
False Claims Act Year in Review

February 10, 2026

I. Overview of Fiscal Year 2025 Enforcement

Fiscal year (FY) 2025 was a groundbreaking year for the False Claims Act (FCA) in several respects. Recoveries under the statute reached an all-time high of nearly \$7 billion, more than double those in each of the prior three fiscal years and \$1.1 billion more than the previous record holder. The FCA was also deployed by the Trump Administration to advance key domestic objectives, pushing the statute into uncharted territories. And yet, despite the substantial recoveries and the statute's expanded use, robust enforcement of the FCA is at risk, as the U.S. Department of Justice (DOJ) appeals a 2024 district court order holding for the first time that the statute's qui tam provisions—the engine of the statute's enforcement—are unconstitutional. From any angle, FY 2025 was significant, with potentially enormous consequences for future FCA activity.

DOJ recently released its year-end report for FY 2025, which ran from October 1, 2024 to September 30, 2025.¹ The report disclosed the year's extraordinary total recovery of \$6.8 billion and provided a window into DOJ's enforcement priorities.² According to the report, those priorities continue to be traditional FCA enforcement areas, including health care, federal procurement, and pandemic relief. Indeed, recoveries related to the Department of Health and Human Services (HHS) and the Department of Defense (DOD)—the agencies most closely associated with health care and procurement, respectively—reached record highs.³ But DOJ recoveries from the past year also highlight new priorities of the Trump Administration, including its emphasis on tariffs and customs avoidance.⁴

¹ Press Release, DOJ, [False Claims Act Settlements and Judgments Exceed \\$6.8B in Fiscal Year 2025](#) (Jan. 16, 2026). DOJ's FY 2025 fact sheet, summarizing notable filings, settlements, and judgments, can be found [here](#). Tables summarizing historical FCA enforcement data can be found [here](#).

² *Id.*

³ [Fraud Statistics – Oct. 1, 1986 – Sept. 30, 2025](#), *supra* note 1.

⁴ WilmerHale Client Alert, [As Tariffs Increase, So Too May the Use of False Claims Actions to Pursue Customs Fraud](#) (Mar. 10, 2025).

Of course, the year's record recoveries are only part of the story. A Florida district court's 2024 decision holding, for the first time, that the qui tam provisions are unconstitutional has introduced the possibility of fundamental changes to FCA practice in the very near future. If the Eleventh Circuit affirms that decision, qui tam suits could disappear from the circuit, as district courts dismiss at least some existing qui tams and relators file new suits in other circuits. Affirmance would also set up a circuit split, inviting review by the Supreme Court, where three Justices have indicated they believe there are substantial arguments that the qui tam device is unconstitutional.

Finally, this past year saw unprecedented use of the FCA by the Trump Administration to advance its political priorities. The Administration has reportedly launched several FCA investigations targeting corporate diversity, equity, and inclusion (DEI) practices as part of its Civil Rights Fraud Initiative.⁵ We expect continued enforcement in this area in FY 2026.

Read on for our more detailed review of the FCA resolutions that contributed to the past year's record recovery, the ongoing litigation over the qui tam provisions, and the Trump Administration's use of the FCA to advance its political priorities.

A. Key Cases and Settlements

1. Health Care

In FY 2025, health care remained by far the largest area of FCA activity, accounting for more than \$5.7 billion of the year's recoveries.⁶ Health care's prominence in FCA enforcement is nothing new, but this year marked a significant increase in both the amount recovered and its share—more than 80%—of the year's total recoveries.

In its year-end report, DOJ highlighted enforcement activity in three areas: managed care, prescription drugs, and medically unnecessary or substandard care.

a. Managed Care

DOJ pursued significant enforcement activity in the managed care space, with an emphasis on the Medicare Advantage program:

- Independent Health agreed to pay up to \$98 million (based on its ability to pay) to resolve allegations that it submitted, or caused to be submitted, unsupported diagnosis codes for Medicare Advantage enrollees.⁷

⁵ WilmerHale Client Alert, [Recent Decisions Quashing DOJ Administrative Subpoenas Provide a Roadmap for Companies Facing DEI-Focused False Claims Act Investigations](#) (Jan. 12, 2026).

⁶ [Fraud Statistics – Oct. 1, 1986 – Sept. 30, 2025](#), *supra* note 1.

⁷ Press Release, DOJ, [Medicare Advantage Provider Independent Health to Pay Up To \\$98M to Settle False Claims Act Suit](#) (Dec. 20, 2024).

