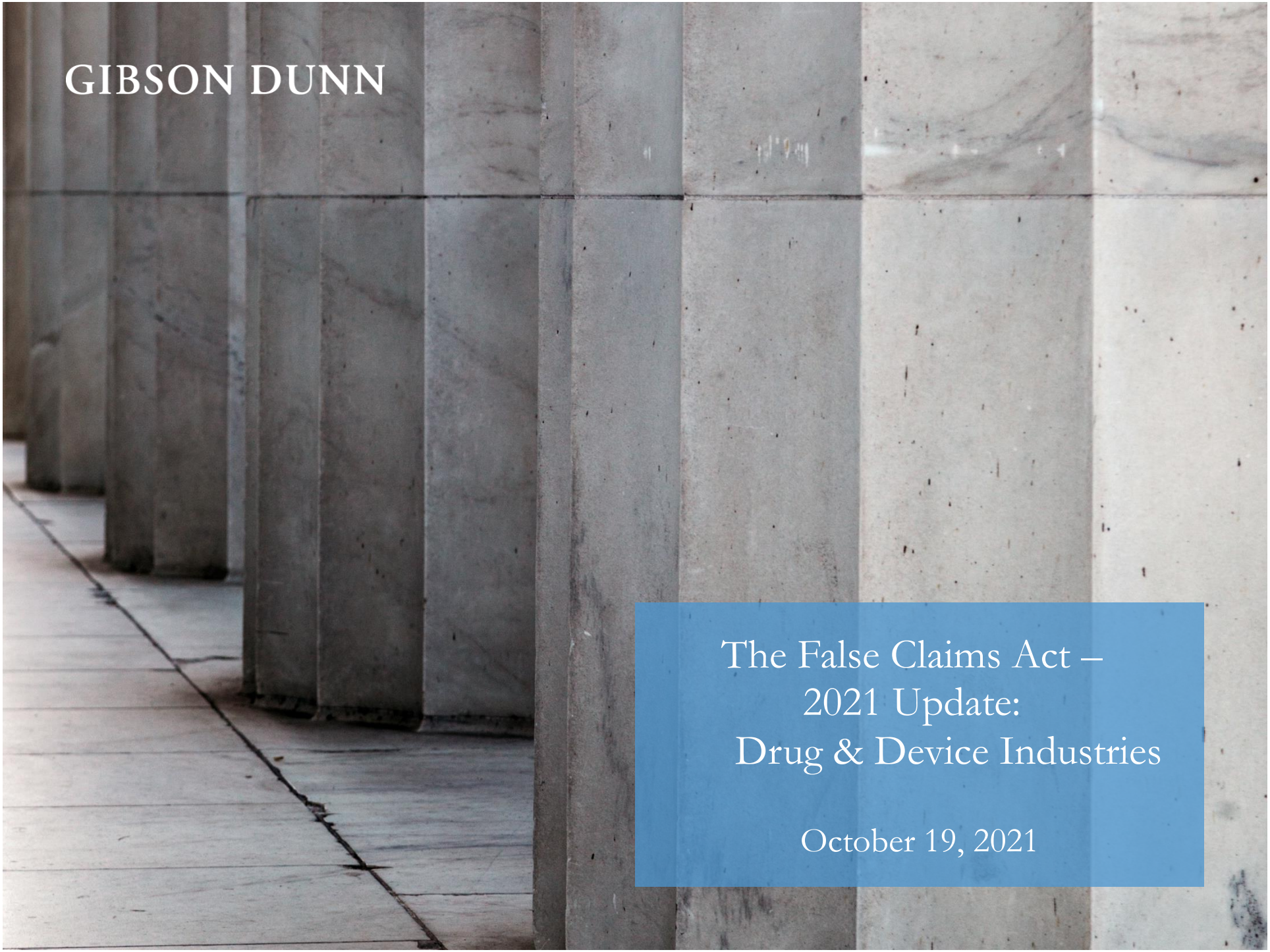

The False Claims Act – 2021 Update: Drug & Device Industries

October 19, 2021

Panelists

Winston Chan is a former federal prosecutor and litigation partner in Gibson Dunn's San Francisco office. He has particular expertise leading matters involving government enforcement defense, internal investigations, compliance counseling, and civil trial litigation for life sciences clients. Mr. Chan is an LMG Life Sciences "Star" and a Chambers-ranked attorney in the category of White Collar Crime and Government Investigations.

Marian Lee is a partner in Gibson Dunn's Washington, D.C. office and Co-Chair of the FDA & Health Care Practice. She has significant experience advising clients on strategic FDA regulatory and compliance matters, risk management, and enforcement actions. She regularly counsels companies during FDA inspections and investigations, and she has led an array of FDA legal assessments for corporate transactions.

John Partridge is a partner in Gibson Dunn's Denver office and Co-Chair of the FDA & Health Care Practice. He has particular experience defending pharmaceutical, medical device, diagnostic, and dietary supplement companies in investigations and litigation involving the federal Anti-Kickback Statute, the FCA, the Federal Food, Drug, and Cosmetic Act, the FCPA, and related state and federal laws.

Brendan Stewart is of counsel in Gibson Dunn's New York office. As a former federal prosecutor, his practice focuses on health care enforcement, compliance, and litigation, as well as other white collar enforcement matters and related litigation. He previously served as an Assistant Chief in the Fraud Section of the U.S. Department of Justice's Criminal Division, where he oversaw a unit of health care fraud prosecutors in the Eastern District of New York from 2017 to 2021.

MCLE Certificate Information

- Most participants should receive their certificate of attendance about eight weeks after the webcast
- All questions regarding MCLE Information should be directed to CLE@gibsondunn.com

Agenda

1	**FCA /AKS Overview and Recent Jurisprudence**
2	**Policy Developments**
3	**FCA Enforcement**
4	**Key Drug & Device Industry Developments / Hot Topics**
5	**Compliance Best Practices**
6	**Questions**

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FCA /AKS Overview and Recent Jurisprudence

The False Claims Act (FCA)

- The FCA, 31 U.S.C. §§ 3729–3733, is the federal government's **primary weapon to redress fraud** against government agencies and programs
- The FCA provides for recovery of **civil penalties and treble damages** from any person who knowingly submits or causes the submission of false or fraudulent claims to the United States for money or property
- Under the FCA, the Attorney General, through DOJ attorneys, investigates and pursues FCA cases
- DOJ devotes substantial resources to pursuing FCA cases—and to considering whether *qui tam* cases merit parallel criminal investigations

"It seems quite clear that the objective of Congress was broadly ***to protect the funds and property of the Government from fraudulent claims*** …."

Rainwater v. United States, 356 U.S. 590 (1958) (emphasis added)

Universal Health Services, Inc. v. United States ex rel. Escobar

579 U.S. 176 (2016)

- The Supreme Court's opinion reached a number of key conclusions that have formed the basis for significant follow-on FCA litigation:
  - The Court deemed the ***"implied false certification"*** theory of liability viable in certain circumstances, but declined to decide whether "all claims for payment implicitly represent that the billing party is legally entitled to payment"
  - The Court stated that the FCA's materiality and scienter requirements are ***"rigorous"*** and must be ***"strict[ly] enforce[d]"***
  - The Court set forth factors for consideration in analyzing what makes a particular regulatory or other requirement "material" to government payment decisions:
    - Whether the government has expressly identified compliance with the provision or regulation as ***a condition of payment***
    - Whether the government would have ***denied payment if it had known of the alleged noncompliance***
    - Whether the government in fact ***continued paying*** despite ***knowledge of the alleged noncompliance***
    - Whether the noncompliance is ***minor or insubstantial***

Post-*Escobar* Materiality – Government Knowledge

***United States ex rel. Bibby v. Mortg. Inves. Corp.*, 987 F.3d 1340 (11th Cir. 2021)**

- The relators alleged that a lender falsely certified charging only fees permitted by Department of Veterans Affairs ("VA") regulations, despite bundling prohibited fees (i.e., attorneys' fees) together with permissible fees
- The district court granted the lender summary judgment on materiality grounds in light of evidence that the **government continued paying claims** after having notice of the alleged improper fees
- The Eleventh Circuit reversed. It held that government payment despite knowledge of a noncompliance is relevant, but "the **significance of continued payment may vary** depending on the circumstances" and **must be evaluated "holistically" alongside other facts regarding government behavior**
- Here, because the VA reminded lenders of applicable fee requirements and ramped up its audit efforts, the court found that a genuine factual issue existed that precluded summary judgment
- The court also found it significant that the VA is required to honor loan guaranties by paying holders in due course "regardless of any fraud by the original lender"

