The FCA's Continuing Evolution and Tactics to Address Allegations

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FCA: State of the Union

- **2018 Statistics**
- Legislative Branch
- Executive Branch
- Judiciary Branch

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2018 Statistics

- DOJ recovered over $2.8 billion in settlements and judgments
- Over 750 new FCA cases filed
- The majority of recoveries and new cases were in the health care industry
  - $2.5 billion recoveries
  - Unprecedented 87% of total FCA recoveries
  - Exceeded $2 billion recoveries for the ninth consecutive year

Notable 2018 Health Care Recoveries

Party	Settlement Amount	Alleged FCA Violation
AmerisourceBergen Corporation and some subsidiaries	$625 million	Wholesale drug manufacturer operated a facility improperly repackaging drugs for patients with cancer
Actelion Pharmaceuticals US, Inc.	$360 million	Pharmaceutical company used a foundation as a conduit to pay thousands of Medicare patients' copayments for taking the company's hypertension drug
DaVita Inc.	$270 million	One physician association submitted incorrect diagnostic codes to Medicare Advantage for inflated payments
Health Management Associates	$260+ million	Hospital chain improperly billed health care programs for inpatient services, submitted inflated claims, and paid physicians in exchange for patient referrals
William Beaumont Hospital	$84.5 million	Detroit area hospital system had improper relationships with eight referring physicians, causing the submission of false claims to Medicaid, Medicare, and TRICARE

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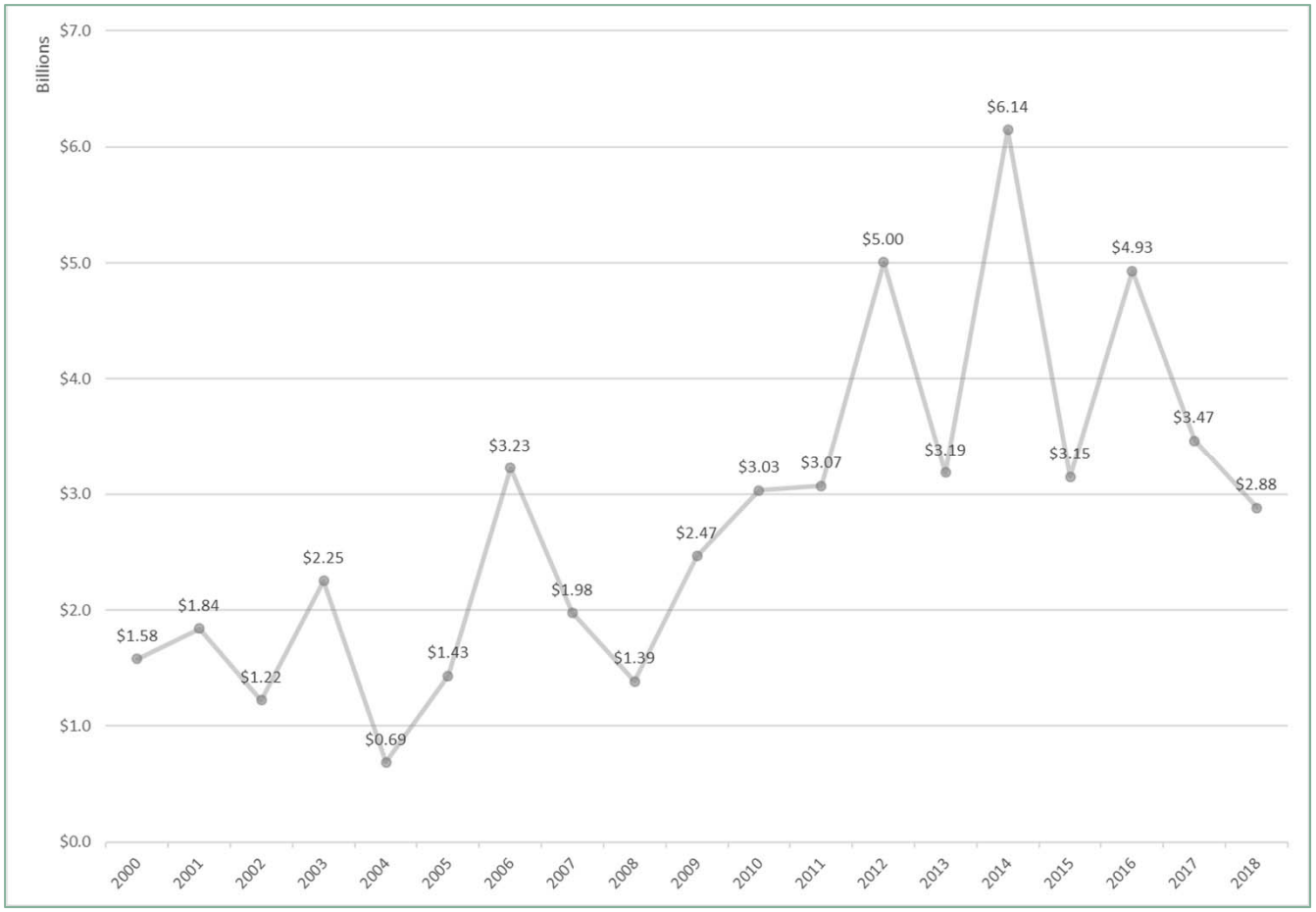
Total Recoveries