- Seoul Medical Group and related parties agreed to pay more than \$60 million to resolve allegations they caused the submission of false diagnosis codes for certain spinal conditions that led to increased payments under the Medicare Advantage program.⁸
- DOJ intervened in a qui tam action concerning alleged kickbacks and discriminatory practices related to Medicare Advantage enrollment by three large health insurance companies (Aetna, Elevance Health, and Humana) and three large insurance brokers.⁹
- DOJ filed an action against Inland Empire Health Plan for allegedly making false statements to Medi-Cal, California's Medicaid program, and misusing surplus Medi-Cal Expansion funding.¹⁰
- Despite setbacks, DOJ continues to litigate against major insurers, including UnitedHealthcare and Elevance Health (formerly, Anthem), for allegedly failing to delete unsupported diagnosis codes that led to inflated payments under the Medicare Advantage program.¹¹

b. Prescription Drugs

DOJ resolved numerous matters in FY 2025 relating to prescription drug pricing, invalid prescriptions, opioid-related misconduct, and kickbacks. Highlights from the report include:

- A \$948.8-million judgment (including \$542 million in civil monetary penalties and \$406.8 million in trebled damages) against Omnicare, the country's largest long-term care pharmacy. At trial, the jury found more than three million fraudulent claims by Omnicare for prescription drugs it dispensed without valid prescriptions to patients in assisted-living and other long-term care facilities.¹² Omnicare's parent company, CVS, was also found to have caused Omnicare to submit false claims and was therefore held jointly and severally liable for \$164 million of Omnicare's penalties.
- Teva Pharmaceuticals' \$425-million settlement to resolve allegations that, in violation of the Anti-Kickback Statute, it paid Medicare patient copays.¹³
- Multiple resolutions related to opioid prescriptions, including a settlement of up to \$350 million with Walgreens for allegedly submitting false claims for illegally filled opioid

⁸ Press Release, DOJ, [Medicare Advantage Provider Seoul Medical Group and Related Parties to Pay Over \\$62M to Settle False Claims Act Suit](#) (Mar. 26, 2025); WilmerHale Client Alert, [DOJ Settles False Claims Act Suit Against Medicare Advantage Provider](#) (Mar. 31, 2025).

⁹ Press Release, DOJ, [The United States Files False Claims Act Complaint Against Three National Health Insurance Companies and Three Brokers Alleging Unlawful Kickbacks and Discrimination Against Disabled Americans](#) (May 1, 2025).

¹⁰ Press Release, DOJ, [United States Files Suit Against California-Based Health Plan for Alleged False Claims to California's Medicaid Program](#) (Sept. 17, 2025).

¹¹ Fact Sheet – False Claims Act – Settlements and Judgments FY2025, *supra* note 1.

¹² Press Release, DOJ, [Statement Of U.S. Attorney Jay Clayton on the Verdict in U.S. v. Omnicare and CVS Health Corporation](#) (Apr. 29, 2025); *United States ex rel. Bassan v. Omnicare, Inc.*, No. 1:15-cv-4179, 2025 WL 1865202, at *1 (S.D.N.Y. July 7, 2025).

¹³ Press Release, DOJ, [Drug Maker Teva Pharmaceuticals Agrees to Pay \\$450M in False Claims Act Settlement to Resolve Kickback Allegations Relating to Copayments and Price Fixing](#) (Oct. 10, 2024); Fact Sheet – False Claims Act – Settlements and Judgments FY2025, *supra* note 1.

prescriptions, and a first-of-its-kind \$323-million settlement in December 2024 with the consultant McKinsey & Co. for allegedly providing advice that caused its client, Purdue Pharma, to submit false claims for OxyContin.¹⁴

- An agreement with Gilead Sciences resolving a civil investigation concerning the company's speaker programs.¹⁵

c. Medically Unnecessary Care

- Pursuing matters involving medically unnecessary services and poor quality of care was also a priority. Highlights from the year include:
 - A \$45-million settlement of a DOJ-initiated suit against Vohra Wound Physicians and its owner alleging medically unnecessary and overbilled wound-care procedures.¹⁶
 - A \$10.25-million settlement with Oroville Hospital to resolve allegations of medically unnecessary inpatient admissions.¹⁷
 - An ongoing, intervened suit against ProMedica and HCR ManorCare alleging substandard and improperly documented nursing home care.¹⁸

2. Procurement, Loans, and Grants

As in prior years, DOJ aggressively pursued misconduct involving federal procurement and financial assistance programs.

a. Military Procurement

A total of \$600 million of FY 2025 recoveries—almost 10% of the total recovery—involved DOD.¹⁹ That amount set a new record and represented a six-fold increase over the prior fiscal year.²⁰ DOJ reported several large resolutions, including:

- Raytheon's agreement in October 2024 to pay \$428 million—the second-largest government-procurement fraud settlement in FCA history—to resolve allegations that it both double-billed the government for a weapons maintenance contract and failed in

¹⁴ [Fact Sheet – False Claims Act – Settlements and Judgments FY2025](#), *supra* note 1. The McKinsey settlement also resolved allegations related to failure to disclose to the U.S. Department of Agriculture conflicts of interest arising from McKinsey's work for Purdue Pharma.

¹⁵ Press Release, DOJ, [U.S. Attorney Announces \\$202 Million Settlement with Gilead Sciences for Using Speaker Programs to Pay Kickbacks to Doctors to Induce Them to Prescribe Gilead's Drugs](#) (Apr. 29, 2025).

¹⁶ Press Release, DOJ, [United States Files False Claims Act Complaint Against Vohra Wound Physicians Management and Its Owner Alleging False Claims for Wound Care Services](#) (Apr. 4, 2025).

