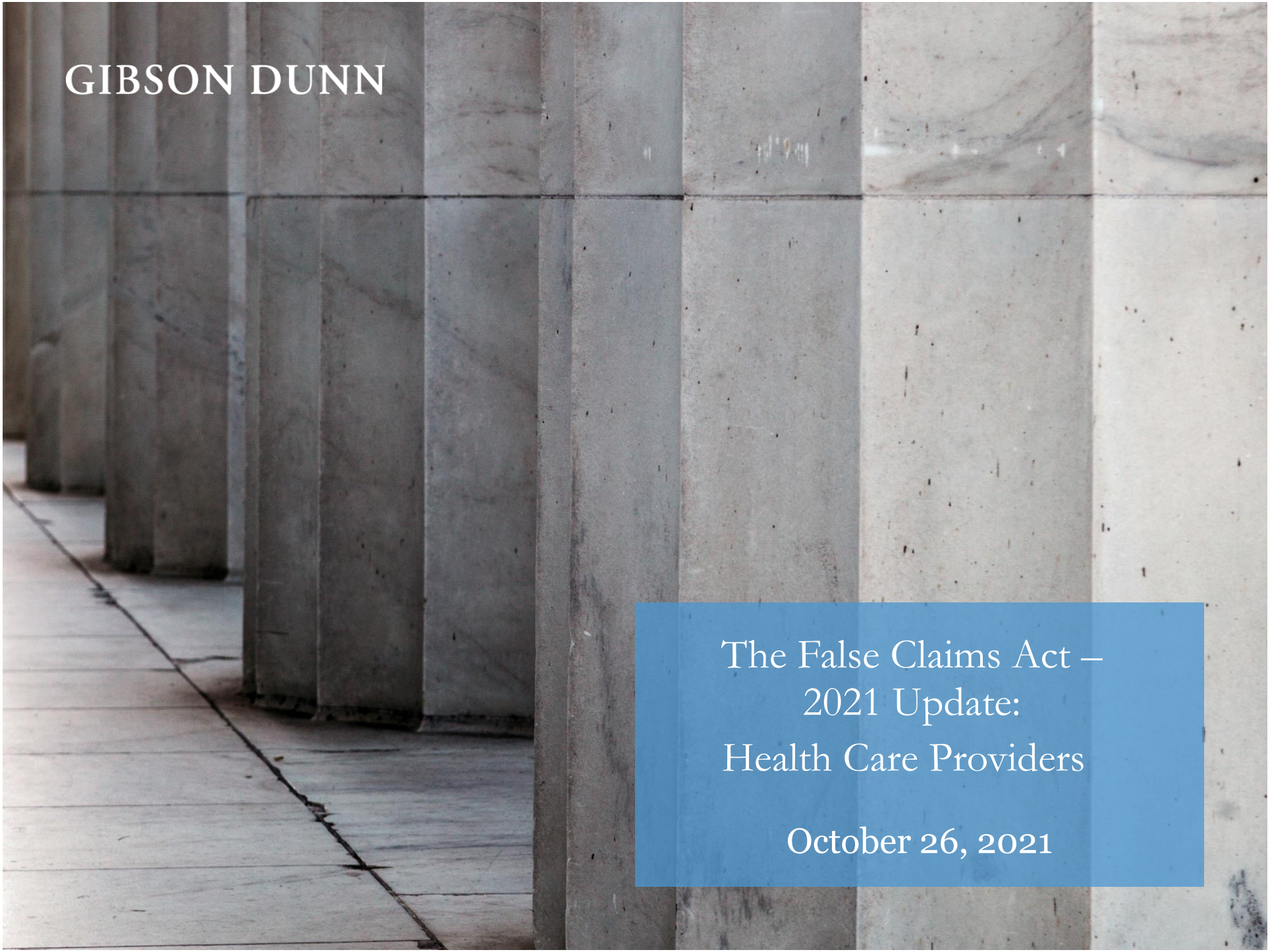

The False Claims Act – 2021 Update: Health Care Providers

October 26, 2021

Today's Presenters

Jonathan Phillips is a partner in the Washington, D.C. office, and Co-Chair of the Firm's False Claims Act and *Qui Tam* Defense Group. Mr. Phillips's practice 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.

Robert Hur is a partner in the Washington, D.C. office, and Co-Chair of the Firm's Crisis Management Practice Group. As United States Attorney for the District of Maryland, he supervised one of the nation's largest and busiest U.S. Attorney's Offices, including its Civil Division and docket of False Claims Act enforcement matters. He also served as Principal Associate Deputy Attorney General, assisting the Deputy Attorney General with oversight of the entire Department of Justice, including the Civil Division.