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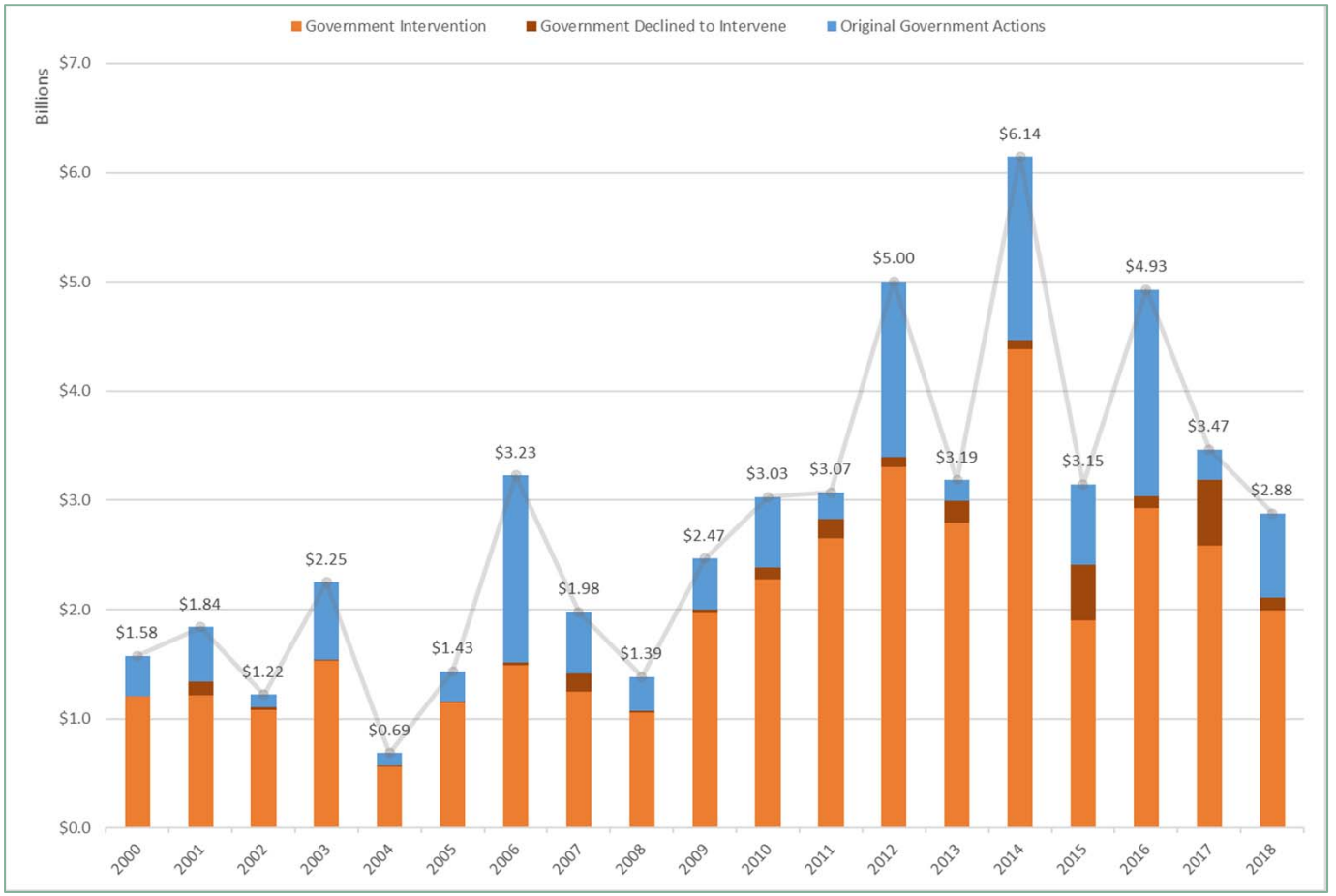
Total Recoveries Deconstructed



