The False Claims Act – 2019 Mid-Year Update: Drug and Device Industries

October 15, 2019

Panelists

Stuart Delery is a partner in the Washington, D.C. office. He represents corporations and individuals in high-stakes litigation and investigations that involve the federal government across the spectrum of regulatory litigation and enforcement. Previously, as the Acting Associate Attorney General of the United States and as Assistant Attorney General for the Civil Division, he supervised the DOJ's enforcement efforts under the FCA and the Federal Food, Drug and Cosmetic Act.

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

John Partridge is a partner in the Denver office and Co-Chair of the FDA & Health Care Practice. He represents corporate and individual clients facing government investigations and associated litigation. He has particular experience defending pharmaceutical and medical device companies in investigations involving the federal Anti-Kickback Statute, the FCA, and the FCPA.

Jonathan Phillips is a partner 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 and medical device clients in investigations by the DOJ, FDA, and HHS OIG. Previously, he served as a Trial Attorney in DOJ's Civil Division, Fraud Section, where he investigated and prosecuted allegations of fraud under the FCA and related statutes.

MCLE Certificate Information

- Most participants should receive their certificate of attendance about four weeks after the webcast
- Virginia Bar Association members should receive their certificate of attendance about six weeks after the webcast
- All questions regarding MCLE Information should be directed to Jeanine McKeown (Gibson Dunn's National Training Administrator) at 213–229-7140 or jmckeown@gibsondunn.com

Agenda

- False Claims Act (FCA) Overview and Recent Jurisprudence
- Department of Justice (DOJ) Enforcement & Policy Developments
- Recent FCA Enforcement: Drugs & Devices
- FCA Enforcement Based on FDCA Violations
- Anti-Kickback Statute (AKS)
- The Opioid Epidemic
- Questions

FCA Overview and Recent Jurisprudence

Overview

- 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" (natural or corporate entity) who knowingly submits or causes the submission of false or fraudulent claims to the United States for money or property
- DOJ attorneys (Civil Division, as well as U.S. Attorneys' Offices) investigate and pursue FCA cases
- DOJ also considers whether *qui tam* cases merit parallel criminal investigations

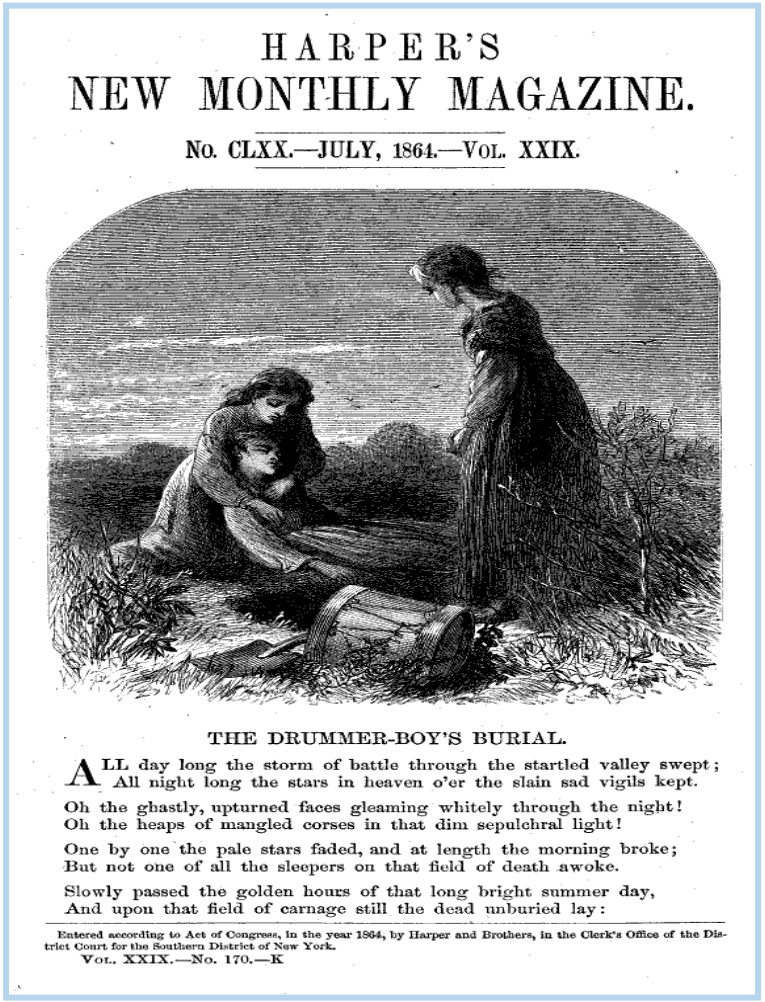
"It seems quite clear that the objective of Congress was broadly ***to protect the funds and property of the Government from fraudulent claims. . . .***"

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

History

- Civil War profiteering prompted enactment of the "Lincoln Law" in 1863

> For sugar [the Government] often got sand; for coffee, rye; for leather, something no better than brown paper; for sound horses and mules, spavined beasts and dying donkeys; and for serviceable muskets and pistols the experimental failures of sanguine inventors, or the refuse of shops and foreign armories.



HARPER'S
NEW MONTHLY MAGAZINE.

No. CLXX.—JULY, 1864.—Vol. XXIX.

THE DRUMMER-BOY'S BURIAL.

ALL day long the storm of battle through the startled valley swept;
All night long the stars in heaven o'er the slain sad vigils kept.

Oh the ghastly, upturned faces gleaming whitely through the night!
Oh the heaps of mangled corses in that dim sepulchral light!

One by one the pale stars faded, and at length the morning broke;
But not one of all the sleepers on that field of death awoke.

Slowly passed the golden hours of that long bright summer day,
And upon that field of carnage still the dead unburied lay:

Vol. XXIX.—No. 170.—K

R. Tomes, *The Fortunes of War*, Harper's New Monthly Magazine 228 (July 1864)

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
(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
(C)	Conspires to violate a liability provision of the FCA	Conspiracy

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

Key Theories

Factual Falsity

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

Legal Falsity / False Certification

- 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 made by contractors who colluded on bids)

Reverse False Claims

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

Damages and Penalties

Simple Damages Calculation

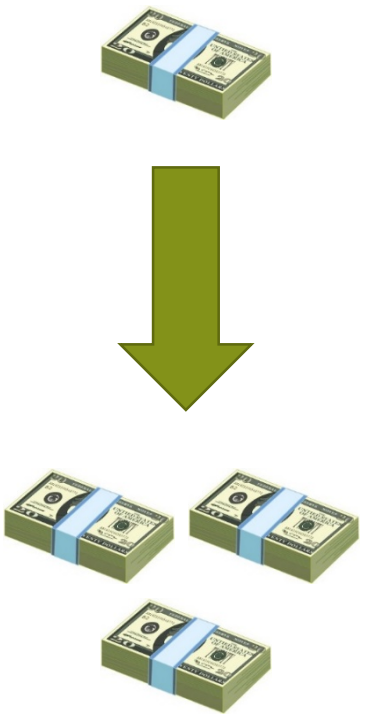
- Treble damages are traditionally calculated by multiplying the Government's loss by three (e.g., if defendant charged Government $100 for goods not received, damages would be $300)

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"

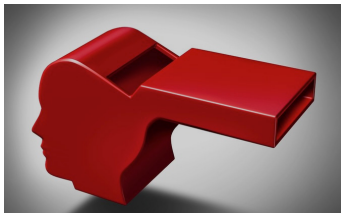
Civil Penalty Per Claim

- Previously $5,500 to $11,000
- Increased by interim rule in 2016, with later adjustment for inflation in 2018 to range of $11,181 to $22,363 per violation (no rule issued yet in 2019 increasing penalties)
- Interim rule was finalized in April 2019
- Final rule does not require DOJ to seek maximum number or amount of penalties available in any particular case
- Penalties are ***in addition to*** treble damages



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 the Government to intervene
  - An increasing number of whistleblower 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 shortly



"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)

Statute of Limitations

- The FCA has two limitations periods:
  - **6 years** from the alleged FCA violation; or
  - 3 years from the date the facts material to the FCA claim are known or reasonably should have been known by a government official, but **no more than 10 years** from the alleged violation

Cochise Consultancy, Inc. v. United States ex rel. Hunt, 139 S. Ct. 1507 (2019)

- Resolving a circuit split, the Supreme Court held that the extended limitations period of **up to 10 years** applies in all FCA cases, whether the Government has intervened or not
- The Court held that courts must look to the Government official's knowledge (not the relator's), as the trigger for the additional 3-year period
- Following *Cochise*, ***relators can now employ the extended limitations period even in cases where the Government has declined to intervene***

