

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA, et al., ex	*	
rel. ADAM WITKIN,	*	
	*	
Plaintiffs and Relator,	*	
v.	*	Civil Action No. 1:11-cv-10790-IT
	*	
MEDTRONIC, INC., & MEDTRONIC	*	
MINIMED, INC.,	*	
	*	
Defendants.	*	

MEMORANDUM & ORDER

November 14, 2025

TALWANI, D.J.

Pending before the court is Defendants Medtronic, Inc., and Medtronic MiniMed, Inc.’s (collectively, “Medtronic”) Motion for Reconsideration [Doc. No. 309] of the court’s order denying Medtronic’s Motion for Summary Judgment [Doc. No. 175], see Mem. & Order [Doc. No. 271], in light of the First Circuit’s ruling in United States v. Regeneron Pharmaceuticals, Inc., 128 F.4th 324 (1st Cir. 2025). In short, the court’s summary judgment order rejected Medtronic’s argument that the phrase “resulting from” in a 2010 amendment to the Anti-Kickback Statute (“AKS”), see 42 U.S.C. 1320a-7b(g), requires but-for causation. The First Circuit subsequently held that the statutory language does require but-for causation. See Regeneron, 128 F.4th at 336.

For the reasons explained below, the court reconsiders its prior order in part and again denies summary judgment.

I. Procedural Background

A. Denial of Summary Judgment

As relevant to the pending Motion for Reconsideration, in March 2024, the court denied summary judgment on the False Claims Act (“FCA”) claims against Medtronic because Relator Adam Witkin (“Relator” or “Witkin”) had presented sufficient evidence that Medtronic provided remunerative activities to healthcare providers related to Medtronic’s continuous glucose monitoring device, the iPro2/iPro CGM (“iPro”). Mem. & Order 6, 37–46 [Doc. No. 271]. The evidence tended to show that Medtronic’s conduct in running gratuitous iPro clinics “crossed the line from mere product support to effectively running the iPro clinics on behalf of the physicians[,]” and further provided “substantial, independent value to physician’s offices in the form of additional in-office staff, repeated iPro clinics, data interpretation, and patient scheduling.” Id. at 38, 40. As to scienter, the court held there was

sufficient evidence for a reasonable jury to find that Medtronic knowingly and willfully violated the AKS by having its sales representatives and Medtronic Managers continuously involved in iPro clinics, and by consistently staffing Medtronic personnel in physician’s offices as a means of ‘adding value’ to those physicians’ practices, in order to induce physicians to prescribe Medtronic’s insulin pumps in lieu of competitors’ products.

Id. at 45.

As to the link between an AKS violation and an FCA violation, the parties disputed the standard of causation required by the phrase “resulting from” in the 2010 amendment to the AKS: “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). The court rejected Medtronic’s argument that the statute requires but-for causation and instead applied a

“sufficiency standard of causation[.]” Mem. & Order 40–41 [Doc. No. 271].¹ The court found Witkin had presented triable evidence under the sufficiency standard because he “proffer[ed] evidence that could support a reasonable jury’s conclusion that the physician’s billing practices were related to Medtronic’s improper conduct vis-à-vis the iPro clinics.” Id. at 43. Thus, the court denied summary judgment as to the FCA claims, holding:

Relator’s allegations that false claims were being submitted to federal health care programs survives summary judgment where he has presented sufficient evidence that: (1) Medtronic sales representatives and Medtronic Managers were consistently involved in running iPro clinics long after those iPro clinics should have been conducted independently by physicians and their staff, and that physicians were therefore improperly billing for services not provided by their own offices, and (2) that Medtronic knowingly offered other benefits to physicians, particularly in the form of free office staff/support (e.g., “DCM in the Office” days), to induce physicians to prescribe Medtronic insulin pumps.

Id. at 46.

In May 2024, Medtronic moved to certify the summary judgment order for interlocutory appeal, and to stay proceedings while the First Circuit decided the issue of causation required by 42 U.S.C. § 1320a-7b(g) in Regeneron. See Mot. for Cert. of Appealability [Doc. No. 277]; Mem. ISO Mot. 1 [Doc. No. 278]. The court declined. See Mem. & Order 2 [Doc. No. 292]. The court entered a scheduling order proposed by the parties that provided: “In the event the First Circuit resolves [Regeneron] . . . during the pendency of this case, any party may request a status conference, . . . or seek other relief as needed.” Scheduling Order 2 [Doc. No. 297].

