



PROGRAM MATERIALS
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Noteworthy False Claims Act Trends and Updates

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Agenda

- Noteworthy News
- Synopsis of the FCA, FWA & FY2025 DOJ Report.
- Nuances between State Statutes and Federal FCA
- Recent Settlements and Notable Opinions
 - Healthcare
 - Cybersecurity
 - PPP
 - Other Areas
- Compliance Suggestions
- Conclusion

Noteworthy News

Recent DOJ False Claims Act Data

- \$5.6 billion in total FCA settlements and judgments in FY 2021.
- \$2.2 billion in total FCA settlements and judgments in FY 2022.
- \$2.8 billion in total FCA settlements and judgments in FY 2023.
- \$2.9 billion in total FCA settlements and judgments in FY 2024.
- **\$6.8 billion in total FCA settlements and judgements in FY 2025.**
- **Healthcare continued to be the number one industry contributing to FCA recoveries (excluding Medicaid) with \$5.7 billion in FY2025.**

False Claims Act Settlements and Judgements

Exceed \$6.8B in Fiscal Year 2025 (Jan. 16, 2026)

- What makes FY 2025 notable is that FCA settlements eclipsed FY 2024 by nearly \$4 billion, 1,297 *qui tam* (whistleblower) lawsuits were filed – the highest in the FCA’s history and an emphasis on “combating fraud in the federal health care system and in the government’s procurement, loan, and grant programs and redressing the improper avoidance or tariffs and customs duties that are owed.”
- Notably, “[t]he 1,297 *qui tam* suits filed in fiscal year 2025 breaks the prior record set in 2024 of 980 such cases. This past year, the Justice Department reported settlements and judgments exceeding \$5.3 billion in these and earlier-filed *qui tam* suits.”

In re TRIHEALTH, Inc., et al., Case No. 25-0306 (6th Cir. Jan. 9, 2026)

- The application for the interlocutory appeal contesting the False Claims Act's *qui tam* provision by arguing that the provision is unconstitutional pursuant to Article II of the U.S. Constitution.
- “Where, as here, there is controlling precedent from this circuit on the issue, none of those conditions are met. See *id.* The district court acknowledged that the constitutionality of the FCA's *qui tam* provision was decided by this court in *United States ex rel. Taxpayers Against Fraud v. General Elec. Co.*, 41 F.3d 1032, 1041 (6th Cir. 1994).”
- **Bottom Line:** once again, the 6th Circuit upheld the FCA *qui tam* provision as being constitutional.

Brief Synopsis of the FCA & FWA

The False Claims Act

- 31 U.S.C. §§ 3729-3733.
- 1863 – Known as the “Lincoln Law” (key amendments – 1943, 1986, 2009 and 2010)
- A case may be initiated by the Government or by an individual, who is either a lawyer or represented by a lawyer, known as a “Relator”
- The general process for Relator’s counsel.
- The Seal
 - The initial seal period
 - Extensions
 - *State Farm* Case
- Government’s Options (intervene, decline to intervene, or dismiss)
- Penalties and Damages
- Relator’s Potential Recovery

What is a claim?

According to §3729(b)(2), a claim

(A) means any request or demand, whether under a contract or otherwise, for money or property and whether or not the United States has title to the money or property, that—

- (i) is presented to an officer, employee, or agent of the United States; or
- (ii) is made to a contractor, grantee, or other recipient, if the money or property is to be spent or used on the Government's behalf or to advance a Government program or interest, and if the United States Government—
 - (I) provides or has provided any portion of the money or property requested or demanded; or
 - (II) will reimburse such contractor, grantee, or other recipient for any portion of the money or property which is requested or demanded; and

(B) does not include requests or demands for money or property that the Government has paid to an individual as compensation for Federal employment or as an income subsidy with no restrictions on that individual's use of the money or property;

Noteworthy Items

- Knowledge (*SuperValu*) (unanimous opinion)
- Materiality (*Escobar*) (unanimous) – holistic approach to materiality
- Dismissal (Polansky) (8-1 opinion)
- Article II (*Zafirov* Oral Argument before 11th Circuit is scheduled for Dec. 12, 2025. A single District Court in FL has held the FCA to be unconstitutional under Article II. “Musings” by a couple of Supreme Court Justices and Fifth Circuit Judges.)
- Reimbursement Requests to a Private Company are FCA “claims” because the Treasury Provided a Portion of the Money Requested. (Wisconsin Bell (unanimous opinion)

HHS OIG STATEMENT

According to the United States Department of Health and Human Services Office of the Inspector General (“HHS-OIG”), **“[t]he five most important Federal fraud and abuse laws that apply to physicians are the False Claims Act (FCA), the Anti-Kickback Statute (AKS), the Physician Self-Referral Law (Stark Law), the Exclusion Authorities, and the Civil Monetary Penalties Law.”**

State & Federal FCA Nuances

NOTE: not all states refer to their statutes as a state FCA.

