The False Claims Act – 2017 Mid-Year Update: Health Care Providers

August 30, 2017

Today's Panelists

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Winston Chan is a partner in the San Francisco office. He has particular experience leading matters involving government enforcement defense, internal investigations, compliance counseling, and civil trial litigation. Previously, he served as an Assistant U.S. Attorney in the Eastern District of NY, where he served in various supervisory roles, including overseeing all criminal investigations involving allegations of False Claims Act violations, kickbacks, and other health care fraud.

Jonathan Phillips is a senior associate in the Washington, D.C. office, where his practice focuses on FDA and health care compliance, enforcement, and litigation, as well as other government enforcement matters and related litigation. He has substantial experience representing pharmaceutical, medical device, and health care provider clients in investigations by the DOJ, FDA, and Department of Health and Human Services Office of Inspector General. Previously, he served as a Trial Attorney in the Civil Division, Fraud Section of the DOJ, where he investigated and prosecuted allegations of fraud against the U.S. under the FCA and related statutes.

Julie Schenker is a litigation associate in the Washington, D.C. office, where she focuses on government enforcement matters, health care compliance, and related litigation. She has represented health care provider clients in investigations by the DOJ and the Department of Health and Human Services Office of Inspector General.

Gibson Dunn FCA Summer Webcast Series

- This has been one in a series of webcasts on the FCA and various industry sectors in which our clients and friends have an interest.
  - FCA and Education Sector (July 26)
  - FCA and Drug & Device Industry (August 2)
  - FCA and Government Contracting (August 9)
  - FCA and Financial Services Sector (August 23)
  - **FCA and Health Care Providers (August 30)**
- The series is available at http://www.gibsondunn.com/publications/pages/webcasts.aspx
- If you have any unanswered questions, please feel free to contact any one of us at:
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Agenda

- FCA Overview
- FCA Enforcement Developments – General
- Recent FCA Enforcement – Providers
    - *Escobar* & Implied Certification
    - Medical Necessity
    - Anti-Kickback Statute and Stark Law
- Questions

FCA Overview

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 is devoting more and more resources to pursuing FCA cases—and 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, 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 – 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.

FCA – Overview of Key FCA Theories

Factual Falsity

- False billing (e.g., 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

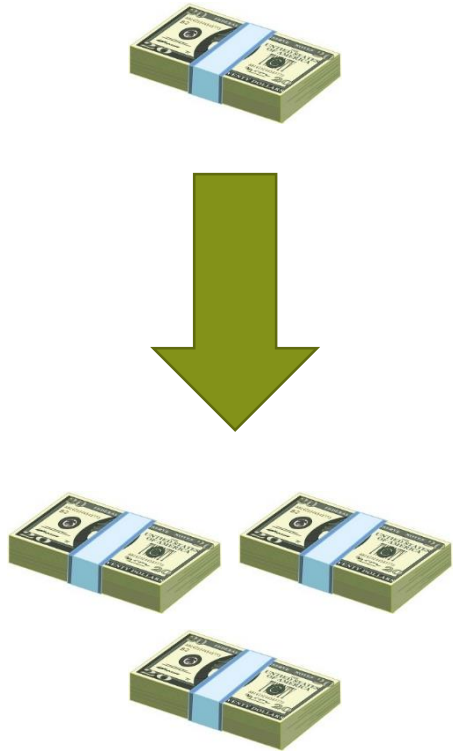
- Obtaining a contract through false statements or fraudulent conduct
- *U.S. ex rel. Marcus v. Hess*, 317 U.S. 537 (1943) (claims by contractors who colluded on bids)

Reverse False Claims

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

FCA – Damages and Penalties

- **Simple Damages Calculation**
  - Treble damages are traditionally calculated by multiplying the government's loss by three (e.g., if defendant charged government $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
  - Nearly doubled effective August 1, 2016
  - 2017 inflation adjustment increased to range of $10,957 to $21,563 per violation



FCA – Statute of Limitations

- The statute of limitations is:
  - 6 years from the date of violation, *or*
  - 3 years from when facts material to the violation are known or reasonably should have been known to the government.
- ***But*** not more than 10 years from the violation.
- In January, HHS OIG finalized a rule that imposes a 10-year limitations period on HHS OIG exclusion actions, aligning exclusions and FCA statute of repose.

FCA – *Qui Tam* Provisions

- ***Qui Tam* Provisions**
  - Enable so-called "relators" to bring cases in the government's name and recover **as much as 30%** of favorable judgment or recovery
  - Allow government to intervene
    - An increasing number of whistleblower cases are pursued **without government intervention** (but often with government statement of interest).
  - DOJ has virtually unlimited dismissal authority—but seldom uses it.

"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 Whistleblower Protections (31 U.S.C. § 3730(h))**
  - Protects employees and others (e.g., contract workers)
  - Relief may include double back pay and interest on back pay; reinstatement (at seniority level); and/or costs and attorneys' fees.

FCA – Public Disclosure and First-to-File Bars

- 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 is an "original source" of the allegations, meaning he **voluntarily disclosed** them 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 contained slight differences in the public disclosure and original source provisions.

- The first-to-file bar 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.**"

Recent Legal Development: Public Disclosure Bar

Amphastar Pharmaceuticals Inc. v. Aventis Pharma SA, 856 F.3d 696 (9th Cir. 2017)

- Affirmed district court dismissal of generic pharmaceutical company's FCA allegations that defendant overcharged the government after fraudulently obtaining a patent on one of its drugs.
- Court found that the allegations were publicly disclosed during discovery in its own earlier patent litigation with defendant.
  - Although government reimbursement of the drug was not publicly disclosed in that suit, that reimbursement was "**an obvious inference based on the publicly disclosed allegations.**"
- Relator also was not an "original source" under the pre-amendment version of the bar because it developed the allegations through the discovery process.
  - Relator admitted this fact in its required disclosures to DOJ.