FCA – Scienter

- ***"Knowingly"*** requires scienter and is defined as:
  - Actual knowledge,
  - Deliberate ignorance, or
  - Reckless disregard
- Negligence is not actionable
- Specific intent to defraud is not required

Recent Jurisprudence – Scienter

United States ex rel. Schutte v. SuperValu, Inc., 9 F.4th 455 (7th Cir. 2021)

- The relator alleged that SuperValu knowingly submitted false reports of its pharmacies' usual and customary ("U&C") drug prices when seeking reimbursements under Medicare and Medicaid
- The district court granted summary judgment to SuperValu on the basis that it lacked scienter, because then-existing case law was unclear on whether SuperValu's interpretation of U&C prices was correct, whether its interpretation was **"objectively reasonable,"** and whether "there was **no authoritative guidance to warn SuperValu away** from its interpretation of U&C price"
- The district court applied the Supreme Court's decision in *Safeco Ins. Co. of Am. v. Burr*, 551 U.S. 47 (2007), which dealt with scienter under the Fair Credit Reporting Act ("FCRA"), and which several other Circuits—but not the Seventh—had applied to the FCA
- The Seventh Circuit affirmed, holding that:
  - *Safeco* applies to the FCA because it interpreted **common-law scienter concepts** that appear in both FCRA and the FCA
  - *Safeco* applies to **all three forms of FCA scienter** (knowledge, deliberate indifference, and reckless disregard)
  - SuperValu's interpretation of the definition of U&C prices satisfied *Safeco*

Recent Jurisprudence – Scienter

***United States ex rel. Prose v. Molina Healthcare of Illinois, Inc.*, 10 F.4th 765 (7th Cir. 2021)**

- Relator, founder of a subcontractor that provided skilled nursing facility ("SNF") services to Medicaid patients enrolled with defendant Molina, alleged that Molina continued to collect higher fees from the government after ceasing to provide those SNF services
- The district court found that the relator's complaint failed to adequately allege that Molina knew the government viewed its billing for SNF services as material to the payment rate
- A majority of the Seventh Circuit panel disagreed and reversed, concluding that the district court "failed to give proper weight to the complaint's description of Molina as a **highly sophisticated member of the medical-services industry**" that would have known the billings were material
- The majority also said that the district court held relator to too high a standard regarding his allegations of Molina's knowledge that the government would consider SNF services material to its rate

FCA – Falsity

Factual Falsity

- False billing (e.g., goods or services not provided)
- Overbilling (e.g., upcoding)

Legal Falsity

- Express certification of compliance with legal requirements
- Submission of claim with representations rendered misleading as to goods or services provided

Promissory Fraud / Fraud in the Inducement

- Obtaining a contract through false statements or fraudulent conduct
- *United States ex rel. Marcus v. Hess*, 317 U.S. 537 (1943) (claims by contractors who colluded on bids)

Reverse False Claims

- Improper avoidance of obligation to pay money to the government
- Retention of government overpayment

Recent Jurisprudence – Falsity / Statistical Evidence

***Est. of Helmly v. Bethany Hospice & Palliative Care of Coastal Georgia, LLC*, 853 F. App'x 496 (11th Cir. 2021)**

- Relators alleged that the defendant hospice company submitted false claims when it billed the government for services provided to patients obtained through a kickback scheme
- Plaintiffs argued that because a significant number of Medicare recipients were referred to the hospice, and because "all or nearly all" patients received Medicare coverage, it was mathematically plausible that the hospice had submitted to the government claims for patients obtained under kickback arrangements
- On appeal, the Eleventh Circuit upheld the district court's dismissal with prejudice, reasoning that **allegations based on numerical probability are mere inferences** that do not suffice to plead fraud with particularity under Rule 9(b)
- The court, noting that a complaint "must allege actual submission of a false claim" with **"some indicia of reliability,"** held that **"numerical probability is not an indicium of reliability"** sufficient to meet the particularity requirement

Recent Jurisprudence – Falsity / Statistical Evidence

***Integra Med Analytics LLC v. Providence Health & Services*, 854 F. App'x 840 (9th Cir. 2021)**

- The relator alleged that Providence submitted false claims to Medicare, basing its complaint primarily on a **statistical analysis of publicly available data** allegedly demonstrating that Providence submitted Medicare claims "with higher-paying diagnosis codes" than other comparable institutions
- The district court denied Providence's motion to dismiss the relator's primary FCA claim
- On appeal, the Ninth Circuit reversed the district court's denial and remanded with instructions to dismiss, holding that the relator failed to adequately plead falsity because its allegations did not eliminate an "obvious alternative (and legal) explanation"
- Thus, dismissal of FCA claims is appropriate where a plaintiff's **statistical data offers only a "possible explanation"** in the face of an **"obvious alternative explanation"**

Recent Jurisprudence – Falsity / Fraudulent Inducement

United States ex rel. Cimino v. Int'l Bus. Machs. Corp., 3 F.4th 412 (D.C. Cir. 2021)

- The relator alleged that IBM had violated the FCA by, among other things, fraudulently inducing the IRS to enter into a license agreement for software it did not want or need
- The district court dismissed the fraudulent inducement claim because, among other things, the relator failed to plausibly plead that IBM's conduct was the but-for cause of the IRS's entering into the agreement
- The D.C. Circuit reversed the dismissal of the fraudulent inducement claim after undertaking a detailed analysis of the fraudulent inducement theory of FCA liability and that theory's causation requirement
- The court held that fraudulent inducement **requires pleading "actual cause" under the common law but-for test** and rejected the relator's argument that "proximate cause under the substantial factor test" alone is sufficient
- "[F]raudulent inducement under the FCA **incorporates** the **common law causation requirement**"

FCA – Public Disclosure Bar

- **Public Disclosure Bar.** A relator's *qui tam* action must be dismissed if **"substantially the same"** allegations or transactions as alleged in the action were **publicly disclosed in certain enumerated sources** such as public hearings, government audits or reports, or the news media
  - **"Original Source" Exception:** A relator may proceed on publicly disclosed allegations if the relator is an "original source" of the allegations, meaning the relator either:
    - voluntarily disclosed them to the government prior to the public disclosure; or
    - voluntarily disclosed them to the government before filing and has knowledge that is "independent of and materially adds to" the public disclosures
  - **2010 Amendments:** PPACA amended the public disclosure provisions in 2010; previously, the bar was expressly jurisdictional and contained differences in the public disclosure and original source provisions
  - **Intervened Cases:** The public disclosure bar does not apply to DOJ

Recent Jurisprudence – Public Disclosure Bar

***United States ex rel. Schweizer v. Canon, Inc.*,**
9 F.4th 269 (5th Cir. 2021)

- The relator filed her first FCA *qui tam* case against a company that was subsequently acquired by Canon before her first FCA lawsuit was settled
- After settlement of her first FCA lawsuit, the relator then filed an FCA *qui tam* case against Canon, alleging the same fraudulent conduct (including violation of the same government contracts) at issue in the first FCA lawsuit
- The Fifth Circuit affirmed the dismissal of the relator's complaint under the public disclosure bar, holding that the scheme alleged against Canon was "based upon" the same allegations and transactions asserted in the relator's first FCA lawsuit
- The court rejected the relator's arguments that the public disclosure bar did not apply because the **companies were different**, that Canon's alleged scheme **occurred at a later time**, and that Canon violated **additional government contracts**

Recent Jurisprudence – Public Disclosure Bar

***United States ex rel. Banigan v. PharMerica, Inc.*, 950 F.3d 134 (1st Cir. 2020)**

- Applying the pre-2010 version of the public disclosure bar, the First Circuit held that, for purposes of the original source exception, a relator's "independent knowledge" need not be based on actual participation in or observation of the alleged conduct; rather, the relator need only have **direct and independent knowledge "of the information on which the allegations are based"**
- The court held that **the fact that the relator learned about the alleged conduct from other people did not disqualify him as an original source**
  - The relator was "a corporate insider" who learned of the underlying conduct during his employment, via communications with the primary participants in the conduct and "documents . . . that he obtained through his own investigative efforts"
  - There was no "intervening agency, instrumentality, or influence" between the sources of the relator's knowledge and the knowledge itself

FCA – First-to-File Bar

- **First-to-File Bar.** The FCA provides that, when a *qui tam* action is **"pending," "no person** other than the Government **may intervene or bring a related action based on the [same] facts"**
  - **The Action:** Most courts that have addressed the issue have concluded that a violation of the bar is not "cured" by filing an amended complaint
- **Intervened Cases.** The first-to-file bar does not apply to DOJ