TAF's *Fraud by the Numbers*

“From July 2024 to July 2025, across both state and federal False Claims Act cases, 292 settlements were announced totaling over \$4.9 billion. Settlement recoveries ranged from a low of \$35,000 to a staggering \$450,000,000, with the median settlement hovering at \$2,505,000. Over 58.2% of settlements involved alleged fraud in the healthcare industry, including kickbacks and Medicare and Medicaid fraud. The next most common type of fraud involved the Paycheck Protection Program (“PPP”), with 18.8% of settlements involving PPP loans.”

Rachel's Fraud by the Number's Article

- This installment of the *Fraud by the Numbers* series, we turn to the State False Claims Act (**FCA**) statutes. To recap several, but not all states and territories have FCA statutes and some are healthcare specific. Interestingly, the U.S. Department of Health and Human Services – Office of the Inspector General (**HHS-OIG**) reviews state false claims. The OIG, “in consultation with the Attorney General, determines whether States have false claims acts that qualify for an incentive under section 1909 of the Social Security Act.”
- Notably, the Texas Medicaid Fraud Prevention Act is quite distinct from the FCA and does not require materiality.
- Additionally, Arkansas has a law that does not have a *qui tam* provision (meaning that a whistleblower cannot bring a case). Instead of filing a private action, a whistleblower who provides information leading to a recovery for Medicaid fraud can receive a reward of up to 10%.
- Finding current state data on whistleblower and/or State FCA recoveries is not as easy. California’s Attorney General website provides an overview of the California False Claims Act and types of cases it has handled under the law; however, no statistics are present. For example, in February 2013, the Texas Attorney General released information that Medicaid Fraud recoveries surpassed \$400 million, reflecting a decade-long emphasis on combatting Medicaid fraud in Texas.

Notable Cases

Areas, settlements & opinions.

AKS Cases

- Biohaven Pharmaceutical Holding Company, a Pfizer subsidiary, agreed to pay \$59.7 million to resolve allegations that, prior to Pfizer's acquisition of the company, Biohaven paid kickbacks to health care providers to induce prescriptions. The government alleged that Biohaven selected and paid certain health care providers with the intent that the speaker honoraria and meals would induce them to prescribe its drug. The government further alleged that certain prescribers who attended multiple programs on the same topic received no educational benefit from attending repeat programs and that certain Biohaven speaker programs were attended by individuals with no educational need to attend, such as the speakers' spouses, family members, friends, or colleagues.

AKS

- QOL Medical LLC and its co-owner and CEO, Frederick Cooper, agreed to pay \$47 million to resolve allegations that they offered kickbacks in the form of free breath testing services to induce claims for QOL’s drug Sucraid. QOL, with the CEO’s approval, distributed free breath test kits to health care providers and asked providers to give the kits to patients with common gastrointestinal symptoms, claiming that the test could “rule in or rule out” the condition for which it was approved. In fact, the test did not specifically diagnose the condition and other conditions could cause a patient to test “positive.”

Grant Fraud

- **Dana-Farber Cancer Institute Agrees to Pay \$15M to Settle Fraud Allegations Related to Scientific Research Grants (Dec. 16, 2025)**
- Dana-Farber Cancer Institute Inc. (Dana-Farber) has agreed to pay \$15,000,000 to resolve allegations that, between 2014 and 2024, it violated the False Claims Act by making materially false statements and certifications related to National Institutes of Health (NIH) research grants.
- As part of the settlement, Dana-Farber admitted that its researchers used funds from six NIH grants to conduct research that resulted in 14 publications in scientific journals containing misrepresented and/or duplicated images and data. The publications reused images to represent different experimental conditions; duplicated images to represent different testing conditions, mice, and/or timepoints; or rotated, magnified, or stretched images.
- Further, Dana-Farber admitted that a supervising researcher failed to exercise sufficient oversight over these researchers, and that Dana-Farber spent funds from those six NIH grants that were unallowable.
- As part of the settlement, Dana-Farber also admitted that another researcher received four NIH grants after submitting grant applications that discussed a journal article authored by the researcher but did not disclose that certain images and data in that article were misrepresented and/or duplicated.
- The United States contends that Dana-Farber caused the submission of false claims to NIH by falsely certifying compliance with grant terms and conditions, spending grant funds on unallowable expenses, and obtaining grants through false and misleading statements.