Recent Legal Development: Public Disclosure Bar

U.S. ex rel. Bellevue v. Universal Health Servs. of Hartgrove, Inc., __ F.3d __, 2017 WL 3392384 (7th Cir. Aug. 8, 2017)

- Relator alleged that a mental health hospital violated the FCA when it submitted claims for payment for treatment of patients who were admitted to the hospital in excess of the hospital's licensed bed capacity.
- Defendant argued that relator's claims were barred by the public disclosure bar, because information about the hospital's admissions above licensed capacity was disclosed in letters and audit reports from state and federal regulators.
- The Seventh Circuit held that the public disclosure bar applied and dismissed relator's claims. The Court explained that relator could not be an "original source" because relator's allegations were "substantially similar to" the publicly disclosed allegations and therefore did not "materially add" to what had already been disclosed.

Recent Legal Developments: First-to-File Bar

U.S. ex rel. Shea v. Cellco Partnership, Inc., 863 F.3d 923 (D.C. Cir. 2017)

U.S. ex rel. Carter v. Halliburton Co., No. 16-1262 (4th Cir. July 31, 2017)

- Both courts addressed the question of whether a violation of the FCA's first-to-file provision requires dismissal of the action or, rather, can be cured by an amendment to the complaint.
- Both held that the first-to-file provision **requires dismissal of the second-filed action**, rejecting the argument that amending the second-filed complaint cures the violation of the first-to-file provision.

Government Players

DOJ

DOJ is devoting more and more resources to pursuing FCA cases—and considering whether *qui tam* cases merit criminal investigation.

State Attorneys General

State AGs are increasingly conducting investigations and pursuing claims under state False Claims Acts.

Cooperation

Inspectors General

U.S. Department of Health and Human Services: Office of Inspector General

FCA – The Yates Memo

2015 Yates memo set forth 6 priorities for civil and criminal investigations by DOJ, which include FCA investigations:

1. Corporations must provide all relevant facts relating to the individuals responsible for the misconduct in order to qualify for cooperation credit
2. Focus on individuals from the inception of corporate investigation
3. Close coordination between DOJ criminal and civil attorneys
4. DOJ will not release culpable individuals from civil or criminal liability when resolving a matter (absent extraordinary circumstances or DOJ policy)
5. Resolution with corporation should not occur without clear plan to resolve related individual cases
6. Civil attorneys should focus on individuals and evaluate whether to bring suit against individual based on consideration beyond individual's ability to pay

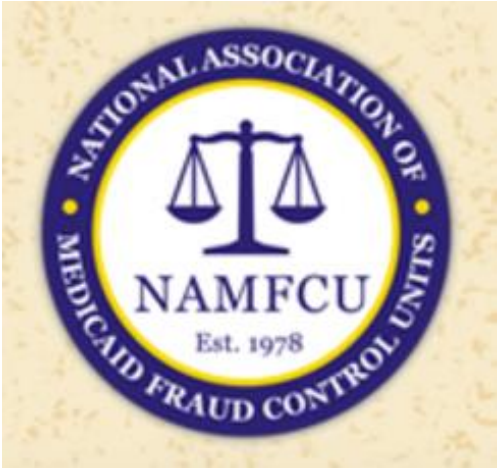
Federal Legislative/Regulatory Developments

- **Health Care Reform**
  - Patient Protection and Affordable Care Act changed key provisions of FCA, including public disclosure bar.
  - House and Senate bills left these changes in place.
  - Changes to FCA are possible depending on continuance and outcome of repeal efforts.

- **Per Claim Penalties**
  - In October 2015, Congress passed legislation requiring agencies to increase FCA penalties to account for inflation.
  - On February 3, 2017, the DOJ issued a final rule increasing the per violation FCA penalty range to $10,957 to $21,563 compared to the pre-2016 range of $5,500 to $11,000.

State Developments

- **State Per Claim Penalties**
  - States are amending their false claims acts to match federal per claim penalties.
  - States have until December 31, 2018 to make amendments.
  - States that do not amend their false claims acts to comply may be deemed less effective than the federal FCA and lose increased share of Medicaid recoveries.