Recent Jurisprudence – First-to-File Bar

***In re Plavix Marketing, Sales Practice & Prods. Liability Litig. (No. II)*, 974 F.3d 228 (3d Cir. 2020)**

- Deepening a Circuit split, the Third Circuit joined the First, Second, and D.C. Circuits in holding that **the FCA's first-to-file bar is not jurisdictional, such that arguments under the first-to-file bar do not implicate the court's subject matter jurisdiction**, even if they are a cause for dismissal
- In contrast, the Fourth, Fifth, Ninth, and Tenth Circuits have held that the bar is jurisdictional
- This distinction can affect how, and when, arguments under the first-to-file bar may be made, and also the standard of review a court applies

The Anti-Kickback Statute (AKS)

- The AKS, 42 U.S.C. § 1320a-7b(b), criminalizes
  - Knowing and willful
  - Payment, offer, solicitation, or receipt of remuneration
  - To induce patient referrals, reward a referral source, or generate business
  - Involving any item or service payable by federal health care programs
- The AKS covers those who **provide (or offer) remuneration** and those who **receive (or solicit) remuneration**
- Since the Affordable Care Act, a "claim that includes items or services **resulting from**" a violation of the AKS is a false claim for purposes of the FCA (42 U.S.C. § 1320a-7b(g))

Recent Jurisprudence – AKS

United States v. Mallory, 988 F.3d 730 (4th Cir. 2021)

- A laboratory that provided blood testing contracted with a consulting company to market and sell the blood tests, through which the consulting company received a base payment and percentage of revenue based on the number of blood tests ordered
- The jury found that the revenue-based commission payments constituted improper remuneration that was intended to induce the sales agents to sell as many tests as possible
- Defendants argued on appeal that (1) the government failed to prove that defendants "knowingly and willfully" violated the AKS and FCA; and (2) that commissions to independent contractor salespeople do not constitute kickbacks under the AKS
- The Fourth Circuit affirmed the jury's verdict and rejected both of defendants' arguments, finding (1) "abundant evidence" supporting knowledge and intent, including that several attorneys had expressed concerns regarding possible AKS violations; and (2) that the AKS's safe harbor for bona fide employment relationships does not extend to independent contractors

Denials of Writs of Certiorari in Key Cases

- *United States ex rel. Druding v. Care Alternatives*, 952 F.3d 89 (3d Cir. 2020)
- *Winter ex rel. United States v. Gardens Reg'l Hosp. & Med. Ctr., Inc.*, 953 F.3d 1108 (9th Cir. 2020)
  - Both courts held that a relator does not need to show **"objective falsehood,"** and that **medical opinions** underlying certifications to the Government can be false or fraudulent
- The Supreme Court denied both writs of certiorari, leaving a potential circuit split over whether FCA falsity requires an "objective falsehood"
  - *Compare United States v. AseraCare, Inc.*, 938 F.3d 1278 (11th Cir. 2019): FCA falsity requires proof of an **"objective falsehood,"** and a **"reasonable disagreement between medical experts** as to the accuracy of" "a clinical judgment" regarding eligibility for benefits "with no other evidence to prove the falsity of the assessment" is **not an "objective falsehood"**

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Policy Developments

FCA – Biden Administration

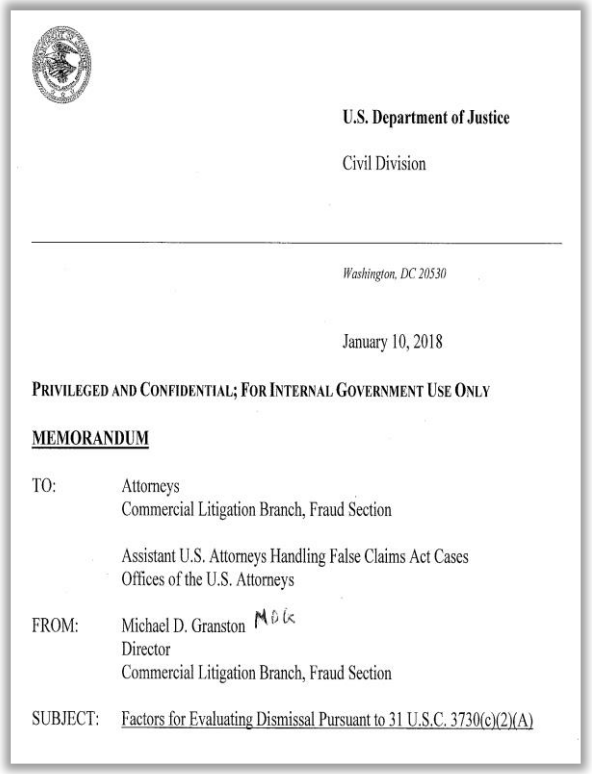
- To date, there have been no major shifts in overarching FCA policy, but the contours of the Biden Administration's priorities are emerging
- With nearly $400 million in FCA settlements in the first half of the year, **more aggressive and forward-leaning** FCA enforcement may well be on the horizon
- The Biden Administration forecasts that its efforts to root out COVID-19-related fraud will result in **"significant cases and recoveries"** under the FCA
- In a February 2021 speech at the Federal Bar Association *Qui Tam* Conference, Acting Assistant Attorney General Brian M. Boynton outlined DOJ's Civil Division's six enforcement priorities:
  1. Pandemic-related fraud;
  2. Opioids;
  3. Fraud targeting seniors;
  4. Electronic health records;
  5. Telehealth; and
  6. Cybersecurity
- Acting AAG Boynton also stated explicitly that observers can "expect the Civil Division to continue to expand its own efforts to identify potential fraudsters, including its reliance on various types of data analysis"

The Future of the Brand Memo

- Jan. 2018 memo by then-Associate Attorney General Rachel Brand
  - DOJ **"may not use compliance with guidance documents as a basis for proving violations of applicable law"** in affirmative civil enforcement cases
  - Codified in Dec. 2018 at Section 1-20.000 of the Justice Manual
- Executive Order 13891 (Oct. 9, 2019):
  - Agencies must treat guidance documents as non-binding unless incorporated into a contract
  - Agencies may impose legally binding requirements only through regulation and adjudication
- Executive Order 13992 (Jan. 20, 2021):
  - Revoked EO 13891
  - Noted that agencies must have **"flexibility to use robust regulatory action"** in key areas
- Interim Final Rule (July 1, 2021):
  - Rescinds DOJ regulations limiting the use of guidance documents
  - Simultaneously-issued Garland Memo: guidance alone cannot form the basis for an enforcement action, but "may be entitled to deference or otherwise carry persuasive weight with respect to the meaning of the applicable legal requirements . . . . **Department attorneys are free to cite or rely on such documents as appropriate"**

The Future of the Granston Memo

- Recent DOJ focus on use of its **dismissal authority** (31 U.S.C. § 3730(c)(2)(A))
- Principles in Granston Memo incorporated into DOJ Justice Manual at Section 4-4.111 in September 2018
- DOJ attorneys should **consider dismissal** for:
  - Facially meritless or duplicative *qui tam* suits
  - Cases seen as interfering with agency policy/programs
  - Suits that threaten DOJ's litigation positions
  - Cases that might reveal classified information
  - Low expected-value suits
  - Actions that frustrate investigative efforts
- Courts divided over which standard applies — the *Swift* (deferential) standard or the *Sequoia Orange* (less deferential) standard



U.S. Department of Justice

Civil Division

Washington, DC 20530

January 10, 2018

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MEMORANDUM

TO: Attorneys
Commercial Litigation Branch, Fraud Section

Assistant U.S. Attorneys Handling False Claims Act Cases
Offices of the U.S. Attorneys

FROM: Michael D. Granston MDG
Director
Commercial Litigation Branch, Fraud Section

SUBJECT: Factors for Evaluating Dismissal Pursuant to 31 U.S.C. 3730(c)(2)(A)

FCA – DOJ Dismissal Authority

- Outcomes in Circuits that have not yet adopted a standard of review remain mixed, but also highlight the ultimate similarities in the standards

Court	Circuit	Approach
D.R.I.	First	Declined to choose, but found *Sequoia Orange* satisfied
S.D.N.Y.	Second	Declined to choose, but found *Sequoia Orange* satisfied
S.D.N.Y.	Second	*Sequoia Orange*
E.D. Pa.	Third	Declined to choose, finding both standards satisfied
E.D. Pa.	Third	Declined to choose, but applied *Sequoia Orange* and found it satisfied
E.D. Va.	Fourth	*Swift* (but found *Sequoia Orange* satisfied)
S.D. Miss.	Fifth	*Swift*
N.D. Ala.	Eleventh	Predicted Circuit Court would apply *Swift*, but found both standards satisfied
S.D. Ala.	Eleventh	Applied *Sequoia Orange* "in abundance of caution" and found it satisfied