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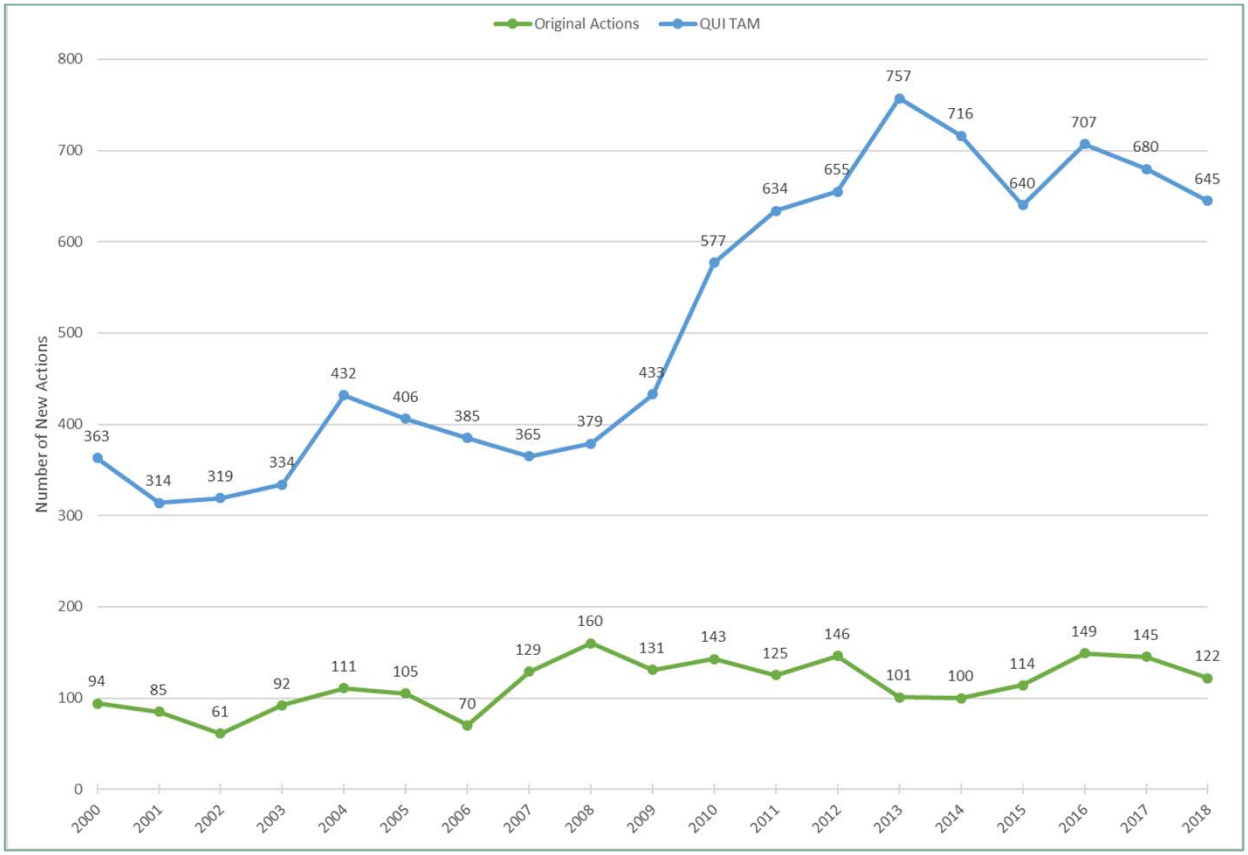
New Cases Filed



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Federal Legislative Developments

Fixing Housing Access Act of 2018 (H.R. 5993)

- Proposed bipartisan legislation **but not passed**
- Unusual mix of pro-plaintiff and pro-defense provisions
- Revised § 3729 by adding subsection (e)
  - Claims arising from federal programs in connection with obtaining either government insurance or guaranty of a loan
  - Pro-defense definitions of damages and materiality
- Revised § 3731(b) to include SOL specific to § 3729(e)
  - Pro-plaintiff: eliminated the ten-year limitation

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Federal Legislative Developments

Tax Reform: Impacting Deductibility of Settlement Payments

- New legislation passed that impacts FCA settlements although it did not address the FCA directly
- Old Approach
  - Compensatory damages deductible
  - DOJ complicated taxpayers' ability to deduct settlement payments
- Tax Cuts and Jobs Act of 2017
  - Forces issue of claiming tax deductions into settlement negotiations
  - Will DOJ change its policy?

