



Key Takeaways from Recent DOJ Pronouncements

The Pharmaceutical Compliance Forum: West Coast Members

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June 26, 2025

DOJ Enforcement Priorities



Priorities Under the Trump Administration

1

Waste, Fraud, and Abuse: Including health care fraud and federal program and procurement fraud that harm public finances.

2

Trade and Customs Fraud: Including tariff evasion.

3

Fraud through VIEs: Including offering fraud, "ramp and dumps," elder fraud, securities fraud, and market manipulation schemes.

4

Fraud Victimized U.S. Investors: Including Ponzi schemes, investment fraud, elder fraud, servicemember fraud, and consumer health and safety threats.

5

National Security: Conduct threatening the U.S. financial system by gatekeepers, including sanctions violations and enabling transactions by cartels, TCOs, hostile nation-states, and terrorist orgs.

6

Material Support to Terrorist Organizations: Including recently designated cartels and TCOs.

7

Complex Money Laundering: Including activities by Chinese Money Laundering Organizations and laundering funds for illegal drug manufacturing.

8

Controlled Substances and FDCA: Unlawful manufacture and distribution of chemicals and equipment for counterfeit pills and unlawful opioid distribution by medical professionals and companies.

9

Bribery and Money Laundering: Impacting U.S. national interests, undermining national security, harming business competitiveness, and enriching foreign corrupt officials.

10

Digital Assets Crimes: Crimes victimizing investors and consumers, using digital assets for criminal conduct, and willful violations facilitating significant criminal activity.



DOJ Corporate Enforcement & Voluntary Disclosure Policies

Corporate Enforcement Policy Revisions (May 12, 2025)

Monitorships

Will not be imposed except for particularly egregious circumstances.

Declinations

Companies that voluntarily self-disclose and meet other criteria will receive a declination, not just a presumption of a declination

More Self-Disclosure Benefits

Provides enhanced “clarity and benefits for companies who in good faith self-disclose either not quickly enough or after—unbeknownst to them—the Department has already become aware of the misconduct.”

9-47.120 - Criminal Division Corporate Enforcement and Voluntary Self-Disclosure Policy

The Criminal Division Corporate Enforcement and Voluntary Self-Disclosure Policy (CEP) applies to all corporate criminal matters handled by the Criminal Division. All resolutions under this provision must be approved by the Assistant Attorney General for the Criminal Division or the individual serving in that capacity, in coordination with the Office of the Deputy Attorney General, as required by Justice Manual 1-14.000 and 9-28.000.

Part I. Declination Under the CEP

The Criminal Division is committed to transparently describing the benefits a company may earn through voluntarily self-disclosing misconduct, which can create important incentives for corporate behavior. The Criminal Division will decline to prosecute a company for criminal conduct when the following factors¹ are met:

1. The company voluntarily self-disclosed the misconduct to the Criminal Division;
2. The company fully cooperated with the Criminal Division's investigation;
3. The company timely and appropriately remediated the misconduct; and
4. There are no aggravating circumstances related to the nature and seriousness of the offense, egregiousness or pervasiveness of the misconduct within the company, severity of harm caused by the misconduct, or criminal adjudication or resolution within the last five years based on similar misconduct by the entity engaged in the current misconduct.

If there are aggravating circumstances, prosecutors retain the discretion to nonetheless recommend a CEP declination based on weighing the severity of those circumstances and the company's cooperation and remediation. As part of the CEP declination, the company will be required to pay all disgorgement/forfeiture as well as restitution/victim compensation payments resulting from the misconduct at issue.² All declinations under the CEP will be made public.

Part II. “Near Miss” Voluntary Self-Disclosures or Aggravating Factors Warranting Resolution

If a company fully cooperated and timely and appropriately remediated but it is ineligible for a declination under Part I of this policy solely because (1) it acted in good faith by self-reporting the misconduct but that self-report did not qualify as a voluntary self-disclosure, as defined in Appendix B, or (2) it had aggravating factors that warrant a criminal resolution, the Criminal Division shall:

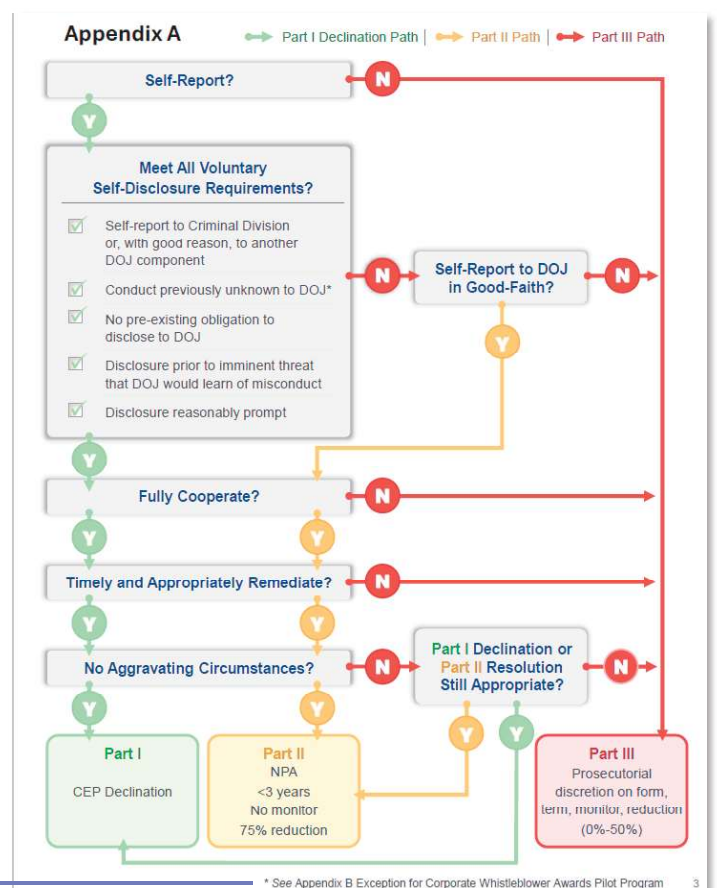
1. Provide an NPA—absent particularly egregious or multiple aggravating circumstances;
2. Allow a term length of fewer than three years;

¹ Factors one through three are defined in Appendix B.

² See also Coordination of Corporate Resolution Penalties in Parallel and/or Joint Investigations and Proceedings Arising from the Same Misconduct, Justice Manual 1-12.100.