FCA– DOJ Dismissal Authority

***United States v. UCB, Inc.*, 970 F.3d 835 (7th Cir. 2020),**
***cert. denied sub nom. Cimznhca, LLC v. United States*, 141 S. Ct. 2878 (2021)**

- The relator argued that the Seventh Circuit improperly expanded its jurisdiction by treating the government's motion to dismiss as a motion to intervene for purposes of dismissal, even though the government never sought to intervene
- The Seventh Circuit called the choice between the *Sequoia Orange* and *Swift* standards "a false one, based on a misunderstanding of the government's rights and obligations under the False Claims Act"
- The court held that *Sequoia Orange* simply means that dismissal "may not violate the substantive component of the Due Process Clause," which the court characterized as a **"bare rationality standard"** targeting **"only the most egregious official conduct"** that "shocks the conscience" or "offend[s] even hardened sensibilities,"
- Although it recognized the value of a *Sequoia Orange*-type standard focused on the outer constitutional limits of the government's prosecutorial discretion, the court stated that it believes the limit lies closer to the more-deferential *Swift* standard

FCA – Proposed Amendments

Proposed Change	Issue That Proposed Change Attempts to Address
Shift the burden of proof to the defendant(s) to disprove materiality	Supreme Court's 2016 *Escobar* decision breathing new life into "materiality" requirement
Make it more difficult for DOJ to dismiss *qui tam* cases	Granston Memo policy encouraging more DOJ dismissal of *qui tams*
Allow DOJ to shift the Government's discovery costs to the defendant(s)	FCA defendants' efforts to seek burdensome discovery from Government to disprove materiality under *Escobar*
Make the FCA's existing anti-retaliation provisions expressly applicable to post-employment retaliation	Conflicting judicial opinions about whether FCA covers post-employment retaliation

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FCA Enforcement

By the Numbers: 2020 Federal Fiscal Year

> $2.2 Billion

Civil settlements and judgments under the FCA

922

New FCA cases filed

73%

New FCA cases initiated by a whistleblower

89%

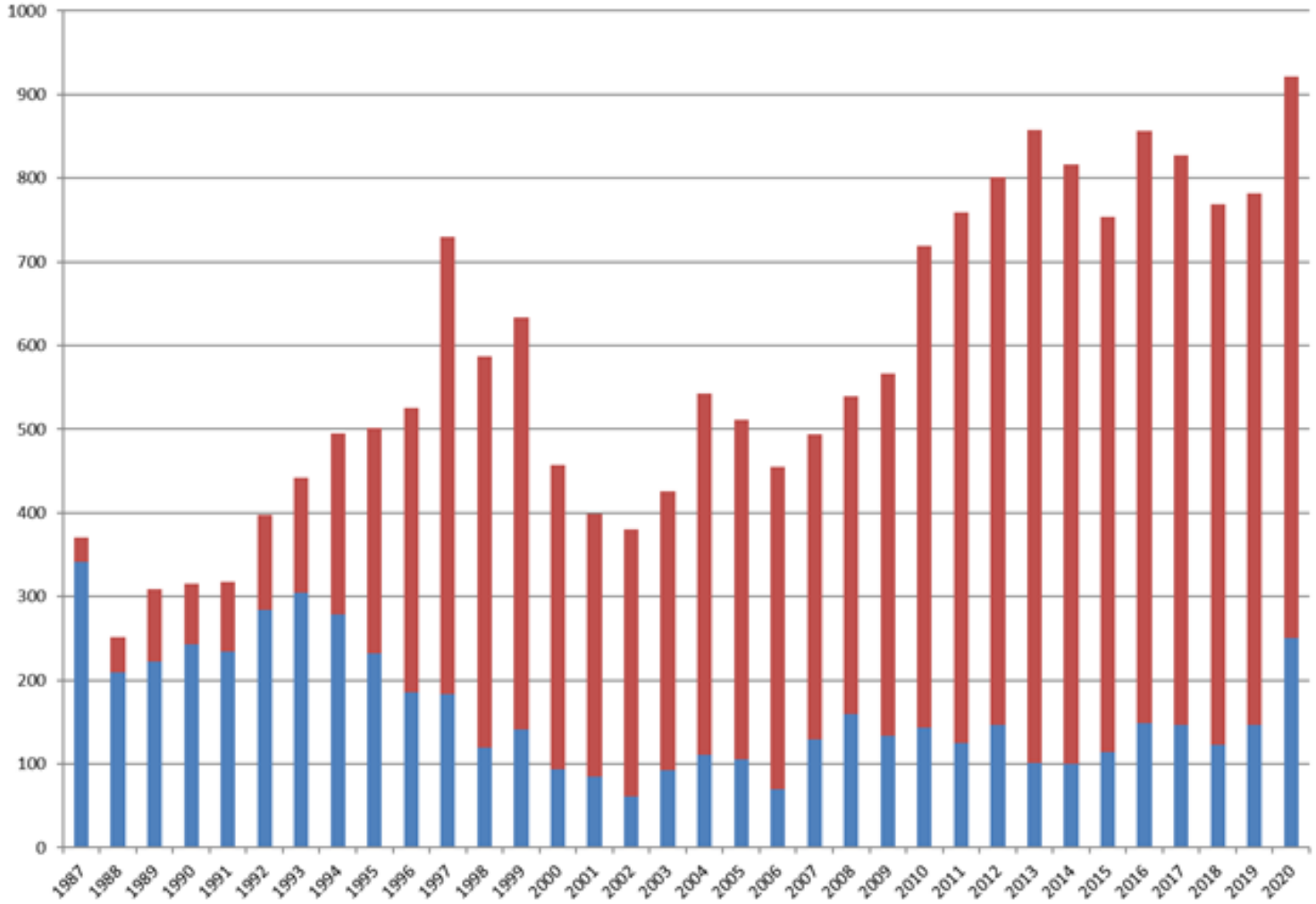
Overall federal recovery from cases in which the government intervened

Source: U.S. Dep't of Justice, "Fraud Statistics – Overview" (Jan. 14, 2021)

FCA – Damages and Penalties

- ***Simple Damages Calculation***
  - Treble damages are traditionally calculated by multiplying the government's loss by three (e.g., if the government charged $100 for goods not received, damages would be $300)
- ***Complex, Contested Damages Calculation***
  - Calculations are more complicated (and less certain) when the government receives goods or services it considers deficient or when there is a "false certification" or "promissory fraud"
- ***Civil Per-Claim Penalty***
  - Previously $5,500 to $11,000
  - Increased by interim rule in 2016, with later adjustments for inflation; current range, per final rule issued in June 2020: ***$11,665 to $23,331 per violation***
  - Lower penalty range still in effect for violations occurring on or before November 2, 2015 ($5,500 to $11,000 per violation)

