

Record FCA Recoveries Signal Intensified Healthcare Focus

By **George Breen**, **Daniel Fundakowski** and **Elizabeth Harris** (February 20, 2026, 6:22 PM EST)

The **release** of the annual U.S. Department of Justice False Claims Act statistics on Jan. 16 — the first such statistics of the second Trump administration — underscores the government's commitment to FCA enforcement in 2026 and beyond.

Fiscal year 2025 yielded record-breaking enforcement results, with settlements and judgments totaling \$6.8 billion for the year ending Sept. 30, 2025, the highest recovery in a single year in the statute's history. This represents more than a two-fold increase from fiscal year 2024's \$3.1 billion in recoveries.[1]

According to the DOJ's release, the FCA "remains one of the government's most powerful weapons against fraud" in the second Trump era.[2] The fiscal year 2025 statistics do reflect matters commenced in the previous administration, and some of the recoveries involve large trial verdicts subject to appeal, including a \$948.8 million **judgment** against Omnicare Inc. and a \$1.6 billion trial **Johnson & Johnson** **target="_blank">verdict** against Johnson & Johnson.

While those circumstances may inflate the final figures, the trajectory suggests that heightened enforcement is likely. Healthcare matters generated more than \$5.7 billion of the total \$6.8 billion recovered in fiscal year 2025, a striking 83% of total recoveries — a substantial increase from 60% in the previous year.

The government's emphasis on record healthcare recoveries and government-initiated healthcare matters indicates that healthcare entities can expect robust enforcement in both 2026 and the years ahead. Yet the administration also continues to focus on current policy objectives, extending the FCA outside the healthcare sector.

Meanwhile, courts continue to grapple with the long-running circuit split on the issue of but-for causation, judgments exceeding eight figures and questions of whether qui tam relators should be bringing FCA cases at all. We analyze key enforcement metrics and emerging issues in detail below.

Healthcare Dominates: \$5.7 Billion in Record Recoveries

Managed Care

The DOJ continued in fiscal year 2025 to aggressively pursue cases alleging false claims in managed care, particularly under the Medicare Advantage program.[3]

The agency continues to litigate matters against major health insurers — alleging, for example, that improper diagnoses were used to inflate reimbursement or that conduct violated the Anti-Kickback Statute. Some of the settlements against MA plans also alleged violations of the FCA through invalid diagnosis codes, resulting in more than \$160 million in recoveries combined.



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More recently, the DOJ secured the largest Medicare Advantage risk adjustment settlement to date. On Jan. 14, Kaiser Permanente affiliates **agreed** to pay \$556 million to resolve allegations that they violated the FCA by submitting invalid diagnosis codes for enrollees.[4]

The settlement, which arose from six whistleblower lawsuits, far exceeds prior MA risk adjustment settlements and signals the DOJ's continued prioritization of enforcement in this space.

Prescription Drugs

Multiple settlements and judgments reported by the DOJ in fiscal year 2025 concerned alleged misconduct by drug manufacturers, pharmacies, and entities involved in drug pricing and dispensing.

Recoveries included matters involving alleged kickbacks and other misconduct relating to opioids. In one settlement, a pharmaceutical consultant entity, McKinsey & Co., agreed to pay \$323 million to resolve allegations that its advice to Purdue Pharma LP caused the submission of false and fraudulent claims to federal healthcare programs.

Medically Unnecessary Services

FCA recoveries in fiscal year 2025 also included substantial claims and settlements totaling millions of dollars against healthcare providers allegedly billing federal healthcare programs for medically unnecessary services and substandard care.

Qui Tam Litigation Surges Despite Constitutional Challenges

Whistleblowers filed more qui tam lawsuits in fiscal year 2025 than in any other year — 1,297 out of the 1,698 new FCA matters overall — shattering last year's record of 980 qui tam suits. Indeed, whistleblower-led litigation is surging, as is FCA enforcement in the healthcare and life sciences industry.

Of the \$5.7 billion in total recoveries in the healthcare sector, \$4.5 billion was recovered from qui tam matters — both declined and intervened cases — representing 79% of the total recoveries and the highest in reported history.