¹⁷ Press Release, DOJ, [California Hospital to Pay \\$10.25M to Resolve False Claims Allegations](#) (Dec. 12, 2024). The settlement also resolved allegations of a kickback and physician self-referral scheme and the use of erroneous diagnosis codes.

¹⁸ Press Release, DOJ, [United States Intervenes and Sues ProMedica Health System, Inc. and Its Affiliates for Providing Grossly Substandard Nursing Home Services](#) (Sept. 2, 2025).

¹⁹ [Fraud Statistics – Oct. 1, 1986 – Sept. 30, 2025](#), *supra* note 1.

²⁰ *Id.*

multiple contracts to submit accurate cost and pricing information that was required by the Truth in Negotiations Act.²¹ The record payment was part of a global resolution at the end of the prior Administration of parallel civil and criminal proceedings that also included a deferred prosecution agreement and a three-year independent monitorship.²²

- Settlements by L3 Technologies (\$62 million) and Lockheed Martin (\$29.74 million) resolving similar defective-pricing allegations concerning manufacturing of drone equipment and F-35 fighter jets.²³

b. Cybersecurity

DOJ continued to investigate cybersecurity-related allegations under its Civil Cyber-Fraud Initiative.²⁴ In FY 2025:

- Health Net Federal Services (HNFS), an administrator of servicemember health benefits, and its corporate parent agreed to pay \$11.2 million to resolve allegations that HNFS falsely certified compliance with cybersecurity requirements in its government contracts.²⁵
- Illumina paid \$9.8 million to resolve allegations that it sold genomic sequencing systems with cybersecurity vulnerabilities to federal agencies.²⁶
- Pennsylvania State University and Georgia Tech Research Corporation agreed to pay \$1.25 million and \$875,000, respectively, to resolve allegations that each failed to implement required cybersecurity controls for research conducted under government contracts.²⁷

c. Pandemic Relief Programs

Enforcement related to pandemic relief programs, such as the Paycheck Protection Program, remained a priority. In FY 2025, there were more than 200 resolutions exceeding \$230 million in aggregate in this area.²⁸ Notable resolutions included:

²¹ Press Release, DOJ, [Raytheon Company to Pay Over \\$950M in Connection with Defective Pricing, Foreign Bribery, and Export Control Schemes](#) (Oct. 16, 2024).

²² *Id.*

²³ [Fact Sheet – False Claims Act – Settlements and Judgments FY2025](#), *supra* note 1.

²⁴ See Press Release, DOJ, [Deputy Attorney General Lisa O. Monaco Announces New Civil Cyber-Fraud Initiative](#) (Oct. 6, 2021).

²⁵ Press Release, DOJ, [Health Net Federal Services, LLC and Centene Corporation Agree to Pay Over \\$11 Million to Resolve False Claims Act Liability for Cybersecurity Violations](#) (Feb. 18, 2025).

²⁶ Press Release, DOJ, [Illumina Inc. to Pay \\$9.8M to Resolve False Claims Act Allegations Arising from Cybersecurity Vulnerabilities in Genomic Sequencing Systems](#) (July 31, 2025).

²⁷ [Fact Sheet – False Claims Act – Settlements and Judgments FY2025](#), *supra* note 1. WilmerHale represented Georgia Tech Research Corporation in the above-referenced matter.

²⁸ *Id.*

- A \$20-million consent judgment to resolve alleged misrepresentations by a Florida businessman, Patrick Walsh, and affiliated companies in connection with Paycheck Protection Program and Economic Injury Disaster Loan applications.²⁹
- An \$8.1-million settlement with Delta Air Lines to resolve allegations that it failed to abide by compensation caps for highly paid executives in violation of the Payroll Support Program created by the Coronavirus Aid, Relief, and Economic Security (CARES) Act to provide financial support to airlines and other businesses.³⁰
- Multiple settlements totaling more than \$19 million in matters related to COVID-19 testing.³¹

3. Tariff and Customs Avoidance

The most notable expansion of FCA activity in FY 2025 involved tariff and customs avoidance, a Trump Administration priority.³² DOJ efforts included the creation of a new cross-agency Trade Fraud Task Force to increase trade-related FCA coordination³³ as well as the following enforcement activities:

- The largest-ever customs-related resolution under the FCA—a \$54.4-million settlement with Ceratizit USA LLC to resolve allegations that it evaded duties on goods imported from China by misrepresenting the country of origin and misclassifying the goods under the Harmonized Tariff Schedule.³⁴
- Multiple smaller settlements for alleged duty evasion on Chinese-imported goods. Importers allegedly misrepresented the country of origin, avoided antidumping and countervailing duties, and incorrectly identified the value of imported goods.³⁵
- A recent lawsuit filed by DOJ against Barco Uniforms, Inc., its owners, and other companies controlled by them, alleging a conspiracy to avoid customs duties by undervaluing and falsifying information regarding imported garments.³⁶

²⁹ Press Release, DOJ, [Florida Businessman Patrick Walsh and Affiliated Companies Agree to \\$20M Consent Judgment to Settle False Claims Act Liability Relating to Fraudulent Pandemic Relief Loans](#) (Mar. 12, 2025).

