United States District Court
District of Massachusetts

United States of America,	)	
Plaintiff,	)	
v.	)	**Civil Action No. 20-11548-NMG**
Teva Pharmaceuticals USA, Inc., and Teva Neuroscience, Inc.,	)	
Defendants.	)	

MEMORANDUM & ORDER

GORTON, J.

The United States ("the government" or "plaintiff") brings this action against Teva Pharmaceuticals USA, Inc. and Teva Neuroscience, Inc. (collectively "Teva" or "defendant") for alleged violations of the Anti-Kickback Statute ("AKS") and the False Claims Act ("FCA"). The government alleges that defendant caused the submission of false claims to Medicare by virtue of kickbacks Teva paid in the form of illegal co-pay subsidies in connection with the sale of its multiple sclerosis drug, Copaxone.

Pending before the Court is Teva's motion for summary judgment and the government's motion for partial summary

judgment on materiality, causation and damages under the FCA. For the reasons that follow, Teva's motion for summary judgment will be denied and the government's motion for partial summary judgment will be allowed.

I. Background

A. False Claims Act and Anti-Kickback Statute

The FCA imposes civil liability for anyone who

> knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval [or] knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim.

31 U.S.C. § 3729(a)(1)(A), (a)(1)(B).

The AKS imposes criminal liability on anyone who

> 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 . . . to purchase . . . or arrange for or recommend purchasing . . . any good . . . for which payment may be made in whole or in part under a Federal health care program[.]

42 U.S.C. § 1320a-7b(b)(2). In 2010, Congress amended the AKS through the Patient Protection and Affordable Care Act, Pub. L. No. 1110148, 124 Stat. 119 (2010), to 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 [the FCA.]" 42 U.S.C. § 1320a-7b(g).

B. Fact History

The government contends that Teva violated the AKS and caused the submission of false claims to Medicare under the FCA by knowingly and willfully paying Copaxone co-pays of Medicare patients via two contracted vendors and two foundations.

In late 2006, after Medicare Part D prescription drug coverage went into effect, Teva contracted with the specialty pharmacy Advanced Care Scripts, Inc. ("ACS"). Teva referred Medicare-eligible Copaxone patients to ACS for help obtaining Medicare Part D coverage and enrolling in co-pay patient assistance programs ("PAPs"). ACS then referred those Medicare-eligible Copaxone patients to two foundations, Chronic Disease Fund ("CDF") and The Assistance Fund ("TAF") which operated PAPs that provided Copaxone co-pay assistance. Later, in 2014, Teva also contracted with AssistRx, Inc. ("AssistRx") for help in enrolling Copaxone patients at TAF.

The government alleges that, from December, 2006 through January, 2017, Teva donated over $350 million to CDF and TAF to cover Medicare co-pay obligations of Copaxone patients. During that decade, Teva raised the wholesale acquisition cost of

Copaxone, that is, the price paid by wholesalers such as pharmacies to the manufacturer, from about $17,000 per year to over $85,000 per year, nearly 20 times the rate of inflation. The government stresses that Teva paid CDF and TAF with the intent of inducing Medicare-reimbursed Copaxone claims which, in turn, yielded Teva enormous revenue from Medicare's Copaxone reimbursements.

C. Procedural History

This action was purportedly filed in August, 2020 as a result of a three-year government civil investigation into Teva's co-pay donations. Defendant's motion to dismiss with respect to the unjust enrichment claim was allowed in September, 2021, but the motion was denied as to the three counts alleging FCA violations.

In April, 2023, Teva moved for summary judgment and the government moved for partial summary judgment on three questions of law it contends are likely to arise at trial. Trial is scheduled to begin on September 18, 2023.

II. Motions for Summary Judgment

A. Legal Standard

The role of summary judgment is "to pierce the pleadings and to assess the proof in order to see whether there is a

genuine need for trial." Mesnick v. Gen. Elec. Co., 950 F.2d 816, 822 (1st Cir. 1991) (quoting Garside v. Osco Drug, Inc., 895 F.2d 46, 50 (1st Cir. 1990)). The burden is on the moving party to show, through the pleadings, discovery and affidavits, "that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a).