Federal Legislative Developments

Tax Cuts and Jobs Act of 2017

- Amended 26 U.S.C. § 162(f)
  - Prohibits deducting Government settlement payments
  - Exception: "amounts constituting restitution or paid to come into compliance with law"
    - Three requirements including the ***settlement agreement itself must identify payment*** "as restitution or as an amount paid to come into compliance with [the violated] law"
- Created 26 U.S.C. § 6050X
  - When entering a settlement agreement for $600+, Government ***must file an IRS report identifying*** the total settlement amount, portion paid to come into compliance with violated law, and portions paid for restitution for harm/damage the violation may have or did cause

Federal Legislative Developments

Senator Chuck Grassley (R-IA)

- Authored 1986 FCA amendments allowing whistleblowers to share in FCA recoveries
- August 2018 op-ed championing the FCA
  - Stressed the importance of whistleblowers to fraud prosecution
- No longer Chairman of the Senate Judiciary Committee
  - New Chairman: Senator Lindsey Graham (R-SC)
    - Graham's proposed Affordable Care Act repeal and replacement could impact the FCA

Legislative and Policy Reform Wish List

- Make Inspector General (IG) Disclosure a Bar to Future *Qui Tam* Actions
  - To prevent unnecessary *qui tam* actions and to incentivize responsible contractor conduct
- Adopt a "Clear and Convincing Evidence" Standard
  - Higher burden of proof to prevent defendants from feeling that they must settle meritless strike suits
  - Justified by the possibility of treble damages, a non-strictly disinterested jury, the fact that the Supreme Court has labeled the FCA a punitive statute, and the fuzziness surrounding the "knowledge" standard
- Compliance Program Safe Harbor
  - If a contractor has its compliance program certified by a government or third-party body charged with analyzing and certifying compliance programs, damages should not exceed the Government's actual loss plus statutory penalties

Legislative and Policy Reform Wish List

- Only Actual Damages Should be Trebled
  - Only the net loss suffered by the Government should be trebled
- Redefine Application of Statutory Penalties
  - Could apply only when there was no loss to the Government
  - Could be used as a cap that is both equal to the sum sought in the claim plus the costs the Government incurred reviewing the claim
- Clarify Double-Damages Limitation under § 3729(a)(2)
  - Congress should clarify what is required and allow a more meaningful period for potential violators to perform a meaningful internal investigation

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Executive Developments

Dismissing *Qui Tam* Actions

Granston Memo 1/10/18

- DOJ internal memo by Michael Granston, Director of the Commercial Litigation Branch of DOJ's Fraud Section
- Directs attorneys to examine several factors and consider the merits of filing a motion to dismiss *qui tam* actions when the Government declines to intervene
  - Dismissal authority under 31 U.S.C. § 3730(c)(2)(a)
- Leaked after DOJ affirmatively denied rumors of a policy change

Executive Developments

Dismissing *Qui Tam* Actions

Granston Memo: Seven Key Factors

1. Curbing Meritless *Qui Tams*
2. Preventing Parasitic or Opportunistic *Qui Tam* Actions
3. Preventing Interference with Agency Policies and Programs
4. Controlling Litigation Brought on Behalf of the United States
5. Safeguarding Classified Information and National Security Interests
6. Preserving Government Resources
7. Addressing Egregious Procedural Errors

Executive Developments

Dismissing *Qui Tam* Actions

Justice Manual § 4-4.111

- Incorporates Granston's key principles, including the seven factors
- "[D]ismissals also provide an important tool to advance the government's interests, preserve limited resources, and avoid adverse precedent"

Deputy Associate Attorney General Stephen Cox 1/28/19

- "The Granston Memo is about our gatekeeping role. . . . Bad cases that result in bad case law inhibit our ability to enforce the False Claims Act in good and meritorious cases"

The Granston Memo in Action

Gilead Sciences Inc. v. United States ex rel. Campie

- DOJ brought life to the Granston Memo when it told SCOTUS it intends to exercise its powers under 31 U.S.C. § 3730(c)(2)(a) and dismiss the case upon remand
  - Likelihood of success on the merits, burdensome discovery, and distraction from agency responsibilities are all factors mentioned in January's Granston Memo
  - The most high-profile execution of the "Granston Doctrine" since the Memo became public
- Ultimately the Supreme Court denied *certiorari* on January 7, 2019

