

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA, <i>et al.</i> ,	*	
<i>ex rel.</i> MICHAEL BAWDUNIAK,	*	
	*	
Plaintiff-Relator,	*	
v.	*	Civil Action No. 1:12-cv-10601-IT
	*	
BIOGEN IDEC INC.,	*	
	*	
Defendant.	*	

MEMORANDUM & ORDER

July 5, 2022

TALWANI, D.J.

Relator Michael Bawduniak’s Third Amended Complaint (“Complaint”) [Doc. No. 132] charged Defendant Biogen Inc. (“Biogen”) with causing health care providers (“HCPs”) to file fraudulent Medicare and Medicaid reimbursement claims in violation of the False Claims Act, 31 U.S.C. § 3729, *et seq.*, and various state laws, by paying kickbacks to influence them to prescribe Biogen’s multiple sclerosis (“MS”) products in violation of Anti-Kickback Statute (“AKS”), 42 U.S.C. § 1320a-7b. Relator now seeks a determination that AKS violations are per se material to federal healthcare claims under the False Claims Act, 31 U.S.C. § 3729(a)(1)(A), and various state false claims acts.¹ Relator’s request is supported by the United States.² The State of Texas

¹ See Motion for Partial Summary Judgment [Doc. No. 477]; Omnibus Motions in Limine, Motion in Limine Number Nine [Doc. No. 566]. The state false claims acts at issue are for California (Cal. Gov’t Code §§ 12650, *et seq.*), Connecticut (Conn. Gen. Stat. Ann. §§ 4-275, *et seq.*); Georgia (Ga. Code Ann. §§ 49-4-168, *et seq.*), Illinois (740 Ill. Comp. Stat. Ann. 175/1, *et seq.*), Massachusetts (M.G.L. c. 12 §§ 5A, *et seq.*) New Jersey (N.J. Stat. Ann. §§2A:32C-1, *et seq.*), New York (N.Y. Fin. Law §§ 187, *et seq.*), North Carolina (N.C.G.S. §1-605, *et seq.*), Tennessee (Tenn. Code §§ 71-5-181, *et seq.*), Texas (Tex. Hum. Res. Code §§ 36.001, *et seq.*), and Wisconsin (Wis. Stat. §§ 20.931, *et seq.*). See Third Amended Complaint [Doc No. 132] (Counts 1, 3, 5, 8, 10, 15, 20, 22, 23, 26, 27, and 30).

² United States’ Statement of Interest [Doc. No. 496].

has weighed in regarding the interpretation of the Texas Medicaid Fraud Prevention Act, Chapter 36 of the Texas Human Resources Code (“TMFPA”).³ Biogen asks the court to reject Relator’s request⁴ and disagrees with the law as set forth by the state of Texas.⁵ For the reasons set forth below, the court finds that a violation of the AKS is per se a violation of the False Claims Act and the state false claims acts raised here (with the exception of Texas’s statute), and that interpretation of the TMFPA (and any materiality requirement therein) is guided by Texas law.

I. Discussion

A. *The Federal False Claims Act*

The False Claims Act (“FCA”) imposes liability on any person who “knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval.” 31 U.S.C. § 3729(a)(1)(A). A “claim” includes direct requests for government payment as well as reimbursement requests made to the recipients of federal funds under a federal benefits program. Id. § 3729(b)(2)(A).

In 2010, the Patient Protection and Affordable Care Act (“PPACA”), Pub. L. No. 1110148, 124 Stat. 119 (2010), amended the federal Anti-Kickback Statute (“AKS”) to provide that “a claim that includes items or services resulting from a violation of [the AKS] constitutes a false or fraudulent claim for purposes of [the FCA].” 42 U.S.C. § 1320a-7b(g) (emphasis added). In Guilfoile v. Shields, 913 F.3d 178 (1st Cir. 2019), while outlining the requirements for pleading an FCA retaliation claim, the First Circuit stated that in light of this statutory amendment, “[a]n AKS violation that results in a federal health care payment is a per se false

³ State of Texas’s Statement of Interest [Doc. No. 530]; State of Texas’s Reply [Doc. No. 557].

⁴ Biogen’s Mem. in Opp. [Doc. No. 488].