Statute of Limitations – Mirror RICO Suits

- RICO suits mirroring FCA suits that challenge off-label drug marketing continue to appear
- The First Circuit recently addressed the relationship between FCA claims and the statute of limitations for RICO claims (as well as state consumer fraud claims)

***In re Celexa & Lexapro Marketing & Sales Practices Litigation*, 915 F.3d 1 (1st Cir. 2019)**

- The Government intervened in a *qui tam* case alleging that the defendant pharmaceutical companies engaged in illegal off-label drug marketing schemes intended to fraudulently induce doctors to prescribe their drugs for off-label uses
- The unsealing of the complaint led more than a dozen consumers and entities to file suit alleging RICO and state consumer fraud violations related to the defendants' alleged illegal off-label marketing schemes
- The First Circuit held that, as a matter of law, the unsealing of the FCA complaint put the plaintiffs on notice that the defendants allegedly had been promoting off-label uses of their products; therefore, **the unsealing of the FCA complaint began the running of the four-year statute of limitations on the plaintiffs' RICO claims** related to the off-label marketing schemes alleged in the FCA complaint

Public Disclosure Bar

- The **public disclosure bar** provides that relator's *qui tam* complaint cannot be "substantially the same" as allegations 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 Affordable Care Act amended the public disclosure bar to its current language in 2010; previously, the bar contained slight differences in the public disclosure and original source provisions
  - **Does not limit DOJ's authority**

Public Disclosure Bar – Original Source Exception

***United States ex rel. Reed v. KeyPoint Gov't Solutions*, 923 F.3d 729 (10th Cir. 2019)**

- A relator satisfies the "materially adds" requirement when she "discloses new information that is sufficiently significant or important that **it would be capable of" influencing the Government's behavior**, as contrasted with a relator who provides only background information or details about a previously disclosed fraud
- A relator who merely identifies a new specific actor engaged in fraud usually would *not* materially add to public disclosures of alleged widespread fraud in an industry with only a few companies
- According to the court, the relator did materially add to the public disclosures about a specific program at her company, meeting the original source exception
- The court remanded on whether her knowledge was "independent" and whether her claims should otherwise survive scrutiny under Rule 12(b)(6) and Rule 9(b)

First-to-File Bar

- 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"**

***United States ex rel. McGuire et al. v. Millennium Labs., Inc.*, 923 F.3d 240 (1st Cir. 2019)**

- The First Circuit, reversing its prior precedent, joined the D.C. Circuit and the Second Circuit in holding that **the FCA's first-to-file bar is not jurisdictional, such that arguments under the first-to-file bar do not implicate the court's subject matter jurisdiction**, even if they are a cause for dismissal
- This distinction can affect how, and when, arguments under the first-to-file bar may be made, and also the standard of review a court applies
- The case is currently on appeal

Estoppel

- As DOJ increasingly pursues parallel criminal and civil investigations in cases involving fraud on the Government, the interplay between criminal and FCA charges becomes increasingly important

***United States v. Whyte*, 918 F.3d 339 (4th Cir. 2019)**

- Defendant owned a company that supplied armored vehicles to multinational forces in Iraq, and was indicted for criminal fraud in July 2012
- In October 2012, a relator filed a civil FCA suit against the defendant, in which the Government declined to intervene
- The defendant ultimately prevailed at trial in his FCA civil suit, but then, over two years later, a jury convicted the defendant in the criminal case
- The Fourth Circuit held that **the Government is not collaterally estopped from pursuing its own criminal case by a prior *qui tam* FCA action in which it did not intervene**

Estoppel

***United States ex rel. Doe v. Heart Solution, PC*, 923 F.3d 308 (3d Cir. 2019)**

- Individual defendant was convicted criminally of defrauding Medicare after admitting at her plea colloquy that Medicare paid her company for diagnostic neurological testing that she falsely represented was supervised by a licensed neurologist
- After her conviction, the Government intervened in a civil *qui tam* FCA case against her and her health care company regarding the same fraudulent certifications
- In granting summary judgment against the defendant *company*, the district court relied on the *individual* defendant's plea
- The Third Circuit held that **although an individual defendant was collaterally estopped from denying the falsity and knowledge elements of a civil FCA claim by her criminal conviction and plea colloquy regarding the same conduct, her employer was not**

Retaliation – Recent Jurisprudence

***Guilfoile v. Shields*, 913 F.3d 178 (1st Cir. 2019)**

- FCA retaliation claims need not meet Rule 9(b)'s particularity requirement, plead the submission of false claims, or plead that compliance with the Anti-Kickback Statute was material
- Instead, FCA retaliation plaintiffs "need only plead that their actions in reporting or raising concerns about their employer's conduct 'reasonably could lead to an FCA action'"

***U.S. ex rel. Grant v. United Airlines Inc.*, 912 F.3d 190 (4th Cir. 2018)**

- Prior Fourth Circuit precedent held that employees engage "in protected activity when 'litigation is a *distinct possibility*, when the conduct reasonably could lead to a viable FCA action, or when . . . litigation is a reasonable possibility'"
- The court rejected the "distinct possibility" standard for "other efforts to stop 1 or more" FCA violations, and instead adopted an "***objective reasonableness***" standard: "an act constitutes protected activity where it is motivated by an *objectively reasonable* belief that the employer is violating, or soon will violate, the FCA"

***U.S. ex rel. Reed v. KeyPoint Gov't Solutions*, 923 F.3d 729 (10th Cir. 2019)**

- Because the relator was a compliance officer, she must plead facts to overcome the presumption that she was just doing her job in reporting fraud internally to her employer—that she took actions beyond what was required to fulfill her compliance job duties
- The relator did not adequately allege that her employer was on notice she was trying to stop FCA violations, and the court affirmed the dismissal of her retaliation claim

Implied (False) Certification & Materiality

***Universal Health Services v. U.S. ex rel. Escobar*, 136 S. Ct. 1989 (2016)**

- Relator brought FCA suit against leading nationwide 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 Supreme 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"

Implied (False) Certification & Materiality (cont.)

Implied certification and "specific representations"

- Drug and device manufacturers themselves do not make representations to the Government in most cases
- Provider claims typically make true statements about the drug being prescribed and the patient's condition

Materiality

- A key issue is whether an FDCA violation, or a misrepresentation during the approval process, is "material" to Government payment for the drug at issue

Post-*Escobar* –Government Knowledge & Materiality

***U.S. ex rel. Lemon v. Nurses To Go, Inc.*, 924 F.3d 155 (5th Cir. 2019)**

- The relators alleged that a hospice provider submitted claims affirming it had complied with various Medicare statutory and regulatory requirements, despite allegedly violating several requirements related to certifications, face-to-face physician patient encounters, and writing plans of care
- The court reversed the district court's 12(b) dismissal, concluding that the allegedly violated regulatory requirements were conditions of payment
- The court articulated three non-exhaustive "factors" for determining materiality:
  - whether the Government expressly conditioned payment on meeting the statutory or regulatory requirements at issue
  - whether the Government would have denied payment if it had known of the violations (i.e., the "government enforcement" factor)
  - whether the defendant's noncompliance was substantial or minor
- The court held that ***generalized allegations that the Government had taken enforcement actions for similar violations against other companies in the past was sufficient*** for the pleadings stage, observing that it did "not expect Relators to know precisely the Government's prosecutorial practices without the benefit of discovery"

Post-*Escobar* Materiality – When Does Government Knowledge Defeat Materiality?

