The False Claims Act – 2018 Mid-Year Update: Drug and Device Industries

August 22, 2018

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

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. She provides FDA regulatory and compliance counseling to life science and health care companies. Ms. Lee has particular experience advising clients on regulatory strategy and diligence assessments, risk management, and enforcement actions relating to medical devices, pharmaceuticals, foods, and cosmetics.

John Partridge is a partner in the Denver office. 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.

Agenda

- FCA Overview and Recent Jurisprudence
- DOJ Policy Developments
- Opioid-Related Enforcement
- Recent FCA Enforcement: Legal Theories
  - Off-Label Promotion
  - Anti-Kickback Statute (AKS)
- Questions

FCA Overview and Recent Jurisprudence

The False Claims Act (FCA)

- The FCA, 31 U.S.C. §§ 3729–3733, is the federal government's ***primary weapon to redress fraud*** against government agencies and programs
- The FCA provides for recovery of ***civil penalties and treble damages*** from any person who knowingly submits or causes the submission of false or fraudulent claims to the United States for money or property
- Under the FCA, the Attorney General, through DOJ attorneys, investigates and pursues FCA cases
- DOJ 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)	Knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government	"Reverse" False Claim
(G)	Conspires to violate a liability provision of the FCA	Conspiracy

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

Universal Health Services, Inc. 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"

FCA – The Continuing Impact of *Escobar*

- 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* Materiality – Government Knowledge

U.S. ex rel. Spay v. CVS Caremark Corp.,
875 F.3d 746 (3d Cir. 2017)

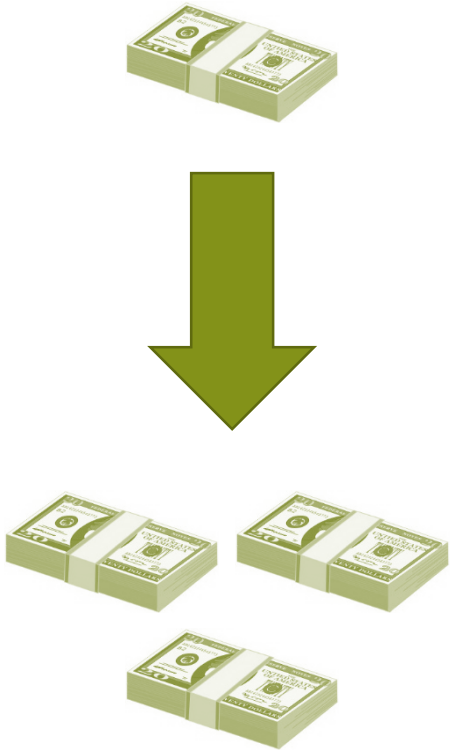
- The Third Circuit considered whether the general industry use of dummy prescriber information on authorized claims that "errored out" because of missing or incorrectly formatted prescriber information constituted material misstatements under *Escobar*
- The record established that ***government employees responsible for authorizing payments "knew that dummy identifiers were being used,"*** but the government nevertheless paid for the prescriptions
- Because the misstatements at issue actually "allowed patients to get their medication," the Third Circuit concluded that ***"they are precisely the type of 'minor or insubstantial' misstatements where '[m]ateriality . . . cannot be found'"***

FCA – Government Knowledge and Discovery

- *Escobar* has facilitated FCA defendants' arguments that they are entitled to ***discovery regarding the government's knowledge of allegedly improper practices***
- Thus, the government has found itself seeking to limit the scope of discovery requests
- In a recent brief, DOJ argued the following:
  - ***In response to the [Defendants'] first two sets of [document] requests, the United States has collected over seven million documents from the files of 143 custodians within components of the Department of Health and Human Services, which amount to five terabytes of electronic material.***
  - The government estimates that there are already over 675,000 documents that agency personnel and DOJ attorneys must review for privilege. . . .
  - The volume of documents collected to date represents a small percentage of the expected production, and underscores the ***inordinate volume of documents*** that will need to be collected due to the overbreadth of the Defendants' discovery requests, unless the Court intervenes.

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
  - 2018 inflation adjustment increased to range of $11,181 to $22,363 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***

Recent Jurisprudence – Statute of Limitations

United States ex rel. Hunt v. Cochise Consultancy Inc., 887 F.3d 1081 (11th Cir. 2018)

- An extended limitations period of up to ten years applies in select FCA cases. 31 U.S.C. § 3731(b)(2) (permitting actions for "3 years after the date when facts material to the right of action are known or reasonably should have been known by the official of the United States charged with responsibility to act in the circumstances")
- Circuits are split in deciding whether the up to ten-year period is only available when the government files or intervenes in the FCA suit, as opposed to *qui tam* actions where the government declines to intervene
- The Eleventh Circuit held that ***relators can employ the extended limitations period even in cases where the government has declined to intervene***—and that the courts must look to the government official's knowledge (not the relator's)

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
  - The January 2018 Granston Memo may result in more frequent use of this power
- ***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

"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)

Recent Jurisprudence – Rule 9(b)

U.S. ex rel. Ibanez v. Bristol-Myers Squibb Co.,
874 F.3d 905 (6th Cir. 2017)

- The district court dismissed employees' FCA suit alleging that pharmaceutical companies engaged in a nationwide scheme to promote an anti-psychotic drug for off-label uses and to improperly induce physicians to prescribe the drug
- The Sixth Circuit affirmed because ***relators failed to plead a specific, representative false claim submitted to the government***
- A complaint must "adequately allege the entire chain—from start to finish—to fairly show defendants cause[d] false claims to be filed," including any "specific intervening conduct" along the chain
- As the Sixth Circuit observed, the causal chain issue "***reveals just what an awkward vehicle the FCA is for punishing off-label promotion schemes***"

Recent Jurisprudence – Retaliation

DiFiore v. CSL Behring, LLC,
879 F.3d 71 (3d Cir. 2018)

- While Director of Marketing for the defendant, plaintiff allegedly became concerned about purported efforts to market drugs for off-label use
- Plaintiff alleged that as a result she suffered adverse employment actions and resigned shortly thereafter
- The district court ***instructed the jury that the FCA retaliation provision required that the protected activity be the "but for" cause of adverse actions***
- On appeal, plaintiff argued that the she only needed to prove that her protected activity was a "motivating factor" in the adverse actions
- Relying on Supreme Court decisions interpreting similar "because of" language in ADEA and Title VII, the ***Third Circuit held that an illegal motive must be the "but for" cause*** of the employer's adverse action

FCA – Public Disclosure and First-to-File Bars

- ***Public Disclosure Bar.*** A relator's *qui tam* complaint cannot be "***substantially the same***" as allegations or transactions ***publicly disclosed in certain enumerated sources*** such as public hearings, government audits or reports, or the news media