Corporate Enforcement Policy Revisions (May 12, 2025)

Corporate Whistleblower Awards Pilot Program Exception: If a whistleblower makes both an internal report to a company and a whistleblower submission to the Department, the company will still qualify for a presumption of a declination under the CEP—even if the whistleblower submits to the Department before the company self-discloses—provided that the company: (1) self-reports the conduct to the Department within 120 days after receiving the whistleblower’s internal report; and (2) meets the other requirements for voluntary self-disclosure and presumption of a declination under the policy.



Corporate Whistleblower Awards Revisions (May 12, 2025)

Department of Justice Corporate Whistleblower Awards Pilot Program¹

Issued: August 1, 2024
Revised: May 12, 2025

I. Introduction

The U.S. Department of Justice (Department) is dedicated to vigorously investigating and prosecuting federal criminal offenses, including corporate crime. Along with the Department's effective False Claims Act *qui tam* program, which incentivizes whistleblowers to report fraud in government programs, the Securities and Exchange Commission, the Commodity Futures Trading Commission, and the Financial Crimes Enforcement Network have also established successful whistleblower programs. The Department has long used information from whistleblowers eligible for awards from the Department's *qui tam* program and other agencies' whistleblower programs to successfully uncover corporate criminal schemes, advance criminal investigations, and prosecute the most culpable individuals and entities. However, other agencies' whistleblower programs do not cover the full scope of corporate crime the Department investigates and prosecutes, leaving gaps that the Department now seeks to fill.

The potential for an award may incentivize those with information about corporate criminal wrongdoing to report original information about criminal conduct that might otherwise go undetected or be difficult to prove. Providing individuals with incentives to report corporate crime may also motivate corporations to create more robust compliance programs that detect and deter criminal conduct, including by encouraging internal reporting of complaints. Strong compliance programs can prevent, identify, and remediate misconduct before it begins or expands, and enable companies to report misconduct to the Department when it occurs.

In addition, the effective use of criminal and civil asset forfeiture is an essential component of the Department's efforts to combat the most sophisticated criminal actors and organizations, including those engaged in corporate crime. Forfeiture plays a critical role in depriving criminals of the proceeds of illegal activity, deterring crime, and restoring assets to victims. Encouraging whistleblowers to come forward with tips that lead to asset forfeiture supports the Department's goal of using asset forfeiture to the fullest extent possible to investigate, identify, seize, and forfeit the assets of criminals and their organizations.

The Attorney General is authorized to pay "awards for information or assistance leading to a civil or criminal forfeiture." See 28 U.S.C. § 524(c). This document sets forth criteria that individuals must meet in order to qualify for payment of an award in the Department's discretion as part of the Department's Corporate Whistleblower Awards Pilot Program (Corporate Whistleblower Awards Pilot Program or Pilot Program).

¹ This memorandum is for internal use only and does not create or confer any privileges, benefits, or rights, substantive or procedural, enforceable by any individual, organization, party, or witness in any administrative, civil, or criminal matter.

Revisions added six new covered subject matter areas as follows:

- Corporate procurement fraud
- Trade, tariff, and customs fraud by corporations
- Corporate sanctions offenses
- Violations by corporations of federal immigration law
- Violations by corporations involving material support of terrorism.
- Violations by corporations related to international cartels or transnational criminal organizations, including money laundering, narcotics, Controlled Substances Act, and other violations

Selection of Monitors Revisions (May 12, 2025)

Factors that prosecutors must consider when determining whether a monitor is appropriate and how those factors should be applied:

- Risk of recurrence of criminal conduct that significantly impacts U.S. interests
- Availability and efficacy of other independent government oversight
- Efficacy of the compliance program and culture of compliance at the time of the resolution
- Maturity of the company's controls and its ability to independently test and update its program

Appropriately tailor and scope the monitor's review and mandate to address the risk of recurrence of the underlying criminal conduct and to reduce unnecessary costs.

- Costs proportionate to:
 - the severity of the underlying criminal conduct and the fine and forfeiture imposed
 - the profits of the relevant corporate entity involved
 - the company's present size and risk profile
- Biannual tri-partite meetings between the company, monitor, and government that require the monitor to clearly state its expectations and goals for the company to prevent monitor overreach
- Collaborative dialogue about the monitor's proposed actions and recommendations

FCPA Enforcement Under Trump 2.0: *Day One Memos*



Office of the Attorney General
Washington, D. C. 20530

February 5, 2025

MEMORANDUM FOR ALL DEPARTMENT EMPLOYEES

FROM: THE ATTORNEY GENERAL 

SUBJECT: TOTAL ELIMINATION OF CARTELS AND TRANSNATIONAL CRIMINAL ORGANIZATIONS¹

On January 20, 2025, President Trump directed the federal government to revise existing national security and counter-narcotics strategies to pursue *total elimination* of Cartels and Transnational Criminal Organizations (TCOs). This policy requires a fundamental change in mindset and approach. We must do more than try to mitigate the enormous harms these groups cause in America. It is not enough to stem the tide of deadly poisons, such as fentanyl, that these groups distribute in our homeland. Rather, we must harness the resources of the Department of Justice and empower federal prosecutors throughout the country to work urgently with the Department of Homeland Security and other parts of the government toward the goal of eliminating these threats to U.S. sovereignty. This memorandum sets forth directives and initiatives to promptly commence those efforts.

I. Charging Priorities

Achieving total elimination of Cartels and TCOs will require additional resources and thoughtful charging decisions by federal prosecutors based on coordination with law enforcement partners.