***U.S. ex rel. Berg v. Honeywell Intern., Inc.*, 740 Fed. Appx. 535 (9th Cir. 2018) *cert. denied*, 139 S. Ct. 1456 (2019)**

- Relators alleged that the contractor falsely promised the amount of energy savings that could be achieved in the contractor's Energy Savings Performance Contracts, and then falsely represented the actual amount of energy savings
- Court affirmed summary judgment for the contractor because (among other things) the relators could not show materiality
- The contractor had disclosed to the Army in its proposal the assumptions and calculations underlying its estimated savings
- The Army had paid the contractor's claims for at least 5 years during which time the Army was aware of the allegations and had conducted its own audit
- Court held that the relators therefore "failed to raise a triable issue as to the element of materiality on the '***demanding***' standard established in *Escobar*"

Relationship between Rule 9(b) and Materiality

***U.S. ex rel. Mateski v. Raytheon Co.*, 745 F. App'x 49 (9th Cir. 2018), *cert. denied sub nom. Mateski v. Raytheon Co.*, 139 S. Ct. 2039 (2019)**

- Relator alleged that the company engaged in a fraudulent scheme to cover up its alleged noncompliance with contractual testing specifications in a subcontract for developing satellite technology
- The court dismissed under Rule 9(b) because the relator failed to allege with particularity: which parts, which tests, whether the tests were never done, whether they were instead done incompletely, and the approximate test dates
  - Without these details, the defendant did not have enough information to defend against the claims, and so the complaint failed to meet Rule 9(b)'s particularity requirement
- For the same reasons, the complaint did not meet the materiality requirement
  - Noting that the *Escobar* materiality standard is "demanding," the court said it was unable to assess whether the noncompliance was material or minor because of the lack of particularity about the alleged violations

Recent Jurisprudence – The "Bundled Payment Defense"

***U.S. ex rel. Simpson v. Bayer Corp.*, 376 F. Supp. 3d 392 (D.N.J. 2019)**

- Relator, a former employee of Bayer, filed a *qui tam* suit in 2005 alleging that Bayer engaged in unlawful marketing, including off-label promotion and payment of kickbacks, to induce sales of its prescription drugs Trasylol and Avelox
- In its motion for partial summary judgment, Bayer argued that it could not be liable under the FCA for claims for surgeries during which Trasylol was administered because the Government pays the same price for a given procedure regardless of whether Trasylol is used
  - Therefore any alleged misrepresentation regarding Trasylol is not capable of influencing the government's decision to pay a claim
- The court denied Bayer's motion and rejected this "bundled payment defense"
- The court declined to certify the question for interlocutory appeal because Bayer failed to demonstrate that immediate appeal would materially advance the litigation's ultimate termination
  - The Trasylol-related FCA claims were only one set of claims within a larger lawsuit; even if Bayer prevailed on this issue, the Avelox-related FCA claims would remain

Recent Jurisprudence – *AseraCare* and FCA Falsity

***United States v. AseraCare, Inc. et al.*, 2019 WL 4251875 (11th Cir. 2019)**

- DOJ alleged that the defendant hospice facility operator had falsely certified the hospice eligibility of many of its Medicare patients, and obtained a jury verdict finding 123 false claims were submitted based principally on an outside expert's review of patient medical records and his own opinion as to whether patients were eligible
- The Eleventh Circuit affirmed the trial court's award of a new trial based on a failure to properly instruct the jury that the FCA requires proof of an "**objective falsehood**"
  - Held that a "clinical judgment of terminal illness warranting hospice benefits cannot be false . . . when there is only a reasonable disagreement between medical experts as to the accuracy of that conclusion, with no other evidence to prove the falsity of the assessment"
  - Recognized that contractor's local coverage determination criteria were only "eligibility guidelines" that were not binding
  - Explained that to show an "objective falsehood," a plaintiff alleging a patient was falsely certified for reimbursed care "must identify facts and circumstances surrounding the patient's certification that are inconsistent with the exercise of a physician's clinical judgment"

Recent Jurisprudence – Scienter

***U.S. ex rel. Skibo v. Greer Labs.*, No. 5:13-cv-110-MOC-DCK (W.D.N.C. Aug. 22, 2019)**

- Relator alleged that defendant, a compounder of custom mix allergy products, violated the FCA by causing claims for reimbursement of its custom mixes that were false because defendant did not separately license each product (as FDA had required under 2015 guidance)
- The court held that there was no genuine issue of fact as to material falsity
  - If FDA regulations required custom mixes to be separately licensed, they could not be lawfully reimbursed by the Government to the doctors who ordered the products from defendant
- However, no reasonable juror could find the requisite knowledge that custom mix products required separate licenses because defendant's conduct demonstrated good faith in interpreting an ambiguous rule
  - Defendant openly advertised its service and disclosed it to FDA during inspections and in various correspondence and submissions to FDA, but was not told separate licenses were necessary before the 2015 guidance
  - FDA's interpretation of regulations before 2015 were unclear, as demonstrated by extensive industry discussion prior to the guidance and the one-year time period needed by FDA to issue the 2015 guidance

Recent Jurisprudence – Rule 9(b)

***U.S. ex rel. Grant v. United Airlines Inc.*, 912 F.3d 190 (4th Cir. 2018)**

- United Airlines was a sub-sub-contractor providing engine maintenance services for military transport aircraft
- Relator, a former technician for United Airlines, alleged that the company: (1) certified uncompleted work as completed; (2) certified repairs performed by uncalibrated and uncertified tools, in violation of the subcontract's requirements; and (3) allowed inspectors to continue certifying repairs after their training and eye exams had expired
- Relator failed to meet Rule 9(b)'s particularity requirement because his complaint alleged a fraudulent scheme without detailing the billing and payment structure
  - Because the complaint alleged only an umbrella payment without describing the billing or payment structure (how the invoices were presented and paid), the complaint left open the possibility that no payments were ever made
  - Alleging a link between the false claims and government payment is especially necessary to meet Rule 9(b)'s requirements where, as in this case, the defendant is several levels removed from a claim to the Government because it is a sub-sub-contractor

DOJ Enforcement & Policy Updates

Government Players

Department of Justice

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

Contracting & Support Agencies

Contracting agencies and support agencies (such as DCAA) increasingly view contract disputes as false claims