³⁰ Press Release, DOJ, [Delta Air Lines Agrees to Pay \\$8.1M to Settle Alleged False Claims Act Violations Related to Payroll Support Program](#) (July 15, 2025).

³¹ Fact Sheet – False Claims Act – Settlements and Judgments FY2025, *supra* note 1.

³² See [As Tariffs Increase, So Too May the Use of False Claims Actions to Pursue Customs Fraud](#), *supra* note 4.

³³ Press Release, DOJ, [Departments of Justice and Homeland Security Partnering on Cross-Agency Trade Fraud Task Force](#) (Aug. 29, 2025); WilmerHale Client Alert, [Tariffs Take Hold Raising the Specter of Criminal and Civil Tariff Enforcement](#) (Aug. 15, 2025).

³⁴ Press Release, DOJ, [Ceratizit USA LLC Agrees to Pay \\$54.4M to Settle False Claims Act Allegations Relating to Evaded Customs Duties](#) (Dec. 18, 2025).

³⁵ Fact Sheet – False Claims Act – Settlements and Judgments FY2025, *supra* note 1.

³⁶ Press Release, DOJ, [United States Files Complaint Against Barco Uniforms and Its Suppliers, Alleging False Claims Act Violations in Connection with Underpaid Customs Duties](#) (Apr. 18, 2025).

B. Forecasting FCA Enforcement in FY 2026

We expect FY 2026 to remain busy for FCA enforcement—and DOJ officials have confirmed as much in recent public comments. At a recent FCA conference, David Metcalf, the United States Attorney for the Eastern District of Pennsylvania, a district with an active FCA docket, described the FCA as an area in which the Trump Administration is expanding enforcement.³⁷ That stands in stark contrast, for example, with the Administration's reduced enforcement under the Foreign Corrupt Practices Act.³⁸

DOJ has also begun to identify its priorities for FY 2026. According to Brenna Jenny, the Deputy Assistant Attorney General for the Commercial Litigation Branch of the Civil Division, DOJ will continue to pursue health care fraud, prioritizing managed care programs like Medicare Advantage.³⁹ Jenny also said that DOJ is pursuing more cases leveraging data analytics, warning companies that "your next whistleblower could be your data."⁴⁰

In addition, we expect expanded FCA enforcement related to key policy priorities of the Trump Administration. As Jenny confirmed, FCA enforcement will continue to target tariff and customs evasion.⁴¹ It will also target, in her words, "discriminatory employment practices."⁴² Indeed, as discussed in detail below, DOJ has indicated that there are currently pending matters related to DEI initiatives.⁴³

II. Constitutionality of the Qui Tam Provisions

The past year also included significant litigation over whether the FCA's qui tam provisions violate Article II of the U.S. Constitution. Initially prompted by a DOJ memo during the George H.W. Bush Administration, the question was revived by multiple Supreme Court Justices' comments in recent cases involving other FCA issues. One district court has already ruled in defendants' favor and dismissed a non-intervened qui tam action on this basis. Other decisions following suit, particularly by circuit courts and eventually the Supreme Court, could fundamentally reshape the future of FCA enforcement.

³⁷ Remarks by David Metcalf, United States Attorney for the Eastern District of Pennsylvania, American Conference Institute, 13th Annual Advanced Forum on False Claims and Qui Tam Enforcement (Jan. 29, 2026); *see also* Memorandum, Assistant Attorney General Brett A. Shumate, [Civil Division Enforcement Priorities](#) (June 11, 2025); WilmerHale Client Alert, [DOJ Civil Division Issues Enforcement Priorities Memorandum](#) (June 13, 2025).

³⁸ WilmerHale, [FCPA Year-in-Review: 2025 Developments and Predictions for 2026](#) (Jan. 28, 2026).

³⁹ Remarks by Brenna Jenny, Deputy Assistant Attorney General for the Commercial Litigation Branch of the Civil Division, American Conference Institute, 13th Annual Advanced Forum on False Claims and Qui Tam Enforcement (Jan. 28, 2026).

⁴⁰ *Id.*

⁴¹ *Id.*

⁴² *Id.*

⁴³ Metcalf, *supra* note 37.

A. The FCA's Qui Tam Provisions

Qui tam suits are a critical and distinct feature of FCA enforcement. These suits are brought by private citizens (qui tam relators) on behalf of the federal government. Under the FCA, DOJ must determine whether it will elect to intervene and take over the litigation. If DOJ declines to intervene, relators may then pursue the cases on their own and receive a greater share of any resulting recovery—up to 30%—with the balance awarded to the federal government.⁴⁴

By incentivizing private citizens to pursue FCA claims, the qui tam provisions have substantially increased the number of FCA suits filed since the statute was amended in 1986.⁴⁵ Relators bring the overwhelming majority of FCA actions, and relator-initiated suits are responsible for most of the recoveries.⁴⁶ In FY 2025, relators filed a record 1,297 qui tam lawsuits, more than three times the number of government-initiated cases, and relator-initiated suits led to \$5.3 billion in judgments and settlements, more than 75% of the \$6.8 billion in total recoveries for the year.⁴⁷ Non-intervened qui tam cases in particular accounted for \$2.3 billion in recoveries.⁴⁸

B. The Constitutionality of the Qui Tam Provisions

The constitutionality of the qui tam provisions was extensively litigated in the 1990s and 2000s,⁴⁹ after DOJ's Office of Legal Counsel concluded, in a widely publicized memorandum, that the provisions unconstitutionally infringed on the Executive's power.⁵⁰ The circuit courts that addressed these early legal challenges, however, uniformly upheld the qui tam provisions, and litigation over the issue all but ceased.

