UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

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UNITED STATES OF AMERICA; the States of CALIFORNIA, COLORADO, CONNECTICUT, DELAWARE, FLORIDA, GEORGIA, HAWAII, ILLINOIS, INDIANA, IOWA, LOUISIANA, MARYLAND, MASSACHUSETTS, MICHIGAN, MINNESOTA, MONTANA, NEVADA, NEW HAMPSHIRE, NEW JERSEY, NEW MEXICO, NEW YORK, NORTH CAROLINA, OKLAHOMA, RHODE ISLAND, TENNESSE, TEXAS, VIRGINIA, WASHINGTON, and WISCONSIN; the DISTRICT OF COLUMBIA, the CITY OF CHICAGO, and the CITY OF NEW YORK; *ex rel.*, CHARLES ARNSTEIN AND HOSSAM SENOUSY,

Plaintiffs and Relators,

-against-

13 Civ. 3702 (CM)

TEVA PHARMACEUTICALS USA, INC., TEVA NEUROSCIENCE, INC., and TEVA SALES AND MARKETING, INC.

Defendants.

x

MEMORANDUM DECISION AND ORDER DENYING DEFENDANTS' MOTION FOR SUMMARY JUDGMENT

McMahon, C.J.:

This *qui tam* suit arises out of Teva's promotional speaker program. Former pharmaceutical sales representatives of Teva Neuroscience, Inc., allege that the speaker program was a conduit through which prescribers were bribed with speaker fees, expensive meals, and alcohol in exchange for prescribing two Teva drugs that treat multiple sclerosis (MS) and

Parkinson's disease. Relators allege that this amounts to a violation of the federal False Claims Act, 31 U.S.C. § 3729(a)(1)(A)–(B), through the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b), as well as to violations of the False Claim Act's analogues in twenty-seven states, Washington, D.C., and two cities.

This case is similar to *United States ex rel. Bilotta v. Novartis Pharm. Corp.*, No. 11-cv-71 (S.D.N.Y.) (*Bilotta*), currently pending in this district before Judge Paul Gardephe. Although the United States (the "Government") chose to intervene in that case, it chose not to do so here. *See United States ex rel. Arnstein v. Teva Pharm. USA, Inc.*, No. 13-cv-3702, 2016 WL 750720, at *2 (S.D.N.Y. Feb. 22, 2016) (*Teva I*). The Government has, however, filed two Statements of Interest. (Dkt. Nos. 138-1, 158.)

On a previous motion to dismiss, this Court severed Relators' federal False Claims Act claim (Count I) from the pendent state and municipal claims (Counts II through XXXIII), and denied without prejudice Defendants' motion to dismiss those claims. *Teva I*, 2016 WL 750720. at *1.

Discovery has concluded, and Defendants now move for summary judgment on Count I. (Defs.' Mem. of Law in Supp. of Their Mot. for Summ. J. ("Defs. Br."), Dkt. No. 129 at 1.) Defendants also ask that this Court decline to exercise supplemental jurisdiction over the pendent state and municipal law claims. (*Id.* at 32.)

For the reasons set forth below, this Court now **DENIES** that motion.

I. Background

The facts of this case were described at length in *Teva I*, 2016 WL 750720, at *1–*11. The Court assumes familiarity with the underlying facts but recounts them briefly below. Unless expressly stated, the facts are undisputed.

A. The Parties

Defendant Teva Pharmaceuticals USA, Inc. ("Teva USA") is an indirect, wholly-owned subsidiary of Teva Pharmaceutical Industries, Ltd., an Israeli pharmaceutical company.[1] (Defs.' Answer to Third Am. Compl. ("Answer"), Dkt. No. 58 ¶ 4.) Defendant Teva Neuroscience, Inc. ("Teva Neuroscience") is an indirect, wholly-owned subsidiary of Teva USA. (*Id.* ¶ 6.) Plaintiffs allege, but Defendants deny, that both Defendant Teva Neuroscience and Defendant Teva Sales & Marketing, Inc. ("Teva Sales & Marketing," and, together with Teva USA and Teva Neuroscience, "Teva" or "Defendants") are each divisions and/or operating units of Defendant Teva USA. (Third Am. Compl. ("TAC"), Dkt. No. 53 ¶¶ 6–7.) Plaintiffs also allege, but Defendants deny, that during the relevant period, Defendants were and functioned as each other's alter egos and/or agents. (TAC ¶ 8.)

Plaintiffs Charles Arnstein and Hossam Senousy ("Relators") are former sales representatives who were hired by Teva Neuroscience in 2006 and 2002, respectively. (Answer ¶¶ 12–13.) They allege that, on January 1, 2014, they and all other Teva Neuroscience employees were transferred to Teva Sales and Marketing. (TAC ¶ 7.)

B. Pharmaceutical Marketing and Speaker Programs

Teva manufactures the two drugs at issue in this case: Azilect® (rasagiline tablets), which treats symptoms of Parkinson's disease, and Copaxone® (glatiramer acetate injection), which treats relapsing-remitting multiple sclerosis. (Answer ¶¶ 93–94.) Copaxone was Teva's first major branded drug, approved by the U.S. Food and Drug Administration ("FDA") in 1996. (*Id.* ¶ 93.)

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[1] Teva Pharmaceutical Industries, Ltd. is not named as a Defendant in this lawsuit.

Like many other pharmaceutical companies, Teva uses a variety of sales and marketing tactics to promote Azilect and Copaxone. (*See* Defs.' Statement of Undisputed Material Facts in Supp. of their Mot. for Summ. J. ("Defs. 56.1"), Dkt. No. 129-1 ¶ 1.)

One familiar tactic used by Teva is "detailing." (*Id.*) Detailing involves "sales representatives visit[ing] physician offices for one-on-one interactions and conduct[ing] small group meeting or events to promote the products of the firms they represent." (Expert Report of Pradeep K. Chintagunta, Ph.D. ("Chintagunta Report") ¶ 16, Ex. 16 to the Decl. of Alexandra M. Lastowski, dated Aug. 13, 2018 ("DX-"), Dkt. No. 129-2.)

Teva also promotes Azilect and Copaxone through a speaker program. (Defs. 56.1 ¶ 1.) Speaker programs are a commonly-used marketing tool in which pharmaceutical companies pay health care providers (doctors, nurse practitioners, *etc.*), to speak about their drugs and/or the diseases the drugs treat. (*Id.* ¶ 6.)

Teva's Azilect and Copaxone speaker programs were divided into "peer-to-peer" programs, *i.e.*, presentations attended by other health care providers, and patient education programs, *i.e.*, programs attended by patients or their family members. (*See*, *e.g.*, DX64 at TNA-0191555.)

Topics covered at these programs included clinical information about MS and Parkinson's disease ("disease state presentations") and information about Azilect and Copaxone. (*See*, *e.g.*, DX118 at TNA-0178955.) The format of these programs varied and could include: breakfast, lunch, and dinner lectures, either onsite or in bars and restaurants; presentations at health care providers' offices; teleconferences and webcasts; roundtables with fellows; patient teleconferences; and "journal clubs." (*See*, *e.g.*, *id.*; DX37 at TNA-0178955.)

By way of illustration, speaker program topics for Azilect and Copaxone have included: "Dopamine Management in Early to Moderate-to-Advanced Parkinson's Disease: A Case Study Approach"; "The Continuum of Parkinson's Disease Treatment: Enhancing Patient Care: Initial Treatment of Early PD"; "Navigating Options in RRMS [Relapsing-Remitting Multiple Sclerosis]"; "and The Current RRMS Landscape and Available Therapies." (Answer ¶¶ 118–22, 127–29, 138.)

Teva's sales team managed some its speaker programs in-house (so-called "local speaker programs"), but also contracted with an outside vendor, Advanced Health Media, LLC ("AHM") for the logistical and event level data management of other programs during the Relevant Period, including programs led by physicians with national influence in their field (so-called "national opinion leaders"). (*See* Expert Report of Paul W. Kim ("Kim Report") at 16, Ex. 284 to the Decl. of Laurie Rubinow dated Sept. 14, 2018 ("PX-"), Dkt. No. 137.) There were more than 12,000 peer-to-peer speaker programs conducted by AHM on behalf of Teva in the United States between 2008 and 2014, with approximately 1,700 in the average year. (Resp. and Counterstatement of Pls.-Relators to Defs. 56.1 ("Rels. 56.1"), Dkt. No. 136 ¶ 170; Expert Report of Dr. Samuel L. Pleasure, Ph.D., M.D. ("Pleasure Report"), PX142 ¶ 45.)

Speaker programs are valuable to pharmaceutical companies. As the Head of Sales at Teva Neuroscience has stated, peer-to-peer "speaker programs are an essential complement to detailing . . . because physicians generally are more receptive to receiving clinical information from their peers than they are to receiving such information from Sales Representatives." (DX60 ¶ 32; *accord, verbatim*, DX61 ¶ 35.) In other words, the medium is the message. Academic studies also find "that the influence of certain physicians on peer drug prescription behavior can be significant." (Chintagunta Report ¶ 26.)

However, these programs can also create value by influencing the presenters themselves. Absent certain safeguards, being paid to speak on behalf of a pharmaceutical company can be seen as an unlawful bribe or kickback. As the FDA has cautioned:

> FDA is concerned that companies may influence the content of educational programs both directly and indirectly. Directly, by being involved in the selection of speakers or in the treatment of topics. Indirectly, through the nature of the relationship between the company and the provider (*e.g.*, if the provider has reason to believe that future financial support from the company depends upon producing programs that promote the company's products.)

(DX18 at 64,095; *see also id.* at 64,098 ("The agency will consider whether invitations . . . are intended . . . to reward high prescribers of the company's products, or to influence 'opinion leaders.'"); *id.* ("The agency will consider whether multiple presentations of the same program are held.").)

There is reason for concern. Speakers may receive thousands of dollars in speaker fees or honoraria. (*See* DX64 at TNA-0191557.) In addition, speakers may be paid by pharmaceutical companies for their time spent attending speaker and compliance trainings. (*See*, *e.g.*, DX37 at TNA-0001357.) Speakers are also reimbursed for airfare, hotel rooms, meals, and alcohol. (*See* Rebuttal Expert Report of Holly J. Humphrey, M.D., M.A.C.P. ("Humphrey Rebuttal Report"), PX161, DX32 ¶ 15.) Speakers who are starting or growing their own private or hospital-based practices may view the speaker programs as well-subsidized marketing events, which can increase both peer referrals and patient self-referrals, thereby expanding their patient base. (*See*, *e.g.*, PX43 at TNA-0431434; PX104 at TNA-0384245; PX141 at TNA-0581478.)

Recognizing these potential conflicts of interest, many hospitals and provider networks have adopted rules that prohibit their employees from participating in promotional speaker programs. (*See*, *e.g.*, DX98 ¶ 11; DX23 ¶ 12.)

C. Relevant Statutes and Legal Framework

Two statutes work in tandem to create liability in this case. The first statute defines the underlying violation; the second provides a private right of action to whistleblowers.

1. The Anti-Kickback Statute

The federal Anti-Kickback Statute ("AKS"), 42 U.S.C. § 1320a-7b(b), criminalizes, among other things, "knowingly or willingly" offering or paying a person "remuneration"—whether kickbacks, bribes, or rebates—to "induce" that person to "recommend" the purchase of a drug covered by a "Federal health care program." *Id.* § 1320a-7b(b)(2). Violators are subject to a fine of up to $100,000 and ten years' imprisonment. *Id.*

"The term 'remuneration' includes . . . transfers of items or services for free or for other than fair market value." *Id.* § 1320a-7a(6).

"Federal health care program" means "any plan or program that provides health benefits, whether directly, through insurance, or otherwise, which is funded directly, in whole or in part, by the United States Government," as well as "any State health care program." *Id.* § 1320a-7b(f). Such programs include Medicare, Medicaid, and TRICARE (part of the United States military's health care system).[2] *See Teva I*, 2016 WL 750720, at *15; *United States ex rel. Kester v. Novartis Pharm. Corp.*, 43 F. Supp. 3d 332, 362 (S.D.N.Y. 2014) (*Novartis V*).

Pursuant to 42 U.S.C. § 1320a-7b(b)(3)(E), the U.S. Department of Health and Human Services ("HHS") has promulgated regulations that carve out certain "safe harbors"—payment and business practices. 42 C.F.R. § 1001.952.

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[2] Because Relators' Third Amended Complaint also asserts claims under state and municipal laws, Relators refer to all relevant public programs as the "Government Healthcare Programs." (Third Am. Compl. ("TAC"), Dkt. No. 53 ¶ 3.) However, because Defendants' motion for summary judgment is directed only to Count I, the federal False Claims Act, I use the statutory term of art "Federal health care programs" throughout this opinion.

Relevant to pharmaceutical speaker programs, the HHS safe harbors include certain "personal services and management contracts." *Id.* § 1001.952(d). This safe harbor holds that, for purposes of the AKS, the term "'remuneration' does not include any payment made by a principal to an agent as compensation for the services of the agent," provided seven conditions are met. *Id.* These include:

> (5) The aggregate compensation paid to the agent over the term of the agreement is set in advance, is consistent with fair market value in arms-length transactions and is not determined in a manner that takes into account the volume or value of any referrals or business otherwise generated between the parties for which payment may be made in whole or in part under Medicare, Medicaid or other Federal health care programs.
>
> (6) The services performed under the agreement do not involve the counselling or promotion of a business arrangement or other activity that violates any State or Federal law.
>
> (7) The aggregate services contracted for do not exceed those which are reasonably necessary to accomplish the commercially reasonable business purpose of the services.

Id. § 1001.952(d)(5)–(7).

The test is conjunctive, and a contractor seeking to avail itself of the personal services safe harbor must meet all seven conditions. *Id.* § 1001.952(d).

2. The False Claims Act

The federal False Claims Act ("FCA"), 31 U.S.C. §§ 3729, *et seq.*, is a Civil War-era statute that imposes criminal and civil liability "on those who present or directly induce the submission of false or fraudulent claims" to the federal Government for payment. *Universal Health Servs., Inc. v. United States ex rel. Escobar*, 136 S. Ct. 1989, 1996 (U.S. 2016) (*Escobar*).

Under the FCA,

> any person who—

> (A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;
>
> (B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim;
>
> [. . .]
>
> is liable to the United States Government for a civil penalty of not less than $5,000 and not more than $10,000, as adjusted by the Federal Civil Penalties Inflation Adjustment Act of 1990 (28 U.S.C. 2461 note; Public Law 104-410), plus 3 times the amount of damages which the Government sustains because of the act of that person.

31 U.S.C. § 3729(a)(1).

Because Congress has recognized that the Government cannot singlehandedly police all fraud against it, the FCA also permits private persons, *a.k.a.*, whistleblowers, to bring *qui tam* suits to recover damages on behalf of the federal Government. 31 U.S.C. § 3730(b); *Teva I*, 2016 WL 750720, at *1. The FCA generally provides for an award to the successful *qui tam* plaintiff of between fifteen and thirty percent of the proceeds of the action—or settlement of the claim—with certain conditions and exceptions. 31 U.S.C. § 3730(d)(1)–(4).

"During the 150-plus years since enactment of the FCA, it has become one of the federal government's most successful enforcement mechanisms against government contractors and in no industry has it been more impactful than in health care." Deborah R. Farringer, *From Guns That Do Not Shoot to Foreign Staplers: Has the Supreme Court's Materiality Standard Under Escobar Provided Clarity for the Health Care Industry About Fraud Under the False Claims Act?*, 83 Brook. L. Rev. 1227, 1228 (2018).