Cooperation

Inspectors General

Department of Defense IG

General Services Administration IG

Contracting Agency IG

By the Numbers: 2018 Federal Fiscal Year

$2.9 billion

Civil Settlements and Judgments Under the FCA

767

New FCA Cases Filed

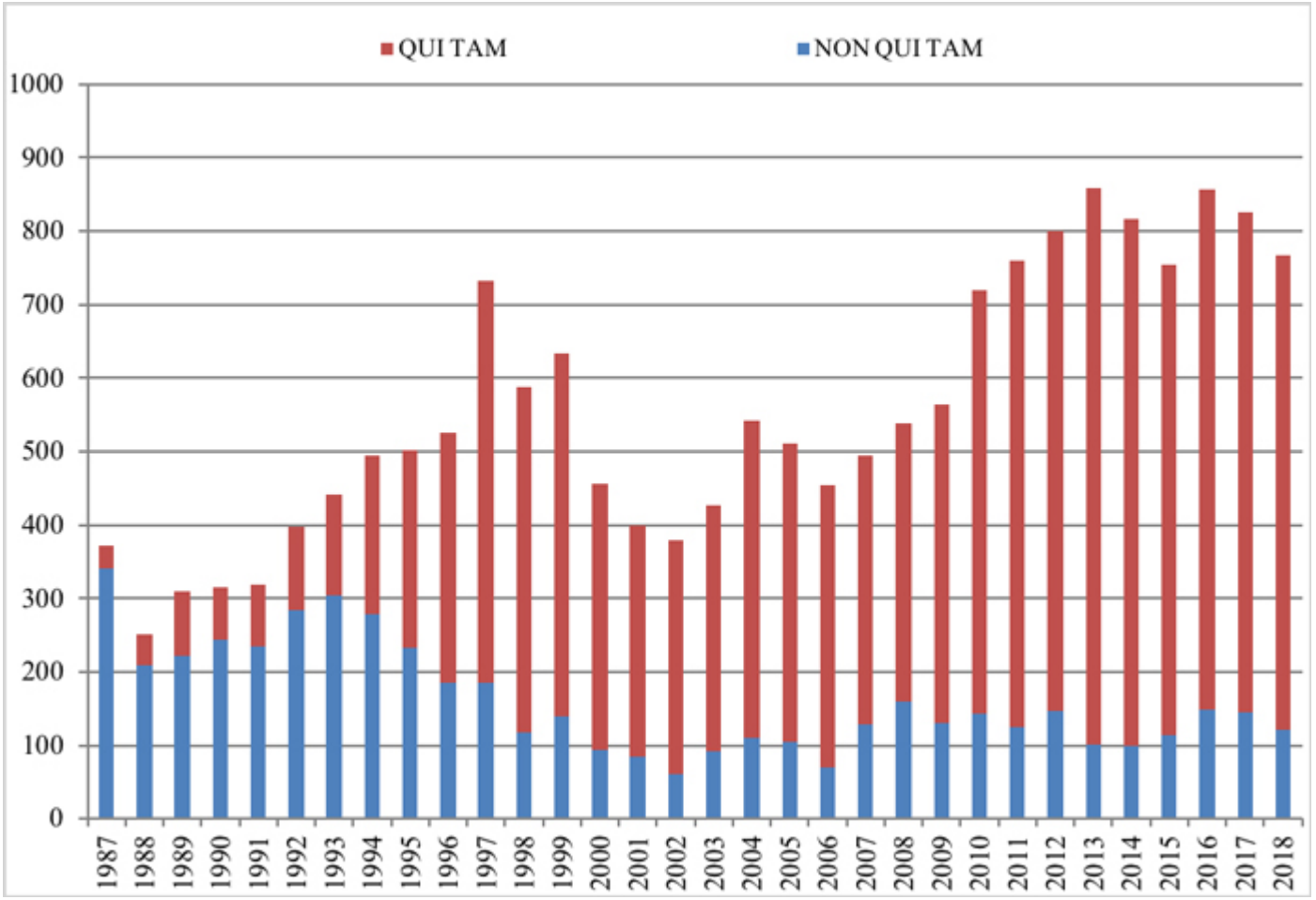
84 percent

Percentage of New FCA Cases Initiated by a Whistleblower

96 percent

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

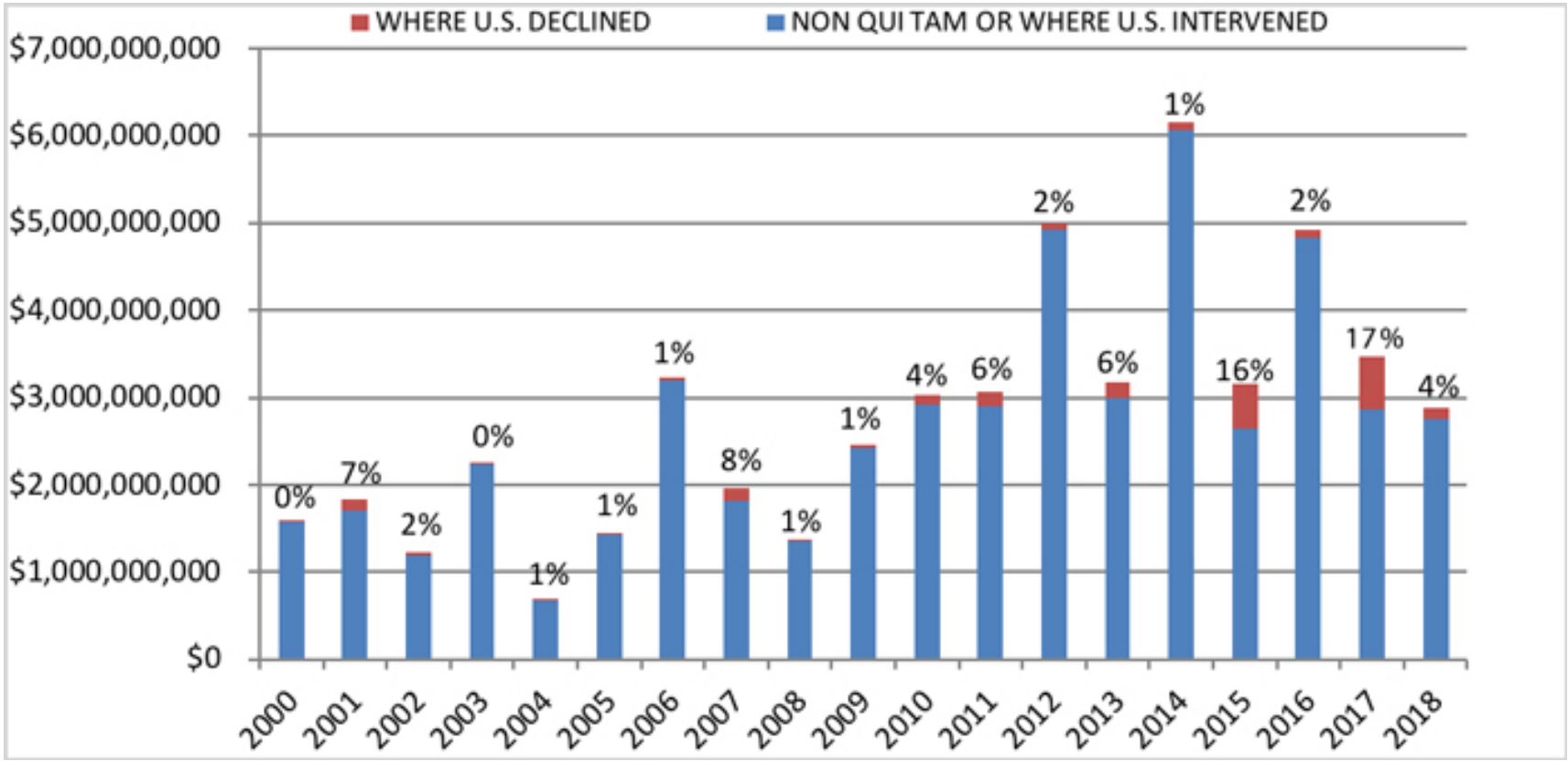
Number of New FCA Suits (1987-2018 Federal Fiscal Years)



767 new cases in 2018 FFY:

- 645 *qui tam* cases
- 122 non-*qui tam* cases

Declined Cases in FCA Settlements / Judgments (2000–2018 Federal Fiscal Years)



Source: DOJ "Fraud Statistics – Overview" (Dec. 21, 2018)

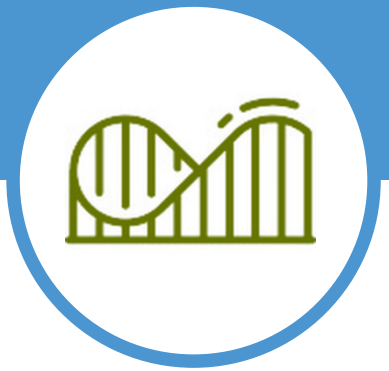
By the Numbers: Mid-Year 2019

>$750 million

FCA recoveries from ***settlements*** in the first half of 2019, according to Gibson Dunn calculations

>$139 million

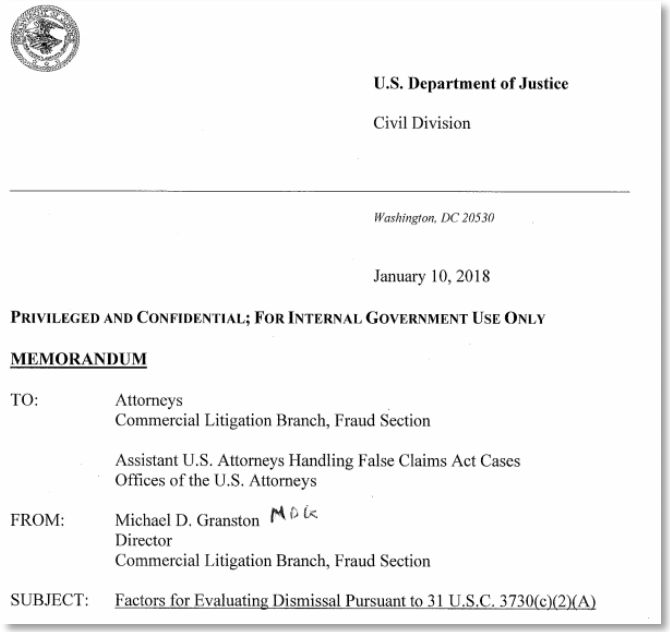
from ***settlements*** involving government contractors in the first half of 2019, according to Gibson Dunn calculations



2nd?

2019 on pace to match dip in 2018 as only year in the past 10 with ***below $3 billion*** in FCA recoveries

The Granston Memo (Jan. 10, 2018)



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)

- Addressed DOJ's use of its dismissal authority (31 U.S.C. § 3730(c)(2)(A))
- Responded to "record increases in *qui tam* actions" and acknowledging that its "rate of intervention has remained relatively static," and underscored that dismissal is "an important tool to advance the Government's interests, preserve limited resources, and avoid adverse precedent"
- Stated that DOJ attorneys should consider dismissal for:
  - Facially meritless or duplicative *qui tam* suits;
  - Cases that agencies view as interfering with policies / agency programs;
  - Suits that threaten DOJ's litigation positions;
  - Cases that might reveal classified information;
  - Low expected-value suits; and
  - Actions that frustrate the Government's investigative efforts
- Incorporated into Justice Manual at Section 4-4.111 in September 2018

Application of the Granston Memo (2019)

- In a March 2019 speech at the Federal Bar Association's FCA Conference, ***then-DOJ Civil Fraud Section Director Michael Granston*** explained DOJ's approach under the memo, stating "dismissal will remain the exception rather than the rule"
  - He expanded that the Government's cost-benefit analysis will focus on the likelihood that the relator can prove the allegations
  - DOJ will not dismiss *qui tam* actions based solely on prospective discovery obligations, so pursuing excessive discovery may not help get a case dismissed
  - But DOJ referenced discovery burden in a recent case urging the Supreme Court to deny certiorari, so that the case could be dismissed
- In remarks in January 2019 at the American Conference Institute's Advanced Forum on FCA Enforcement, ***Deputy Associate Attorney General Stephen Cox*** acknowledged DOJ's use of its dismissal authority has increased since 2017
  - Mr. Cox stated that while DOJ "will remain judicious," it "will use this tool more consistently to preserve our resources for cases that are in the United States' interests," noting DOJ plays "a gatekeeping role" in the "partnership" between *qui tam* relators and the Government

Application of the Granston Memo (2019) (cont.)

