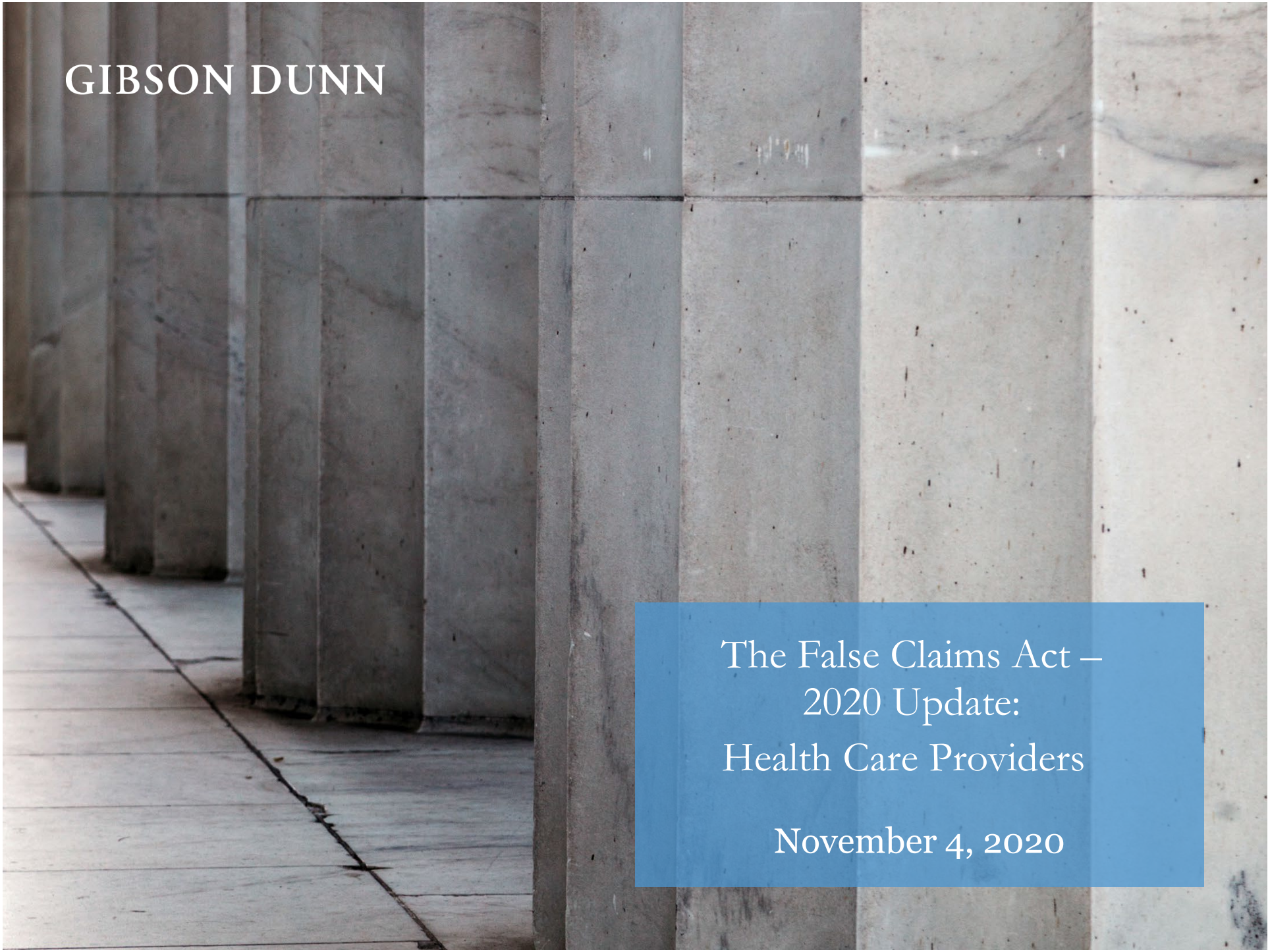

The False Claims Act – 2020 Update: Health Care Providers

November 4, 2020

Today's Presenters

Winston Chan is a former federal prosecutor and litigation partner in Gibson, Dunn & Crutcher'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.

Jonathan Phillips is a partner in the Washington, D.C. office where he focuses on compliance, enforcement, and litigation in the health care and government contracting fields, as well as other white collar enforcement matters and related litigation. A former Trial Attorney in DOJ's Civil Fraud section, he has particular experience representing clients in enforcement actions by the DOJ, Department of Health and Human Services, and Department of Defense brought under the False Claims Act and related statutes.

Jessica Wright is an associate in the San Francisco office. She practices in the firm's Litigation Department and focuses on white collar defense and investigations. She has experience representing health care clients in False Claims Act investigations.

Julie Schenker is an associate in the Washington, D.C. office where she focuses on health care enforcement and compliance matters, other white collar defense and investigations, and related litigation. She has represented health care provider clients regarding the False Claims Act, Anti-Kickback Statute, and Stark Law, as well as other health care-related matters.

MCLE Certificate Information

- Most participants should anticipate receiving their certificate of attendance in four weeks following the webcast
- Virginia Bar Association members should anticipate receiving their certificate of attendance six weeks following the webcast
- Please direct all questions regarding MCLE to CLE@gibsondunn.com

Agenda

1	**FCA Overview and Recent Jurisprudence**
2	**Enforcement Trends and Developments**
3	**Hot Topics for Health Care Providers**
4	**FCA Compliance Best Practices**
5	**Questions**

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FCA 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)

FCA Falsity: Post-Brand Memo Developments

DOJ and HHS Recent Proposed/Interim Final Rules

- **DOJ:** Interim final rule codifying the requirements of Executive Order 13891 which, among other things, limited use of guidance documents in criminal and civil enforcement actions. The purposes of DOJ's rule is to ensure that ***DOJ does not use guidance documents to impose obligations on regulated parties that are not already reflected in duly enacted statutes or the regulations*** lawfully promulgated under them.
- **HHS:** On August 20, 2020, HHS proposed a similar guidance-related rule that would require HHS components to ensure appropriate public notice when issuing new "guidance documents" and ***to clarify those documents' legal impacts***.

Post-*United States v. AseraCare, Inc.*, 938 F.3d 1278, 1293 (11th Cir. 2019) "Objective Falsity"

- **Third Circuit:** In *United States ex rel. Druding v. Care Alternatives*, the Third Circuit stated that a "physician's judgment may be scrutinized and considered 'false'" and that a "difference of medical opinion is enough evidence to create a triable dispute of fact regarding FCA falsity." 952 F.3d 89, 100 (3d Cir. 2020).
  - DOJ Brief (Amicus): "This Court should reject the 'objective falsity' requirement imposed by the district court and hold, consistent with the two other courts of appeals [Sixth and Tenth Circuits] that have directly addressed this issue, that expert testimony may be sufficient to establish the falsity of claims premised on medical judgments."
- **Ninth Circuit:** The Ninth Circuit reached a similar conclusion to the Third Circuit in *Winter ex rel. United States v. Gardens Regional Hospital and Medical Center*, holding that an FCA claim based on an alleged lack of medical necessity may be sufficient to survive a motion to dismiss. 953 F.3d 1108, 1117 (9th Cir. 2020).
  - DOJ Brief (Amicus): "The district court's 'objective falsehood' requirement is fundamentally flawed."

