September 24, 2026

FCA Enforcement in 2026: Key Trends and DOJ Initiatives

GIBSON DUNN

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AGENDA

Key Takeaways

1. 2026 reflects significant momentum towards another year of record recoveries, or at least new cases
2. DOJ’s policy initiatives are yielding resolutions, but they—and more longstanding enforcement areas—will have a long tail
3. The FCA remains within the Civil Division, but with the creation of the National Fraud Enforcement Division, DOJ’s overall fraud enforcement authority has shifted
4. The incentives for data-driven *qui tam* cases are stronger than ever
5. Novel legal theories continue to pervade established and new areas of enforcement

The Enforcement Landscape

01

Enforcement Trends by the Numbers

FY 2025

$6.8B
FY 2025 settlements and judgments
All-time record

1,297
Qui tams filed in FY 2025
All-time record

FY 2026 to date

~$4.0B
FY 2026 settlements and judgments to date

780+
Qui tams filed in first half of FY 2026, according to DOJ

FY 2000 – FY 2026 to date

~$83.5B
FCA recoveries

16,097+
New *qui tams* filed

$1.45B in FCA Recoveries in Three Weeks

$541.5M
Provider network
Aug. 26

Theory
Self-disclosed alleged false diagnosis codes submitted to inflate Medicare Advantage payments

Up to $525M
Wound-care practice (in bankruptcy)
Sept. 14

Theory
Alleged false Medicare billing for skin substitutes; DOJ valued its claims at roughly $1.5B

~$385M
Manufacturer
Sept. 14

Theory
Products allegedly manufactured under conditions posing an "unacceptable risk" of contamination

Policy Initiatives Are Yielding Tangible Results

POLICY ANNOUNCEMENT	FIRST RESOLUTION	TOTAL RESOLUTIONS SINCE ANNOUNCEMENT
AG memorandum on gender-related care Apr. 22, 2025	May 15, 2026	6 resolutions | ~$19.8M in disclosed settlement payments
Civil Rights Fraud Initiative May 19, 2025	Apr. 10, 2026	3 resolutions | $63.6M
DOJ-HHS FCA Working Group (Medicare Advantage a top priority) July 2, 2025	Jan. 14, 2026	5 MA resolutions | ~$1.27B
Trade Fraud Task Force Aug. 29, 2025	Nov. 26, 2025	6 civil FCA resolutions | ~$642M

The Civil FCA Remains in the Civil Division

National Fraud Enforcement Division

Five stated priorities (Aug. 13 McDonald memo):

- Public Trust and Financial Integrity
- Health care
- Internal Revenue
- Global Trade and Commerce
- Corporate Misconduct

Civil Division — Civil Fraud Section

- The OLP review following the creation of the Fraud Division did not move FCA enforcement into the new Division
- But the new rule governing the Fraud Division splits authority over criminal health care matters between it and the Criminal Division—meaning that companies at risk of parallel criminal/civil health care matters have three DOJ components to contend with rather than two

DOJ's Benefits-Fraud Fast Track Initiative Creates New Challenges and Potential Opportunities

Day 0
Qui tam filed

Day 60
Target for initial review

Day 120
Outer bound for initial review

Day 240
Outer bound for additional investigation without DAAG approval

Day 360
Outer bound for additional investigation with DAAG approval

Initial review ends in one of three determinations

Declination: non-novel theory; <$10M in alleged damages; corroborated facts; aggravating factors

Further investigation: extensions require increasingly senior DOJ officials to approve

Dismissal: allegations lack specificity or are legally deficient

The 120-day investigative period

Plan
Schedule for prompt IG subpoenas / CIDs and early witness interviews

Targeted requests
Possible interviews and testimony in lieu of some document categories

Subpoena enforcement
Definitive response deadlines; missed deadline → enforcement action

Relator's counsel
May be asked to assist in the investigation

Damages analysis staged
Intervene on liability evidence; refine damages in discovery

FOCUS Initiative: Data-Driven Relators Are Becoming Institutionalized

What DOJ says it wants from relators

1. **Pre-filing diligence:** Evidence the relator tested the theory before filing and considered alternate explanations

2. **Analytical rigor:** "[H]igh quality, reliable, and predictive data analyses and signals"

3. **Familiarity with program rules:** Understanding of the payment rules the data is measured against

FOCUS Initiative for Data Miners Filing Qui Tam Complaints

The size and complexity of federal benefits programs and the lack of consistent controls to

"Since Fiscal Year 2024, data miners have filed more than 45% of all *qui tam* complaints."