  - ***"Original source" exception:*** A relator may proceed on publicly disclosed allegations if he 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

- ***First-to-File Bar.*** The FCA provides that, when a *qui tam* action is ***"pending," "no person*** other than the Government ***may intervene or bring a related action based on the [same] facts"***

Recent Jurisprudence – First-to-File Bar

U.S. ex rel. Wood v. Allergan, Inc.,
No. 17-2191 (2d Cir. Aug. 9, 2018)

- Relator, a former Allergan sales representative alleged that the company provided free products to physicians in violation of the AKS and FCA
- Because two related suits had been filed before relator's suit (but remained under seal at that point), the district court and the circuit court addressed 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
- The Second Circuit sided with the D.C. Circuit and the Fourth Circuit, which had held that ***the first-to-file provision requires dismissal of the second-filed action***, and rejected relator's argument that amending the second-filed complaint cures the violation of the first-to-file provision

DOJ Policy Developments

Key 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 and private insurance fraud prevention acts

HHS OIG

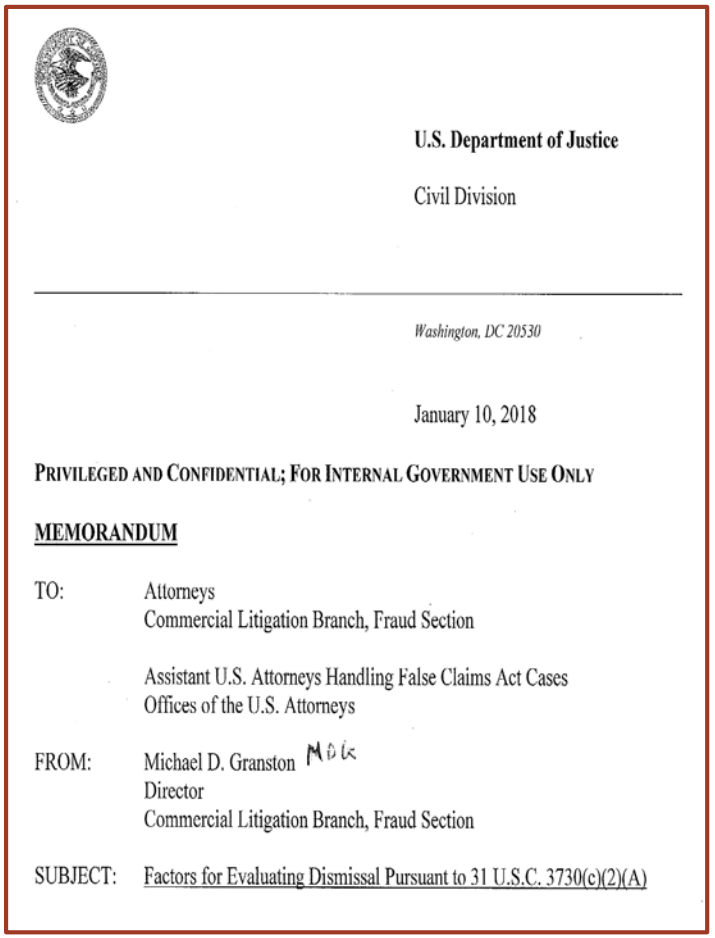
HHS OIG focuses on fraud and abuse implicating federal payors and wields exclusion authority

FDA

FDA polices the FDCA and regulations relating to, *inter alia*, promotional activity, manufacturing practices, and clinical trials

FCA – The Granston Memo (Jan. 10, 2018)

- This internal memo focuses on DOJ's use of its ***dismissal authority*** (31 U.S.C. § 3730(c)(2)(A))
- Responding to "record increases in *qui tam* actions" and acknowledging that its "rate of intervention has remained relatively static," DOJ underscored that ***dismissal is "an important tool to advance the government's interests, preserve limited resources, and avoid adverse precedent"***
- 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
  - Actions that frustrate the government's investigative efforts



U.S. Department of Justice

Civil Division

Washington, DC 20530

January 10, 2018

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MEMORANDUM

TO: Attorneys
Commercial Litigation Branch, Fraud Section

Assistant U.S. Attorneys Handling False Claims Act Cases
Offices of the U.S. Attorneys

FROM: Michael D. Granston MDG
Director
Commercial Litigation Branch, Fraud Section

SUBJECT: Factors for Evaluating Dismissal Pursuant to 31 U.S.C. 3730(c)(2)(A)

FCA – The Brand Memo (Jan. 25, 2018)

- Agencies commonly issue ***guidance documents interpreting legislation and regulations***, and the government has sometimes employed evidence that a defendant violated such guidance to prove a violation of the underlying statute or regulation.

- A January 25, 2018 DOJ internal memo ***prohibits DOJ from:***
  - (1) using noncompliance with other agencies' "guidance documents as a basis for proving violations of applicable law in" affirmative civil enforcement cases, and
  - (2) using "its enforcement authority to effectively convert agency guidance documents into binding rules."

Former Associate Attorney General Rachel Brand

FCA – The Brand Memo (cont.)

- Under the Brand Memo, DOJ will be more ***limited in its ability to wield guidance affirmatively***
  - AKS cases, in particular, have frequently involved reliance on non-binding guidance and recommendations (e.g., HHS OIG *Compliance Program Guidance for Pharmaceutical Manufacturers*)

- Guidance may still be relevant for other reasons:
  - DOJ may continue to use "***agency guidance documents for proper purposes***":
    - where a guidance document "simply explain[s] or paraphrase[s] legal mandates from existing statutes or regulations"; or
    - as "evidence that a party read such a guidance document to help prove that the party had requisite knowledge of the mandate"

- Nothing in the Brand Memo suggests that the government will be able to use this policy decision to limit a defendant's use of guidance documents ***to defend*** itself

FCA – Additional DOJ Policy Initiatives (2018)

- In a June 14, 2018 speech, ***Acting Associate Attorney General Jesse Panuccio*** described three additional DOJ policy initiatives to reform FCA enforcement:

Cooperation Credit	Whereas DOJ has delineated the benefits of cooperation in other investigations (e.g., antitrust, FCPA), less guidance has been available in the FCA space
Compliance Program Credit	DOJ will "reward companies that invest in strong compliance measures"
Efforts to Prevent "Piling On"	DOJ attorneys will promote coordination within the agency and with other regulatory bodies to ensure that defendants are subject to fair punishment and receive the benefit of finality that should accompany a settlement

Opioid Enforcement

Opioid Epidemic – High-Level Attention

THE WALL STREET JOURNAL.