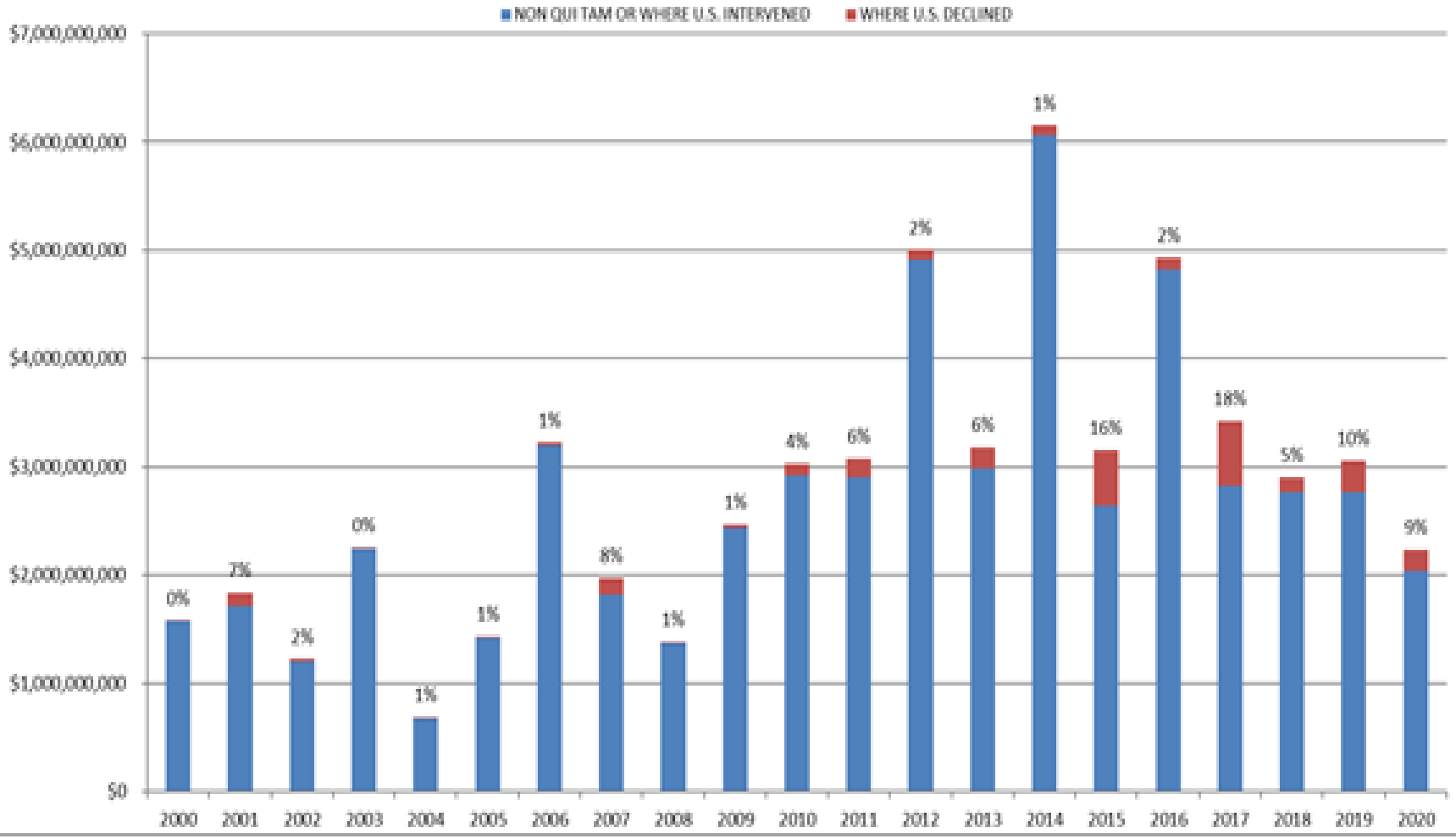
Number of New FCA Suits (FFY 1987–2020)



FFY 2020: 922 new FCA suits • 672 *qui tam* • 250 non-*qui tam*

Source: DOJ, "Fraud Statistics – Overview"

Recoveries through Settlements & Judgments (FFY 2000–2020)



FFY 2020: >$2.2B • $2.04B intervened & non-*qui tam* • $193M declined

Source: DOJ, "Fraud Statistics – Overview"

Drug and Device Companies – Key Legal Theories

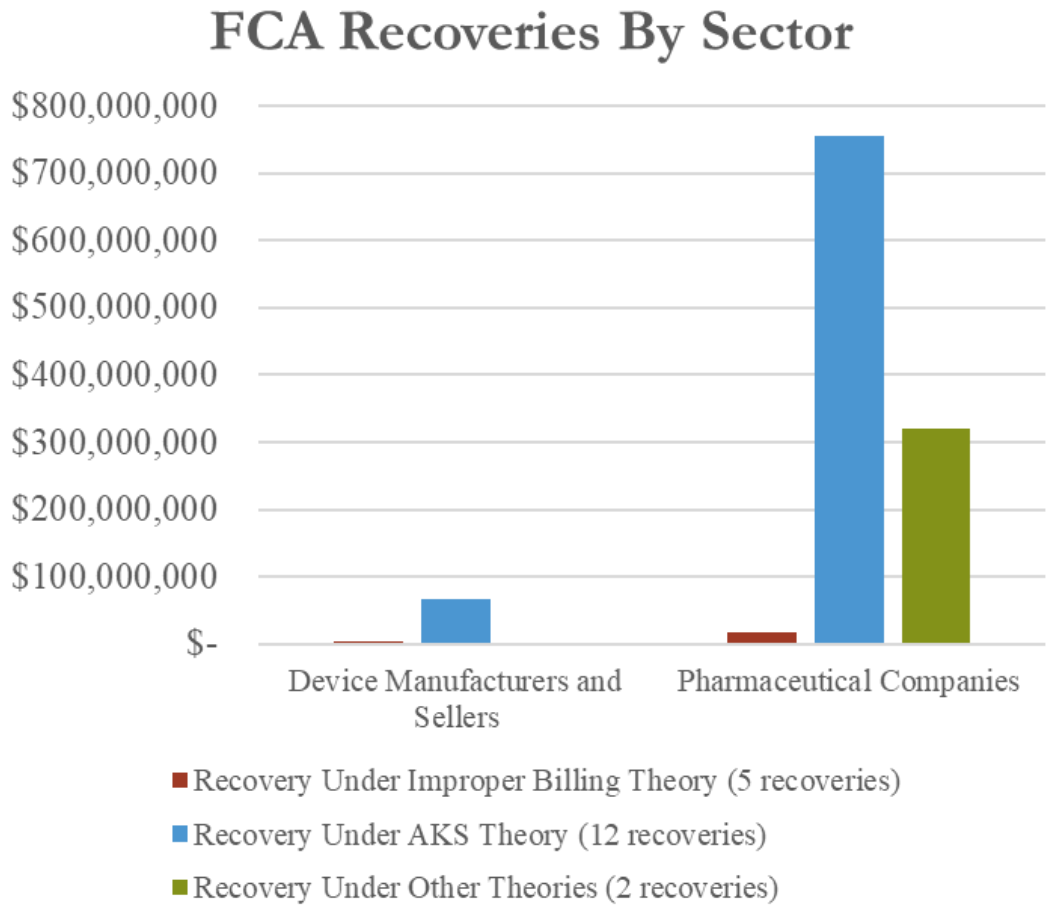
FCA allegations against drug and device companies typically are based on one (or more) of the following legal theories:

1. **AKS.** Payment of remuneration to providers in a position to prescribe the company's drug or device violates the AKS and, in turn, the FCA
2. **Off-Label Promotion.** By promoting a drug or device for an off-label use, the company (a) causes the target physicians to submit false claims for reimbursement of a noncompensable use of the drug, and/or (b) engages in a fraudulent course of conduct that can make resulting claims for reimbursement by prescribing physicians fraudulent claims
3. **Violations of the FDCA.** Allegations that misbranding, adulteration, or pre- or post-approval regulatory violations make claims for reimbursement of associated drugs "false" because (a) the products are tainted by the violative conduct, or (b) there is an "implied certification" of compliance with material regulations when claims for payment of the drugs are submitted
4. **Price Reporting Violations.** Allegations that the company did not report accurate product price information, such as best price, under government program (e.g., Medicaid rebate agreement) requirements
5. **Improper Billing.** Allegations that the company submitted claims for services or materials that were not provided and/or were not medically necessary, or "upcoded" to a higher-reimbursement service or material than what was actually provided

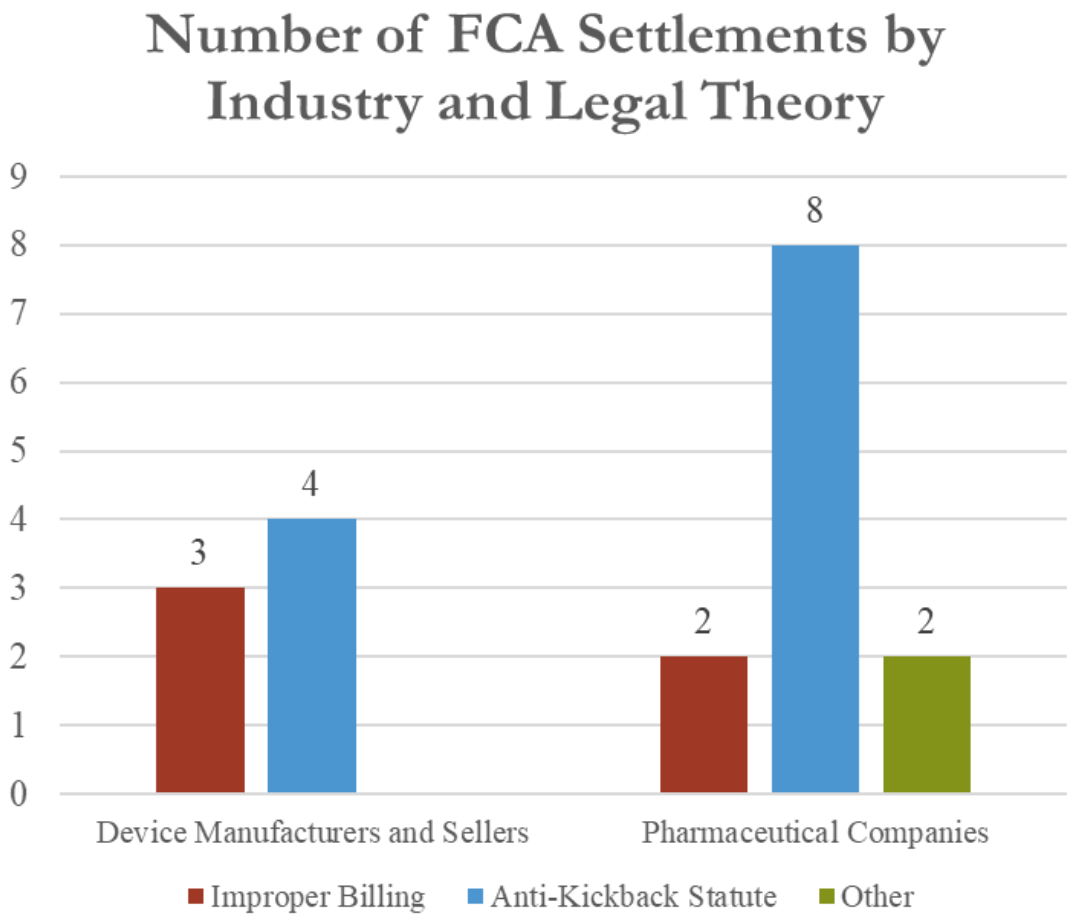
Drug and Device Companies – 2020 FCA Recoveries

