

HEALTH CARE LAW

A Return to *United States ex rel. Zafirov* and Vertex Pharmaceuticals

By Robert M. Radick

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Since this column began on May 1, 2025, certain critically important cases have warranted repeat attention. *United States ex rel. Zafirov v. Florida Medical Associates, LLC* has been the focus of this column on two occasions.

First, the column's inaugural edition discussed a district court decision in *Zafirov* that struck down the qui tam provision of the False Claims Act (FCA) as an unconstitutional violation of the U.S. Constitution's Appointments Clause. Then, in January 2026, the column returned to *Zafirov* for discussion of the oral argument that, one month earlier, had taken place before the Eleventh Circuit regarding the government's and relator's challenges to the district court's decision.

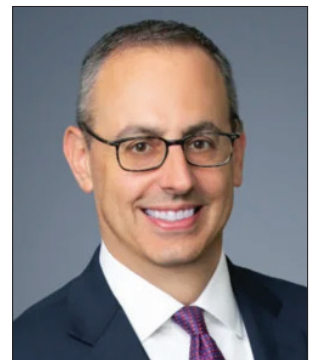
Vertex Pharmaceuticals Inc. v. U.S. Department of Health and Human Services has likewise been the focus of this column on two occasions. The first was in June 2025, after a district judge in the District of Columbia upheld an advisory opinion by which the Department of Health and Human Services (HHS) had found that a fertility support program Vertex proposed to offer in connection with its gene-editing treatment for those suffering from blood disorders violated the Anti-Kickback Statute (AKS).

Subsequently, in June 2026, this column revisited Vertex after the Court of Appeals for the District of Columbia Circuit heard oral argument on Vertex's appeal of the district court's decision.

Both cases now return for their third (and perhaps not final) appearance. This edition of the column discusses: (1) the Sept. 1, 2026 opinion in *Zafirov*, by which the Eleventh Circuit vacated the district court's decision and rejected the argument that the FCA's qui tam provision violates the Appointments Clause; and (2) the Sept. 4, 2026 decision in *Vertex*, by which the Court of Appeals for the District of Columbia Circuit partially affirmed the lower court's decision, finding that Vertex's proposed fertility program constituted "remuneration... to induce" the use of its gene-editing treatment in violation of the AKS, but remanded for assessment of additional issues.

Zafirov: Eleventh Circuit Weighs in on Constitutionality of FCA's Qui Tam Provisions

On Sept. 1, 2026, in the midst of various challenges to and decisions regarding the constitutionality of the FCA's qui tam provision in other



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jurisdictions, a three-judge panel of the Eleventh Circuit issued its long-awaited decision in *United States ex rel. Zafirov v. Florida Medical Associates, LLC*, No. 24-13581, 2026 WL 2581886 (11th Cir. Sept. 1, 2026). *Zafirov* was the only case in which a district court had accepted the argument that the qui tam provision violated Article II's Appointments Clause.

As discussed previously, the *Zafirov* matter began when the relator, Dr. Clarissa Zafirov, filed a case in 2019 against her former employer and related entities, alleging that they knowingly submitted false diagnosis codes to obtain excess Medicare payments. The defendants moved in February 2024 for judgment on the pleadings, arguing that the FCA's qui tam provision violated the Appointments, Take Care, and Vesting Clauses of Article II of the Constitution.

In a September 2024 decision, Judge Kathryn Kimball Mizelle of the Middle District of Florida ruled that relators qualify as "Officers of the United States" and thus their positions are required to conform to the provisions and restrictions of the Appointments Clause. Finding that the qui tam provision "directly defies the Appointments Clause by permitting unaccountable, unsworn, private actors to exercise core executive power with substantial consequences to members of the public," Judge Mizelle declared the qui tam provision unconstitutional.