A circuit split remains on the standard for judicial review of DOJ use of its FCA dismissal authority, and the Granston Memo may bring to a head this circuit split:

- ***Sequoia* test**: The Government may dismiss if: (1) it identifies a valid government purpose; and (2) a rational relation exists between the dismissal and accomplishment of that purpose; unless (3) dismissal is fraudulent, arbitrary and capricious, or illegal. *U.S. ex rel. Sequoia Orange Co. v. Baird-Neece Packing Corp.*, 151 F.3d 1139, 1145 (9th Cir. 1998)

- ***Swift* test**: The Government has "an unfettered right to dismiss" FCA actions under 3730(c)(2)(A), and so dismissals are "unreviewable" with a possible exception for dismissals constituting "fraud on the court." *Swift v. United States*, 318 F.3d 250, 253 (D.C. Cir. 2003)

Application of The Granston Memo (2019) (cont.)

- Recent district court decisions considered Government motions to dismiss FCA lawsuits against pharmaceutical companies and marketing consultants alleging violations of the AKS related to patient assistance programs:
  - ***United States v. EMD Serono, Inc.*** (E.D. Pa. 2019): A district court judge, following *Sequoia*, agreed with DOJ that allegations lacked merit, and pursuing case would be too costly and contrary to the public interest, and dismissed the case
  - ***United States ex rel. CIMZNHCA, LLC v. UCB, Inc.*** (S.D. Ill. 2019): Following *Sequoia*, the court denied DOJ's motion to dismiss and ruled that the Government had not sufficiently investigated to move for dismissal
- District court judges in Minnesota, Mississippi, and Texas agreed with the *Swift* standard, but observed that the Government would still be entitled to dismissal even under *Sequoia*; in all three cases the court granted the Government's motion to dismiss

Apparent Shift in Yates Memo Policy on Cooperation and Individual Accountability

The Yates Memo

- Sent in September 2015 by former Deputy Attorney General Sally Yates
- Brought increased emphasis on the need to pursue individual prosecutions for those involved in corporate wrongdoing
- Also instituted a rigid cooperation credit policy that required corporations to "provide to the [DOJ] ***all*** relevant facts about the individuals involved in corporate misconduct," to be eligible for ***any*** cooperation credit, in both criminal and civil cases

DOJ Pulls Back from Yates Memo

- In November 2018, then-Deputy Attorney General Rod Rosenstein announced a set of policy changes to "restore" discretion to DOJ attorneys (i.e., cooperation credit was no longer "all or nothing")
- Explained that DOJ will give cooperation credit to companies that identify every individual who was "***substantially involved in or responsible for*** the criminal conduct" under investigation in white collar investigations
- Noted that DOJ attorneys also may "negotiate civil releases for individuals who do not warrant additional investigation in corporate civil settlement agreements"

Cooperation Credit Guidance (May 7, 2019)

- DOJ's formal policy identifying cooperation eligible for credit included in Justice Manual Section 4-4.112
- Guidance is the latest chapter in effort to scale back "all or nothing" approach to cooperation credit in 2015 Yates Memo and to describe the bases for cooperation credit
- Driven by belief that all or nothing approach had been counterproductive in civil cases because it deprived DOJ of the "flexibility" it needed "to accept settlements that remedy the harm and deter future violations"
- Guidance provides clarity regarding DOJ's overall approach and flexible standards provide opportunities for defendants to formulate creative negotiation and litigation strategies
- But the guidance lacks specificity regarding several critical issues (e.g., what constitutes cooperation and how to assess the value that cooperation provides to DOJ)

Cooperation Credit Guidance (cont.)

- Under the Guidance, defendants may receive varying levels of cooperation credit depending on their efforts in cooperation categories including:
  - "[i]dentifying individuals substantially involved in or responsible for the misconduct";
  - making individuals available who have "relevant information";
  - "[a]dmitting liability or accepting responsibility for the relevant conduct"; and
  - "[a]ssisting in the determination or recovery" of losses
- Guidance notes that cooperation must have value for DOJ, measured by:
  - "timeliness and voluntariness" of cooperation
  - "truthfulness, completeness, and reliability" of information provided
  - "nature and extent" of the cooperation
  - "significance and usefulness of the cooperation" to DOJ
- Full credit requires self-disclosure of all those involved in misconduct, full investigation cooperation, and remedial steps to prevent and detect similar wrongdoing
- Unlike criminal case cooperation guidance, no percentage reductions in penalties or damages; instead, DOJ may reduce the multiple sought

Proposed Stark Law and AKS Reforms

- On October 9, 2019, HHS announced proposed changes to the Stark Law and AKS intended to protect value-based arrangements and coordinated care
- Under the proposed rules, specialty physician practices could share patient information with primary-care physicians to manage care, or work with hospitals on discharges using data analytics
- The safe harbors would allow hospitals to pay physicians incentives as part of CMS-sponsored care models; care coordination activities to boost quality, outcomes or efficiency; and value-based care relationships with significant downside risk
  - Patient engagement and support arrangements are also covered by the proposed safe harbors, and could include using a home health aide to help patients with medication or medical devices
- However, the proposed new safe harbors **exclude** device manufacturers and pharmaceutical companies from participating:
  - "Pharmaceutical manufacturers, distributors, and suppliers of DMEPOS, and laboratories are not included in the proposed definition of 'VBE participant' in paragraph 1001.952(ee) for the reasons described earlier in this preamble."
  - CMS state this is still under consideration and seek comment on this definition

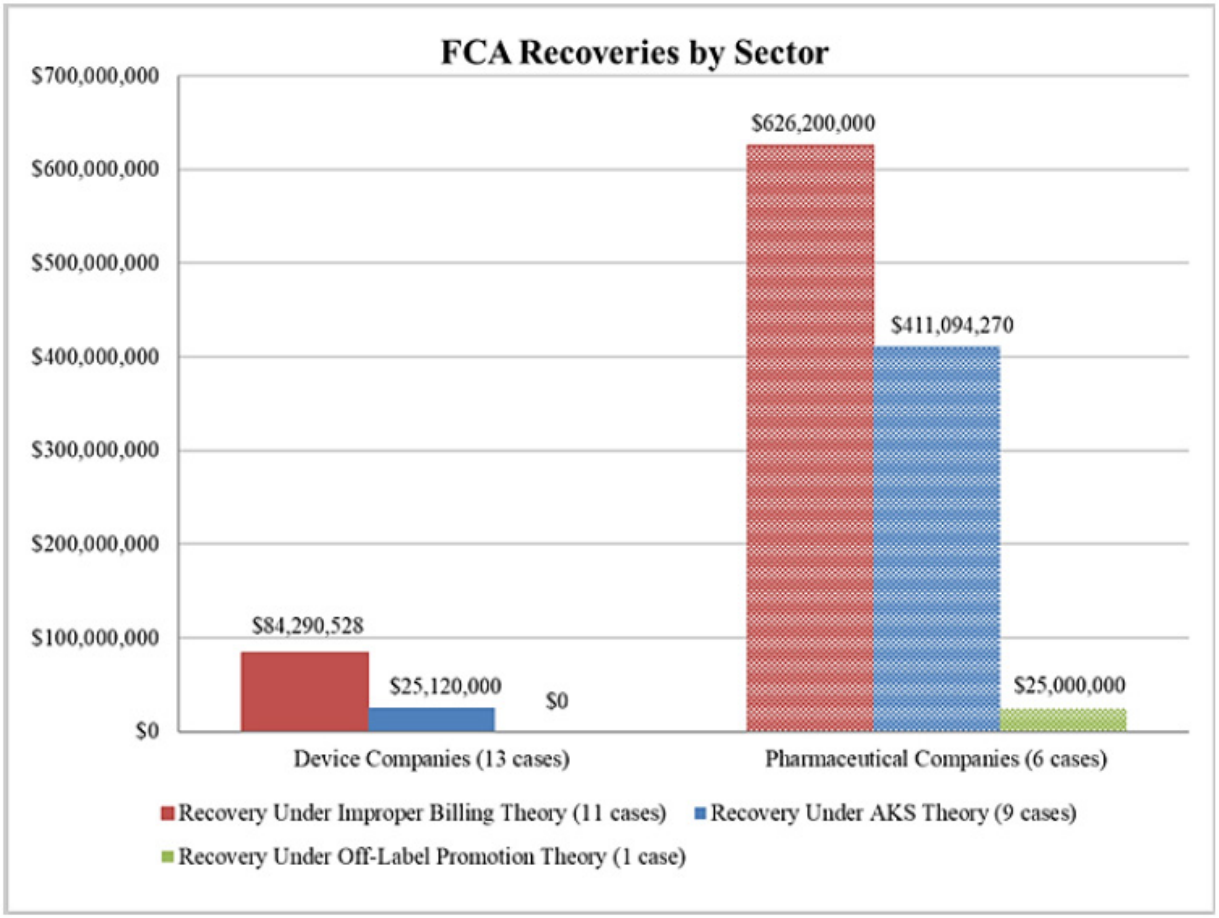
Recent FCA Enforcement: Drugs and Devices

