ALM | LAW.COM

New York Law Journal

Further Developments in Constitutional Challenges to the False Claims Act, and Lessons From the Indictment of Two Telemedicine Corporations

By Robert M. Radick
February 26, 2026

The prior edition of this Healthcare Enforcement column discussed the Dec. 12, 2025 oral argument that took place before the Eleventh Circuit in the case *United States ex rel. Zafirov v. Florida Medical Associates, LLC, et al*., No. 24-13581 which relates to the increasingly litigated question of whether the qui tam provision of the False Claims Act (FCA) violates the Appointments Clause of the United States Constitution.

Among the points noted in the article's discussion of *Zafirov* was that, in the case captioned *In re: TriHealth, Inc., et al*. Nos. 25-306/307, another circuit court of appeals, the Sixth Circuit, was simultaneously considering a district court's certification of an interlocutory appeal as to the constitutionality of the FCA's qui tam provision, and that a prompt decision in *In re: TriHealth* could give the Sixth Circuit the next chance to weigh in on this hard-fought issue.

However, as we discuss in this first part of today's column, on Jan. 9, 2026, the Sixth Circuit issued a decision rejecting the interlocutory appeal in *In re: TriHealth*, leaving *Zafirov* (and the Third Circuit's pending case *United States ex rel. Penelow, et al. v. Janssen Products, L.P.*, No. 25-1818), as the next matters in which the constitutionality of the qui tam provision will likely be decided.

Next, turning from the constitutionality of the qui tam provision to a new criminal enforcement action, the second part of this article addresses the recent indictment of Done Global and a related company, Mindful Mental Wellness, both of which operate in the telehealth space and allegedly used a subscription-based program to provide patients with access to roughly 40 million pills of the ADHD drug Adderall.


Robert M. Radick

As is discussed in further detail below, the Done Global and Mindful Mental Wellness indictment appear to reflect not only the government's commitment to enforcement actions against telehealth entities that provide access to controlled substances, but also the government's view that, at least in the realm of controlled substance distribution, tandem (or, more accurately in this case, seriatim) prosecutions of individuals and corporate entities may be warranted.

'In re: TriHealth' and the Constitutional Validity of the FCA's Qui Tam Provision

On Jan. 9, 2026, a three-judge panel from the Sixth Circuit issued a short order in *In re: TriHealth*, denying defendants' petitions for interlocutory appeals to address whether the qui tam provision of the FCA is

unconstitutional under the Appointments and Take Care Clauses of Article II of the United States Constitution. Order dated Jan. 9, 2026, *In re: TriHealth, Inc.*, Nos. 25-0306/0307, Dkt. No. 14 at 2 (6th Cir. Jan. 9, 2026).

The *TriHealth* matter arose when physician and Relator Timothy Murphy initiated a lawsuit against TriHealth, an integrated health care system based in Cincinnati, Ohio, under the FCA's qui tam provisions. TriHealth employed Murphy as its Physician Practices Chief Financial Officer until he resigned. Murphy alleged that TriHealth paid a physician group in excess of its productivity to incentivize referrals to TriHealth's hospitals, and that the hospitals allegedly subsidized the losses. Another relator, Dr. Set Shahbabian, brought similar FCA claims against TriHealth and Mayfield Clinic, Inc.

The United States declined to intervene in the cases and TriHealth moved to dismiss based on, *inter alia*, arguments that the qui tam provisions of the FCA violates the Constitution. The district court denied TriHealth's constitutional challenges, finding it was bound by Sixth Circuit precedent. Order dated July 28, 2025, *United States ex rel. Shahbabian v. TriHealth, Inc.*, No. 20-cv-67, Dkt. No. 66 at 17 (S.D. Ohio July 28, 2025).

In 1994, the Sixth Circuit in *Taxpayers Against Fraud* rejected defendant's arguments that the qui tam provisions "deputize" private citizens in the name of the government, inappropriately taking the prosecutorial function away from the Executive Branch and interfering with its discretion. The Sixth Circuit concluded that the qui tam process allows the Executive Branch to maintain sufficient control over the relator's conduct, even if the government turns down the opportunity to intervene, and the officer is not an "officer" within the meaning of the Appointments Clause.

Although the district court in *TriHealth* applied *Taxpayers Against Fraud* to reject the defendants' constitutional challenge to the qui tam provision of the FCA, the district court also took the unusual step of certifying the constitutional question for appeal to the Sixth Circuit. In this regard, while noting the binding precedential authority of *Taxpayers Against Fraud*, the district court also observed that that "reasonable jurists could disagree as to whether the FCA violates Article II," and cited, as evidence of such potential for reasonable disagreement, the pendency of the Eleventh Circuit's appellate decision regarding *United States ex rel. Zafirov v. Florida Medical Associates*, 751 F. Supp. 3d 1293 (M.D. Fla. 2024), in which a district court had held that the FCA's qui tam provision violates the Appointments Clause of Article II. Order dated July 28, 2025 at 17.