After considerable waiting and speculation about how the *Zafirov* decision would fare in the court of appeals, the Eleventh Circuit vacated Judge Mizelle's ruling, thereby setting aside what to that point had been the sole decision adopting an argument suggested in Justice Clarence Thomas's dissenting opinion in *United States ex rel. Polansky v. Executive Health Resources, Inc.*, 599 U.S. 419, 449 (2023) (expressing doubt that Congress can "authorize a private relator to wield executive authority to represent the United States' interests in civil litigation").

Writing for a panel that also included Circuit Judge Robert Luck and Southern District of Florida Judge Federico Moreno (sitting by

designation), Circuit Judge Elizabeth Branch held that "relators are not officers of the United States because they do not occupy a continuing position established by law." In doing so, the Eleventh Circuit stated that it was "join[ing] [its] sister circuits that have addressed this issue," namely the Fifth, Sixth, Ninth, and Tenth Circuits.

In reaching its decision in *Zafirov* that relators are not subject to the provisions of the Appointments Clause, the panel applied the two-part test from *Lucia v. SEC*, 585 U.S. 237 (2018), which determines whether a government employee is an officer of the United States.

Under that test, an individual is an officer if he or she "occup[ies] a 'continuing' position established by law," and also "exercise[s] significant authority pursuant to the laws of the United States." The panel "assume[d] without deciding" that *Lucia* governs the Appointments Clause inquiry as to relators, even though they are not government employees. It then resolved the case on *Lucia*'s "continuing position" prong alone, finding it unnecessary to address *Lucia*'s "significant authority" prong.

Relying on *United States v. Germaine*, 99 U.S. 508 (1879), and *Auffmordt v. Hedden*, 137 U.S. 310 (1890), the Eleventh Circuit looked at four features of a relator's role to determine whether a relator holds a "continuing position established by law"—the permanence of the relator's tenure, the duration of that tenure, whether the relator receives a "continuing emolument," and whether the relator's "duties continue, though the person be changed."

As to tenure, the panel likened relators to the surgeon appointed by the Commissioner of Pensions to examine pension applicants in *Germaine* and the merchant appraiser responsible for appraising imported merchandise in *Auffmordt*. The court found that, like these roles, a relator's tenure is "occasional and temporary because it lasts the length of one case, a relator may bring multiple cases in a year or none, and relators are not required to keep a place of business."

As to duration, the court rejected the relevance of defendants' point that some FCA cases go on for years, explaining that the Supreme Court has

focused not on how long a person spends fulfilling his duties, but rather on whether those duties are “permanent” or “occasional and intermittent.” On that issue, the court noted again that a relator’s tenure is not permanent, and that a relator’s duties “do not extend over any case further than as he is selected to act.”

The Eleventh Circuit likewise found that any recovery a relator receives is not a “continuing emolument.” The court held that a relator receives only “a one-time award contingent on the success of his case,” paid from the judgment rather than from “any regular appropriation,” and works on an intermittent basis without any “penalty for a refusal to perform” (other than losing the contingent fee).

Finally, the panel held that a relator’s duties are “personal,” such that when a relator dies or goes bankrupt, “another relator does not replace [him]; instead, a personal representative or trustee of the relator’s estate can carry forward the case on his behalf.”

The panel was unpersuaded by the defendants’ counterarguments. For example, it distinguished on two grounds the independent counsel who was found to be an officer in *Morrison v. Olson*, 487 U.S. 654 (1988): first, unlike a relator, an independent counsel who resigns is replaced by a successor “with the same jurisdiction,” and second, independent counsels are paid from a “permanent indefinite appropriation” within the Justice Department. The court also rejected Judge Mizelle’s construct that there exists an “office of relator.”

The decision noted that the term “is not in the FCA or any other law,” and that the proper inquiry is whether an individual occupies a continuing position, not whether the office is a continuing one.

Finally, in a footnote, the court declined to adopt the Second Circuit’s continuing-position framework from *United States v. Donziger*, 38 F.4th 290, 297 (2d Cir. 2022), on which Judge Mizelle had relied, choosing instead to “rely directly on the guidance the Supreme Court has provided” in *Germaine and Auffmordt*.

