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More Developments in the Constitutional Challenge to the False Claims Act, and Appellate Consideration of the Scope of the Antikickback Statute

By Robert M. Radick
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Prior issues of this column have addressed a broad range of healthcare enforcement topics, but one subject has arisen more than any other: the hotly disputed question of whether the qui tam provision of the False Claims Act (FCA) violates the U.S. Constitution.

As the constitutional challenge to the qui tam provision has been raised in more and more cases, a handful have found their way to the courts of appeals, including the Eleventh Circuit in *United States ex rel. Zafirov v. Florida Medical Associates,* No. 24-13581 (see the Jan. 4, 2026 edition of this column for a discussion of the appellate arguments in *Zafirov*), and the Sixth Circuit in *In re: TriHealth*, Nos. 25-306/307 (discussed in the Feb. 26, 2026 edition).

This edition of the column addresses the latest appellate consideration of the constitutional challenge to the qui tam provision: the March 18, 2026 oral argument held before the Third Circuit in *United States ex rel. Penelow v. Janssen Products LP,* No. 25-1818.

In addition, almost a year ago, this column discussed the district court's decision in *Vertex Pharmaceuticals Inc. v. U.S. Department of Health and Human Services*, 24-cv-2046, in which the plaintiff sought to limit the scope of the Antikickback Statute (AKS) to only "corrupt" arrangements or transactions.


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The District Court for the District of Columbia rejected the plaintiff's arguments and found that the AKS reaches any form of remuneration, whether "corrupt" or not, as long as the payment is intended to induce the purchase of federally reimbursable healthcare goods and services. On Feb. 23, 2026, the Court of Appeals for the District of Columbia heard oral argument on the plaintiff's appeal in *Vertex*, and this edition of the column discusses that oral argument as well.

Penelow: The Latest Challenge to the Constitutionality of the FCA's Qui Tam Provision

On March 18, 2026, a three-judge panel from the Third Circuit heard oral argument in United States ex rel. *Penelow*, an appeal from a March 2025 decision issued in the District of New Jersey.

The *Penelow* appeal involves a range of complex issues, including the constitutional challenge to the FCA's qui tam provision.

Four courts of appeals—the Fifth, Sixth, Ninth and Tenth Circuits—have previously rejected the same constitutional challenge that is now before the Third Circuit in *Penelow*, and the Eleventh Circuit's appellate ruling in *Zafirov*, which relates to the decision by which a judge in the Middle District of Florida struck down the qui tam provision on Appointment Clause grounds, remains pending.

In *Penelow,* the district court held that the FCA's qui tam provision does not constitute an impermissible delegation of executive power to a private party, rejecting defendant Janssen's attempted reliance on the district court's decision in *Zafirov*. Instead, the district court followed "every federal circuit court of appeals that has addressed this issue" and affirmed the constitutionality of the qui tam mechanism.

The Third Circuit panel that heard Janssen's appeal in *Penelow* was made up of Judges Paul Matey (an appointee of President Donald Trump), Arianna Freeman, and Cindy Chung (both appointees of President Joe Biden). Following argument on issues related to off-label marketing, as well as materiality and causation under the FCA, the constitutional challenge took center stage.

On behalf of two amici curiae who argued in support of Janssen (the Chamber of Commerce of the United States, and the American Tort Reform Association), counsel for the amici presented the constitutional argument. Counsel argued that the FCA's qui tam provision is unconstitutional because it vests "a core executive power—the power to pursue claims and penalties on behalf of the United States—in private individuals who are not controlled by the president." Counsel also noted that when Congress revived the qui tam mechanism in 1986, the Justice Department's Office of Legal Counsel viewed it as "patently unconstitutional."

Turning to history, counsel for the amici argued that whereas the government relies primarily on the "historical pedigree" of the qui tam provision, that history is "muddled at best," "early qui tam provisions were different from the modern FCA," and "the mere adoption [of the qui tam provision] in an early Congress is not talismanic" because "history alone cannot immunize a constitutional defect."