Post-*United States v. AseraCare, Inc.*, 938 F.3d 1278, 1293 (11th Cir. 2019)
"Objective Falsity"

- On September 16, 2020, Care Alternatives filed a petition for writ of certiorari before the Supreme Court, asking the Court to take on its appeal of the Third Circuit's decision and decide the following question – "*Whether a physician's honestly held clinical judgment regarding hospice certification can be 'false' under the False Claims Act based solely on a reasonable difference of opinion among physicians.*"
- The "circuit split" identified was over whether and to what extent a physician's clinical judgment can be deemed "false" under the FCA. The "split" breaks down more or less as follows over the question of whether "reasonable" disagreements over a physician's clinical judgment can establish that clinical judgment was "false" under the FCA:

Reasonable Disagreements Are Sufficient:	Reasonable Disagreement Typically Insufficient
3rd Circuit (*Druding*) – Difference of opinion causes triable issue of falsity	**5th Circuit** (*Riley*) – "Lies" but not mere "errors" can establish falsity
9th Circuit (*Winter*) – Contradictory evidence can establish falsity	**6th Circuit** (*Paulus*) – "Good faith" opinion does not establish falsity
10th Circuit (*Polukoff*) – Reasonable differences cause triable issue of falsity	**11th Circuit** (*AseraCare*) – Reasonable differences are insufficient to establish falsity

Post-*Escobar* Materiality – Government Knowledge

***United States ex rel. Janssen v. Lawrence Mem. Hosp.*, 949 F.3d 533 (10th Cir. 2020)**

- The case concerned alleged certifications made by a hospital to Medicare regarding patient arrival times, and the district court granted summary judgment to defendant on materiality
- The Tenth Circuit affirmed, finding it significant that CMS's third-party investigative service had investigated relator's allegations after she raised them via CMS's hotline prior to filing suit—and that CMS did "nothing in response and continue[d] to pay [defendant's] Medicare claims"
- "Although CMS may not have independently verified [defendant's] noncompliance—and thus may not have obtained 'actual knowledge' of the alleged infractions—**its inaction in the face of detailed allegations from a former employee suggests immateriality**"
- Further, the court assessed additional factors leading to its conclusion of materiality, including that arrival time was but a "***factor of a factor***" used to report the hospital's performance score—i.e., "arrival time is only incorporated into a subset of measures for which [the hospital] reports data . . . . Thus, at most, [the hospital's] alleged misconduct affected only a subset of a subset of the data reported under the . . . programs."

Post-*Escobar* Scienter

United States ex rel. Complin v. North Carolina Baptist Hosp., 818 F. App'x 179 (4th Cir. 2020)

- The court rejected relator's argument that scienter could be "inferr[ed] from the alleged regulatory violation itself . . . because **the FCA does not punish 'honest mistakes or incorrect claims submitted through negligence'**"
- The court emphasized the **ambiguity of the regulation at issue** in the case, including the open question of whether the rule "even . . . applies in the first place to the transactions in question"
- The "regulation" at issue was the "**Related-Party Rule**" . . . "which requires hospitals to report their costs for providing care to their own employees as 'related-party transactions,' and to submit for Medicare reimbursement only their actual, out-of-pocket costs rather than the amount charged." An exception exists for plans administered by third-party administrators
- In the course of its analysis, the court cited favorably to FCA case law applying the Safeco rule that reckless disregard cannot exist where the alleged fraud "turns on a **disputed interpretive** question" and the defendant has not been "**warned away**" from its interpretation

Recent Jurisprudence – Scienter

Ruckh v. Salus Rehabilitation, LLC, No. 18-10500, — F.3d —-, 2020 WL 3467393 (11th Cir. June 25, 2020)

- Relator alleged that a nursing home facility and related entities were misrepresenting the services they provided and also failed to comply with Medicaid requirements (e.g., upcoding).
- $100 million jury verdict before trebling; district court granted a motion to set aside the verdict, finding relators had failed to provide sufficient evidence of materiality and scienter at trial. The Eleventh Circuit reversed and reinstated the verdict in part.
- ***Scienter***: The Eleventh Circuit, despite the district court's observation that there was no evidence of a "massive, authorized, cohesive, concerted, enduring, top-down corporate scheme," held that relator's evidence showing company management was allegedly aware of and approved the practices at issue supported the jury's finding that the defendants acted with scienter.

- In August, the Eleventh Circuit **denied a request for a rehearing *en banc***.

FCA – Public Disclosure and First-to-File Bars

- **Public Disclosure Bar.** A relator's *qui tam* complaint cannot be "**substantially the same**" as allegations or transactions **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 he/she is an "original source" of the allegations, meaning he/she 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:** The public disclosure provisions were amended to the current language by PPACA in 2010; previously, the bar was jurisdictional and contained differences in the public disclosure and original source provisions
- **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 first-to-file and public disclosure bars do not apply to DOJ

Recent Jurisprudence – Public Disclosure Bar

***United States ex rel. Holloway v. Heartland Hospice, Inc.*, 960 F.3d 836 (6th Cir. 2020)**

- The Sixth Circuit unanimously held that ***relators are "agents" of the government for purposes of the public disclosure bar***, such that disclosure to a relator in a federal civil case may trigger the bar.
- The court subsequently affirmed dismissal of a case alleging substantially the same scheme as three prior *qui tam* suits involving the defendant's parent company.
- In that case, the relator—a former consultant for Heartland—alleged that the defendants certified patients as eligible for hospice under Medicare regulations even when the patients were not terminally ill, thereby "leech[ing] millions of dollars from the federal government in payments for unnecessary hospice care."
- Although the court ruled in the defendant's favor, it nevertheless rejected several alternative categories of potential public disclosures identified by the defendant, explaining that a DOJ settlement of FCA claims and a *qui tam* complaint filed against other entities, though involving similar schemes, did not qualify because ***courts do not infer industry-wide disclosure from allegations against a particular company.***

Recent Jurisprudence – First-to-File Bar

***In re Plavix Marketing, Sales Practice & Prods. Liability Litig. (No. II)*, --- F.3d ---, 2020 WL 5200681 (3d Cir. Sept. 1, 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

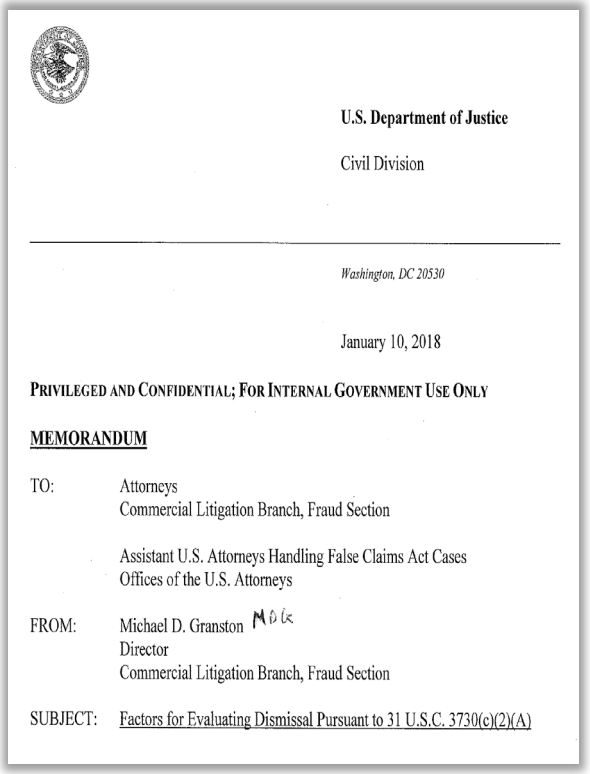
Recent Jurisprudence – Rule 9(b) Particularity