The Eleventh Circuit’s decision in *Zafirov* is unlikely to be the last word on the constitutionality of the FCA’s qui tam provision. In fact, the panel declined to reach the defendants’ Take Care Clause and Vesting Clause challenges, and remanded for the district court to assess those matters in the first instance.

Thus, while the Eleventh Circuit’s decision avoids a circuit split on the Appointments Clause question, it leaves open the broader Article II challenge to the qui tam provision, a challenge in which certain Supreme Court justices have already signaled their interest. Further, given that the Third Circuit is still considering largely identical questions in *United States ex rel. Penelow v. Janssen Products, L.P.*, No. 25-1818, the constitutional validity of the FCA’s qui tam provision remains a live issue.

Vertex: D.C. Circuit Finds Proposed “Fertility Support Program” to Violate AKS

On Sept. 4, 2026—just three days after the Eleventh Circuit issued its opinion in *Zafirov*—the D.C. Circuit released its decision in *Vertex Pharmaceuticals Inc. v. U.S. Department of Health and Human Services*, No. 25-5133, 2026 WL 2617588 (D.C. Cir. Sept. 4, 2026), another important case regarding the reach of government enforcement tools in health care matters.

The facts underlying the D.C. Circuit’s decision in *Vertex* relate to *Casgevvy*, a gene therapy treatment that Vertex developed for patients suffering from two hereditary blood disorders. Because the *Casgevvy* treatment required intensive chemotherapy, which could have a significantly harmful impact on patient fertility, Vertex developed a proposed “Fertility Support Program” by which *Casgevvy* patients could receive up to \$70,000 for fertility services.

The fertility program was initially offered solely to patients with private insurance because of Vertex’s concerns regarding the program’s compliance with the AKS and the Beneficiary Inducement Statute (BIS), but in June 2023, Vertex submitted a request to HHS for an advisory

opinion regarding the program's legality for those insured through federal health care programs.

In July 2024—following HHS's requests for additional information, substantial government delay, and Vertex's filing of a lawsuit in the U.S. District Court for the District of Columbia seeking an order that would compel the release of the advisory opinion—HHS issued an opinion finding that the Fertility Support Program would violate both the AKS and the BIS. Vertex challenged HHS's decision in the district court, but Chief Judge James Boasberg of the D.C. District Court ruled in HHS's favor.

Regarding the AKS, Judge Boasberg declined to adopt Vertex's argument that the terms "remuneration" and "induce" in the AKS carry "a specialized criminal meaning" such that they prohibit only transactions that have corrupt intent. Instead, giving the words in the AKS their ordinary meaning, Judge Boasberg found that Vertex's Fertility Support Program constituted "remuneration," that its motive was to "induce others to purchase" Casgevy, and that HHS was therefore justified in finding that the program would violate the AKS.

Regarding the civil counterpart to the AKS, HHS had concluded in its advisory opinion that the Fertility Support Program did not qualify under an exception to the BIS for arrangements 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). Judge Boasberg agreed, finding that 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 patient harm."

Vertex appealed to the D.C. Circuit, oral argument took place on Feb. 23, 2026, and, as noted, the D.C. Circuit issued its decision on Sept. 4, 2026. The three-judge panel that decided the Vertex appeal consisted of Circuit Judges A. Raymond Randolph, Neomi Rao, and Justin Walker, with Judge Rao writing the opinion for the court.

On the question of whether the Fertility Support

Program would run afoul of the AKS, the D.C. Circuit affirmed those portions of the HHS Advisory Opinion and the district court decision which had found that the Vertex fertility program would violate the AKS.

The D.C. Circuit's analysis focused primarily on the definition of the term "induce," seeking to determine whether "inducing" in the language of the AKS aligns with its commonly understood meaning of "influencing," or whether in the AKS it instead has a more specialized, criminal-law meaning that reflects "criminal solicitation" (intentionally encouraging another to commit a crime) or "criminal facilitation" (assisting a wrongdoer with the intent to further the commission of a crime).