~$1.16 billion in civil recoveries from drug and device companies in 2020

- AKS: $822.6m
- Off-Label Promotion and Other Allegations: $320.7m
- Improper Billing: $19.5m



Drug and Device Companies – 2020 FCA Recoveries



In 2020, DOJ cited the **AKS as the recovery theory in the vast majority** of settlements with drug and device companies

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Key Drug & Device Industry Developments and Hot Topics

Drug & Device Hot Topics

Key Industry Developments and Hot Topics

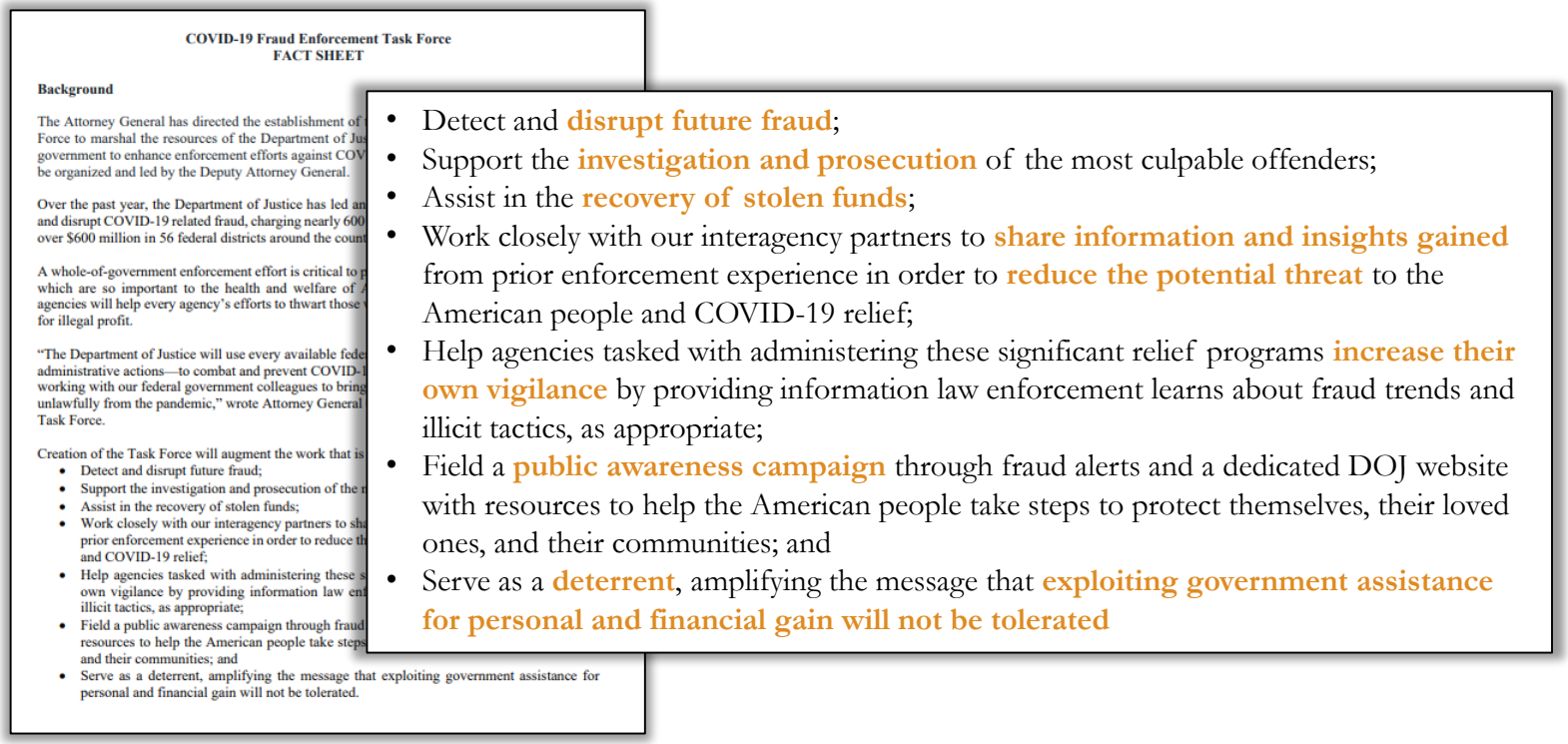
- COVID-19 and FCA Enforcement
- Speaker Programs, Advisory Board, and Consulting Relationships
- Product / Practice Support
- Find-a-Doctor / Surgeon Locator Tools
- Free Equipment / Free Goods / Demo and Evaluation Products
- FDA Regulatory Issues
- FCA and Antitrust Overlap

DOJ Enforcement Priorities in the COVID-19 Era

- DOJ has **continued to focus on COVID-19-related fraud** in 2021
- In January 2021, DOJ announced its **first civil settlement under the COVID Paycheck Protection Program**
- Acting Assistant Attorney General (AAG) Brian M. Boynton gave a speech in February in which he identified **COVID-19-related fraud as the top enforcement priority**
  - Acting AAG Boynton described ongoing efforts by DOJ and other agencies to "identify, monitor, and investigate the misuse of critical pandemic relief monies"
- In May 2021, Acting U.S. Attorney (AUSA) Philip A. Talbert and HHS-OIG released a statement to the public and providers regarding the COVID-19 vaccine
  - Providers participating in the U.S. Centers for Disease Control and Prevention COVID-19 Vaccination Program sign an agreement to receive and dispense COVID-19 vaccines; the **agreement imposes liability under the False Claims Act** for noncompliance
  - AUSA Talbert stated, "This violation of the terms and conditions of CDC's vaccination program is also a **potential violation of the civil False Claims Act** and other civil and criminal statutes"

COVID-19 Fraud Enforcement Task Force

- In May 2021, DOJ announced the **formation of a COVID-19 Fraud Enforcement Task Force**, to be organized and led by Deputy Attorney General Lisa Monaco
  - Attorney General Merrick Garland has directed the Task Force "to marshal the resources of the Department of Justice in partnership with agencies across government to **enhance enforcement efforts against COVID-19 related fraud**"



COVID-19 Fraud Enforcement Task Force
FACT SHEET

Background

The Attorney General has directed the establishment of
Force to marshal the resources of the Department of Ju
government to enhance enforcement efforts against COV
be organized and led by the Deputy Attorney General.

Over the past year, the Department of Justice has led an
and disrupt COVID-19 related fraud, charging nearly 600
over $600 million in 56 federal districts around the coun

A whole-of-government enforcement effort is critical to p
which are so important to the health and welfare of
agencies will help every agency's efforts to thwart those
for illegal profit.

"The Department of Justice will use every available fede
administrative actions—to combat and prevent COVID-
working with our federal government colleagues to bring
unlawfully from the pandemic," wrote Attorney General
Task Force.

Creation of the Task Force will augment the work that is

- Detect and disrupt future fraud;
- Support the investigation and prosecution of the
- Assist in the recovery of stolen funds;
- Work closely with our interagency partners to sh
  prior enforcement experience in order to reduce th
  and COVID-19 relief;
- Help agencies tasked with administering these s
  own vigilance by providing information law en
  illicit tactics, as appropriate;
- Field a public awareness campaign through fraud
  resources to help the American people take steps
  and their communities; and
- Serve as a deterrent, amplifying the message that exploiting government assistance for personal and financial gain will not be tolerated.