3. The 2010 Amendments to the AKS

"In the healthcare context, the AKS commonly serves as an FCA predicate[.]" *United States ex rel. Wheeler v. Union Treatment Ctrs., LLC*, No. CV SA-13-CA-4-XR, 2019 WL

571349, at *5 (W.D. Tex. Feb. 12, 2019). Although the AKS is a criminal statute, and does not create a private right of action, *Donovan v. Rothman*, 106 F. Supp. 2d 513, 516 (S.D.N.Y. 2000), courts began some decades ago to "create[] private rights of action by allowing private parties to enforce the AKS through the FCA." 2 Hooper Lundy & Bookman, Treatise on Health Care Law § 8.29 (Matthew Bender, rev. ed. 2018); *see also United States ex rel. Roy v. Anthony*, 914 F. Supp. 1504, 1506 (S.D. Ohio 1994); *United States ex rel. Pogue v. Am. Healthcorp*, 914 F. Supp. 1507, 1513 (M.D. Tenn. 1996).

On March 23, 2010, as part of the Patient Protection and Affordable Care Act ("PPACA"), Congress both codified this private right of action, and amended the AKS by adding the following language: "In addition to the penalties provided for in this section or section 1320a-7a of this title, a claim that includes items or services resulting from a violation of this section constitutes a false or fraudulent claim for purposes of subchapter III of chapter 37 of Title 31," *i.e.*, the FCA. 42 U.S.C. § 1320a-7b(g).

The amendment also clarified that "any claim connected in any way to an AKS violation was ineligible for reimbursement, even if the party that submitted the claim had no knowledge of the AKS violation." *United States ex rel. Kester v. Novartis Pharm. Corp.*, 41 F. Supp. 3d 323, 332 (S.D.N.Y.2014) (*Novartis IV*). "The legislative history of Section 1320a–7b(g) makes it completely clear that Congress only intended that provision to correct [a] strict interpretation of the false certification theory." *Id.* at 334.[3] That interpretation had held that, because the party directly submitting reimbursement claims to the Government (a hospital) did not know about a kickback scheme involving a surgeon, who operated in that hospital, and a device company, the relators had failed to state a claim under the FCA. *Id.* Congress reacted to that decision by

[3] This "strict interpretation" had been announced in one portion of a district court case, *United States ex rel. Thomas v. Bailey*, No. 06-cv-465, 2008 WL 4853630 (E.D. Ark. Nov. 6, 2008).

passing the 2010 amendments, because it disagreed that "a claim that results from a kickback and that is fraudulent when submitted by a wrongdoer" could be somehow "laundered into a 'clean' claim when an innocent third party finally submits the claim to the government for payment." *Id.* (citing 155 Cong. Rec. S10852–01, 2009 WL 3460582); *see also id.* at 335 ("By enacting Section 1320a–7b(g), Congress made clear that the fact that the certifications were made by an innocent party submitting a claim without knowledge of an AKS violation did not remove the taint of falsity from the certifications.").

D. Procedural History

1. Initial Pleadings

Relators filed this case under seal on May 31, 2013, (Dkt. No. 1), and simultaneously served a copy on the Government, in accordance with 31 U.S.C. § 3730(b)(2). *See Teva I*, 2016 WL 750720, at *1.

Approximately two years later, after the Government formally declined to intervene, Relators served the Second Amended Complaint ("SAC") on Defendants. (Dkt. No. 13.) The Second Amended Complaint alleged violations of the False Claims Act with respect to the following federal health care programs: Medicare Part D, Medicaid, Veterans Administration Healthcare, and TRICARE. *Teva I*, 2016 WL 750720, at *21–*22.

2. The Now-Defunct *Mikes* Framework

On June 5, 2015, Defendants moved to dismiss the SAC in its entirety pursuant to Federal Rules of Civil Procedure 12(b)(6) and 9(b). (Dkt. Nos. 30–33.) That motion was denied. *Teva I*, 2016 WL 750720, at *1.

In considering Defendants' motion, this Court looked at the Complaint's allegations through the controlling law at the time, *United States ex rel. Mikes v. Straus*, 274 F.3d 687 (2d Cir. 2001). *See Teva I*, 2016 WL 750720, at *19–*20.

The *Mikes* framework arose in FCA cases where the plaintiffs pursued a "certification theory" of liability, *i.e.*, "a false representation of compliance with a federal statute or regulation or a prescribed contractual term." *Mikes*, 274 F.3d at 696. The *Mikes* court distinguished between false certification, sometimes referred to as "legal falsity," and fraud "involv[ing] an incorrect description of goods or services provided," which the *Mikes* court referred to as "factual falsity." *Id.* at 696–97.

The *Mikes* court acknowledged that not all "legally false" claims would or should give rise to liability under the FCA. *Id.* at 697. "[I]t would be anomalous to find liability when the alleged noncompliance would not have influenced the government's decision to pay." *Id.* Thus, the *Mikes* court held: "a claim under the Act is legally false only where a party certifies compliance with a statute or regulation *as a condition to governmental payment.*" *Id.* (emphasis added).

The *Mikes* court identified two subcategories of false certifications, "express" and "implied." *Id.* at 697–702. "Express certification" applies if a contractor must expressly certify compliance with a particular legal requirement at the same time that it submits that claim to the Government for payment. *Id.* at 698. Under the *Mikes* framework, a court considering an FCA claim on a theory of express certification needed only read the language of the claim form to determine whether purported compliance with a legal requirement rendered the claim "false." The requirement that claimants certify compliance with the particular statute or rule at issue was termed the "particularity requirement." *Bishop v. Wells Fargo & Co.*, 870 F.3d 104, 106 (2d Cir. 2017) (*Bishop*).

"Implied certification," by contrast, is "based on the notion that the act of submitting a claim for reimbursement itself implies compliance with governing federal rules that are a

precondition to payment." *Mikes*, 274 F.3d at 699. In an implied certification case, the contractor does not need to certify its compliance with the underlying condition explicitly each time it submits a claim for payment.

In order to cabin the liability that could result from such a theory, the *Mikes* court concluded that the implied certification theory of FCA liability "appropriately applied only when the underlying statute or regulation upon which the plaintiff relies expressly states the provider must comply in order to be paid." *Id.* at 700. This theory—called the "express-designation requirement"—operated like a default contract rule; the court relied on Congress to specify when compliance with certain statutes was a "condition to payment." *See Bishop*, 870 F.3d at 106.

While it was good law, the *Mikes* analysis could be applied to FCA claims premised on violations of the AKS. *See, e.g.*, *Novartis IV*, 41 F. Supp. 3d at 335. The 2010 PPACA amendments did not use the phrase "condition of payment;" instead, it said that "a claim that includes items or services resulting from a violation of this section constitutes a false or fraudulent claim for purposes of" the FCA. 42 U.S.C. § 1320a-7b(g). Still, "the new provision did nothing to alter the false certification theory of claim 'falsity' articulated in *Mikes* and its progeny." *Id.* (citing various cases).

Nonetheless, the 2010 PPACA amendments were not retroactive. *Id.* at 332. As a result, in *Teva I*, the Court held that Relators could "prevail on a theory of implied certification . . . with respect to claims that were submitted after March 23, 2010." 2016 WL 750720, at *20. However, "Any claims arising prior to that date would have to be accompanied by express certifications in order to be actionable under the FCA." *Id.*

The Court ordered Relators to amend the SAC within 30 days to flesh out the false and fraudulent nature of certain express certification claims or to drop those claims from the lawsuit. *Teva I*, 2016 WL 750720, at *1, *25–*26, *28.

Relators elected to drop certain claims that were premised on express certification with respect to Medicaid and all claims that were premised on express certification with respect to TRICARE. (TAC ¶ 19.)

3. *Escobar* Overrules *Mikes*

The governing law changed very shortly after this Court's decision in *Teva I*, when the United States Supreme Court replaced the "condition of payment" rule with a common law materiality standard. *Universal Health Servs., Inc. v. United States ex rel. Escobar*, 136 S. Ct. 1989, 2002–04 (2016) (*Escobar*). The Supreme Court reasoned, "Instead of adopting a circumscribed view of what it means for a claim to be false or fraudulent, concerns about fair notice and open-ended liability can be effectively addressed through strict enforcement of the Act's materiality and scienter requirements." *Id.* at 2002 (internal quotation omitted).

The Supreme Court effectively abolished the need to divide cases into "express" and "implied" certification claims:

> We . . . hold that False Claims Act liability for failing to disclose violations of legal requirements does not turn upon whether those requirements were expressly designated as conditions of payment. Defendants can be liable for violating requirements even if they were not expressly designated as conditions of payment. Conversely, even when a requirement is expressly designated a condition of payment, not every violation of such a requirement gives rise to liability. What matters is not the label the Government attaches to a requirement, but whether the defendant knowingly violated a requirement *that the defendant knows is material to the Government's payment decision.*

Id. at 1996 (emphasis added).

Materiality, the Supreme Court said, "look[s] to the effect on the likely or actual behavior of the recipient of the alleged misrepresentation." *Id.* (citing 26 R. Lord, Williston on Contracts § 69:12, p. 549 (4th ed. 2003) (Williston)). And, to illustrate how a False Claims Act plaintiff could prove materiality, *Escobar* laid out high-level, non-exhaustive guideposts:

> In sum, when evaluating materiality under the False Claims Act, the Government's decision to expressly identify a provision as a condition of payment is relevant, but not automatically dispositive. Likewise, proof of materiality can include, but is not necessarily limited to, evidence that the defendant knows that the Government consistently refuses to pay claims in the mine run of cases based on noncompliance with the particular statutory, regulatory, or contractual requirement. Conversely, if the Government pays a particular claim in full despite its actual knowledge that certain requirements were violated, that is very strong evidence that those requirements are not material. Or, if the Government regularly pays a particular type of claim in full despite actual knowledge that certain requirements were violated, and has signaled no change in position, that is strong evidence that the requirements are not material.

136 S. Ct. at 2003–04; *see also id.* at 2003 (citing *United States ex rel. Marcus v. Hess*, 317 U.S. 537, 543 (1943) (misrepresentation was material where the Government otherwise would not have placed money in a joint fund for payment to the defendant-contractors)).

Recently, the Second Circuit confirmed that "the express-designation requirement for implied false certification claims and the particularity requirement for express false certification claims . . . did not survive *Escobar*." *Bishop*, 870 F.3d at 106; *id.* ("In place of *Mikes*'s requirements, the *Escobar* Court set out a 'familiar and rigorous' materiality standard.").

4. Summary Judgment

After discovery, Defendants move for summary judgment on the federal FCA claim, as well as dismissal of all pendent state and municipal law claims. (Dkt. No. 128.)

Pursuant to the Court's order dated December 11, 2018, (Dkt. No. 154), the parties have also submitted supplemental briefing on the element of materiality under 31 U.S.C. § 3729(a)(1)(A), following *Escobar*. (*See* Dkt. Nos. 156–60.)

II. Legal Standard

A party is entitled to summary judgment when there is no "genuine dispute as to any material fact" and the undisputed facts warrant judgment for the moving party as a matter of law. Fed. R. Civ. P. 56(a); *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247–48 (1986).

Whether any disputed issue of fact exists is for the Court to determine. *Balderman v. U.S. Veterans Admin.*, 870 F.2d 57, 60 (2d Cir. 1989). The moving party has the initial burden of demonstrating the absence of a disputed issue of material fact. *Celotex v. Catrett*, 477 U.S. 317, 322–23 (1986).

Once the motion for summary judgment is properly made, the burden shifts to the non-moving party, which "must set forth specific facts showing that there is a genuine issue for trial." *Anderson*, 477 U.S. at 250. The nonmovant "may not rely on conclusory allegations or unsubstantiated speculation," *Scotto v. Almenas*, 143 F.3d 105, 114 (2d Cir. 1998), but must support the existence of an alleged dispute with specific citation to the record materials. *See* Fed. R. Civ. P. 56(c)(1).

While the Court must view the record "in the light most favorable to the nonmoving party," *Leberman v. John Blair & Co.*, 880 F.2d 1555, 1559 (2d Cir. 1989) (citations omitted), and "resolve all ambiguities and draw all reasonable inferences in favor of the party against whom summary judgment is sought," *Heyman v. Commerce & Indus. Ins. Co.*, 524 F.2d 1317, 1320 (2d Cir. 1975) (citations omitted), the non-moving party nevertheless "must do more than simply show that there is some metaphysical doubt as to the material facts." *Matsushita Elec.*,

475 U.S. at 586 (citations omitted). Not every disputed factual issue is material in light of the substantive law that governs the case. *Anderson*, 477 U.S. at 248. "Only disputes over facts that might affect the outcome of the suit under the governing law will properly preclude the entry of summary judgment." *Id.*

III. Discussion

Defendants argue that Relators have failed to make out a prima facie case on their FCA claim. (Defs. Br. at 1–2.) Specifically, Defendants argue that: (i) Relators have not raised a genuine issue of material fact that Teva committed an AKS violation through its speaker program; (ii) Relators have failed to link any purported AKS violation to the prescription reimbursement claims that form the basis for their FCA action; and (iii) Relators have failed to offer any evidence that any misrepresentation about AKS compliance was material to the Government for purposes of the FCA. (*Id.* at 2.)

For the reasons discussed below, these arguments fail.

A. Relators Raise a Genuine Issue of Material Fact with Respect to Whether Teva Violated the AKS

Defendants argue that they are entitled to summary judgment because Relators have "failed to create a triable issue on their claim that Teva's speaker program violated the AKS." (Defs. Br. at 17.) They argue, first, that Relators have failed to raise an issue of material fact that "'one purpose' of Teva's speaker program was to induce or reward speakers' prescribing." (*Id.*) Second, they argue that Relators fail to offer evidence that there existed an overarching or "sweeping" scheme related to the speaker program, as opposed to isolated instances of misconduct. (*Id.*) Third, Defendants argue that Relators' damages calculations are not supported by the evidence. (*Id.*)

1. Relators Raise a Genuine Issue of Material Fact That "One Purpose" of the Speaker Program Was To Reward Prescription Writing

Through the FCA, Relators allege that Teva violated subsection 1320a-7b(b)(2)(A) of the AKS, (TAC ¶ 171), which states:

> (2) 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 such person—
>
> (A) to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, [. . .]
>
> shall be guilty of a felony and upon conviction thereof, shall be fined not more than $100,000 or imprisoned for not more than 10 years, or both.

42 U.S.C. § 1320a-7b(b)(2).

This provision of the AKS "criminalizes the payment of any funds or benefits designed to encourage an individual to refer another party to a [Federal health care] provider for services to be paid for by [a Federal health care] program." *United States v. Miles*, 360 F.3d 472, 479 (5th Cir. 2004).

To prove liability under the statute, the Government or relator must show that the defendant: "(1) knowingly and willfully made a payment or offer of payment, (2) as an inducement to the payee, (3) to refer an individual, (4) to another for the furnishing of an item or service that could be paid for by a federal health care program." *Id.* 479–80.

Inducing referrals need not be the primary purpose for the kickback. Instead, a party need only prove that "one purpose" of the defendant's bribe is to induce referrals. *United States v. Narco Freedom, Inc.*, 95 F. Supp. 3d 747, 759 (S.D.N.Y. 2015); *United States v. Borrasi*, 639 F.3d 774, 781–82 (7th Cir. 2011); *United States v. McClatchey*, 217 F.3d 823, 834–35 (10th Cir.