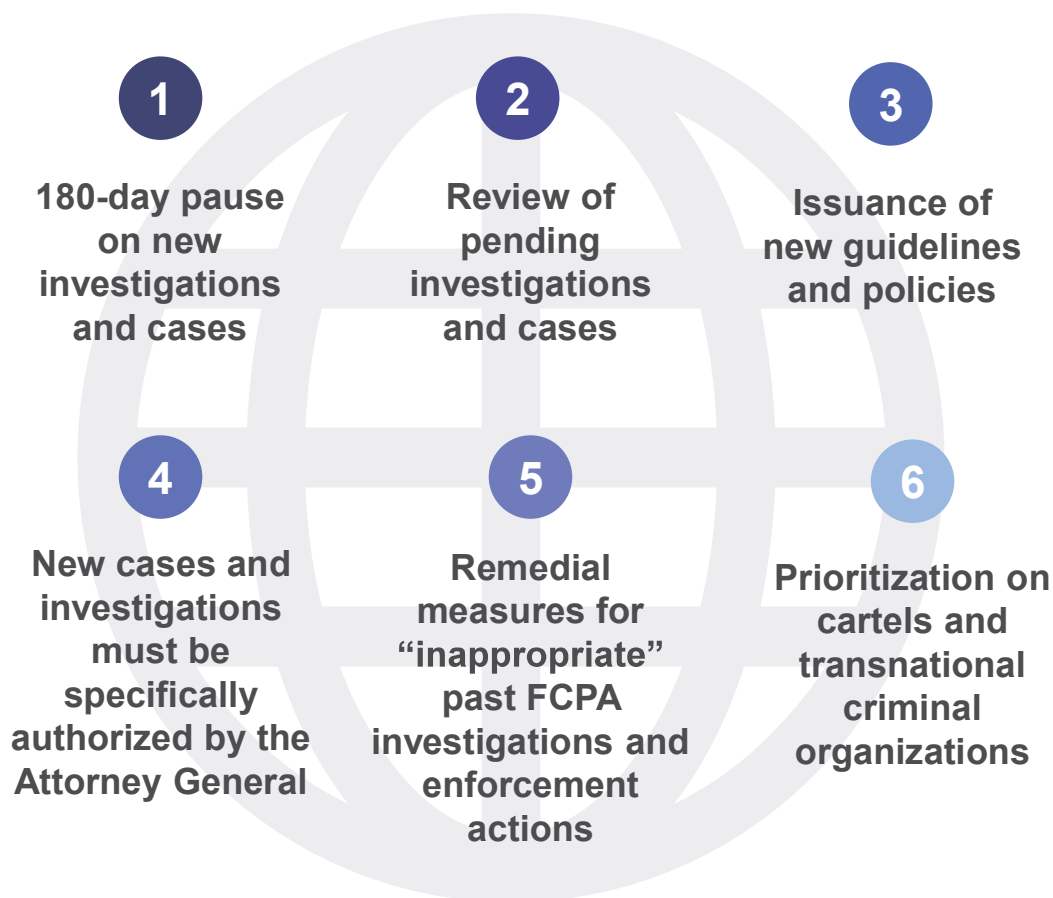
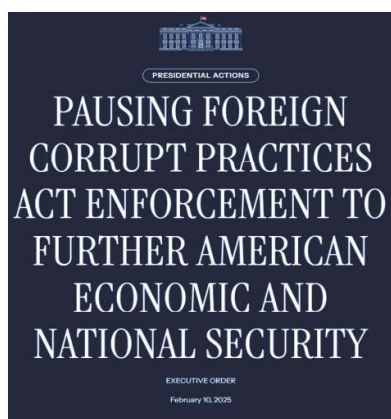
For leaders and managers of Cartels and TCOs, the most serious, readily provable offenses under the Department's general charging policy will typically include capital crimes, terrorism charges, racketeering charges, Continuing Criminal Enterprise offenses under 21 U.S.C. § 848, violations of the Foreign Narcotics Kingpin Designation Act under 21 U.S.C. § 1906, violations of the International Emergency Economic Powers Act under 50 U.S.C. § 1705 (IEEPA), and machinegun charges under 18 U.S.C. §§ 924(c)(1)(B)(ii) and 924(o).

¹ This guidance is not intended to, does not, and may not be relied upon to create, any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

Foreign Corrupt Practices Act. The Criminal Division's Foreign Corrupt Practices Act Unit shall prioritize investigations related to foreign bribery that facilitates the criminal operations of Cartels and TCOs, and shift focus away from investigations and cases that do not involve such a connection. Examples of such cases include bribery of foreign officials to facilitate human smuggling and the trafficking of narcotics and firearms.

The requirements in Justice Manual § 9-47.110 requiring authorization by the Criminal Division for an investigation or prosecution of a case under the Foreign Corrupt Practices Act and Foreign Extortion Prevention Act, as well as the requirement that such investigations and prosecutions be conducted by trial attorneys of the Fraud Section, are suspended for all matters relating to foreign bribery associated with Cartels and TCOs. U.S. Attorney's Offices shall provide the Foreign Corrupt Practices Act Unit with 24 hours' advance notice of the intention to seek charges and make available to the Unit upon request any existing memoranda relating to the contemplated charges. No new or additional paperwork will be required by the Foreign Corrupt Practices Act Unit in connection with these notices and consultations.

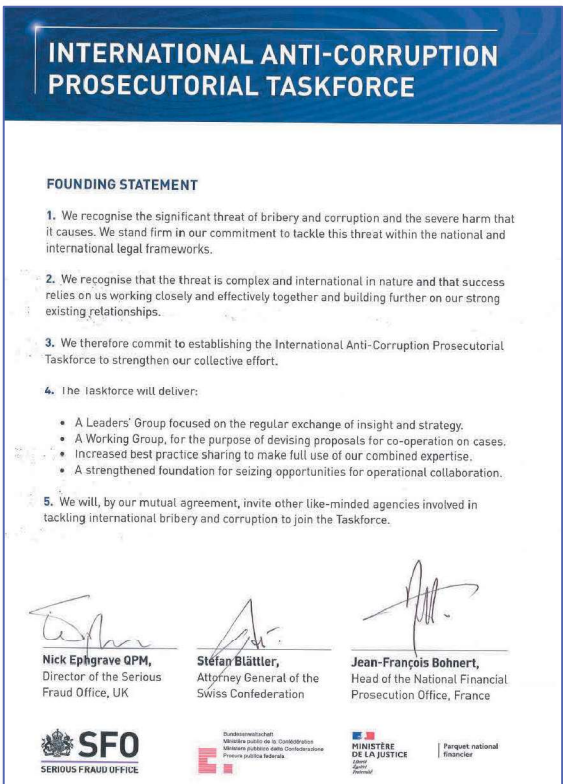
FCPA Enforcement Under Trump 2.0: *Key EO Takeaways*