Healthcare and Cybersecurity

Healthcare

- Nov. 25, 2025 - Austin Emergency Center, LLC, Austin ER, LLC, AEC ER 4, LLC, Pahala Ventures, LLC, AEC Physicians, PLLC, and AEC Pflugerville, LLC (collectively, “Austin Emergency Center”) have agreed to pay the United States \$429,231 to resolve overbilling allegations under the False Claims Act.

Cybersecurity

- 1st Case (March 2022)* - United States ex rel. Shawn Lawler, v. CHS, et al. - \$930,000 settlement.
- July 31, 2025 – defense contractor and private equity firm self-disclosure of cybersecurity violations leads to \$1.75 million FCA settlement.

PPP & Other Areas

PPP

- United States ex rel. Karen Bloomfield v. ESI, et al., Case No. 1:22-cv-789 (E.D. Va.)*
 - Declined case.
 - Settled for \$5.75 million
 - Issue of first impression – what constitutes an “employee” for purposes of PPP loans.

Other Areas

- “In the first eight months of 2025, the US Department of Justice (DOJ) announced four significant settlements involving allegations of knowingly and improperly evading customs duties on imports under the False Claims Act (FCA). These settlements – and DOJ’s related actions – further underscore the federal government’s ongoing commitment to redirect resources and enforcement strategies toward combating tariff evasion.”

Compliance Considerations

Risk Mitigation before and after knowledge of a Government investigation.

HHS-OIG Guidance 2023

OIG's November 6, 2023 announcement – the release of its *General Compliance Program Guidance*.

While a **compliance program is mandatory pursuant to 42 C.F.R. § 483.85**, OIG's Guidance is not legally binding.

The guidance relates to fraud, waste and abuse laws and are comprised of the following:

- (1) written policies and procedures;
- (2) compliance leadership and oversight;
- (3) training and education;
- (4) effective lines of communication with the compliance officer and disclosure program;
- (5) enforcing standards: consequences and incentives;
- (6) **risk assessment, auditing, and monitoring**; and
- (7) responding to detected offenses and developing corrective action initiatives.

<https://www.physicianspractice.com/view/two-different-hhs-office-items-to-note>

DOJ's Evaluation of Corporate Compliance Programs (last updated Sept. 2024)

- Per the introduction, “[t]he ‘Principles of Federal Prosecution of Business Organizations’ in the Justice Manual describe specific factors that prosecutors should consider in conducting an investigation of a corporation, determining whether to bring charges, and negotiating plea or other agreements.”
- “These factors include ‘the adequacy and effectiveness of the corporation’s compliance program at the time of the offense, as well as at the time of a charging decision’ **and the corporation’s remedial efforts ‘to implement an adequate and effective corporate compliance program or to improve an existing one.’”**

Three Questions Prosecutors Should Ask...

1. Is the corporation's compliance program **well designed?**
2. Is the program being applied **earnestly and in good faith?** In other words, is the program adequately resourced and empowered to function effectively?
3. Does the corporation's compliance program **work in practice?**

Additional Notable Items

- The **starting point** for a prosecutor's evaluation of whether a company has a well-designed compliance program is to understand the company's business from a commercial perspective, **how the company has identified, assessed, and defined its risk profile, including specific factors that mitigate the company's risk**, and the degree to which the program devotes appropriate scrutiny and resources to the remaining spectrum of risks.
- **Risk Management Process** – What methodology has the company used to identify, analyze, and address the particular risks it faces? What features of the company reduce its exposure to such risks? Is the company's approach to risk management proactive or reactive? What information has the company identified and collected to help detect the type of misconduct in question? How has that information informed the company's compliance program?
- **Management of Emerging Risks to Ensure Compliance.**
 - How does the company assess the potential impact of new technologies, such as artificial intelligence (AI)⁴, on its ability to comply with criminal laws?
 - Is management of risks related to use of AI and other new technologies integrated into broader enterprise risk management (ERM) strategies?
 - What is the company's approach to governance regarding the use of new technologies such as AI in its commercial business and in its compliance program?

Conclusion

Take-Aways

- Compliance programs are critical for both risk and liability mitigation.
- Healthcare remains a top area of focus for the DOJ and Relators alike.
- To date, every Circuit Court to address the Constitutionality of the FCA under both Article III and Article II has upheld it.
- Cybersecurity, tariffs and private equity defendants continue to be areas to watch.

READ THE CODE.

Thank You & Questions

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