United States ex rel. Benaissa v. Trinity Health, No. 19-1207, — F.3d. —-, 2020 WL 3455795 (8th Cir. June 25, 2020)

- Relator—a trauma surgeon who operated at the defendants' regional hospital system—alleged that defendants compensated five physicians for referrals, rather than for their skills or credentials, in violation of the Stark Law and AKS.
- After the district court dismissed the claims under Rule 9(b), relator argued on appeal that he pleaded the particular details of a scheme paired with "reliable indicia" supporting an inference that claims were submitted. Relator pointed to his allegation that defendants derived nearly 30% of their annual revenue from Medicare reimbursements and it was likely that at least some of their claims submitted would be for services provided by those particular physicians.
- The Eighth Circuit affirmed dismissal under Rule 9(b), holding that the relator lacked "*firsthand knowledge of* [*defendants'*] *billing practices*" and had not pleaded any details about those billing indicating a reliable "*basis for knowledge*" that fraudulent claims were submitted, such as dates and descriptions of particular services coupled with "*a description of the billing system that the records were likely entered into*."

FCA – DOJ Dismissal Authority

- 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)



U.S. Department of Justice

Civil Division

Washington, DC 20530

January 10, 2018

PRIVILEGED AND CONFIDENTIAL; FOR INTERNAL GOVERNMENT USE ONLY

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

United States v. UCB, Inc., 970 F.3d 835 (7th Cir. 2020)

- 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 DOJ's exercise of its dismissal authority should be evaluated under the Federal Rule of Civil Procedure 41 standard concerning voluntary dismissals
- In the Seventh Circuit, **the voluntary dismissal right conferred by Rule 41 is "absolute" provided the notice of dismissal is served before the opposing party moves for summary judgment**
- The court also held, however, that **the government must intervene before it can move for dismissal—and so the "good cause" standard in the FCA still governs in the event that DOJ decides to dismiss a case** after initially declining to intervene
- The court characterized its holding as lying "much nearer to *Swift* than *Sequoia Orange*"

FCA – DOJ Dismissal Authority

United States v. Academy Mortgage Corp., 968 F.3d 996 (9th Cir. 2020)

- The Ninth Circuit considered the district court's denial of the government's motion to dismiss the case under Section 3730(c)(2)(A)
- The district court's decision in June 2018 held that **the government's cost-benefit justification was insufficient to satisfy the *Sequoia Orange* standard; the government claimed that discovery would be burdensome, but according to the court the government's limited investigation meant its justification was based on an incomplete understanding** of the potential recovery in the case
- The government appealed under the collateral order doctrine rather than seeking to have the issue certified for interlocutory review
- The Ninth Circuit held that **the collateral order doctrine does not apply to denials of motions to dismiss under Section 3730(c)(2)(A), "at least in cases where the Government has not exercised its right to intervene"**
- The court thus dismissed the appeal for lack of jurisdiction

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

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Enforcement Trends and Developments

By the Numbers: 2019 Federal Fiscal Year

> $3 Billion

Civil settlements and judgments under the FCA

782

New FCA cases filed

81%

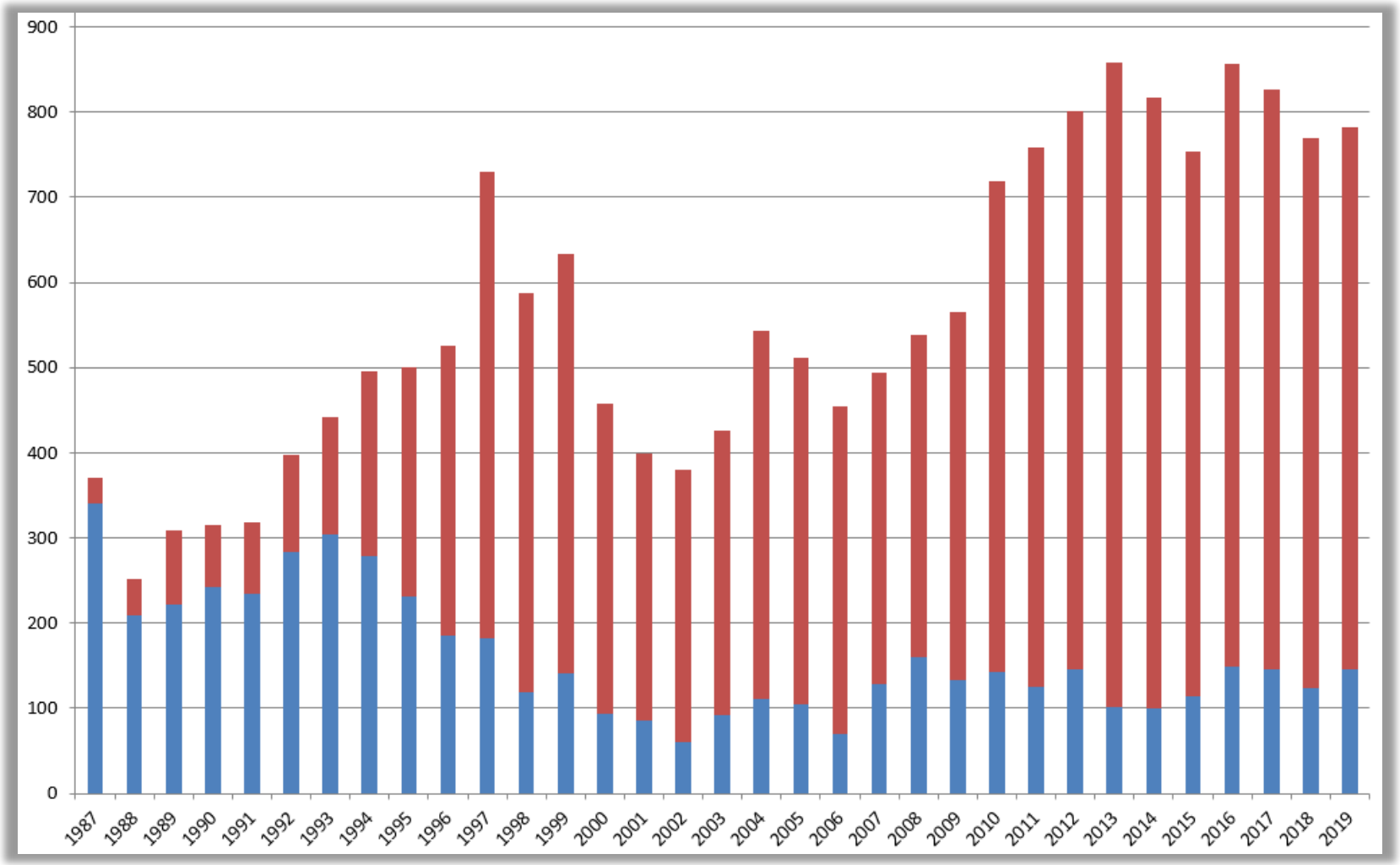
New FCA cases initiated by a whistleblower

63%

Overall federal recovery from cases in which the government intervened

Source: U.S. Dep't of Justice, "Fraud Statistics – Overview" (Jan. 9, 2020)