Drugs and Devices – Key Legal Theories

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

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

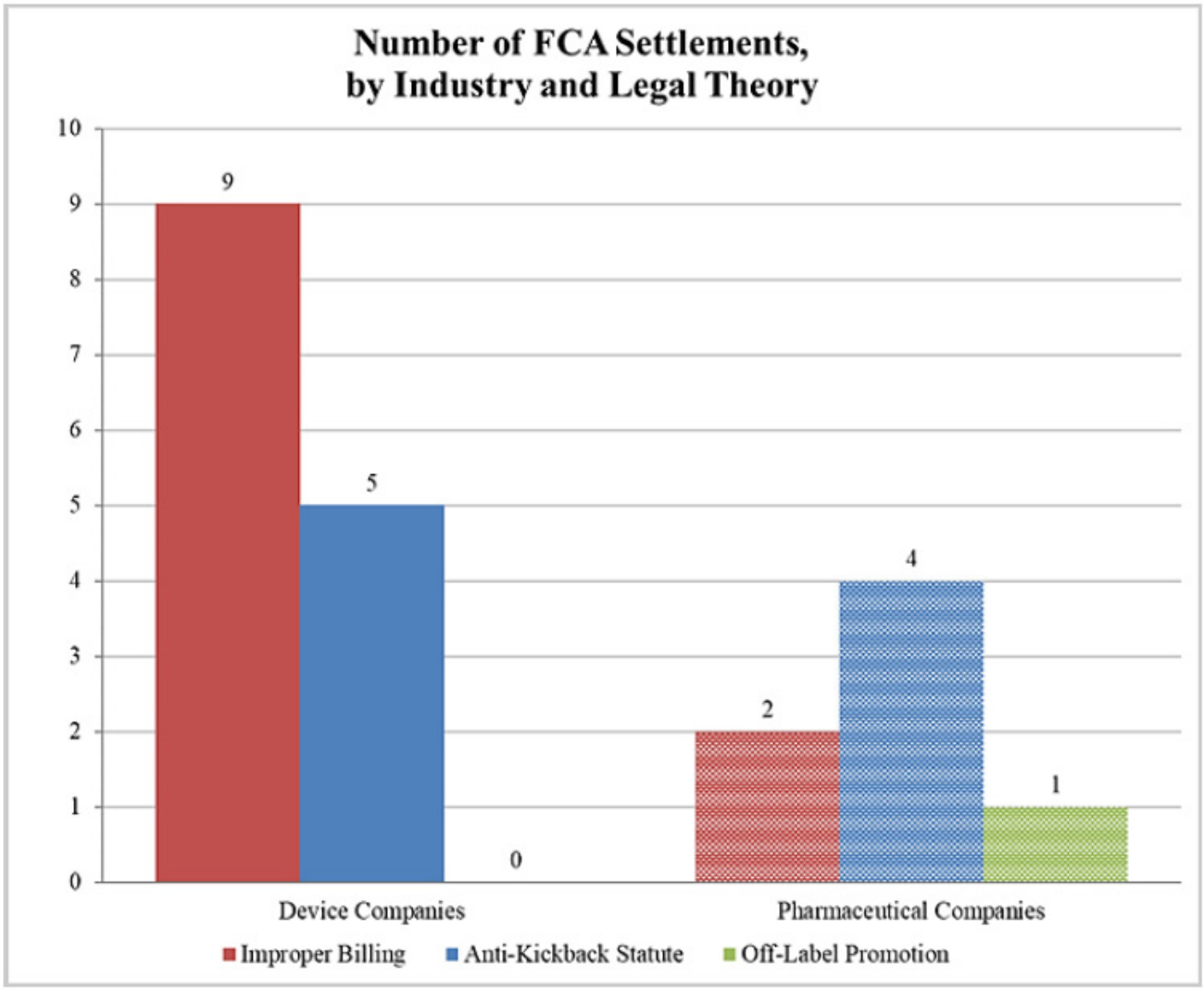
Drug and Device Companies – 2018 FCA Recoveries



Approx. **$1.1 billion** in recoveries from drug and device companies in 2018:

- Off-label: $25 million
- AKS: $436 million
- Price reporting and other allegations: $710 million

Drug and Device Companies – 2018 FCA Recoveries



Drug and Device – 2019 FCA Recoveries Year-to-Date

- Year-to-date, **$1.3 billion** made in civil recoveries from drug and device manufacturers
  - 12 cases – the majority of civil drug and device recoveries – relied on an AKS theory, accounting for $503.5 million of the YTD total
  - Other settled claims include marketing allegedly defective or unreliable products and marketing to induce medically unnecessary utilization by HCPs

FCA Enforcement Based on FDCA Violations: Instrumed and CareFusion

Instrumed – FCA Settlement

In September 2019, Avalign Technologies, Inc. and its subsidiary **Instrumed** International, Inc., agreed to pay **$9.5 million** to settle a civil fraud lawsuit under the FCA for **manufacturing and selling medical devices that were not cleared by the FDA**

- **Instrumed** acknowledged that it could **not** claim pre-amendments exemption status for the devices, which included surgical trocars, tongs, drills, tenaculums, clamps, curettes, and valvulotomes
- Instrumed and **CareFusion**, a customer and distributor of Instrumed devices exchanged correspondence regarding the evidence to support **pre-amendments status** that would permit marketing without FDA clearance/approval.
- Instrumed sold the devices **between 2007 and 2014**
- Some of the devices were used in procedures for which providers submitted claims for **reimbursement** to **federal health care programs**

Instrumed – FCA Settlement (cont.)

FDA remarks on FCA settlement:

"*U.S. patients rely on FDA oversight to ensure that medical devices are safe and effective. When companies fail to follow FDA rules, they put patients' health at risk. We will continue to investigate and bring to justice companies that attempt to evade FDA requirements and jeopardize the public health.*"

– Mark S. McCormack, Special Agent in Charge of FDA's Office of Criminal Investigations

Instrumed –FDA Enforcement History

Backdrop of FDA enforcement history:

- FDA Inspection and Form FDA 483 - July-Aug 2013
- FDA Warning Letter – March 2014
- Market Withdrawal and Recall – December 2014

Instrumed – FDA Enforcement History (cont.)

- **FDA Establishment Inspection** - July 29, 2013 to August 1, 2013:
  - FDA inspection of Instrumed's facilities resulted in **inspectional observations** (Form FDA 483)
- **FDA Warning Letter** - March 28, 2014:
  - Stated that **25 medical devices** lacked pre-amendments exemption status, 510(k) clearance, or premarket approval ("PMA") to permit marketing in United States
  - Identified **12 violations** of Quality Systems regulations relating to:
    - Failure to establish, maintain, and implement processes controls for design validation and verification, investigation of complaints, corrective and preventative actions ("CAPAs"), medical device reporting ("MDR"), and device labeling
  - Stated that Instrumed's devices were **adulterated** and **misbranded** in violation of the FDCA
- In May 2015, FDA rejected Instrumed's pre-amendments determination request

Instrumed – FDA Enforcement History (cont.)

Product Recalls – September 2014–November 2017:

- In September 2014, Instrumed **initiated 28 medical device recalls** due to lack of PMA or 510(k) clearance
- On October 9, 2014, Instrumed sent "urgent market withdrawal" letters to **all affected customers** instructing return of all recalled devices
- **21 of the 28 recalls** were of medical devices sold by **CareFusion**

Fallout for Distributor: CareFusion FCA Settlement

FCA liability of CareFusion as distributor of Instrumed's uncleared devices

- In May 2019, **CareFusion** agreed to pay **$3.3 million** to settle FCA claims arising from its sale of the Instrumed-manufactured devices
  - From 2007 to 2014, CareFusion "distributed medical devices for which the device manufacturer [Instrumed] had not obtained the required approvals or clearances from the FDA and for which the manufacturer could not demonstrate that the pre-amendments exception applied"
  - Instrumed's evidence that was provided to CareFusion to justify the devices' pre-amendments status was "insufficient"
  - Some of those devices were used in procedures for which providers submitted claims for reimbursement to federal health care programs
  - CareFusion ceased selling and distributing the devices in 2014 after Instrumed initiated the medical device recalls

Fallout for Distributor: CareFusion FCA Settlement (cont.)