2000); *United States v. Davis*, 132 F.3d 1092, 1094 (5th Cir. 1998); *United States v. Kats*, 871 F.2d 105, 108 (9th Cir. 1989) (per curiam); *United States v. Greber*, 760 F.2d 68, 71–72 (3d Cir. 1985).

In cases where a company's speaker program is alleged to have violated the AKS, scienter may be established by, among other things, evidence that senior management was "basing representatives' compensation on doctors' prescription-writing; [] failing to monitor events; and [] imposing no discipline when sales representatives were reported for non-compliance with [the company's] policies and the anti-kickback laws." *Bilotta*, 50 F. Supp. 3d at 519. The inference also arises from evidence showing that the company violated its own compliance policies and industry standards. *Id.*

Teva first argues that Relators have failed to meet their burden to show that even "one purpose" of the speaker program was to reward or incentivize prescription writing, because there is no evidence of *quid pro quo* agreements, no evidence that the speaker program was intended to influence speakers as opposed to attendees, and no payments in excess of fair market value that could provide evidence of the requisite scienter. (Defs. Br. at 18–20.)

a) The AKS Does Not Require Evidence of a* Quid Pro Quo *Arrangement

Defendants first argue, as they did in their motion to dismiss, that Relators have failed to show that the honoraria were "negotiated in exchange for or conditioned upon" speakers' writing prescriptions." (Defs. Br. at 18 (internal quotation omitted).) The failure to demonstrate a *quid pro quo* arrangement, they argue, entitles them to summary judgment. (*Id.*)

Relators respond that the AKS does not require evidence of a *quid pro quo* arrangement to find a violation, and that scienter may be established through other evidence. (Pls.-Relators' Mem. of Law in Opp. to Defs. Mot. for Summ. J. ("Rels. Opp."), Dkt. No. 135 at 16–17.)

The Parties' use of the phrase "*quid pro quo*" requires some clarification.

Although the AKS requires that the offer or payment be made "to induce" a person, courts "consistently treat[] the AKS's inducement element as an intent requirement." *United States ex rel. Parikh v. Citizens Med. Ctr.*, 977 F. Supp. 2d 654, 665 (S.D. Tex. 2013), *aff'd sub nom. United States ex rel. Parikh v. Brown*, 587 F. App'x 123 (5th Cir. 2014) (citing *Davis*, 132 F.3d at 1094; *McClatchey*, 217 F.3d at 835). Because intent is all that is required, it does not matter whether "a particular referral results." *Parikh*, 977 F. Supp. 2d at 665. Thus, the statute does not require evidence of a "*quid pro quo*" in the sense that each bribe must successfully generate referrals. *United States ex rel. Kester v. Novartis Pharm. Corp.*, 23 F. Supp. 3d 242, 263 (S.D.N.Y. 2014) (*Novartis I*); *see also Teva I*, 2016 WL 750720, at *17.[4]

There is no need for the plaintiff to offer evidence about any negotiations between the payor and the person receiving the kickback, because there is no requirement that the payor attempt to bring about this result by means of a conversation or express conditions. Were it otherwise, it would make little sense for Congress to have created two separate criminal offenses, one for "offer[ing] or pay[ing]" unlawful remuneration, 42 U.S.C. § 1320a-7b(b)(2), and the other for "solicit[ing] or receiv[ing]" it, *id.* § 1320a-7b(b)(1). The statute also does not require evidence of negotiations with the party receiving the kickback. Rather, the payor must offer or pay "with the intent to gain influence over the reason or judgment of a person making referral decisions." *McClatchey*, 217 F.3d at 834.

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[4] Of course, evidence that such referrals did result—or that a speaker's overall prescriptions increased—will support an inference of intent. *Bilotta*, 50 F. Supp. 3d at 520; *see also United States ex rel. King v. Solvay Pharm., Inc.*, 871 F.3d 318, 332 (5th Cir. 2017), *cert. denied* 138 S. Ct. 2030 (2018); *United States ex rel. Gonzalez v. Fresenius Med. Care N. Am.*, 748 F. Supp. 2d 95, 113 n.31 (W.D. Tex. 2010), *aff'd sub nom. Gonzalez v. Fresenius Med. Care N. Am.*, 689 F.3d 470 (5th Cir. 2012).

Defendants are incorrect that, in the absence of *quid pro quo* evidence, payors could be found guilty "merely because they hoped or expected or believed that referrals may ensue from remuneration that was designed wholly for other purposes." *Id.* As the *McClatchey* court explained, a payor "may *lawfully* enter into a business relationship with a doctor and even hope for or expect referrals from that doctor, so long as [the payor] is motivated to enter the relationship *for legal reasons entirely distinct* from its collateral hope for referrals." *Id.* (emphasis added). Thus, in a case where all facets of the business arrangements between a payor and doctor are aboveboard, the jury might require evidence of a *quid pro quo* to enable it to make the "difficult factual determination" of "distinguish[ing] between a motivating factor and a collateral hope or expectation." *Id.* n.7. However, because Relators have proffered several indicia of an unlawful relationship between Teva and its speakers, this is not such a case.

As a result, Relators' case does not fail for want of *quid pro quo* evidence.

b) There Exists a Genuine Issue of Material Fact About the Efficacy of Teva's Compliance Program

Teva next argues that Relators offer no evidence of intent to induce, because its "extensive policies, training, speaker selection criteria and processes, and layers of compliance safeguards were all designed to guard against the use of speaker fees for any illicit purpose." (Defs. Br. at 19 (citing Defs. 56.1 ¶¶ 92–123).) Teva says there is no genuine issue of fact that it has a robust compliance program, which has ferreted out non-compliance on this and other issues.

Teva relies principally on its written compliance policies: several iterations of the *Teva Integrity Principles* (TIPS), an undated "U.S. Business Conduct Policy," a "Centralized Activity Review and Evaluation" ("CARE") policy, a document called "Standard Operating Procedures: 2013 Teva Business Rules," and the Compliance Committee charter, dated 2007. (DX106–107,

DX110, DX112, DX116, DX119, DX126; *see also* DX8–13, DX30–31, DX58 (written compliance policies, including duplicates of exhibits already discussed, and sample speaker agreement for promotional programs); DX109 (job posting for compliance director, dated 2005).) Teva also submits federal Government and industry guidance documents. (*See* DX17 (2009 version of the Code on Interactions with Health Care Professionals issued by the Pharmaceutical Research and Manufacturers of America (the "PhRMA Guidelines")); DX18 & DX24 (FDA guidance documents)).)

Teva also points to documents showing that, from time to time, it disseminated these policies to its employees. These documents include a 2008 e-mail to sales personnel circulating a revised version of the forthcoming 2009 TIPs, and e-mails requiring that employees complete a compliance training module through its online portal, the Learning Management System. (DX111, DX118, DX123; *see also* DX124–25 (deposition testimony of employees recalling that they were required to undergo training).) This evidence provides some indication that senior management distributed policies to its employees.

Relators respond that Teva's claim of a strong compliance program is "largely unsupported" by the evidence cited, and that Teva's compliance policies were "weak and unenforced." (Rels. Opp. at 17.)

Relators raise a genuine issue of material fact on this score. Certainly, Teva has written compliance policies, and these policies contain all of the right language. But that evidences little, since the existence of a written compliance policy says nothing about whether it is followed. "Formal policies, of course, are only as good as their implementation; the very nature of a sham is that it pretends to be compliant when it is not." *United States ex rel. Booker v.*

Pfizer, Inc., 188 F. Supp. 3d 122, 134 (D. Mass. 2016) (*Booker II*), *aff'd*, 847 F.3d 52 (1st Cir. 2017). The question is whether these policies are worth the paper they are written on.

First, although Teva claims it is undisputed that its "compliance personnel discovered, investigated, and disciplined Teva employees for violations of Teva policies, including termination, forfeiting bonuses, and remedial training," (Defs. 56.1 ¶ 122), Teva bases its assertion on records from a grand total of four compliance investigations—three of which have nothing to do with the kind of AKS violations alleged in this case. (*See* DX130 (infraction occurred during detailing/"advocate development," not a speaker program); DX132 (same); DX133 (speaker investigated for using his own slides rather than Teva-approved materials).) The fourth records shows that, on one occasion, Teva investigated a sales representative who "facilitated a 1:1 speaker program in violation of policy, [and] facilitated a speaker program with an inappropriate target audience for the benefit of the speaker," among other violations not related to the AKS. (DX131 at 1–2.) Teva claims that the employee was fired as a result. However, "Action taken: Terminated" could refer either to the employee or to the investigation itself; and Teva has not introduced any testimony that clarifies the matter. (*Id.*)

Second, Relators' expert Paul W. Kim, J.D., M.P.H., member and Chair of the Healthcare Group at the law firm Cole Schotz P.C., (Kim Report at 1–2), opines, based on his familiarity with health care compliance policies across many types of provider corporations (including drug companies), (*id.* at App'x A), that, during the Relevant Period, Teva had a singularly weak compliance department, with a very small staff (one that is too small to attend the speaker programs they purport to monitor), overseen for many years by a former paralegal with no formal compliance training, all of which evidences a lack of commitment to the written policy. (*Id.* at 24–26, 28, 36–37.) He also points out that among other things, prior to July 2012, Teva

had no written protocol for investigating or responding to reports of misconduct. (*Id.* at 44.) Finally, push-back from sales representatives rendered it impossible for Teva to track such critical compliance-related data, such as total compensation to paid speakers, (*id.* at 16), and how often a single health care provider, including speakers, attended programs on a given drug (*id.* at 13–14). A compliance department that lacks compliance data is no compliance department at all; neither is a compliance department that is not proactive, but simply responds to complaints.

Of course, Teva proffers its own expert, Jon Smollen, J.D., Practice Professor of Law at Temple Law School in Philadelphia, Pennsylvania, and Director of its Center for Compliance and Ethics, (Report of Jon Smollen, J.D. ("Smollen Report"), DX105 at 2–4), who opines that the company does have robust compliance policies that comply with relevant guidelines. I agree that his testimony raises an issue of fact—though I note that he undercuts his own conclusion with statements like (1) during the early part of the Relevant Period, 2006 to 2008, some training took place, but it was not conducted with any regular frequency (*see id.* 33–35); (2) monitoring and auditing efforts during this period were focused on other marketing tactics (sampling and detailing), not on speaker programs (*id.* at 35); (3) the length of time it took Teva to roll out an updated speaker program that complied with the 2009 PhRMA Guidelines and the Huron Consulting report was four years, even as other companies adopted standards from the same Guidelines as early as 2010, (*id.* at 45); and (4) when outside consultants and members of Teva's compliance department began conducting compliance audits of speaker programs, they provided advance notice to the sales personnel they would be observing (*id.* at 55–56).

Neither expert's credentials or conclusions were the subject of a *Daubert* motion, although, for the first time in its reply brief, Teva has argued that Relators' expert Kim "bears none of the hallmarks of reliability necessary for the opinion to be admissible under *Daubert*."

(Defs.' Reply Mem. of Law in Further Supp. of their Mot. for Summ. J. ("Defs. Reply"), Dkt. No. 141 at 16 (quoting *Berk v. St. Vincent's Hosp. & Med. Ctr.*, 380 F. Supp. 2d 334, 355 (S.D.N.Y. 2005).) A passing argument in a reply brief is not a substitute for a proper *Daubert* motion. As far as this court is concerned, the Parties have waived any *Daubert* arguments by not raising them at summary judgment. If I can consider an expert's at summary judgment, a jury can consider it at trial.

Obviously, the clash of experts creates a genuine issue of material fact about whether Teva's compliance policy was adequately designed, and whether it was more honored in the breach or in the observance. This precludes summary judgment in favor of Teva on the issue of whether its compliance program definitively proves an absence of the requisite scienter under the AKS.

c) There Is a Genuine Issue of Material Fact Whether Teva Tracked Speakers' Prescription Writing

Next, Teva argues that "if the investment in a speaker program had been intended in part to induce speaker prescriptions, it is inconceivable that the company would not have tracked the number of prescriptions written by speakers specifically to assess the impact of speaker payments on speaker' prescribing habits." (Defs. Br. at 19 (internal quotation omitted).) Defendants argue that "the undisputed evidence confirms that Teva did no such tracking." (*Id.*; *see also id.* at 25 ("Here, Teva did not track the prescriptions written by speakers, but rather the prescriptions written by attendees."); *see also* Defs. 56.1 ¶¶ 29–32.)

Teva's disingenuous argument is based on a single marketing mix analysis that an outside consultant, ZS Associates ("ZS"), performed at various times "when asked" over the Relevant Period. (*See* Defs. 56.1 ¶¶ 29–32; DX53 at 99:1 (testimony of senior product manager for Copaxone that analysis was done "when asked," rather than annually); *see also* PX204 at 38:5–

17 (testimony of ZS employee that ZS was not involved in analyzing ROI of speaker programs for Teva between 2007 and 2011).) Evidence of Teva's behavior with respect to just one study—a study that does not comprehend all analyses of its speaker program—does not entitle it to summary judgment on the issue of intent.

Relators, moreover, have introduced substantial evidence that Teva did, in fact, track speakers' prescription writing, thereby raising a genuine issue of material fact. (Rels. 56.1 ¶¶ 2–4.)

Relators have introduced evidence that Teva did this at the level of its senior management. For example, they have proffered a slide deck focusing on AHM speaker programs in 2009 and 2008. (*See* PX213). The slide deck shows that Teva tracked attendee prescribing at *speaker training* programs, and that they did so at the level of "Trx/Dr/Month," *i.e.*, total prescriptions of Azilect per doctor per month, both "3 months post" and "6 months post" training. (PX213 at slide titled "Peer - Peer ROI"; *see also id.* at 1 (showing transmission of this document from an associate product manager for Parkinson's Marketing to a senior product manager for Copaxone ("Attached is the slide deck that includes the AHM ROI analysis.").) By definition, this metric could include only paid speakers.

Relators also introduce a declaration from a former Teva employees whose primary responsibilities were "training speakers for Teva's peer-to-peer and patient programs" on Azilect and Copaxone in New England. (PX137 ¶¶ 5–6.) That employee testified, "Teva carefully tracked the IMS data detailing the prescribing habits with respect to Azilect and Copaxone for the [health care providers] that spoke on behalf of Teva." (PX137 ¶ 6.)

Relators also offer evidence that the tracking of speakers was done by Teva's sales team. The sales representatives responsible for a given region, as well as their managers, closely

tracked prescriptions of all health care providers for whom they were responsible, especially paid speakers. (Rels. Opp. at 17, 19; *see also* Rels. 56.1 ¶¶ 2–4, 29–32, 79).) Defendants do not dispute this: "Speaker also were customers of Teva's products and Teva sales representatives were aware of all their customers' prescribing." (Defs. Reply at 13–14.)

As just one example of how closely Teva sales representatives tracked individual speakers: a "Field Activity Report" for the Buffalo, NY territory shows detailed Azilect and Copaxone prescribing information for a group of physicians—[B.M.], [L.D.], [T.G.], [L.M.], [D.H.], [B.W.], [P.K.], and [B.Y.]—on pages TNA-0088227–29, and then identifies these very same physicians as paid speakers who have completed speaker programs in recent months on pages TNA-0088230–31. (PX115). Similarly, a "Territory Analysis" from the Akron/Canton region includes detailed, half-page summaries devoted to individual speakers, complete with line graphs showing each individual speaker's market share of Azilect and Copaxone over time. (PX 49 at TNA-0135105–08.)