FCA Enforcement Developments

By the Numbers: 2016

$4.7 billion

Civil Settlements and Judgments Under the FCA

800

New FCA Cases Filed

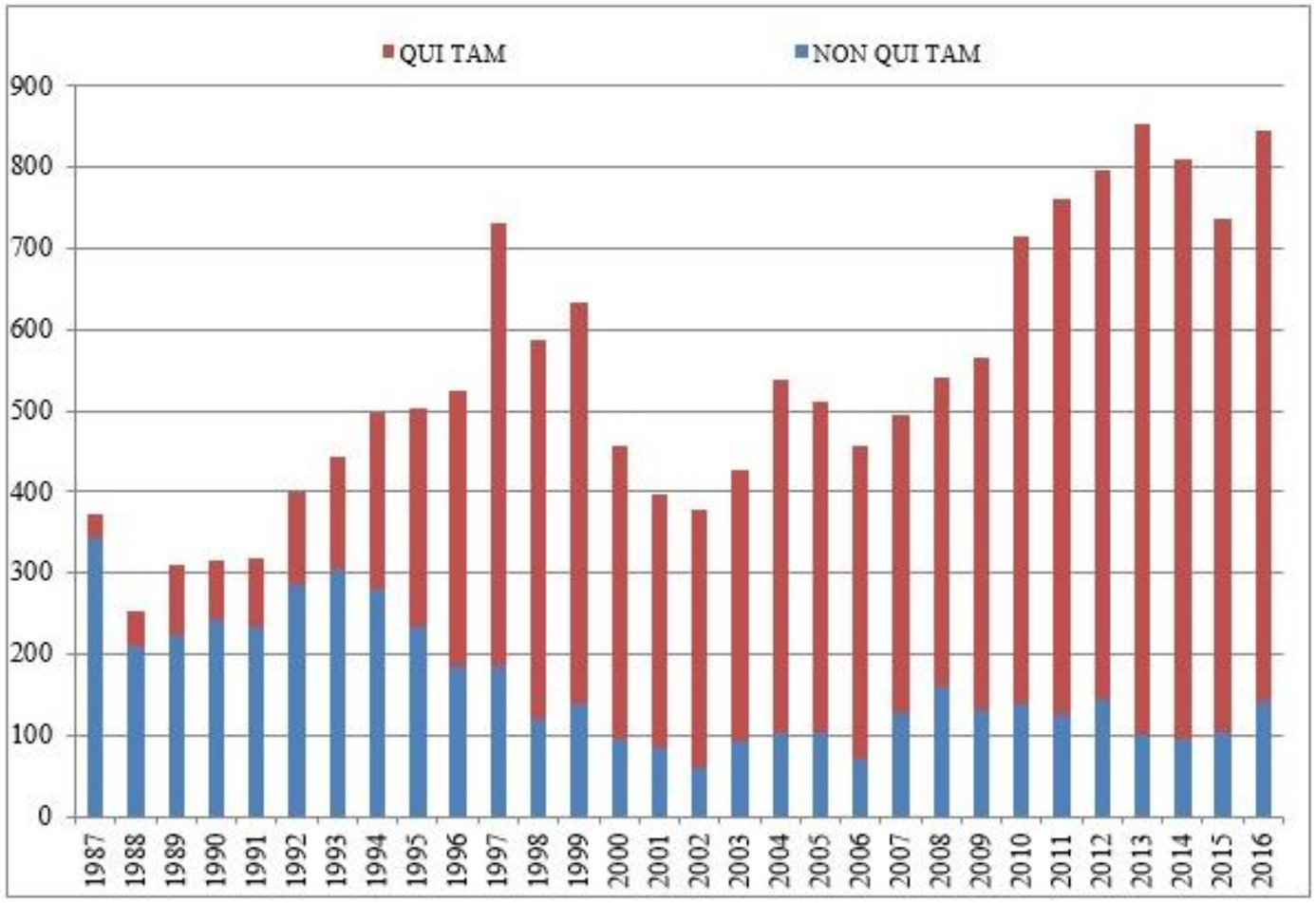
83 percent

Percentage of New FCA Cases Initiated by a Whistleblower

98 percent

Percentage of Overall Federal Recovery from Cases in which the Government Intervened

Number of New FCA Suits (1987-2016)

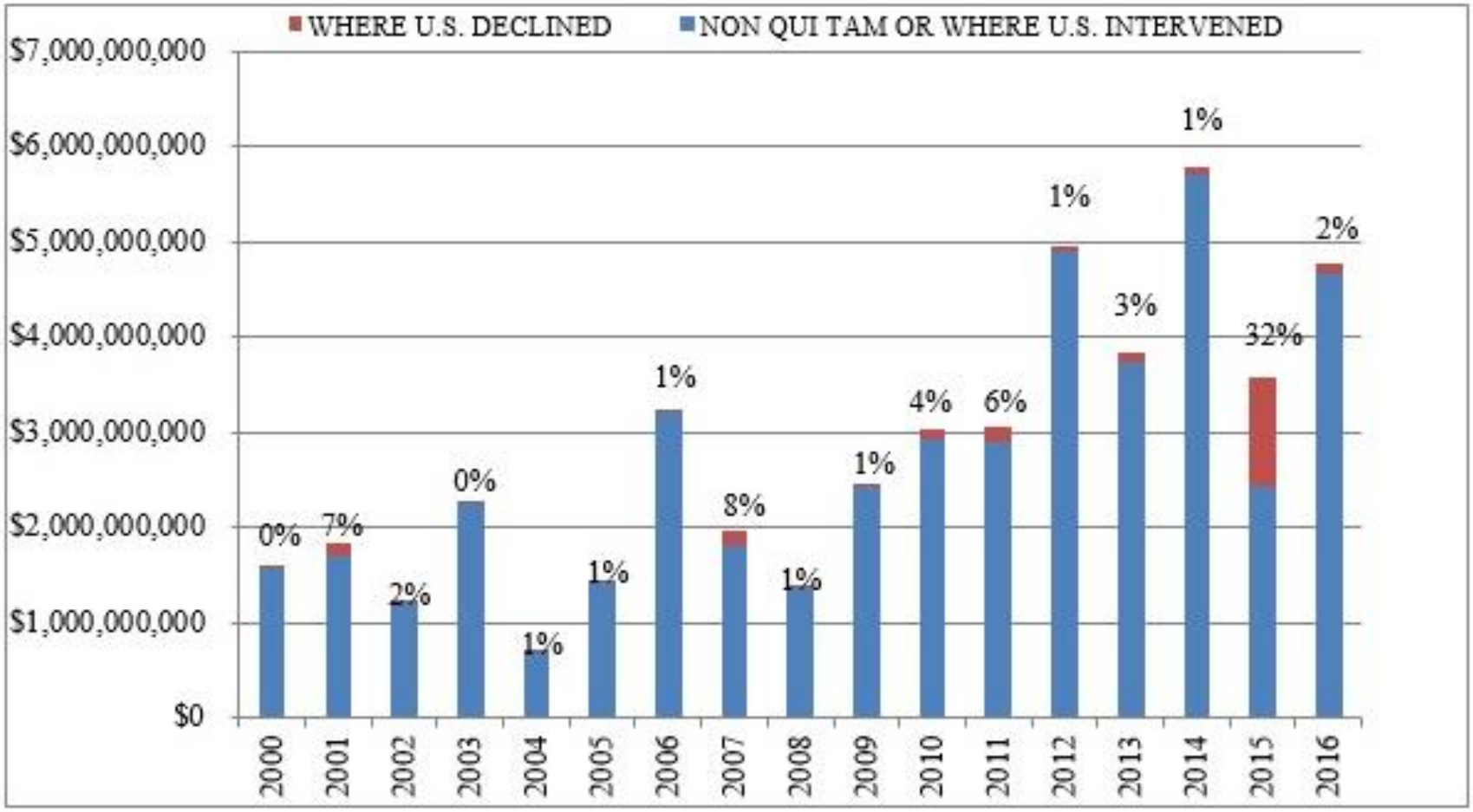


Source: DOJ "Fraud Statistics – Overview" (Dec. 13, 2016)

570 new cases in 2016 related to government health program funds:

- 501 *qui tam* cases
- 69 non-*qui tam* cases

Declined Cases in FCA Settlements / Judgments



Source: DOJ "Fraud Statistics – Overview" (Dec. 13, 2016)