FDA remarks on CareFusion's FCA Settlement

"*Americans rely on FDA oversight to ensure that their medical devices are safe and effective. When companies sell devices without proper authorization, they may be putting patients' health at risk. We will continue to investigate and bring to justice companies that attempt to subvert the regulatory functions of the FDA, which are intended to protect the public health. We commend the efforts of the Department of Justice for their vigorous pursuit of justice in this matter.*"

– Jeffrey E. Shuren, M.D., director of the Center for Devices and Radiological Health at FDA

Anti-Kickback Statute

AKS

- 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**
- 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))

Remuneration, Exceptions, and Safe Harbors

- **Remuneration** includes anything of value, such as:
  - Cash, gifts, hospitality
  - Advisory board and speaking engagement compensation
- **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*

AKS – DOJ Questions

- Focusing on potential relief in administrative and other costs to providers, several *qui tam* relators have classified **reimbursement and product support** as improper "remuneration"
  - *See, e.g., U.S. ex rel. Health Choice Group, LLC v. Bayer Corp.* (E.D. Tex.) (alleging remuneration in the form of "free nurse services" to patients and assistance to providers with benefit verifications and prior authorization forms)
- In litigating DOJ's motion to dismiss this *qui tam* suit, the relator shared that DOJ, in evaluating the relator's proof of misconduct, asked for evidence that:
  - Defendants have **quantified for a physician the financial gain he or she could realize** from the product support services
  - Prescribing physicians have **eliminated staff or reduced salaries** on account of receiving product support services
  - Product support was **withdrawn or denied due to declining or insufficient volumes of prescribing**
  - The offer of product support **skewed clinical judgment or resulted in overutilization**

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 **separate element** of AKS liability is the **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

AKS – Recent Jurisprudence

- Jurisprudence on the AKS continues to evolve as courts address whether the statute prohibits any provision of value, even when the relators could not show a *quid pro quo* relationship between remuneration and referrals

***United States ex rel. Charles Arnstein v. Teva Pharm. USA, Inc.*, No. 13 CIV. 3702 (CM), 2019 WL 1245656 (S.D.N.Y. Feb. 27, 2019)**

- The court addressed whether a pharmaceutical company's promotional speaker program, which allegedly offered speaker fees and expensive meals in exchange for prescribing certain products, constituted an illegal kickback scheme
- The court held that **a *quid pro quo* relationship between remuneration and referrals *is not* a requirement** under the AKS
- "Offering or paying a person 'remuneration,'" with the intent of inducing the person to recommend a drug, was sufficient to constitute an AKS violation, even if the attempt did not succeed in securing referrals

Recent Settlements

- ***Covidien*** (March 2019)
  - Manufacturer of vein ablation products agreed to pay nearly $17.5 million to resolve allegations that it violated the AKS (and thus the FCA) by providing remuneration to HCPs in the form of "lunch and learn" meetings and dinners, vein screening events, and market development support
- ***Jazz Pharmaceuticals, Lundbeck, and Alexion Pharmaceuticals*** (April 2019)
  - The drug manufacturers agreed to pay a total of $122.6 million to resolve allegations that they violated the FCA by making payments to charitable organizations that, according to the Government, amounted to illegal kickbacks because the funds were used to pay copays of Medicare and other government-funded health care beneficiaries using their drugs and were therefore inducements

Recent Settlements (cont.)

- ***Astellas Pharma*** (April 2019)
  - Astellas agreed to pay $100 million and entered into five-year CIA to settle allegations that it violated the AKS (and thus the FCA) by working with two foundations to offer copay assistance funds to Medicare beneficiaries to help them pay for a androgen receptor inhibitor to treat a specific type of prostrate cancer (when only Astellas sold such an inhibitor for that indication)
  - Astellas allegedly promoted these funds as an advantage over competing drugs during the time the funds were open

- ***US WorldMeds LLC*** (April 2019)
  - A Parkinson's Disease drug manufacturer agreed to pay $17.5 million to resolve claims that it used a third-party foundation to cover Medicare copays for its drug at the same time it substantially increased the price of the drug
  - The Government also alleged that US WorldMeds paid for health care providers' lavish meals, private plane rides, and all-expense-paid trips to encourage them to prescribe two of its drugs, in violation of the AKS

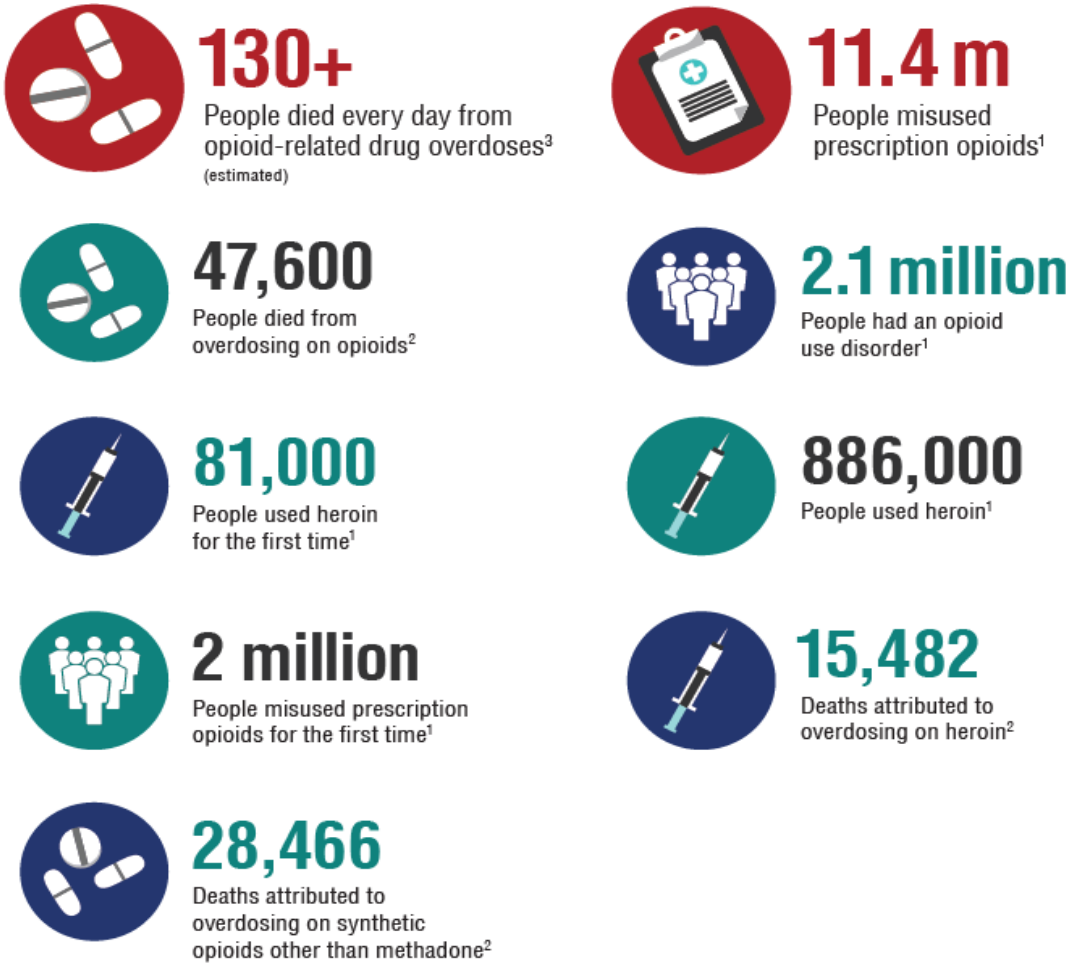
Recent Settlements (cont.)