Global Enforcement: *Non-U.S. Agencies Respond*

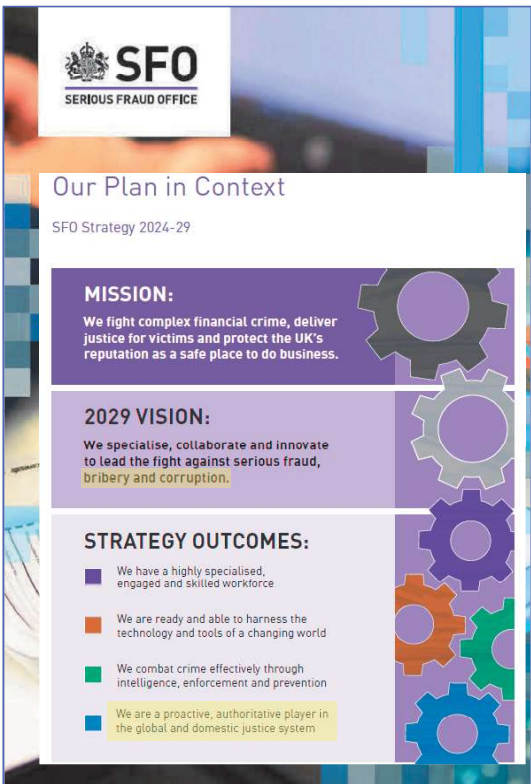
(March 20, 2025)

UK, Switzerland, and France form
Joint Anti-Corruption Task Force

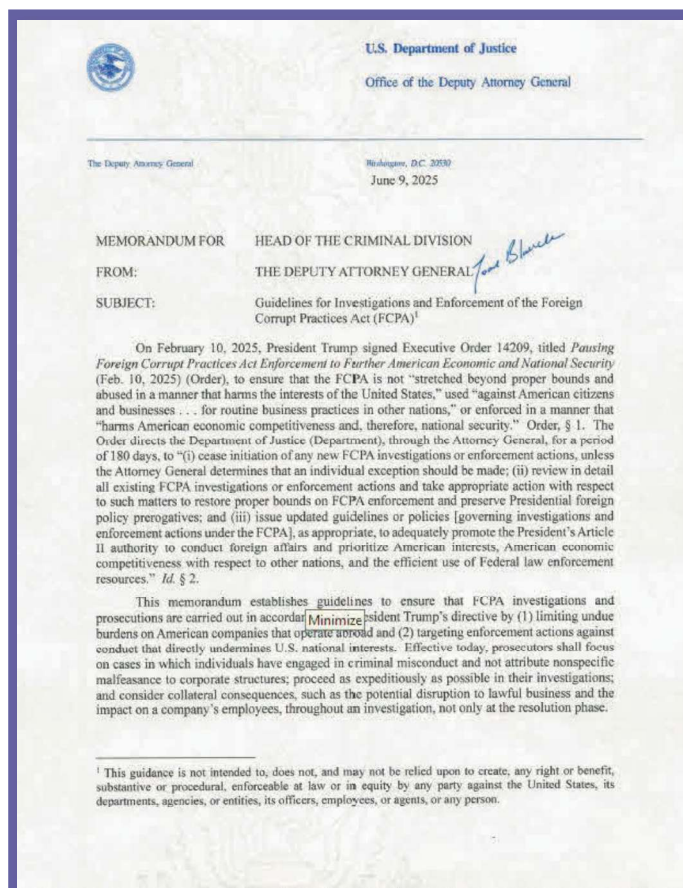


(April 3, 2025)

UK Reaffirms Commitment to
Combat Bribery Globally



FCPA Enforcement: *Guidelines for Investigations and Enforcement of the FCPA (June 9, 2025)*



Key Takeaways:

Goal of the memo is to ensure FCPA investigations and prosecutions:

- Limit undue burdens on American companies that operate abroad
- Target enforcement actions against conduct that directly undermines U.S. national interests

The memo instructs prosecutors to:

- Focus on cases where individuals have engaged in misconduct, as opposed to attributing malfeasance to corporate structures
- Proceed as expeditiously as possible
- Consider collateral consequences, such as business disruptions and impact on employees throughout the entirety of the investigation

Outlines that “the initiation of all new FCPA investigations or enforcement actions **must be authorized by the Assistant Attorney General for the Criminal Division** (or the official acting in that capacity) or a more senior Department official.”

FCPA Enforcement: *Guidelines for Investigations and Enforcement of the FCPA (June 9, 2025)*

FCPA investigations and prosecutions will center on misconduct that:

Is associated with the criminal operations of a Cartel or Transnational Criminal Organization

- Pursuing money launderers or shell companies that have laundered on behalf of Cartels or TCOs
- Focus on employees of state-owned entities or other foreign officials who have received bribes from Cartels or TCOs

Deprived specific and identifiable U.S. entities of fair access to compete

- Will not be focused on nationality of particular individuals or companies
- Prioritizing misconduct that undermined the principle of fair access to compete and/or resulted in economic injury to specific and identifiable American companies or individuals
- FEPA cases should consider whether similar harm has been inflicted by foreign officials

Involves key infrastructure or assets

- Key sectors are outlined as defense, intelligence, or critical infrastructure

Bears strong indicia of corrupt intent tied to particular individuals and serious misconduct

- Focus on, “substantial bribe payments, proven and sophisticated efforts to conceal bribe payments, fraudulent conduct in furtherance of the bribery scheme, and efforts to obstruct justice”
- Will not penalize U.S. citizens or businesses for “routine business practices in other nations” or “corporate conduct that involves de minimis or low-dollar, generally accepted business courtesies”



False Claims Act Updates



False Claims Act Settlements & Judgments

Last year, the DOJ obtained over \$2.9 billion in FCA settlements and judgments from civil cases involving fraud and false claims against the Government.



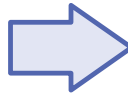
\$1.67 billion involved health care fraud.



False Claims Act

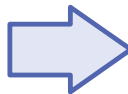
Creates liability against any person who

- Knowingly
 - Actual Knowledge
 - Reckless Disregard
 - Deliberate Indifference
- Submits
- False Claim
- Materiality



Implied Certification Doctrine

Requesting payment from the government without disclosing a known material breach can violate the FCA



Reverse False Claim

Failure to Return Overpayments or Failure to Pay Obligation (tariffs)

Whistleblower Provisions & *Qui Tam* Relators

Allow private persons to sue on behalf of the Government

Known as “*qui tam*” actions, where the plaintiff is a “relator”

Relators are generally entitled to a portion of any recovery, as well as legal fees and expenses

***Qui tam* actions are filed under seal and trigger a Government investigation**

Government may either:

Intervene in the action
(i.e., take over the case)

Decline to intervene
(relator may proceed on their own)

Government intervention can increase the likelihood of the court finding liability

Anti-Kickback Statute (AKS)

AKS Overview

- AKS makes it a criminal offense to “knowingly and willfully offer, pay, solicit, or receive any remuneration to induce or reward referrals of items or services reimbursable by a federal healthcare program.”
- “Remuneration” includes the transfer of anything of value, directly or indirectly, in cash or in kind.
- No actual knowledge of the AKS or specific intent required.

