

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

UNITED STATES OF AMERICA, et al.,	:	
Ex rel. CHARLES STRUNCK, et al.,	:	CIVIL ACTION
Plaintiffs,	:	
	:	
v.	:	
	:	
MALLINCKRODT ARD LLC,	:	
Defendant.	:	Nos. 12-175, 13-1776
	:	

MEMORANDUM

Schiller, J.

January 21, 2020

This litigation originally came before the Court in 2012 and 2013 pursuant to the *qui tam* provisions of the False Claims Act (“FCA”), 31 U.S.C. § 3730(b)(1), against Defendant (hereinafter “Mallinckrodt” or “Company”). The United States of America (hereinafter the “Government”) elected to intervene on March 7, 2019. The Government filed a complaint in intervention (“Complaint”) and the parties stipulated to dismiss the relators’ claims.

The Complaint alleges that between 2010 and 2014, Mallinckrodt engaged in a scheme to defraud Medicare Part D; it alleges violations of the FCA based on underlying violations of the federal Anti-kickback statute (“AKS”), 42 U.S.C. § 1320a-7b. Mallinckrodt filed a motion to dismiss the Complaint and to strike portions thereof.¹ For the reasons set forth below, Mallinckrodt’s motions are denied.

I. BACKGROUND

Mallinckrodt is a pharmaceutical company, formerly Questcor Pharmaceuticals, Inc. Medicare is a federally-funded healthcare program administered by the United States Department

¹ Mallinckrodt also filed a motion to compel arbitration of relator Clark’s employment claims. Because the parties have agreed to dismiss those claims, that motion is now moot.

of Health and Human Services (“HHS”). Medicare Part D is a program, established in 2006, that provides prescription drug coverage for enrolled Medicare beneficiaries.

Medicare Part D beneficiaries must often make a partial payment, known as a copayment for their prescription drugs. Copay obligations can be substantial for expensive medications. Copay obligations vary depending on a beneficiary’s total Part D covered expenses for the year up to that date. To illustrate, in 2010, a standard Part D prescription plan had a deductible of \$310—meaning, Medicare would not pay for prescription drugs until a beneficiary had paid \$310 in drug costs out of pocket. After reaching the deductible, the beneficiary paid a 25% copay for covered medication and Part D paid the remaining 75% until the beneficiary spent \$2,830, the amount of the “initial coverage limit.” After meeting the initial coverage limit, the beneficiary paid 100% of the prescription cost until he or she hit the annual out-of-pocket threshold of \$4,550 in out-of-pocket costs. At that point, the beneficiary entered what is referred to as the “catastrophic coverage” phase. In the catastrophic coverage period, the beneficiary paid a 5% copay for brand name drugs and Medicare covered the remainder. *See* 42 U.S.C. § 1395w-102. These financial thresholds have increased each year since 2006 pursuant to a statutory formula.

Per the Complaint, in 2001, Mallinckrodt acquired a drug commonly referred to as Acthar. Acthar is approved by the U.S. Food and Drug Administration (“FDA”) to treat acute exacerbations of multiple sclerosis (“MS”), lupus, and rheumatoid arthritis (“RA”). Acthar is also approved to treat a rare seizure disorder in children known as infantile spasms (“IS”). (Compl. ¶ 64.) In 2007, Mallinckrodt enacted an “orphan pricing strategy,” which involved drastically increasing the price of Acthar and moving away from marketing it to treat MS. (*Id.* ¶ 68.) “From the time of the acquisition [of Acthar] until December 2014, Mallinckrodt raised Acthar’s per-vial price from approximately \$50 per 5 milliliter vial to over \$32,200 per vial.” (*Id.* ¶ 3.) By doing so,

the Company believed it would no longer be able to sell Acthar to MS patients because there were many low-cost alternatives available for MS treatment. (*Id.* ¶ 71.) Mallinckrodt terminated its MS sales force and “dedicated remaining account representatives to work with IS prescribers.” (*Id.*)

At first, Mallinckrodt was correct, it had priced itself out of the market for MS treatment—in December 2007 MS referrals were down to just eight vials, compared to an average of 250 vials per month before the price change. (Compl. ¶ 72.) However, the Company quickly realized that if it subsidized MS patients’ copays for Acthar, it could market the drug as free to doctors and patients while charging the much higher price and making millions of dollars from Medicare and other insurance companies. The Complaint alleges that Mallinckrodt enacted an illegal scheme to subsidize Medicare customers’ copays through donations to “copay assistance funds” that it “designed, created, and used as a money conduit to pay patient copay subsidies for Acthar (but no other drug).” (*Id.* ¶ 84.)