POLITICS

Trump Calls On Justice Department to Sue Opioid Companies

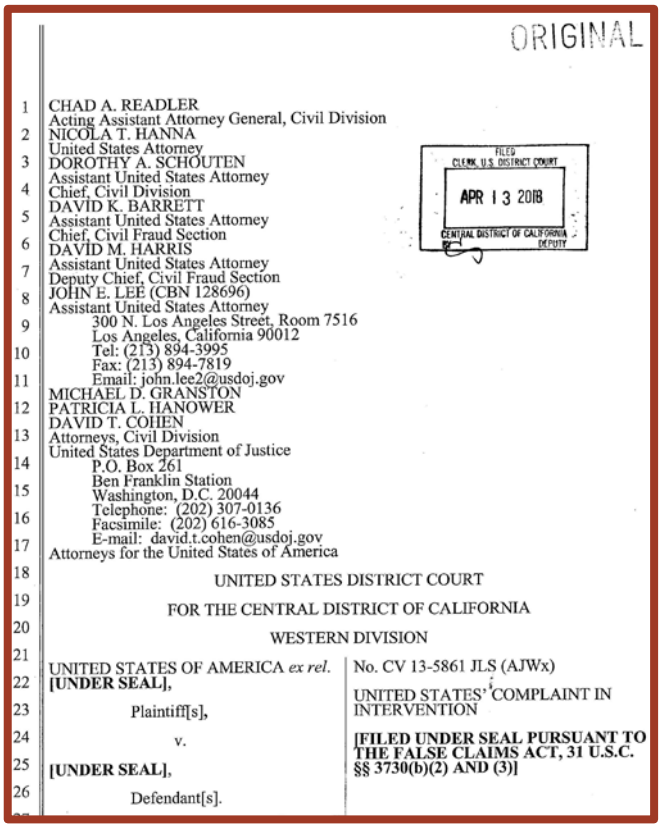
Trump asks Attorney General Jeff Sessions to bring federal lawsuit, separate from state and local litigation against drugmakers

Opioid Epidemic – DOJ Initiatives

- In August 2017, AG Sessions announced the formation of a pilot ***Opioid Fraud and Abuse Detection Unit***, armed with a data analytics team
- Earlier this year, DOJ announced the creation of the ***Prescription Interdiction & Litigation Task Force***, which will "deploy and coordinate all available criminal and civil law enforcement tools" "with a particular focus on opioid manufacturers and distributors"
- In accompanying remarks, Deputy Assistant Attorney General Stephen Cox stated that ***DOJ will employ the FCA as a weapon to address the opioid epidemic***
- In June 2018, DOJ announced "***the largest health care fraud takedown operation in American history***," involving charges against 601 people, including 76 doctors, 23 pharmacists, 19 nurses, and other medical personnel with more than $2 billion in medical fraud

Opioid Epidemic – Insys Therapeutics, Inc.

- In April 2018, ***DOJ intervened in 5 separate FCA suits against Insys Therapeutics***



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DEPUTY

UNITED STATES DISTRICT COURT

FOR THE CENTRAL DISTRICT OF CALIFORNIA

WESTERN DIVISION

UNITED STATES OF AMERICA *ex rel.* **[UNDER SEAL]**,

Plaintiff[s],

v.

[UNDER SEAL],

Defendant[s].

No. CV 13-5861 JLS (AJWx)

UNITED STATES' COMPLAINT IN INTERVENTION

[FILED UNDER SEAL PURSUANT TO THE FALSE CLAIMS ACT, 31 U.S.C. §§ 3730(b)(2) AND (3)]

2. Fentanyl is a powerful, but highly addictive, opioid painkiller. Defendant Insys Therapeutics, Inc. (Insys) is the manufacturer of Subsys, a sublingual spray form of fentanyl. In 2012, Subsys was approved by the Food and Drug Administration (FDA) for the treatment of persistent breakthrough pain in adult cancer patients who are already receiving, and tolerant to, around-the-clock opioid therapy.

3. Since 2012, Insys has knowingly offered and paid kickbacks to induce physicians and nurse practitioners to prescribe Subsys for their patients. Many of these kickbacks have taken the form of speaker program payments for speeches to physicians that were, in fact, shams. Insys has also hired prescribers' relatives and friends in order to induce prescriptions of Subsys. Insys has also provided prescribers with lavish meals and entertainment to induce them to prescribe Subsys.

4. Insys has knowingly caused Medicare and other federal health care programs to pay for Subsys for uses for which it was not covered. Insys has done this by (1) encouraging physicians to prescribe Subsys in situations where it was not medically reasonable and necessary based on patients' medical conditions (i.e., because a patient did not have cancer), and (2) by misrepresenting patients' medical diagnoses to Medicare Part D Plan Sponsors or Pharmacy Benefits Managers in order to obtain reimbursement for Subsys.

