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Recent Developments in 'Regeneron', and Eleventh Circuit Argument Regarding the Constitutionality of the False Claims Act's Qui Tam Provision

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The first edition of this column, published on May 1, 2025, included discussion of two critically important cases in the healthcare enforcement arena: (1) *United States v. Regeneron Pharmaceuticals*, in which the First Circuit held that but-for causation is necessary for an alleged violation of the Antikickback Statute (AKS) to give rise to liability under the False Claims Act (FCA); and (2) *United States ex rel. Zafirov v. Florida Medical Associates*, in which a district court ruled that the qui tam provision of the FCA violates the Appointments Clause of Article II, Section 2 of the U.S. Constitution.

This edition of the column now returns to both *Regeneron* and *Zafirov*, to discuss recent developments in these still ongoing and still important matters. In *Regeneron*, following the First Circuit's ruling and the remand of the case back to the district court, recent filings and decisions reflect the government's efforts to modify its FCA theory and escape the burdens of but-for causation, as well as the defendant's efforts to avoid summary judgment in the government's favor. In *Zafirov*, after extensive appellate briefing (including by various amici curiae), oral argument occurred before the Eleventh Circuit on Dec. 12, 2025, and *Zafirov* is now teed up for a decision that not only could create a circuit split but is likely in any event to bring the constitutional validity of the FCA's qui tam provision before the Supreme Court.


Robert M. Radick

Regeneron and the Government's Efforts to Avoid But-For Causation

In the *Regeneron* case, the government sued Regeneron on the theory that the use of a charitable foundation to make copayment assistance payments on behalf of patients who received the anti-macular degeneration drug Eylea constituted a kickback scheme. The government further argued that the existence of the kickback itself gave rise to FCA liability because, under a 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."

However, after extensive litigation over whether FCA liability required a causal link between the

kickback and the claim, both the district court and, in an interlocutory appeal, the First Circuit rejected the government's argument, holding that an alleged kickback can create FCA liability under the 2010 amendment only if the plaintiff establishes that, but for the kickback, the claim would not have been submitted to the government for reimbursement.

Following the First Circuit's decision in *Regeneron*, proceedings returned to the United States District Court for the District of Massachusetts, 20-cv-11217 (FDS). There, starting in May 2025 the government sought to shift its theory of FCA liability from the so-called "2010 amendment" pathway to an alternative "false certification" pathway, which in turn would presumably permit it to avoid the potentially insurmountable burdens of the but-for causation standard. In particular, after the case's remand to the district court, the government sought leave to file what would be its second summary judgment motion in the case, with this second such motion adopting, for the first time, the theory that Regeneron's potential FCA liability arose not from the 2010 amendment, but rather because the copayment assistance program caused those who submitted claims for reimbursement for Eylea to "falsely certify" that there had been AKS compliance.

On Aug. 4, 2025, Judge F. Dennis Saylor IV issued a decision granting the government's motion for leave to file the summary judgment motion by which it intended to make the above-described shift in its theory of the case. Although recognizing that "typically, a plaintiff must bear the risk that its choice of litigation strategy ultimately proves problematic,"

Judge Saylor held that his own reconsideration of and decision to reverse himself on the issue of whether the but-for causation standard applied, combined with the First Circuit's subsequent adoption of the but-for requirement, "amounted to a critical shift in the appliable law," such that "it would be unfair in these circumstances to chain the government to [the 2010 amendment pathway]."

Having secured the district court's approval for the filing of a summary judgment motion in which it would modify its theory of liability, on Oct. 1, 2025 (and again on Oct. 16, 2025, due to the need to correct an admitted factual error), the government filed its second motion for summary judgment, this time asserting that it was entitled to judgment as a matter of law on three aspects of its FCA case—namely, that: (1) every claim for Eylea reimbursement that was within the time period covered by the case had contained an explicit or implicit certification of compliance with the AKS; (2) there could be no dispute that certifications of AKS compliance were material to government payment decisions; and (3) in a false certification case, the requisite causal link between the kickback and the claim for payment is not but-for causation, but rather that the defendant's conduct "naturally and foreseeably caused providers to present false claims or to make or use false certifications."