A critical trend for corporate counsel to note is the unprecedented success of relators, i.e., whistleblowers, proceeding without government intervention. For the first time, more funds were recovered in healthcare FCA cases where the government declined to intervene (\$2.27 billion) than in cases it joined (\$2.23 billion).

While the 401 new non-qui tam matters the DOJ opened across all sectors in fiscal year 2025 were lower than in fiscal year 2023 (506) and fiscal year 2024 (425), healthcare trended in the opposite direction, with 183 new government-initiated matters. This number is also the highest on record, compared to 96 in fiscal year 2023 and 87 in fiscal year 2024.

Fiscal Year 2025-2026 Enforcement

2025 and 2026 have seen new or enhanced enforcement areas.

Customs Enforcement Intensifies Under Trade Fraud Task Force

In August 2025, the DOJ, in coordination with the U.S. Department of Homeland Security, launched a cross-agency trade fraud task force to "bring robust enforcement against importers and other parties who seek to defraud the United States." [5]

Schemes to avoid increased tariff costs by underreporting the value of goods imported into the U.S. may trigger the reverse FCA under Title 31 of the U.S. Code, Section 3729(a)(1)(G), which imposes liability where money owed to the government is not paid.

Also, in December 2025, Ceratizit USA LLC, a North Carolina-based distributor of tungsten carbide products, agreed to pay \$54.4 million to resolve FCA allegations for knowingly failing to pay duties on products imported from China.[6] The settlement was characterized by the DOJ as the largest

customs fraud resolution ever recovered under the FCA.[7]

Cybersecurity Fraud Settlements Triple

The DOJ reported recovering more than \$52 million in nine cybersecurity fraud settlements in fiscal year 2025. Civil cybersecurity settlements have more than tripled in each of the past two years, and cyber compliance remains a top priority in FCA cases brought by the DOJ.[8]

Settlements in fiscal year 2025 resulted from allegations that government contractors falsely certified compliance with cybersecurity requirements in government contracts, or that they sold systems with cybersecurity vulnerabilities to federal agencies.

DEI Programs Face FCA Scrutiny

The DOJ is continuing to use the FCA to scrutinize allegedly illegal diversity, equity and inclusion initiatives at major U.S. companies doing business with the federal government.[9]

The agency is examining not just the policies, but also how DEI programs are implemented. The reported use of civil investigative demands in this context underscores that the DOJ is treating these matters as potential fraud investigations, not merely policy disputes.

Accordingly, companies with DEI initiatives, especially those that are government contractors, grantees or other recipients of federal funds, should proceed carefully and deliberately.

Notably, on Feb. 6, the U.S. Court of Appeals for the Fourth Circuit concluded, among other things, that the plaintiffs in *National Association of Diversity Officers in Higher Education v. Trump*[10] were unlikely to succeed in their First Amendment challenge to the certification provision of Executive Order No. 14173, which directs agencies to combat DEI practices.

The certification provision requires federal agencies to include terms in federal contracts and grant awards that compliance with federal anti-discrimination laws "is material to the government's payment decisions" for purposes of the FCA — and that such grantors and grant awardees are required to certify that they do "not operate any programs promoting DEI that violate any applicable Federal anti-discrimination laws."

Although the Fourth Circuit did not foreclose the possibility of future successful challenges "[i]f the President, his subordinates, or another grantor misinterprets federal antidiscrimination law[,]" the court concluded that it is ultimately bound by the text of the certification provision — which "requires only that plaintiffs certify compliance with federal antidiscrimination laws" already in existence — and that "plaintiffs have no protectable speech interest in operating ... DEI programs that violate federal antidiscrimination law."

The decision vacated a 2025 injunction from the U.S. District Court for the District of Maryland, and allows Executive Order No. 14173 and Executive Order No. 14151 — which directs agencies to terminate DEI offices, equity-related grants and contracts — to go forward with respect to the DOJ. [11]

New National Fraud Enforcement Division Launches as DOJ-HHS Coordination Expands

On Jan. 28, 2026, the White House announced the nomination of Associate Deputy Attorney General Colin McDonald to lead the new DOJ Division for National Fraud Enforcement.[12] It remains to be seen how this will intersect with existing civil FCA enforcement mechanisms.