In the spring of 2010, Mallinckrodt began exploring a relationship with a foundation called the Chronic Disease Fund (“CDF”) to establish a copay assistance fund specific to MS exacerbation. CDF was an organization that operated funds that provided services and financial assistance to needy people undergoing medical treatment for certain diseases. CDF already had a patient assistance fund for people with MS, so Mallinckrodt limited its fund definition to MS exacerbation patients in order to prevent its donations from being used to cover copays for chronic MS drugs, or any drug other than Acthar. Mallinckrodt established the “MS Acute Exacerbation Fund” specifically for patients with government insurance such as Medicare Part D and specifically to pay Acthar copays, thereby “shifting the drug’s ever-increasing cost to Medicare.” (Compl. ¶ 2, 92-93.) From its inception until 2014, the MS Acute Exacerbation Fund paid Medicare copays for Acthar and not for any other drug. (*Id.* ¶ 99.) “[A]t a time when Acthar cost

\$30,000, Mallinckrodt could spend \$1,500 to subsidize a five percent Medicare copay knowing it would reap as much as \$28,500 in sales revenue from that prescription.” (*Id.* ¶ 6.) Limiting the fund definition to MS exacerbation prevented other drugs from being financed through the fund, but it did not stop Mallinckrodt from referring Acthar patients who used the drug for chronic or long-term maintenance. (*Id.* ¶¶ 102-3.)

Mallinckrodt then repeated the same scheme to subsidize Acthar copays for Lupus and RA patients. Mallinckrodt established the “Lupus Exacerbation Fund” in November 2011 and from that point until 2014, the fund paid Medicare copays of Acthar and no other drug. (Compl. ¶¶ 116-17.) This fund was narrowly defined to exclude other drugs, but it did not exclude Acthar patients who used the drug for long-term maintenance. (*Id.* ¶ 118.) In September of 2012, Mallinckrodt established the “Exacerbation of Rheumatoid Arthritis Fund,” which paid the Medicare copays of Acthar and no other drugs. (*Id.* ¶¶ 124-26.) Again, the fund was supposedly limited to “exacerbation” patients, but Mallinckrodt referred long-term-use patients to the fund as well. (*Id.* ¶ 127.)

Mallinckrodt saw to it that Acthar patients with copays in excess of \$150 were automatically offered copay assistance through CDF. (*Id.* ¶ 130.) Mallinckrodt’s own referral program sent more than 98 percent of patients who received copay assistance from the MS, Lupus, and RA exacerbation funds to CDF. (*Id.* ¶ 132.) Almost every patient Mallinckrodt sent to CDF qualified for copay assistance. (*Id.* ¶ 133.) Mallinckrodt also maintained a patient assistance program (“PAP”) that provided free Acthar to certain financially needy patients. However, patients with Medicare or other insurance coverage were sent to CDF, not to the PAP, and patients whose insurance coverage for Acthar was denied had to exhaust all appeal options before Mallinckrodt would refer them to the PAP. (*Id.* ¶ 135.)

Mallinckrodt closely monitored the fund balances and the number of patients covered by the funds so it could correlate its “donations” with actual demand. (Compl. ¶ 146.) The Company received financial reports from CDF containing information regarding the number of patients enrolled, the amount the fund paid out, the percentage of patients who were approved for subsidies, the average copay amount for those patients, and more. (*Id.* ¶ 147.) Because Acthar was the only drug covered by the exacerbation funds, Mallinckrodt was able to ensure its contributions to CDF directly corresponded with the number of Acthar prescriptions it subsidized.