A claim that results from a kickback under the AKS is a fraudulent claim under the False Claims Act



State law corollaries to AKS should also be considered



Potential penalties include fines, jail terms, and exclusion from participation in federal healthcare programs

Expectations for Anti-Kickback Investigations

Sham agreements: little or no work required for compensation

- Speaking arrangements
- Continuing education programs
- Research

Lavish gifts: “lavish” just isn’t what it used to be

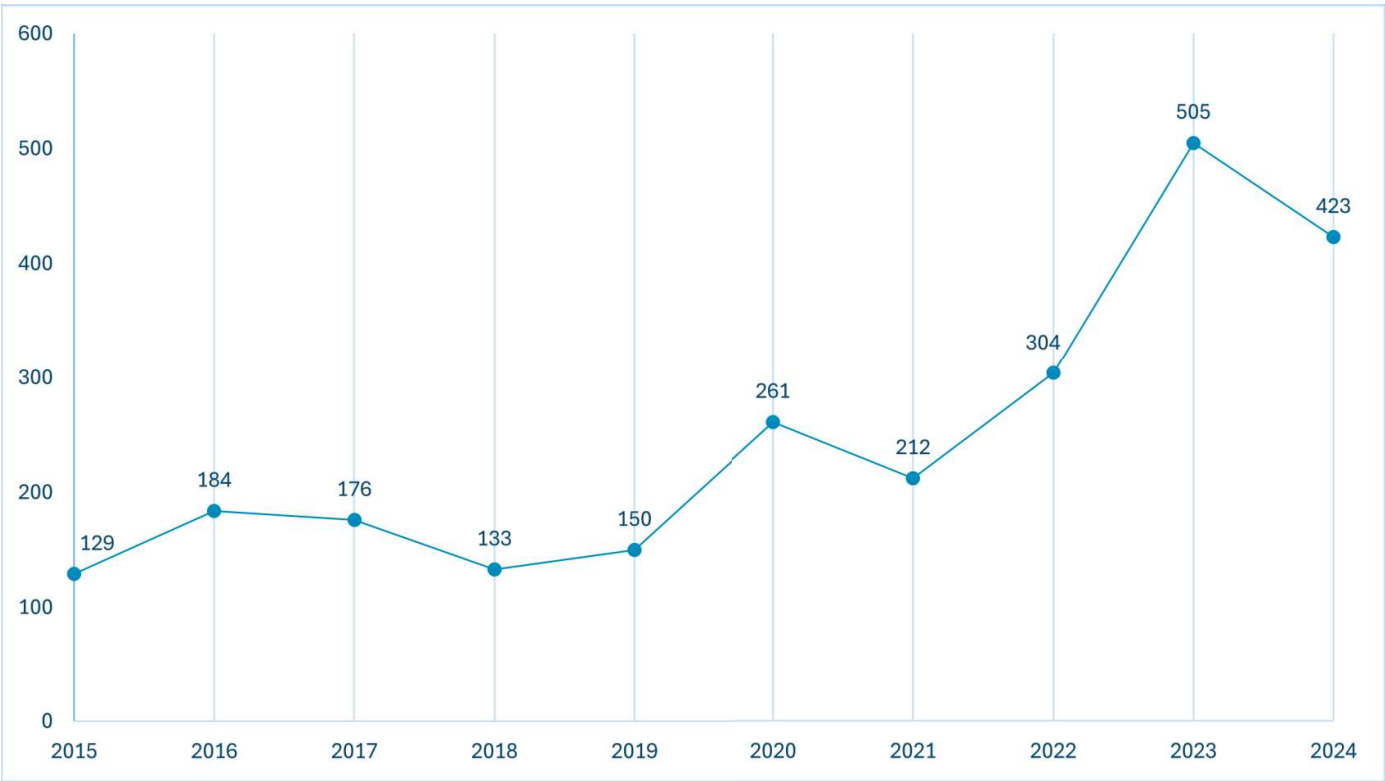
- Meals
- Alcohol
- Sporting events

Commission arrangements with third-party marketers

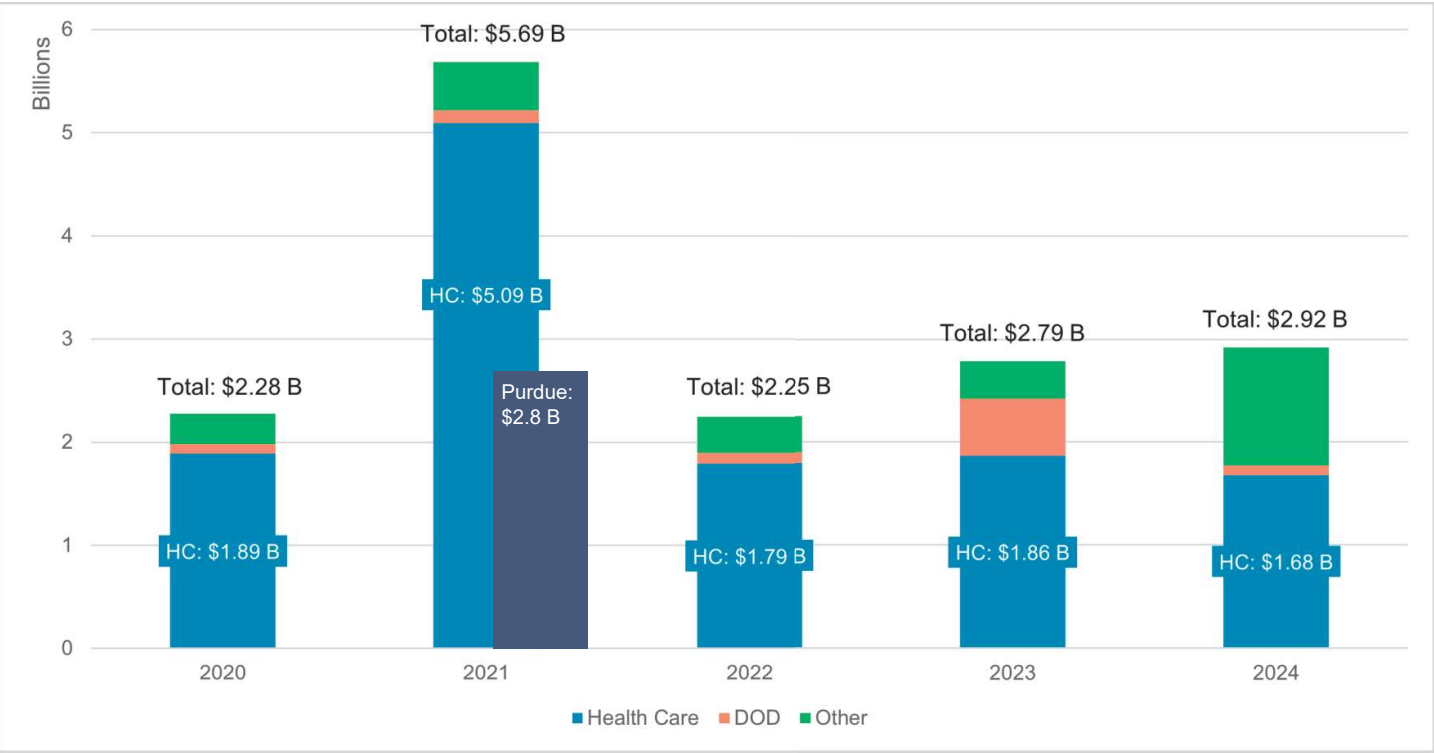
New Qui Tam Filings



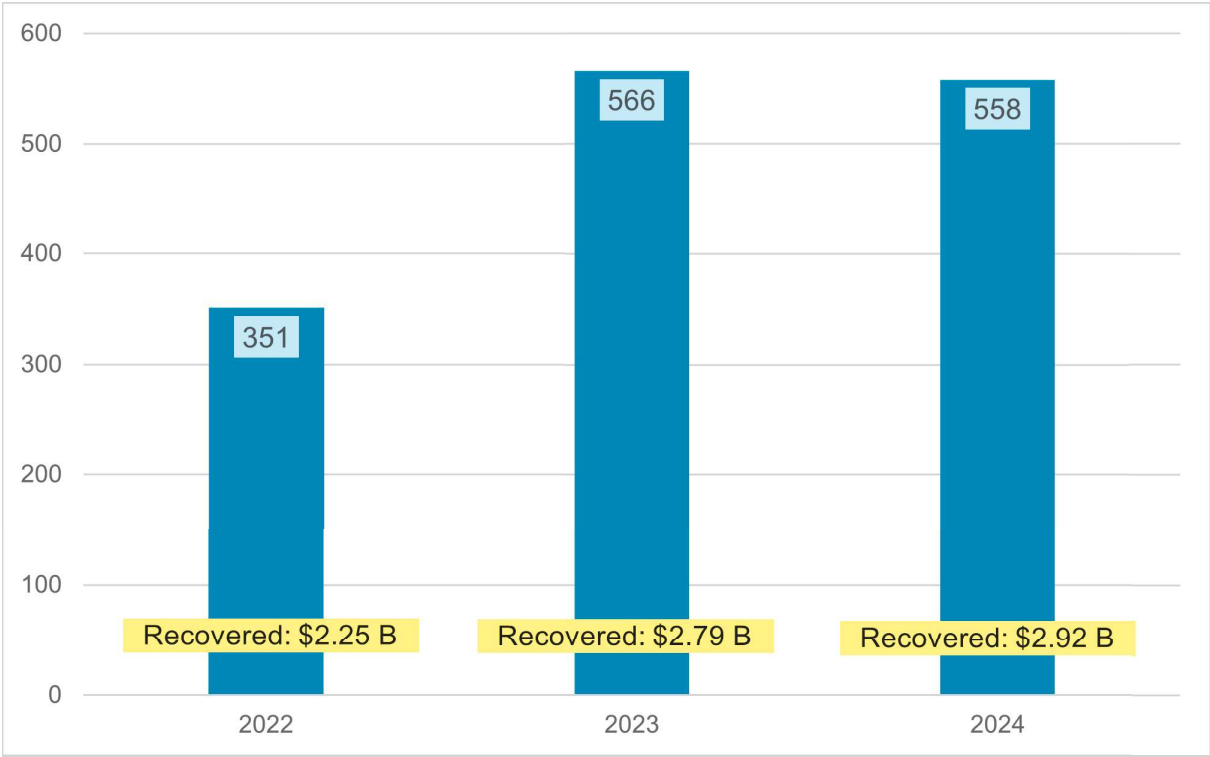
DOJ Initiated FCA Matters



Total Recovery



Settlements and Judgments





FCA Case Study



Case Study: Constitutionality of FCA's Qui Tam Provisions



Zafirov ex rel. United States v. Florida Medical Associates, LLC (Sept. 30, 2024)

- Judge Kathryn Mizelle of the U.S. District Court of the Middle District of Florida held that FCA's qui tam procedures violate Article II's Appointments Clause by permitting "unaccountable, unsworn, private actors to exercise core executive power with substantial consequences to members of the public."
- Judge Mizelle found that the FCA's qui tam procedures improperly give a private party—the relator—authority to control litigation on behalf of the United States, a responsibility that the Constitution exclusively vests in the Executive Branch.