By the Numbers: 2017 To-Date

$1.3 billion

FCA recoveries from settlements in the first half of 2017

$370 million

Judgments from FCA cases in the first half of 2017

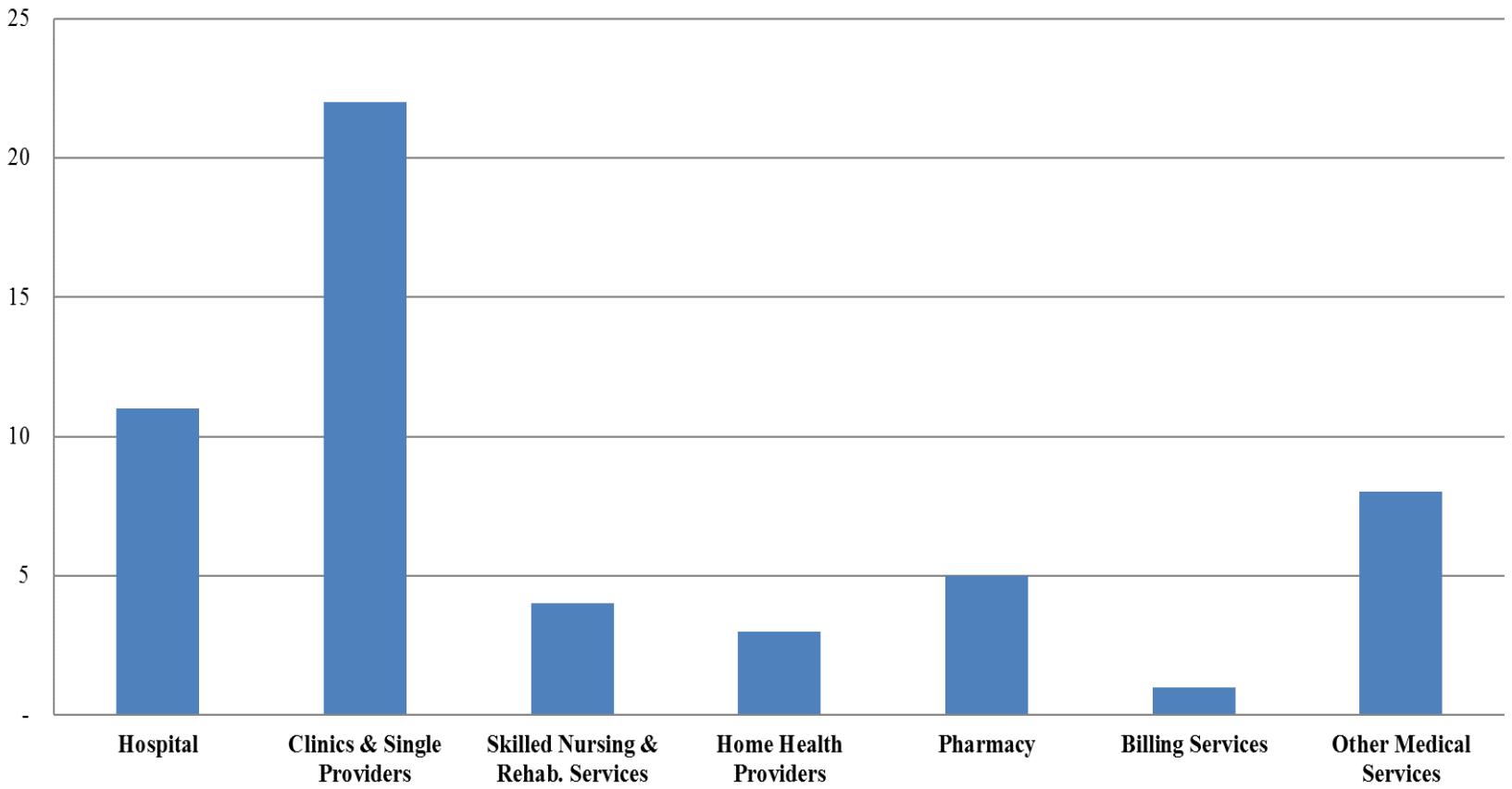
8th

DOJ remains on pace for 8th consecutive year exceeding $3 billion in total FCA recoveries

2017 FCA Recoveries Through June: Providers

- **$817 million** in recoveries from providers from January through June 2017, including:
  - Clinics & single providers (22 cases): $192.6 million
  - Hospitals (11 cases): $174.4 million
  - Skilled nursing facilities (4 cases): $55.6 million
  - Home health care providers (3 cases): $23.7 million
  - All other providers (14 cases): $370.6 million