GIBSON DUNN

FCA Enforcement Developments

GIBSON DUNN

By the Numbers: 2017

$3.7 billion

Civil Settlements and Judgments Under the FCA

799

New FCA Cases Filed

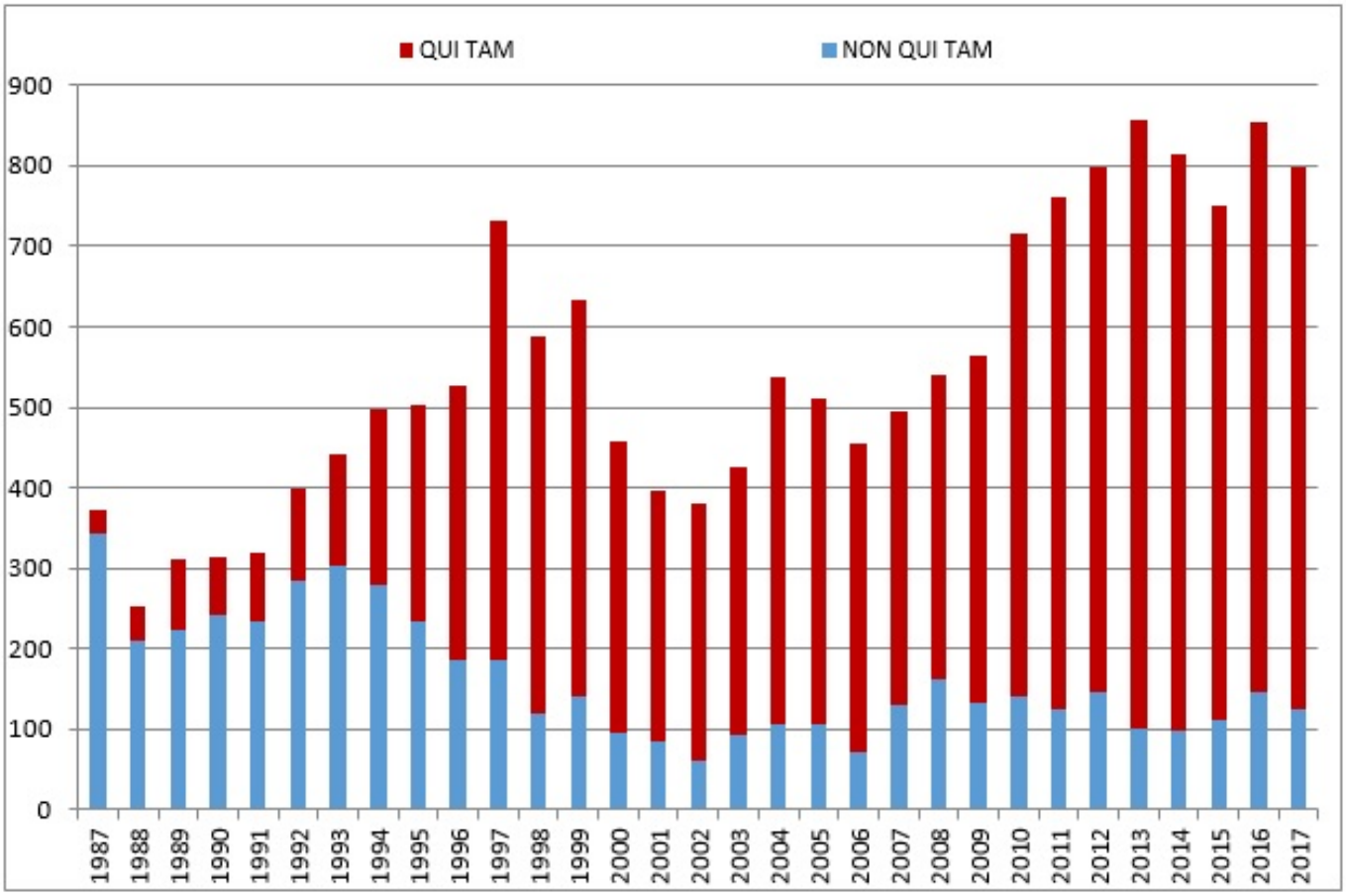
84 percent

Percentage of New FCA Cases Initiated by a Whistleblower

89 percent

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

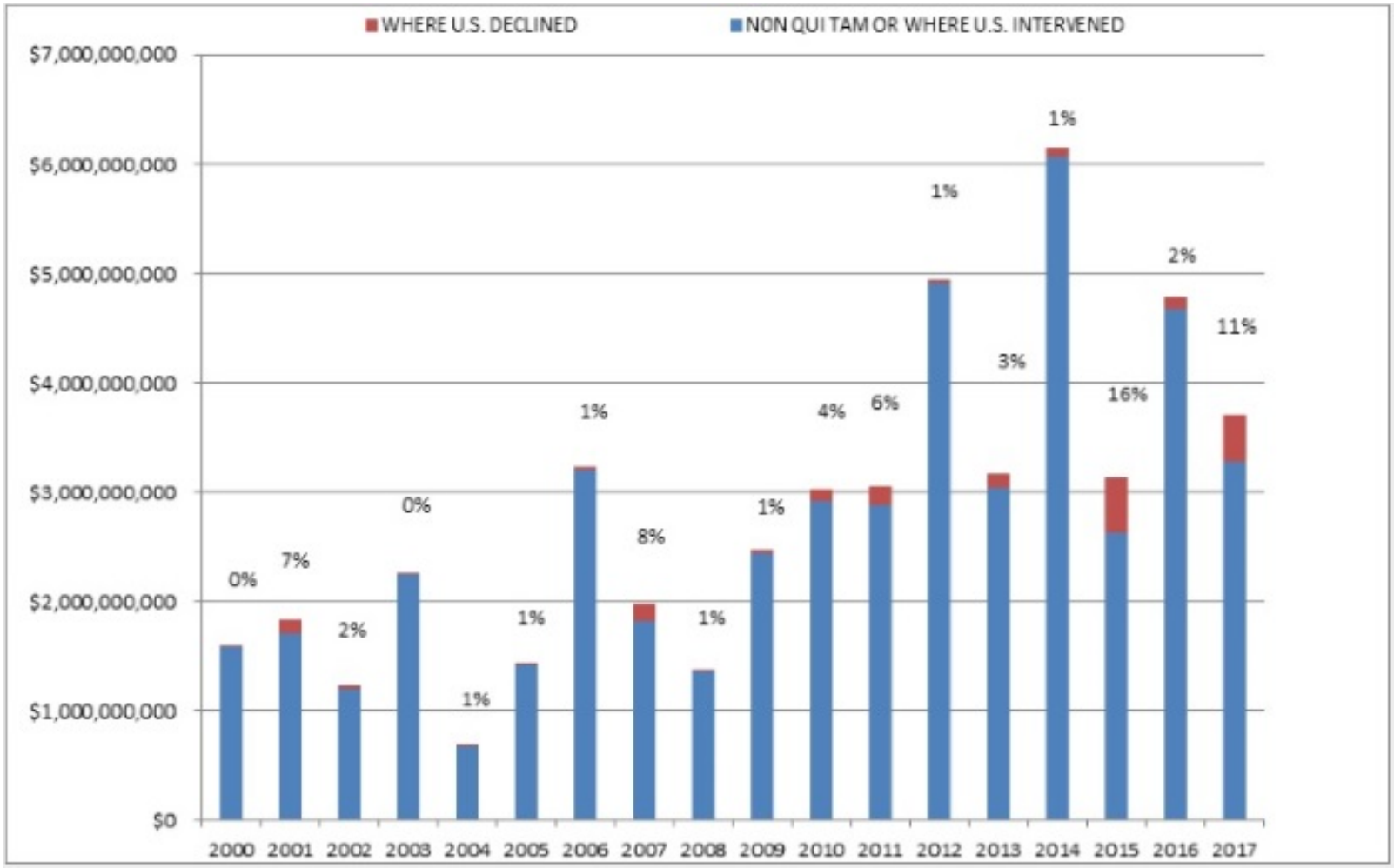
Number of New FCA Suits (1987-2017)



799 new cases in 2017 related to government health program funds:

- 674 *qui tam* cases
- 125 non-*qui tam* cases

Declined Cases in FCA Settlements / Judgments (2000–2017)



Source: DOJ "Fraud Statistics – Overview" (Dec. 21, 2017)

By the Numbers: Mid-Year 2018

>$600 million

FCA recoveries from ***settlements*** in the first half of 2018

$114 million

Judgments from FCA cases in the first half of 2018

9th?