(FCA) qui tam complaints, and through this work the Civil Division will support the NFED's anti-fraud work.

The Department received a record number of FCA qui tam complaints (980) in Fiscal Year

"So far in Fiscal Year 2026, the Department has already received over 780 *qui tam* complaints, putting the Department on pace for another record."

Fraud Oversight through Careful Use of Statistics (FOCUS) initiative, to improve the Department's ability to prioritize working with the most successful data miners.

"[T]hrough this work the Civil Division will support the NFED's anti-fraud work."

datasets.

For example, data miners have been particularly active with respect to pandemic assistance loans. The Small Business Administration (SBA) has publicly released certain

DOJ's Recent Changes to the Justice Manual May Have Limited Impact

On September 18, DOJ announced changes to the Justice Manual that largely reprise earlier policy announcements

	Announcement Under First Trump Administration	Sept. 18 Announcement
Use of sub-regulatory guidance	Brand Memo (Jan. 25, 2018) • "[M]ay not use noncompliance with guidance documents as a basis for proving violations of applicable law" • "[S]hould not treat a party's noncompliance with an agency guidance document as presumptively or conclusively establishing that the party violated the applicable statute or regulation"	JM 1-19.210 • "[M]ay not bring actions based solely on allegations of noncompliance with guidance documents" • "[S]hould not treat a party's noncompliance with a guidance document as itself a violation of applicable [law]"
DOJ's Section 3730(c)(2)(A) authority	Granston Memo (Jan. 10, 2018) • **"[S]hould . . . consider** whether the government's interests are served . . . by seeking dismissal"	JM 4-4.111 • **"[W]ill in each case assess** whether the government's interests are served by seeking dismissal"

Qui Tam Constitutionality Litigation Continues

- Highly anticipated *Zafirov* decision from Eleventh Circuit came down on Sept. 1, 2026
- The court reversed Judge Mizelle's Sept. 2024 opinion that had found the *qui tam* provisions of the FCA unconstitutional
- The case was decided on narrow Appointments Clause grounds; the Vesting Clause and Take Care Clause issues remain live on remand

What to watch

- Pending Third Circuit appeal (*Penelow*)
- Eleventh Circuit remand and a potential second-round appeal
- Timing of a potential Supreme Court case
- Meanwhile: *qui tam* filings continue at record pace

Caselaw on Limiting Principles for FCA Liability Remains Critical

U.S. ex rel. Palmer v. Tata Consulting Services (5th Cir. 2026)

- A reverse false claim theory requires an established, not contingent, duty to pay money to the government
- Court rejected reverse FCA theory based on visa fees, aligning with the D.C., Second, and Ninth Circuits
- Case has broader implications, including for other regulatory licensing and fee regimes; relators and DOJ cannot base a reverse FCA theory on an alleged failure to submit a more expensive license application
- Case has even broader implications for FCA enforcement, given the prominence of the “reverse” FCA theory in everything from health care cases to trade fraud cases

Health Care & Life Sciences

02

Headline DOJ Initiatives Have Significant Implications for Health Care Enforcement

DOJ-HHS FCA Working Group	Medicare Advantage and AKS enforcement were both identified as priorities in July 2025, and the 2026 resolution record confirms DOJ's focus on these areas
FOCUS	With DOJ publicly and formally encouraging data mining by relators, we can anticipate even more *qui tams* filed based on public data (e.g., Medicare claims data, Open Payments data)
Fast-track initiative	Medicaid spending will continue to drive significant potential exposure, and potentially on an accelerated timeline

Anti-Kickback Statute Enforcement Remains a DOJ Mainstay

$4.75M Feb. 27

Gastroenterology practice

- Alleged automatic "special stain" ordering

$8.3M+ May 1

Mobile PET scan provider

- Alleged above-market "supervision" fees for referring cardiologists
- FMV opinion letter allegedly rested on inaccuracies; later withdrawn

$13.6M May 14

Pharmaceutical manufacturer

- Alleged speaker-program honoraria and high-end meals; duplicate programs

~$2M June 1

Former executives and referring physician

- Alleged MSO "investment distribution" kickbacks alongside prior criminal penalties

$30M June 17

Pathology laboratory, MSO, and owners

- Alleged free or below-cost in-office labs for exclusive referrals; automatic serial testing

$32M Sept. 10

Pharmaceutical manufacturer

- Self-disclosed alleged copays paid through two patient assistance foundations to induce purchases of its drug

Medicare Advantage Is Increasingly a Pillar of FCA Enforcement

$556M Jan. 14

Integrated health system and affiliated health plans

- Alleged pressure on physicians to alter records after visits, adding diagnoses never considered or addressed