The Granston Memo in Action

- December 2018: DOJ moved to dismiss 11 FCA cases brought by "shell company" whistleblowers against drug manufacturers citing Granston factors
  - Meritless; burdensome; allegations contradicted HHS OIG guidance
- Theory of liability that patient assistance services supplied by drug manufacturers are unlawful kickbacks
- Whistleblowers had backing from National Healthcare Analysis Group (NHCA)
- January 2019: NHCA filed robust oppositions
  - Accused DOJ of attempting to "legalize certain kickbacks" from drug manufacturers to physicians
  - "The FCA does not — and cannot — authorize the executive branch to rewrite the AKS so as to legalize certain kickbacks or gut the statute by making pronouncements as to what it means"

Executive Developments

Agency "Guidance"

- Extends AG Jeff Sessions 11/16/17
  - DOJ from using its *own* guidance documents to create *de facto* obligations, standards, or rights
- Brand Memo 1/25/18
  - DOJ memo by Rachel Brand, then Associate Attorney General
  - Expanded prohibition to *another agency's* guidance
- Justice Manual § 1-20.100
  - Incorporates Brand Memo
  - Expands to criminal enforcement

Agency Guidance: Caution

Justice Manual § 1-20.201

"Where a guidance document describes a relevant statute or regulation, the Department may use ***awareness*** of the guidance document (or its contents) as evidence that the party had the requisite ***scienter, notice, or knowledge of the law***."

Executive Developments

"Piling On"

Rosenstein Speech 5/9/18

> "Our new policy discourages 'piling on' by instructing Department components to ***appropriately coordinate*** with one another and with other enforcement agencies ***in imposing multiple penalties on a company in relation to investigations of the same misconduct***"

Justice Manual § 1-12.100

- DOJ attorneys "should remain mindful of their ***ethical obligation*** not to use criminal enforcement authority unfairly to extract, or to attempt to extract, additional civil or administrative monetary payments"
- DOJ attorneys "should coordinate with one another to ***avoid the unnecessary imposition of duplicative fines, penalties, and/or forfeiture*** against the company"

Cooperation Credit

Yates Memo

To qualify for cooperation credit corporations must provide "***all*** relevant facts relating to the ***individuals responsible*** for the misconduct"

2018 New Qualification Standard

- Rosenstein Speech 11/29/18
- Justice Manual § 4-3.100

Executive Developments

Eligibility Requirement for Cooperation Credit in Civil Cases

Rosenstein	Justice Manual
Corporation "must identify all wrongdoing by ***senior officials***, including members of senior management or the board of directors"	"[A] corporation ***must provide meaningful assistance*** to the government's investigation" No cooperation credit if "a corporation that ***conceals involvement*** in the misconduct by members of ***senior management*** or the ***board*** of directors, or otherwise demonstrates a ***lack of good faith*** in its representations regarding the nature or scope of the misconduct"

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Maximum Cooperation Credit in Civil Cases

Rosenstein	Justice Manual
Corporation "must identify ***every*** individual who was ***substantially involved*** in or ***responsible*** for the criminal conduct."	"[A] corporation must do a ***timely self-analysis*** and be ***proactive*** in ***voluntarily disclosing*** wrongdoing and identifying all individuals ***substantially involved*** in or responsible for the misconduct, without making the government compel such disclosures with subpoenas or other investigative demands."

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Cooperation Credit Certainty

How does this apply in FCA cases?

- Penalties or damages?
- Reduce total or adjust trebling?
- Interaction with § 3729(a)(2)?
  - Voluntary disclosure within 30 days of discovery may reduce damages from treble to double
- Cooperation credit should be quantifiable

Cooperation Credit Certainty

Deputy Associate Attorney General Stephen Cox 1/28/19

- "The Department has significant discretion under the False Claims Act to resolve cases in a way that provides a material discount based on cooperation while still making the government whole. **Stay tuned on this front**."