B. Regeneron

In February 2025, the First Circuit decided Regeneron. As relevant here, the First Circuit was careful to distinguish between two theories of FCA liability predicated on an AKS violation.

¹ In so deciding, the court recognized the existence of alternate theories of liability that do not require but-for causation, including “express and implied certification theories of falsity.” Id. at 42 (citing United States ex rel. Hutcheson v. Blackstone Med., Inc., 647 F.3d 377, 392–94 (1st Cir. 2011); Gov’t Statement of Interest 9–10 [Doc. No. 250]).

The first theory pertains to the 2010 amendment to the AKS, which “turn[s] an AKS kickback into a per se FCA violation.” Regeneron, 128 F.4th at 327. The First Circuit considered the statutory language from the 2010 amendment, see 42 U.S.C. § 1320a-7b(g), and held that the statutory phrase “resulting from” requires but-for causation. Id. at 327–30; see also id. at 330 (rejecting government’s contrary theory and noting that this court had accepted that theory in its summary judgment order).

The second theory precedes the 2010 amendment. “Under this [false-certification] theory, a defendant violates the FCA when presenting (or causing to be presented) a claim that misrepresents compliance with a ‘statutory, regulatory, or contractual requirement’ that ‘the defendant knows is material to the [g]overnment’s payment decision.’” Id. at 332 (citation omitted). Thus, “a defendant who falsely represented AKS compliance when seeking a payment from Medicare could be liable under the FCA.” Id. The First Circuit highlighted that “claims under the 2010 amendment run on a separate track than do claims under a false-certification theory[.]” and that these tracks treat causation differently. Id. at 334. “[F]alse-certification claims require no proof of causation[.]” Id.

II. Standard of Review

A. Reconsideration

To succeed on a motion for reconsideration, the moving party generally must show (1) an intervening change in the controlling law; (2) the need to correct a clear error of law; or (3) newly discovered evidence not available to the court when the order was issued. See In re Genzyme Corp. Sec. Litig., 754 F.3d 31, 46 (1st Cir. 2014). “Unless the court has misapprehended some material fact or point of law, such a motion is normally not a promising vehicle for revisiting a party’s case and rearguing theories previously advanced and rejected.”

Palmer v. Champion Mortg., 465 F.3d 24, 30 (1st Cir. 2006) (citation omitted). A party is generally not entitled to present new arguments on a motion for reconsideration. Global Naps, Inc. v. Verizon New England, Inc., 489 F.3d 13, 26 (1st Cir. 2007).

B. Summary Judgment

Under Rule 56 of the Federal Rules of Civil Procedure, summary judgment is appropriate when “the movant shows 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 when, under the governing substantive law, it could affect the outcome of the case. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986); Baker v. St. Paul Travelers, Inc., 670 F.3d 119, 125 (1st Cir. 2012). A dispute is genuine if a reasonable jury could return a verdict for the non-moving party. Anderson, 477 U.S. at 248.

The moving party bears the initial burden of establishing the absence of a genuine dispute of material fact. Celotex Corp. v. Catrett, 477 U.S. 317, 323 (1986). This burden can be satisfied in two ways: (1) by submitting affirmative evidence that negates an essential element of the non-moving party’s claim or (2) by demonstrating that the non-moving party failed to establish an essential element of its claim. Id. at 323-324.

Once the moving party establishes the absence of a genuine dispute of material fact, the burden shifts to the non-moving party to set forth facts demonstrating that a genuine dispute of material fact remains. Id. at 324. The non-moving party cannot oppose a properly supported summary judgment motion by “rest[ing] on mere allegations or denials of [the] pleadings.” Anderson, 477 U.S. at 256. Rather, the non-moving party must “go beyond the pleadings and by [his or] her own affidavits, or by ‘the depositions, answers to interrogatories, and admissions on file,’ designate ‘specific facts showing that there is a genuine issue for trial.’” Celotex, 477 U.S.

at 324 (quoting Fed. R. Civ. P. 56(e)). Disputes over facts “that are irrelevant or unnecessary” will not preclude summary judgment. Anderson, 477 U.S. at 248.