After ***8 consecutive years exceeding $3 billion*** in FCA recoveries, the streak is in jeopardy this year

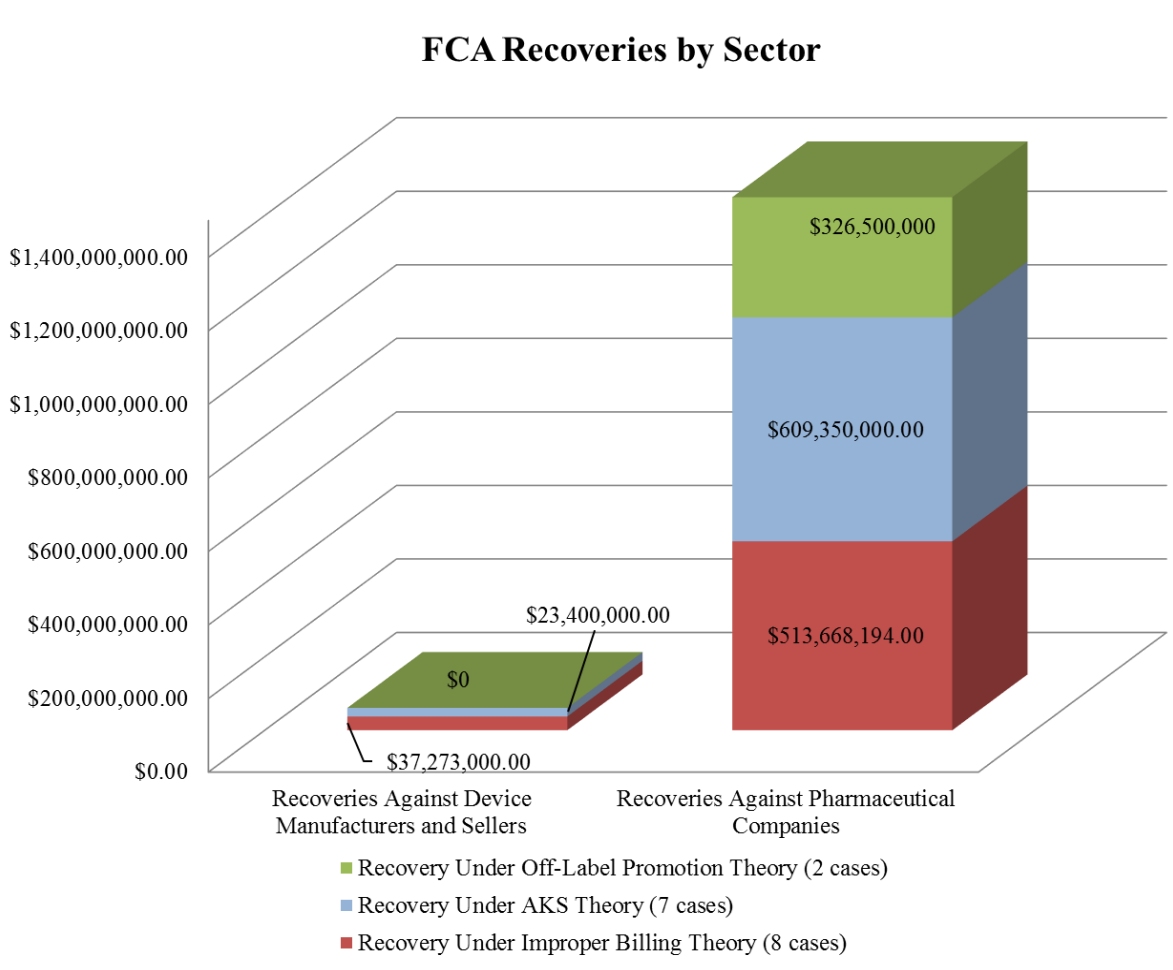
Recent FCA Enforcement: Drugs and Devices

Recent Case Law Developments – Key Legal Theories

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

1. ***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
2. ***Violations of the Federal Food, Drug, and Cosmetic Act (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
3. ***Anti-Kickback Statute (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
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

2017 FCA Recoveries – Drug and Device Companies



Approx. **$1.5 billion** in recoveries from drug and device companies in CY2017:

- AKS: $632.8 million
- Off-label: $326.5 million
- Price reporting and other allegations: $550.9 million

2018 FCA Recoveries to Date: Drug and Device

- **$93.5 million** in recoveries from drug and device manufacturers year-to-date:
  - AKS (3 cases): $28.9 million
  - Government health program requirements (5 cases): $64.6 million

Off-Label Promotion

Off-Label Promotion and the FCA

- Two potential ***theories of FCA liability*** have historically been asserted to support allegations based on promotional conduct:
  - ***Causing false provider claims:*** A company "causes" false claims by promoting a provider's off-label use of a drug that is not compensable by government programs
  - ***Implied certification:*** Misbranding violations under the FDCA are actionable based on a theory of implied false certification of compliance
- DOJ and relators also have argued that off-label promotion is a fraudulent course of conduct that makes resulting claims actionable under the FCA

Off-Label Promotion – FDA's Approach

- FDA recognizes that ***"off-label" use*** within the practice of medicine is legal and often standard of care
- ***Promotion of "off-label" use is not expressly prohibited by the FDCA***; however, FDA's longstanding view is that off-label promotion –
  - Constitutes false or misleading labeling
  - Creates a new unapproved product for which approval is required
  - Misbrands product by promoting a "new intended use" for which "adequate directions" are lacking
- ***Continuing tension with "scientific exchange"***
  - FDA does not intend to "restrict the full exchange of scientific information concerning the [investigational] drug, including dissemination of scientific findings in scientific or lay media" (21 C.F.R. § 312.7)

FDA: Focus on False and Misleading Speech

- "***Promotional material*** that drug makers share with patients and providers ***can be a helpful tool*** for encouraging patients to seek medical care and raising awareness about new and different treatment options."
- However, a key aspect of FDA's oversight lies in combatting "claims in prescription drug promotion that have the ***potential to deceive or mislead*** consumers and healthcare professionals."
- Recognized the need for "***clear rules*** for how sponsors can present certain information, even elements as straightforward as the product name, and do so without introducing features that could mislead patients."