Recent statements by various Supreme Court Justices, however, have reinvigorated the legal challenges to the qui tam provisions. Indeed, just last Term, Justices Thomas and Kavanaugh reiterated their view that the FCA's "qui tam provisions raise substantial constitutional questions under Article II" that the Court should take up "in an appropriate case."⁵¹

⁴⁴ 31 U.S.C. § 3730(b)(4), (d)(2).

⁴⁵ See [False Claims Act Settlements and Judgments Exceed \\$6.8B in Fiscal Year 2025](#), *supra* note 1.

⁴⁶ [Fraud Statistics – Oct. 1, 1986 – Sept. 30, 2025](#), *supra* note 1.

⁴⁷ [False Claims Act Settlements and Judgments Exceed \\$6.8B in Fiscal Year 2025](#), *supra* note 1.

⁴⁸ [Fraud Statistics – Oct. 1, 1986 – Sept. 30, 2025](#), *supra* note 1.

⁴⁹ See, e.g., *United States ex rel. Kelly v. Boeing Co.*, 9 F.3d 743, 749–59 (9th Cir. 1993); *United States ex rel. Taxpayers Against Fraud v. Gen. Elec. Co.*, 41 F.3d 1032, 1040–42 (6th Cir. 1994); *Riley v. St. Luke's Episcopal Hosp.*, 252 F.3d 749 (5th Cir. 2001); *United States ex rel. Stone v. Rockwell Int'l Corp.*, 282 F.3d 787, 804–07 (10th Cir. 2002); see also *United States ex rel. Kreindler & Kreindler v. United Techs. Corp.*, 985 F.2d 1148, 1155 (2d Cir. 1993) (in rejecting Article III challenge, explaining that the qui tam "provisions do not usurp the executive branch's litigating function").

⁵⁰ Memorandum, Assistant Attorney General William P. Barr, [Constitutionality of the Qui Tam Provisions of the False Claims Act](#), 13 Op. O.L.C. 207 (July 18, 1989).

⁵¹ *Wis. Bell, Inc. v. United States ex rel. Heath*, 604 U.S. 140, 167 (2025) (Kavanaugh, J., joined by Thomas, J., concurring); see also *United States ex rel. Polansky v. Exec. Health Res., Inc.*, 599 U.S. 419, 449 (2023) (Thomas, J., dissenting); *id.* at 442 (Kavanaugh, J., joined by Barrett, J., concurring).

These challenges are now winding their way through the lower courts. One 2024 decision from a district court in the Eleventh Circuit, *United States ex rel. Zafirov v. Florida Medical Associates, LLC*, has already held that the qui tam provisions are unconstitutional.⁵² In *Zafirov*, the defendants raised three constitutional challenges to the qui tam provisions, arguing that the provisions violate (1) the Appointments Clause because relators exercise “significant authority” and occupy a “continuing position” but lack presidential appointment; (2) the Take Care Clause because relators’ power to bring FCA actions improperly outsources the President’s obligation to take care that the laws are faithfully executed; and (3) the Vesting Clause because the Constitution vests all executive power in the President and relators improperly exercise some of that power.⁵³ The district court held the qui tam provisions unconstitutional under the Appointments Clause without reaching the defendants’ arguments under the Take Care and Vesting Clauses.⁵⁴ In so holding, the district court did not address the important question of whether *all* qui tam suits are unconstitutional or only those in which DOJ chooses not to intervene.

The relator and the United States appealed the district court’s order, and the Eleventh Circuit held oral argument in December 2025.⁵⁵ Notably, although DOJ has reversed course from the prior Administration on many issues—including by taking a more expansive view of Article II in certain contexts⁵⁶—DOJ defended the qui tam provisions against the Article II challenges here. It is difficult to assess how the panel will decide the case based on oral argument, but at a minimum the judges are taking the challenges seriously. In particular, the panel expressed skepticism of the relator’s and DOJ’s position that relators do not exercise “significant authority” for Appointments Clause purposes. The panel seemed more open, however, to their fallback position that even if relators exercise significant executive power, they do not occupy a “continuing position” that would require presidential appointment. The panel also appeared interested in the defendants’ other challenges under the Vesting and Take Care Clauses, which the district court did not decide and which the panel suggested might be more appropriate grounds for resolving the constitutionality of the qui tam provisions. Nonetheless, the panel questioned whether it should decide those issues on its own or remand the case for a ruling by the district court first. We expect a decision in the coming months.