The constitutional defect here, according to amici, was that relators are empowered to exercise significant executive authority, occupy a continuing office, and serve as "officers of the United States." Judge Matey then pressed counsel to identify the "office" that relators occupy, and counsel responded that "the office is the office of the relator" under the FCA, which counsel described as "most closely analogous to a special counsel."

Judge Matey next probed the issue of substitutability, noting that the cases in which individuals were held to be officers of the United States "all involved positions that people could be swapped in and out of, which is different here" because relators typically cannot be replaced. Counsel for the amici disputed the point, noting that relators can be substituted for upon death, bankruptcy, or procedural dismissal.

Further, counsel argued that even if there cannot be a substitution of relators, that renders the constitutional problems of the qui tam provision "worse, not better" because a relator is "somebody who's not even an officer of the United States [but] is exercising the serious power to pursue potentially ruinous fines and penalties on private companies and individuals."

Judge Chung interjected by raising the posture of the constitutional challenge, noting that the argument being advanced was a facial rather than an as-applied challenge, which in turn requires that there be no set of circumstances under which the qui tam provision could be valid. Chung then asked, "Why isn't it valid if the government intervenes and accepts the case or intervenes and dismisses the case?" Counsel responded that even during the sealing period the relator exercises "the power of the United States to initiate a suit," which counsel acknowledged is "less problematic" than the exact situation before the court (in which the relator pursued the case to completion), but that "even the initiation of a suit is a violation of Article 2."

Matey then picked up Cung's line of questions, and asked whether, in a case in which the government did not intervene, there is a "facial challenge that you can sustain?" Counsel responded that "in any case where there's not an intervention, there's a clear Article 2 violation... because someone has done something on behalf of the United States who is not empowered to do so, with that "something" being initiating a case... in the name of the United States and forcing the United States government to make a choice as to whether to get in or not."

The oral argument next turned to the counsel for the government and his response to the various issues raised on appeal, including the constitutionality of the qui tam provision. As the above arguments reflect, the government had not intervened in the *Penelow* matter throughout most of its litigation history.

However, following Janssen's advancement of a constitutional challenge to the qui tam provision, the government intervened as a party for the limited purpose of addressing the constitutional arguments, and also proceeded as amicus curiae on other issues, such as whether the off-label marketing of a drug rendered a claim for reimbursement of that drug false under the FCA.

As to the constitutional challenge, government counsel (who, notably, is the same Department of Justice attorney who argued the *Vertex* matter described in the next section of this column) acknowledged that qui tam suits "differ somewhat" from other situations in which Congress has authorized private persons to bring suits to enforce federal law, acknowledged that those differences "would create significant Article II questions if qui tam suits were a novel development in American law," and then said, "[b]ut they're not."

Government counsel proceeded to argue that "qui tam has deep historical roots," and that contrary to the position of amici's counsel, "abundant evidence since the founding shows that Congress, the executive branch, and courts have all accepted qui tam suits as a constitutionally permissible means of redressing and deterring violations of federal law."

Judge Matey interjected to inquire about the scope and expansiveness of the government's argument, asking whether the government was asserting that all prior statutes in which an individual could bring suits on behalf of the sovereign confirmed the constitutionality of the qui tam provision in the FCA, and whether the historical analogues that gave individuals the right to sue on behalf of the government meant that Congress could "create nonofficers who exercise significant authority but do so for a limited time in, say, foreign affairs or commerce..."

Counsel for the government responded that only certain historical qui tam provisions were appropriate analogues to the FCA, and also confirmed that the government was not defending a wider range of potential authority by non-officers in areas such as foreign affairs, but rather, "[o]ur argument is specific to qui tam litigation."