⁵ Biogen’s Resp. to State of Texas [Doc. 554].

claim under the FCA.” *Id.* at 190 (quoting United States ex re. Lutz v. United States, 853 F.3d 131, 135 (4th Cir. 2017)). The First Circuit explained that “drawing on the ‘resulting from’ language of the 2010 amendment, 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.” *Id.* (citing United States ex rel. Greenfield v. Medco Health Sols., Inc., 880 F.3d 89, 96-98 (3d Cir. 2018) and United States ex rel. Bawduniak v. Biogen Idec, Inc., 2018 WL 1996829, at *5-6 (D. Mass. Apr. 27, 2018)).

Biogen urges the court first to disregard Guilfoile because the First Circuit did not “assess the full implications of the AKS provision” where “the issue before [the Court] [was] not the standard for proving an FCA violation based on AKS, but rather the requirements for pleading an FCA retaliation claim.” *Id.* at 190 (emphasis in original). 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. That the analysis concerned a retaliation claim rather than a direct FCA claim could be of greater concern if the analysis noted any relevant difference, but here the First Circuit’s analysis was focused singularly on the text and legislative history of the AKS. The First Circuit’s analysis may not be binding, but it is persuasive.

Biogen further argues that finding a per se violation is inconsistent with the Supreme Court’s “demanding” materiality inquiry articulated in Universal Health Servs., Inc. v. United States (“Escobar”), 579 U.S. 176, 194 (2016). The Court in Escobar rejected a judgment that held “any statutory, regulatory, or contractual violation is material [under the FCA] so long as the defendant knows that the Government would be entitled to refuse payment were it aware of the violation.” *Id.* at 195. In this case, however, it is not a violation of a random statutory or

regulatory provision that would be per se material but an AKS violation, where the AKS specifically provides that such a violation “constitutes a false or fraudulent claim for purposes of [the FCA].” 42 U.S.C. § 1320a-7b(g).

Guilfoile noted that 31 U.S.C. § 3729(a)(1)(A), which prohibits the knowing submission of false claims, does not contain the term “material.” 913 F.3d at 187 n.7. Instead, “the ‘materiality’ requirement in regard to § 3729(a)(1)(A)” is “judicially created because it derives from a general reading of materiality into all sections of the FCA rather than from the statutory language.” Id. (citing U.S. ex rel. Hutcheson v. Blackstone Med., Inc., 647 F.3d 377, 388 n.13 (1st Cir. 2011)).

Guilfoile “read the AKS amendment as obviating the need for a plaintiff to plead materiality -- that is, to plead that compliance with the AKS was material to the government’s decision to pay any specific claim.” Guilfoile, 913 F.3d at 190 (emphasis in original). The First Circuit reasoned that “[t]his 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.’” Id. (quoting 42 U.S.C. § 1320a-7b(g)). In the First Circuit’s analysis, “use of the term ‘constitutes’ would be meaningless if the courts had to engage in a materiality analysis . . . after establishing a claim resulted from an AKS violation.” Id. As such, the First Circuit found that the 2010 AKS Amendment “has the benefit . . . of bypassing judicially created theories of materiality . . . that ‘do more to obscure than clarify the issues before’ a court considering an FCA claim.” Id. at 191 (quoting Hutcheson, 647 F.3d at 385-86).

Guilfoile also examined the statutory language in light of the legislative history “which indicates Congress’s intent to ‘ensure that all claims resulting from illegal kickbacks are ‘false and fraudulent’” and to ‘strengthen [] whistleblower actions based on medical care kickbacks . . .

[b]y making all claims that stem from an illegal kickback subject to the False Claims Act.” Id. (quoting 155 Cong. Rec. S10852-01, S10853 (daily ed. Oct. 28, 2009) (statement of Sen. Kaufman)). The First Circuit explained that “[i]f a plaintiff must plead and prove that compliance with the AKS was ‘material’ to a claim ‘resulting from’ an AKS violation, § 1320a-7b(g) would not represent the strengthening of whistleblower actions that Congress intended.” Id.