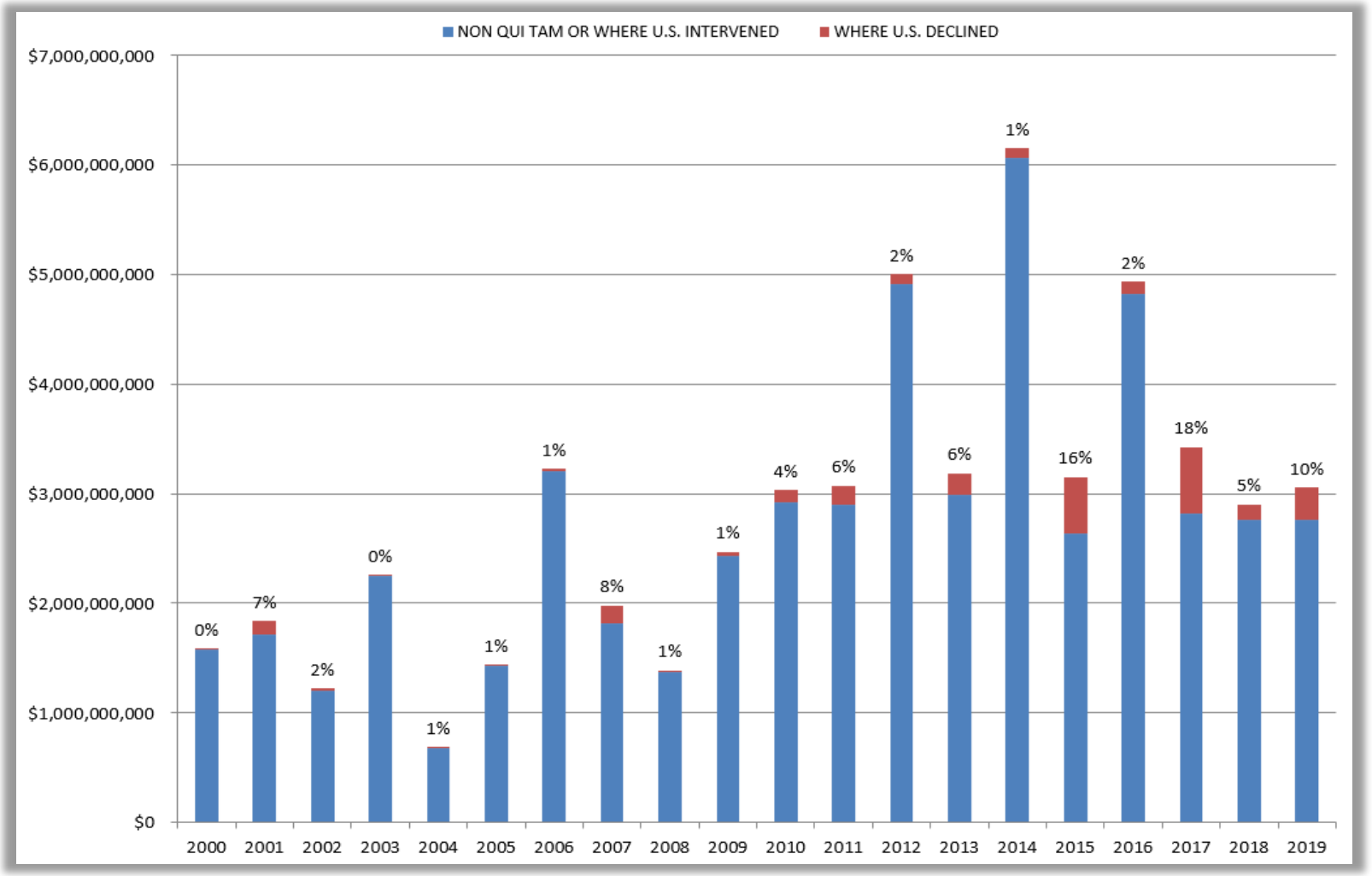
Number of New FCA Suits (FFY 1987–2019)



FFY 2019: 782 new FCA suits • 636 *qui tam* • 146 non-*qui tam*

Source: DOJ, "Fraud Statistics – Overview"

Recoveries through Settlements & Judgments (FFY 2000–2019)



FFY 2019: >$3B • $2.74B intervened & non-*qui tam* • $293M declined

Source: DOJ, "Fraud Statistics – Overview"

By the Numbers: 2020 Year to Date

>$737 million

FCA civil recoveries from *settlements* with health care providers in 2020 to date, according to Gibson Dunn calculations

>$442 million

from civil settlements involving *non-AKS billing theories (e.g., upcoding)* with health care providers in 2020 to date, according to Gibson Dunn calculations

1st?

2020 is *very close* to the pace set in 2019 for FCA civil recoveries with health care providers

Health Care Providers – Additional 2020 Stats (to date)

Avg. settlement = ~$11.3 million

More than a dozen 8-figure settlements

~37% did not involve whistleblowers

≥ 40 *qui tam* settlements

Largest settlement: $119.6 million

> 50% involve clinics & single providers

Health Care Providers – Key Legal Theories

FCA allegations against health care providers typically are based on one (or more) of the following legal theories:

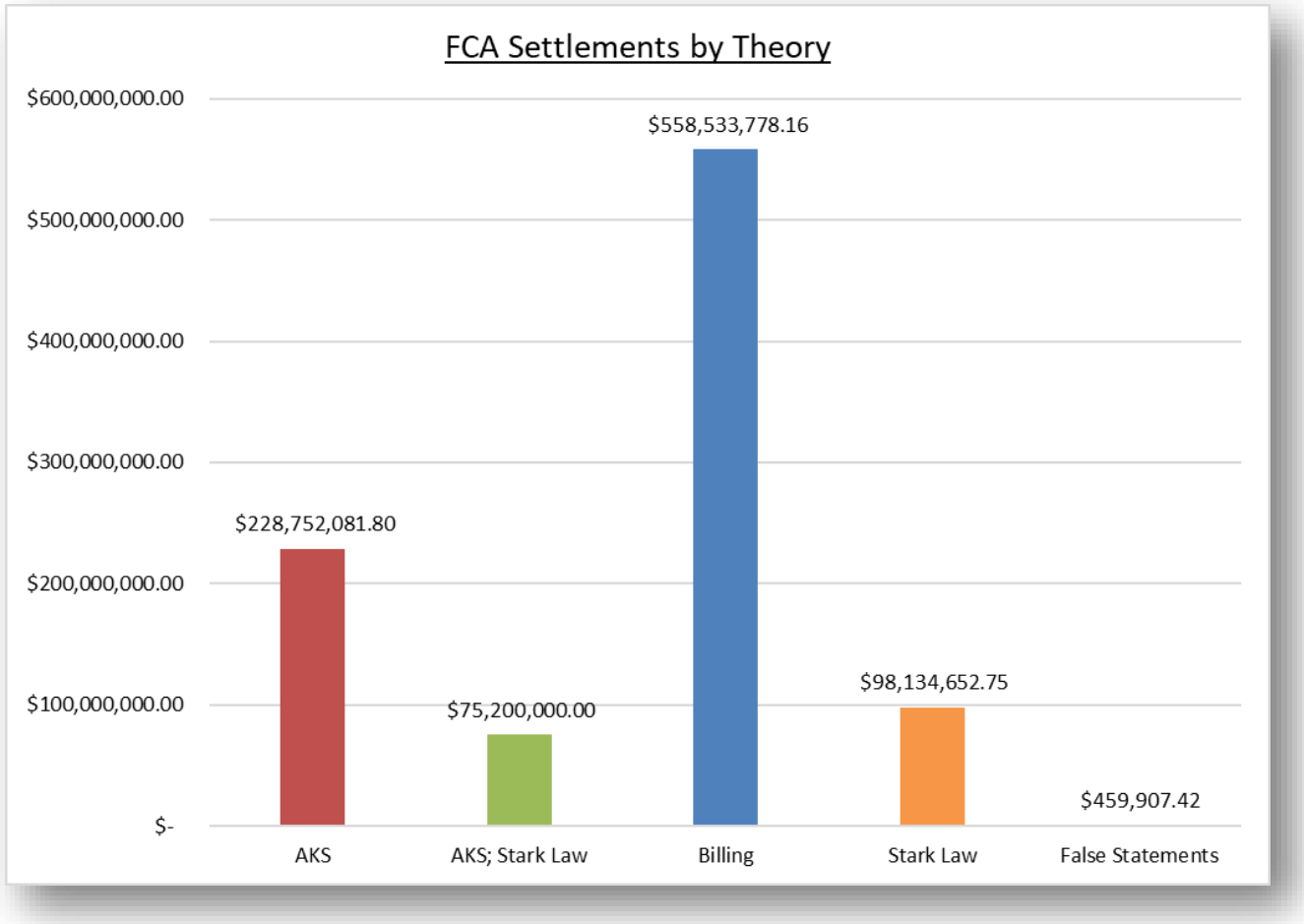
1. **Medically Unnecessary Medical Care.** Billing federal health care programs for medical care that was medically unnecessary for the underlying patient
2. **"Upcoding."** Providing the billing code of a more expensive procedure instead of the appropriate code for the services actually rendered
3. **Services Not Provided.** Billing federal health care programs for services the provider did not, in fact, provide to the patient; in some instances, billing for procedures performed by a provider who was not qualified to perform the procedure
4. **Ineligible Services.** Billing for services for which the patient was ineligible (for example, submitting claims to federal health care programs for patients who were not eligible for the hospice care they nonetheless received)
5. **AKS.** Payment of remuneration to other providers in a position to refer patients to the provider
6. **Stark Law.** Violation of the prohibition of physician self-referral (i.e., referral of a patient to another provider with whom the physician has a financial relationship)