Matey also pushed back on the government's position that relators "do not occupy a continuing office," positing that "one can be an officer in both common understanding and constitutional theory without actually having an office they correspond to." Government counsel disagreed, contending that "an officer is someone who occupies an office," and that "[a] relator does not occupy an office because the role of a relator... cannot be handed off to any other relator."

The remainder of the argument in *Penelow* related to matters other than the qui tam provision, and one week after oral argument, the Third Circuit determined that *Penelow* was appropriate for mediation and assigned the case to a special mediator. Of course, in the event the case is not resolved through mediation, *Penelow*, together with *Zafirov*, may result in circuit-level decisions on the constitutionality of the FCA's qui tam provision, and therefore warrant diligent and ongoing attention.

Vertex Pharmaceuticals and the Reach of the AKS

On Feb. 23, 2026, a three-judge panel from the D.C. Circuit heard oral argument in *Vertex Pharmaceuticals Inc. v. U.S. Department of Health*

and Human Services, No. 25-5133, an appeal from a March 2025 decision issued by Chief Judge James E. Boasberg of the D.C. District Court.

In *Vertex*, Judge Boasberg had upheld a Department of Health and Human Services (HHS) advisory opinion finding Vertex's proposed "Fertility Support Program"—which would offer up to $70,000 in fertility treatments to help offset the effects of chemotherapy that is part of CASGEVY, the company's potentially curative gene-editing therapy for those with serious blood diseases—constituted "prohibited remuneration" under both the criminal AKS and the civil Beneficiary Inducement Statute (BIS).

Boasberg held first that HHS reasonably concluded that Vertex's proposed Fertility Support Program did not qualify under the BIS's "Promotes Access to Care Exception," which exempts from the BIS's prohibitions those forms of remuneration that "promote[] access to care and pose[] a low risk of harm to patients and Federal health care programs." 42 U.S.C. §1320a-7a(i)(6)(F).

In this regard, Boasberg found that, given the absence of available data regarding "using and accessing novel gene therapies," HHS was "entitled to significant deference on its determination that it lacked sufficient information to find that the [Fertility Support] Program would improve access to care while posing a low risk of harm to patients." 774 F. Supp. 3d 211, 220-21 (D.D.C. 2025).

Turning to the AKS issue, Boasberg rejected Vertex's argument that the statutory terms "remuneration" and "induce" carry a "specialized criminal-law meaning" such that they reach only transactions that have corrupt intent. Instead, interpreting the words to have their ordinary meaning, Boasberg accepted as proper the HHS finding that Vertex's proposed program would violate the AKS, since the fertility services constitute "remuneration" and Vertex's motive for providing that remuneration would be "to induce others to purchase" its gene-editing therapy. Vertex filed an appeal in the D.C. Circuit Court of Appeals.

The D.C. Circuit panel that heard oral argument in *Vertex* was made up of Circuit Judges A. Raymond Randolph (an appointee of President George H. W. Bush), Neomi Rao, and Justin Walker (appointees of President Donald Trump). Counsel for Vertex began by arguing that the AKS's text requires a corrupt transaction that "distorts medical decision making from the medical merits," in part because the statute refers to paying or receiving a kickback, bribe, or rebate.

Judge Walker quickly interjected, positing that, because Vertex could, but does not, reduce the cost of its gene therapy product by $70,000, it takes the full amount of the government's reimbursement for its gene therapy product and then uses $70,000 of that amount to fund fertility treatments that government health care programs do not cover. This, according to Judge Walker, is "almost exactly what the anti-kickback statute is designed to prevent," because by means of the Fertility Support Program, Vertex is "making the government pay for stuff the government doesn't want to pay for."

Vertex's counsel responded by challenging Judge Walker's logic, because the government will pay for the full reimbursement share amount for the gene therapy regardless of whether the patient receives fertility treatments. Counsel then brought the discussion back to his position that whereas HHS's Advisory Opinion "assume[d] that any influence on decision-making was enough to violate the statute," in fact the AKS requires something "improper" or "wrongful" about the remuneration and its influence.