When reviewing a motion for summary judgment, the court must take all properly supported evidence in the light most favorable to the non-movant and draw all reasonable inferences in the non-movant’s favor. Griggs-Ryan v. Smith, 904 F.2d 112, 115 (1st Cir. 1990). “Credibility determinations, the weighing of evidence, and the drawing of legitimate inferences from the facts are jury functions, not those of a judge . . . ruling on a motion for summary judgment.” Anderson, 477 U.S. at 255.

III. Discussion

A. Per Se Theory of FCA Liability

As to the per se theory of FCA liability based on the 2010 amendment to the AKS, the court finds the standard of reconsideration has been met because Regeneron’s requirement of but-for causation is an intervening change in controlling law. See In re Genzyme Corp. Sec. Litig., 754 F.3d at 46. Accordingly, the Motion for Reconsideration is GRANTED as to that theory of liability, and the court reconsiders its order on summary judgment as follows.²

Although the First Circuit did not elaborate on what but-for causation entails, the district court opinion it affirmed is instructive. When applying the but-for causation standard, the district court noted that the standard does not require “prov[ing] that the AKS violation was the only cause of the resulting false claim[,]” but rather that “it was more likely than not that the AKS violation was the cause of the false claim[,]” which may be proven “through circumstantial evidence and reasonable inferences.” United States v. Regeneron Pharms., Inc., 2023 WL

² In its summary judgment order, the court detailed at length the relevant facts viewed in the light most favorable to Witkin, see Mem. & Order 5–29 [Doc. No. 271], which the court does not repeat here.

6296393, at *12 (D. Mass. Sept. 27, 2023). The court added that it “sees no reason why [a plaintiff’s] evidence may not, in the right circumstances, include proof of temporal proximity[,]” although temporal proximity alone “may not be sufficient, and the reasonableness of the inference may be attenuated as the time period grows longer.” Id. (citations omitted).

There, the alleged AKS violations were based on the defendant’s “efforts to funnel money into [a third-party charity] specifically to reimburse the copays of” patients prescribed the defendant’s drug. Id. at *2. Before 2011, another manufacturer was the only manufacturer-donor to the fund and remained its leading donor until the end of 2013; in 2014, the defendant became the fund’s only manufacturer-donor. Id. The evidence the court found sufficient to survive summary judgment on the but-for causation standard was an expert report that filtered disbursement data from the third-party charity in 2013 and 2014 “in conjunction with Medicare claims data and performed a ‘matching’ analysis identifying Medicare claims for which [the charity] paid some or all of the beneficiary’s copay.” Id. at *12. The court also considered evidence that the price of an alternative therapy that was not covered by the charity’s fund “was dramatically lower than the price of [defendant’s drug], and it is surely true that physicians and patients alike would take the out-of-pocket cost of a drug into account when making medical decisions.” Id.

Here, the court similarly considered evidence matching the presence of Medtronic personnel with an uptick in specific claims submitted by healthcare providers:

Witkin submitted evidence of CMS claims data from physicians who had Medtronic sales representatives and Managers extensively and repeatedly participate in iPro clinics, and has provided temporal links between certain physicians’ claims data to certain patients known to have attended iPro clinics. Rel. Post-Hrg. Mem. 15-19 [Doc. No. 221] (listing specific claims from Adventist Medical Center, Portland Diabetes and Endocrinology Center, Dr. Berelowitz, Dr. Krishnamurthy, Dr. Ravuri, and Dr. Stephens) (citing Exs. 328-330 [Doc. No. 224 *SEALED*] (Excel files showing insurance claims for patients); see also Rel.

Resp. Def. SMF, Ex. 325 (Excel file of Relator Witkin's territory claims data) [Doc. No. 195-75 *SEALED*]. Medtronic does not dispute the validity of Relator's CMS data or the dates on which the relevant events occurred. Def. Resp. Post-Hrg. Mem. 15-17 [Doc. No. 226].