Noting that the AKS "does not directly prohibit the inducement of clearly unlawful activity," and that "the selection of medical services by a recipient of Medicare and Medicaid is generally lawful," the D.C. Circuit found that to "induce" under the AKS has its ordinary meaning of "influencing," rather than any specialized criminal law context.

Further, the D.C. Circuit held that the existence of safe harbors to the AKS weighs heavily in favor of interpreting "induce" to have its ordinary meaning rather than any criminal law implications; otherwise, if the term "induce" were limited to reaching only corrupt or illegal conduct, the safe harbors would not be needed to protect legitimate conduct, and there would be "vast superfluity" in the statute.

Having determined that the term "induce" in the AKS has its ordinary meaning of "to influence," the D.C. Circuit next turned to the meaning of the word "remuneration." Noting that the parties disagreed as to whether "remuneration" reaches a "wide range of payments, or only corrupt payments and transactions," the D.C. Circuit adopted the former definition.

In particular, the D.C. Circuit observed that the AKS uses broad language (including the phrase "any remuneration") to capture the types of payments the statute prohibits, and prohibits "rebates," which reaches a broader set of transactions than those that are "inherently corrupt."

On this basis, the court rejected *Vertex's* narrow reading of the statute and found that the AKS includes a broad prohibition on any form of remuneration paid to influence medical decisionmaking, regardless of whether the payment represents an improper quid pro quo with corrupt intent. Against this backdrop, the court further found that the financial incentives that were part of the Fertility Support Program would induce the purchase of Casgevy by patients who might otherwise decline to use it, thereby violating the AKS.

Having determined that the implementation of the Fertility Support Program would violate a criminal law statute and constitute a felony offense, there was perhaps little more that the D.C. Circuit could do or say that would render its ruling anything other than a fundamental loss for *Vertex*. Nonetheless, the remainder of the D.C. Circuit's decision went on to rule in *Vertex's* favor on two other aspects of the case.

First, with regard to HHS's determination that it lacked data to show that the Fertility Support Program qualified under the "Promotes Access to Care Exception" and therefore would not violate the civil BIS, the D.C. Circuit found that HHS "failed to reasonably explain" why the exception did not apply.

In particular, the court noted that, "[d]espite months of delay... HHS did not explain what data it lacked, nor why it could not readily obtain that data, nor why *Vertex's* detailed evidence was insufficient to show that the program would improve patient access to Casgevy." The D.C. Circuit thus found that HHS's decision regarding the BIS was arbitrary and capricious, and set it aside.

Second, in the district court proceedings, *Vertex* had argued that HHS's regulations regarding advisory opinion requests impermissibly extend the time for the agency to respond to such requests. Although the district court had found

both that *Vertex* lacked standing to raise the argument and that the eventual issuance of the advisory opinion rendered the argument moot, the D.C. Circuit disagreed.

Turning to the merits of the argument, the court found HHS's challenged timing provisions contrary to law, in that Congress had permitted HHS only 60 days to issue an advisory opinion after the request was made, but HHS regulations permitted the agency two delays—one by suspending the start of the 60-day clock until the agency has "formally accepted" the request for an advisory opinion, and another that tolled the clock if HHS requested additional information or advice from an outside expert.

Finding that "HHS has no authority to circumvent th[e] [60-day] statutory deadline," the court reversed on this issue and remanded to the district court for further proceedings.

The *Vertex* case's next stop will not be in the district court, however. On Oct. 9, 2026, *Vertex* petitioned the U.S. Supreme Court for a writ of certiorari, arguing that the government's interpretation of the AKS represents the latest in a series of "overbroad reading[s] of an anti-corruption statute," that the "purported crime is merely helping patients access medically necessary treatment without suffering permanent infertility," and that the D.C. Circuit's decision further deepens a "3-3 circuit split regarding the meaning of 'induce' in federal criminal anti-kickback statutes." The result is that, for now at least, the last word in *Vertex* has not yet been written.

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