Brendan Stewart is of counsel in the New York office. As a former federal prosecutor since 2012, his practice focuses on health care enforcement, compliance, and litigation as well as other white collar enforcement matters and related litigation. Prior to joining Gibson Dunn, Mr. Stewart 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 anticipate receiving their certificate of attendance in eight weeks following the webcast
- Please direct all questions regarding MCLE to CLE@gibsondunn.com

Agenda

1	**FCA Overview and Recent Jurisprudence**
2	**Policy Developments**
3	**Enforcement Trends and Developments**
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 – Key Provisions

31 U.S.C. § 3729(a)(1)	Statutory Prohibition	Summary
(A)	Knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval	False/Fraudulent Claim
(B)	Knowingly makes or uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim	False Record/Statement
(C)	Conspires to violate a liability provision of the FCA	Conspiracy
(G)	Knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the government	"Reverse" False Claim

FCA – Overview of Key FCA Theories

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/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

FCA – *Qui Tam* Provisions

- ***Qui Tam Provisions***
  - Enable so-called "relators" to bring cases in the government's name and receive ***as much as 30%*** of recovery or judgment
  - Allow government to intervene
    - An increasing number of cases are pursued ***without government intervention*** (but often with government statement of interest)
  - DOJ has broad dismissal authority
    - We will cover ongoing developments in DOJ's use of this power
- ***FCA Whistleblower Protections (31 U.S.C. § 3730(h))***
  - Protect employees and others (e.g., contract workers)
  - Relief may include double back pay and interest on back pay; reinstatement (at same level); or costs and attorneys' fees
  - Case law continues to develop, e.g., around meaning of the anti-retaliation provision's causation language ("because of")

"In short, sir, I have based the [*qui tam* provision] upon the old-fashioned idea of holding out a temptation and '***setting a rogue to catch a rogue***,' which is the safest and most expeditious way I have ever discovered of bringing rogues to justice."

Statement of Senator Howard, Cong. Globe, 37th Cong. 955-56 (1863)

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)

Recent Jurisprudence – FCA Causation

***United States ex rel. Martino-Fleming v. S. Bay Mental Health Ctrs.*,**

No. 15-CV-13065 (D. Mass. May 19, 2021)

- Relator alleged the submission of claims for Medicaid payment by mental health treatment facility that were due to alleged violations of personnel licensure requirements. A private equity firm that purchased the facility through an intermediate entity was named as a defendant in the action.
- The Court denied PE firm's motion for summary judgment, finding that the PE firm **could be liable for "causing" false claims even without any direct involvement in the facility's claims submission**.
- The Court noted that the PE firm, during the diligence process, had received a report indicating noncompliance with licensure requirements, and found that because the PE firm "**had the power to fix the regulatory violations which caused the presentation of false claims but failed to do so**," FCA causation could be shown.

Materiality

- *Universal Health Services, Inc. v. United States ex rel. Escobar*, 579 U.S. 176 (2016), 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. Invs. Corp.,
987 F.3d 1340 (11th Cir. 2021)*

- Relators alleged that Mortgage Investors Corporation charged veterans fees that were prohibited by Veterans Affairs ("VA") regulations while falsely certifying to the VA that they were collecting permissible fees, thereby inducing the VA to insure the loans.
- After the district court granted defendants summary judgment on the element of materiality, relators argued on appeal that there was still an issue of material fact despite the government's continued payment with actual knowledge of defendant's violations.
- The Eleventh Circuit reversed, reviewing the VA's behavior "***holistically***" to conclude that there was evidence of materiality. The court considered that the VA was required, by law, to honor guaranties once issued, "regardless of any fraud by the original lender," and ultimately held that "[t]o resolve the issue by weighing conflicting evidence was error." In doing so, the court reiterated that no single element is dispositive, including "government knowledge and its enforcement action."