A fact is material if it "might affect the outcome of the suit under the governing law . . . ." Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986). A genuine issue of material fact exists where the evidence with respect to the material fact in dispute "is such that a reasonable jury could return a verdict for the nonmoving party." Id.

If the moving party satisfies its burden, the burden shifts to the non-moving party to set forth specific facts showing that there is a genuine, triable issue. Celotex Corp. v. Catrett, 477 U.S. 317, 324 (1986). The Court must view the entire record in the light most favorable to the non-moving party and make all reasonable inferences in that party's favor. O'Connor v. Steeves, 994 F.2d 905, 907 (1st Cir. 1993). Summary judgment is warranted if, after viewing the record in the non-moving party's favor, the Court determines that no genuine issue of material

fact exists and that the moving party is entitled to judgment as a matter of law.

B. Teva's Motion for Summary Judgment

Teva advances two arguments in support of its motion for summary judgment on all counts. First, Teva argues that the government cannot prove that a kickback was the "but for" cause of any particular false claim because there is no evidence that but for Teva's donations to CDF and TAF, any claims submitted to Medicare for Copaxone that were funded by CDF or TAF would not have otherwise been submitted for reimbursement. Second, Teva contends that the government cannot prove scienter, i.e. "willfully" under the AKS or with "knowledge," "deliberate ignorance" or "reckless disregard" under the FCA.

1. Causation

With respect to Teva's first argument, the standard of causation for AKS-based false claims is also the subject of the government's motion for partial summary judgment and thus is discussed here as well as in greater detail below.

The First Circuit has previously stated that

> if there is a sufficient causal connection between an AKS violation and a claim submitted to the federal government, that claim is false within the meaning of the FCA.

Guilfoile v. Shields, 913 F.3d 178, 190 (1st Cir. 2019) (citing United States ex rel. Greenfield v. Medco Health Sols., Inc., 880 F.3d 89, 96-98 (3d Cir. 2018). The government must prove a "causal connection" between Teva's contributions to CDF and TAF and the resulting co-pay-assisted Copaxone claims that Medicare reimbursed. Guilfoile, 913 F.3d at 190.

To establish causation, the government proffers four categories of evidence, including that Teva intended to induce Copaxone prescription fills and Medicare Copaxone patients told Teva they needed financial assistance to afford the drug. Furthermore, the government cites contemporaneous Teva employee emails and other documents that demonstrate that Teva knew it would have lost Copaxone sales if it did not provide co-pay assistance.

For example, in a November, 2008 email, a Senior Director of Finance and Planning at Teva writes, "[w]e would lose most of these patients if we didn't provide coverage through the [Medicare] doughnut hole." In a "Teva Neuroscience 2012-2014 Workplan" presentation created in October, 2011, a slide titled "Patient Assistance Program" states that the program "[d]emonstrated significant ROI; result of not funding directly impacts top line revenue." Teva's documents indicate that Teva

understood it was profitable to provide co-pay assistance to generate sales.

Government experts also reviewed Teva's payments to CDF and TAF and enrollments of and disbursements for Copaxone patients of those funds. In particular, government data analysis expert Ian Dew reviewed data from Teva, CDF, TAF, ACS and AssistRx to identify Medicare claims for which CDF and TAF paid some or all of the beneficiary's co-pay for Copaxone. He further identified 345,970 matched Medicare claims for Copaxone, with a total paid amount of $1.49 billion, for patients who were 1) referred by Teva to ACS or AssistRx and 2) enrolled for assistance at CDF or TAF by ACS or AssistRx following a Teva payment to the responsive foundation.

Resolving every doubt in favor of the government as the non-moving party and construing the evidence in the light most favorable to it, the factual evidence is more than sufficient to withstand Teva's summary judgment motion on the issue of causation. See O'Connor, 994 F.2d at 907. The government has established evidence of "a sufficient causal connection" between Teva's payments to CDF and ATF and the resulting Medicare Copaxone claims.

2. Scienter

Teva next argues that it is entitled to summary judgment because the government has failed to show that its officers and employees acted with requisite scienter, meaning they did not "knowingly" violate the FCA or "willfully" violate the AKS.