Sales representatives linked prescriber habits with their retention as paid speakers for Teva. An excerpt of a field report from Maine discusses prescribing statistics for Dr. [C.] and Dr. [R.], and then observes, "Based on volume of scripts generated, we need to stay committed to working with Dr. [C.] and Dr. [R.]" on speaker programs. (PX6 at TNA-0183976.)

Additional examples abound in the record, only some of which I choose to excerpt here. (*See* PX9 at TNA-174200 ("Developing speakers like Dr. [L.], Dr. [D.], and Dr. [R.] has produced new Azilect Rx in the months following the programs."); PX14 at 7 of 9 ("I have seen great increases in sales for many of our speakers. Dr. [K.], Dr. [L.], Dr. [V.], and Dr. [R.] have shown significant share increases for Copaxone. Dr. [L.] and Dr. [A.] have both increased their use of Azilect."); PX16 at 6 of 9 (describing increases of four physicians since becoming

speakers: Dr. [F.] from 2.5% to 4.8% market share; Dr. [B.] from 11% to 15.5%; Dr. [R.] from 45% to 47%; and Dr. [G.] from 29% to 34.6%); PX19 at 7 of 10 (noting that nurse practitioner [S.G.] increased her Azilect prescriptions after she became a speaker and that Dr. [C.S.]'s Copaxone market share is up 62% since he started speaking for Teva); PX2 at TNA-0014190 ("MS Market Analysis and Update" from the St. Louis region showing speaker Dr. [G.]'s rolling twelve-month total prescriptions as 2,141 and Copaxone share as 46%, and stating immediately afterwards, "The previous strategy has been to use Dr. [G.] with patient groups and physician lunches"); PX40 (presentation with entire slides dedicated to specific speakers, Dr. [T.] and Dr. [T.], including line graphs showing their market share over time); PX32 at 5 of 7 (observing that sales representative used Azilect speaker programs with Dr. [M.] and Dr. [K.], whose shares grew from 0.7% and 6% to 26.3% and 12%, respectively); *see also* Rels. 56.1 ¶¶ 2–4.)

Teva has no real answer to this evidence, except to argue that "Awareness of market share of speakers does not equate to tracking the market share of speakers in relation to speaker programs." (Defs. Reply at 13.) However, the evidence suggests more than "awareness." The evidence excerpted above includes dozens of examples of sales representatives' using speaker prescriptions to see whether the programs were producing tangible results and to suggest working more closely with high volume prescribing speakers.

Teva's final "Hail Mary" is to argue that "advocate" is not a synonym for "speaker." (Defs. Reply at 12–13). Therefore, any documents showing that Teva tracked "advocate" prescriptions does not necessarily mean that it tracked "speaker" prescriptions. (*Id.*) But if "advocate" and "speaker" are not synonymous—a proposition not free from doubt[5]—Relators

[5] Moreover, while many Teva witnesses testified that "advocate" and "speaker" were not synonyms, they admitted that the terms overlapped significantly. (Defs.' Reply Mem. of Law in Further Supp. of their Mot. for Summ. J. ("Defs. Reply"), Dkt. No. 141 at 12 n.13.) A former regional sales manager struggled to think of any speakers who had not been advocates, (*see* DX170 at 20:20–22:9; another two witnesses stated simply that an

have introduced substantial evidence that explicitly uses the term "speaker," rather than advocate, as demonstrated by the evidence excerpted above.

Teva's motion for summary judgment on the grounds that it did not track speakers is, therefore, denied.

d) There Is a Genuine Issue of Material Fact About Whether Teva Paid Its Speakers at Fair Market Value

Defendants argue that "the undisputed evidence that Teva compensated its speakers at fair market value is by itself fatal to Relators' claims," because a court cannot infer a defendant's intent to induce if there is no excess payment. (Defs. Br. at 19; *id.* at 20 (citing *United States ex rel. Perales v. St. Margaret's Hosp.*, 243 F. Supp. 2d 843, 851 (C.D. Ill. 2003) (*Perales*).) Teva also contends that Relators must show Teva's compensation to speakers was excessive compared to that of other pharmaceutical companies. (Defs. Br. at 20 (citing *United States ex rel. Brown v. Celgene Corp.*, 226 F. Supp. 3d 1032, 1054–55 (C.D. Cal. 2016) (*Brown*)).)

First, assuming *arguendo* that Defendants correctly state the law, (*but see United States ex rel. Booker v. Pfizer, Inc.*, 9 F. Supp. 3d 34, 53 (D. Mass. 2014) (*Booker I*)), Teva's evidence does not show that it indisputably paid fair market value to all speakers throughout the Relevant Period. Teva cites only to a handful of internal compliance policies, which dutifully recite the AKS requirement that speakers are required to be paid "fair market value" but do not specify what amount would constitute "fair market value." (DX11 at TNA-0625389; DX8 at TNA-0001684; DX35 at 8 of 30.) Teva also cites no payment records from the Relevant Period and makes no market comparisons.

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advocate was "not necessarily" a speaker, (DX171 at 214:19–216:21; *accord* DX174 at 193:14–16); and two others agreed that a reference to "advocates" could include paid speakers as well as other advocates, (DX172 at 246:11–247:2; *accord* DX173 at 284:21–285:7).

Teva does offer one report from Huron Consulting that includes recommended honoraria for contracted speakers, (DX37–38 (draft and final versions)), but this policy did not become effective until July 1, 2012, which is roughly five and a half years into the Relevant Period (*see* DX41 at 1). The Huron Report also does not enable this Court to conclude that Teva lacked the requisite intent under the AKS even after its adoption, because Relators have introduced evidence that Teva provided expensive dinners and alcohol during its speaker programs, in addition to honoraria, throughout the Relevant Period. (*See* Humphrey Rebuttal Report at ¶ 15 (listing examples of events where cost of food and alcohol at speaker programs exceeded $65 per person, with many events exceeding Teva's own $125 per person limit); *see also id.* ¶ 15(kk) (example of program where speaker spoke only to two Teva sales representatives, and program costs exceeded $1,188).)

Teva's argument that Relators must show Teva paid its speakers more highly than other pharmaceutical companies is also wrong. If true, such evidence would of course be one way to prove an AKS violation—but it is not the only way.

In *Brown*, 226 F. Supp. 3d at 1054, the relator affirmatively set out to prove Celgene's intent under the AKS by arguing, in part, that Celgene's annual cap on honoraria was higher than that of other companies, and that the honoraria Celgene paid to its speakers "were several times the amount of money the same doctors charged to perform other tasks." *Id.* The court held that the appropriate apples-to-apples comparison was the hourly rate paid by other programs for the same service, rather than the annual cap across companies or what each speaker charged for non-lecture services. *Id.*

Here, however, Relators by and large do not disagree that Teva paid honoraria after July 1, 2012, in accordance with the compensation schedules recommended by Huron. (*But see*

PX179 (identifying hundreds of occasions after July 1, 2012, when Teva violated its own written fair market value policies by not reducing speaker compensation when the speaker gave multiple programs on the same day).) Instead, Relators argue Teva exceeded fair market value when it made *any* honorarium payments to speakers for sham programs. (*See* Rels. 56.1 ¶ 27.) Because these programs had no legitimate purpose, except to reward or increase speaker prescriptions, any payments made to speakers for these programs would exceed "fair market value."

In sum, whether Teva possessed the requisite intent under the AKS is a hotly disputed issue of material fact.

2. A Reasonable Jury Could Find that Teva's Speaker Program Was a Sham

Teva next argues that Relators have failed to develop material facts in support of their allegations that its speaker program was a sham. (Defs. Br. at 21.)

Specifically, Teva claims that the following facts remain undisputed following discovery: (1) there is no evidence that the programs were on a regular basis given to the same attendees repeatedly, or to no one at all; (2) eligibility to serve as speaker was not contingent on the number of prescriptions the physician wrote; (3) at all times during the relevant time period, no speaker could be engaged for Teva absent a valid business justification; (4) the speaker programs were valuable to those in attendance because: (i) the labels and indications for both Azilect and Copaxone changed over the course of the Relevant Period; and (ii) Teva updated its speaker program materials annually and made changes to the slide decks to reflect developments in the MS and Parkinson's disease states and marketplaces; and (5) the program provided a valuable promotional service to Teva. (*Id.* at 21–22.)

a) There Is a Genuine Issue of Material Fact Whether Speaker Programs Were Regularly Given Without Legitimate Attendees

Teva urges this Court to find that Relators have "no evidence that the programs were on a regular basis given to the same attendees repeatedly, or to no one at all." (Defs. Br. at 21–22; Defs. 56.1 ¶ 76.)

In support of their claim that low-attendance programs were rare, Defendants proffer attendance data for portions of the Relevant Period. For example, they submit a report of all AHM events in 2009. (DX156 at 4–28 (listing events and attendance).) While Defendants have not summarized this data, it does appear that many of the events had more than two attendees. (*Id.*) Teva has also submitted a PowerPoint presentation on AHM speaker programs conducted from January 1, 2013 through April 2, 2013, showing that each peer-to-peer program had four attendees on average, (DX157 at 5 of 17); as well as a presentation on the 2011 AHM speaker programs, showing that each program had four to five attendees on average, (DX158 at 6 of 24).

In response, Relators submit their own summary exhibits, in the form of their supplementary interrogatory responses, which show many examples of programs with zero or one appropriate attendees. For example, they submit a 140-page spreadsheet of speaker programs from 2008 to 2014 and a four-page spreadsheet of additional speaker programs from 2013 to 2014 that include "thousands of examples of speaker programs with one or zero attendees." (Rels. 56.1 ¶ 74 (citing PX173; PX184).) Relators have also submitted, among other evidence: (i) three spreadsheets totaling 55 pages containing examples of programs between 2009 and 2014 where a paid speaker gave a lecture to a Teva sales representative who was the only member of the audience (as there were either no other attendees or all other attendees were illegitimate), (*id.* (citing PX175; PX188; PX195)); (ii) a spreadsheet showing programs from 2011 to 2014 in which there was only one legitimate attendee ("one-on-one" programs), (*id.*

(citing PX173)); and (iii) a spreadsheet in which Relators highlight 29 examples of Teva's miscounting attendees in its 2009 AHM program spreadsheet at DX156, by failing to account for paid speakers and Teva sales representatives in the audience (PX271).

Relators have also submitted evidence showing that the same programs were repeatedly presented to the same attendees. For example, they have introduced evidence showing 1,500 examples of health care providers' attending three or more events related to the same drug within six months, (Rels. 56.1 ¶ 75 (citing PX177)); paid speakers who attended speaker programs on the same topic for which they also serve as a speaker, (Rels. 56.1 ¶ 74 (citing PX166; PX172; PX185; and PX193)); and health care providers' "rotating" by attending sequential Teva programs as the speaker at one and audience member at the other, (*id.* (citing PX169)).

Defendants have no answer to Relators' evidence, except to argue that one of the many exhibits submitted by Relators, PX271, contains "no information about who the attendees were" and otherwise uses "unreliable data." (Defs. Reply at 19.) According to Defendants, the data in Relators' spreadsheets comes from AHM 360, which the Senior Director of Account Management at AHM has testified "isn't the official data" but rather "just a tool that we use to help facilitate reporting." (*See* Expert Report of Pierre-Yves Cremieux, Ph.D. ("Cremieux Report"), DX97 ¶ 46 n.45.) However, Defendants apparently rely on the very same AHM data to support their own arguments regarding attendance, and they have given no indication why their data may be relied upon for the proposition that low attendance was rare, whereas Relators' data may not be relied upon for the proposition that there were thousands of instances of low attendance. (*See* Defs. Reply at 19; *see also* Expert Rebuttal Report of Joel W. Hay, Ph.D. ("Hay Rebuttal Report"), PX281 ¶ 11.)

b) There Is a Genuine Issue of Material Fact Whether Speakers Were Chosen for Their Potential to Prescribe More Azilect and Copaxone

Defendants next argue that Relators have failed to show that "eligibility to serve as a speaker was [] contingent on the number of prescriptions the physician wrote," as opposed to other factors, including a legitimate needs assessment, speaking ability, and academic qualifications. (Defs. Br. at 21; Defs. 56.1 ¶¶ 3–5.)

Relators have offered ample evidence that sales volume, as opposed to other factors, drove speaker bureau nominations.

Defendants do not dispute that recommendations for the speaker's bureau came initially from the Sales and Marketing Departments, rather than from, for example, Medical Affairs or Compliance. (Defs. Br. at 7.) And, while Teva argues that it "used a number of criteria embedded in a multilayered approval process to ensure that effective speakers were chosen," (Defs. Br. at 21; Defs. 56.1 ¶¶ 33–37), the record raises a genuine issue of material fact about whether the nominations process conformed to Teva's own internal procedures and protocols. (*See, e.g.*, PX68 at TNA-0096541 (e-mail requesting addition to the speaker bureau at 5:03 p.m. and e-mail granting addition at 9:22 a.m. the following morning); PX71 at TNA-0384305–08 (demonstrating how sales representatives were able to secure a late addition for Dr. [H.] to the speaker bureau by attaching a screenshot of his prescribing data compared to other physicians, despite Copaxone brand managers "not see[ing] an experience level that might warrant an exception to the rule"); PX77 at TNA-0384474–75 ("proactive[ly]" adding high-volume prescriber to speaker bureau despite not "hav[ing] many details at this point").)

Second, prescription volume was routinely discussed during the nominations process. Indeed, the record is replete with examples of sales representatives' and managers disregarding

other criteria—speaking ability, academic qualifications—in favor of drug volume. (*See, e.g.*, PX44 at TNA-0411339 (listing "Develop top 20 volume prescribes [*sic*] as COP advocates" as a goal); PX20 at 8 of 11 (discussing how sales rep targeted "loyal Teva/Copaxone advocates" for speaker programs); PX35 at TNA-0100491 ("In terms of [G.], I think it is important to keep her on both MS and PD simply based on volume and her being 'Dr. [G.]'."); PX37 at TNA-0008657 ("We don't think we will need Dr. [M.] as a speaker next year. [. . .] [H]is volume isn't as important to our territory as Dr. [G., C., and A.]."); PX60 at TNA-0297932 (replacing physician with nurse practitioner on speaker bureau because "Dr. [L.] has taken a job as a hospitalist and will no longer be seeing PD patient [*sic*] in a clinical setting"); PX29 at 4 of 6 ("Target physicians based upon volume and potential for share change."); PX7 at TNA-0283460 ("The two physicians who continue to be a concern are Dr. [P.] and Dr. [B.]. [. . .] We are, however, confident that we will be able to turn these two customers around given our level of activity with them."); PX8 at TNA-0278223 ("For Copaxone he is trending to be down . . . Our plan to combat this is to utilize him for both peer-to-peer discussions . . . and for patient programs."); PX10 at 1 (in response to questions regarding whether the sales rep has any additions for the bureau, "Dr. [K.] has expressed interest. [. . .] Considering he is #9 in our top 10 for volume prescribers, I suggest that we give him the opportunity."); PX10 at TNA-0176097 (listing speakers "in order of importance (by the RSM)"); PX12 at 0176970 ("At this time I'm more interested in pursuing tactics with prescribers in our territory. [K.] is a great speaker, but isn't writing drug. Freeing up the [K.] money has given us the opportunity to" schedule speaker programs "with someone like Dr. [R.] or Dr. [L.]") (emphasis in original); PX13 at 9 of 13 ("Dave worked with Dr. [C.] do [*sic*] his first Azilect talk this year and it went very well. He

was never an Azilect supporter and Dave was got him [*sic*] prescribing Azilect in just a few months.").)