$117.7M Mar. 11

National health insurer

- Alleged mining for new diagnoses while not withdrawing unsupported codes the same reviews revealed

$56.5M June 3

In-home assessment vendors and founder

- Alleged chronic-condition diagnoses unsupported by records and not made by any treating provider

$541.5M Aug. 26

Physician-owned primary care network

- Self-disclosed alleged false diagnosis codes submitted to inflate MA payments

Medical Necessity, Billing, and Overpayment Theories Remain Enforcement Focal Points

- ~$130M in resolutions/judgments thus far in 2026
- Types of entities involved: DME supplier; physician practices; pharmacy chain; behavioral health providers; hospitals; diagnostic test developer
- Notable examples:
  - $40M resolution with supermarket pharmacy chain (May 12) stemming from alleged false reporting of discount-program prices
  - $32M resolution with psychiatric hospital operator and executives (May 27) based on alleged retained overpayments in breach of a Corporate Integrity Agreement

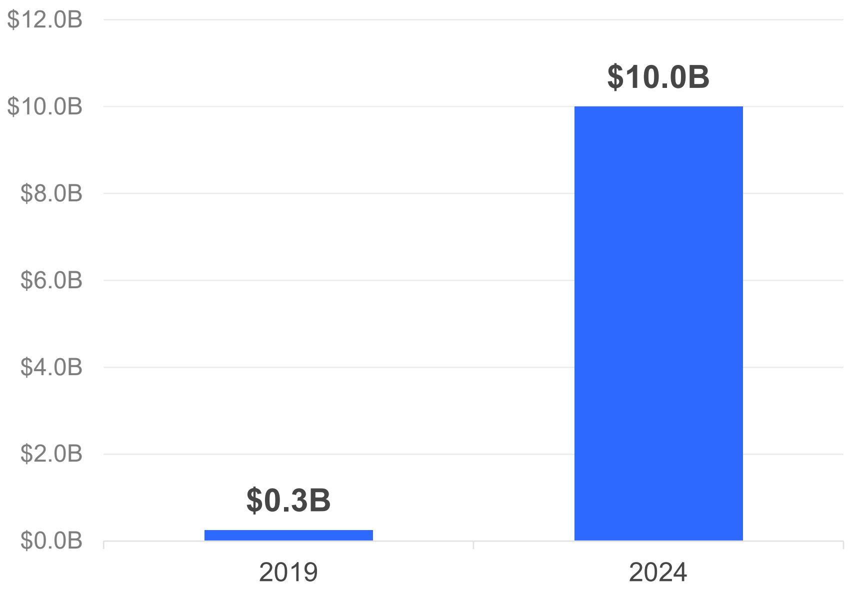
The "Worthless Products or Services" Theory Continues to Be Reinvented

2010	2013	2014	2019	2026
Pharma. manufacturer **$600M civil** Allegedly adulterated drugs from a single plant; cGMP failures rendered products non-reimbursable	**Generic drug manufacturer** **$350M civil** Allegedly adulterated generics and false cGMP-compliance statements	**Nursing home operator** **$38M** Alleged materially substandard care	**Nursing home operator** **~$18M** Alleged "grossly deficient" care	**Manufacturer** **~$385M** Products allegedly made under conditions posing an "unacceptable risk" of contamination

- In parallel, some courts have issued decisions limiting the theory, most notably:
  - *U.S. ex rel. Absher v. Momence Meadows Nursing Ctr.* (7th Cir. 2014): performance of "worthless services" must be "so deficient that for all practical purposes it is the equivalent of no performance at all" (citation and quotation marks omitted)

Program Spending Continues to Drive Exposure—Skin Substitutes as a Case Study

Medicare Part B Skin-Substitute Pending (approx.) (CMS reporting)



"A lot more skin substitute cases" are in the pipeline, per DAAG (Jan. 2026)

Three resolutions in ten months

$45M Nov. 21, 2025

Wound-care physician group and owner

- Alleged medically unnecessary procedures; five-year CIA

>$309M Dec. 12, 2025

Wound-graft company owners

- Grafts allegedly applied regardless of medical necessity, driven by distributor kickbacks; owners sentenced to 14–15.5 years

up to $525M Sept. 14, 2026

Mobile wound-care practice (in bankruptcy)

- Alleged skin-substitute billing DOJ valued at ~$1.5B

Courts Continue to Grapple with Both Recurring Issues and Novel Theories

U.S. ex rel. Adventist Health v. AbbVie
9th Cir. Mar. 17, 2026

- Unanimous reversal: a covered entity may pursue a *qui tam* alleging manufacturers charged above the 340B ceiling price
- Lack of a private right of action under 340B does not bar an FCA claim; the relator enforces the FCA, not the 340B statute