- FDA Commissioner Scott Gottlieb (December 2017)

Recent FDA Guidance Documents (June 2018)

- ***Medical Product Communications That Are Consistent with the FDA-Required Labeling***
  - Recognizes that FDA-required labeling is limited in content and scope
  - Focuses on whether the communication is "consistent" with FDA-required labeling
    - Examples: Information about the effects or use of a product in specific patient subgroups that are included in its approved patient population; patient compliance/adherence; onset of action

- ***Drug and Device Manufacturer Communications with Payors, Formulary Committees, and Similar Entities***
  - For approved indications: Addresses "Health Care Economic Information" (HCEI) that "relates to" an approved indication and is based on "Competent and Reliable Scientific Evidence" (CARSE)
  - For unapproved products or uses: Addresses discussion of anticipated FDA review timeline, product pricing, patient support programs and utilization projections, and other information

Novo Nordisk

- In September 2017, Novo Nordisk agreed to pay $58M to settle FCA claims based on off-label theories and FD&C Act misbranding claims relating to the promotion of the diabetes drug Victoza
- Government focused on communications relating to the Risk Evaluation and Mitigation Strategy (REMS) for the drug
- Government alleged that the firm downplayed the risks associated with the drug and information in the REMS
- Government alleged that the firm suggested there were no new safety concerns, but the REMS modification provided "new safety information"

Case Study: AngioDynamics, Inc.

AngioDynamics

- In July 2018, AngioDynamics agreed to pay $12.5M to resolve allegations that the company caused providers to submit false claims to federal healthcare programs relating to two medical devices – LC Bead and Perforator Vein Ablation Kit (PVAK)
- AngioDynamics served as U.S. distributor for LC Bead, which was manufactured by Biocompatibles
- In 2016, Biocompatibles pled guilty to misbranding LC Bead ($11M in criminal fine and forfeiture) and paid $25M to resolve FCA allegations relating to use of LC Bead as a chemotherapy drug-delivery device

Case Study: AngioDynamics, Inc. (cont.)

Regulatory History—LC Bead

- 510(k) clearance: Embolization of hypervascular tumors and arteriovenous malformations
- Use at issue: Chemotherapy drug-delivery device
- FDA's view: Drug-delivery use was not covered under 510(k) and PMA approval may be required
- According to the government, firm assured FDA that they would not market LC Bead for use as a chemotherapy drug-delivery device without seeking additional approval/clearance
- FDA rejected applications to market LC Bead as a chemotherapy drug-delivery device

Case Study: AngioDynamics, Inc. (cont.)

Allegations—LC Bead

- Allegedly promoted LC Bead as "superior," "safer," and "less toxic" than alternative treatments, despite lacking substantiating data
- Allegedly trained personnel that product was a "drug-delivery device" and "specifically designed for chemoembolization"
- Allegedly instructed providers to use inaccurate billing codes to obtain reimbursement because company was aware that insurers were denying coverage

Case Study: AngioDynamics, Inc. (cont.)

Regulatory History—PVAK Vein Device

- AngioDynamics paid $1 million of the $12.5 million settlement to resolve claims related to PVAK
- 510(k) clearance: Treatment of superficial vein reflux of the greater saphenous vein associated with varicosities and treatment of incompetence and reflux of superficial veins in the lower extremity
- FDA allegedly informed the firm that use of the kit on perforator veins would be a new indication for use
- Firm voluntarily recalled product and allegedly informed customers that use of PVAK on perforator veins was not within the 510(k) clearance
- Firm sold PVAK under new name, 400 Micron Kit

Case Study: AngioDynamics, Inc. (cont.)

Allegations—Vein Device

- Allegedly continued to market the product as a "perforator kit" and telling providers that the product was eligible for Medicare reimbursement when used for that purpose
- Allegation that a majority of procedures performed with the 400 micron kit were perforator vein ablations, with a portion resulting in submission of healthcare claims to federal payers

Recent Jurisprudence – Off-Label Promotion

U.S. ex rel. King v. Solvay Pharmaceuticals, Inc.,
871 F.3d 318 (5th Cir. 2017)

- Relators, former sales and marketing employees, alleged that Solvay engaged in off-label marketing and improper promotion of three drugs
- Despite supposed evidence that the company discussed off-label drug uses with physicians and sponsored off-label use studies, the court found there was insufficient evidence to show that the company's actions caused the submission of any false claims
- The Fifth Circuit also was dubious that mere allegations of off-label promotion would satisfy *Escobar*'s materiality standard
- Because "Medicaid pays for claims without asking whether the drugs were prescribed for off-label uses or asking for what purposes the drugs were prescribed[,]" the Fifth Circuit reasoned that "it is unlikely that prescribing off-label is material to Medicaid's payment decisions under the FCA"

Anti-Kickback Statute

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).

AKS – Key Points

- ***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*

AKS – 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

AKS – DOJ and Patient Assistance Programs

- In recent years, pharmaceutical companies' relationships with ***charitable organizations*** have come under scrutiny for potential AKS-based FCA violations
- These USAO investigations have led to ***multiple resolutions***, including:
  - Pfizer (2018) (May 2018) ($23.8M)
  - United Therapeutics (Dec. 2017) ($210M)
- In the first half of 2018, Jazz Pharmaceuticals and H. Lundbeck A/S disclosed resolutions in principle with DOJ involving settlements of more than $50M

AKS – HHS OIG on Patient Assistance Programs

- ***2005 Special Advisory Bulletin ("SAB"):*** HHS OIG stated that the way for companies to support patients with "few, if any [AKS] concerns" was through "cash donations to independent, *bona fide* charitable assistance programs"
- ***2014 SAB:*** HHS OIG reiterated the importance of independence of charities and cautioned that limitations on drug choice specified by a patient assistance charity increases the likelihood that such assistance will be viewed as improper
- ***November 2017 Rescinded Advisory Opinion:*** Citing patient steering risks, HHS OIG rescinded a favorable advisory opinion initially authored in 2006 regarding AKS liability for Caring Voice Coalition's charitable drug subsidy program