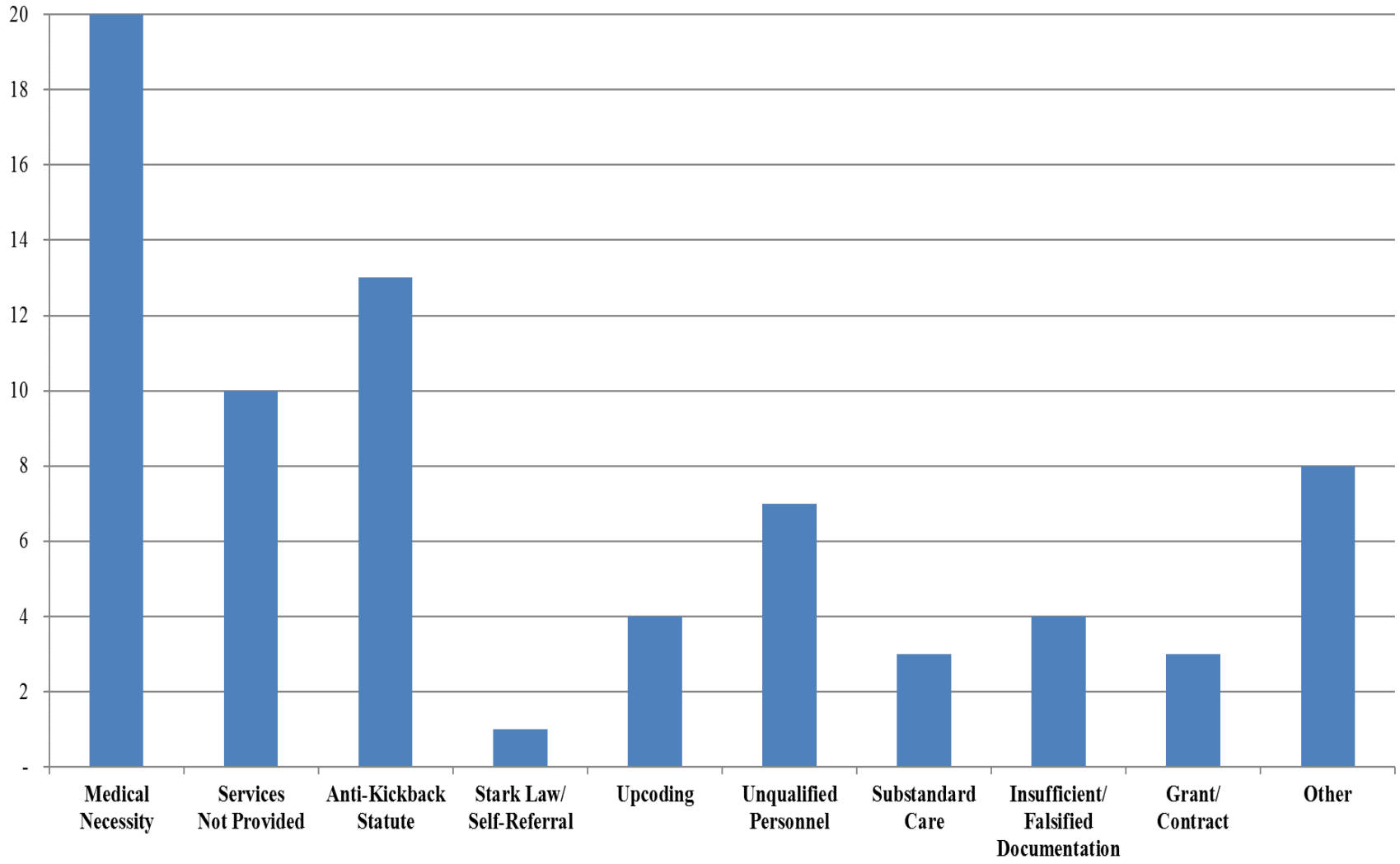
2017 FCA Settlements with Providers, by Provider Type



54 settlements with providers in the first half of 2017:

- Clinics & single providers were by far the largest category, with 22 settlements
- Hospitals came in second, with 11 settlements

2017 FCA Settlements with Providers, by Allegation Type



Federal Legislative/Regulatory Developments

- **New Inquiries Added to HHS-OIG Work Plan**
  - As part of its new policy to regularly update its investigative work plan, in July HHS-OIG announced **14 new inquiries** into potentially fraudulent Medicare and Medicaid claims made by providers.
  - The types of providers include, among others: hospitals, home health agencies, ambulances, adult day care centers, and telehealth providers.
  - The types of issues include, among others:
    - Whether hospice, skilled nursing facility, and home health care claims covered by Medicare Part A were improperly billed to Medicare Part B
    - Whether adult day care centers are in compliance with applicable regulations and standards regarding health and safety
    - Whether telehealth videoconferencing services were properly provided to beneficiaries located in a practitioner's office or medical facility, rather than a beneficiary's home or office

Recent Statements from the New Administration

"We cannot afford to lose a single dollar to corruption, and you can be sure that if I am confirmed, I will make it a high priority of the department to root out and prosecute fraud in federal programs and to recover monies lost due to fraud or ***false claims***."

– Attorney General Jeff Sessions III
(Senate Judiciary Committee Hearing on Nomination of Sen. Jeff Sessions to be Attorney General (Jan. 10, 2017))

"We certainly will continue to enforce [the FCA]" and the DOJ will ensure that "whistleblowers receive any protection they are entitled to by law or regulation."

– Deputy Attorney General Rod Rosenstein
(Senate Judiciary Committee Hearing on Nominations of Rod Rosenstein (Mar. 7, 2017))

Recent Statements from the New Administration

"Nobody supports care being billed for [w]hat isn't needed or . . . hasn't been provided. And [the FCA] is one of those areas that I think we need to be ***very, very focused***. I'm . . . certain that there are some bad actors out there."

– Secretary Tom Price, Department of Health and Human Services
(Senate Finance Committee Hearing on Nomination of Rep. Price to be HHS Secretary (Jan. 24, 2017))

Recent FCA Enforcement: Providers

Key Legal Theories

1. Improper Financial Relationships

- AKS / Stark Law
- Providing anything of value to induce referrals or other business

2. Billing / Coding / Coverage

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

3. Medical Necessity

- Providing services that are not medically necessary
- Inflating volume or value of services provided (e.g., inpatient rather than outpatient care)

4. Quality of Care

- Providing substandard care (e.g., using unqualified personnel)
- Charging the government for "worthless" services

5. Overpayments

- Nexus of "reverse FCA" and the ACA 60-Day Rule

Recent Enforcement Trends

Enforcement actions and legal theories in three areas, in particular, have seen significant developments this year:

1. *Escobar &* Implied Certification
2. Medical Necessity
3. Anti-Kickback Statute & Stark Law

Recent FCA Enforcement: *Escobar* & Implied Certification

Universal Health Services, Inc. v. U.S. ex rel. Escobar

136 S. Ct. 1989 (2016)

- Relator brought FCA suit against leading nation-wide provider of mental health services, alleging that hospital provided inadequate care to a teenage patient by using personnel to deliver counseling services who did not meet state regulations governing staffing qualifications.

- The Court held that the implied certification theory can provide a basis for FCA liability "at least in certain circumstances":

1. "the claim does not merely request payment, but also makes **specific representations about the goods or services provided**," and
2. "the defendant's **failure to disclose noncompliance with material statutory, regulatory, or contractual requirements** makes those representations misleading half-truths."

Escobar First Condition: Specific Representations

Implied certification can be a basis for liability "at least" where two conditions are satisfied. The first condition is that "the claim does not merely request payment, but also makes specific representations about the goods or services provided."

- *Escobar:* UHS submitted claims with payment codes that corresponded to specific counseling services and used NPI numbers that corresponded to specific job titles

Escobar Second Condition: Materiality

Implied certification can be policed through the FCA's "materiality" and "scienter" requirements.