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 to Medicare regarding patient arrival times, and the district court granted summary judgment to defendants on materiality
- The Tenth Circuit affirmed, finding it significant that the Centers for Medicare and Medicaid Services' third-party investigative service had investigated the 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**"

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

Post-*Escobar* 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 intepretation of U&C prices was correct, SuperValu's interpretation was **"objectively reasonable,"** and "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 – Statistical Arguments and Rule 8 Pleading

Integra Med Analytics LLC v. Providence Health & Servs.,

854 F. App'x 840 (9th Cir. 2021)

- Integra alleged that Providence Health submitted claims to Medicare coded for more lucrative diagnoses that were unsupported by patients' conditions, in violation of the FCA.
- After the district court denied Providence Health's motion to dismiss Integra's primary FCA claim, defendants argued on appeal that Integra failed to adequately plead false or fraudulent conduct.
- The Ninth Circuit reversed dismissal under Rule 8, holding that Integra's statistical analysis failed to rule out the possibility that Providence's Medicare billing methods were "at the forefront of a national trend" of coding procedures at higher diagnosis codes, which was an "obvious alternative explanation" under *Iqbal*. As such, Integra only offered a "*possible* explanation," that could not underpin a plausible claim for relief.

Recent Jurisprudence – Statistical Arguments and Rule 9(b) Particularity

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

- Relators alleged that Bethany Hospice violated the Georgia False Medicaid Claims Act and the FCA when it billed the government for services provided to Medicare and Medicaid patients referred in violation of the AKS.
- Relators argued that because a significant number of Medicare recipients were referred to Bethany Hospice, and because "all or nearly all" of the patients received coverage from Medicare, it was mathematically probable that the hospice had submitted claims to the government for patients obtained through kickback agreements.
- After the district court court granted Bethany Hospice's motion to dismiss, relators argued on appeal that their complaint contained sufficient indicia of reliability to support, even if they did not include details about specific claims submitted to the government.
- The Eleventh Circuit affirmed under Rule 9(b), holding that allegations based upon numerical probability were not "an indicium of reliability" sufficient to "allege actual submission of a false claim" under the FCA.

Policy Developments

FCA – Biden Administration

- 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"

DOJ Enforcement Priorities – Civil Cyber-Fraud Initiative

- On October 6, 2021, Deputy Attorney General Lisa O. Monaco **announced the launch of DOJ's Civil Cyber-Fraud Initiative**, combining the department's civil fraud enforcement, government procurement and cybersecurity expertise "to combat new and emerging cyber threats to the security of sensitive information and critical systems."

"***For too long, companies have chosen silence under the mistaken belief that it is less risky to hide a breach than to bring it forward and to report it***"

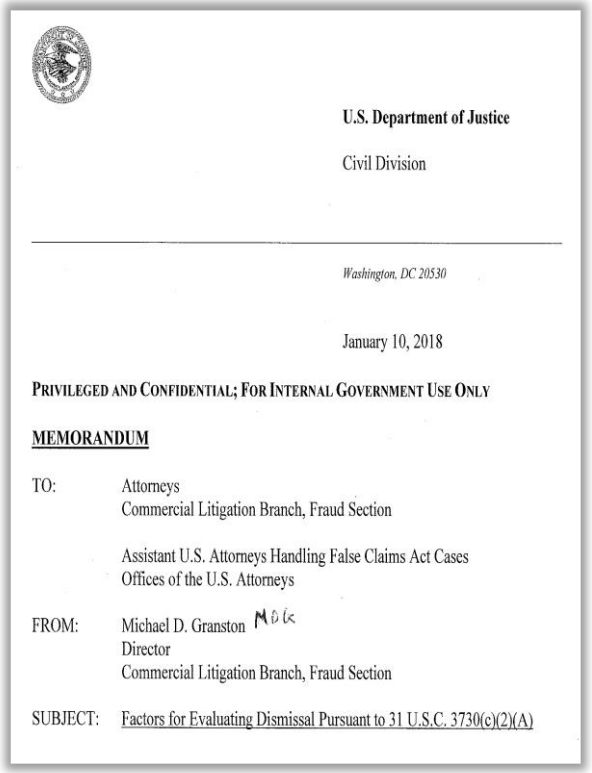
  - The Civil Cyber-Fraud Initiative will use the FCA to pursue cybersecurity-related fraud by government contractors and grant receipients that are "knowingly providing deficient cybersecurity products or services, knowingly misrepresenting their cybersecurity practices or protocols, or knowingly violating obligations to monitor and report cybersecurity incidents and breaches."
  - Previous cybersecurity FCA actions have been brought by *qui tam* relators.
  - The announcement is part of the Administration's increasing emphasis on cybersecurity requirements, including those for government contractors

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)



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

- 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 – 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