Defendants' only response is that "market share was a proxy for a physician's clinical experience and influence." (Defs. Reply at 15 (citing deposition testimony of various Teva employees).) This statement is highly questionable, as the record shows that clinical experience and influence were frequently discussed separately from market share and drug volume. (*See* PX6 at TNA-0183978 ("As mentioned earlier, all of this creates some nice opportunity for Dr. [R.]. He isn't the most knowledgeable PD physician, but writes a lot of scripts and has a favorable opinion of Azilect. Seems like we have nothing to lose by utilizing him more."); PX11 at TNA-0182100 (in an e-mail exchange with the Regional Sales Manager for New England, "Regarding Dr. [S.], I was on the fence about her from the beginning. She isn't a good speaker, and her response to this initiative is on par with her urgency toward any initiative. She isn't someone who is worth getting in front of other customers[.]"); *id.* ("Dr. [S.], though, not the best speaker, may still warrant consideration as an AHM Speaker. Hi [*sic*] volume, high decile and much MS!"); *id.* ("I agree. Let's get her committed to a date with Amy and trained!"); *see also* PX67 at TNA-0017291 ("I wanted to make sure we could get [P.] trained for the second half of the year. She has expressed interest and is very important to our business (**she is our #2 behind Dr. [S.], making up nearly 10% of our business**).") (emphasis in original); PX79 at TNA-0222666 ("Dr. [S.] is on a short list of Azilect 'game changers (decile 9 - second highest volume after [A.]' for us this year. As a result we have made him a priority with respect to programs . . . he alone could carry our volume forecasts for the remaining months should he come on board with Azilect.").)

c) *There Is a Genuine Issue of Material Fact Whether Teva Always Had a Valid Business Justification for Hiring Speakers*

Teva argues that "at all times during the relevant time period, no speaker could be engaged for Teva absent a valid business justification." (Defs. Br. at 21.) Teva bases this claim solely on the fact that such a requirement could be found in its written policies, including the Teva Integrity Principles, as well as a single needs assessment conducted by its Marketing Department in 2011, aimed at the upcoming 2012 year. (*See* Defs. 56.1 ¶ 2; DX64.)

Obviously, this evidence does not entitle Teva to summary judgment. The existence of written policies does not prove that "no speaker could be engaged for Teva absent a valid business justification" for the entirety of the Relevant Period, particularly where Teva has neither cited to any evidence that it actually engaged in any needs analysis before 2011 or explained why the 2011 analysis was sufficient to determine Teva's business needs after 2012. (*See* Rels. 56.1 ¶ 37(a); PX197 ¶ 11 (testimony of Teva's Director of Compliance from 2006 to 2012 that Teva began conducting the needs assessment "late in [his] tenure").)

There is also no evidence that the 2011 analysis was an effective speaker program control. The numbers produced in the 2011 analysis appear simply to have been calculated by taking the number of practicing neurologists in the United States and multiplying those neurologists by the percentage Teva wished to reach (which was, unsurprisingly, 100%) and by the number of times each year they wished to reach them. (DX64.) This number was then divided by the average number of attendees per peer-to-peer program, which the analysis expressly states Teva did not know, since it only had numbers based on the AHM data. (*Id.*) As the movant on summary judgment, Teva bears the burden of demonstrating that the needs assessment satisfied the legitimate needs of the business. On its own, a single needs assessment performed in the middle of the Relevant Period, without further context, does not suffice.

d) There Is a Genuine Issue of Material Fact Whether Teva Designed Its Program Content in a Sham Manner

Teva argues Relators have not proved that Teva designed its speaker programs materials in a sham manner. Teva argues that, throughout the Relevant Period, the content responded to the needs and interests of attendees. (Defs. Br. at 6–8, 22.) In particular, Teva argues it is undisputed that the company "updated its speaker program materials annually and made changes to the slide decks to reflect developments in the MS and PD disease states and marketplaces." (*Id.* at 22; Defs. 56.1 ¶¶ 45–73, 139.) They also claim it is undisputed that "the labels and indications for both Copaxone and Azilect changed over the course of the Relevant Time Period." (Defs. Br. at 22; Defs. 56.1 ¶¶ 47–56, 140.)

Relators do not dispute that Teva updated its presentation materials annually, or that the labels for Azilect and Copaxone changed. (*See* Rels. 56.1 ¶¶ 45–73, 139–140.) However, Relators argue that these changes were not "significant" to attendees, and that the materials remained "objectively rudimentary and repetitive in nature." (Rels. Opp. at 8; *see also* Rels. 56.1 at ¶¶ 41–44, 46–56, 59–63, 67–75, 169–187.) Relators further point out that content developers engaged by Teva were paid speakers. (Rels. 56.1 ¶ 42 (citing PX235 at 31:7–13).)

As evidence that the program content lacked educational value for attendees, Relators offer the expert report of Dr. Samuel Pleasure, M.D., Ph.D., Professor of Neurology at the University of California, San Francisco. (Pleasure Report at App'x A.) Dr. Pleasure was asked to evaluate the medical educational value of the materials presented at Teva speaker programs. (*Id.* ¶ 7.) Dr. Pleasure reviewed the medical information presented across over 500 Teva promotional slide decks for Azilect and Copaxone, including training decks, which were used between 2006 and 2016. (*Id.* ¶¶ 7, 32.) Dr. Pleasure concluded: (a) Teva's materials did not take into account who would be in the audience and what they should receive from an

educational perspective, (*id.* ¶¶ 36, 46); (b) the peer-to-peer slide decks were "inappropriate for the education of" practicing neurologists, (*id.* ¶ 37); and (c) the material was not presented in an unbiased way, as required by the PhRMA Guidelines, (*id.* ¶ 39). His principal reasons for so concluding were that the presentations "presented the pathophysiology and clinical features of PD and MS at extremely simplistic levels," which in some cases were "barely appropriate for medical students"; and contained references to studies regarding the use of Teva drugs that were already a few years old and that would already have been familiar to treating physicians. (*Id.* ¶¶ 38–40.) Dr. Pleasure also concluded that because Teva required the slides to be presented sequentially and required the materials to be presented in full, the simplistic disease state information at the beginning of the presentation would have caused neurologists "to become inattentive at a very early stage of the presentations." (*Id.* ¶ 38.)

Dr. Pleasure also opined that, while there were "interesting and important advances in the field of clinical care of MS and PD" between 2004 and 2016, Teva's slide decks did not present this information in a full and unbiased way, such as to have educational or practical value for neurologists attending these presentations. (Rebuttal Expert Report and Declaration of Samuel Pleasure, Ph.D., M.D. ("Pleasure Rebuttal Report"), DX90 ¶ 11.) For example, the presentations did not disclose that the placebo group in the PRECISE trial "contained patients at a higher risk to develop MS than the treatment group," and the GALA trial was a placebo-controlled trial, rather than a head-to-head comparison of Copaxone against other agents. (*Id.*) Dr. Pleasure also opined that neurologists would already have been familiar with these studies through medical journals and other literature. (*Id.*)

Defendants have not challenged Dr. Pleasure's undoubted expertise. To controvert his report, Defendants offer two kinds of evidence.

First, they introduce the declarations of two physician content developers, who opine that, in their experience, Teva's materials were superior in educational content to those of other pharmaceutical companies. (*See*, *e.g.*, DX83 ¶ 19.) Neither of these physicians, however, was qualified as an expert. Of course, it is axiomatic that declarations must be based on personal knowledge, and Teva cannot use these declarations to create a genuine issue of material fact that the materials responded to the needs and interests of attendees, except insofar as the declarants can personally attest to having found value in these programs as attendees. Moreover, this could simply be a scathing indictment of the rest of the pharmaceutical industry, rather than as evidence of the educational adequacy of Teva's programs.

Second, Defendants argue it is irrelevant that the program content had limited educational value, because its value was primarily promotional.[6] In support, Defendants proffer the expert report of Dr. Pradeep K. Chintagunta, Ph.D., Joseph T. and Bernice S. Lewis Distinguished Professor of Marketing at the Graduate School of Business at the University of Chicago. (*See* Chintagunta Report ¶ 1; *see also id.* at App'x A.) Reviewing academic literature regarding pharmaceutical marketing, Dr. Chintagunta concluded that conducting peer-to-peer speaker programs would have been valuable to Teva during the Relevant Period, even though both Azilect and Copaxone were established treatments, (*id.* ¶¶ 30–34), because (1) as a drug becomes more established, physicians seek to conform their prescribing behavior to that of their peers, and rely less on technical and performance considerations, (*id.* ¶ 31); and, (2) as treatment practices for a condition shift over time, physicians require new information that allows them to compare old treatment options against new ones, (*id.* ¶ 32). Dr. Chintagunta also opined that the latter

[6] Certain of Teva's documents call this into question. (*See*, *e.g.*, DX11 at TNA-0625388 ("All promotional programs must have some educational or patient care benefit.").)

category of information would be valuable where the drugs treat chronic conditions, since the effectiveness of these drugs is difficult to monitor. (*Id.* ¶ 33.)

Reviewing materials related to the Azilect and Copaxone marketing mix, the ZS studies measuring ROI of the speaker programs for attendees, and declarations of physicians who participated in content development, Dr. Chintagunta concluded that there were changes in the treatment options of Parkinson's disease and MS, which would have supported speaker programs as a valid promotional spend tactic during this period. (*Id.* ¶¶ 52–59.) Dr. Chintagunta stopped short, however, of opining that the materials were responsive to the needs and interests of attendees. It is also unclear whether Dr. Chintagunta reviewed the content of the speaker materials themselves or merely evaluated the program as a whole in response to Teva's proportional marketing spend.

The Court finds that there is a genuine issue of material fact as to whether Teva created the content for its presentations in what Relators characterize as a sham manner.

e) There Is a Genuine Issue of Material Fact Whether Teva Structured Speaker Program Events in a Sham Manner

Teva also argues that Relators have not proved that Teva structured its speaker program "events" in a sham manner. (Defs. Br. at 22; Defs. 56.1 ¶ 76.) This argument responds to Relators' allegations that, in addition to the presentation materials themselves, the program venues, activities (such as food and alcohol that were served), and audience composition stripped these programs of any legitimate educational value.

Teva argues that even when attendance was low and the programs took place outside of the office environment, audience members found the speaker programs valuable because they engaged in spirited dialogues with their colleagues and discussed new advances in the field. (*See, e.g.*, DX23 ¶¶ 20–21 (declaration of Dr. [J.S.] stating, "[I]n my experience, no two of

Teva's speaker programs were alike as there would always be new ideas exchanged between speakers and attendees of different practice groups" and "although I understand that relators have alleged that on occasion Dr. [B.A.] and I were the only HCPs present at programs, I found each of these programs to be educational and valuable[.]").)

In response, Relators submit that Teva routinely carried out speaker program events in a sham manner, as evidenced by the location at which many programs were held, the amount of alcohol served, and the fact that the audience was frequently made up of either Teva representatives, speakers themselves, repeat attendees, or physicians' family members. Relators set out to prove this by defining criteria for events whose activities would serve no legitimate educational purpose, including criteria that violated Teva's own compliance policies—and then producing data showing that events with these criteria regularly took place.

Relators offer the expert report of Dr. Holly J. Humphrey, M.D., M.A.C.P., former Dean of Medical Education at the University of Chicago. (Expert Report of Dr. Holly J. Humphrey, M.D., M.A.C.P. ("Humphrey Report"), PX162 ¶ 1; *see also id.* App'x A (listing qualifications and experience).) Informed by various third-party standards regarding continuing education for physicians, including publications from the Accreditation Council for Continuing Medical Education, the 2002 and 2008 PhRMA Guidelines, the recommendations in the 2009 Huron report, as well as by her own expertise in medical education, Dr. Humphrey concluded that there would be no educational value for: (a) a physician who attends three or more events related to the same drug within six months; (b) a physician who serves as a speaker for a given drug and then attends a lecture about the same drug within twelve months; (c) a physician who attends any speaker program where the food and beverage cost exceeds $65 per person; (d) a physician who serves as a speaker for a given drug where the only audience member is the sales representative

or another "ineligible" attendee; (e) a physician who is the only legitimate attendee for an event related to a given drug; and (f) a non-health care professional attendee who is the spouse of a physician for an event related to a given drug. (*Id.* ¶ 38–48.)

Dr. Humphrey based her conclusions on, among other things, the fact that practicing physicians typically build off of their foundational knowledge and clinical experience, and therefore require only one lecture to learn about a new drug or treatment, (*id.* ¶ 50); if a physician still had not learned about the new drug or treatment after the second presentation, a third, identical presentation in a lecture format would have no educational value, (*id.*); the PhRMA Guidelines require that any meals served in connection with a presentation be "modest by local standards," and the average cost of a meal in New York City was less than $65, (*id.* ¶ 52); a lecturer generally has more information, experience, and expertise than one who attends the lecture, such that there would be no legitimate value to "rotating" presenters and audience members, (*id.* ¶ 51), and "one-on-one tutoring sessions are not . . . a legitimate form of medical education," (*id.* ¶ 53).

Relators then offer considerable data showing that events not qualifying as useful under Dr. Humphrey's rules occurred regularly. (*See* Rels. 56.1 ¶ 74 (describing PX166–95).) For that data, Teva has no answers.

The Court finds that Relators have raised a genuine issue of material fact that Teva structured its speaker programs in a sham manner. At trial, a jury may weigh the testimony of various paid speakers against the expert testimony of Dr. Humphrey to conclude whether the speaker program served a legitimate purpose or was designed as a conduit for speaker fees.

3. Relators Raise a Genuine Issue of Material Fact that the AKS Violations Reflected a Companywide Scheme by Teva, Rather than Isolated Instances of Misconduct

In Defendants' earlier motion to dismiss the SAC for failure to plead fraud with particularity, Defendants argued that Relators were required to "plead particular details about individual false claims." (*See* Dkt. No. 39 at 6.) Relators responded that "*every* claim submitted by the physicians who received kickbacks from the Teva speaker programs was false," because the AKS compliance certifications in those claims would have been tainted by the prescribers' participation in the sham speaker program. (*Id.* (summarizing Relators' argument).) In order to proceed on this "taint" theory, the Court held in *Teva I* that Relators would be required to show that the speaker program had a "universal and improper" purpose. 2016 WL 750720, at *17.

Defendants argue that, following discovery, they are entitled to summary judgment because "Relators are stuck with the case they allege but cannot prove." (Defs. Reply at 18.) This is because Relators' only evidence "consists of Relators' characterization of a smattering of documents from disparate sales representatives," from which the Court cannot "infer a company-wide scheme." (*Id.*)

Relators respond that the record amply supports the existence of a universal and improper scheme, namely because of the volume of the record and consistency of the evidence across Teva's nationwide sales force and marketing operations. (Rels. Opp. at 20; Rels. 56.1 ¶¶ 208–34.)

The record on summary judgment indeed creates a genuine issue of material fact about whether the speaker program had as its "universal" purpose rewarding speakers for writing Azilect and Copaxone prescriptions. Relators have introduced deposition testimony, e-mails, performance reviews, and strategy documents from senior Teva employees who supervised the program, including current and former national sales directors, area sales managers, and regional

sales managers. A reasonable jury, viewing this evidence in the light most favorable to Relators, could conclude that the speaker program represented a coordinated scheme to increase prescription writing by speakers. (*See* Rels. 56.1 ¶¶ 208–34.)