- Relators have unfettered discretion to decide whom to investigate, whom to charge in the complaint, which claims to pursue, and which legal theories to employ—until DOJ intervenes, if it ever does. Furthermore, a relator decides whether to appeal and which arguments to preserve, thereby shaping the broader legal landscape for the federal government.

Case Study: Constitutionality of FCA's Qui Tam Provisions



Zafirov ex rel. United States v. Florida Medical Associates, LLC (11th Cir.)

- The U.S. & Zafirov have filed briefs with the Eleventh Circuit urging reversal of the district court decision.
- While some circuit courts, like the Ninth, have already addressed this argument, there are a number that have not resolved FCA Article II challenges, including the First, Second, Third, Fourth, Seventh, Eleventh, and D.C. Circuits.
- Justice Thomas, joined by a Kavanaugh and Barrett concurrence, dissented in *United States ex rel. Polansky v. Executive Health Resources, Inc.*, 599 U.S. 419 (2023) (“Polansky”), suggesting that the FCA’s qui tam procedures violate Article II of the Constitution.

DOJ's Main Areas of Focus under the FCA





AKS & Sponsored Genetic Testing



Sponsored Genetic Testing Programs – AO 22-06

In April 2022, HHS-OIG issued Advisory Opinion 22-06 (AO 22-06) and for the first time weighed in on the legality of sponsored genetic testing.

The arrangement addressed in AO 22-06 involved a biopharmaceutical company that offered free genetic tests that screen for a gene mutation associated with a heart disorder for which they manufacture drugs.