AKS and PAPs – Factors Raising Potential Government Concern

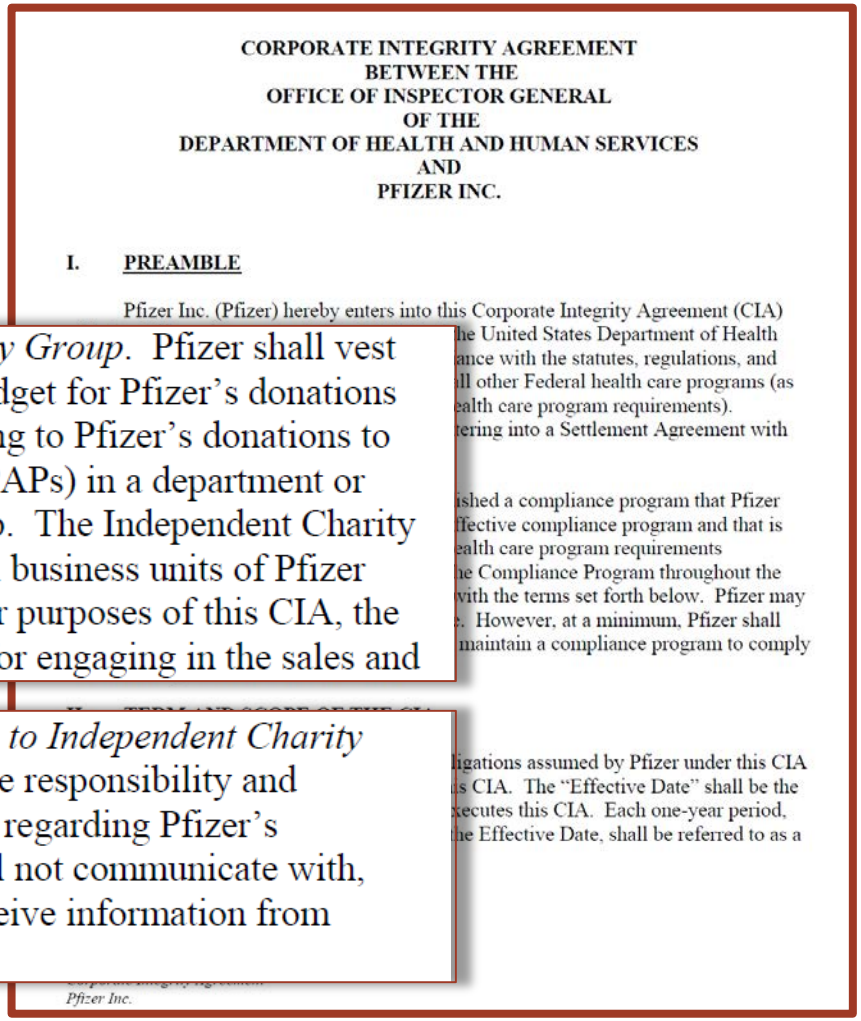
- **Disease Definitions** – where the charity allows the donors to directly or indirectly influence the identification of its disease categories.
  - Arrangements that "artificially define their disease categories so narrowly that the earmarking effectively results in the subsidization of one (or a very few) of donors' particular products" may implicate the AKS.

- **Data** – where the charity provides disaggregated or patient-specific data to manufacturer or donor.

- **Product** – special considerations where the manufacturer donates product to the charity or patient eligibility is defined with reference to the cost of a particular drug.
  - OIG warned that in-kind donations "have the effect of creating a direct correlation between the donation and use of a particular donor's product."
  - Relatedly, "a disease fund that covers only a single product, or the products made or marketed by only a single manufacturer that is a major donor to the fund, will be subject to scrutiny."

AKS – Patient Assistance Programs – CIAs

- Recent CIAs stemming from patient assistance program-related FCA resolutions provide some guidance on ***compliance controls to mitigate risk***



CORPORATE INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
PFIZER INC.

I. PREAMBLE

Pfizer Inc. (Pfizer) hereby enters into this Corporate Integrity Agreement (CIA)
he United States Department of Health
ance with the statutes, regulations, and
ll other Federal health care programs (as
ealth care program requirements).
tering into a Settlement Agreement with

ished a compliance program that Pfizer
ffective compliance program and that is
ealth care program requirements
e Compliance Program throughout the
vith the terms set forth below. Pfizer may
. However, at a minimum, Pfizer shall
maintain a compliance program to comply

ligations assumed by Pfizer under this CIA
s CIA. The "Effective Date" shall be the
xecutes this CIA. Each one-year period,
he Effective Date, shall be referred to as a

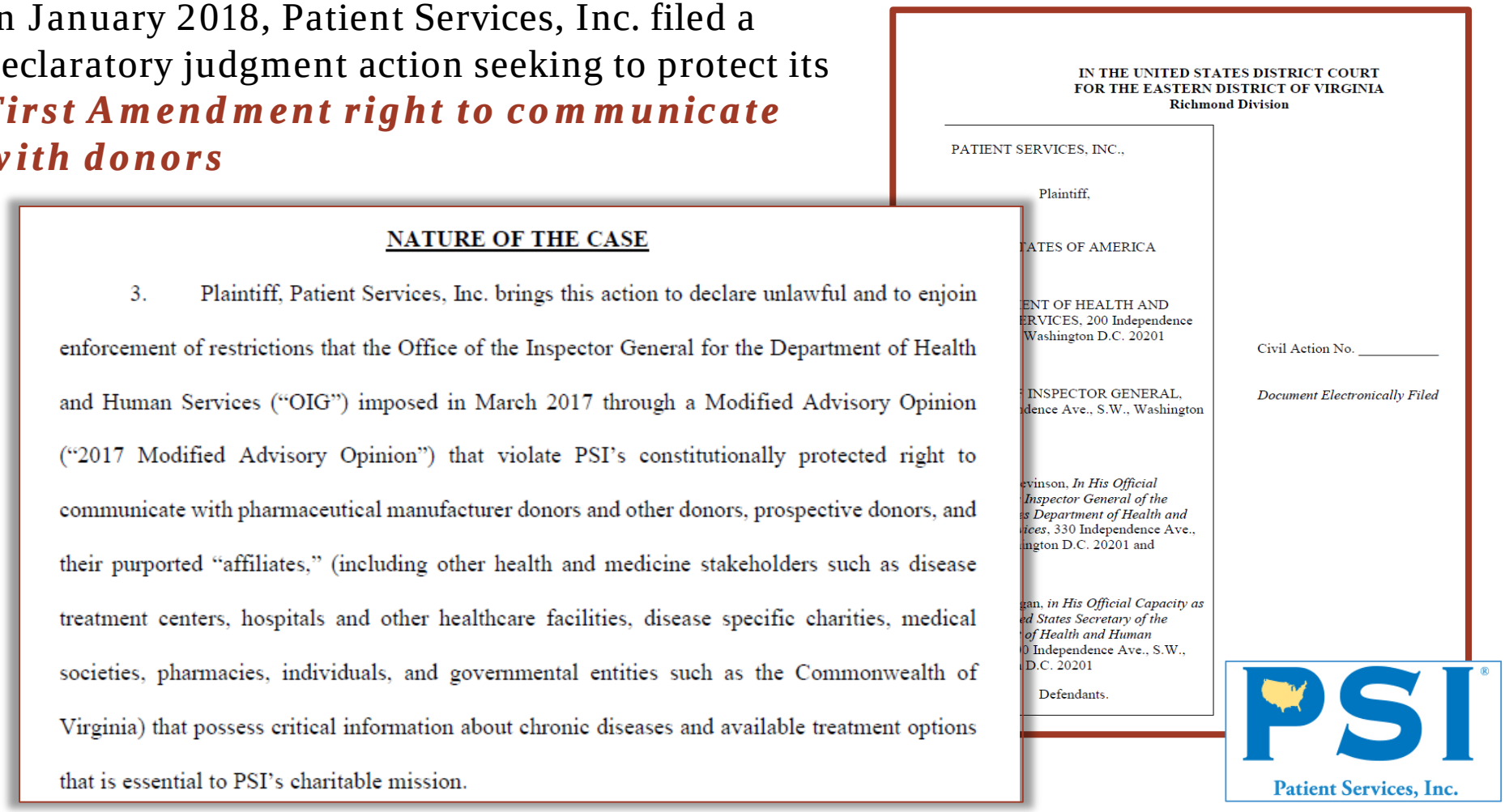
Pfizer Inc.