- ***Mallinckrodt ARD LLC*** (September 2019)
  - The company paid $15.4 million to resolve allegations that it paid illegal kickbacks to doctors in the form of lavish dinners and entertainment to induce prescriptions of the company's drug, Acthar, from 2009 through 2013

- ***Avanir Pharmaceuticals*** (September 2019)
  - The pharmaceutical manufacturer was charged in a one-count criminal indictment for paying kickbacks to a physician to induce prescriptions of its drug, Nuedexta
  - The U.S. Attorney's Office for the Northern District of Ohio also announced indictments of four individuals, including former Avanir employees and one of the top prescribers of Nuedexta in the country, who were allegedly involved in the kickback scheme
  - Avanir also agreed to pay more than $95 million to resolve civil FCA allegations stemming from the alleged kickback scheme, as well purported off-label marketing of Nuedexta to providers in long-term care facilities to induce them to prescribe it for behaviors commonly associated with dementia (for which the drug is not approved)

The Opioid Epidemic

The Opioid Epidemic By The Numbers



Source: HHS https://www.hhs.gov/opioids/sites/default/files/2019-09/opioids-infographic.pdf

FDA Focus on Opioids

"The opioid crisis is one of the largest and most complex public health tragedies that our nation has ever faced. It remains the biggest public health crisis facing the FDA. . . . Sadly, the scope of the epidemic reflects many past mistakes and many parties who missed opportunities to stem the crisis, including the FDA. . . .

At the FDA, we've worked to learn from past mistakes, and we intend to make sure that we're acting forcefully enough to address new threats that could extend this crisis. . . . [G]iven the scope of this crisis, and its human toll, we've committed to act more quickly as we confront new risks. We've changed our approach and are taking a much more aggressive approach to regulatory action."

Former FDA Commissioner Scott Gottlieb, M.D.

Opioids – FDA Initiatives

Addressing the Opioid Drug Approval Process

- Issued a Draft Guidance, **"Opioid Analgesic Drugs: Considerations for Benefit-Risk Assessment Framework" (June 2019)** to describe the benefit-risk assessment for evaluating opioid new drug applications
  - Product risks relating to misuse, abuse, opioid use disorder, accidental exposure, and overdose, for both patients and others
  - Evidence supporting the proposed duration of use for each proposed indication
  - Whether the drug presents "any novel risks not typically associated with opioid analgesic drugs" and has "any characteristics that would mitigate the risks of overdose, abuse or the development of addiction"
- Held a public hearing on **standards for future opioid approvals and incentives for new therapeutics** to treat pain and addiction
- Held an advisory committee meeting to discuss **pediatric risks for OxyContin extended-release tablets and pediatric data** considerations for opioid analgesics
- **Rejected a citizen petition** calling for a moratorium on the approval of any new or reformulated opioid medications

Opioids – FDA Initiatives (cont.)

Strengthening safety controls

- Expanded the Opioid Risk Evaluation and Mitigation Strategy (REMS) to include immediate-release opioid analgesics intended for use in an outpatient setting and to cover information about pain management, safe use of opioids, and non-opioid alternatives
- Expanded the REMS for immediate-release fentanyl (TIRF), which is used to manage breakthrough pain, to require prescribers to document a patient's opioid tolerance with each prescription of TIRF for outpatient use, among other controls
- Required labeling to guide prescribers on gradual, individualized tapering off opioids
- Considering requirement for fixed-quantity blister packaging

Encouraging the development of alternatives

- Medication-assisted treatments (MATs)
- Issued guidance on modified-release opioid products
- Changed packaging of opioid-based anti-diarrheal medication (Imodium) to curb abuse
- Expanded the availability of naloxone to reduce opioid overdose deaths, including the approval of auto-injector and intranasal forms and the 1st generic version of naloxone nasal spray -- OTC availability may be next

Opioids – FDA Enforcement

"The illicit sale of opioids online is a particularly critical concern as the nature of the epidemic shifts from one where new addiction was primarily formed in the medical setting, to a crisis where more and more of the new exposure is through illicit drugs. These drugs are often purchased online and received through the mail." - Former FDA Commissioner Scott Gottlieb, M.D.

Illegal online sales of opioids

- Since September 2017, FDA has issued dozens of Warning Letters identifying more than 450 websites for the illegal marketing of opioids
- In October 2019, FDA and DEA issued joint Warning Letters (for the first time) to website operators for illegal online sales of opioids

"Issuing these warning letters is not only an effort to deter the availability of dangerous illegal opioids, but it is also a testament to the close cooperation between DEA and FDA. We will continue to attack organizations that facilitate the sale of dangerous drugs, putting profit over public safety."
- Acting DEA Administrator Uttam Dhillon

Opioids – FDA Enforcement (cont.)

Security of the drug supply chain and cGMP's for opioids

- In February 2019, FDA issued its first Warning Letter under the Drug Supply Chain Security Act (DSCSA) to McKesson Corp.
  - Under DSCSA, firms must respond to notifications that there was illegitimate product in the supply chain, quarantine and investigate suspect products, and maintain records of related investigations and the disposition of the product
- In July 2019, FDA issued Warning Letters to three repackers of opioid APIs for cGMP violations, e.g., cracked bottles of repackaged opioids, incomplete certificates of analysis about quality and sourcing

"Opioids that leave the legitimate supply chain could end up being sold illegally, or a patient who was appropriately prescribed these drugs to treat pain may not get the treatment they need or may unknowingly take a medication that's not meant for them. . . . The security of the supply chain, and continued implementation and enforcement of DSCSA, is an important tool in our efforts to ensure that the American public can have confidence in the products they receive, and that illegitimate opioid products do not find their way into the hands of patients."
- Former FDA Commissioner Scott Gottlieb

Opioids – FDA Enforcement (cont.)

False and misleading claims about treatments for opioid addiction or pain treatment alternatives

- In March 2019, FDA issued a Warning Letter to Nutra Pharma for marketing homeopathic products with claims about treating addiction and chronic pain, including pain associated with cancer and other serious conditions
- In 2018, FDA and FTC had issued joint Warning Letters to marketers and distributors of 12 opioid cessation products for claims about their ability to treat opioid addiction and withdrawal

"We've dedicated new resources to our enforcement work and I consider these activities the cornerstone of our consumer protection mission and one of our most significant institutional obligations. We're especially focused on those who would exploit Americans harmed by the opioid crisis with the false promise of products that can treat pain or addiction, but that offer no such benefit." - Former FDA Commissioner Scott Gottlieb

Opioids – DOJ

"As the opioid epidemic continues to destroy lives and communities, we can and must do better. . . . [T]he Department will not rest until those that peddle opioids for profits are held to account. . . . [I]f you behave like a drug dealer, we will find you and ensure that the American justice system treats you like the drug dealer you are."

"They've been operating as though nobody could see them for a long period of time. Now we have the data."

- Assistant Attorney General Brian A. Benczkowski

Opioids – DOJ

DOJ Use of Data Analytics in Opioid Enforcement

- DOJ aims to use state and federal prescription and medical billing data to identify patterns of overprescription of opioids
- Led by a data scientist with a PhD and staffed by veteran healthcare fraud prosecutors working in Washington and out in the field
- Pull and examine a data culled from Medicare, Medicaid, the Centers for Disease Control and Prevention, state pharmacy databases and other sources
- Agents use the data to proceed with traditional law-enforcement techniques such as undercover stings, search warrants and cultivating cooperating informants to further develop the case into one that can be brought before a judge and jury

> **"Here it is often straight up cash for prescriptions, no different than the exchange of money for drugs that takes place on the street every day."**
> **- Former Head of DOJ Fraud Section Sandra Moser**

Opioids – DOJ

Appalachian Regional Prescription Opioid (ARPO) Strike Force

- Criminal Division initiative which began its work in December 2018
- In April 2019, DOJ announced it was charging 60 defendants across 11 federal districts, including 31 doctors, seven pharmacists, eight nurse practitioners, and seven other licensed medical professionals, for their alleged participation in the illegal prescribing and distributing of opioids and other dangerous narcotics and for health care fraud schemes
    - 11 of the charged defendants convicted by guilty plea as of September 2019
- In September 2019, DOJ announced federal charges against 13 criminal defendants – 11 of whom are medical professionals – relating to the overprescription of controlled substances through "pill mill" networks across five Appalachian districts

Opioids – Insys Therapeutics, Inc.

Insys Therapeutics: agreed to pay **$225 million** to settle the Government's criminal and civil investigations relating to its promotion of Subsys

- DOJ alleged that the company **paid kickbacks** and engaged in other **unlawful marketing practices** to induce physicians and nurse practitioners to prescribe its opioid to patients, including:
  - Sham speaker programs,
  - Providing jobs to prescribers' relatives and friends, and
  - Paying for lavish meals and entertainment to induce health care providers to prescribe Subsys
- The resolution included:
  - $195 million to settle civil lawsuits stemming from whistleblower
  - A fine of $2 million and forfeiture of $28 million
- Insys also entered into an "unprecedented" five-year CIA and Conditional Exclusion Release

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