Mem. & Order 43–44 [Doc. No. 271]; see also id. at 24–27 (summarizing evidence supporting Witkin's assertion that “physicians were . . . submitting improper claims . . . in offices where Medtronic [personnel] were frequently present, either during prescheduled ‘DCM in the Office’ or ‘TM in the Office’ days, or during iPro clinics purportedly run by the physician's office alone”). The court found “there is evidence in the record to support Witkin's claim that designated Medtronic field personnel . . . were instructed to ‘work with [the] office to identify and schedule 4-6 patients for the clinic,’ ‘come[] into the office on [the] scheduled day with Medtronic owned equipment,’ place and train the patient on the iPro, and follow-up to review the interpretation[,]” with documents indicating that “demonstration clinics[] should lead to . . . selling Medtronic products.” Id. at 13 (citations omitted). The court also found that Witkin had “presented evidence showing that to address a ‘stagnant’ account in one physician's office, [Medtronic personnel] reported ‘implement[ing] weekly iPro clinics coupled with a ‘TM in the clinic day[,]’ . . . resulting in an 850% growth in Medtronic pump prescriptions in that previously stagnant physician's office.” Id. at 14 (citations omitted); see also id. at 20 (Medtronic's services to this office “removed competitors from the office and resulted in [the physician] being ‘100% Medtronic[]’”). Finally, the court found sufficient Witkin's reliance on “indirect evidence that Medtronic's presence resulted in physician billing, where a reasonable jury could infer that more likely than not the defendant presented a false bill to the government[.]” Id. (internal quotation marks and citation omitted).

In sum, although the court previously rejected (and thus did not consider) the application of a but-for causation standard, the court now finds Witkin proffered evidence sufficient to

survive summary judgment under such a standard. The extensive activities of Medtronic personnel, which the court determined to constitute remuneration under the AKS, see Mem. & Order 6, 37–46 [Doc. No. 271], provide more concrete evidence of causation than the “temporal proximity” questioned by the district court in Regeneron or the cases it cited. See Regeneron, 2023 WL 6296393, at *12; United States ex rel. Greenfield v. Medco Health Sols., Inc., 880 F.3d 89, 99–100 (3d Cir. 2018) (rejecting application of but-for causation but finding temporal proximity insufficient based solely on evidence of donations to charities during broad time period of submitted claims); United States ex rel. Martin v. Hathaway, 63 F.4th 1043, 1053 (6th Cir. 2023) (evidence of but-for causation insufficient where alleged hiring scheme fell through, submitted claims “would [] have occurred anyway, no matter whether the underlying business dispute occurred[,]” and one identified claim was “over seven months after” the alleged quid pro quo, which was too long to create an inference of cause and effect).

Accordingly, because the court finds that Witkin’s evidence is sufficient to survive summary judgment as to the causation issue on his FCA claims even under the standard now set forth in Regeneron, Medtronic’s Motion for Summary Judgment [Doc. No. 175] is DENIED.

B. False Certification Theory of FCA Liability

The parties dispute the false certification theory’s role here.³ Medtronic’s Motion for Reconsideration argues that but-for causation as required by Regeneron is dispositive. Mem. ISO Mot. for Reconsideration 1, 7 [Doc. No. 309-1]. Witkin’s opposition argues that reconsideration

³ Although the phrase “false certification” does not appear in the statute, the First Circuit followed the parties’ lead in using the phrase “to describe the body of case law linking the FCA and AKS without reference to the 2010 amendment . . . [p]urely for the sake of simplicity[.]” Regeneron, 128 F.4th at 332 n.2. Here, Medtronic refers to that theory of liability as “false certification” and Witkin refers to it as “material falsity.” For simplicity, this court follows the First Circuit’s lead in using the term “false certification.”

is unwarranted because Regeneron preserved the false certification theory. Opp. to Mot. for Reconsideration 4–11 [Doc. No. 312]. On reply, Medtronic argues that Witkin failed to raise the false certification theory in summary judgment and only raised it for the first time in a “sur-reply brief, to which Medtronic had no opportunity to respond[.]” Reply ISO Mot. for Reconsideration 4 [Doc. No. 317], and suggests further briefing is warranted under that theory if the court “has any doubt[.]” id. at 5.