II. STANDARD OF REVIEW

In deciding a motion to dismiss for failure to state a claim, pursuant to Fed. R. Civ. P. 12(b)(6), the court must accept as true all factual allegations in the complaint, construe the complaint in the light most favorable to the plaintiff, and determine if there is a reasonable reading of the complaint under which the plaintiff is entitled to relief. *United States ex rel. Bergman v. Abbot Labs.*, 995 F. Supp. 2d. 357, 364 (E.D. Pa. 2014). “To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to ‘state a claim to relief that is plausible on its face.’” *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 557 (2007)). The plausibility requirement “asks for more than a sheer possibility that a defendant has acted unlawfully.” *Ashcroft*, 556 U.S. at 678.

“In alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake. Malice, intent, knowledge, and other conditions of a person’s mind may be alleged generally.” Fed. R. Civ. P. 9(b). This standard “requires, at a minimum, that plaintiffs support their allegations of . . . fraud with all of the essential factual background . . . that is, the who, what, when, where and how of the events at issue.” *Abbot Labs.*, 995 F. Supp. 2d. at

364 (E.D. Pa. 2014) (quoting *United States ex rel. Streck v. Allergan, Inc.*, 894 F. Supp. 2d. 584, 601 (E.D. Pa. 2012)).

III. DISCUSSION

A. Motion to Dismiss

Defendant argues for dismissal for failure to state a claim based on certain regulatory guidance that, it claims, defeats the scienter element of the Government's cause of action. The FCA is the government's primary tool for combatting fraud. The FCA confers liability on any person who "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval[.]" 31 U.S.C. § 3729(a)(1)(A). Additionally, FCA liability arises if a defendant "knowingly makes, uses, or causes to be made or used, a false record or statements material to a false or fraudulent claim[.]" 31 U.S.C. § 3729(a)(1)(B). A plaintiff properly states a claim for violation of the statute by alleging "(1) the defendant presented a claim for payment to the United States; (2) the claim was false; (3) the defendant knew the claim was false; and (4) the false statement was material to the decision." *United States ex rel. Streck v. Bristol-Myers Squibb Co.*, 370 F. Supp. 3d 491, 495 (E.D. Pa. 2019).

1. Defendant caused claims for payment to be presented to the United States

Mallinckrodt does not dispute that the Complaint alleges it caused claims for payment to be submitted to the United States. The Complaint alleges that during the time period when Mallinckrodt used its donations to CDF to pay Acthar copay subsidies, "patients used these subsidies at pharmacies to purchase Acthar prescriptions, and the pharmacies submitted claims to Medicare Part D sponsors seeking Medicare reimbursement for those prescriptions." (Compl. ¶ 206.) In fact, the Complaint includes more than 120 specific examples of claims submitted to

Medicare on behalf of Acthar patients that received copay subsidies from CDF, which exceeds the pleading requirement. (*Id.* ¶¶ 186-193; Ex. 1-4.)

2. *The claims were false and the false statement was material*

Mallinckrodt contends that the Complaint fails to allege sufficient facts to establish that those claims were false for purposes of the FCA. A false claim can be factually or legally false. *U.S. ex rel. Greenfield v. Medco Health Sols., Inc.*, 880 F.3d 89, 94 (3d Cir. 2018). A claim “is legally false when the claimant lies about its compliance with a statutory, regulatory, or contractual requirement.” *Id.* Here, it is alleged that Mallinckrodt’s claims were false because of their certification of compliance with, and actual violations of the AKS. “[A] claim that includes items and services resulting from a violation of [the AKS] constitutes a false or fraudulent claim for purposes of [the FCA].” *Id.* at 95. Additionally, compliance with the AKS is a material condition of payment under the FCA. *U.S. ex rel. Nevyas v. Allergan, Inc.*, Civ. A. No. 09-432, 2015 WL 4064629, at *4 (E.D. Pa. July 2, 2015). Therefore, if the Complaint sufficiently alleges AKS violations, then the resulting claims were false and material for purposes of the FCA.