The Eleventh Circuit is the first court of appeals in this latest round of challenges to consider these arguments. In March, the Third Circuit will hear an appeal of a district court order upholding the constitutionality of the qui tam provisions.⁵⁷ Other circuits will likely follow as

⁵² 751 F.Supp.3d 1293, 1304 (M.D. Fla. 2024).

⁵³ *Id.*

⁵⁴ *Id.*

⁵⁵ See *United States ex rel. Zafirov v. Fla. Med. Assocs.*, No. 24-13581 (11th Cir.).

⁵⁶ For example, in February 2025, DOJ sent a [letter](#) notifying Congress pursuant to 28 U.S.C. § 530D that DOJ had determined that certain statutory restrictions on the President’s ability to remove administrative law judges violate Article II and that DOJ will no longer defend those restrictions in pending litigation.

⁵⁷ See *United States ex rel. Penelow et al. v. Janssen Prods., LP*, No. 25-1818 (3d Cir.).

defendants increasingly challenge the constitutionality of the FCA's qui tam provisions in response to relator-initiated litigation.

C. Potential Implications of the Challenges to the Qui Tam Provisions

The current challenges to the qui tam provisions could have a significant impact on FCA enforcement—and that impact may be felt in short order. A decision in *Zafirov* holding that the provisions are unconstitutional would upend FCA practice in the Eleventh Circuit. At a minimum, all pending non-intervened cases in the circuit would likely be dismissed (or at least stayed pending Supreme Court review). A broad ruling could potentially lead to the dismissal of *all* relator-initiated suits in the circuit. The number of future FCA cases filed in the circuit would also plummet, because relators would affirmatively look to bring new cases in circuits with established precedent upholding the constitutionality of the qui tam provisions, or decline to sue altogether. Indeed, given the unstable ground in the Eleventh Circuit, we would expect that relators' counsel are already choosing—where possible—to sue in circuits with more favorable law.

An Eleventh Circuit decision striking down the qui tam provisions in *Zafirov* could also prompt Supreme Court review in light of the significance of such a ruling and contrary decisions rejecting earlier legal challenges in other circuits. It is difficult to predict how the Supreme Court would decide the new legal challenges if and when they reach the Court. Three Justices have underscored "substantial arguments that the qui tam device is inconsistent with Article II."⁵⁸ And recent decisions by the Court have reinvigorated Article II arguments in a number of contexts.⁵⁹ But the Justices may be wary of foreclosing FCA qui tam suits, which have a long history dating back to the Civil War and which the government and relators argue render substantial assistance in deterring and penalizing fraud on the United States. A ruling barring qui tam suits would also put the Court at odds with the Trump Administration, which is using the FCA to further its policy priorities in part by expressly soliciting whistleblowers.⁶⁰

Given at least three Justices' recent interest, defendants will no doubt continue to press this defense to relator-initiated litigation. And although DOJ continues to defend the constitutionality of the qui tam provisions, we also expect it to exercise its broad statutory authority to dismiss qui tam actions with much greater frequency under this Administration. Indeed, as compared to the preceding four years of the Biden Administration—which saw an

⁵⁸ See *Polansky*, 599 U.S. at 449 (Thomas, J., dissenting); *id.* at 442 (Kavanaugh, J., joined by Barrett, J., concurring).

⁵⁹ See generally, e.g., *Collins v. Yellen*, 594 U.S. 220 (2021) (holding that the Federal Housing Finance Agency's for-cause removal restrictions violate Article II); *Seila Law LLC v. CFPB*, 591 U.S. 197 (2020) (similar, regarding the CFPB); *Trump v. United States*, 603 U.S. 593 (2024) (holding that expansive presidential immunity follows from Article II).

⁶⁰ See, e.g., Shumate, *Civil Division Enforcement Priorities*, *supra* note 37, at 1.

average of 6 dismissals per year—DOJ dismissed 25 qui tam cases in the first year of the Trump Administration alone.⁶¹

III. Targeting Diversity Initiatives and Gender-Affirming Care

The Trump Administration has signaled that it will use the FCA to advance its policy objectives, including tariff and customs enforcement—areas of historical DOJ enforcement—and the new and more politically charged priorities of eliminating diversity initiatives and restricting gender-affirming care.⁶² The Administration has launched several FCA investigations targeting corporate DEI practices and indicated that it intends to use the FCA to investigate the provision of gender-affirming care.⁶³ It has also openly encouraged whistleblowers to report incriminating information and file qui tam suits.⁶⁴ This unprecedented use of the FCA has increased the risk of enforcement activity and led many institutions to adopt policy changes to reduce their risk profile. At the same time, the novel uses of the FCA give rise to potential defenses for entities under investigation. In addition to arguments about falsity and scienter, defendants might also have strong arguments relating to materiality, particularly in light of statements by Supreme Court Justices questioning FCA enforcement against collateral policy priorities that do not “go to the essence” of the federal contract or funding award.⁶⁵

A. DEI

The Trump Administration has made clear through multiple executive actions that eliminating DEI practices is a key priority—and that the FCA is an important tool in meeting that objective.⁶⁶ On January 21, 2025, President Trump issued an executive order directing executive agencies “to combat illegal private-sector DEI preferences, mandates, policies, programs, and activities” that “violate the text and spirit of our longstanding Federal civil-rights laws.”⁶⁷ The order instructed agencies to ensure that government contracts and grants require recipients to certify that they do not operate illegal DEI programs and to agree that their

⁶¹ Jenny, *supra* note 39.