- Materiality "look[s] to the effect on the likely or actual behavior of the recipient of the alleged misrepresentation."
- Violation is "material" if:
  - "A reasonable man would attach importance to [the misrepresented information] in determining his choice of action in the transaction"; or,
  - "the defendant knew or had reason to know that the recipient of the representation attaches importance to the specific matter 'in determining his choice of action,' even though a reasonable person would not."

Escobar Second Condition: Materiality

Court holds that "materiality cannot rest on a single fact or occurrence as always determinative," but gives the following guidance for evaluating materiality:

- Government's right to refuse payment if aware of the violation is insufficient, by itself, to demonstrate materiality.
- Noncompliance cannot be minor or insubstantial.
- Proof can include, but is not limited to, "evidence that the defendant knows that the Government consistently refuses to pay claims in the mine run of cases based on noncompliance with the particular statutory, regulatory or contractual requirement."
- Government's payment of "particular claim," or practice of paying "particular type of claims," with "actual knowledge" of violation of certain requirements, is "strong evidence" that those requirements are not material.

Post-*Escobar*: Specific Representations

Some courts applying *Escobar* have appeared to require, without expressly addressing the issue, that *both* conditions must be satisfied for implied certification.

- *U.S. v. Sanford-Brown*, 840 F.3d 445 (7th Cir. 2016) (holding no implied certification liability because relator failed to plead a "specific representation")
- *U.S. ex rel. Campie v. Gilead Sci.*, 2017 WL 2884047 (9th Cir. July 7, 2017) (noting both the presence of "specific representations" and the clear materiality of FDA approval to federal funding)

The U.S. District Court for the Southern District of New York recently held more explicitly that *Escobar* requires both conditions.

- In *U.S. ex rel. Forcier v. Computer Sciences Corp.*, No. 12-cv-01750 (S.D.N.Y. Aug. 10, 2017), the court found that the implied certification claim may only proceed if CSC made "specific representations that were rendered misleading by its failure to disclose noncompliance with material regulatory requirements"
- The court noted that other district courts in the Circuit have interpreted *Escobar* as imposing the two "affirmative limitations," and this court would join that majority

Post-*Escobar*: Specific Representations

Other courts have expressly refused to require pleading both conditions:

- *U.S. ex rel. Landis v. Tailwind Sports Corp., et al.*, 2017 WL 573470 (D.D.C. Feb. 13, 2017)
  - Court denied defendant's MSJ, stating that, where the claim forms in question make no specific representations, *Escobar* does not apply.
  - Instead, under the D.C. Circuit's pre-Escobar law, "all the government must show is that the contractor withheld information about its noncompliance with material contractual requirements."
- *U.S. ex rel. Badr v. Triple Canopy, Inc.*, 857 F.3d 174 (4th Cir. 2017) (holding that express representation of compliance is not required for there to be an actionable "half-truth" under *Escobar*)

Post-*Escobar* Materiality: Impact of Government Intervention

U.S. ex rel. Badr v. Triple Canopy, Inc., 857 F.3d 174 (4th Cir. 2017)

- Reversed dismissal of allegations that defendant violated FCA by falsifying marksmanship scores of guards providing security for facilities in Iraq.
- Held that *both* of *Escobar*'s "two conditions" are ***not required*** to allege a valid implied false certification claim.
  - Defendant was not required to certify compliance or make a "specific representation" with regard to marksmanship qualifications, but omissions as to those issues fell "squarely within the rule that half-truths . . . can be actionable."
- In analyzing materiality, the Fourth Circuit concluded that evidence that the "Government did not renew its contract for base security with Triple Canopy and ***immediately intervened in the litigation*** . . . are evidence that Triple Canopy's falsehood affected the Government's decision to pay."

Post-*Escobar* Materiality: Impact of Government Intervention

U.S. ex rel. Petratos v. Genentech Inc., 855 F.3d 481 (3d Cir. 2017)

- Affirmed dismissal of allegations that pharmaceutical company failed to disclose data showing certain common and severe side effects, based on a lack of materiality.
- The Third Circuit noted that the relator "not only fails to plead that [the government] consistently refuses to pay' claims like those alleged . . . but essentially concedes that [it] would **consistently reimburse** these claims with full knowledge of the purported noncompliance."
- In rejecting materiality, the Third Circuit found persuasive that the Government took **no action** after relator disclosed the allegations forming the basis of the complaint: "And in those six years, the Department of Justice has taken no action against Genentech and **declined to intervene** in this suit."

Post-*Escobar* Materiality: Government Knowledge

Since *Escobar*, a number of other courts have cited "government knowledge" as support for dismissing claims on materiality grounds:

- *City of Chicago v. Purdue Pharma et al.*, 211 F. Supp. 3d 1058 (N.D. Ill. 2016) (dismissing implied certification claims because government continued to pay for opioids even after becoming aware of alleged "deceptive marketing" of the drugs)
- *U.S. ex rel. Kelly v. Serco*, 846 F.3d 325 (9th Cir. 2017) (no materiality where government accepted and paid defendant's reports that on their face did not comply with time-charging guidelines)
- *U.S. ex rel. McBride v. Halliburton Co.*, 848 F.3d 1027 (D.C. Cir. 2017) (affirming summary judgment where government investigation of alleged inflated costs did not result in any disallowance and company continued to receive award fees for exceptional performance)

Post-*Escobar* Materiality: Representations to FDA

U.S. ex rel. Campie v. Gilead Sci., 2017 WL 2884047 (9th Cir. July 7, 2017)

- Ninth Circuit reversed district court's dismissal of allegations that defendant fraudulently obtained approval for certain drugs by making false statements to FDA about certain manufacturing and quality testing items.
- The court appeared to clearly require both of *Escobar*'s "two conditions" by requiring a "specific representation": "To succeed on [an implied certification] claim . . . [the defendant] must not merely request payment, but also make specific representations about the goods or services provided."
- However, the court reasoned the **drugs' proprietary names alone could constitute a false representation**, because the drug names themselves represent FDA approval.