Some representative examples of this evidence are the following:

- Teva's standard performance review rubric for sales representatives for 2011 included the following "general competency," on which employees were graded: "Understands the concept *of growing market share through of* [*sic*] *key advocates* through the process of education and preparing to speak." (*See, e.g.*, PX128 at 9 of 12 (emphasis added).)

- Regional managers attached lists of physicians ranked by sales volume to e-mails soliciting opinions on whom to include in that year's speaker bureau. (PX126 at TNA-0004797.)

- Product managers for Parkinson's Marketing at Teva Neuroscience discussed how they had sorted their list of target speakers for the nationwide speaker program by, first and foremost, "PD market volume." (PX130 at TNA-0214505.)

- After speaking with the Senior Director of Sales, an executive sales representative sent an e-mail summarizing the day she spent with a Teva compliance officer, whom she stated "wasn't really working 'with' us" because he said that the patient programs and physician programs "can appear like we are offering 'kickbacks.'" (PX391 at TNA-0244587.) The Senior Director of Sales circulated her e-mail to the senior sales and compliance teams, stating, "Call if you ever need sales perspective." (*Id.* at TNA-0244586.)

- Following a Sales & Professional Leadership Team Meeting, Teva Neuroscience's National Sales Director circulated highlights of the meeting to sales managers across the country. (PX120 at TNA-0122039.) Highlights included the head of the Adirondack Region's strategy of "AHM's, AHM's, AHM's," adding, "This is the closest thing I have to a silver bullet." (*Id.*)

The cases cited by Defendants in support of granting summary judgment are also distinguishable. For example, in *Booker II*, 188 F. Supp. 3d at 134, the relators had relied largely on the testimony of one sales representative, which the district court held was insufficient to establish a nationwide scheme. *Id.*; *see also id.* at 135 ("Relators are left with the say-so of one sales representative, . . . weighed against substantial evidence that Pfizer instructed its sales force on compliance issues and internally tracked results in a manner inconsistent with [his]

testimony."). Here, there is considerable document-based and testimonial evidence that would support an inference of a "universal and improper scheme."

In *Brown*, 226 F. Supp. 3d at 1055, the district court granted summary judgment to Celgene on the portion of relator's claim related to speaker programs because there was "no evidence that Celgene considered the number of prescriptions a doctor had written in deciding whether to employ the doctor as a speaker," "no evidence that speeches were given in unconventional venues or in the absence of bona fide attendees," and no evidence that "Celgene tracked the number of prescriptions written by speakers." *Id.* Here, by contrast, Relators have offered significant evidence of each of these facts, as discussed earlier in the opinion. *See also id.* (distinguishing the facts in *Brown* from those in *Teva I*).

Finally, Defendants' invocation of *United States ex rel. Ruckh v. Salus Rehabilitation, LLC*, 304 F. Supp. 3d 1258, 1268–69 (M.D. Fla. 2018), for the proposition that Relators must offer evidence of a "top down directive" if they are to survive summary judgment, fails to persuade. The cited portion of *Ruckh* held that relators had failed to establish the existence of a scheme as against the "Management Entity"—an LLC that sat atop the specialized nursing facilities alleged to have submitted false claims. *Id.* In holding that "a scattering of claims in a smattering of facilities is a wholly insufficient basis from which to infer the existence of a massive, authorized, cohesive, concerted, enduring, top-down, corporate scheme to defraud the government," the court meant that relators had adduced absolutely no evidence at summary judgment that any of the misconduct at issue was attributable to the Management Entity. *Id.* ("The defendants correctly conclude that the evidence fails to support a verdict against the Management Entity[.]"). Here, as already discussed, Relators have proffered evidence of both the widespread and top-down nature of the scheme; they have shown both evidence of violations

occurring at speaker programs throughout the country, and that management of all relevant entities was aware of (and perhaps sanctioned) such tactics. And while Defendants have denied that they functioned as each other's alter egos and/or agents at all relevant times, (Answer ¶ 8), they have not argued, based on *Ruckh*, that the evidence against any particular defendant is inadequate.

4. There Is No Basis for this Court to Exclude Relators' Damages Calculations

Defendants also argue that Relators' damages expert cannot properly calculate damages based on all prescriptions for Azilect and Copaxone written by speaker bureau physicians, since there is no evidence of a "sweeping" scheme. (Defs. Br. at 25.)

I have already found that Relators have raised a genuine issue of material fact with respect to whether there was a corporate-wide scheme (a term I have come to prefer to phrase "universal and improper," which is not a phrase with any legal import and which broadens impermissibly the Relators' burden to show a corporate-wide scheme, as opposed to a few rogue incidents). Therefore, this is not a basis to exclude Relators' damages calculations.

B. Relators Have Linked the Purported AKS Violations to Specific Prescription Reimbursement Claims

Defendants have also moved for summary judgment on the grounds that Relators fail to link particular claims submitted to the Government to the AKS violations at issue. The Court finds that Relators have met their burden of production to show causation, under the standard recently articulated by the Third Circuit in *United States ex rel. Greenfield v. Medco Health Sols., Inc.*, 880 F.3d 89 (3d Cir. 2018) (*Greenfield*).

1. To Meet Their Burden of Production, Relators Need Not Show That Any Speaker Increased His or Her Prescription Writing for Azilect or Copaxone in Response to Teva's Alleged Kickbacks

The parties disagree over the applicable causation standard.

Defendants argue that, because the 2010 PPACA amendments state that "items or services *resulting from* a violation" of the AKS are compensable under the FCA, Relators must prove that the kickbacks caused the physicians to write the prescriptions at issue. (Defs. Br. at 26–27 (citing 42 U.S.C. § 1320a-7b(g)) (emphasis added).) They call this an "inducing linkage." (Defs. Br. at 27.)

Relators counter that this is "nothing more than a recycled 'but-for' causation argument," which this Court previously rejected, and argues that the statute does not require the bribe to have actually succeeded in producing a referral for the parties' behavior to constitute a violation. (Rels. Opp. at 25.) The Government concurs, arguing that Relators have established the requisite link by showing that a doctor who received a kickback thereafter wrote prescriptions for the relevant drugs. (Statement of Interest of the United States of America in Resp. to Defs.' Mot. for Summ. J. ("Gov't SOI"), Dkt. No. 138-1 at 2–3.)

The law on this issue is not well developed. But, after canvassing the relevant case law, a few guiding principles emerge.

First, the FCA does not require the kickback to be the "but for" cause of the prescription. As the Third Circuit recently recognized, a strict "but for" prescribing requirement would not only dilute the entire theory of legal claim falsity, but, specifically, "would dilute the False Claims Act's requirements vis-à-vis the Anti-Kickback Statute, as direct causation would be a precondition to bringing a False Claims Act case but not an Anti-Kickback Statute case." *Greenfield*, 880 F.3d at 97; *see also Guilfoile v. Shields*, 913 F.3d 178, 190 (1st Cir. 2019) (recognizing *Greenfield*'s causation theory). Moreover, "The FCA and AKS seek to safeguard the independence of medical decision-making from the taint of kickbacks," and requiring "but for" prescribing—as Defendants propose—"[could] lead to under-enforcement as courts would

struggle to unravel why doctors or pharmacists recommended a given drug or service to patients." Richard Strassberg, William Harrington, & Annie E. Railton, *Two Recent Cases Illustrate Need to Rely on Causal Concepts in FCA Cases*, N.Y.L.J. (Online) (June 28, 2018), https://www.law.com/newyorklawjournal/2018/06/28/two-recent-cases-illustrate-need-to-rely-on-causal-concepts-in-fca-cases/.

Second, and relatedly, the Court is mindful that Relators' burden of production at this stage is not satisfied by a mere "correlation equals causation" argument. "At summary judgment, an FCA plaintiff must do more than 'merely . . . describe a private scheme in detail" and argue "that claims requesting illegal payments must have been submitted, were likely submitted[,] or should have been submitted to the Government.'" *Pink v. Khan*, No. 13-cv-4924, 2018 WL 5831222, at *5 (E.D. Pa. Nov. 7, 2018) (quoting *Greenfield*, 880 F.3d at 98).

To resolve this dilemma, courts have articulated a "middle of the road" approach. This approach holds that, "A kickback does not morph into a false claim unless a particular patient is exposed to an illegal recommendation or referral and a provider submits a claim for reimbursement pertaining to that patient." *Greenfield*, 880 F.3d at 100. "A 'link' is required, but it is less than" showing that the bribe succeeded in producing the prescription. *Id.* at 98. "For a False Claims Act violation, [a relator] must prove that at least one of [defendant's] claims sought reimbursement for medical care that was provided in violation of the Anti-Kickback Statute (as a kickback renders a subsequent claim ineligible for payment)." *Id.*

Put simply,

> [A] claim is false if it seeks reimbursement for a prescription that was not provided in compliance with the Anti-Kickback Statute, regardless of whether the claim was the result of a *quid-pro-quo* exchange or would have been submitted even absent the kickback. *See Greenfield*, 880 F.3d at 96. Relators need not show that a *quid pro quo* exchange occurred, or that the physicians would not have

> prescribed Defendant's medication but for the kickbacks. It is sufficient to show that Defendant paid kickbacks to a physician for the purpose of inducing the physician to prescribe specific drugs, and that the physician then prescribed those drugs, even if the physician would have prescribed those drugs absent the kickback.

United States ex rel. Bawduniak v. Biogen Idec, Inc., No. 12-cv-10601, 2018 WL 1996829, at *3 (D. Mass. Apr. 27, 2018) (*Bawduniak*); *accord United States ex rel. Scalamogna v. Steel Valley Ambulence*, No. 14-cv-524, 2018 WL 3122391, at *7 (W.D. Pa. June 26, 2018) ("An FCA violation based on the above-cited provisions of the Anti-Kickback Statute [42 U.S.C. § 1320a-7(b)(2)(A)] requires that a patient be exposed to an illegal referral; that a provider submits a claim for government reimbursement pertaining to that patient; and that a party to the transaction . . . offers a kickback to the referrer in exchange for the referral."). In other words, Relators need only show that the speakers' referral of Teva drugs "actually sat in the causal chain." Strassberg *et al.*

Relators did precisely this and so have met their burden of production.

Relators' damages expert, Dr. Joel W. Hay, Ph.D., has identified two potential sets of false claims submitted within the Relevant Period, after conducting an extensive review of doctors' prescription records. The first set consists of (i) actual claims of prescriptions for Azilect and Copaxone, (ii) written by paid Teva speakers, and (iii) submitted to three Federal health care programs, Medicare Part D, Medicaid, and TRICARE, (iv) at any time after that speaker was paid by Teva to speak about Azilect or Copaxone, through the end of the Relevant Period. (Expert Report of Dr. Joel W. Hay, Ph.D. ("Hay Report"), DX103 ¶¶ 20–23.)

The second set of claims consists of (i) actual claims of prescriptions for Azilect and Copaxone, (ii) written by paid Teva speakers, and (iii) submitted to three Federal health care programs, Medicare Part D, Medicaid, and TRICARE (iv) within six months of a speaker's being paid to speak about a given drug (iv) at a "sham" speaker program, the criteria for which

were identified by Relators' expert Dr. Humphrey. (*Id.* ¶¶ 25–26.) These criteria include, among other things, programs for which the average meal costs exceeded $65 per person and speaker programs in which a non-medical spouse of a speaker or attendee was in attendance. (*Id.* ¶ 26.) Dr. Hay uses this six month period because, "Teva specifically tied prescriptions written in the six months of participating in a speaker program in measuring its own return on investment." (*Id.* ¶ 25.)[7]

In summary, by linking payments to speakers to prescription writing, Plaintiffs have successfully met their burden of production at this stage of the proceedings.

Defendants have cited no authority that would lead to a different outcome. Indeed, all cases they cite can be distinguished on their facts.

In *United States ex rel. King v. Solvay Pharm., Inc.*, 871 F.3d 318, 332 (5th Cir. 2017), the Fifth Circuit found no underlying AKS violation. *Id.* ("There was nothing illegal about paying physicians for their participation in these types of programs and there is no evidence that participation was conditioned upon prescribing Solvay's drugs to Medicaid patients."); *id.* ("[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.") (emphasis added). Thus, the court did not have occasion to address the contours of causation when an AKS violation had been established.

In *United States v. Choudhry*, 262 F. Supp. 3d 1299, 1310 (M.D. Fla. 2017), the relator "concede[d] that it possesse[d] no specific claims or billing data" and so could only "speculate[]

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[7] To the extent Defendants' reply can be read to challenge Relators' damages expert's use of a six-month window as the appropriate period for which to calculate damages, this issue is not appropriate for resolution on the pending motion. (*See* Defs. Reply at 6.) This is particularly true where Defendants have not moved to exclude this expert testimony under *Daubert v. Merrell Dow Pharms. Inc.*, 509 U.S. 579 (1993). Vigorous cross-examination is Defendants' remedy.

that an unlawful kickback scheme exists." *Id.* Similarly, in *United States ex rel. Stop Ill. Mktg. Fraud, LLC v. Addus Homecare Corp.*, No. 13-cv-9059, 2018 WL 1411124, at *6 (N.D. Ill. Mar. 21, 2018), a motion to dismiss, relators did not allege with specificity that third parties had made *any* referrals whatsoever to the defendant.

For the first time in their reply brief, Defendants argue that the proper standard is not, in fact, "but for" causation, but instead "proximate causation." (Defs.' Reply Mem. of Law in Further Supp. of their Mot. for Summ. J., Dkt. No. 141 ("Defs. Reply"), at 3.) They argue that this requirement originates with the "causes to be presented" language in the FCA, 31 U.S.C. § 3729(a)(1)(A), rather than the "resulting from" language in the AKS, 42 U.S.C. § 1320a-7b(g). According to Defendants, because Relators have not shown that Teva proximately caused any particular claims to be presented to the Government, they cannot prevail.

"The FCA does not provide a special definition for causation, and neither the Supreme Court nor any Circuit Court of Appeals has grafted such a special definition on the FCA. Absent an FCA-specific definition of causation, the Court will apply common-law tort causation concepts." *United States ex rel. Franklin v. Parke-Davis, Div. of Warner-Lambert Co.*, No. 96-cv-11651, 2003 WL 22048255, at *4 (D. Mass. Aug. 22, 2003) (*Franklin II*). For a "cause to be presented" claim, the unlawful behavior must be a "substantial factor in bringing about [the] filing" of a false claim and the filing must be "a normal consequence of the situation created by that scheme." *United States ex rel. Schmidt v. Zimmer, Inc.*, 386 F.3d 235, 244–45 (3d Cir. 2004) (*Schmidt*); *see also United States ex rel. Feldman v. City of New York*, 808 F. Supp. 2d 641, 650 (S.D.N.Y. 2011) (approving causation standard from *Schmidt*).

With respect to the second prong, the "normal consequence" requirement is simply foreseeability by another name. *See Franklin II*, 2003 WL 22048255, at *4 (citing *Rodriguez-*

Cirilo v. Garcia, 115 F.3d 50, 54 (1st Cir. 1997) (Campbell, J., concurring)). Defendants do not argue that Relators' claim founders on these shoals. It was, of course, foreseeable—indeed, desirable—that paying speakers would cause those same speakers to write prescriptions for Azilect and Copaxone, which would be submitted to, among other insurers, federal health care programs. *Cf. United States ex rel. Franklin v. Parke-Davis, Div. of Warner-Lambert Co.*, 147 F. Supp. 2d 39, 52–53 (D. Mass. 2001) (*Franklin I*) ("In this case, when all reasonable inferences are drawn in favor of the Relator, the participation of doctors and pharmacists in the submission of false Medicaid claims was not only foreseeable, it was an intended consequence of the alleged scheme of fraud."); *Schmidt*, 386 F.3d at 245 ("false certifications of compliance were necessary consequences of Zimmer's marketing scheme").[8]

The crux of Defendants' argument is instead the "substantial factor" prong. Defendants propose that the "substantial factor" standard incorporates "but for" causation, as a principle of tort law, and therefore requires that the kickback have actually caused a speaker to prescribe a Teva drug.