Enforcement Trends and Developments

By the Numbers: 2020 Federal Fiscal Year

> $2.2 Billion

Civil settlements and judgments under the FCA

922

New FCA cases filed

73%

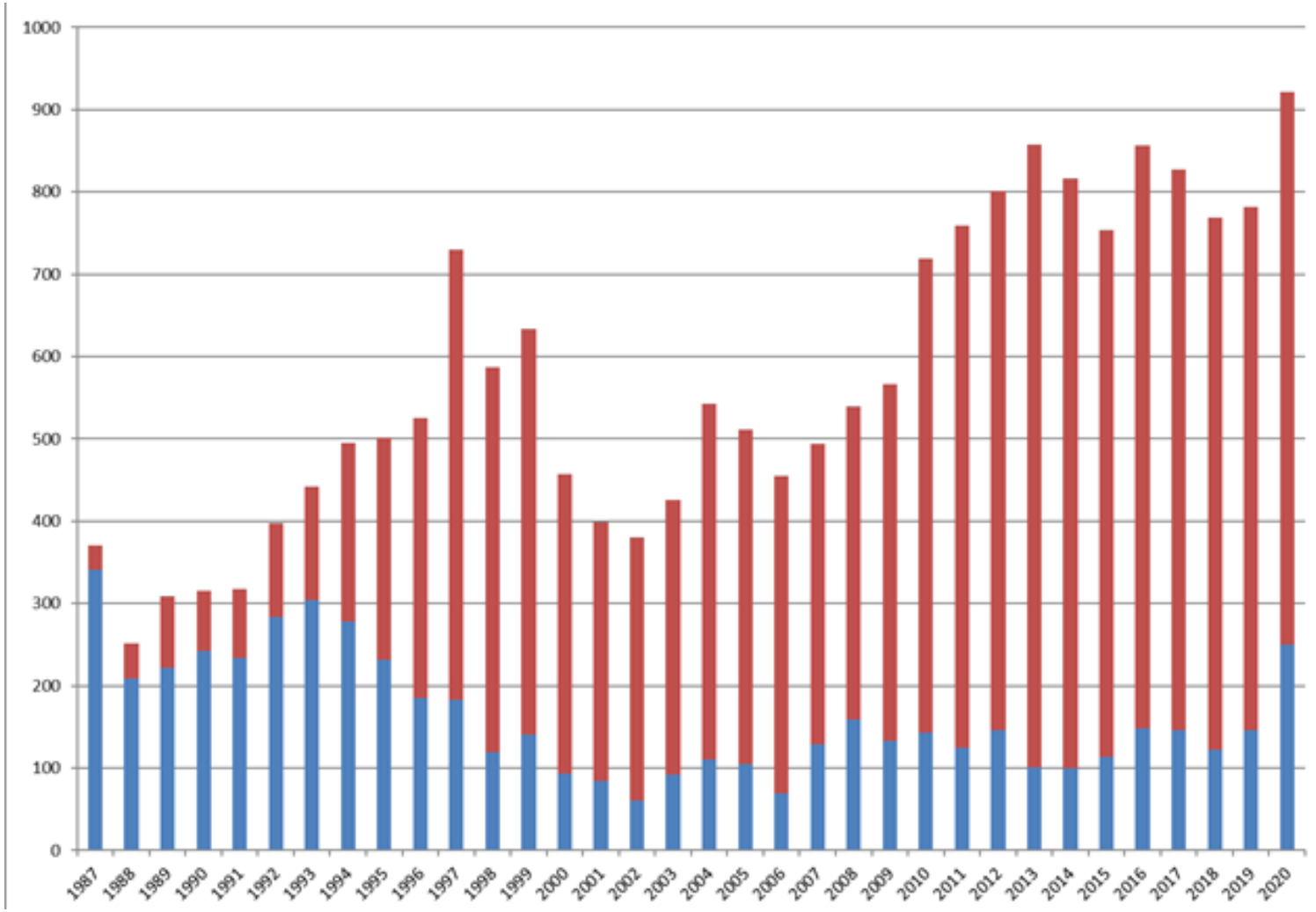
New FCA cases initiated by a whistleblower