U.S. ex rel. Sheldon v. Allergan Sales
4th Cir. Mar. 13, 2026

- Subjective scienter was adequately pleaded where the manufacturer urged CMS to change language in the relevant drug discount rule and CMS issued guidance emphasizing the existing requirement

U.S. ex rel. Lynn v. City of Detroit
6th Cir. Apr. 10, 2026

- A promise of future compliance cannot anchor a false-certification claim
- Has implications throughout FCA enforcement, including based on the AKS

Government Contracting

03

Cybersecurity FCA Enforcement Remains an Area to Watch

$2.04M

Aerospace and defense contractor (Sept. 1)

Alleged failure to implement NIST SP 800-171 controls on a covered network

Regulatory context

- **CMMC Phase 1** took effect Nov. 10, 2025
- **CMMC Phase 2** third-party assessment requirements were paused July 13, 2026
- **CMMC Reform Task Force review** (through mid-September 2026) could reshape certification and assessment requirements

Caselaw development: *U.S. ex rel. Pannek v. Archer Daniels Midland* (N.D. Ill. Sept. 2, 2026)

Court dismissed a declined *qui tam* case for failure to plead the materiality of any of the alleged statements related to ADM's cybersecurity practices, finding that the relator had at most pleaded that adherence to certain regulations was a condition of payment

DOJ's claimed recoveries since launch of Civil Cyber-Fraud Initiative (as of June 2026):

15 cybersecurity FCA settlements; over $73.5M total

Matters Premised on Traditional Procurement Fraud Allegations Remain an Enforcement Focal Point

$3.45M Jan. 26
Nuclear site services contractor
- Alleged billing of excessive idle time; employees directed to record full shifts

$2.6M Jan. 26
Shipping-container manufacturer
- Alleged foreign-flagged vessels on ~35 defense contracts despite U.S.-flag requirements

$2.4M Feb. 5
Postal facilities contractor
- Allegedly altered documentation inflating labor hours and materials

$30M Feb. 11
Asphalt suppliers
- Alleged failure to perform mix-design testing on federally funded road projects; alleged false QC results

$15M verdict Mar. 13
Reverse FCA at trial
- Jury verdict and judgment on a lost-government-property theory; $15M is before trebling and penalties

$10.5M Mar. 17
Weld-table supplier
- Product substitution and cost allegations

Contract Eligibility Remains a Core Enforcement Theory

Contractor eligibility also remains a mainstay of FCA enforcement theories, including in the small business context

Subsidy programs
$17M+ | May 6

- Wireless carrier; FCC low-income broadband programs
- Alleged ineligible enrollments; failure to screen, train, or supervise third-party sales agents
- Alleged inaction after an FCC Office of Inspector General warning

SDVOSB set-asides
$3.6M and $21.3M
June 2 and June 9

- Alleged false SDVOSB certification across seven contracts
- Alleged use of supposed SDVOSBs as “pass-through" entities, with non-small companies controlling contract execution, staffing, and financial administration

Organizational conflict of interest
$7.75M | July 28

- Aerospace and defense contractor allegedly employed a government official who had participated personally and substantially in three contracts awarded to the company

DEI / Civil Rights Initiative

04

The Civil Rights Fraud Initiative Is Yielding Significant DOJ Resolutions in a Short Period

- DOJ launched the Civil Rights Fraud Initiative on May 19, 2025
- It took a mere 11 months for the initiative to yield its first FCA resolution, in April 2026
- Since then, DOJ has announced two more such resolutions, in August and September
- Each settlement has had a higher dollar value than the one before it
- In total, DOJ has recovered from these three settlements nearly as much as it has recovered from 15 settlements under the Civil Cyber-Fraud Initiative: ~$63.6M vs. over $73.5M, respectively
- More settlements are possible before the end of 2026

PRESS RELEASE

Justice Department Establishes Civil Rights Fraud Initiative

Monday, May 19, 2025

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For Immediate Re

Office of Public Af

May 19, 2025

MEMORANDUM FOR OFFICE OF THE ASSOCIATE ATTORNEY GENERAL
CIVIL DIVISION
CIVIL RIGHTS DIVISION
CRIMINAL DIVISION
EXECUTIVE OFFICE FOR UNITED STATES ATTORNEYS
ALL UNITED STATES ATTORNEYS