However, Defendants are incorrect that Relators can survive summary judgment only by producing evidence of an increase in speakers' prescriptions. Under the Third Circuit's test in *Greenfield*, a plaintiff in an AKS/FCA legal falsity case satisfies his burden of production for causation by showing that a physician referred or recommended a patient to a provider after receiving an illegal payment from that provider. Accordingly, Relators' burden of production for the "substantial factor" prong is satisfied under largely the same circumstances that the "resulting from" test is satisfied. *See, e.g.*, *Thomas*, 2008 WL 4853630, at *14 ("A jury could find that that

[8] The AKS requires only that the item that is the subject of referral "could be paid for by a federal health care program." *United States v. Miles*, 360 F.3d 472, 480 (5th Cir. 2004).

scheme was a substantial factor in bringing about Dr. Chan's submitting false and fraudulent claims when he sought payment for surgeries using Blackstone products while accepting payments from them under the allegedly sham consulting agreement."), *superseded on other grounds by* 42 U.S.C. § 1320a-7b(g).[9] Reading the FCA in the manner Defendants propose would effectively render "but for" prescribing a legal prerequisite in "cause to be presented" AKS cases, but not in cases where the defendant itself presents the claims to the Government, a distinction the case law does not recognize, and one which would undermine Congress' goal of increasing FCA enforcement with respect to the AKS. Both *Bawduniak* and *Novartis IV*, for example, were "cause[] to be presented" AKS cases against pharmaceutical companies, and the courts in both cases expressly held that the FCA did not require the kickbacks at issue to have actually altered providers' prescribing behavior. *Bawduniak*, 2018 WL 1996829, at *3; *Novartis IV*, 41 F. Supp. 3d at 331–32.

Teva argues, also for the first time in reply, that because the Government's damages expert in *Bilotta* conducted an analysis of speaker prescribing habits to show proximate causation, and Relators' damages expert did not, this entitles them to summary judgment. (Defs. Reply at 6–7.) They are mistaken. Even if the strategic behavior of litigants in other cases could conclusively establish the law—and of course it cannot—the Government in *Bilotta* apparently utilized this approach out of an abundance of caution, without conceding that this was uniformly required in AKS cases: "Although unnecessary to do so, the Government can show that NPC's kickbacks did in fact influence the recipients' prescribing decisions." Mem. of Law in Opp. to Def.'s Mot. for Summ. J. and in Supp. of the United States' Cross-Mot. for Partial Summ. J.

[9] In enacting 42 U.S.C. § 1320a-7b(g), Congress overruled the portion of the opinion holding that the relator could not recover for claims submitted by the hospital, since it was unaware of the kickback scheme. However, the quoted language relates to a portion of the opinion that was not statutorily overruled, a discussion of whether the medical device manufacturer defendants had knowingly caused the surgeon to present legally false claims.

("*Bilotta* Gov't Opp.") at 45, *Bilotta*, No. 11-cv-71 (S.D.N.Y. Aug. 29, 2018), Dkt. No. 230; *accord id.* at 35–45; *see also* Expert Rep. of Daniel L. McFadden ("McFadden Report") ¶¶ 23–24, attached as Ex. A to the Decl. of Jacob Lillywhite in Opp. to the Mot. to Preclude the Expert Testimony of Daniel L. McFadden dated Nov. 19, 2018, Dkt. No. 281, *Bilotta*, No. 11-cv-71 (S.D.N.Y. Nov. 19, 2018).

Notably, the Government's expert in *Bilotta* calculated damages as "*the total number of prescriptions written by a given doctor* during the period when [the expert's] modeling reflects . . . that a doctor was influenced by kickbacks." McFadden Report ¶ 57. In other words, the Government's expert in *Bilotta* did not base damages on the difference between all prescriptions written and those prescriptions that would not have been written absent the kickback. Instead, the report utilizes the same false certification theory Relators pursue in the instant case, which makes Defendants liable for claims made as the result of *exposure* to an illegal referral.

In short, Relators have met their burden of production for a *prima facie* case on summary judgment, because they have shown that Teva paid kickbacks to specific physicians (and other health care providers) for the purpose of inducing them to prescribe Azilect and Copaxone, and that the providers then prescribed those drugs. To get to trial, they need not demonstrate that the providers would not have prescribed those drugs absent the kickbacks. On the record, they have raised an inference of causation—albeit not the strongest one—that a jury may use to find liability.

Of course, this is not a theory against which there can be no defense. Defendants may call witnesses—likely, doctors—who will testify that, for some portion of the damages period, their patients were not "exposed to" an illegal referral from Teva, either because the witnesses' relationships with Teva ended well before the prescriptions at issue, or because the witnesses'

sound medical judgment broke the chain of causation, such that Teva's speaker payments played no part in their decision to prescribe Azilect and Copaxone. They, in turn, will be subject to cross-examination by Relators.

Therefore, Defendants' motion for summary judgment on these grounds is denied.

C. Relators Raise a Genuine Issue of Material Fact That Certifying Compliance with the AKS Was Material to the Federal Health Care Programs' Decisions to Reimburse Azilect and Copaxone Prescriptions

Relators have brought claims under two subsections of the FCA: 31 U.S.C. § 3729(a)(1)(A), making liable a person who "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval"; and 42 U.S.C. § 3729(a)(1)(B), making liable a person who "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim."[10] (*See* TAC ¶ 169–170.)

Subsection § 3729(a)(1)(A) does not explicitly include any materiality requirement. However, the Supreme Court has read a materiality requirement into the "false or fraudulent" language of that subsection. *Escobar*, 136 S. Ct. at 1999 (holding that Congress "intends to incorporate the well-settled meaning of the common law terms it uses" and that "the term 'fraudulent' is a paradigmatic example of a statutory term that incorporates the common-law meaning of fraud") (internal citation omitted). And subsection 3729(a)(1)(B) requires, by its terms, that a defendant caused to be made or used a false record or statement that is "material" to the false and fraudulent claim.

[10] Relators allege that Teva "has violated 31 U.S.C. § 3729(a)(1)(B) by causing the States to submit false claims to the United States Government on Form CMS-64 (Quarterly Medicaid Statement of Expenditures for the Medical Assistance Program), which falsely certified that all drugs for which federal reimbursement was sought, including [Azilect and Copaxone], were paid for in compliance with federal law, including the AKA [*sic*][.]" (TAC ¶ 170.)

Defendants argue that, based on the evidence, Relators have not met their burden to show that the alleged noncompliance with the AKS was "material" to the Government's payment decisions under *Escobar*.

1. The AKS Violations That Occurred After March 23, 2010 Are Material as a Matter of Law

Relators first argue that the Court can and should find AKS violations to be material as a matter of law for all claims in this case. (Pls.-Relators' Suppl. Br. Pursuant to the Court's Order Dated Dec. 11, 2018, Dkt. No. 156 ("Rels. Suppl. Opp."), at 4–5). I cannot do that, but I agree as to one subset of claims: those that Teva (i) caused to be presented in violation of subsection § 3729(a)(1)(A) *and* (ii) were submitted after March 23, 2010.

The 2010 amendments to the AKS state that "a claim that includes items or services resulting from a violation of this section constitutes a false or fraudulent claim for purposes of subchapter III of chapter 37 of Title 31." 42 U.S.C. § 1320a-7b(g). Therefore, for claims submitted after the effective date of the amendment, and where liability comes from "knowingly . . . caus[ing] to be presented, a false or fraudulent claim for payment or approval," 31 U.S.C. § 3729(a)(1)(A), there is no need for an independent assessment of materiality. Congress has decreed these claims to be "fraudulent," and as the Court observed in *Escobar*, a fraudulent claim is necessarily material because only material misrepresentations (or omissions) qualify as "fraudulent" under the common law. 136 S. Ct. at 1999. Or, as the court held in *United States v. Berkeley Heartlab, Inc.*, No. 14-cv-230, 2017 WL 6015574, at *2 (D.S.C. Dec. 4, 2017) (*Berkeley Heartlab II*), "the only reasonable inference" from the text of the PPACA amendment "is that AKS violations are *per se* material." *Id.*; *accord Guilfoile*, 913 F.3d at 190 ("This construction inescapably follows from the statute's plain language stating that a claim resulting from a violation of the AKS 'constitutes a false or fraudulent claim.'").

Relators urge this Court to follow the example of other district courts that have concluded that AKS violations were material as a matter of law even before the 2010 PPACA amendments went into effect. *See, e.g.*, *Berkeley Heartlab II*, 2017 WL 6015574, at *2 ("This Court . . . has no trouble concluding that compliance with the AKS is a material condition of payment before March 23, 2010.") (internal quotations omitted).

Based on a close reading of *Escobar*, however, I cannot so hold.

First, *Escobar*'s dictates are clear: plaintiffs must offer proof capable of giving rise to the inference that the defendant's misrepresentations were material to the Government's decision to pay the claims at issue. *Escobar*, 136 S. Ct. at 2003–04. The materiality standard is, moreover, "rigorous"—so much so that the fact that a certain requirement has been designated a condition of payment is "relevant to but not dispositive of the materiality inquiry." *Id.* at 2001–02.

The *Escobar* decision also contemplates that a defendant will have an opportunity to provide evidence of a lack of materiality—specifically by demonstrating that the Government "pays a particular claim in full despite its actual knowledge that certain requirements were violated." *Id.* at 2003. That the 2010 PPACA amendments preclude Teva from presenting this defense for the later portion of the Relevant Period does not mean it should be barred from presenting its evidence with respect to the earlier portion.

The Court also is not persuaded by Relators' arguments that the violations in this case go to the "very the essence of the bargain" because "the Government does not get what it bargained for when a defendant is paid by CMS for services tainted by a kickback." (Rels. Suppl. Opp. at 3 (citing *United States ex rel. Wilkins v. United Health Grp., Inc.*, 659 F.3d 295, 314 (3d Cir. 2011)).) This is not only circular; it is also the argument that prevailed in *Mikes*, and *Mikes* does not work anymore. Whenever a contractor violates any contractual or regulatory provision, the

Government does not get what it bargained for. Moreover, the "essence of the bargain" language comes from a footnote in *Escobar* and appears nowhere else in the opinion. 136 S. Ct. at 2003 n.5; *see also Rambaran v. Sec'y, Dep't of Corr.*, 821 F.3d 1325, 1333 (11th Cir. 2016) ("[J]ust as Congress does not generally 'hide elephants in mouseholes,' the Supreme Court does not hide clearly established federal law in parenthetical quotations of [state] courts' decisions.") (internal citation omitted)).

Relators' reliance on *United States ex rel. Wood v. Allergan, Inc.*, 246 F. Supp. 3d 772, 817 (S.D.N.Y. 2017), *rev'd and remanded on other grounds*, 899 F.3d 163 (2d Cir. 2018), is misplaced. As Defendants correctly observe, the *Wood* court did not find that AKS violations are material *per se*. *Id.* The court there concluded only that "compliance with the AKS [was] plausibly a material condition of payment." *Id.*; *see also id.* at 818 n.29 (listing various factual allegations in the complaint supporting materiality). Furthermore, an opinion deciding a motion to dismiss that is confined to its facts is of little relevance on a motion for summary judgment.

The Court now reviews Relators' pre-2010 amendment evidence to determine whether it raises a genuine issue of triable fact with respect to materiality—or whether, as Defendants argue, there has been a "fundamental failure of proof." (Defs.' Resp. to Relators' Suppl. Br. Pursuant to the Court's Dec. 11, 2018 Order, Dkt. No. 159 ("Defs. Reply to Rels. Suppl. Opp."), at 2.)

2. Relators Offer Evidence that Certifying Compliance with the AKS Was Material to the Federal Health Care Programs' Decisions to Reimburse Azilect and Copaxone Prescriptions

a) **Bilotta**

The Government's decision to take over the prosecution of *Bilotta*, the factually similar case currently proceeding before my colleague, the Hon. Paul Gardephe, provides strong evidence that AKS violations were material to the Government's payment decisions prior to the

effective date of the 2010 PPACA amendments. (*See* Gov't SOI at 8–9 (stating that the Government "frequently pursues FCA actions . . . to recoup funds paid for claims tainted by AKS violations."); *id.* (citing *Bilotta*, 50 F. Supp. 3d 497).)

As previously discussed, the claims in *Bilotta* arose out of conduct strikingly similar to the conduct alleged here. *Bilotta*, 50 F. Supp. 3d at 502 ("Novartis induced doctors to prescribe these drugs primarily through the use of 'sham' speaker events."). Moreover, the Government's Intervenor Complaint in *Bilotta* sought recovery, in part, for claims that were submitted prior to the effective date of the 2010 PPACA Amendments. *See* U.S. Am. Compl. ¶ 175, *United States ex rel. Bilotta v. Novartis Pharm. Corp.*, No. 11-cv-71 (S.D.N.Y. Aug. 26, 2013), ECF No. 62. This strongly indicates that violations arising out of speaker program AKS violations affect the Government's decision to pay the claims at issue.

b) Defendants' Compliance Expert's Report and Corporate Integrity Agreements

Relators' strongest evidence is that the Government has enforced the FCA against pharmaceutical companies for similar behavior, and that the claims for which they sought reimbursement arose prior to the effective date of the 2010 PPACA amendments.

Relators offer the report of Defendants' compliance expert Jon Smollen, as well as to examples of various Corporate Integrity Agreements ("CIAs") referenced therein. (Suppl. Counterstatement of Pls.'-Relators Pursuant to Local Civil Rule 56.1(b) and the Court's Order Dated Dec. 11, 2018 ("Rels. Suppl. 56.1") Dkt. No. 157 ¶ 8.i–u (citing to Smollen Report at 13–19).) They argue that the report and CIAs constitute evidence that "AKS violations could and did result in enforcement actions" by the Government. (Rels. Suppl. Opp. at 9.)

Defendants counter that Relators fail to "explain the similarities between any of the past enforcement actions referenced . . . and the conduct they allege violated the AKS here, because

there is no such linkage." (Defs. Reply to Rels. Suppl. Opp. at 4.) Further, "the lion's share of the enforcement actions cited by Relators focused primarily on FCA cases premised on 'off-label' promotion rather than AKS violations." (*Id.* at 4 n.4.)

These CIAs—agreements between the HHS's Office of the Inspector General ("OIG") and other pharmaceutical companies accused of violating the AKS through their speaker programs—suggest that the misrepresentations at issue in this case would be material to the Government, which raises a genuine issue of material fact.

Defendants' expert explains, "As part of the resolution of an action brought under the False Claims Act, OIG will consider, given the specific conduct at issue and other factors, whether to exclude a health care provider, manufacturer, or supplier from participation in federal health care programs. In lieu of exclusion, OIG may agree to a waiver of its exclusion authority in exchange for a company's agreement to enter into a CIA." (Smollen Report at 13 (citing "Criteria for implementing section 1128(b)(7) exclusion authority," April 18, 2016, *available at* https://oig.hhs.gov/exclusions/files/1128b7exclusion-criteria.pdf).) Thus, these CIAs constitute examples of the Government's enforcing the FCA against pharmaceutical companies.