91%

Overall federal recovery from cases in which the government intervened

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

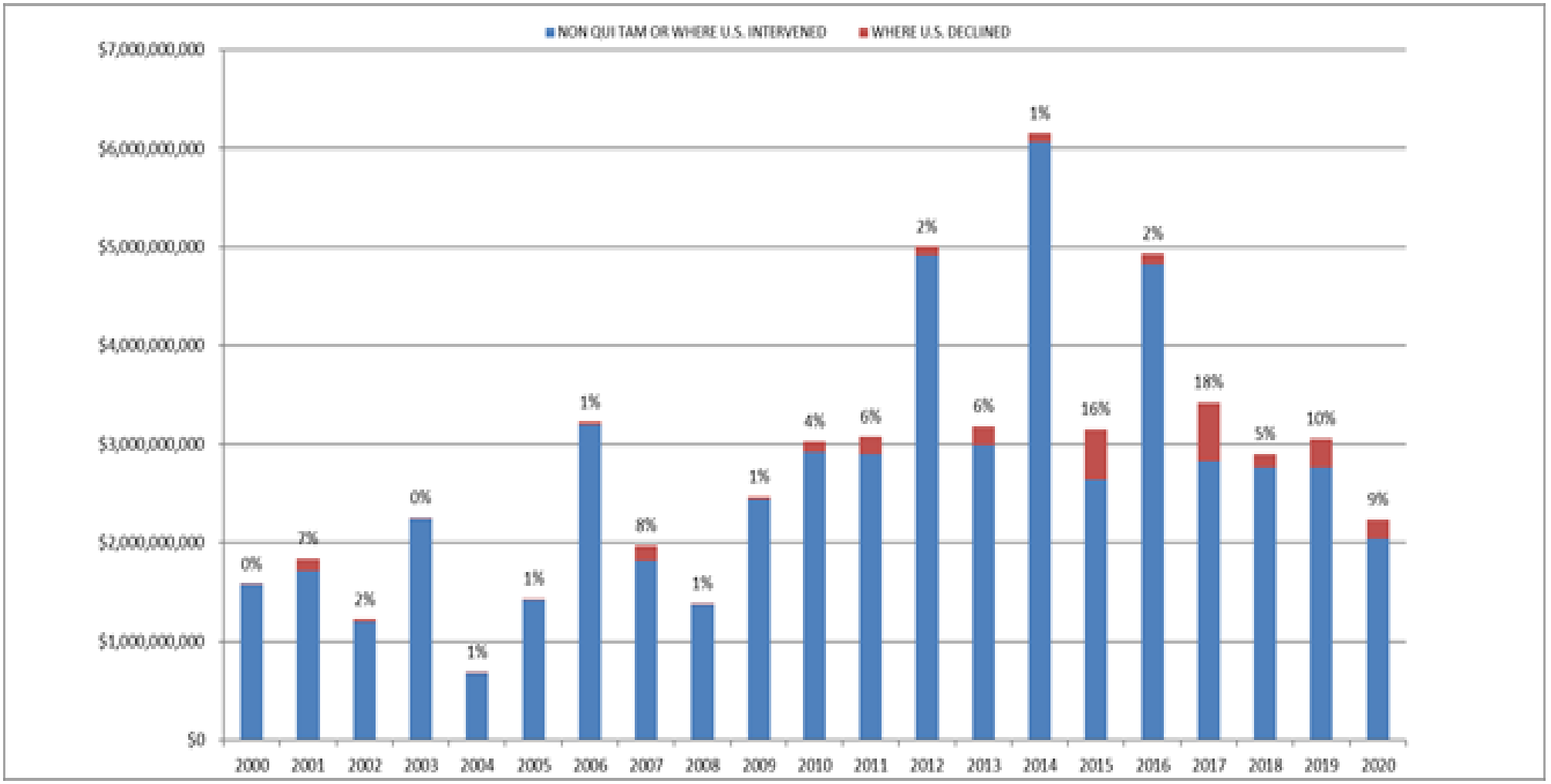
Number of New FCA Suits (FFY 1987–2020)



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"

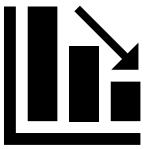
By the Numbers: 2021 Year to Date

>$590 million

FCA civil recoveries from ***settlements*** with health care providers in 2021 to date, according to Gibson Dunn calculations

>$223 million

from civil settlements involving ***non-AKS billing theories (e.g., upcoding)*** with health care providers in 2021 to date, according to Gibson Dunn calculations



2020 > 2021

2021 is ***slightly below*** the pace set in 2020 for FCA civil recoveries with health care providers

Health Care Providers – Additional 2021 Stats (to date)

Avg. settlement = ~$12.3 million

More than a dozen 8-figure settlements

~33% did not involve whistleblowers

> 32 *qui tam* settlements

Largest settlement: $136 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:

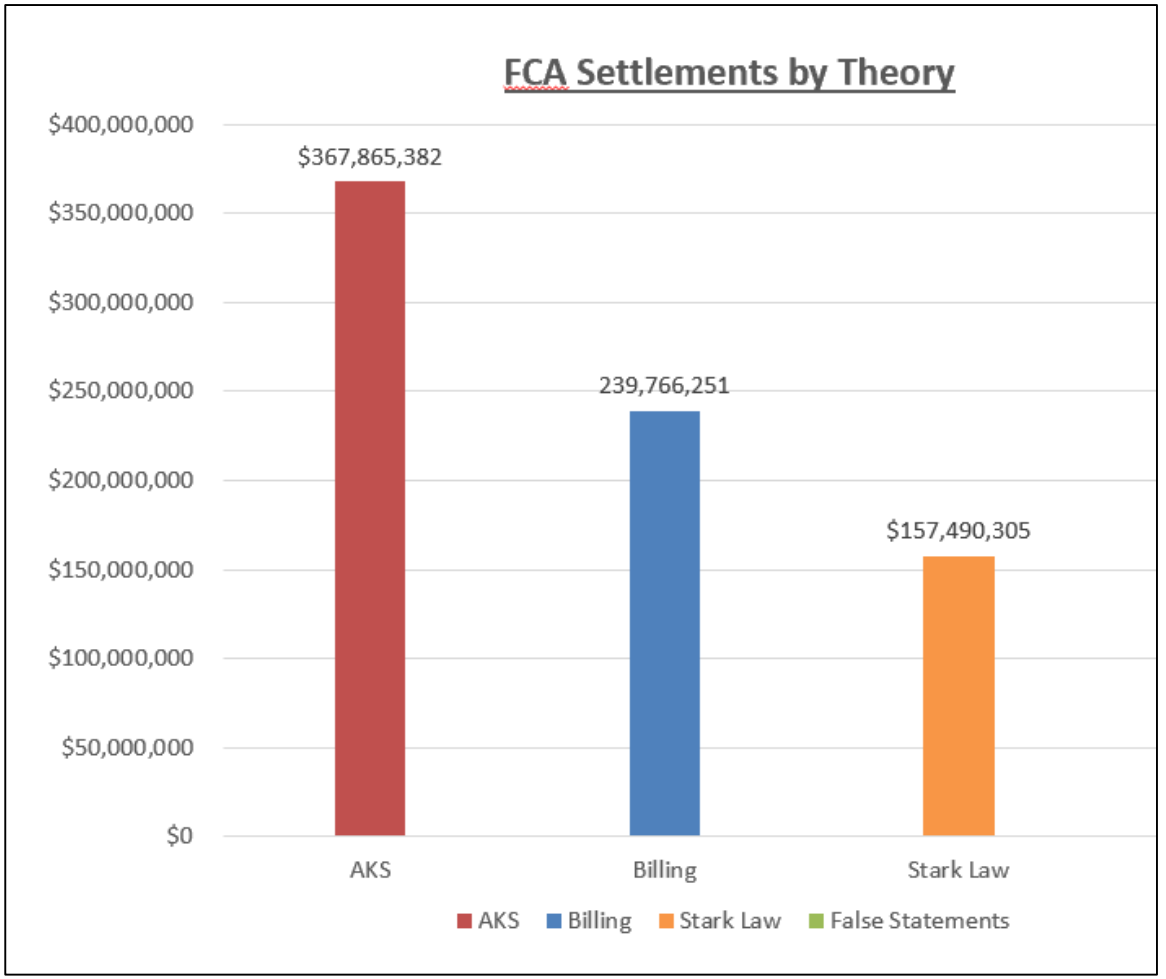
1. **Medically Unnecessary Medical Care.** Billing federal health care programs for medical care that was medically unnecessary for the underlying patient
2. **"Upcoding."** Providing the billing code of a more expensive procedure instead of the appropriate code for the services actually rendered
3. **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 – 2021 FCA Recoveries