Under AKS, it is illegal to,

knowingly and willfully offer[] or pay[] any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person—to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program[.]

42 U.S.C. § 1320a-7(b)(2)(B). It is sufficient that at least one purpose of the remuneration was to induce Medicare purchases. *See United States v. Greber*, 760 F.2d 68, 72 (3d Cir. 1985).

The Complaint alleges facts sufficient to plead violations of the AKS. First, the Complaint alleges that Mallinckrodt indirectly paid remuneration to Acthar patients in the form of copay subsidies funneled through CDF. The Complaint alleges that Mallinckrodt made at least fifty

payments to CDF, totaling over \$23 million, knowing that the money would be used to pay Medicare copays for Acthar and no other drug. (*See* Compl. ¶¶ 150, 155.) Next, the Complaint includes numerous allegations that indicate Defendant paid such remuneration with the intent to induce Medicare-reimbursed sales of Acthar. Because of the funds it established at CDF, Mallinckrodt was able to market Acthar as free to doctors and patients, regardless of its actual, exorbitant price. (*Id.* ¶¶ 138-145.) Mallinckrodt sales representatives indicated that the copay assistance offered through CDF was one of the most important tools they used to get doctors to prescribe Acthar. (*Id.* ¶ 143.) Moreover, Mallinckrodt created copay assistance funds specifically for patients with government insurance and excluded Medicare patients from its free drug program, instead sending those patients to CDF to receive a copay subsidy and require Medicare to shoulder the cost. (*Id.* ¶¶ 134-36.) Therefore, the Complaint plausibly alleges that Mallinckrodt paid remuneration to induce Medicare-reimbursed purchases of Acthar.

3. Defendant knowingly submitted false claims

a. Statutory language

Finally, the Complaint alleges that Defendant paid such remuneration knowingly and willfully. “The [FCA’s] scienter requirement defines ‘knowing’ and ‘knowingly’ to mean that a person has ‘actual knowledge of the information,’ ‘acts in deliberate ignorance of the truth or falsity of the information,’ or ‘acts in reckless disregard of the truth or falsity of the information.’” *Universal Health Servs., Inc. v. United States*, 136 S. Ct. 1989, 1996, 195 L. Ed. 2d 348 (2016), (quoting § 3729(b)(1)(A)). Although the Government is only required to allege scienter generally, and AKS does not require a specific intent to violate the statute, the Government has pled considerable facts to establish Mallinckrodt was aware its scheme was illegal. *See* Fed. R. Civ. P. 9(b), § 1320a-7b(h). The Complaint alleges that Mallinckrodt’s training programs and policies

reflected an understanding of the AKS. (Compl. ¶¶ 163-64.) Further, it alleges that the Company knew it would be unlawful to directly pay Medicare copays on its own product, so it insisted on structuring the CDF funds such that only Acthar would be covered. (*Id.* ¶¶ 167-69.) Indeed, the Complaint alleges that Mallinckrodt’s Reimbursement Manager emailed articles regarding the illegality of copay subsidies for Medicare Part D patients to the Commercial VP during the relevant time period. (*Id.* ¶ 168.) Thus, the Complaint sufficiently pleads a knowing violation of the statutory language of the AKS, and, therefore, the FCA.

b. Regulatory guidance

In fact, Defendant does not argue that the Complaint fails to allege a violation based on the statutory language of the AKS. Instead, Mallinckrodt argues that certain regulatory guidance in effect during the relevant time period seemingly approved of schemes such as this, so Mallinckrodt could not have acted knowingly. (Mot. to Dismiss and Strike at 2.) To put Defendant’s argument in context, the Court will provide a brief summary of the material on which Mallinckrodt relies.