Biogen contends that the First Circuit in Guilfoile did not have an opportunity to decide whether a plaintiff must plead or prove materiality for claims that predate the 2010 AKS Amendment since the claims at issue in that case occurred after the amendment. Again, however, the Court’s analysis is persuasive if not binding. The First Circuit noted that the 2010 AKS amendment was “essentially codif[ying] the long-standing view that AKS violations are ‘material’ in the FCA context” and that “[p]rior to the 2010 AKS amendment, courts had consistently held that compliance with the AKS (or the lack thereof) was ‘material’ to the government’s decision to pay a given claim based on the theory that the government’s payment was contingent on the submitting entity’s express or implied certification that it had complied with the AKS.” Id. at 191 n.12 (collecting cases prior to 2010 AKS amendments demonstrating that compliance with AKS is material).

In the First Circuit’s words, “[t]he legislative history suggests that the 2010 amendment was intended to codify the link between AKS violations and false claims within the meaning of the FCA as well as to correct one district court case holding that claims for payment resulting from AKS violations could be laundered if the claims were submitted to the government by a party who was unaware that a kickback had occurred.” Guilfoile, 913 F.3d at 191 n. 12 (citing 155 Cong. Rec. S10852-01, S10853-54 (daily ed. Oct. 28, 2009) (internal quotation marks omitted) (emphasis added)).

B. *The State False Claims Acts (Other than Texas's)*

Relator also seeks a determination that federal AKS violations are per se material to false claims acts in California (Cal. Gov't Code §§ 12650, *et seq.*), Connecticut (Conn. Gen. Stat. Ann. §§ 4-275, *et seq.*); Georgia (Ga. Code Ann. §§ 49-4-168, *et seq.*), Illinois (740 Ill. Comp. Stat. Ann. 175/1, *et seq.*), Massachusetts (M.G.L. c. 12 §§ 5A, *et seq.*) New Jersey (N.J. Stat. Ann. §§2A:32C-1, *et seq.*), New York (N.Y. Fin. Law §§ 187, *et seq.*), North Carolina (N.C.G.S. §1-605, *et seq.*), Tennessee (Tenn. Code §§ 71-5-181, *et seq.*), and Wisconsin (Wis. Stat. §§ 20.931, *et seq.*). Defendant opposes Relator's request and contends that the laws of each of these states have the same requirements as the federal False Claims Act. See Biogen's Objs. to Relator's Proposed Jury Instr. and Verdict Form, Instr. T [Doc. No. 593-2]. Accordingly, where the Defendant offers no separate argument as to why the court's analysis should not apply to the state laws, the court finds that a violation of the federal AKS is per se a violation of these states' statutes.

C. *Texas's False Claims Act*

Relator also seeks a determination that federal AKS violations are per se material to false claims act claims in Texas under Tex. Hum. Res. Code §§ 36.001, *et seq.* In his proposed jury instructions, however, Relator stated that the Texas statute was not modeled on the False Claims Act, and he provided different proposed jury instruction for claims under the TMFPA. See Relator's Proposed Jury Instr., Instr. T and U [Doc. No. 571-3]. Biogen objected to Relator's statement that the TMFPA is not modeled on the False Claims Act, and that the TMFPA is "significantly" different from the FCA, but did not otherwise object to Relator's proposed instruction on the TMFPA. See Biogen's Objs. to Relator's Proposed Jury Instr. and Verdict Form, Instr. T [Doc. No. 593-2]. Texas states that the TMFPA has similarities to, but does not

mirror, the FCA, and moreover, that a violation of the Texas Anti-Kickback Statute is per se a violation of the TMFPA. State of Texas's Statement of Interest [Doc. No. 530]. Biogen responds in part by asserting that Relator did not allege a violation of the Texas Anti-Kickback Statute. Biogen's Resp. to State of Texas [Doc. 554].

The court finds that interpretation of the TMFPA (and any materiality requirement therein) is guided by Texas law. At this juncture, where the parties appear to be in close agreement, the court anticipates instructing the jury in accordance with Relator's Proposed Jury Instruction U (with the word "significantly" deleted, as proposed by Biogen).

II. Conclusion

Accordingly, the court finds that a violation of the federal AKS is per se a violation of the False Claims Act, even prior to March 23, 2010, the date of the 2010 AKS Amendment, and is per se a violation of state statutes (other than Texas's) at issue here. The jury will be instructed as to any violation of the TMFPA as set forth above.

IT IS SO ORDERED.

July 5, 2022

/s/ Indira Talwani
United States District Judge