Post-*Escobar* Materiality: Representations to FDA

U.S. ex rel. Campie v. Gilead Sci., 2017 WL 2884047 (9th Cir. July 7, 2017)

- Finally, the court also found the other *Escobar* condition—materiality—was established in the pleading:
  - "**FDA approval is the *sine qua non* of federal funding**. . . ."
  - The court rejected the argument that FDA's decision not to withdraw approval, even after becoming aware of the allegedly withheld manufacturing issues, showed a lack of materiality.
    - The court noted "there are many reasons the FDA may choose not to withdraw a drug approval," and FDA did not need to choose to do so here because the manufacturing issues had passed.
- The court observed that "the issues raised by the parties here are matters of proof, not legal grounds to dismiss relators' complaint."

Recent FCA Enforcement: Medical Necessity

Case Study: Genesis HealthCare

Genesis HealthCare Inc.

- In June, skilled nursing facility operator Genesis HealthCare Inc. paid **$53.6 million** to settle 6 *qui tam* lawsuits and government investigations.

- Allegations involved a system-wide theory of medical necessity and upcoding issues, and included claims that the company and its subsidiaries submitted false claims for medically unnecessary hospice services, medically unnecessary therapy services, and care that was grossly substandard or essentially worthless.

- Press release noted that settlement was based on company's ability to pay.

Case Study: Genesis HealthCare (cont'd)

"We will continue to **vigorously pursue companies** and individuals who provide care that is **grossly deficient or unnecessary**."

U.S. Attorney Brian J. Stretch for the Northern District of California

$53.6 million	$9.67 relator share

Consulate Health Care

- In contrast, skilled nursing facility operator Consulate Health Care went to trial in a case declined by the government and wound up with a jury verdict nearly 6.5x the settlement in Genesis.
- The relator, a former nurse at two Consulate facilities, alleged that the defendant artificially increased the amount of care patients required, resulting in inflated reimbursements.
- The jury found the alleged misconduct resulted in $115 million in single damages.
- Under the statute, which mandates treble damages and civil penalties, the final verdict was **$347 million**.

Case Study: Team Health

Team Health

- Team Health and its subsidiaries provide staffing to hospitals, including doctors for emergency rooms and hospitalists.
- Team Health allegedly billed Medicare, Medicaid, and other federal health programs for higher and more expensive levels of medical service than were actually performed ("**up-coding**").
- Allegations included that there was "**corporate pressure**" on hospitalists with lower billing levels to "catch up" to their peers.
- Team Health paid **$60 million** and entered into a 5 year corporate integrity agreement to resolve the allegations.

Case Study: Agape Senior Community, Inc.

Agape Senior Community, Inc.

- Relators alleged that defendants caused the submission of false claims for hospice care reimbursement by falsifying physician certifications that patients required such care.
- To prove their case, relators sought to use statistical sampling, but the District Court would not permit the method.
- Relators and defendants then sought to mediate, and reached a $2.5 million settlement; the government vetoed it.
- Court certified for interlocutory review the question of whether statistical sampling could be used to prove False Claims Act liability.

Case Study: Agape (*cont'd*)

United States ex rel. Michaels v. Agape Senior Community, Inc., 848 F.3d 330 (4th Cir. 2017)

- Declined to reach statistical sampling issue
- Unanimously decided that it had erred in granting interlocutory review of the issue, since the statistical sampling question was not a purely legal one
- For now, district court decision denying relators the use of statistical sampling stands

Last week, two years after DOJ vetoed its initial offer, Agape announced it would settle the case **for a mere $275,000.**

Case Study: AseraCare Inc.

AseraCare Inc.

- Government alleged that AseraCare submitted false claims to Medicare for hospice services for ineligible beneficiaries.
- In March 2016, the Northern District of Alabama granted summary judgment for AseraCare because the government **failed to show evidence of objective falsity**.
- The District Court ruled that without allegations that the physicians relied upon false information, or that clinicians failed to disclose important information to them, the government's case rested on a "**contradiction based on clinical judgment or opinion [which] alone cannot constitute falsity under the FCA as a matter of law.**" *U.S. ex rel. Paradies v. AseraCare, Inc.*, 2016 WL 1270521 (N.D. Ala. Mar. 31, 2016).
- The government has appealed this case to the 11th Circuit.

Objective Falsity

Other courts have similarly declined to find objective falsity where care and services were provided according to the provider's clinical judgment:

- *U.S. ex rel. Polukoff v. St. Marks Hospital*, No. 2:16-cv-00304 (D. Utah Jan. 19, 2017) (finding that representations to the government based on a physician's determination that a procedure was "medically reasonable and necessary" could not be proven objectively false)
- *U.S. ex rel. Dooley v. Metic Transplantation Lab*, No. CV 13-07039 (C.D. Cal. June 27, 2017) (holding that defendants could only be found to have submitted objectively false claims if they, in their medical opinion, knew that their selection of the tests at issue was not medically necessary)
- *United States v. Paulus*, 2017 WL 908409 (E.D. Ky. Mar. 7, 2017) (declining to find objective falsity where disagreements in expert testimony demonstrated that the degree of the diagnosis made by defendant physician was not an "objectively verifiable fact")

Objective Falsity

But some courts have allowed cases to proceed past motions to dismiss where alleged false claims seem to be predicated on clinical judgments:

- *U.S. ex rel. Groat v. Boston Heart Diag. Corp.*, 2017 WL 2533341 (D.D.C. June 9, 2017) (denying motion to dismiss because the Court could not determine, without weighing the evidence, whether relator's allegations regarding medical necessity stem from a mere difference of clinical judgment)
- *U.S. ex rel. Hinkle v. Caris Healthcare, L.P.*, 2017 WL 3670652 (E.D. Tenn. May 30, 2017) (denying motion to dismiss where government sufficiently alleged that the relevant physicians could not have legitimately exercised their clinical judgment because they relied on false information from defendants)

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Recent FCA Enforcement: Anti-Kickback Statute & Stark Law

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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 PPACA, 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).

The Anti-Kickback Statute (AKS)

- **Remuneration** includes anything of value, such as:
  - Cash, gifts, hospitality
  - Advisory board salaries
  - Compensation for speaking engagements

- **Statutory exceptions** and **regulatory safe harbors** protect certain payment and business practices that could otherwise implicate the AKS from criminal and civil prosecution, including certain:
  - Discounts
  - Payments to bona fide employees
  - Personal services / management contracts
  - Equipment / space rental contracts

- To be protected by a safe harbor, the arrangement must satisfy all of its requirements.