Medicare Part D went into effect on January 1, 2006. On November 22, 2005, the Office of the Inspector General (“OIG”) of HHS issued guidance to the healthcare industry in the form of a Special Advisory Bulletin related to how Medicare Part D patients could benefit from patient assistance programs without running afoul of the AKS. *See* HHS OIG, Special Advisory Bulletin on Patient Assistance Programs for Medicare Part D Enrollees, 70 Fed. Reg. 70623 (Nov. 22, 2005) (“2005 SAB”). PAPs provide financial assistance to needy patients—often to patients with chronic conditions who must pay high drug costs. At the time the 2005 SAB was published, its guidance was necessarily speculative because Medicare Part D coverage had not yet begun. HHS OIG was “concerned about the use of cost-sharing subsidies to shield [Part D] beneficiaries from the economic effects of drug pricing, thus eliminating a market safeguard against inflated prices.” 2005 SAB at 70626. It included a non-exhaustive list of what it saw as potential abuses, which

included, “[pharmaceutical manufacturers] colluding with independent charity programs to ensure that the manufacturer’s contributions only or primarily benefit patients using its products[.]” *Id.* However, the SAB advised the industry that *so long as certain conditions were met*, “donations from a pharmaceutical manufacturer to an independent, *bona fide* charity that provides cost-sharing subsidies for Part D drugs should raise few, if any anti-kickback statute concerns[.]” *Id.* at 70624.

HHS OIG also issued advisory opinions to organizations that requested clarification of their compliance with the AKS. In September of 2006, *prior to* Mallinckrodt’s establishment of the subject funds with CDF, CDF received a favorable advisory opinion from HHS OIG. The advisory opinion relied on CDF to self-certify compliance with certain safeguards. It concluded the OIG would not impose sanctions on CDF but, “that the Arrangement could potentially generate prohibited remuneration under the anti-kickback statute, if the requisite intent to induce or reward referrals of Federal health care program business were present[.]” OIG Advisory Opinion No. 06-10 (Sept. 14, 2006) at 2.

On May 30, 2014, HHS OIG issued a Supplemental Special Advisory Bulletin (“Supplemental SAB”), which updated the 2005 SAB. The Supplemental SAB “reiterates and amplifies [HHS OIG] guidance, based on practices and trends we have seen in the industry.” Supplemental Special Advisory Bulletin: Independent Charity Patient Assistance Program, 79 Fed. Reg. 31, 123 (May 30, 2014). The Supplemental SAB noted that, in the years since the initial guidance, HHS OIG became aware that some PAPs are “establishing narrowly defined disease funds and covering a limited number of drugs within those funds.” *Id.* at 31121. It went on to say that funds that cover a single drug or drugs made by a single manufacturer “will be subject to scrutiny.” *Id.* Mallinckrodt characterizes the Supplemental SAB as a stark change in position from

the 2005 guidance (Reply Mem. in Supp. of Mot. to Dismiss at 3.) However, the 2005 SAB similarly cautioned against narrowly defined disease funds. *See* 2005 SAB at 70627 (“[W]e are concerned that, in some cases, charities may artificially define their disease categories so narrowly that the earmarking effectively results in the subsidization of one (or a very few) of donor’s particular products.”)

i. The parties’ respective arguments

Mallinckrodt argues that the Complaint should be dismissed because, “(1) the conduct alleged complied with the regulatory guidance relating to patient assistance programs in effect during the relevant time frame and thus did not violate AKS, and (2) the initial regulatory guidance was, at best, ambiguous and thus the United States does not allege that [Mallinckrodt] acted knowingly.” (Def.’s Reply Mem. in Supp. of Mot. To Dismiss at 4.) The Government, on the other hand, contends that the HHS OIG guidance is irrelevant because it does not alter the elements of an AKS violation or relate to what the Government is required to plead to survive a motion to dismiss. (Resp. in Opp’n To Mot. To Dismiss at 11.) Additionally, the Government argues that if it was required to plead Mallinckrodt’s non-compliance with regulatory guidance, it has done so. (*Id.* at 15.)