In its Nov. 5, 2025 brief in opposition to the government's summary judgment motion, *Regeneron* challenged each of the government's three arguments. First, as to whether claims for Eylea reimbursement contained explicit or implied certifications of compliance with the AKS, Regeneron contended that no such finding was possible on the record before the Court, primarily because the government had not provided the certifications for any Eylea claims submitted during the time period in question, let alone a certification that related to any of the eleven specific Eylea claims identified in the government's complaint.

Second, in response to the government's argument that certifications of AKS compliance

are necessarily material to government payment decisions, Regeneron contended that there is no such per se materiality. Instead, relying on the Supreme Court's decision in *Universal Health Services, Inc. v. United States ex rel. Escobar*, 579 U.S. 176 (2016), *Regeneron* argued that the materiality inquiry "turns on a fact-intensive assessment" that includes "the 'particular type of claim' at issue, the particular 'noncompliance' at issue, and whether the government routinely reimburses such claims despite similar 'noncompliance'"—all of which, *Regeneron* argued, weigh against a finding of materiality given that CMS had "explicitly encouraged manufacturers to donate to co-pay charities" such as the one at issue in the case.

Third, regarding the government's argument that it need only show that Regeneron caused providers to present false claims or make false certifications, Regeneron characterized the government's argument as an assertion that "proof of actual causation is unnecessary." In fact, although acknowledging that the order by which the district court allowed the government to file a second summary judgment motion included the statement that the "particular standard for causation under the 2010 amendment" (i.e., but-for causation) does not apply in false certification cases, Regeneron argued that the text of the FCA requires "some proof of actual causality," and that the "presumptively correct" form of causation which the government must show is that, but for the alleged AKS violation, a claim would not have been submitted. Thus, Regeneron contended, but-for causation is an element of an AKS-predicated FCA violation even when the government does not proceed under the 2010 amendment pathway.

On Nov. 25, 2025, Saylor heard oral argument on the government's motion for summary judgment as to the above-described aspects of its case, and the court took the matter under advisement. It thus remains to be seen how the court will address the parties' arguments; how the complex issues in *Regeneron* will be resolved; and if and when this hard-fought matter will, more than five years after its initiation, finally proceed to trial.

Zafirov and the Constitutional Validity of the FCA's Qui Tam Provision

On Dec. 12, 2025, a three-judge panel from the Eleventh Circuit heard oral argument in *Zafirov v. Florida Medical Associates*, No. 24-13581, an appeal from a September 2024 decision issued by Judge Kathryn Kimball Mizelle of the Middle District of Florida.

In *Zafirov,* Mizelle had held that the FCA's qui tam provision violates the Appointments Clause of Article II of the Constitution, which governs the appointments of "Officers of the United States." Judge Mizelle reasoned that the qui tam provision, and in particular the authority it gives to private citizens who become relators, "directly defies the Appointments Clause by permitting unaccountable, unsworn, private actors to exercise core executive power with substantial consequences to members of the public." Mizelle's opinion did not, however, address additional constitutional challenges that the defendants in the case had made against the qui tam provision under Article II's Vesting and Take Care Clauses.

According to those arguments, the qui tam provision is unconstitutional for the additional reason that it takes from the office of the president authority that the Constitution vests solely in the executive branch, and leaves the president without the ability to "take care" that the laws are faithfully executed.

The *Zafirov* case is just one of a growing number of matters in which FCA defendants have challenged the constitutionality of the qui

tam provision, and to this day *Zafirov* stands as the only successful such challenge. In fact, since the issuance of Mizelle's decision more than fifteen months ago, numerous parties have relied on *Zafirov* without success, with district courts writing off the decision as unpersuasive and "contrary" to the "overwhelming weight of the law." *Kane v. Select Med. Corp.*, 2025 WL 1726253, at *1 n.1 (M.D. Fla. June 20, 2025) (declining to follow *Zafirov)*; see also *Kenley Emergency Med. v. Schumacher Grp. of Louisiana Inc.,* 2025 WL 1359065, at *5 (N.D. Cal. May 9, 2025) (finding *Zafirov* "not persuasive").

Further, four other courts of appeals—in the Fifth, Sixth, Ninth and Tenth Circuits—have previously rejected the same constitutional challenge to the qui tam provision that ultimately succeeded with Mizelle in Zafirov.

Notwithstanding Zafirov's failure to find a foothold in the other courts that have reviewed the identical issues, the Eleventh Circuit panel that heard oral argument in *Zafirov* appears to seriously be considering the constitutional validity of the FCA's qui tam provision.