- Detect and **disrupt future fraud**;
- Support the **investigation and prosecution** of the most culpable offenders;
- Assist in the **recovery of stolen funds**;
- Work closely with our interagency partners to **share information and insights gained** from prior enforcement experience in order to **reduce the potential threat** to the American people and COVID-19 relief;
- Help agencies tasked with administering these significant relief programs **increase their own vigilance** by providing information law enforcement learns about fraud trends and illicit tactics, as appropriate;
- Field a **public awareness campaign** through fraud alerts and a dedicated DOJ website with resources to help the American people take steps to protect themselves, their loved ones, and their communities; and
- Serve as a **deterrent**, amplifying the message that **exploiting government assistance for personal and financial gain will not be tolerated**

HHS OIG Special Fraud Alert: Speaker Programs

- **In November 2020, HHS OIG released a Special Fraud Alert regarding speaker programs that highlighted the fraud and abuse risks of such programs**
  - The Special Fraud Alert identified "significant concerns about companies offering or paying remuneration (and HCPs soliciting or receiving remuneration) in connection with speaker programs"
- The Special Fraud Alert provided a non-exhaustive list of "suspect characteristics" related to speaker programs. Examples of these characteristics include:
  - HCPs attending programs on the same or substantially the same topics more than once,
  - Programs where little to no substantive information is presented,
  - Programs taking place at locations, such as restaurants or entertainment or sports venues, that are "not conducive to the exchange of educational information," and
  - Programs providing alcohol, or a meal exceeding "modest value"

DEPARTMENT OF HEALTH AND HUMAN SERVICES
OFFICE OF INSPECTOR GENERAL
WASHINGTON, DC 20201

Speaker Programs, Advisory Board, and Consulting Relationships

- **HHS OIG "Roadmap for New Physicians."** HHS OIG advises physicians that "some pharmaceutical and device companies have used sham consulting agreements and other arrangements" to induce use of products, including "opportunities to work as a consultant or promotional speaker for the drug or device industry"
- **PhRMA Guidelines.** PhRMA Code advises that consultants may receive "reasonable compensation for" services and "reimbursement for reasonable travel, lodging, and meal expenses incurred as part of providing those services"
- ***United States ex rel. Arnstein v. Teva Pharm.* (S.D.N.Y. Feb. 27, 2019).** According to the court (which applied the Third Circuit's *Greenfield v. Medco Health Solutions* decision), relators "need not demonstrate that the providers would not have prescribed those drugs absent" the speaker fees; instead, "**Relators need only show that the speakers' referral of [] drugs 'actually sat in the causal chain.'**"

Case Study: Speaker Programs

	Nature of Case	Key Relator / Government Allegations
teva	***United States ex rel. Arnstein v. Teva Pharm.* (S.D.N.Y. Feb. 27, 2019)** In February 2019, the district court denied Teva's motion for summary judgment as to alleged FCA violations In January 2020, Teva agreed to pay $54 million to resolve the claims	• Relators alleged that Teva used speaker events to encourage doctors to prescribe two of its drugs • Relators presented evidence reflecting thousands of examples in which there was only one or no legitimate attendees at speaker events and where excessive money was spent on food and alcohol • According to the court, relators "need not demonstrate that the providers would not have prescribed those drugs absent" the speaker fees; instead, "Relators need only show that the speakers' referral of . . . drugs 'actually sat in the causal chain'"
Shire	In January 2017, Shire agreed to pay $350 million to settle allegations that it violated the FCA by paying kickbacks to providers to use or "overuse" its FDA-approved human skin substitute	• DOJ alleged that company sales reps induced physicians and clinics to use the product with cash and rebates, "lavish" dinners and entertainment, medical supplies, and payments for "purported speaking engagements" • The settlement, a record recovery for a kickback case against a device company, resolved six *qui tams* against Shire and a predecessor company • Three executives who supervised the alleged kickback scheme, and some providers who received kickbacks, were criminally convicted

Speaker Programs

Speaker Program FCA Resolution Precedents

Entity	Date	Resolution	# Years	Drugs	Intervened?	CIA?
Novartis	July 2020	$591.5M	10	10	Y	Y
Warner Chilcott	Oct. 2015	$125M	4	2	Y	N
Avanir	Sept. 2019	$108.8M	6	1	Y	Y
Teva	Jan. 2020	$54M	12	2	N	N
Salix	June 2016	$46.5M	4	7	Y	N
Serono	May 2011	$44.3M	7	1	Y	Y
Kos	July 2010	$41M	6	2	Y	N
Daiichi Sankyo	Jan. 2015	$39M	7	4	Y	Y
Forest Labs	Dec. 2016	$36M	4	3	Y*	Y
DUSA	Aug. 2020	$20.75M	2	1	Y	Y

* The Government filed notice that it was not intervening but would be continuing its investigation and requested that the Court maintain the action in the name of the United States.

Product / Practice Support

Medical device makers and pharmaceutical companies often provide certain **product support services** such as:

- Reimbursement support / HUB services
- Find-a-doctor websites that connect patients with physicians qualified to use the companies' products

There is no statutory exemption or regulatory safe harbor for practice support services, but HHS OIG has endorsed companies' ability to offer product support services with "**no substantial independent value**"

- But the guidance cautions against providing support "**in tandem with another service of program that confers a benefit**" on the referring provider
- The guidance also states that the AKS "would be implicated if a manufacturer were to **couple a reimbursement support service with a promise** that a purchaser will pay for ordered products only if the purchaser is reimbursed by a Federal health care program"

"[Certain support services] may include **billing assistance tailored to the purchased products**, **reimbursement consultation**, and other programs **specifically tied to support of the purchased product**.
Standing alone, services that have **no substantial independent value** to the purchaser may not implicate the [AKS]."

- OIG Compliance Program Guidance for Pharmaceutical Manufacturers
68 Fed. Reg. 23,735 (May 5, 2003)

Product / Practice Support

In assessing the appropriateness of providing practice and product support services, device companies should consider:

Value and scope of support	What services have "substantial independent value" and what services are "limited"?
Connection between support and the relevant product and/or other services	What services are "tied" to the product or provided "in tandem" with other, valuable services?

Enforcement authorities and whistleblowers also may argue that certain practice support provides independent value to physicians by:

- **Relieving the practices of expenses** they otherwise would have to incur; and/or
- **Presenting the practices with opportunities** to make more money (e.g., by gaining efficiency or more patients)

Product / Practice Support

As to seminar and/or other scheduling assistance and find-a-doctor websites, device makers should consider the value of:

- **All connected or packaged support** (e.g., with other coding, billing, and reimbursement assistance; educational assistance; or other practice support or practice assessment tools, features, and resources)
- Whether the services involve **pure product support** or a **FMV-based service**
- **Channeled referrals** or **additional advertising** benefits from seminar listings and find-a-doctor websites

Device makers also should consider the rationale behind (and optics of) any mechanisms in place for selecting physicians to receive the support, including:

- Fixed, objective **criteria** connected to product performance; inclusion of volume- or usage-based criteria; and consistency of applying said criteria
- **Method of communicating** the availability and benefit of the support in question to physicians (e.g., quantifying a potential financial gain)
- Use of **dedicated, specialized personnel** (e.g., third-party consultants or practice advisors)
- Interaction between any such personnel and **company sales representatives** and/or sharing of **sales-related information** or conducting other **ROI analyses**

Case Studies: Practice Support

Case	Key Relator / Government Allegations
United States ex rel. Wolf v. Merit Medical Systems, Inc., No. 2:16-cv-01855 (D.N.J. Oct. 14, 2020)	• In October 2020, Merit Medical Systems, Inc. ("MMSI") agreed to pay $18 million and enter a five-year CIA to settle allegations that it violated the FCA by paying kickbacks to providers • MMSI allegedly made improper payments to surgeons under a "Local Advertising Program" that provided "millions of dollars in free advertising assistance, practice development, practice support" and "educational" grants; DOJ rejected MMSI's claims that the programs were designed to "increase the awareness" of medical treatments, and alleged that MMSI selected physicians to reward past sales, induce future sales, and divert additional business
United States ex rel. Forney v. Medtronic, Inc., NO. 15-6264 (E.D. Pa. June 19, 2017)	• In June 2017, a district court granted Medtronic's motion to dismiss FCA allegations that Medtronic offered surgical support and other free services as kickbacks to influence physicians and hospitals into buying its medical implants • Relator alleged that Medtronic promoted its free services—including surgical support, implant device follow-up, and free staff to clinics that purchased their devices—and that it used them to pull in new clients, but the court found no evidence of illegal intent • The court held that Medtronic was allowed to provide support services **"specifically tied to support of the purchased product"** so long as they don't exceed **"substantial independent value to the purchaser"**