The FCA defines "knowingly" as three alternative mental states: the person has 1) "actual knowledge of the information," 2) "acts in deliberate ignorance of the truth or falsity of the information" or 3) "acts in reckless disregard of the truth or falsity of the information." 31 U.S.C. § 3729(b)(1)(A); United States ex rel. Schutte v. SuperValu Inc., 143 S. Ct. 1391, 1400-01 (2023). To establish a knowing violation, defendant must have acted voluntarily and deliberately, not "by mistake or by accident or even negligently." United States v. Bay State Ambulance & Hosp. Rental Serv., Inc., 874 F.2d 20, 33 (1st Cir. 1989)

To establish a violation of the AKS, defendant must have acted both knowingly and willfully. See United States ex rel. Gohil v. Sanofi U.S. Servs. Inc., No. CV 02-2964, 2020 WL 4260797, at *13 (E.D. Pa. July 24, 2020) ("The AKS's scienter element is harder to meet than the FCA's scienter standard."). The First Circuit defines "willfully" as

> to do something purposely, with the intent to violate the law, to do something purposely that law forbids.

Bay State Ambulance & Hosp. Rental Serv., Inc., 874 F.2d at 33.

Teva submits that the government cannot prove that any Teva employee knew his or her conduct was illegal or intended to violate the law. Again, construing the evidence in the light most favorable to the non-moving party, see O'Connor, 994 F.2d at 907, the Court finds that the government has proffered sufficient evidence from which a jury could reasonably conclude that Teva's employees acted both knowingly and willfully.

For example, Teva's 30(b)(6) deposition testimony confirms that Teva's employees knew the AKS prohibited Medicare patients from participating in patient assistance programs. In 2010, the president of CDF sent Teva a "legal analysis of the risks associated with a Medicare Only PAP," prepared by Kevin McAnaney, the Chief of the Industry Guidance Branch of HHS-OIG from 1997 through 2003. That analysis stated:

> As a threshold matter, any knowing payments by a pharmaceutical manufacturer or other provider to satisfy a federal health care program enrollee's cost sharing obligations would almost certainly violate the federal anti-kickback statute.

Moreover, in May, 2012, a Teva employee circulated a 2008 presentation from Sidley Austin LLP titled "Legal Considerations in Developing Patient Assistance Programs" which emphasized that

> PAPs present all of the usual risks of fraud and abuse associated with kickbacks [and] the independent charity PAP must not function as a conduit for payments by the pharmaceutical manufacturer to patients.

The documents and testimony cited in the parties' statements of facts demonstrate that the government has gathered sufficient evidence, beyond the examples recited above, to defeat Teva's motion for summary judgment based on a lack of scienter.

C. The Government's Motion for Partial Summary Judgment

The government moves for partial summary judgment as to three questions of law it anticipates will arise at trial: 1) the materiality of violations of the AKS, 42 U.S.C. § 1320a-7b(b)(2), under the FCA, 31 U.S.C. §§ 3729-33; 2) the legal standard for FCA causation for claims "resulting from" AKS violations under 42 U.S.C. § 1320a-7b(g) and 3) the measure of damages applicable to the government's AKS-based FCA claims.

1. Materiality

The government, citing 42 U.S.C. § 1320a-7b(g) and Guilfoile, 913 F.3d at 190, submits that claims submitted to Medicare that include items or services resulting from kickbacks under the AKS are per se materially false or fraudulent for

purposes of the FCA. The Court agrees. Indeed, the plain language of the 2010 amendment to the AKS states 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). The First Circuit has held that "[a]n AKS violation that results in a federal health care payment is a per se false claim under the FCA." Guilfoile, 913 F.3d at 190.

With respect to claims that predate the 2010 AKS amendment, the First Circuit examined the legislative history and observed that the 2010 AKS amendment "essentially codifies the long-standing view that AKS violations are 'material' in the FCA context." Id. at 191; see also United States ex rel. Bawduniak v. Biogen Idec Inc., No. 12-cv-10601-IT, 2022 WL 2438971, at *2-3 (D. Mass. July 5, 2022).