FROM: THE DEPUTY ATTORNEY GENERAL

SUBJECT: Civil Rights Fraud Initiative

From Executive Order to Three Resolutions

Jan. 21, 2025

EO 14173
White House orders contract language stating that federal anti-discrimination compliance is material under the FCA

May 19, 2025

Civil Rights Fraud Initiative
DOJ announces it will use the FCA against federal funding recipients that violate civil rights laws

Feb. 19, 2026

DOJ states its theory
DAAG remarks set out falsity, materiality, scienter, and remedies theories

Mar. 26, 2026

EO 14398
White House defines "racially discriminatory DEI activities"; 30-day directive for a certification and records-access clause

Apr. 10, 2026

First resolution: ~$17.1M
Technology company; government-initiated; penalties included

Aug. 25, 2026

Second resolution: $21.5M
Professional services firm; *qui tam*; penalties included; parallel Indiana and Florida settlements

Sept. 14, 2026

Third resolution: $25M
Consulting and technology services firm; government-initiated; penalties included

Civil Rights Fraud Initiative: DOJ's Stated Theory (Feb. 2026)

On February 19, DOJ's DAAG for the Commercial Litigation Branch laid out the details of DOJ's FCA theory in DEI cases

- **Falsity**
  - DOJ not investigating companies simply for maintaining DEI programs; rather, its theory requires a predicate violation of federal antidiscrimination law
  - Focus on preferential hiring/promotion, use of protected traits to select for program participation, and "diverse slate" policies
  - Three claimed recurring fact patterns: demographic goals and tracking, compensation/incentives tied to demographic targets, and requirements that employees set DEI objectives for compensation/advancement purposes
  - DOJ views position as strongest where practices demonstrably influenced specific employment decisions
- **Materiality**
  - DOJ views race- and sex-based preferencing as taking a contractor "outside the conditions" of federal support
- **Scienter**
  - DOJ views facts as strongest where management directives result in conforming hires, internal communications prioritize candidates by protected trait, or contractor's actual practices are out of line with its OFCCP disclosures
- **Remedies**
  - DOJ intends to seek civil penalties in resolved cases, departing from longstanding policy

Civil Rights Fraud Initiative Resolutions: The Emerging DOJ Theory

Theory of falsity

Resolutions all rely on alleged certifications of compliance with Title VII via FAR 52.222-26

Resolutions all allege that companies incentivized employees to carry out demographic goals through compensation- and promotion-related consequences

Theory of materiality

No resolution claims that individuals were not hired who should have been

No resolution states a theory of significance of alleged practices to specific government contracts

Theory of scienter

Only one resolution claims that alleged goals actually drove hiring practice changes, without any allegation of a connection to specific management directives

Theory of harm to the government

Resolutions all claim that the costs of companies' DEI programs were allocated to and reimbursed under federal contracts

All three resolutions include civil penalties

What to watch

- Implications for cost-allocation theory, particularly in any resolutions involving contracts for goods
- Potential for more increases in settlement amounts
- Whether future settlements allege that particular hiring decisions should have been made but weren't, along with a theory of materiality to specific government contracts

Risk Remains Potential for Anti-Discrimination FCA Enforcement Beyond DEI and Government Contracting

U.S. ex rel. Shea v. eHealth, Inc. **(D. Mass. Mar. 25, 2026)**

- Intervened case in which DOJ alleges that the defendants (a group of insurers and brokers) violated the FCA by paying/receiving kickbacks in connection with Medicare Advantage beneficiary enrollment, in violation of the AKS and federal anti-discrimination law
- Court denied the defendants' motion to dismiss, ruling (in relevant part) that DOJ had adequately pled that certain defendants discriminated against disabled beneficiaries and then falsely represented compliance with anti-discrimination requirements
- On materiality, the court held that "intentionally minimizing the enrollment" of disabled beneficiaries "is neither 'minor nor insubstantial' . . . . It directly undercuts the purpose of the MA program, which is explicitly to connect eligible beneficiaries, who may be disabled, to health insurance plans."