⁶² *Id.*

⁶³ [Recent Decisions Quashing DOJ Administrative Subpoenas Provide a Roadmap for Companies Facing DEI-Focused False Claims Act Investigations](#), *supra* note 5.

⁶⁴ Press Release, DOJ, [Justice Department Establishes Civil Rights Fraud Initiative](#) (May 19, 2025); *see also* WilmerHale Client Alert, [DOJ Announces Civil Rights Fraud Initiative: Department Will Seek To Use The False Claims Act To Enforce Civil Rights Laws Against Universities And Government Contractors](#) (May 20, 2025).

⁶⁵ *See Kousisis v. United States*, 605 U.S. 114, 145 (Thomas, J., concurring); *see also* WilmerHale Client Alert, [Supreme Court Rejects Economic-Loss Requirement for Wire Fraud but Underscores Materiality as a Limiting Element of Federal Fraud Statutes](#) (May 30, 2025).

⁶⁶ The Trump Administration issued several DEI-related orders. *See, e.g.*, WilmerHale Client Alert, [President Trump’s Second Term: Anti-DEI Executive Orders](#) (Jan. 22, 2025).

⁶⁷ Exec. Order 14173, [Ending Illegal Discrimination and Restoring Merit-Based Opportunity](#) (Jan. 21, 2025).

compliance with federal anti-discrimination laws “is material to the government’s payment decisions” under the FCA.⁶⁸

DOJ quickly followed the White House’s lead. On February 5, 2025, Attorney General Pamela Bondi ordered each DOJ component to confirm the termination of all DEI programs and recommend “actions to align Department programs, … enforcement activities, … and litigating positions with requirement of equal dignity and respect.”⁶⁹ The Attorney General at the same time directed DOJ’s Civil Rights Division to “investigate, eliminate, and penalize illegal [DEI practices] in the private sector and in educational institutions that receive federal funds.”⁷⁰ The Attorney General also raised the possibility of DEI-related criminal investigations.⁷¹

Three months later, DOJ announced a Civil Rights Fraud Initiative to “pursue claims against any recipient of federal funds that knowingly violates federal civil rights laws.”⁷² As part of this initiative, DOJ’s Civil Fraud Section and Civil Rights Division, along with other federal agencies, “will work in concert.”⁷³ DOJ’s press release strongly encouraged “anyone with knowledge of discrimination by federal funding recipients to consider filing a qui tam action.”⁷⁴

Following this announcement, DOJ’s Civil Division directed its attorneys to prioritize DEI-related enforcement and “aggressively investigate and, as appropriate, pursue” potential FCA claims related to purported civil rights violations.⁷⁵ On July 29, 2025, DOJ issued a memorandum titled “Guidance for Recipients of Federal Funding Regarding Unlawful Discrimination,” setting forth DOJ’s views regarding potentially discriminatory practices, including those labeled as DEI programs.⁷⁶ The memorandum stated that “[u]sing race, sex, or other protected characteristics for employment, program participation, resource allocation, or other similar activities, opportunities, or benefits, is unlawful,” and provided “a non-exhaustive list of unlawful practices.”⁷⁷

DOJ has reportedly launched several FCA investigations related to corporate DEI practices.⁷⁸ Companies across different industries have reportedly received civil investigative demands (CIDs) requesting documents and information regarding workplace programs.⁷⁹ It remains unclear how many investigations are open and how many will be initiated over the next year.

⁶⁸ *Id.*

⁶⁹ Memorandum, Attorney General, [Eliminating Internal Discriminatory Practices](#), at 2 (Feb. 5, 2025).

⁷⁰ Memorandum, Attorney General, [Ending Illegal DEI and DEI Discrimination and Preferences](#), at 1 (Feb. 5, 2025).

⁷¹ *Id.* at 2.

⁷² [Justice Department Establishes Civil Rights Fraud Initiative](#), *supra* note 64.

⁷³ *Id.*

⁷⁴ *Id.*

⁷⁵ Shumate, [Civil Division Enforcement Priorities](#), *supra* note 37, at 1.

⁷⁶ Memorandum, Attorney General, [Guidance for Recipients of Federal Funding Regarding Unlawful Discrimination](#) (July 29, 2025).

⁷⁷ *Id.* at 1, 4.

⁷⁸ Lydia Wheeler, [Justice Department Using Fraud Law to Target Companies on DEI](#), Wall St. J. (Dec. 28, 2025).