Health Care Providers – 2019 FCA Recoveries

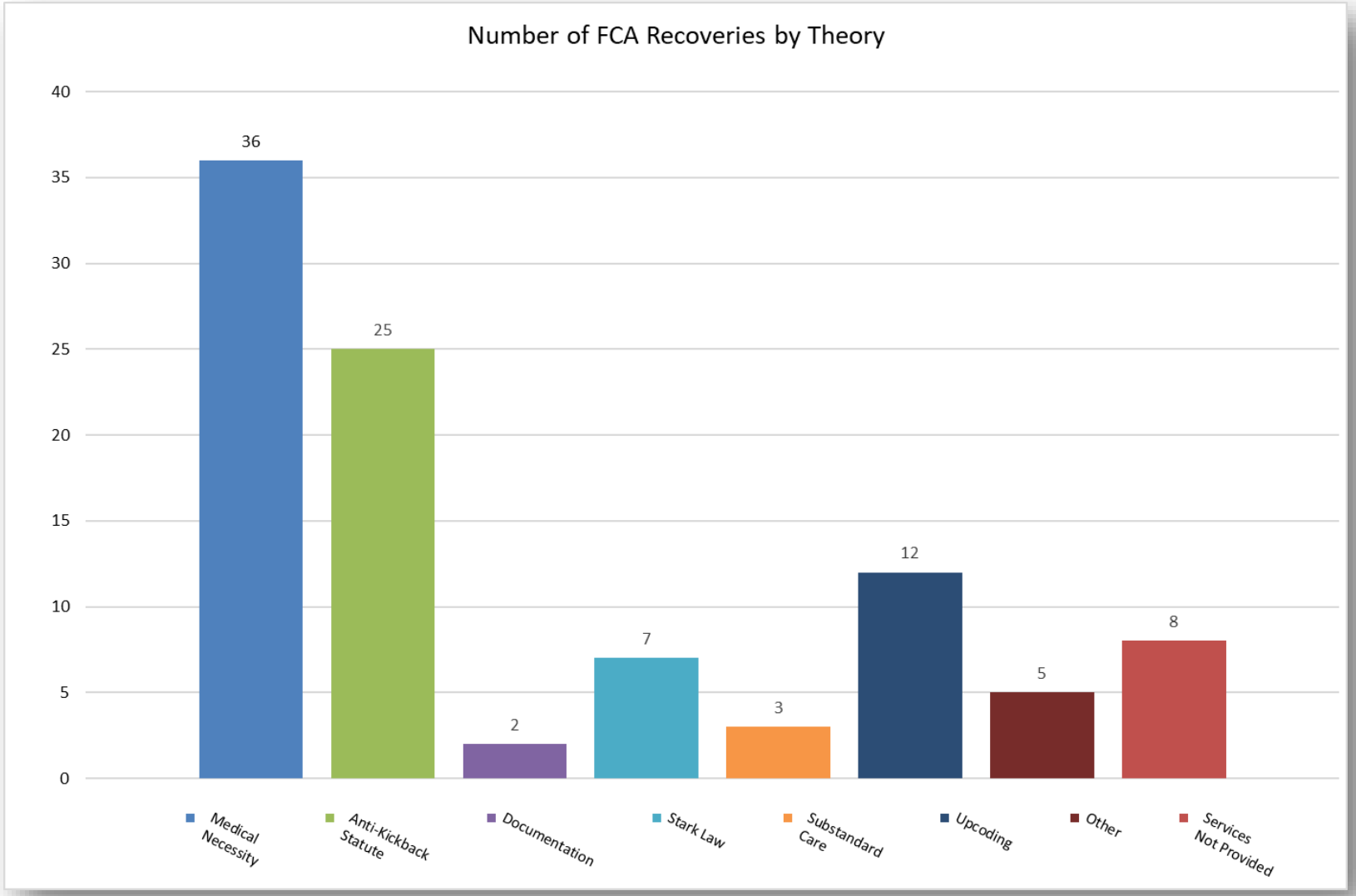
~$991 million in civil recoveries from health care providers in 2019

- **Improper Billing:** ~$558.5 million
- **AKS:** ~$303 million
- **Stark Law:** ~$173 million

****Note: Multiple theories may be asserted in a given settlement*



Health Care Providers – 2019 FCA Recoveries



2020 Resolutions: Medical Necessity

***United States ex rel. Krauss v. Guardian Elder Care Holdings, Inc.*, (E.D. Pa.)**

- Operator of nursing facilities in Pennsylvania, Ohio, and West Virginia agreed to pay more than $15.4 million to settle allegations that it overbilled for medically unnecessary rehabilitation therapy services.
- Allegations included that "certain patients suffered from dementia and did not need or want rehabilitation therapy, but Guardian Elder Care allegedly pressured therapists to provide those services anyway to meet revenue goals."

***United States ex rel. Anderson v. Encore Rehabilitation Services, LLC* (E.D. MI) [and related lawsuits]**

- A rehabilitation services company agreed to pay more than $4 million to resolve allegations that it caused three skilled nursing facilities to submit claims for reimbursement for unnecessary or inaccurately recorded time allegedly spent on rehabilitation services.
- Allegations included that Encore recorded "group therapy minutes as individual therapy when concurrent or group therapy was actually provided."