Financial Services

05

COVID Relief Resolutions Remain High Volume but Focused on Borrowers

23
H1 2026 PPP resolutions
~$76M; most under $4M

6
More since June 30
incl. $11.8M (aerospace manufacturer, Aug. 12)

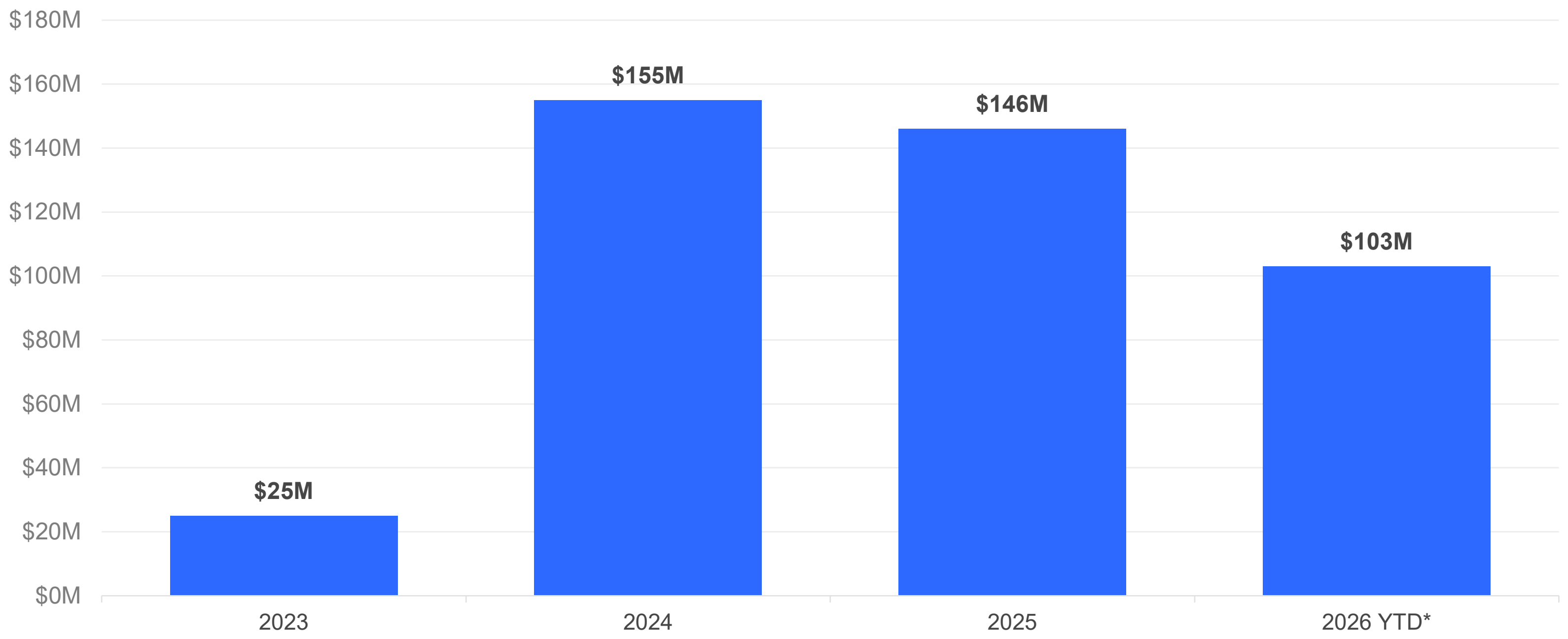
Resolution with a regional bank (Jan. 7, $7.7M)

- Bank allegedly submitted forgiveness applications for loans it had evidence were fraudulently obtained
- Prior lender cases: $18,673 (Sept. 2022); up to $120M (fintech lender) (May 2024)

COVID Relief FCA Enforcement Is Likely Far from Over

- With $103M in PPP resolutions to date, CY 2026 is on pace to match the amounts recovered via PPP resolutions in 2024 and 2025
- Given DOJ's FOCUS initiative, we can also expect a robust inflow of new PPP *qui tams* driven by data mining
- With the new Fraud Division taking up small business program-related fraud, the potential for parallel civil/criminal cases may also increase

PPP FCA Recoveries, CY 2023 – CY 2026 YTD



PPP Cases Continue to Raise Important Public Disclosure Bar Questions

U.S. ex rel. Relator, LLC v. Erskine
9th Cir., July 15, 2026

- Data-mining relator alleged a mortgage lender falsely certified PPP eligibility, use of funds, economic necessity, and headcount
- Reversed dismissal: a NAICS lending code on PandemicOversight.gov did not conclusively establish ineligibility; a lender's own website is not "news media"

U.S. ex rel. Relator, LLC v. Cardinalli
C.D. Cal., Feb. 9, 2026

- Same relator, PPP borrower defendant
- Case dismissed without leave to amend
- SBA data plus a 2019 news article substantially disclosed the fraud; relator not an original source

Trade & Customs

06

DOJ's Trade Enforcement Authority Has Grown More Complex

Fraud Division — Global Trade & Commerce Enforcement Section

- Illicit transshipment and country-of-origin fraud
- Undervaluation to evade duties
- Sanctions evasion
- Foreign forced-labor schemes
- Jurisdiction overlaps with the Criminal Division; co-signed the July 2026 DOJ-DHS Resource Guide