⁷⁹ *Id.*

The companies targeted in these investigations have not, so far, challenged the basis for DOJ's investigations in court by filing petitions to set aside or modify the underlying CIDs. But as discussed in the next section, recent court decisions quashing administrative subpoenas targeting gender-affirming care may support future challenges to DEI-related CIDs.⁸⁰

In addition, on January 8, 2026, Vice President JD Vance announced the creation of a new DOJ division dedicated to national fraud enforcement, to be led by a newly appointed Assistant Attorney General.⁸¹ This division will oversee multidistrict and multi-agency fraud investigations and work closely with federal entities to identify and dismantle complex fraud schemes.⁸² The FCA is likely to serve as the central legal basis for civil investigations and enforcement under this initiative.⁸³

B. Gender-Affirming Care

The Trump Administration has also declared its intent to use the FCA to target gender-affirming care. In January 2025, President Trump directed federal agencies to limit gender-affirming care for those under 19 years of age.⁸⁴ In response, Attorney General Bondi instructed the Civil Division's Fraud Section to investigate potential FCA violations in connection with claims submitted to federal health care programs "for any non-covered services related to radical gender experimentations."⁸⁵ DOJ emphasized that "[f]alsely billing the government for the chemical or surgical mutilation of a child is a violation" of the FCA and encouraged whistleblowers to report such cases.⁸⁶ The Civil Division later confirmed that it is prioritizing these investigations.⁸⁷

In July 2025, DOJ announced that it sent more than 20 subpoenas to doctors and clinics involved in providing gender-affirming care, indicating that DOJ was investigating potential "healthcare fraud" and "false statements."⁸⁸ The subpoenas requested sensitive and confidential records, including patient and provider records, personnel files, billing data, and third-party communications.⁸⁹ DOJ subsequently appeared to indicate that the administrative

⁸⁰ [Recent Decisions Quashing DOJ Administrative Subpoenas Provide a Roadmap for Companies Facing DEI-Focused False Claims Act Investigations](#), *supra* note 5.

⁸¹ [WilmerHale Client Alert, JD Vance Announces New White House/DOJ Fraud Enforcement Initiative](#) (Jan. 9, 2026); *see also* [The White House, Fact Sheet: President Donald J. Trump Establishes New Department of Justice Division for National Fraud Enforcement](#) (Jan. 8, 2026).

⁸² [JD Vance Announces New White House/DOJ Fraud Enforcement Initiative](#), *supra* note 81.

⁸³ *Id.*

⁸⁴ Exec. Order 14187, [Protecting Children from Chemical and Surgical Mutilation](#) (Jan. 28, 2025).

⁸⁵ Memorandum, Attorney General, [Preventing the Mutilation of American Children](#), at 4 (Apr. 22, 2025).

⁸⁶ *Id.* at 4.

⁸⁷ Shumate, [Civil Division Enforcement Priorities](#), *supra* note 37, at 1.

⁸⁸ Press Release, DOJ, [Department of Justice Subpoenas Doctors and Clinics Involved in Performing Transgender Medical Procedures on Children](#) (July 9, 2025).

⁸⁹ Chris Geidner, [Multiple Judges Call Out DOJ's Methods of Defending Its Invasive Trans Care Subpoenas](#), Law Dork (Nov. 23, 2025); *see also* Chris Geidner, [Judge Orders DOJ to Give More Info on Subpoenas Targeting Trans Minors Medical Care](#), Law Dork (Aug. 21, 2025).

subpoenas sought information related only to investigations under the Food, Drug, and Cosmetic Act, not to FCA investigations (which are typically conducted by issuing CIDs).⁹⁰

Given the sweeping nature of these requests, several hospitals and patient groups have moved to set aside or modify the subpoenas, arguing that the subpoenas were issued for an improper purpose—to deter access to lawful medical care that the Trump Administration opposes.⁹¹ Hospitals and patient groups have also argued that the highly sensitive patient and provider information sought is irrelevant to any authorized federal purpose, and that the requests are overbroad, vague, and unduly burdensome.⁹² To date, these arguments have been successful as courts have granted motions to quash or narrow the DOJ subpoenas and have sharply criticized DOJ's unsupported legal theories.⁹³ These decisions might provide a roadmap for parties seeking to set aside FCA CIDs in appropriate cases.

Just a few months into FY 2026, it remains to be seen how much the rhetoric from the White House and DOJ will transform the FCA landscape in the year to come. But the Trump Administration's clear intent to expand enforcement to target DEI and gender-affirming care carries the potential to politicize the FCA in unprecedented ways.

⁹⁰ See, e.g., Decl. of Lisa Hsiao ¶ 5, *In re Administrative Subpoena No. 25-1431-019*, No. 1:25-mc-91324 (D. Mass. Nov. 7, 2025), ECF No. 37 (indicating that Civil Division's authority to issue administrative subpoenas under HIPAA is limited to investigations under the Food, Drug, and Cosmetic Act).

⁹¹ [Recent Decisions Quashing DOJ Administrative Subpoenas Provide a Roadmap for Companies Facing DEI- Focused False Claims Act Investigations](#) (Jan. 12, 2026).

⁹² *Id.*

⁹³ *Id.*

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