He pointed to decisions by the Fifth, Seventh, and Ninth Circuit Courts of Appeals, as well as the Supreme Court in *United States v. Hansen*, 599 U.S. 762 (2023), and argued that these cases all support an interpretation of the term "inducement" as requiring criminal intent or criminal solicitation, rather than mere intent to influence.

Judge Rao weighed in that she found counsel's interpretation "intuitively very appealing," since the AKS is a criminal statute and the word "induce" therefore should require some aspect of wrongdoing. However, she questioned whether that was Congress's intent since the statute was written so broadly.

Counsel responded that if HHS were correct that "induce" merely means influence, even the hiring

of an advertising agency to market a healthcare product or service, or a situation in which a "generous aunt" provides her niece with money to access care she otherwise could not afford, would violate the AKS due to the "absurd breadth" of HHS's interpretation. Further, counsel argued that by eliminating corrupt intent and focusing only on influence, HHS's construction of the AKS would criminalize the same lifting of financial barriers that Congress was attempting to encourage through the BIS's "Promotes Access to Care Exception."

When it was the government's turn, the Department of Justice attorney who advocated on behalf of HHS began with the argument that the AKS does not require a separate showing of "corruption" because when remuneration is offered with the purpose of inducing medical decisions, the offer itself creates a financial conflict that "inherently corrupts" medical decision-making. Counsel also posited that there is no tension arising from the fact that conduct may be civilly exempt under the BIS while illegal under the AKS, because, contrary to Vertex's assertion, the BIS is not the "civil counterpart" to the AKS.

Judge Walker responded by questioning HHS's finding that the Fertility Support Program does not qualify under the Promoting Access to Care Exception to the BIS, given that it mitigates a side effect (the fertility consequence) of the Vertex gene therapy. Counsel for the government countered that mitigating fertility consequences does not increase "access" under the intended definition of that term, and that while "some people can choose to bear and some others might not choose to bear" certain side effects, that is not "an issue of access."

After acknowledging that the government would not "fight... hard" against a potential remand to HHS for further development of whether the Promoting Access to Care Exception should apply, counsel asserted that the BIS analysis was not the key issue, and the focus instead should be on the legal question of whether the Vertex program constituted "remuneration" intended to "induce" medical decisions such that it is prohibited by the AKS.

He also argued that *Vertex* was misguided in relying on *United States v. Hansen* for the concept that the proposed arrangement must be "corrupt" to violate the AKS, noting that in the Fourth Circuit's decision in *Pharmaceutical Coalition for Patient Access v. United States*, 126 F.4th 947 (4th Cir. 2025), the court held that the statute in question in *Hansen* (which related to inducing illegal aliens to enter or reside in the United States) forbade the inducement of *criminal* conduct, whereas the AKS forbids the use of remuneration to induce *lawful medical decisions*.

Thus, according to counsel, if you interpret the AKS to require corrupt intent or the inducement of an unlawful act, it would "decimate" the statute and "leave it essentially a husk of itself."

Given the nature of the argument before it, it appears somewhat unlikely that the appellate panel in *Vertex* will accept plaintiff's invitation to limit the reach of the AKS to only those arrangements that are inappropriate or corrupt, in part because no such requirement appears in the statute itself. Nonetheless, as with many oral arguments, there is no meaningful way to predict how the D.C. Circuit will rule in *Vertex*, and *Vertex* will most likely be the subject of a Supreme Court certiorari petition no matter what the panel decides.

Robert M. Radick *is a principal of Morvillo Abramowitz Grand Iason & Anello. He was formerly the Chief of Health Care Fraud Prosecutions and the Deputy Chief of the Public Integrity Section of the U.S. Attorney's Office for the Eastern District of New York.* **Emily Smit**, *an associate at the firm, assisted in the preparation of this article.*