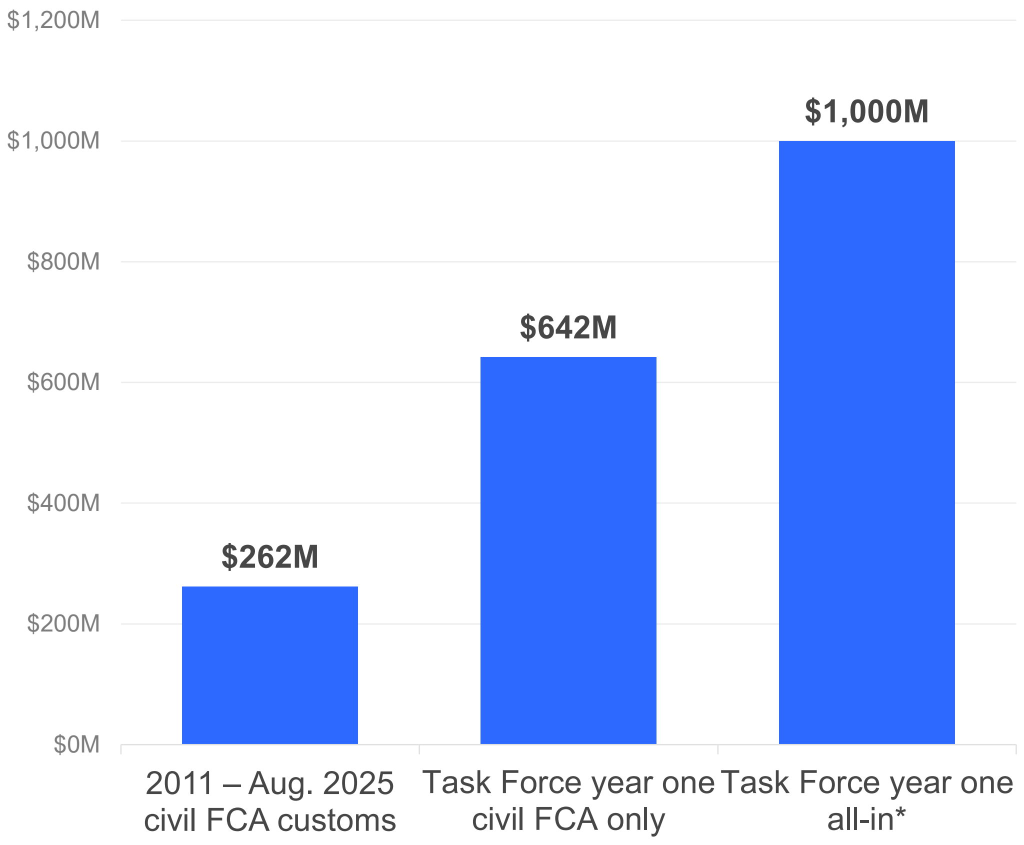
Criminal Division

- Continues to have jurisdiction over criminal trade fraud matters
- Overlapping jurisdiction with Fraud Division means two sets of prosecutors may evaluate the same conduct

Civil Division — Civil Fraud Section

- Civil FCA customs cases, including the reverse FCA duty theory
- Intervention decisions on relator-filed customs *qui tams*
- Civil Frauds' FCA resolutions expressly reserve criminal claims; with criminal enforcement authority now allocated to both the Fraud Division and the Criminal Division, parallel proceedings could become more complex

Year One of the Trade Fraud Task Force Has Yielded Significant Recoveries for DOJ



~$642M

Task Force civil FCA resolutions, Nov. 2025 – Sept. 2026 (six resolutions)

>$1B

DOJ's claimed all-in year-one figure: civil and criminal recoveries, penalties, forfeitures, and charged losses

~$550M

Largest customs FCA recovery ever (May 13) — alone more than double the prior fourteen years

Trade Resolutions Confirm Centrality of Evasion and Country-of-Origin Theories

$11.8M Nov. 2025
Audio-electronics company
- Alleged evasion of antidumping and countervailing duties
- First Task Force settlement

$54.4M Dec. 2025
Manufacturer
- Alleged misrepresentation of country of origin, misclassification, and failure to pay marking duties
- Largest customs settlement until May 2026