To the extent that Medtronic seeks reconsideration based on the false certification theory, the court finds the standard for reconsideration has not been met.

First and most importantly, Regeneron did not disturb the false certification theory of liability, which “require[s] no proof of causation” and remains an alternate “pathway to FCA liability for an AKS violation when someone falsely represents compliance with a material requirement that there be no AKS violation in connection with the claim.” Regeneron, 128 F.4th at 333, 334. Medtronic thus cannot show an intervening change in controlling law, a need to correct a clear error of law, or newly discovered evidence. See In re Genzyme Corp. Sec. Litig., 754 F.3d at 46.

Second, Medtronic did not move for summary judgment on this theory. In its moving papers, Medtronic only argued that Witkin had failed to proffer evidence of “any element of a substantive FCA violation” or that “any specific false claims [were] directly induced by Medtronic’s conduct[.]” Mem. ISO Mot. for Summ. J. 32, 34 [Doc. No. 176]. To the extent Medtronic suggests this broad argument encompassed any theory of liability and Medtronic was prejudiced because it “had no opportunity to respond” to rebuttals based on the false certification theory, see Reconsideration Reply 4 [Doc. No. 317], this is incorrect. The theory was present in the summary judgment briefing prior to Witkin’s surreply. In Medtronic’s summary judgment

reply, Medtronic argued that “in any False Claims Act case, regardless of the theory of liability, the government or relator must prove that the defendant knowingly ‘present[ed], or cause[d] to be presented’ to the government a claim for payment that is materially false.” Reply ISO Mot. for Summ. J. 10 (emphasis added) [Doc. No. 249]. The government’s Statement of Interest cited this Reply and noted that “Defendants correctly observe that there is another theory of liability available to Relator—implied certification.” Gov’t Statement of Interest 9 [Doc. No. 250]. Medtronic also discussed cases involving implied and express false certification theories in its responses to Witkin’s notices of supplemental authority and an earlier Statement of Interest filed by the government.⁴ See, e.g., Defs.’ Response 2–4 [Doc. No. 238] (citing Hutcheson, 647 F.3d at 391–92; Universal Health Servs., Inc. v. United States ex rel. Escobar, 579 U.S. 176, 185–87 (2016)).⁵ Medtronic thus failed to argue for summary judgment on the false certification theory, and even if this was the result of “nothing more than [Medtronic] having second thoughts about its best arguments, [Medtronic is] bound by the choices [it] make[s].” Glob. Naps, 489 F.3d at 26.

Accordingly, to the extent Medtronic’s motion seeks reconsideration of the court’s order on summary judgment based on arguments under a false certification theory, the Motion is DENIED.

⁴ These were filed prior to the supplemental reply and sur-reply this court directed the parties to file after the case was reassigned. See Elec. Clerk’s Notes [Doc. No. 248]; Tr. of 7/21/2023 Status Conference at 13:13–14:9 [Doc. No. 252].

⁵ Medtronic’s position is also belied by its acknowledgment that the false certification theory was present in the pleadings. See Reply ISO Mot. for Reconsideration at 3 [Doc. No. 317]; see also, e.g., Second Am. Compl. ¶¶ 107–08 [Doc. No. 74] (quoting Provider/Supplier Agreement, Form CMS-855, which certifies “understanding that payment of claims are conditioned upon the ‘underlying transaction complying with . . . the Federal Anti-Kickback Statute . . .’” and thus, “claims submitted in violation of the AKS . . . violate material conditions of payment of government healthcare programs, and are false claims under the FCA”).

IV. Conclusion

For the foregoing reasons, Medtronic's Motion for Reconsideration [Doc. No. 309] is GRANTED as to the per se theory of FCA liability and DENIED as to the false certification theory. On reconsideration, Medtronic's Motion for Summary Judgment [Doc. No. 175] is DENIED.

IT IS SO ORDERED.

November 14, 2025

/s/ Indira Talwani
United States District Judge