ii. The Complaint pleads non-compliance with regulatory guidance

Mallinckrodt’s first argument is premised on the idea that it was, in fact, acting in compliance with the 2005 SAB. According to Defendant, the conduct alleged in the Complaint, even if true, was compliant with the 2005 SAB, and therefore the Government failed to plead a violation of the AKS or FCA. The Court disagrees. The 2005 SAB indicated that in order for pharmaceutical manufacturers to lawfully contribute to PAPs for Medicare Part D beneficiaries, the following conditions had to be met:

- (i) Neither the pharmaceutical manufacturer nor any affiliate of the manufacturer (including, without limitation, any employee, agent, officer, shareholder, or contractor...) exerts any direct or indirect influence or control over the charity or the subsidy program;
- (ii) The charity awards assistance in a truly independent manner that severs any link between the pharmaceutical manufacturer's funding and the beneficiary (i.e., the assistance provided to the beneficiary cannot be attributed to the donating pharmaceutical manufacturer);
- (iii) The charity awards assistance without regard to the pharmaceutical manufacturer's interests and without regard to the beneficiary's choice of product, provider, practitioner, supplier, or Part D drug plan;
- (iv) The charity provides assistance based upon a reasonable, verifiable, and uniform measure of financial need that is applied in a consistent manner; and
- (v) The pharmaceutical manufacturer does not solicit or receive data from the charity that would facilitate the manufacturer in correlating the amount or frequency of its donations with the number of subsidized prescriptions for its products.

2005 SAB at 70626.

The Government has alleged that Mallinckrodt engaged in conduct that did not comport with those conditions. The Government has alleged that Mallinckrodt exerted control over the various funds it set up through CDF. Specifically, it alleges that Mallinckrodt insisted on establishing new, separate "exacerbation" funds for each funded disease in order to ensure that only patients treating with Acthar would receive the benefits of its "donations." Further, the Government alleges that Mallinckrodt received data from CDF that allowed it to correlate the amount and frequency of its donations with the number of subsidized Acthar prescriptions. Thus, the Government has pled non-compliance with the 2005 SAB and Mallinckrodt's first argument fails.

iii. *Regulatory guidance does not preclude a finding that the Complaint alleges scienter*

Next, Mallinckrodt argues that the 2005 guidance was ambiguous, and therefore it could not have acted knowingly. Defendant argues that because HHS OIG issued updated guidance in 2014, the 2005 guidance was necessarily ambiguous and Defendant cannot be held responsible for its actions. Defendant cites this Court's opinion in *United States ex rel. Pritsker v. Sodexo, Inc.*, Civ. A. No. 03-6003, 2009 WL 579380, at *6 (E.D. Pa Mar. 6, 2009), for the proposition that "an ambiguous regulatory interpretation that reasonably could be read to authorize Defendant's conduct precludes a finding that Defendants knowingly submitted a false claim." Defendant relies heavily on a footnote in the 2005 guidance that states, "in *rare circumstances*, there may be only one drug covered by Part D for the diseases in a particular category... In these *unusual circumstances*, the fact that a disease category only includes one drug or manufacturer would not, *standing alone*, be determinative of an [AKS] violation." SAB 2005 at n. 19 (emphasis added); *see also* OIG Advisory Opinion No. 06-10 at n. 7. Even read in isolation, that statement certainly does not constitute an endorsement of the type of conduct alleged here. Moreover, the footnote goes on to say "[s]uch a determination could only be made on a case-by-case basis after examining all of the applicable facts and circumstances, including the intent of the parties." *Id.* Thus, the footnote does not negate, or even obfuscate, the fact that the 2005 SAB warned pharmaceutical companies that using charities as a conduit to pay copay subsidies to Medicare beneficiaries was an AKS violation. *See* 2005 SAB at 70627. Regardless, Mallinckrodt's argument "focuses on its state of mind, and is properly addressed after full development of the factual record." *United States ex rel. Nevyas v. Allergan, Inc.*, Civ. A. No. 09-432, 2015 WL 4064629, at *6 (E.D. Pa. July 2, 2015). The Court finds that at this stage of the proceeding, the Government has alleged facts that

plausibly state a knowing violation of the AKS and FCA. Defendant's motion to dismiss the United States' Complaint is denied.