Thus, the Court finds that a violation of the AKS is per se material for FCA purposes.

2. Causation

As addressed above, this Court will follow the First Circuit's guidance as to the legal standard for FCA causation for claims "resulting from" AKS violations. The government need not prove "but for" causation. Rather, the First Circuit, citing the Third Circuit, has held that

> if there is a sufficient causal connection between an AKS violation and a claim submitted to the federal government, that claim is false within the meaning of the FCA.

Guilfoile, 913 F.3d at 190 (citing Greenfield, 880 F.3d at 96-98).

Teva vehemently disagrees with that standard and urges the Court to follow guidance of the Sixth and Eighth Circuits which adopt a "but for" standard. Teva argues that because Guilfoile only addressed whether plaintiff had adequately pled an FCA retaliation claim rather than an FCA violation, the First Circuit did not fully address the issue of what constitutes a "sufficient causal connection."

As other courts in this district have noted, however,

> that the First Circuit analyzed the statute at the pleading stage rather than at summary judgment or at trial is itself of no moment, where the meaning of the statute is the same at all stages of the proceedings.

Bawduniak, No. 12-cv-10601-IT, 2022 WL 2438971, at *2. Moreover, the analysis of the First Circuit focused "singularly on the text and legislative history of the AKS" and failed to note any relevant difference between a retaliation claim and a direct FCA claim. Id. The Court finds the First Circuit's analysis persuasive, if not binding. Id.

3. Damages

The government, citing United States v. Rogan, 517 F.3d 449 (7th Cir. 2008), asserts that the correct measure of damages for the government's AKS-based FCA claims in this case is the entirety of the government's expenditures for claims resulting from the illegal kickbacks. Although the government concedes that the First Circuit has yet to rule directly on the measure of damages for AKS-tainted false claims, it encourages the Court to apply its approach to damages here, contending that "every court that has considered" the measure of damages has adopted that method.

Upon a careful review of the caselaw presented in the pleadings of both parties, the Court will continue to apply the government's damages standard which has been proffered in prior rulings in this case. See United States v. Teva Pharms. USA, Inc., No. CV 20-11548-NMG, 2022 WL 6820648, at *5 (D. Mass. Oct. 11, 2022).

As United States Magistrate Judge Jennifer C. Boal previously stated in her June, 2022 order in this case, the Seventh Circuit explained the basis for its measure of damages for AKS-based false claims in Rogan as follows:

> [Defendant] did not furnish any medical service to the United States. The government offers a subsidy (from the patients' perspective, a form of insurance), with conditions. When the conditions are not satisfied, nothing is due. Thus the entire amount that [defendant] received on these . . . claims must be paid back.

Rogan, 517 F.3d at 453. The rationale here is that the government simply would not have paid those Medicare claims had it known they were submitted in violation of certain Medicare requirements such as the AKS or the Stark Law, 42 U.S.C. § 1395nn. See, e.g., Yates v. Pinellas Hematology & Oncology, P.A., 21 F.4th 1288, 1304 (11th Cir. 2021) ("In the context of Medicare claims, . . . courts have measured damages as the difference between what the government paid and what it would have paid had the defendant's claim been truthful and accurate."); United States ex rel. Drakeford v. Tuomey, 792 F.3d 364, 386 (4th Cir. 2015) ("Compliance with the Stark Law is a condition precedent to reimbursement of claims submitted to Medicare. When [defendant] failed to satisfy that condition, the government owed it nothing."); United States v. Mackby, 339 F.3d 1013, 1019 (9th Cir. 2003) ("Had [the defendant] been truthful, the government would have known that [it] was entitled to nothing.").

Thus, the Court will measure damages in this case as the entirety of the government's payments for the claims resulting from the illegal kickbacks.

ORDER

For the foregoing reasons, Teva's motion for summary judgment (Docket No. 159) is **DENIED** but the government's motion for partial summary judgment (Docket No. 160) is **ALLOWED**.

So ordered.

/s/ Nathaniel M. Gorton
Nathaniel M. Gorton
United States District Judge

Dated: July 14, 2023