Executive Developments

Enforcement Priorities

- Health Care
  - Opioid Crisis
  - Drug Pricing
  - Compliance with Current Good Manufacturing Practices and home-based health services
  - Patient Assistance Programs (PAPs)
  - Electronic Health Records (HER) Vendors
  - Hospice Care
- Government Contracts
  - All aspects: proposals, eligibility, certification, and performance
  - Domestic Preferences: Trade Agreements Act (TAA), Buy American Act (BAA)
  - Infrastructure
- Imports/Antidumping
- Third Parties (facilitating or permitting others to commit fraud)

New Leadership: AG Nominee Bill Barr

- While the nominee made critical comments in the past, his recent nomination hearing indicates he will diligently enforce the FCA
- **1989: Barr Memo regarding the FCA being unconstitutional**
  - "violates separation of powers"
  - "establishes a basis for governance by tyranny"
- **2001: Barr Interview**
  - Wanted DOJ to attack the FCA's constitutionality
    - "violation of the appointments clause"
    - "standing issue of the Supreme Court"
  - The *qui tam* statute is "an abomination"
- **2019: Barr reversed position at AG nomination hearing**

New Leadership: AG Nominee Bill Barr

2019 AG Nomination Hearing

- Grassley: Is the False Claims Act **unconstitutional**?
- Barr: **No, Senator. It's been upheld by the Supreme Court**.
- Grassley: Do you consider the False Claims Act to be an **abomination**?
- Barr: **No**, I don't.
- Grassley: Does the False Claims Act **benefit the taxpayer** specifically its provisions to empower and protect whistleblowers?
- Barr: **Yes**, Senator.
- Grassley: If confirmed, do you commit to not take any actions to undermine the False Claims Act; further if confirmed, will you continue current justice department staff and funding levels to properly support and prosecute False Claims Act cases?
- Barr: **Yes, I will diligently enforce the False Claims Act**.

Additional Remedies

- U.S. Commodity Futures Trading Commission (CFTC)
  - Issued largest whistleblower reward in July 2018: $30 million
  - CFTC's press release: hopes the large reward incentivizes future whistleblowers
- SEC Whistleblower Program
  - Another successful program…but not for long?
  - 2017: three of the ten largest awards made, one exceeding $20 million
  - June 29, 2018 announced proposed amendments including capping whistleblower awards

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- **Judiciary Branch**

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Supreme Court Developments

- The Supreme Court has considered FCA issues four times in the past four years
- 2018: granted *certiorari* in *Cochise Consultancy Inc. v. United States ex rel. Hunt*, Case No. 18-315
  - Potentially resolving three-way statute of limitations circuit split

Hunt Background: Two Statutes of Limitations

- § 3731(b)(1)
  - **Six years** after date on which a violation under § 3729 was committed
- § 3731(b)(2)
  - **Three years** after the date when facts material to the right of action are known or reasonably should have been known by the US official charged with responsibility to act in the circumstances, but no more than **ten years** after the date the violation occurred

Hunt: SOL Three-Way Circuit Split

- **Fourth, Fifth, and Tenth Circuits**
  - Relators cannot take advantage of the three-year statute of limitations period unless the Government intervenes
- **Third and Ninth Circuits**
  - Relators can use the three-year statute of limitations, but the limitations period begins to run when the relator, not the Government, knows or should know of the facts underlying the alleged fraud
- **Eleventh Circuit**
  - The three-year limitations period applies even where the Government declines to intervene
  - A relator may file a claim within three years of the date on which the Government first knows or should know of the alleged fraud—even if the relator has known of the alleged violation for much longer—as long as the filing occurs within ten years of the violation

Hunt: Supreme Court resolution?

Cochise Consultancy Inc. v. United States ex rel. Hunt, Case No. 18-315

- On November 16, 2018, Supreme Court granted *certiorari*
- Oral argument set for March 19, 2019
- If the Court decides relators *can* use (b)(2) after the Government declines, the Court should also decide whose knowledge triggers the SOL clock

Escobar Materiality

Universal Health Servs., Inc. v. United States ex rel. Escobar, 136 S. Ct. 1989 (2016)

- Materiality is a "demanding" and "rigorous" standard
  - "A misrepresentation cannot be deemed material merely because the Government designates compliance with a particular statutory, regulatory, or contractual requirement as a condition of payment"
- Materiality assessment in *Escobar*
  - Claim is not material if "noncompliance is minor or insubstantial"
  - If the Government has "actual knowledge" of noncompliance and still pays, that is "strong evidence" against materiality
  - Evidence that requirement was "condition of payment" or Government could have declined to pay had it known of noncompliance does not suffice to show materiality

Escobar Materiality

- Denied *certiorari* for two big *Escobar* materiality cases on January 7, 2019
  - *Gilead Sciences Inc. v. United States ex rel. Campie*, Case No. 17-936
    - Ninth Circuit decision overturning dismissal and interpreting *Escobar* as requiring knowledge of noncompliance, not allegations of noncompliance
  - *United States ex rel. Harman v. Trinity Industries, Inc.*, Case No. 17-1149
    - Fifth Circuit overturned a $663 million judgment against Trinity Industries, Inc., a guardrail manufacturer