In certifying the constitutional question for appeal, the district court in *TriHealth* also noted recent concurring and dissenting opinions in which Supreme Court justices have called into question the constitutional viability of the FCA's qui tam provision. Order dated July 28, 2025 at 10-12, 18.

In particular, as the district recognized in *TriHealth*, 32 years had passed since the *Taxpayers Against Fraud* decision, and several Supreme Court justices had since come to suggest that the court might take up the constitutionality of the qui tam provision. In his dissenting opinion in *United States ex rel. Polansky v. Executive Health Resources, Inc.*, 599 U.S. 419, 449-50 (2023), for example, Justice Clarence Thomas expressed doubt that Congress can "authorize a private relator to wield executive authority to represent the United States' interests in civil litigation," and Justices Brett Kavanaugh and Amy Coney Barrett joined that part of the opinion.

Kavanaugh also wrote a separate concurring opinion, joined by Justice Barrett, in which he emphasized that there are "substantial arguments" the qui tam provision violates Article II. And, in *Wisconsin Bell, Inc. v. United States ex rel. Heath,* 604 U.S. 140, 167 (2025), Kavanaugh issued a concurring opinion, which Thomas joined, stressing that the FCA "*qui tam* provisions raise substantial constitutional questions under Article II" and concluding that "in an appropriate case, the court should consider the competing arguments on the Article II issue."

Despite the uncertainty expressed by the district court in *TriHealth*, and notwithstanding the Supreme Court's statements on the matter and the pending appeal in *Zafirov*, the Sixth Circuit disagreed with the district court and rejected the petition for an interlocutory appeal. In its decision, the Sixth Circuit ruled that that the 1994 decision in *Taxpayers Against Fraud* "leave[s] no substantial grounds for a difference of opinion on the issue"—the second requirement of a three factor test used by the Sixth Circuit as guidance whether to permit certified appeals. Order dated Jan. 9, 2026 at 2. (The other two factors of the test are

"the order involves a controlling question of law," and "an immediate appeal may materially advance the ultimate termination of the litigation.")

To overrule the ruling in *Taxpayers Against Fraud*, the Sixth Circuit explained, the court would need to sit *en banc*. Order dated Jan. 9, 2026 at 2 (citing 6 Cir. R. 32.1(b)). The court's ruling raises questions as to whether, rather than denying the petition for an interlocutory appeal, the Sixth Circuit could have gone *en banc* to consider overturning *Taxpayers Against Fraud*, and if so, why it did not. It is worth noting in this regard that while defendants may technically petition for a rehearing *en banc* of the denial for interlocutory appeal pursuant to Federal Rule 35 of the Federal Rules of Appellate Procedure, under Rule 35's demanding standard, the petition is unlikely to be granted unless a conflicting decision by the Supreme Court is issued.

Moreover, relying on *Taxpayers Against Fraud* as precedential weight, rather than proceeding *en banc*, perhaps buys the Sixth Circuit additional time to see how *Zafirov* and the other cases in which the issue is pending ultimately shake out. In any event, for now, all eyes should remain squarely on *Zafirov*.

The Corporate Criminal Prosecutions of Done Global and Mindful Mental Wellness

In a press release issued on Dec. 17, 2025, the Department of Justice announced that on the preceding day, a grand jury sitting in the Northern District of California had handed up an indictment charging Done Global (described as a "digital health company") and Mindful Mental Wellness (a medical practice in Florida that Done Global had incorporated) with crimes stemming from a conspiracy to illegally distribute Adderall. Although the charges against Done Global and Mindful Mental Wellness are combined in a single standalone indictment and bear a docket number (25-cr-432) that is distinct from any prior cases in the Northern District of California, discussion of this corporate criminal enforcement action first requires a brief description of two individual prosecutions that preceded it.

The litigation history of criminal matters related to Done Global dates back to at least June 12, 2024, when an indictment in the case docketed as 24-cr-329 (N.D. Cal.) was handed up against Ms. Ruthia He (He), the founder and CEO of Done Global, and David Brody, a psychiatrist and the clinical president of a related entity known as Done Health P.C.