Also, in July 2025, DOJ and the U.S. Department of Health and Human Services jointly announced that they will be strengthening their collaboration to advance priority enforcement areas through a DOJ-HHS False Claims Act working group.[13]

Gender-Affirming Care Emerges as Enforcement Priority

On June 11, 2025, Assistant Attorney General Brett A. Shumate issued a memorandum to all DOJ Civil Division employees, signaling aggressive use of the FCA to pursue healthcare providers that bill

the federal government for "impermissible services." [14]

This includes providers that attempt to evade state bans on gender dysphoria treatments by knowingly submitting false claims to state Medicaid programs.

The Civil Division will also investigate and pursue those submitting alleged false claims in connection with drugs or services, including puberty blockers, hormones or surgery, used to facilitate a child's gender transition.

Other Noteworthy Cases

If we look back at 2025, FCA case law suggests that there are interesting questions ahead for 2026.

First Circuit Deepens AKS Causation Circuit Split

Federal appellate courts last year continued to address the causation standard for FCA violations predicated on noncompliance with the AKS.

A 2010 amendment to the AKS, codified at Title 42 of the U.S. Code, Section 1320a-7b(g), provides that any claim for Medicare reimbursement "that includes items or services resulting from a violation of [the AKS] constitutes a false or fraudulent claim for purposes of [the FCA]."

In the past, the U.S. Courts of Appeals for the Sixth and Eighth Circuits have interpreted "resulting from" to require but-for causation, while the U.S. Court of Appeals for the Third Circuit has held that a plaintiff need only prove a link between the alleged kickbacks and the care received.

In the February 2025 case of *U.S. v. Regeneron Pharmaceuticals*, the U.S. Court of Appeals for the First Circuit followed the Sixth and Eighth Circuits in adopting the but-for standard, which means that to show that a claim results from a violation of the AKS, the government must prove that a claim would not have been submitted but for the illegal kickback. [15]

Zafirov and the Constitutional Future of Qui Tam Provisions

Finally, a case now being considered by the U.S. Court of Appeals for the Eleventh Circuit presents the question of whether the FCA's qui tam provisions violate the appointments clause of the U.S. Constitution.

At oral argument on Dec. 12, 2025, in *U.S. ex rel. Zafirov v. Florida Medical Associates LLC*, [16] Daniel Winik, representing the U.S. government, urged the Eleventh Circuit to join the growing list of district courts and appellate courts that have rejected constitutional challenges to the qui tam provisions.

The Eleventh Circuit case originates from a Sept. 30, 2024, decision by U.S. District Judge Kathryn Kimball Mizelle of the U.S. District Court for the Middle District of Florida, which in turn follows the reasoning of a dissenting opinion in the 2023 U.S. Supreme Court case of *U.S. ex rel. Polansky v. Executive Health Resources*. In *Polansky*, Justice Clarence Thomas characterized the qui tam provisions of the FCA as a "constitutional Twilight Zone." [17]

While that twilight zone may be disappearing — the Sixth Circuit in *In re: TriHealth* denied two petitions for interlocutory appeal on Jan. 9, reaffirming long-standing circuit precedent upholding the constitutionality of the FCA's qui tam provisions — the constitutional debate is far from over. [18]

The Third Circuit is scheduled to hear oral argument on March 20 in *Jessica Penelow v. Janssen Products LP*, in which the U.S. Chamber of Commerce argues in an amicus brief that the FCA's qui tam provisions violate the vesting clause, appointments clause and take care clause of the Constitution. [19]

The U.S. has been permitted to intervene and is expected to argue that the FCA's qui tam provisions are consistent with Article II. Both counsel for the Chamber of Commerce and counsel for the U.S. argued before the Eleventh Circuit in *Zafirov* on Dec. 12, 2025. The outcome of both cases may have significant implications for FCA enforcement nationwide.

Conclusion

Companies should continue to evaluate existing compliance programs regarding the FCA — particularly with respect to healthcare, discrimination, trade and cybersecurity — and ensure adequate processes are in place.