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

Illinois Health Care Fraud, LLC v. Sayeed, 957 F.3d 743, 745 (7th Cir. 2020)

- Relator alleged in-home health care services providers and associated entities engaged in an illegal patient referral scheme whereby provider purportedly purchased access to patient files from a nonprofit senior care organization.
- After a bench trial, the district court entered judgment for the defendants, concluding there was no evidence that any remuneration was paid with the intent to induce "*referrals*."
- Among other arguments, relator argued at trial that the provider had violated the AKS when it entered into a contract with the non-profit under which it paid a monthly fee that was "*intended to secure access to client information*" in the non-profit's files, which was then used by the provider to solicit business.
- On appeal, the Seventh Circuit held that the district court had not adequately addressed whether this "*file-access theory*" of liability could "constitute a prohibited referral under the Anti-Kickback Statute."

2020 Resolutions: AKS

***United States of America ex rel. Louis Longo v. Wheeling Hospital, Inc. et al.,* (N.D. W. Va.)**

- DOJ alleged that, from 2007 to 2020, under the direction and control of its prior management, West Virginia-based Wheeling Hospital systematically violated the Stark Law and the AKS by knowingly and willfully paying improper compensation to referring physicians that was based on the volume or value of the physicians' referrals or that was above fair market value.
- In September 2020, the acute care hospital agreed to pay *$50 million* to resolve these claims.

***United States ex rel. Allison v. Southwest Orthopaedic Specialists, PLLC, et al.,* (W.D. Okla.)**

- In July 2020, an Oklahoma specialty hospital, its management company, a related physician group and two physicians agreed to pay *$72.3 million* to resolve allegations regarding an improper relationship between the entities. The settlement resolved allegations that from 2006 until 2018, the hospital and its management company provided improper remuneration to the physician group and certain of its physicians in exchange for patient referrals.
- Remunerations came as: (i) free or below-fair-market-value office space, employees, and supplies, (ii) compensation in excess of fair market value, (iii) equity buyback provisions and (iv) preferential investment opportunities.

AKS: 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

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

AKS: EHR and the Opioid Epidemic

Practice Fusion (January 2020)

- On January 27, 2020, DOJ announced that Practice Fusion, Inc., a San Francisco-based health information technology developer, agreed pay $145 million to resolve criminal and civil investigations relating to its electronic health records (EHR) software.
- As part of its criminal resolution, Practice Fusion admitted to soliciting and receiving kickbacks from a major opioid company in exchange for the use of its EHR software to "nudge" physicians into prescribing the company's opioid pain medications.
- Practice Fusion has executed a deferred prosecution agreement and agreed to pay over $26 million in criminal fines and forfeiture as part of that agreement.
- In separate civil settlements, Practice Fusion agreed to pay a total of approximately **$118.6 million** to the federal government and states to resolve allegations based on kickbacks the company accepted from the opioid company and other pharmaceutical companies, and allegations that Practice Fusion caused users to submit false claims for federal incentive payments through its misrepresentation of the capabilities of its EHR software.

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Hot Topics for Health Care Providers

The CARES Act

- The **Coronavirus Aid, Relief, and Economic Security Act (CARES Act)**
  - Largest emergency stimulus package in history – $2.2 trillion in government funds to mitigate effects of COVID-19
  - Key programs:
    - Paycheck Protection Program (PPP) – Small Business Administration (SBA) loan program
    - Main Street Lending Program (Federal Reserve)
    - "Provider Relief Fund"
  - Created Pandemic Response Accountability Committee (PRAC) and Special Inspector General for Pandemic Recovery (SIGPR)
    - SIGPR empowered to conduct audits and investigations into CARES Act relief programs

DOJ Enforcement Priorities in the COVID-19 Era

- DOJ has made clear that it sees the FCA as a prime tool for addressing fraud in COVID-19 stimulus programs
- Then-Principal Deputy Assistant Attorney General Ethan Davis gave a speech in June that made DOJ's focus on the programs clear:
  - "Going forward, the Civil Division will make it a priority to use the False Claims Act to **combat fraud** in the Paycheck Protection Program"
  - "We will use the False Claims Act to hold accountable those who knowingly attempt to skirt th[e] requirements" of the **Main Street Credit Facility**
  - "Our enforcement efforts may also include, in appropriate cases, **private equity firms** that sometimes invest in companies receiving CARES Act funds. . . . Where a private equity firm takes an active role in illegal conduct by the acquired company, it can expose itself to False Claims Act liability"
  - **But:** "You can rest assured that the Civil Division will not pursue companies that made **immaterial or inadvertent technical mistakes** in processing paperwork, or that **simply and honestly misunderstood** the rules, terms and conditions, or certification requirements"

Key DOJ Enforcement Tools in the COVID-19 Era

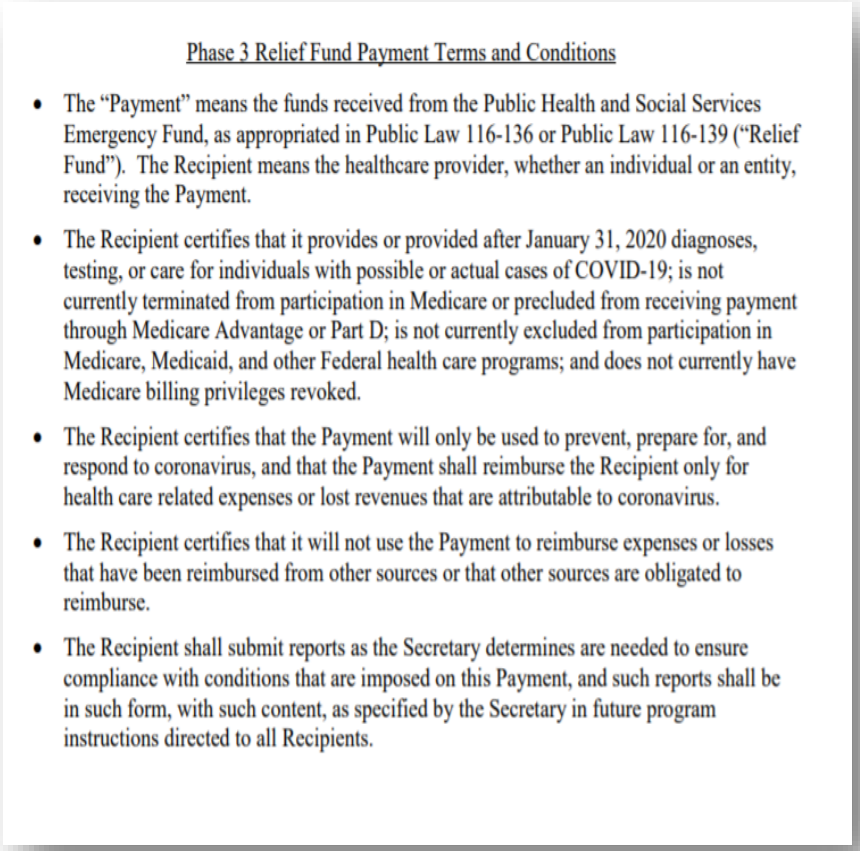
- **Coronavirus Fraud Coordinator:** In a March 16 memorandum to all U.S. Attorneys and a March 20 press release, AG William Barr announced that DOJ will prioritize the investigation and prosecution of coronavirus-related fraud. In addition, Attorney General Barr directed U.S. Attorneys to appoint a "*Coronavirus Fraud Coordinator*" in each district—responsible for coordinating enforcement and conducting public outreach and awareness—and also established a national system for whistleblowers to report suspected fraud.
- **Special Inspector General for Pandemic Recovery (SPIGR):** In June 2020, the Senate confirmed Brian Miller to this position. Miller has been a White House lawyer since 2018, and was previously a federal prosecutor and inspector general for the General Services Administration. *SPIGR has been staffing with experienced health care fraud prosecutors.*
- **"MOUs" with USAOs**
- **Agency Partnerships (e.g., HHS, FTC, SEC)**