Escobar Materiality: Stay Tuned

Brookdale Senior Living Communities, Inc. v. United States ex rel. Prather, Case No. 18-699

- Petition for *certiorari* is pending
- "Whether the failure to plead facts relating to past government practices in an FCA action can weigh against a finding of materiality"
- "Whether an FCA allegation fails when the pleadings make no reference to the defendant's knowledge that the alleged violation was material to the government's payment decision"

FCA Constitutionality

Intermountain Health Care Inc. v. United States ex rel. Polukoff, Case No. 18-911

- Petition for *certiorari* pending
- Argues FCA is unconstitutional
  - Violates the Appointments Clause because whistleblowers are not appointed by anyone
  - Even if whistleblowers are not officers, "the FCA impermissibly vests a core function of officers — civil law enforcement — in nonofficer [whistleblowers]"
- Also seeks resolution of Rule 9(b) circuit split

Supreme Court Possibilities

Rule 9(b) Heightened Pleading Standard

- **2018 continued trend of rejecting *certiorari* on the circuit split**
  - Denied 11th Circuit appeal in *United States ex rel. Chase v. Chapters Health System Inc.*, No. 17-1477 (Oct. 1, 2018)
- Pro-Defense Interpretation: Fourth, Sixth, Eighth, and Eleventh Circuits
  - "[P]leading an ***actual false claim*** with particularity is an indispensable element of a complaint that alleges a FCA violation in compliance with Rule 9(b)"
    - *United States ex rel. Bledsoe v. Cmty. Health Sys., Inc.*, 501 F.3d 493, 504 (6th Cir. 2007) (emphasis added)
- Pro-Plaintiff Interpretation: First, Third, Fifth, Seventh, and Ninth Circuits
  - Sufficient to allege "particular details of a scheme to submit false claims paired with ***reliable indicia that lead to a strong inference*** that claims were actually submitted."
    - *United States ex rel. Grubbs v. Kanneganti*, 565 F.3d 180, 190 (5th Cir. 2009) (emphasis added)

Rule 9(b) Heightened Pleading Standard

- **Group Fraud Pleading Standard**
  - If defendants have "the exact same role in a fraud," Rule 9(b) does not require distinguishing between them
    - *United States ex rel. Silingo v. WellPoint, Inc.*, 904 F.3d 667 (9th Cir. 2018)

Federal Court Developments

Rule 9(b) and First-to-File Bar

- Circuit split regarding whether a Rule 9(b) deficient complaint can bar a later filed complaint
  - Second and D.C. Circuits allow a deficient complaint to bar other similar complaints
    - *United States ex rel. Batiste v. SLM Corp.*, 659 F.3d 1204 (D.C. Cir. 2011)
    - *United States ex rel. Wood v. Allergan Inc.*, 899 F.3d 163 (2d Cir. 2018)
  - Sixth Circuit prohibits the "legally infirm [complaint] under Rule 9(b)" to serve as a first-to-file bar
    - *Walburn v. Lockheed Martin Corp.*, 431 F.3d 966, 973 (6th Cir. 2005)

Federal Court Developments

Addressing Mandate to Strictly Enforce Scienter

- Third Circuit: no scienter where defendant acted on an incorrect, but reasonable, interpretation of relevant regulatory and statutory guidance
  - *United States ex rel. Streck v. Allergan*, No. 17-1014, 2018 WL 3949031 (3d Cir. 2018)
- Sixth Circuit: although 9(b) heightened pleading standards do not apply to pleading scienter, "the mere possibility of misconduct . . . is insufficient."
  - *United States ex rel. Harper v. Muskingum Watershed Conservancy District*, 739 Fed. App'x 330 (6th Cir. 2018)
- Seventh Circuit: scienter requires specific factual allegations; general allegations that defendant violated existing duty is insufficient
  - *United States ex rel. Berkowitz v. Automation Aids, Inc.*, 896 F.3d 834 (7th Cir. 2018)