The advisory opinion was favorable, finding this arrangement would generate prohibited remuneration that may induce patients to purchase (or healthcare providers to prescribe) the requestor's drug. However, the arrangement posed a sufficiently low risk of fraud and abuse because:



Several features of the arrangement to provide free genetic testing and counseling made it unlikely to lead to overutilization;



The arrangement is unlikely to skew clinical decision-making; and



Safeguards in place to prevent use of the arrangement as a marketing or sales tool.

Sponsored Genetic Testing Programs – AO 24-12

In December 2024, HHS-OIG issued AO 24-12. The requestor manufactures a drug for an ultra-rare genetic kidney condition and has an arrangement with a genetic-testing lab to offer free genetic testing, genetic counseling, and disease-awareness education. The requestor covers the full cost of these services, without requiring prescription or recommendation of its products.

The advisory opinion was favorable, finding this arrangement would generate prohibited remuneration that may induce patients to purchase (or healthcare providers to prescribe) the requestor's drug. However, the arrangement posed a sufficiently low risk of fraud and abuse because:



Several features of the arrangement to provide free genetic testing and counseling made it unlikely to lead to overutilization;



The arrangement is unlikely to skew clinical decision-making; and



Safeguards in place to prevent use of the arrangement as a marketing or sales tool.

Sponsored Genetic Testing Programs – Compliance

The following recommendations are drawn from aspects of these genetic-testing programs that HHS-OIG credited as lessening the risk of fraud and improper inducements:

Programs should be designed to minimize the risk of overutilization or improper utilization of genetic testing by patients. This may include:

Genetic-testing results that indicate only whether a patient carries a genetic mutation, which does not in and of itself determine whether the patient has or will develop the disease and thus whether the patient may be prescribed a certain drug.

Testing results narrowly tailored to rule out a condition rather than diagnose one.

Programs should be designed to avoid the possibility of skewing or influencing healthcare providers' clinical decision-making. This may include:

Providers ordering tests that are not required or recommended to prescribe or administer any products manufactured by the test sponsor.

Distribution of materials or testing kits are not tied to a provider's use of the arrangement or history of prescribing medications or other therapies.

Sponsored Genetic Testing Programs – Compliance

The following recommendations are drawn from aspects of these genetic-testing programs that HHS-OIG credited as lessening the risk of fraud and improper inducements:

Programs should be designed to minimize the risk of fraud, especially in terms of the payment structure for these tests and prohibiting the use of this arrangement as a marketing or sales tool. This may include the following:

Test sponsors do not receive any individually identifiable patient information, including information identifying the healthcare professional ordering the test, enabling it to target marketing of the drug.

The company's sales force is prohibited from accessing any data received from the third-party vendors to use for sales or marketing activities.

The company is prohibited from soliciting information from providers about whether they have ordered any genetic tests.



Trump Administration Focus on Tariffs & Customs Avoidance

Tariffs & Customs Avoidance



America First Trade Policy Memorandum address 3 areas:

- Unfair trade practices by other countries;
- Trade relations with China; and
- Additional economic security matters.

DOJ Enforcement of Trade Violations

Misrepresenting Country of Origin

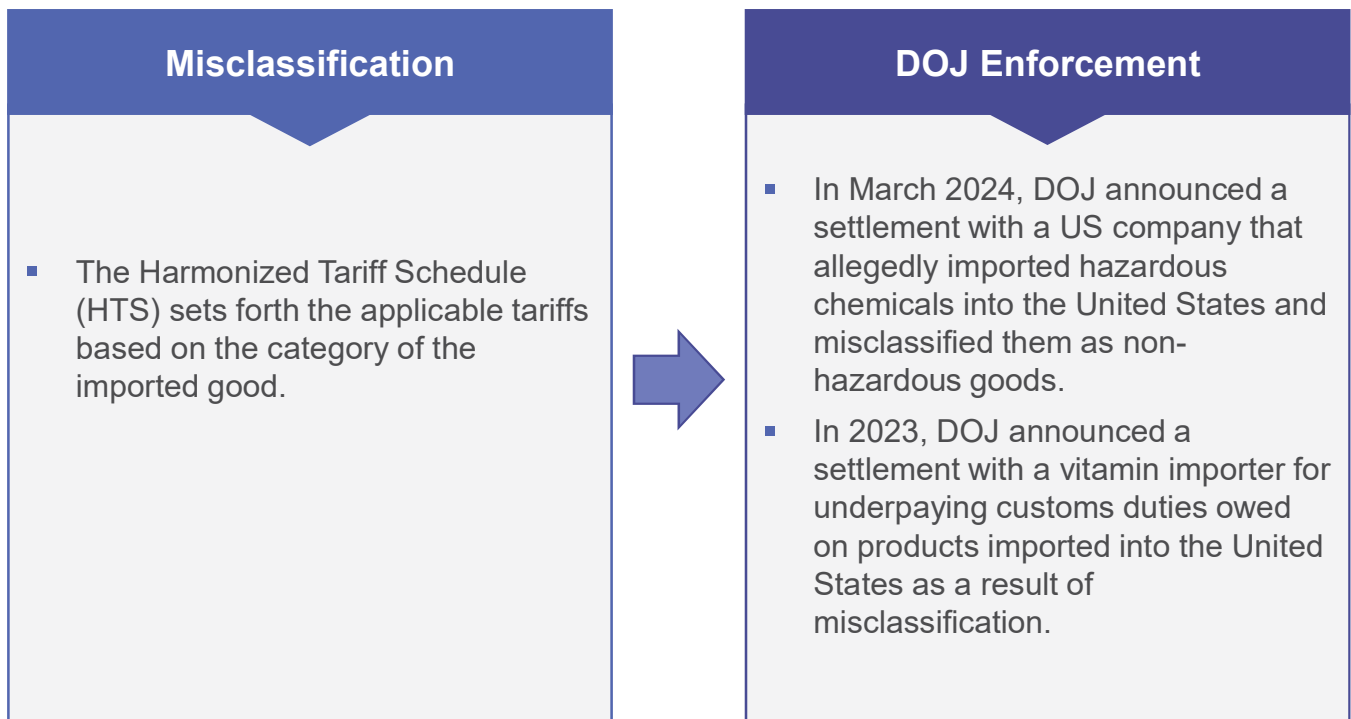
- CFR defines “country of origin” as the country of manufacture, production, or growth of any article of foreign origin entering the United States or where it underwent “substantial transformation” into the final product being imported.
- Importers of goods may falsify the stated origin of goods on customs entry documents, invoices, or product labels.
- Importers may also seek to avoid paying higher tariffs through transshipment whereby a company will route a product through a lower-tariff country and perform some minor repackaging or processing before final export to the United States.