Health Care Provider COVID-Related Focus Areas

CARES Act - "Provider Relief Fund"	FCA liability can attach where providers in receipt of money from the **Provider Relief Fund** knowingly violate the conditions of the program, and/or falsely certify compliance with those terms and conditions (e.g., prohibition on balance billing); the CARES Act also expanded the pre-existing **Medicare Accelerated and Advance Payment Programs**. Providers could be subject to reverse FCA liability for failure to pay back these loans.
PPP Loans	DOJ, with the assistance of other agencies, is focused on providers who "***double dip***" by receiving COVID-19-related payments for the same expenses under multiple government programs. Providers should also be aware of misuse of PPP loan funds, which can result in FCA liability.
Telehealth	Telehealth remains a key area of potential FCA liability, particularly in the COVID era. While the government has relaxed enforcement of certain telehealth provisions, providers should stay vigilant.
AKS	Despite some indication from the government that it would exempt COVID-related discounts and other payment arrangements by providers, AKS liability for such arrangements remains a possibility if not done in good faith.

COVID-19: Examples of "Terms & Conditions"

Examples of Key Terms & Conditions from Relief Programs



Phase 3 Relief Fund Payment Terms and Conditions

- The "Payment" means the funds received from the Public Health and Social Services Emergency Fund, as appropriated in Public Law 116-136 or Public Law 116-139 ("Relief Fund"). The Recipient means the healthcare provider, whether an individual or an entity, receiving the Payment.
- The Recipient certifies that it provides or provided after January 31, 2020 diagnoses, testing, or care for individuals with possible or actual cases of COVID-19; is not currently terminated from participation in Medicare or precluded from receiving payment through Medicare Advantage or Part D; is not currently excluded from participation in Medicare, Medicaid, and other Federal health care programs; and does not currently have Medicare billing privileges revoked.
- The Recipient certifies that the Payment will only be used to prevent, prepare for, and respond to coronavirus, and that the Payment shall reimburse the Recipient only for health care related expenses or lost revenues that are attributable to coronavirus.
- The Recipient certifies that it will not use the Payment to reimburse expenses or losses that have been reimbursed from other sources or that other sources are obligated to reimburse.
- The Recipient shall submit reports as the Secretary determines are needed to ensure compliance with conditions that are imposed on this Payment, and such reports shall be in such form, with such content, as specified by the Secretary in future program instructions directed to all Recipients.

Provider Relief Fund "Phase 3"

- Provides diagnoses, testing, or care for individuals with possible or actual cases of COVID-19;
- Not currently "excluded" from federal health care programs;
- Payment will "only be used to prevent, prepare for, and respond to coronavirus," and the funds "shall reimburse the Recipient only for health care related expenses or lost revenues that are attributable to coronavirus."

COVID-19: "Terms & Conditions" Risk Areas

Provider Relief Fund – "Terms & Conditions" Risk Areas

Prohibition on "Balance Billing"	For all care for a presumptive or actual case of COVID-19, recipient of funds must certify that it will **not** seek to collect from the patient **out-of-pocket expenses** in an amount ***greater than*** what the patient would have otherwise been required to pay if the care had been provided by an in-network provider.
Poor Recordkeeping	Recipient of funds must maintain **appropriate records and cost documentation** to substantiate the reimbursement of costs. The Recipient must also promptly submit copies of such records and cost documentation upon the request of the Secretary, and Recipient agrees to fully cooperate in all audits the Secretary, Inspector General, or Pandemic Response Accountability Committee conducts.
False Statements	Recipient must certify that all information it provides as part of its application for payment, as well as all information and reports relating to the payment that it provides in the future at the government's request, are **true, accurate and complete**, to the best of its knowledge.
Non-COVID Expenses	Recipient must certify that payment will only be used to **prevent, prepare for, and respond to coronavirus**, and that payment will reimburse the Recipient only for health care-related **expenses or lost revenues that are attributable to coronavirus.**

DOJ is Committed to Pre-Existing Focus Areas Even Through COVID-19 Enforcement

Pre-Pandemic Focus Areas:

- "*Quality of care*"
- *Nursing homes* and *elder care facilities*
- *Opioids*
- *Telemedicine*

LAW.COM | New York Law Journal

Next for America's Nursing Homes: A Legal Pandemic

Bloomberg Law

Fraud Suits, DOJ Probes Await Nursing Homes After Virus Abates

THE UNITED STATES DEPARTMENT of JUSTICE

Department of Justice Launches a National Nursing Home Initiative

THE NATIONAL LAW REVIEW

DOJ Creates National Rapid Response Strike Force As Focus on Health Care Fraud Continues to Grow

FDA U.S. FOOD & DRUG ADMINISTRATION

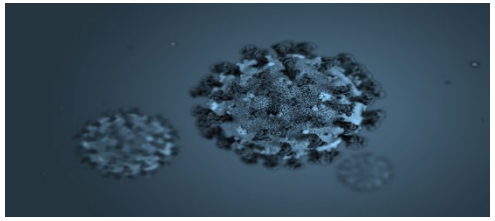
FDA Insight: The Opioid Epidemic and COVID-19 Pandemic

COVID-19: Impact on Telemedicine

- **Increased Focus on Telemedicine.** COVID-19 has upended almost every industry, but its effect on health care providers has been particularly pronounced
  - The pandemic has increased demand for telehealth services
  - As the number of patients seeking remote care has risen, HCPs have accelerated their efforts to expand and facilitate access to such services, especially for at-risk populations
- **Government Response.** Federal and state regulators have moved to ease—and, in some cases, eliminate—certain restrictions applicable to telehealth services (e.g., restrictions on eligible beneficiaries and services) and to telemedicine generally
- **AKS, FCA, and Other Legal Risks.** Risks remain, and it is not yet clear if (or how) demand for telehealth services will change when COVID-19 is in the rearview mirror, or how regulators will respond once the crisis has passed

Regulatory Efforts to Increase the Use of Telehealth Services

- **FDA is exercising enforcement discretion over various telehealth devices**
- **HHS has waived many Medicare coverage requirements**, vastly expanding the population eligible to receive telehealth services
- **CMS and many states have relaxed licensure requirements**, enabling doctors to render telehealth services across state lines with minimal delays



Telemedicine: AKS and FCA Risk Areas

Despite the legislative and administrative loosening of certain restrictions in light of the COVID-19 pandemic, telemedicine continues to raise legal risks, including under the AKS and FCA

Anti-Kickback Statute

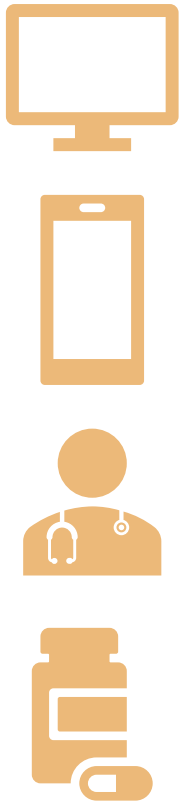
- Telehealth arrangements commonly involve **coordination and potential referrals among multiple parties** (e.g., Party A refers potential patients (or provides IT equipment, or leases retail space) to Party B to facilitate Party B's provision of telehealth services, while Party B may, but is not required to, refer patients back to Party A)
- These arrangements may implicate the AKS, but if structured properly, may present a low risk of fraud and abuse and/or fall under one of the AKS **safe harbors**