Critically, the Smollen Report provides specific examples of CIAs that were issued because of FCA actions premised on AKS violations related to speaker programs: for example, those with Novartis and with EMD Serono, dated April and September of 2010, respectively. (Smollen Report at 18 & nn.85, 87.) Examples of sanctions arising out of the same conduct are relevant to materiality. *United States v. Luce*, No. 11-cv-5158, 2016 WL 6892857, at *2 (N.D. Ill. Nov. 23, 2016), *rev'd in part and remanded on other grounds*, 873 F.3d 999 (7th Cir. 2017) ("[T]his Court's decision was not based merely on whether the verification form was 'labeled a

condition of payment,' but also considered the "likely or actual behavior of the recipient'—namely, that HUD did in fact debar Luce upon determining his certifications were false.").

Defendants are correct that some of the proffered CIAs did not arise from FCA cases centered on AKS violations (and that Relators have wholly failed to explain the relevance of others). For example, the Cephalon CIA arose from Cephalon's "unlawful promotion of three drugs . . . for uses not approved by the [FDA]," and the CIA includes no other indicia that Cephalon was implicated in AKS violations. (*See* Cephalon CIA at 48, excerpted at DX153 and available in full at https://oig.hhs.gov/fraud/cia/agreements/cephalon.pdf.) These CIAs lack probative value on the issue of materiality.

c) Teva Internal Documents

Relators also proffer various materials internal to Teva, including: compliance presentations; different versions of the Teva Integrity Principles; deposition testimony from Teva employees; internal e-mails; and reports by Teva's third-party consultants. (*See* Rels. Suppl. Opp. at 8–13; Rels. Suppl. 56.1 ¶¶ 3–6, 8.a–c, v–w.) Relators argue that this demonstrates that Teva "clearly knew that the Government would refuse to reimburse for claims arising from AKS violations and, indeed, that it pursues civil and criminal enforcement actions when it discovers such violations." (Rels. Suppl. Opp. at 11.)

Defendants argue that these materials do not create a genuine issue of triable fact with respect to materiality because they "show[] nothing more than Teva's awareness of—and consistent insistence on compliance with—the AKS and the FCA, that certain payment arrangements ***could result*** in violations of the AKS, and that violations of the AKS ***could result*** in enforcement actions by the government." (Defs. Reply to Rels. Suppl. Opp. at 5 (emphasis in original).)

This Court agrees with Defendants that most of this evidence does not show that the Government "consistently refuses to pay" prescription drug claims based on AKS violations. *Escobar*, 136 S. Ct. at 2003. Several of the internal communications and compliance documents demonstrate merely that Teva and its employees were concerned about violating the AKS—either out of general prudence or with respect to a particular feature of the speaker program. But, this evidence does not mention the Government's likely or historical sanctions under the AKS, let alone under the FCA. (*See* PX391; PX197 ¶¶ 8, 12; PX344 at 289:20–293:12; PX198 at TNA-0237743.) Therefore, this evidence is probative only insofar as it reinforces that compliance with the AKS was a "condition of payment" for the federal health care programs.

Some of the internal compliance materials referenced do raise the specter of hypothetical FCA liability. (*See* PX303 at TNA0462845; PX227 at TNA-0213414; DX50 at TNA-0625526; DX51 at TNA-0190256; DX52 at TNA-0244572; DX12 at TNA-0722060; DX112 at TNA-0625461–62; DX13 at TNA-0596783–84; DX126 at TNA-0001637–38.) However, these forward-looking warnings—which are unaccompanied by any example of Government sanctions—demonstrate only that the Government "would be entitled to refuse payment were it aware of the violation," not that the violation was "so central" that the Government "would not have paid these claims had it known of these violations." *Escobar*, 136 S. Ct. at 2004. Under *Escobar*, this weighs in favor of materiality but is not dispositive.

Next, Relators proffer evidence that the Government has historically pursued pharmaceutical companies for violations of the AKS. (DX40, DX108, DX121.) This evidence consists of two high-level slides used in multiple PowerPoint presentations. They include a bullet point list of "recent enforcement actions" and a brief description of the "recent enforcement environment." (Fig. 1, DX40.) The slides provide some evidence that, as of

September 24, 2010, pharmaceutical companies had collectively paid billions of dollars to settle FCA violations stemming from the AKS.[11] (*Id.* (listing as examples "Pfizer 2.3 billion," "Serono $704 million," and "Merck $650 million," among others).)

While this evidence does not demonstrate that the Government "consistently refuses to pay claims" based on AKS violations like the ones at issue here, *Escobar*, 136 S. Ct. at 2003, other district courts have found that evidence of other enforcement measures "weighs slightly in favor of [a finding of] materiality" under the FCA. *United States ex rel. Emanuele v. Medicor Assocs.*, 242 F. Supp. 3d 409, 431 (W.D. Pa. 2017). In keeping with these opinions, this Court assigns some probative value to these slides.

d) Relators' Expert Report

Relators next proffer the report of their compliance expert Paul Kim, as evidence that "Teva failed to adopt an effective compliance program to avoid violations of the AKS with respect to its Speaker Programs" despite its knowledge that such violations could result. (Rels. Suppl. 56.1 ¶ 5 (citing Kim Report at 5–46).) They also argue that the report constitutes evidence that certain payments to health care providers can trigger AKS liability, (*id.* ¶ 1), and that, "at all pertinent times, compliance with the AKS has been a condition of participation and payment for the Government Healthcare Programs," (*id.* ¶ 7 (citing Kim Report at 46–48)).

None of the above is probative on the issue of materiality. Even if Teva did in fact fail to adopt an effective compliance program, this would provide a juror no information about whether Teva's AKS violations would affect the Government's decision to pay for Azilect and Copaxone

[11] Based on Defendants' compliance expert's report, the Court is aware that several of these bullet points may refer to a combination of criminal AKS violations and civil FCA enforcement actions. (*See* Smollen Report at 13–19.) However, this is unclear from the face of the documents.

prescriptions. Relators' latter two propositions, moreover, are uncontested. (*See* discussion of "condition of payment" provisions, *infra.*)

e) "Condition of Payment" Provisions

Escobar explicitly states that "condition of payment" language is one of several relevant considerations: "Whether a provision is labeled a condition of payment is relevant to but not dispositive of the materiality inquiry." *Escobar*, 136 S. Ct. at 2001. The opinion reiterates this principle: "In sum, when evaluating materiality under the False Claims Act, the Government's decision to expressly identify a provision as a condition of payment is relevant, but not automatically dispositive." *Id.* at 2003.

Relators argue, and Defendants do not dispute, that "compliance with the AKS has been a condition of payment for the Government Healthcare Programs at all relevant times." (Rels. Suppl. Opp. at 5–6.)

Specifically, Relators point to 42 C.F.R. § 423.505(h)(1), which went into effect on March 22, 2005 and requires all Medicare Part D plan sponsors to certify with CMS that they comply with all "[f]ederal laws and regulations designed to prevent fraud, waste, and abuse, including but not limited to applicable provisions of Federal criminal law, the False Claims Act (31 U.S.C. §§ 3729 *et seq.*), and the anti-kickback statute (section 1128B(b) of the Act)."

In its Statement of Interest, the Government also points to language in CMS Form 855S, which is signed by all providers enrolling in the Medicare program, and which states that they "understand that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with such laws, regulations and program instructions (including, but not limited to, the Federal Anti-Kickback Statute[.])" (Gov't SOI at 8 & n.3).

Relators also point to the report of their compliance expert, Paul Kim, who notes in his report that Provider Agreements between state Medicaid agencies and fee-for-service providers "include[], in one form or another, language that either expressly states or implicitly requires providers to agree to comply with both federal and state laws applicable to the Medicaid Program, including the AKS and FCA." (Kim Report at 47.) He also observes that the claim forms that providers complete and file with the state Medicaid agency require providers to certify compliance with all applicable state and federal laws, including the AKS and the FCA. (*Id.*) Kim also observes that providers are required to make similar certifications under the managed care model, and that states themselves are also required to certify that their Medicaid funds are spent in accordance with federal statutes and regulations. (*Id.* at 48.) Kim concludes that, "providers must comply with all the federal requirements applicable to the Medicaid Program, including the AKS and FCA, as a condition of participation in and a condition of payment from the Medicaid Program . . . at all times relevant to this litigation." (*Id.*)

Although this evidence would have been persuasive when *Mikes* controlled, it is weak proof of materiality after *Escobar*, particularly where the "condition of payment" language refers broadly to "all applicable statutes and regulations." This is not the kind of evidence that would enable a finder of fact to determine whether the Government would have been likely to pay the claims at issue had it known of the violations.

In sum, Relators have offered the following record evidence, which the Court finds could lead a reasonable jury to conclude that the AKS violations at issue in this case were material to the Government's payment decisions: (i) the Government has pursued FCA cases against pharmaceutical companies on the basis of AKS violations arising in connection with their speaker programs prior to the 2010 amendments; (ii) the Government has criminally prosecuted

pharmaceutical companies for AKS violations prior to the 2010 amendments; and, least persuasively, (iii) compliance with the AKS was a "condition of payment" for the Federal health care programs at all pertinent times.

3. Defendants Also Offer Evidence That Certifying Compliance with the AKS Was Not Material to the Federal Health Care Programs' Decisions to Reimburse Azilect and Copaxone Prescriptions

Under *Escobar*, "if the Government regularly pays a particular type of claim in full despite actual knowledge that certain requirements were violated, and has signaled no change in position, that is strong evidence that the requirements are not material." *Escobar*, 136 S. Ct. at 2003–04.

Defendants argue that this is precisely what occurred here, since it is undisputed that: (1) Relators disclosed all material facts regarding their claims to the Government in 2013, as is required in *qui tam* suits, (*see* TAC ¶ 14); and (2) the Government continued to reimburse pharmacies and patients for prescriptions for Azilect and Copaxone (*see* Hay Report ¶ 22, calculating damages through 2015 and reserving right to calculate damages through the present). (*See* Defs. Br. at 30; Defs. Reply to Rels. Suppl. Opp. at 8–9.) Moreover, Defendants argue, "since *Escobar*, circuit courts have uniformly recognized that continued payment by the federal government after it learns of the alleged fraud substantially increases the burden on the relator in establishing materiality." (Defs. Br. at 30 (citing *United States ex rel. Bachert v. Triple Canopy, Inc.*, 321 F. Supp. 3d 613, 620 (E.D. Va. 2018)).)

Relators respond that mere disclosure of the allegations and continued payment are insufficient to establish that the Government had "actual knowledge that certain requirements were violated." (Rels. Suppl. Opp. at 13–17.) "Teva has not cited to a scintilla of evidence in the record as to what the Government investigated and/or what Teva produced to the Government as part of that investigation." (*Id.* at 15.)

I agree with Relators that evidence that the (legally compelled) disclosure of their complaint, combined with evidence of continued payment, is insufficient to warrant granting summary judgment to Defendants. It remains Defendants' burden on a motion for summary judgment to show that there is no genuine issue of material fact, and Relators are correct that, based on the record, a reasonable jury could draw different conclusions about the implications of the Government's continued payment. In *Rose v. Stephens Inst.*, No. 09-cv-05966, 2016 WL 5076214, at *6 (N.D. Cal. Sept. 20, 2016), for example, the court found that the "DOE's decision not to take action against AAU despite its awareness of the allegations in this case is not terribly relevant to materiality," in part because the DOE had cited no reasons for that decision. *Id.* The DOE's inaction, moreover, "could well have been based on difficulties of proof or resource constraints, or the fact that the truth of the allegations has yet to be proven," and, in any case, there were no facts from which to infer "actual knowledge." *Id.*; *see also United States v. Berkeley Heartlab, Inc.*, No. 14-cv-230, 2017 WL 4803911, at *7 (D.S.C. Oct. 23, 2017) (*Berkeley Heartlab I*) ("The Government does not enjoy the luxury of refusing to reimburse health care claims the moment it suspects there may be wrongdoing.").

Appellate decisions since *Escobar* confirm that summary judgment is appropriate if the Defendant introduces evidence that the Government conducted a detailed investigation and subsequently declined to take any action against the defendant. In these cases, the Government's inaction left no genuine issue of triable fact for the jury, because the only reasonable conclusion was that the Government believed the claims meritless or would not have changed its calculus even if the allegations were true. For example, in *United States ex rel. McBride v. Halliburton Co.*, 848 F.3d 1027, 1029 (D.C. Cir. 2017), the court upheld the district court's award of summary judgment to the defendants because the Government had declined to take action after

"issuing written questions to KBR and visiting Camp B-3 to review records and interview KBR's personnel." *Id.* at 1029. There, the court held, "[W]e have the benefit of hindsight and should not ignore what actually occurred: the [Government] investigated McBride's allegations and did not disallow any charged costs. In fact, KBR continued to receive an award fee for exceptional performance . . . even after the Government learned of the allegations. This is 'very strong evidence' that the requirements allegedly violated by the maintenance of inflated headcounts are not material." *Id.* at 1034 (citing *Escobar*, 136 S. Ct. at 2003).

Likewise, in *Abbott v. BP Exploration & Prod. Inc.*, 851 F.3d 384, 388 (5th Cir. 2017), the Fifth Circuit affirmed the district court's grant of summary judgment to defendants because the allegations "led to Congressional hearings," an admitted rarity, "an investigation by a federal agency, and a DOI Report, [which] considered many of the same arguments advanced" by the plaintiffs but nonetheless found that there was compliance with the relevant regulations. *Id.*; *see also United States v. Sanford-Brown, Ltd.*, 840 F.3d 445, 447 (7th Cir. 2016) (summary judgment was appropriate where evidence showed that the "subsidizing agency and other federal agencies in this case 'have already examined SBC multiple times over and concluded that neither administrative penalties nor termination was warranted.'"); *United States ex rel. Kelly v. Serco, Inc.*, 846 F.3d 325, 334 (9th Cir. 2017) (summary judgment was appropriate where the Government's project manager had agreed that the contractor could provide its reporting in a format that did not comply with ANSI-748).

Here, Defendants have presented no evidence that any investigation into Teva's speaker programs took place, let alone its scope or any findings. Presumably, some evidence regarding the scope and thoroughness of any investigation by DOJ was within Defendants' control, since

they would have been its target. They did not bother to put the nail in the coffin by introducing it.

In sum, the Court finds that, because Relators have introduced evidence that the Government pursues FCA cases against pharmaceutical companies based on AKS violations involving speaker programs, and because Defendants have not pointed to evidence in the record that the Government continued to pay despite "actual knowledge" of wrongdoing, there is a genuine issue of triable fact on whether these AKS violations were material, and summary judgment is premature.

IV. Conclusion

For the reasons stated above, the Defendants' motion for summary judgment is **DENIED**.

In accordance with this Court's order dated December 11, 2018, Relators have three days to submit an updated Proposed Joint Pre-Trial Order, Proposed Jury Charge, Proposed Voir Dire Questions, and Proposed Verdict Form. Pursuant to that same order, the deadline will not be extended.

The Clerk of Court is respectfully requested to close the motion at Docket Number 128.

Pursuant to this Court's order in *Teva I*, 2016 WL 750720, at *28, the pendent state and municipal law claims remain on the Court's suspense calendar until the federal claim has been resolved.

Dated: February 27, 2019

Chief Judge

BY ECF TO ALL PARTIES