"In some industries, it is acceptable to reward those who refer business to you. However, in the Federal health care programs, paying for referrals is a crime."

- HHS OIG, *A Roadmap for Physicians, Fraud and Abuse Laws*

The Anti-Kickback Statute – Scienter

- **Willful** means "act[ing] with an **evil-meaning mind**, that is to say . . . with **knowledge that [the] conduct [i]s unlawful**."
  - *Bryan v. United States*, 524 U.S. 184 (1998).

- A key element of AKS liability is intent to induce referrals.
  - **"One purpose test":** Some courts have held that if even "**one purpose**" is to induce referrals, reward a referral source, or generate business, the government views the inducement element as satisfied.

Physician Self-Referral Law (Stark Law)

- The Stark Law, 42 U.S.C. § 1395nn, prohibits:
  - Physicians who have a financial relationship with a health care entity from referring patients to that entity to receive "designated health services" reimbursed by federal health care programs; and
  - The health care entity from submitting claims to federal health care programs for those services resulting from a prohibited referral.
- **DOJ** and **HHS OIG** are the dual enforcers of the Stark Law.

Physician Self-Referral Law (Stark Law)

- The Stark Law contains **multiple exceptions**.
- **Fair market value** compensation—so long as the value is independent of the value or volume of referrals—is generally permissible.
- **Designated health services** include:
  - Clinical laboratory services
  - Physical / occupational therapy services
  - Radiology / radiation services
  - DME / prosthetics / orthotics
  - Parenteral / enteral nutrients, equipment and supplies
  - Home health services
  - Inpatient and outpatient hospital services

"The Stark Law is ***intended to prevent overutilization of services by physicians who [stand] to profit*** from referring patients to facilities or entities …."

U.S. ex rel. Drakeford v. Tuomey Healthcare Sys., 792 F.3d 364, 373 (4th Cir. 2015)

Applicable Law – Relationship of the Statutes

- The government and relators often pursue alleged AKS and Stark violations in tandem in FCA cases involving providers.
- Since PPACA, claims "**resulting from**" violations of the AKS are false for purposes of the FCA.
  - 42 U.S.C. § 1320a–7b(g)
  - *See, e.g.*, *U.S. ex rel. Kester v. Novartis Pharms. Corp.*, 41 F. Supp. 3d 323, 331-33 (S.D.N.Y. 2014)
- Claims resulting from Stark Law violations also may be false for FCA purposes.
  - *See, e.g.*, *U.S. ex rel. Drakeford v. Tuomey Healthcare Sys.*, 792 F.3d 364, 382 (4th Cir. 2015)

AKS and Stark Law – Penalties

- **Potential consequences of AKS violation:**
  - Jail terms of up to five years
  - Fines of up to $25,000 per violation or twice the alleged gain or loss
  - Exclusion from participation in federal health care programs
  - Civil penalties of up to $50,000 per kickback plus three times the amount of remuneration

- **Potential consequences of Stark Law violations:**
  - Denial of payments
  - Refund of payments
  - Civil penalties of $15,000 per service
  - Civil assessments of as much as three times the amount claimed

Case Study: Mercy Hospitals

Mercy Hospitals

- In May, two Missouri hospitals agreed to pay $34 million to resolve allegations that they violated the Stark Law, resulting in false claims under the FCA.

- Government alleged that the hospitals paid oncologists in part based on a formula that considered the value of their patient referrals, and then submitted claims to Medicare for chemotherapy services referred by those physicians.

Case Study: Mercy Hospitals (*cont'd*)

"This settlement protects patients and the public by enforcing the federal protections against profit incentives for physicians. **Patients deserve assurances that they are receiving appropriate medical care, unbiased by hidden incentives.** And taxpayers deserve assurances that the cost of public health care programs is not inflated by unnecessary procedures and services."

Acting U.S. Attorney Thomas M. Larson, Western District of Missouri

$34 million resolution	$5.44 million relator share

Case Study: Pacific Alliance Medical Center

Pacific Alliance Medical Center

- PAMC allegedly violated the False Claims Act by engaging in improper financial relationships with referring physicians.
- These relationships took the form of:
  (1) paying above-market rates to rent office space in physicians' offices, and
  (2) marketing arrangements.
- The lawsuit alleged that these relationships violated the Anti-Kickback Statute and the Stark Law.

Case Study: Pacific Alliance Medical Center (cont'd)

PAMC

"This settlement is **a warning to health care companies** that think they can boost their profits by entering into **improper financial arrangements with referring physicians**."

Special Agent in Charge Christian J. Schrank of the Department of Health and Human Services, Office of Inspector General

$42 million	$9.2 million relator share

Case Study: Indiana University Health / HealthNet

IU Health / HealthNet

- IU Health allegedly provided HealthNet with a more than $10 million interest-free line of credit.
- The government alleged that HealthNet was not expected to repay a substantial portion of this loan and that this financial arrangement was intended to induce HealthNet to refer its OB/GYN patients to IU Health's Methodist Hospital.

Case Study: Indiana University Health / HealthNet (cont'd)

"The payment of illegal remuneration to induce patient referrals **interferes with health care providers' independent judgment** when they make referral decisions for their patients."

Deputy Assistant Attorney General Joyce R. Branda for the Civil Division

$18 million resolution	$2.8 million relator share

Case Study: U.S. ex rel. Ruscher v. Omnicare

U.S. ex rel. Ruscher v. Omnicare, 663 Fed. App'x 368 (5th Cir. 2016)

- A former employee of Omnicare, a long term care pharmacy, alleged that the company violated the AKS by offering prompt payment discounts and writing off debt owed to it by skilled nursing facilities in exchange for referrals.
- The court explained that although relators "need only show that **one purpose of [] remuneration [is] to induce [] referrals** . . . [t]here is no AKS violation . . . where the defendant **merely hopes or expects referrals from benefits that were designed wholly for other purposes**."
- The Fifth Circuit's decision offers some limits to the government's expansive interpretation of the "one purpose" test.

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Questions?

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