Compliance programs should include internal reporting mechanisms that are accessible and facilitate an appropriate investigation of complaints. And as the DOJ's use of the FCA to challenge DEI programs increases, entities should examine not only their policies under federal, state and local civil rights laws, but also how DEI programs are implemented.

Regarding the constitutionality of the FCA's qui tam provisions, we will see what happens in the coming months.

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[1] Department of Justice, False Claims Act Settlements and Judgments Exceed \$6.8B in Fiscal Year 2025, January 16, 2026, available at <https://www.justice.gov/opa/pr/false-claims-act-settlements-and-judgments-exceed-68b-fiscal-year-2025>.

[2] Id.

[3] DOJ, Fact Sheet, False Claims Act Settlements and Judgments, FY 2025, January 16, 2026, available at <https://www.justice.gov/opa/media/1424126/dl>.

[4] DOJ Press Release, Kaiser Permanente Affiliates Pay \$556M to Resolve False Claims Act Allegations, January 14, 2026, available at <https://www.justice.gov/opa/pr/kaiser-permanente-affiliates-pay-556m-resolve-false-claims-act-allegations>.

[5] DOJ Press Release, Departments of Justice and Homeland Security Partnering on Cross-Agency Trade Fraud Task Force, August 29, 2025, available at <https://www.justice.gov/opa/pr/departments-justice-and-homeland-security-partnering-cross-agency-trade-fraud-task-force>.

[6] DOJ Press Release, Ceratizit USA LLC Agrees to Pay \$54.4M to Settle False Claims Act Allegations Relating to Evaded Customs Duties, December 18, 2025, available at <https://www.justice.gov/opa/pr/ceratizit-usa-llc-agrees-pay-544m-settle-false-claims-act-allegations-relating-evaded-0>.

[7] DOJ Fact Sheet, *supra* note 3.

[8] Id.

[9] The Wall Street Journal, Justice Department Using Fraud Law to Target Companies on DEI, December 28, 2025, available at <https://www.wsj.com/politics/policy/trump-doj-dei-fraud-investigations-93213d52>.

[10] [National Association of Diversity Officers in Higher Education et al. v. Trump](#) , No. 25-01189

(4th Cir. February 6, 2026).

[11] 769 F. Supp.3d 465 (D. Md. 2025). Note that a narrow injunction out of the U.S. District Court for the Northern District of Illinois, now being reviewed by the Seventh Circuit, may prevent the U.S. Department of Labor from requiring the certification that EO 14173 requires.

[12] The White House, Fact Sheet: President Donald J. Trump Establishes New Department of Justice Division for National Fraud Enforcement, January 8, 2026, available at <https://www.whitehouse.gov/fact-sheets/2026/01/fact-sheet-president-donald-j-trump-establishes-new-department-of-justice-division-for-national-fraud-enforcement/>; Law360, Trump Announces Pick For New Assistant AG for Fraud Role, January 28, 2026, available at <https://www.law360.com/pulse/articles/2435482/trump-announces-pick-for-new-assistant-ag-for-fraud-role>.

[13] DOJ Press Release, DOJ-HHS False Claims Act Working Group, July 2, 2025, available at <https://www.justice.gov/opa/pr/doj-hhs-false-claims-act-working-group>.

[14] DOJ Memorandum, Civil Division Enforcement Priorities, June 11, 2025, available at <https://www.justice.gov/civil/media/1404046/dl?inline>.

[15] **United States v. Regeneron Pharmaceuticals** , 2025 WL 520466 (1st Cir. 2025).

[16] United States ex rel. Zafirov v. Florida Medical Associates LLC et al., No. 24-13581.

[17] **United States ex rel. Zafirov v. Florida Medical Associates LLC** , 751 F. Supp. 3d 1293 (M.D. Fla. 2024); **United States ex rel. Polansky v. Executive Health Resources** , 599 U.S. 419 (2023).

[18] In re: TriHealth Inc., Nos. 25-306/307 (6th Cir., January 9, 2026).

[19] Jessica Penelow et al. v. Janssen Products LP, No. 25-1818 (3d. Cir).