B. Motion to Strike

Finally, Defendant asks the Court to strike a paragraph of the Complaint that, it argues, is prejudicial and immaterial to the case. (Mot. to Dismiss and Strike at 23.) "The court may strike from a pleading an insufficient defense or any redundant, immaterial, impertinent, or scandalous matter." Fed. R. Civ. P. 12(f). "The purpose of a motion to strike is to clean up the pleadings, streamline litigation, and avoid unnecessary forays into immaterial matters. A motion to strike is not favored and will be denied unless the allegations have no possible relation to the controversy and may cause prejudice to one of the parties." *Providence Town Ctr. LP v. Raymours Furniture Co, Inc.*, Civ. A. No. 09-3902, 2009 WL 3821935, *1 (E.D. Pa. Nov. 13, 2009) (internal quotation marks and citation omitted).

At issue here is paragraph 199 of the Complaint and its accompanying footnote. The paragraph states, "[t]he United States regularly enforces the AKS and pursues FCA liability based on underlying violations of the AKS. In particular, it has pursued matters against drug companies like Mallinckrodt for conduct like that alleged here." (Compl. ¶ 199.) The accompanying footnote provides citations to press releases disseminated by the Department of Justice relating to settlements with other pharmaceutical manufacturers relating to similar conduct. Mallinckrodt argues that this paragraph and footnote should be stricken because they are immaterial to the case at bar in that they relate to "other drug companies involving other drugs, other funds, and other charities[.]" (Mot. to Dismiss and Strike at 23.) Mallinckrodt goes on to argue that "the fact that there have been such settlements serves only to underscore that the OIG's 2005 guidance and its

subsequent advisory opinions through 2014 were at best ambiguous.” (*Id.* at 24.) The Court finds Mallinckrodt’s arguments unavailing.

First, Mallinckrodt takes issue with the Government referencing *other* matters involving *other* pharmaceutical manufacturers, yet much of its argument in support of dismissing the Complaint is based on HHS OIG advisory opinions issued to *other* charities involving *other* funds. Indeed, those opinions explicitly state “[t]his advisory opinion has no application to, and cannot be relied upon by, any other individual or entity” and “has no applicability to other arrangements, even those which appear similar in nature or scope.” (Def.’s Mot. to Dismiss Ex. D at 7-8; E at 10; F at 9-10; G at 14; H at 10; I at 14; J at 9; K at 10-11.) Yet, Mallinckrodt found them relevant to its case. Moreover, Mallinckrodt’s contention that the challenged material is actually beneficial to it undermines its argument that the material should be stricken because it may cause prejudice. The paragraph is situated in the portion of the Complaint that relates to the allegations of materiality under the FCA, it underscores that AKS violations are *per se* material under the FCA. The Court does not agree with Mallinckrodt that the allegations in that paragraph bare no possible relation to the controversy. The motion to strike the paragraph and footnote is denied.

IV. CONCLUSION

For the foregoing reasons, Defendant’s motions are denied. An Order consistent with this Memorandum will be docketed separately.

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

UNITED STATES OF AMERICA, et al.,	:	
Ex rel. CHARLES STRUNCK, et al.,	:	CIVIL ACTION
Plaintiffs,	:	
	:	
v.	:	
	:	
MALLINCKRODT ARD LLC,	:	
Defendant.	:	Nos. 12-175, 13-1776
	:	

ORDER

AND NOW, this **21st** day of **January 2020**, upon consideration of Defendant’s Motion to Dismiss the Government’s Complaint in Intervention and to Strike Portions Thereof (Document No. 73), the Government’s Response, and Defendant’s Reply, and for the reasons set forth in this Court’s Memorandum dated January 21, 2020, it is **ORDERED**:

1. Defendant’s Motion to Dismiss is **DENIED**.
2. Defendant’s Motion to Strike is **DENIED**.
3. Defendant’s Motion to Compel Arbitration (Document No. 72 in Civ. A. 12-175; Document No. 56 in Civ. A. 13-1776) is **DENIED as moot**.

BY THE COURT:



Berle M. Schiller, J.