Falsity

- FCA bars a "false or fraudulent claim" without defining the falsity element
- Tenth Circuit: rejected "bright-line rule that medical judgment can never serve as a basis for an FCA claim"
  - *United States ex rel. Polukoff v. St. Mark's Hospital,* 895 F.3d 730 (10th Cir. 2018)
  - *See also United States v. Paulus,* Case No. 17-5410 (6th Cir. 2018)
- Ninth Circuit: although incorrect under applicable regulations and statutes, calculations underlying cost estimates submitted for a Government contract were sufficiently clear and thus not objectively false under the FCA
  - "[T]he statutory phrase 'known to be false' does not mean incorrect as a matter of proper accounting methods, it means a lie"
  - *United States ex rel. Berg v. Honeywell International, Inc.,* 740 Fed. App'x 535 (9th Cir. 2018)

Federal Court Developments

Public Disclosure Bar

- Requires dismissal "if substantially the same allegations or transactions" have been publicly disclosed and relator is not the original source (31 U.S.C. § 3730(e)(4))
- ***United States v. Omnicare, Inc.*, 903 F.3d 78 (3d Cir. 2018)**
  - Holding: No public disclosure bar "where a relator's non-public information permits an inference of fraud that could not have been supported by the public disclosures alone"
  - Relator used publicly available information to reveal non-public information the relator knew

Federal Court Developments

First-to-File Bar

- Prohibits relators from bringing *qui tam* actions when a related suit is pending (31 U.S.C. § 3730(b)(5))
- **Recent trend**: Relators try to circumvent the first-to-file bar by filing amended complaints and arguing similar cases that may have been pending when they first filed their original case are no longer pending so the bar does not apply
- Second and D.C. Circuits requires dismissal
  - *United States ex rel. Wood v. Allergan Inc.*, 899 F.3d 163 (2d Cir. 2018)
  - *United States ex rel. Shea v. Cellco P'ship*, 863 F.3d 926 (D.C. Cir. 2017)
- First Circuit allows case to proceed
  - *United States ex rel. Gadbois v. Pharmerica*, 809 F.3d 1 (1st Cir. 2015)

Private Equity FCA Suit

- *United States ex rel. Medrano and Lopez v. Diabetic Care Rx LLC dba Patient Care America*, case number 0:15-cv-62617, S.D. Fla.
  - *Qui tam* action alleged a compounding pharmacy of running a kickback scheme inducing Tricare to pay over $68 million for medically unnecessary prescriptions
  - Government named the pharmacy's private equity owner as a second defendant when it intervened

Federal Court Developments

Moving to Maintain Seal After Dismissal

Trend: relators counsel ask courts to keep cases under seal when the Government declines to intervene and moves to dismiss

Relators argue

- Statute does not explicitly require lifting the seal if the case does not proceed and the court has the authority to maintain or lift the seal
- Note successful attempts but those cases remain under seal and thus are not published or reported
- Relators avoid retaliation
- Defendants avoid negative publicity

Published Opinions

- Generally deny requests finding need to public access weighs in favor of unsealing
  - *See, e.g.*, *United States ex rel. Grover v. Related Companies, LP*, 4 F. Supp. 3d 21 (D.D.C. 2013)

Federal Court Developments

Partial Intervention

United States ex rel. Brooks v. Stevens-Henager College, Inc., No. 2:15-cv-00199, 2019 WL 186663 (D. Utah Jan. 14, 2019)

- **Holding**: Under the FCA's plain language and legislative history, relators do not have a right to litigate non-intervened parts of a case
  - "Congress' silence as to a relator's right to prosecute the non-intervened claims leads to the conclusion that no such right exists."
  - In *United States ex rel. Sikkenga v. Regence BlueCross BlueShield of Utah*, 472 F.3d 702, 725 (10th Cir. 2006), the Tenth Circuit held § 3731(b)(2) "was not intended to apply to private qui tam suits." Only § 3731(b)(1) applies to relators.
  - "Put simply, the Tenth Circuit's interpretation of § 3731(b) suggests that either the Government or the relators conducts the action, not both."

Discovery Reform Wish List

- *"Brady"*-like Disclosure Obligations
  - Including obligations to make early disclosure of evidence that tends to negate intent, bears favorably on other elements of liability, or mitigates or eliminates damages
- DOJ Immediate Duty to Preserve
  - Require the preservation of all potentially relevant materials
  - Trigger the automatic duplication and preservation of all relevant government employee email accounts
  - Adverse inferences or jury instructions regarding relevant information if the Government fails to preserve

Discovery Reform Wish List

- Lower the Threshold for Obtaining Key Evidence (and in a Timely Manner)
  - Allow defense access to sealed materials
  - The real party in interest should not have to jump through hoops to get discovery
    - E.g., *Touhy* requests
  - Require a relator to notify the company of the allegation(s) at least 180 days before filing a *qui tam* complaint

Questions?

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