Find-a-Doctor / Surgeon Locator Tools

DOJ and whistleblowers have been pursuing AKS theories based on "find a doctor" websites and related tools, especially where companies spend marketing / advertising budget to direct consumers to such sites

- "Find a Doctor" tools are **common within the industry**
- The sites increase otherwise limited **information available to public** regarding qualified providers and practices
- But DOJ views as problematic where being listed has "**value**" and the listing is **tied to use of company's products**

There are concerns with (and potential barriers to) DOJ pursuing these theories:

- **Referral Services Safe Harbor.** "'[R]emuneration' does not include any payment or exchange of anything of value between an individual or entity . . . and another entity serving as a referral service," so long as four standards are satisfied. Sites are often analogous to, even if not technically within, the safe harbor
- **First Amendment.** Sharing of truthful, non-misleading information regarding providers who perform procedures is protected by the First Amendment (under *Sorrell v. IMS Health Inc.*, 131 S. Ct. 2653 (2011))

Free Equipment / Goods / Demo and Evaluation Products

Provision of **free equipment, goods, or evaluation products** has long attracted FCA and AKS scrutiny.

	Nature of Case	Key Government Allegations
PCLS	In March 2021, an owner of a now-defunct urine drug testing lab agreed to pay over $2 million to resolve FCA and AKS allegations	• From 2013 to 2015, Physicians Choice Laboratory Services allegedly provided urine drug testing equipment, including desktop analyzers and associated supplies and services, among other benefits, to physicians in exchange for referrals of patient samples to the laboratory for testing

ResMed	In January 2020, ResMed Corp., a California-based DME supplier agreed to pay $37.5 million to resolve FCA and AKS allegations	• Among other things, ResMed allegedly provided:
		  • Sleep labs with free and below-cost positive airway pressure masks and diagnostic machines, as well as free installation of these machines; and
		  • Non-sleep specialist physicians free home sleep testing devices referred to as "ApneaLink"
		• ResMed entered into a Corporate Integrity Agreement with HHS OIG

Recent Jurisprudence – "Fraud-on-the-FDA" Theory

***United States ex rel. Dan Abrams Co. LLC v. Medtronic Inc.*,**
850 F. App'x 508 (9th Cir. 2021)

- The Ninth Circuit reaffirmed that "fraud-on-the-FDA" theories may state a valid FCA claim sufficient to survive a motion to dismiss
- Relator alleged that Medtronic fraudulently obtained FDA 510(k) clearance for devices used in spinal fusion surgeries, some of which could allegedly only be used for a contraindicated use
- The district court dismissed for failure to state a claim because the allegations were offered "solely as a predicate for the claim that the [devices] were intended for off-label use," for which the government allows reimbursement
- On appeal, the Ninth Circuit affirmed most of the dismissal of relators' claims, but reversed as to the contraindicated-only devices, holding that the FCA may serve as a vehicle to bring a fraud-on-the-FDA claim there, where the relator alleged that the devices were not properly cleared for *any* use by the FDA

Off-Label Promotion: FDA's Revised "Intended Use" Definition

- **Amended "intended use" regulations, effective September 1, 2021**
- **Evidentiary sources of intended use**
  - "expressions"
  - "circumstances surrounding the distribution of the article"
  - "design or composition of article"
    - Designing stent to be sized for a use that is different from the purported use
    - Products containing API (or analogues or controlled substance)
    - Marketing a device that uses ultrasonic waves as a therapeutic massager, when the waves affect the underlying tissue through a sonic mechanism
- **Firm will not be regarded as intending a new unapproved use based solely on the firm's knowledge of unapproved uses by HCP's**
    - Disseminating safety information to minimize risk associated with unapproved use
    - Following social media account of rare disease non-profit while investigating potential drug therapy for the disease

HHS-OIG Review of FDA's Accelerated Approval Pathway

- In July 2021, Acting FDA Commissioner Janet Woodcock requested OIG's independent review of FDA's interactions with a pharmaceutical company during the review of the Alzheimer's disease drug, Aduhelm, to determine whether these interactions were consistent with FDA policies and procedures
- In August 2021, HHS-OIG announced review of FDA's accelerated approval pathway
  - Accelerated Approval: pathway for approval of drugs that treat serious conditions and that fill an unmet medical need (based on surrogate endpoint)
- Controversy over approval of Aduhelm
  - "alleged scientific disputes within the FDA"
  - FDA Advisory Committee's vote against approval
  - "allegations of an inappropriately close relationship between the FDA and the industry"

FCA and Antitrust Overlap

DOJ and *qui tam* relators are pursuing cases alleging that violations of the antitrust laws let companies charge **inflated prices**, thereby causing false claims to be submitted to the government.

	Nature of Case	Key Government Allegations
TARO APOTEX	In October 2021, three generic pharmaceutical manufacturers agreed to pay over $447 million to resolve alleged violations of the FCA arising from alleged conspiracies to fix the price of various generic drugs	• Between 2013 and 2015, the companies allegedly paid and received compensation prohibited by the AKS through arrangements on price, supply, and allocation of customers with other pharmaceutical manufacturers for certain drugs manufactured by the companies • All three companies previously entered into DPAs and agreed to pay criminal penalties for their allegedly collusive conduct

Each company also entered into a five-year corporate integrity agreement with HHS-OIG, which included provisions aimed to ensure competitive conduct

- For example, each CIA required that the company's policies and procedures address "**appropriate interactions** with customers and potential customers and **with competitors** in accordance with all applicable legal requirements . . ."

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Compliance Best Practices

Minimizing Exposure

- Set a compliance-focused "**tone from the top**"
- Adopt and implement **reasonable compliance policies and controls**
  - A strong internal compliance program may not prevent a rogue employee from committing fraud, but it may help to defeat scienter
- Train employees on compliance policies and reporting options
- **Audit, monitor, and test** the compliance program's effectiveness
- **Investigate and remediate**
  - Develop standards and procedures to prevent, detect, and respond to improper conduct

Risk Assessment

- Monitor government interactions
- Understand compliance requirements
- Account for internal quality control measures
- Evaluate business partners
- Have a strong HR system in place—most whistleblowers are aggrieved/disgruntled former employees
- Document the government's knowledge, awareness, and ratification of contractual and programmatic deviations
- Take care in responding to billing inquiries, as incorrect explanations may be used as evidence of fraud
- Documentation and transparency are key

Investigation Responsiveness

- Critical to know of FCA complaints as soon as possible
- Foster an environment in which employees and other interested parties report concerns internally
- Separate the message from the messenger, take allegations seriously, and follow up
- *Qui tam* warning signs:
  - HR issues;
  - Exit interview statements;
  - Unexpected audits;
  - Requests for billing explanations;
  - Increased web activity; and
  - Former employees contacted
- Proactively engage with and present your case to DOJ and USAO
- The most critical juncture is the government's intervention decision

Questions?

Upcoming Webcasts & Additional Resources

Upcoming Webcasts

- October 26| False Claims Act – 2021 Update for Health Care Providers | 12:00 – 1:30 pm ET

  To register, please click here.

- November 3 | Compliance Monitors: Everything that you wanted to know but were afraid to ask | 12:00 – 1:30 pm ET To register, please click here.

- November 9 | Managing Internal Audit and Investigations | 12:00 – 1:30 pm ET To register, please click here.

- December 9 | What's Next: Spoofing and Manipulation in Commodities and Derivatives Markets | 12:00 – 1:15 pm ET To register, please click here.

FCA Publications and Recent Recorded Webcasts

FCA Publications

- **Private Equity Firms and PPP Fraud Liability Under the False Claims Act** (September 23, 2021)

https://www.gibsondunn.com/private-equity-firms-and-ppp-fraud-liability-under-the-false-claims-act/

- **Surge in False Claims Act Enforcement Continues** (August 16, 2021)

https://www.gibsondunn.com/surge-in-false-claims-act-enforcement-continues/

- **2021 Mid-Year False Claims Act Update** (July 26, 2021)

https://www.gibsondunn.com/2021-mid-year-false-claims-act-update/

Recent Recorded Webcasts

- **National Security Enforcement: Developments and Trends** click here

- **Economic Espionage and Intellectual Property Theft: Trends and Developments with Threats and Enforcement** click here
- **The False Claims Act – 2021 Update for Financial Services** click here
- **The False Claims Act – 2021 Update for Government Contractors click here**