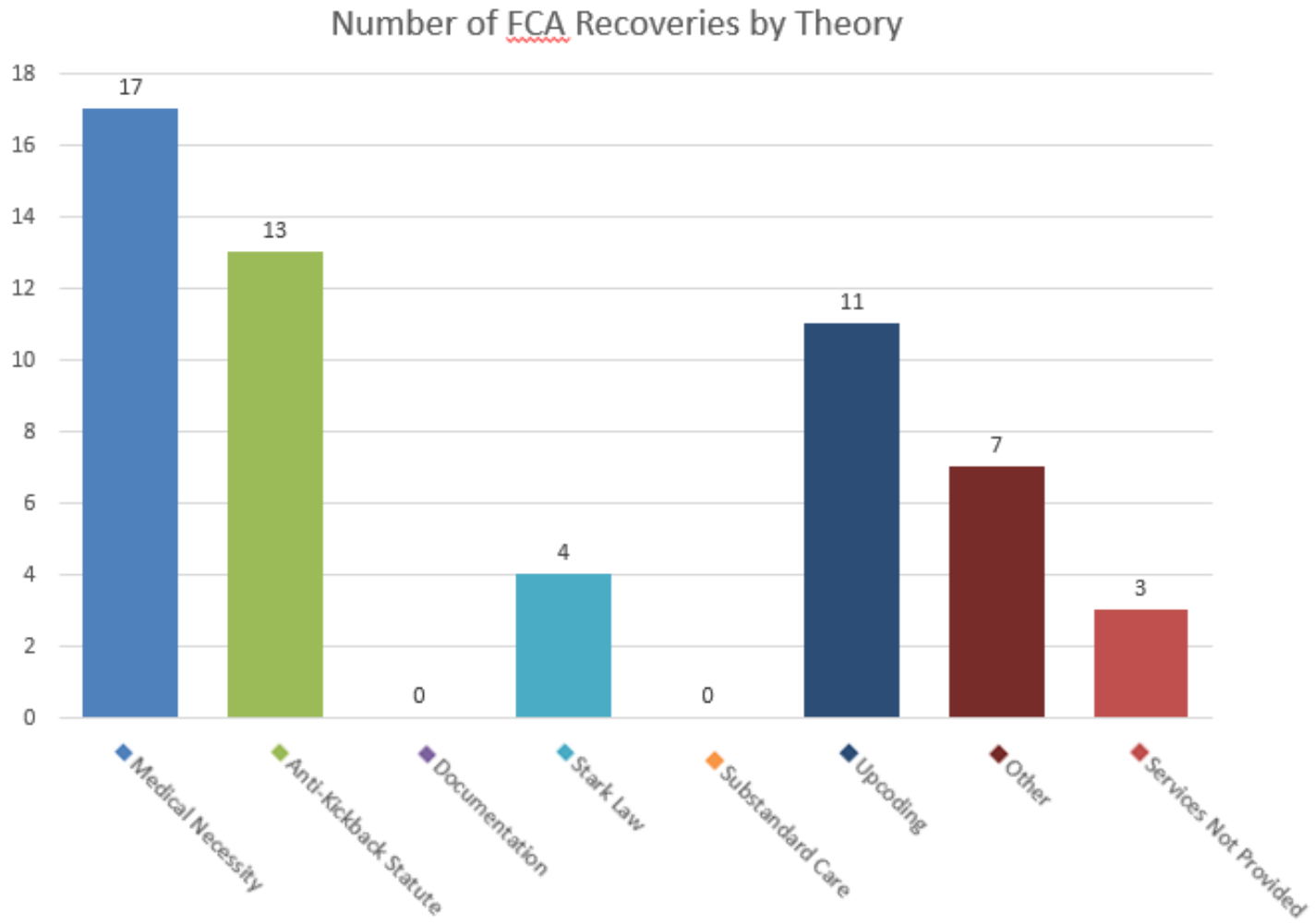
~$590 million in civil recoveries from health care providers in 2021

- **Government Health Program Requirements (Billing):** ~$240 million
- **AKS:** ~$367 million
- **Stark Law:** ~$157 million

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



Health Care Providers – 2021 FCA Recoveries



2021 Resolutions: Medical Necessity

***United States ex rel. Levy v. San Mateo County and the San Mateo County Medical Center, C.A.*, (N.D. Cal.)**

- San Mateo County Medical Center and San Mateo County (collectively SMMC), located in California, agreed to pay $11.4 million to settle allegations that it overbilled for medically unnecessary inpatient care.
- Allegations included that "SMMC admitted certain patients for whom inpatient care was not medically reasonable or necessary," such as "admit[ance] for reasons other than medical status, including social reasons and lack of available alternative placements."

***United States ex rel. Hayward v. SavaSeniorCare, LLC, et al.* (M.D. Tenn.) [and related lawsuits]**

- A nursing home operator agreed to pay $11.2 million to resolve allegations that it caused skilled nursing facilities to submit claims for reimbursement for unnecessary, unreasonable, or unskilled rehabilitation services provided to Medicare patients.
- Allegations included that Sava exerted "significant pressure on its SNFs to meet unrealistic financial goals" "without regard for its patients' actual clinic needs."