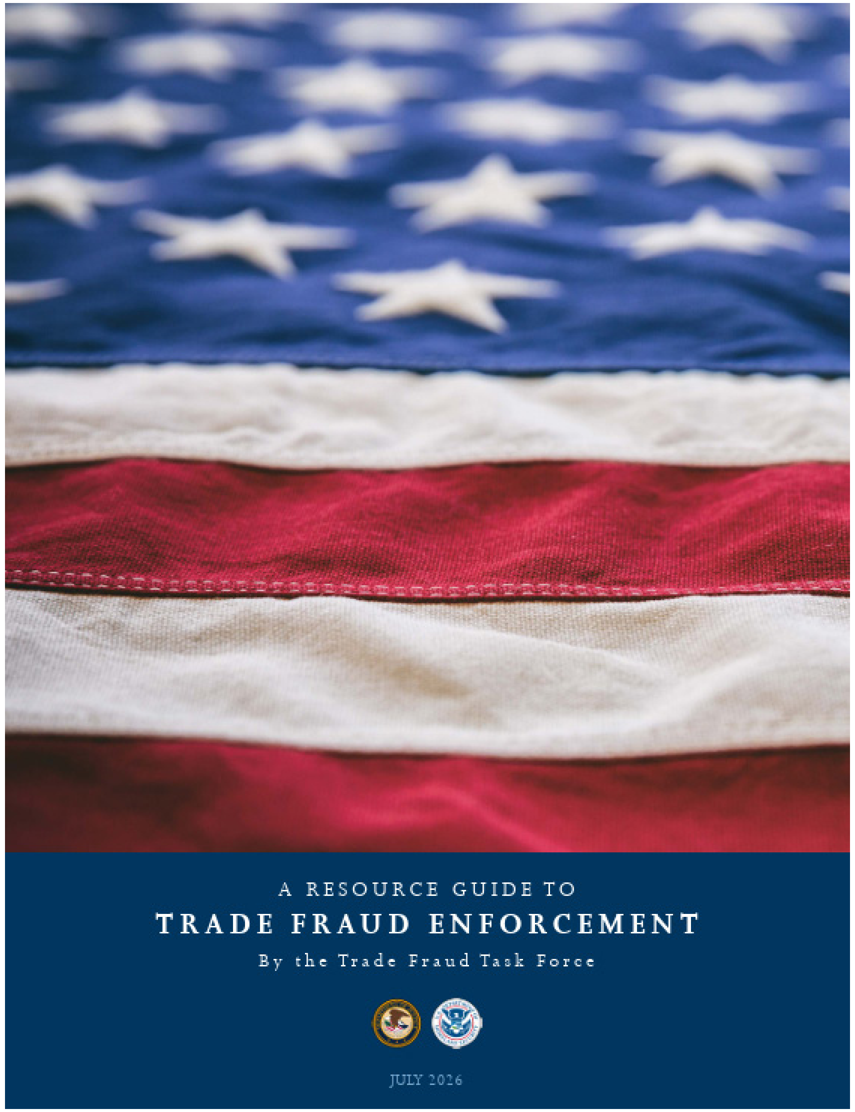
$2.1M April 2026
Fitness equipment company
- Alleged undervaluation of imported goods

~$550M May 2026
Aluminum importer and affiliated warehouses
- Alleged evasion of antidumping and countervailing duties
- Largest-ever customs FCA settlement

$19M May 2026
Steel distributors and two individuals
- Allegedly declared steel Canadian or U.S.-origin when made in China, Indonesia, Italy, Turkey, or Vietnam

$5.15M Sept. 2026
LED manufacturer's U.S. affiliate
- LEDs allegedly declared Taiwan-origin rather than China

DOJ-DHS Resource Guide (July 2026)



Upcoming October Programs

2026/2027 White Collar Webcast Series

Date and Time	Program	Registration Link
Thursday, October 8, 2026 10:00 AM – 11:00 AM PT 1:00 PM – 2:00 PM ET	**European Enforcement Update** Speakers: Benno Schwarz, Pierre-Emmanuel Fender, Katharina Humphrey, Oleh Vretsona, Finn Zeidler	Event Details
Tuesday, October 20, 2026 9:00 AM – 10:00 AM PT 12:00 PM – 1:00 PM ET	**Attorney-Client Privilege Best Practices** Speakers: Melissa Farrar, Diana Feinstein, George Hazel, Katharina Humphrey, Allan Neil	Event Details
Thursday, October 22, 2026 9:00 AM – 10:00 AM PT 12:00 PM – 1:00 PM ET	**Protecting Your Executives** Speakers: Douglas Fuchs, Barry Berke, Reed Brodsky, Sarah Eddy, Patrick Stokes	Event Details

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