False Claims Act

- Recent legislation has (temporarily) waived some restrictions, but **telehealth practices typically present certain FCA risks**
- Federal claims "resulting from" an AKS violation are false post-ACA
- Further, telehealth providers generally may not assess patients by telephone (and must instead) use real-time audio-visual communication to assess patients at specific qualifying sites
- Seeking federal reimbursement for such services typically may violate the FCA if done in violation of legal restrictions or requirements

Telemedicine: Provider Fact Patterns and AKS/FCA Risks

- **Potential "Remuneration" / "Inducements"**
  - Payments to telehealth companies
  - Advertising for / referrals to telehealth companies
  - Opportunity to earn telehealth per-visit fees (and other reimbursement)
  - Referrals to specialists / labs
  - Usage of particular devices
  - Patient pricing arrangements
  - Other situations that may be "arranging" for furnishment of health care items or services
- **Potential Intent "to Induce"**
  - In recent advisory opinions, OIG has suggested that one purpose of telehealth relationships "could be to induce referrals of Federal health care program business"
  - AKS/FCA investigation risk factors include patient steering, intrusion on independent clinical decision-making, likelihood of increasing inappropriate utilization / program costs, and analyses of ROI (or leverage, pull-through, etc.)



Telemedicine: Key Advisory Opinions

HHS OIG has provided some **insight into how regulators will analyze telehealth fact patterns**

OIG Ad. Op. 18-03

May 31, 2018

Proposed Arrangement

Nonprofit health center to provide equipment / services to facilitate telemedicine visits to County Clinic (located ~80 miles away) for HIV prevention consultations

Risk Mitigation Factors

- Safeguards to avoid inappropriate patient steering (e.g., Clinic's freedom to refer to other centers / HCPs)
- Low likelihood of inappropriate increase in program costs
- Patients as primary beneficiaries
- Public health focus on HIV

OIG Ad. Op. 19-02

January 29, 2019

Proposed Arrangement

Pharma company to loan smartphones to needy patients to receive adherence data from sensor embedded in prescription antipsychotic drug

Risk Mitigation Factors

- Not advertised to patients (but part of HCP education)
- No additional HCP reimbursement
- Low impact on HCP judgment
- Limited functionality smartphone and needy patient population

OIG Ad. Op. 19-04

September 10, 2019

Proposed Arrangement

Tech company to make available to beneficiaries an online HCP appointment directory app (with HCPs paying per-click fees for listing and advertising)

Risk Mitigation Factors

- No filtering of HCPs based on fees paid or "non-user-centric criteria"
- FMV (set in advance) for listing
- Requestor not a provider / supplier (and no promotion of particular items / services)
- Not targeted to federal beneficiaries

Telemedicine: Safe Harbors and Related Good Practices

Several **safe harbors** may permit appropriately structured telemedicine arrangements that otherwise implicate the AKS (and provide general guardrails for arrangements)

- **Leases for Space or Equipment [42 C.F.R. § 1001.952(b)–(c)]**
  - May permit certain arrangements under which one party provides telemedicine equipment, and/or the space to use that equipment, to a second party that provides telehealth services to patients
- **Personal Services and Management Contracts [42 C.F.R. § 1001.952(d); HHS OIG Op. No. 18-03]**
  - May permit certain arrangements under which physicians receive money from an entity, and use equipment provided by the entity, to provide telehealth services to the entity's customers
  - According to HHS OIG, such arrangements may be permissible even where physicians refer patients back to the entity, as long as such referrals are not required under the terms of the contract
- **Promotes Access to Care [81 Fed. Reg. 88,368 (Dec. 7, 2016); HHS OIG Op. No. 17-01]**
  - May permit certain arrangements—with no explicit cost limitation—that "promote[] access to care and pose[] a low risk of harm to patients and Federal health care programs"
    - Such arrangements must, among other things, "improve[] a particular beneficiary's ability to obtain" care by providing tools and/or resources necessary to remove "socioeconomic, educational, geographic, mobility, or other barriers" to care or treatment [81 Fed. Reg. at 88,392]

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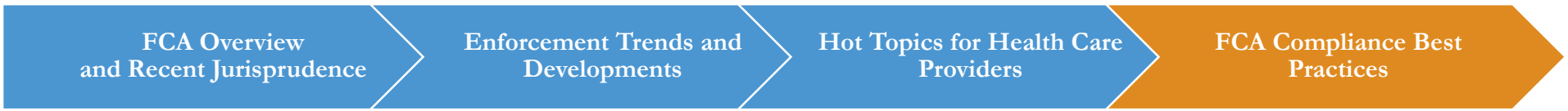
FCA Compliance Best Practices



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
  - Internal compliance and reporting programs also help prevent smaller regulatory issues or other concerns from giving rise to FCA issues.
- 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

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Questions?

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Upcoming Gibson Dunn Webcasts

- **November 9 | Spoofing: What it is, where it's going** | 12:00 – 1:30 pm EST REGISTER
- **November 12 | Managing Internal Audit and Investigations |** 11:30 – 12:30 EST REGISTER
- **November 16 | Corporate Compliance and Sentencing Guidelines |** 12:00 – 2:00 pm EST REGISTER
- **November 18 | SEC Enforcement Focus on COVID-19 Issues and Recent Accounting Cases** | 12:00 – 1:15 pm EST REGISTER
- **November 19 | Managing Parallel Enforcement Investigations by State and Local Prosecutors in California** | 4:00 – 5:00 pm EST REGISTER
- **December 2 | What's next? The Legislative and Policy Landscape After the 2020 Election** | 12:00 – 1:00 pm EST REGISTER
- **December 8 | Congressional Investigations and Oversight Post-Election |**12:00 – 1:00 pm EST REGISTER
- **December 10 | International Anti-Money Laundering and Sanctions Enforcement** | 12:00 – 1:30 pm EST REGISTER

Publications and Recorded Webcasts

Publications

- 2020 Mid-Year False Claims Update (July 17, 2020): https://www.gibsondunn.com/2020-mid-year-false-claims-act-update/
- Implications of COVID-19 Crisis for False Claims Act Compliance (March 31, 2020): https://www.gibsondunn.com/implications-of-covid-19-crisis-for-false-claims-act-compliance/

Recorded Webcasts

- The False Claims Act: Updated for the Drug and Medical Device Manufacturing Sectors (October 22, 2020)
  https://www.gibsondunn.com/webcast-the-false-claims-act-updates-for-drug-device-manufacturers/
- The False Claims Act: Updates for the Government Contracting Sector (October 13, 2020)
  https://www.gibsondunn.com/webcast-the-false-claims-act-updates-for-the-government-contracting-sector/
- The False Claims Act: Updates for the Financial Services Sector (October 6, 2020)
  https://www.gibsondunn.com/webcast-the-false-claims-act-updates-for-the-financial-services-sector/

Gibson Dunn COVID-19 Resources: https://www.gibsondunn.com/category/publications/

Gibson Dunn False Claims Act/Qui Tam Defense Practice: https://www.gibsondunn.com/practice/false-claims-actqui-tam-defense/

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