According to the indictment against both individuals, Done Global operated on a subscription-based model, by which individual members paid a monthly fee to the company in return for what was advertised as "online diagnosis, treatment, and refills of medication for attention deficit hyperactivity disorder." The indictment also alleged that the company had a network of prescribing doctors (including Brody) and nurse practitioners whom the company "paid to diagnose... members with ADHD and to write prescriptions for controlled substances, including Adderall and other stimulants."

The indictment further alleged a host of fraudulent and misleading practices by He and Brody, such as exploiting "emergency flexibilities" during COVID to provide easy access to Adderall; hiring medical professionals who would prescribe Adderall at an initial telemedicine encounter and who He and Brody believed were not concerned about drug-seeking behavior by patients; falsely claiming that Done Global could accurately diagnose ADHD in shorter appointment times than medical clinics; and pressuring, making lucrative payments to, and otherwise causing practitioners to prescribe Adderall and other stimulants even when the patients did not qualify and the prescriptions were not for a legitimate medical purpose in the usual course of professional practices.

Based on these allegations and others, the indictment charged each defendant with one count of conspiring to illegally distribute a controlled substance, four counts of distributing or aiding and abetting the illegal distribution of controlled substances, one count of conspiracy to commit health care fraud, and one count of conspiring to obstruct justice (this last charge appears at some point to have been dropped against Brody).

On Sept. 29, 2025, after extensive pretrial motions and proceedings, He and Brody proceeded to trial on the counts against them, and on Nov. 18, 2025, a jury returned a verdict finding He and Brody guilty of all counts. The court initially set the matter down for sentencing on Feb. 25, 2026, but as of the writing of this article, sentencing for both He and Brody is scheduled to occur on April 15, 2026.

It was against this backdrop—after an approximately six week trial against two individuals, including

the company founder; the conviction of both defendants on all counts against them; and more than 15 months of pretrial proceedings—that the government then elected to take matters further and indict the corporate entities as well.

On Dec. 16, 2025, just under a month after the trial against He and Brody had concluded, Acting Assistant Attorney General Matthew Galeotti announced that Done Global had been indicted for one count of conspiring to distribute controlled substances (the same charge that had been Count One in the case against the individuals), four substantive counts of distributing and aiding and abetting the distribution of controlled substances (involving the exact same four prescriptions as DOJ relied upon in the case against the individual defendants), one count of conspiracy to commit health care fraud (also the same as Count Six in the individuals' indictment), and one count of obstruction of justice (the same as Count Seven in the individuals' indictment).

In addition, the corporate entity Mindful Mental Wellness, which was alleged to have been essentially a re-branding of Done Health that became necessary when pharmacies were no longer willing to fill prescriptions Done Health had issued, likewise was indicted on the conspiracy charge in Count One.

By taking the highly unusual step of indicting a corporation after individual executives (including the founder and Chief Executive) had already been convicted at trial for the same conduct, the government's actions raise more questions than they answer.

On the one hand, news reporting in Bloomberg noted that "DOJ was in negotiations with the company to reach a settlement in the months leading up to [the] trial [of He and Brody], and they were re-engaged after the trial conviction but without success." The indictment of Done Global and Mindful Mental Wellness thus may have been the last straw for a DOJ that was in a strengthened negotiating posture due to the individual convictions, and was frustrated by its inability to enter into a deferred prosecution agreement, non-prosecution agreement, or other type of resolution with a seemingly non-cooperative company.

Alternatively, the corporate indictments may have reflected a heightened degree of government aggressiveness in the telehealth space, especially when a telemedicine business model was allegedly being used to facilitate the improper prescribing and potential abuse of controlled substances.

Or, perhaps due to other aggravating factors (whether openly alleged, such as the type of obstructive conduct referred to in the indictment, or known only to DOJ), the government's application of the Justice Manual's Principles of Federal Prosecutions of Business Organizations resulted in Done Global being one of the rare cases where a corporate indictment was necessary to "adequately satisfy the goals of federal prosecution."

Regardless, it had only been in May 2025 that Matthew Galeotti, in a memo entitled "Focus, Fairness, and Efficiency in the Fight Against White Collar Crime," stated that "the Department's first priority is to prosecute individual criminals," because "[i]t is individuals—whether executives, officers, or employees of companies—who commit these crimes."

Thus, by indicting Done Global and Mindful Mental Wellness even after the conclusion of successful individual prosecutions for the precise same conduct, DOJ may be suggesting that in particular circumstances—whether related to the nature of the industry in which the conduct occurred (here, telemedicine), the dangerousness of the products a corporation provides, or the unique circumstances presented by companies that decline to cooperate—unusually aggravating factors may cause DOJ to deviate from the norm.

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.*