2021 Resolutions: Upcoding

Connections Community Support Programs, Inc. (D. Del.)

- CCSP, which (pre-bankruptcy) provided mental health and addiction treatment in Delaware, agreed to pay $13.8 million to resolve claims that it billed Medicaid for mental health services using incorrect procedure codes for the person performing the service, resulting in higher payments than were permitted.
- The settlement also resolves allegations that CCSP billed for mental health services performed by individuals whose professional qualifications did not allow them to bill Medicare or Medicaid for reimbursement.

Dr. Njideka Udochi (D. Md.)

- Dr. Njideka Udochi, a family practice physician in Maryland, agreed to pay $663,000 to resolve allegations that she billed Medicare for fraudulent neurostimulator billings, arising from the use of an auricular stimulation ("P-Stim") device.
- The settlement resolves allegations that Dr. Udochi falsely billed Medicare using the HCPCS code for a neurosurgical procedure of an invasive and extensive nature for a device implanted into the patient, where in fact the P-Stim devices were taped behind the ears of patients and often removed by her patients at home without assistance.

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

U.S. ex rel. Lutz v. Mallory, 988 F.3d 730 (4th Cir. 2021)

- A blood testing laboratory contracted with a consulting company to market and sell the tests. The consulting company received a base payment and a percentage of revenue based on the number of blood tests ordered.
- The jury found that the laboratory's revenue-based commission payments constituted improper remuneration intended to induce sales of as many laboratory tests as possible.
- Defendants argued on appeal that the government failed to prove that the defendants "***knowingly and willfully***" violated the AKS and that, accordingly, the defendants could not have "knowingly" violated the FCA. The Fourth Circuit disagreed, given that the defendants were unable to "identify any specific legal opinion" that could support a "good-faith belief that their conduct . . . did not violate the Anti-Kickback Statute."
- Defendants also argued that commissions to independent contractor salespeople do not constitute kickbacks under the AKS. Although the court noted that the AKS does contain a safe harbor for bona fide employment relationships, it explained that HHS-OIG "has expressly recognized that this safe harbor does not cover independent contractors."

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))

2021 Resolutions: AKS

***United States ex rel. Rauch, et al. v. Oaktree Medical Centre, P.C., et al.*, No. 6:15-cv-01589-DCC (D.S.C.) [and related cases]**

- Four pain management clinics, a drug testing laboratory, and a substance abuse counseling center, all owned and operatated by a chiropractor in South Carolina, agreed to pay ***$136 million*** total for allegedly providing illegal financial incentives to providers to induce referrals of urine drug tests in violation of the Stark Law and the Anti-Kickback Statute.
- The settlement also resolves allegations that the counseling center and drug testing laboratory billed for unnecessary urine drug tests.

***United States ex rel. Brouse st al. v. Akron General Health Systme, Inc. et al.*, (N.D. Ohio)**

- In July 2021, a regional hospital system based in Akron, Ohio, agreed to pay ***$21 million*** to resolve allegations regarding improper relationships with certain referring physicians.
- The allegations were that from 2010 to 2016, the hospital system paid compensation "substantially in excess" of fair market value to area physician groups to secure patient referrals, in violation of the AKS and the Physician Self-Referral Law, and then submitted claims for services provided to these illegally referred patients, in violation of the FCA.

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 March 2021, Oglethorpe Inc., a Florida company operating two psychiatric hospitals and a substance abuse treatment facility in Ohio, agreed to pay **$10.25 million** to resolve FCA and AKS allegations.	• Oglethorpe allegedly: • Provided free long-distance van transportation to patients to induce them to seek treatment at the defendants' facilities, and then submitted claims for services provided to these patients. • Oglethorpe entered into a Corporate Integrity Agreement with HHS OIG.

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FCA Compliance Best Practices

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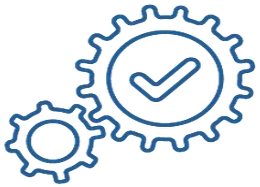
Minimizing Exposure

- 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?

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** (September 14, 2021)
  https://www.gibsondunn.com/webcast-national-security-enforcement-developments-and-trends/
- **Economic Espionage and Intellectual Property Theft: Trends and Developments with Threats and Enforcement** (September 23, 2021)
  https://www.gibsondunn.com/webcast-economic-espionage-and-intellectual-property-theft-trends-and-developments-with-threats-and-enforcement/

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