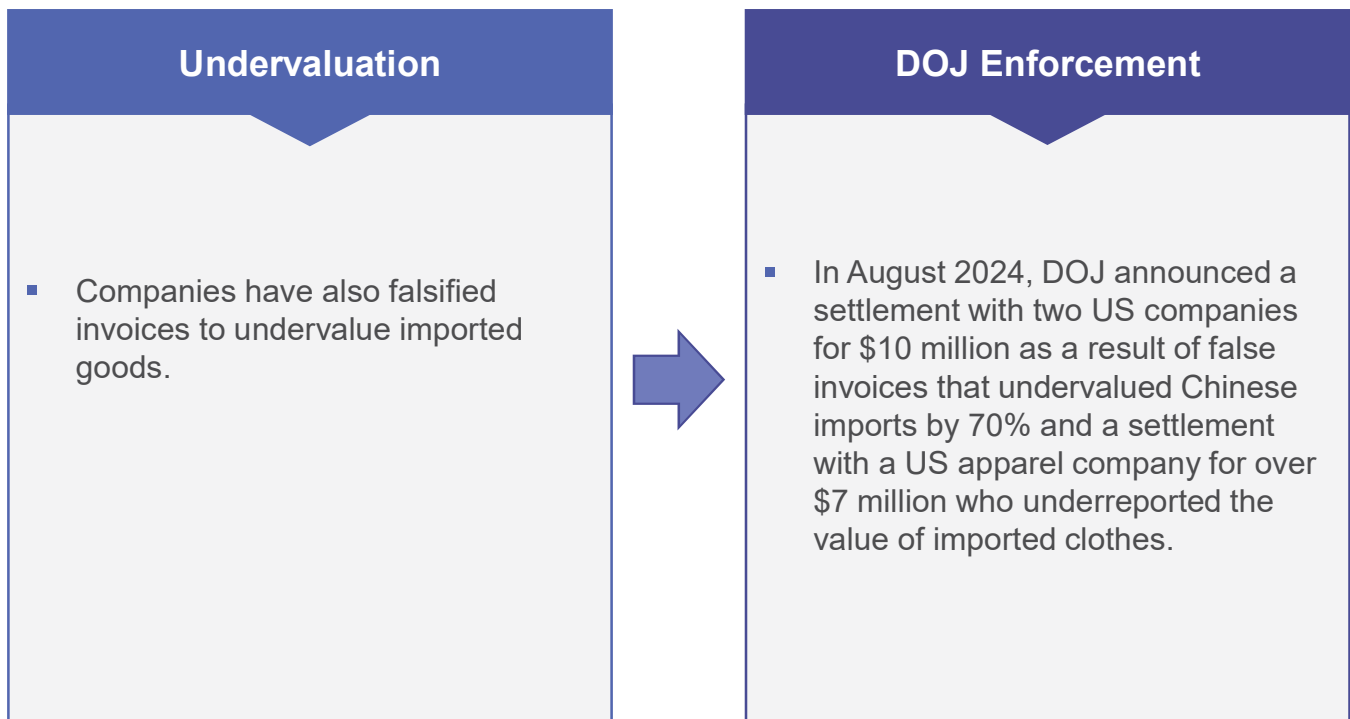
DOJ Enforcement

- March 25, 2025 DOJ settlement for \$8.1 million with a company alleged to have caused false information to be submitted to CBP regarding the identity of the manufacturers and the country of origin of wood flooring imported from China.

DOJ Enforcement of Trade Violations



DOJ Enforcement of Trade Violations



Tariff/Customs Compliance

Steps to Consider:

- 1 Review All Contracts:** Determine where tariff vulnerabilities exist and look for ways to gain tariff-related flexibility
- 2 Risk Minimization:** Review customs compliance to ensure not underpaying customs tariffs. This includes examination of “country of origin,” USMCA compliance, classification, valuation
- 3 Post-Entry Checks and Filing Post-Summary Corrections (PSC):** No penalty for filing PSCs.
- 4 Reasonable Care Memorandum:** Most common requests include review of classification status
- 5 Minimize Supply Chain Risks:** Understand supply chain, ensure compliance, review flow-down conditions



Cybersecurity

Cybersecurity Initiative

In October 2021, DOJ announced it would hold accountable entities and individuals who knowingly:

- Provide deficient cybersecurity products or services;
- Misrepresent their cybersecurity practices or protocols; or
- Fail to monitor and report cybersecurity incidents or breaches

Examples of recent cyber-fraud settlements:

- Feb. 18, 2025 DOJ announced \$11.25 million settlement with Health Net and its parent Centene Corp. to resolve allegations falsely certified compliance with cybersecurity requirements under a Department of Defense TRICARE contract. Health Net did not comply with these requirements, falsely certified compliance in annual certifications, and ignored reports from auditors about cybersecurity risks on its systems and networks.
- March 26, 2025 DOJ announced \$4.6 million settlement with MORSECORP Inc. to resolve allegations that it allegedly used a third party to host emails without requiring and ensuring that such third party met appropriate security requirements, failed to implement all cybersecurity controls in National Institute of Standards and Technology (NIST) Special Publication (SP) 800-171, failed to have a written plan for each of its covered information systems, and failed to correct its reported NIST SP 800-171 score.
- August 22, 2024 DOJ intervened in an FCA action against Georgia Tech asserting claims that a Lab failed to develop a required system security plan and failed to use antivirus tools, and that the university submitted a false assessment of its cybersecurity compliance to DoD.
- March 14, 2023 DOJ announced \$300,000 settlement with Jelly Bean Communications Design for failure to protect data on a federally funded child health insurance website that led to exposure of 500,000 applicants after a cyber-attack

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Adam represents companies and their executives in internal and government investigations, white collar criminal defense matters, and parallel civil litigation related to allegations of bribery, government procurement fraud, COVID-19 and CARES Act fraud, anti-money laundering violations, and matters involving organized crime. He has particular experience representing individuals and government contractors in internal and government-facing investigations related to allegations of False Claims Act (FCA) violations, procurement fraud, and bribery, among other issues.

Before joining MoFo, Adam spent 13 years at the U.S. Department of Justice (DOJ) where he served in senior level leadership positions in multiple administrations. As Associate Deputy Attorney General, he advised the Deputy Attorney General on litigation and policy matters and was designated to coordinate DOJ's efforts to investigate and prosecute fraud in connection with COVID-19 and CARES Act relief funds.



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