickback scheme. *See, e.g.*, FAC ¶ 70 (describing importance of satisfying customer needs); *id.* ¶¶ 74–75 (describing the tracking of sales results); *id.* ¶¶ 81–82 (describing sales strategy). Nothing in the FAC suggests a crime—much less a *knowing* and *willful* commission of one. *See, e.g.*, *U.S. ex rel. Fitzer v. Allergan, Inc.*, No. 17-cv-668, 2021 WL 4133713, at *8 (D. Md. Sept. 10, 2021) (dismissing relator's complaint alleging that a device manufacturer acted with criminal "intent to induce referrals" through a "marketing scheme [designed] to increase the number of . . . procedures performed" because such an allegation of scienter was "a legal conclusion unsupported by any factual allegations").

2. Relator does not allege scienter under the False Claims Act.

Separately, liability under the FCA requires that a party *knowingly* presented or caused to be presented a false claim or a false statement material to a false claim. *See* 31 U.S.C. § 3729(a)(1)(A), (B). Acting "knowingly" requires "actual knowledge"; acting in "deliberate ignorance of the truth or falsity of the information"; or acting in "reckless disregard of the truth or falsity of the information." *Id.* § 3729(b)(1). And where the defendant's conduct comports with a reasonable interpretation of an ambiguous statutory requirement, no liability exists under the FCA, no matter what the defendant's subjective intent might have been. *See, e.g.*, *Safeco Ins. Co. of Am. v. Burr*, 551 U.S. 47, 70 n.20 (2007); *U.S. ex rel. McGrath v. Microsemi Corp.*, 690 F. App'x 551, 552 (9th Cir. 2017) (affirming dismissal of the complaint where scienter could not be shown due to defendant's "reasonable" interpretation of an ambiguous provision). Here, it is eminently reasonable to think that the conduct alleged here—providing meals as part of business meetings and conducting speaker programs in order to inform medical providers of the benefits of an FDA-approved device, performing clinical trials, and seeking expanded coverage from CMS—is not criminal under the AKS. In particular, where details such as how many people attended the purported meals or the fair market value of the honoraria are not even alleged in the FAC, "no . . .

reasonable person" would think that the alleged conduct constituted a kickback. *Hart*, 821 F. App'x at 562–63.

Perhaps in an effort to get around its inability to allege scienter, Relator vaguely alleges that Abbott "disguises kickback schemes." FAC ¶ 119. For example, Relator alleges that Abbott hid the true cost of hosting events by, for instance, miscategorizing certain costs. *Id.* ¶ 120. But the FAC fails to allege any facts explaining how such an accounting—which could be explained by any number of reasons unrelated to the AKS—suggests an illegal kickback. In *Novartis*, for example, the court explained, "[t]he fact that some speaker events went over-budget, and that Novartis salespeople concealed the excess spending in Novartis' internal records, is not enough to allege a kickback scheme orchestrated by Novartis." 2020 WL 1436706, at *5; *see also U.S. ex rel. Durkin v. Cnty. of San Diego*, No. 15-cv-2674, 2018 WL 3361148, at *6 (S.D. Cal. July 10, 2018) (allegation that defendant "hid" a material fact was insufficient). The same conclusion is warranted here, particularly since the FAC alleges only one instance of this purported concealment—related to the cost of "the first TMVR Summit in January 2017"—but never connects this event to the submission of any false claims. FAC ¶ 120.

The Court should similarly reject Relator's reference to concealment when alleging that Abbott allowed speakers to use their own slides during speaker programs. *Id.* ¶ 125. This is a non sequitur, not evidence of concealment. Regardless, the FAC never explains how allowing speakers to choose their own slides could amount to any wrongdoing, let alone establishes any connection to the submission of claims.[6]

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[6] In addition for failing for all the reasons discussed above (*see supra* § II.A–E), Count III also should be dismissed because the FAC does not allege the requirements for conspiracy liability or reverse false-claims liability with particularity. *See, e.g.*, *U.S. ex rel. DeCesare v. Americare In Home Nursing*, 757 F. Supp. 2d 573, 584 (E.D. Va. 2010); *U.S. ex rel. Taul v. Nagel Enters., Inc.*, No.

III. Relator's State Law Claims Should Be Dismissed.

Finally, Relator's State FCA claims should all also be dismissed. First, those claims are all premised on the same deficient allegations that support the federal claims and thus fail for the same reasons. *See, e.g.*, *Solis*, 445 F. Supp. 3d at 802 (dismissing state FCA claims where the federal FCA claims all failed); *Dan Abrams*, 2017 WL 4023092, at *12 (same).

Second, the claims independently fail Rule 9(b), which requires that a plaintiff "must allege some specificity with respect to *each asserted state*." *U.S. ex rel. Nowak v. Medtronic, Inc.*, 806 F. Supp. 2d 310, 357 (D. Mass. 2011) (emphasis added). Here, Relator has not alleged with particularity if, how, or when any purportedly false claims were submitted to each specific State identified in the FAC—instead just making the same generic allegation for each State that Abbott "caused hundreds of thousands of false claims to be made." FAC ¶¶ 144, 156, 168, 180, 193, 204, 214, 226, 237, 248, 260, 282, 293, 305, 317, 329, 341, 353, 364, 376, 388, 400, 410, 420, 432, 444. That is insufficient. *See, e.g.*, *Nowak*, 806 F. Supp. 2d at 357; *U.S. ex rel. Wall v. Vista Hospice Care, Inc.*, 778 F. Supp. 2d 709, 723 (N.D. Tex. 2011).

With respect to Massachusetts, Relator's claim also fails because an artificial entity cannot bring a *qui tam* action on behalf of that State. *See Phone Recovery Servs., LLC v. Verizon of New England, Inc.*, 480 Mass. 224, 228–30 (2018).

CONCLUSION

For the reasons discussed above, the FAC should be dismissed in full.

14-cv-0061-VEH, 2017 WL 432460, at *13 (N.D. Ala. Feb. 1, 2017). The reverse false-claim theory is also improperly duplicative of the other FCA counts. *See, e.g.*, *Pencheng Si v. Laogai Rsch. Found.*, 71 F. Supp. 3d 73, 97 (D.D.C. 2014).

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