The Eleventh Circuit panel in *Zafirov* was made up of Circuit Judges Elizabeth Branch and Robert Luck (both appointees of President Donald Trump), and Southern District of Florida Judge Federico Moreno (sitting by designation, and an appointee of President George H. W. Bush). After counsel for the government began the oral argument by noting that every court of appeals and every other district court have rejected Judge Mizelle's holding, Branch interjected, clarifying that the circuit courts' decisions on the matter are about 25 years old (the most recent was issued in 2002), and that since then, certain Supreme Court justices have suggested they might take up the constitutionality of the qui tam provision under Article II.

In particular, Judges Branch and Luck specifically questioned counsel for the government and the relator as to how the court should interpret Justice Thomas's dissenting opinion in *United States ex rel. Polansky v. Executive Health Resources, Inc.,* 599 U.S. 419, 449 (2023), in which Thomas expressed doubt that Congress can "authorize a private relator to wield executive authority to represent the United States' interests in civil litigation."

Relatedly, Judges Luck and Branch peppered the government's and relator's counsel with questions concerning the extent of a relator's authority, with the two judges seeming to view relators as possessing "significant authority under the laws of the United States"—one element of the two-prong Appointments Clause test Mizelle had applied below. Luck noted that in practice, a relator is a private person who effectively tells the United States how to use its investigative authority, since by statute the government must investigate claims a relator makes in a qui tam suit filed under seal. Moreno added that, practically speaking, in at least 80% of qui tam suits, the government declines to intervene and relators therefore end up conducting the litigation themselves.

The government and relator argued in response that the panel need not reach the analytical prong that addresses "significant authority," because relators do not occupy a continuing office established by law, which is first element of the Appointments Clause test. Counsel for the government and the relator also argued that even if relators occupied a continuing position, their only unilateral power is to bring an action under seal. In this regard, counsel for the relator noted that relators cannot marshal government resources for their cases, and cannot direct the government how to proceed. Further, relator's counsel argued that in declined cases, although

relators occupy what Judge Luck referred to as the "driver's seat," the government remains in the passenger's seat and is "able to grab the wheel at any time," whereas the relator can only proceed like other private litigants, in that they lack government resources and are not suddenly handed a "windbreaker and a gun."

When it was counsel for the FCA defendants' turn to address (and defend) Mizelle's decision, Luck reiterated a prior question he had posed—namely, whether the Supreme Court or any circuit court had ever applied the Appointments Clause to a private person with no employment or contractual relationship with the government—and asked whether the issue is more appropriately considered under another provision of Article II. Of note, the government did not object to a remand of the case so the district court could consider the Vesting Clause issue in the first instance, and defendants' counsel somewhat similarly urged that all constitutional arguments be considered, but argued that such consideration could happen at the appellate level.

There was also much discussion during oral argument as to the history of qui tam statutes, including whether early versions of such statutes, and the long-standing judicial acceptance of qui tam suits, should be relevant to the circuit's analysis. Counsel for the government and the relator argued that this history is necessary to determine (and is supportive of) the constitutionality of the qui tam provision. Counsel for defendants took a different tack, arguing that history is insufficient on this issue, and that reliance on judicial affirmance of early qui tam statutes "prove[s] far too much" because those statutes did not provide for government control and often permitted relators to engage in criminal prosecutions.

Counsel on behalf of amicus curia the U.S. Chamber of Commerce, who shared argument time with counsel for the defendants, likewise argued that judicial affirmance of historical qui tam statutes was of little relevance, because it was only after the 1986 amendments to the FCA that thousands of cases began to be filed each year in which relators possessed and exercised the power to seek "daunting monetary penalties on behalf of the United States, [which] is a quintessential executive power."

Of course, attempting to decipher a case's likely outcome from oral argument is an inherently speculative endeavor, and there is no way to predict how the Eleventh Circuit will rule in *Zafirov*. Moreover, regardless of how the Eleventh Circuit resolves the case, Zafirov will likely end up as the subject of a certiorari petition before the Supreme Court, and two other circuits may also offer their views in the meantime—the Sixth Circuit, which, in *In re TriHealth, Inc*., No. 25-0306, is considering whether to address the district court's certification of Article II issues regarding the FCA's qui tam provision; and the Third Circuit, which is considering the constitutionality of the qui tam provision in *United States v. Janssen Products*, No. 25-1818.

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