1. Role and Responsibilities of Independent Charity Group. Pfizer shall vest sole responsibility and authority for developing the annual budget for Pfizer's donations to Independent Charity PAPs and for all other activities relating to Pfizer's donations to Independent Charity PAPs (including interactions with such PAPs) in a department or group within Pfizer known as the "Independent Charity Group. The Independent Charity Group shall be separate and independent from the commercial business units of Pfizer (referred to hereafter as the "commercial business units"). For purposes of this CIA, the commercial business units are the business units responsible for engaging in the sales and

2. Communications Regarding Pfizer's Donations to Independent Charity PAPs. Pfizer shall vest in the Independent Charity Group sole responsibility and authority for communicating with Independent Charity PAPs regarding Pfizer's donations to such PAPs. The commercial business units shall not communicate with, influence, or be involved in any communications with, or receive information from Independent Charity PAPs.

AKS – Patient Assistance Programs – First Amendment

- In January 2018, Patient Services, Inc. filed a declaratory judgment action seeking to protect its ***First Amendment right to communicate with donors***



IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA
Richmond Division

PATIENT SERVICES, INC.,

Plaintiff,

TATES OF AMERICA

ENT OF HEALTH AND
ERVICES, 200 Independence
Washington D.C. 20201

INSPECTOR GENERAL,
dence Ave., S.W., Washington

evinson, *In His Official*
Inspector General of the
s Department of Health and
ices, 330 Independence Ave.,
ington D.C. 20201 and

gan, *in His Official Capacity as*
ed States Secretary of the
of Health and Human
0 Independence Ave., S.W.,
D.C. 20201

Defendants.

Civil Action No. _____

Document Electronically Filed

NATURE OF THE CASE

3. Plaintiff, Patient Services, Inc. brings this action to declare unlawful and to enjoin enforcement of restrictions that the Office of the Inspector General for the Department of Health and Human Services ("OIG") imposed in March 2017 through a Modified Advisory Opinion ("2017 Modified Advisory Opinion") that violate PSI's constitutionally protected right to communicate with pharmaceutical manufacturer donors and other donors, prospective donors, and their purported "affiliates," (including other health and medicine stakeholders such as disease treatment centers, hospitals and other healthcare facilities, disease specific charities, medical societies, pharmacies, individuals, and governmental entities such as the Commonwealth of Virginia) that possess critical information about chronic diseases and available treatment options that is essential to PSI's charitable mission.

PSI®
Patient Services, Inc.

Recent Jurisprudence – AKS and "Tainted" Claims

- ***U.S. ex rel. Greenfield v. Medco Health Solutions, Inc.***, 880 F.3d 89 (3d Cir. 2018)
  - Relator, a former Area VP for a specialty pharmacy (Accredo) alleged that the company made donations to hemophilia charities that then recommended the company to hemophilia patients; according to relator, this violated the AKS and FCA
  - The district court granted Accredo's SJ motion because relator did not show that the charities' referrals "resulted from" the donations
  - DOJ filed a brief on appeal arguing that the district court erred in requiring relator to show that patients chose the company because of the charities' recommendations

Recent Jurisprudence – AKS and "Tainted" Claims (cont.)

- ***U.S. ex rel. Greenfield v. Medco Health Solutions, Inc.***, 880 F.3d 89 (3d Cir. 2018)
  - The Third Circuit affirmed, holding that ***relator must show, at a minimum, that at least one patient for whom the company submitted reimbursement claims was exposed to a referral from a charity that received a donation***
  - The court stated that it would be "too exacting" to "require a relator to prove that federal beneficiaries would not have used the relevant services absent the alleged kickback scheme"
  - "***A kickback does not morph into a false claim unless a particular patient is exposed to an illegal recommendation or referral and a provider submits a claim for reimbursement pertaining to that patient***"

Recent Jurisprudence – AKS and "Tainted" Claims (cont.)

- ***U.S. ex rel. King v. Solvay Pharmaceuticals, Inc.***, 871 F.3d 318 (5th Cir. 2017)
  - Relators, former sales and marketing employees, alleged that Solvay engaged in off-label marketing and improper promotion of three drugs in violation of, *inter alia*, the AKS and the FCA
  - The Fifth Circuit affirmed summary judgment in favor of Solvay
    - Relators offered ***no credible evidence that payments to physician-consultants caused those physicians to write prescriptions that were reimbursed by Medicaid***
    - Rather, the evidence showed that ***physicians participated in Solvay speaker programs and were compensated for consulting or presenting***

Recent Jurisprudence – AKS and "Tainted" Claims (cont.)

- ***U.S. ex rel. King v. Solvay Pharmaceuticals, Inc.***, 871 F.3d 318 (5th Cir. 2017)
  - "There was ***nothing illegal about paying physicians for their participation in these types of [marketing] programs and there is no evidence that participation was conditioned upon prescribing Solvay's drugs to Medicaid patients***"
  - Acknowledging that Solvay likely "intended these programs to boost prescriptions[,]" the Fifth Circuit nonetheless concluded that "it would be speculation to infer that compensation for professional services legally rendered actually caused the physicians to prescribe Solvay's drugs to Medicaid patients"

Recent Jurisprudence – AKS and "Scienter"

- ***United States v. Nerey***, 877 F.3d 956 (11th Cir. 2017)
  - Defendant, a provider of services to patients at home health agencies, was convicted of conspiracy to defraud the United States and paying and accepting kickbacks in violation of the AKS
  - The Eleventh Circuit reaffirmed that "willful conduct" under the AKS requires strong evidence of scienter, i.e., that an act was "***committed voluntarily and purposely, with the specific intent to do something the law forbids, that is with a bad purpose, either to disobey or disregard the law***"

Recent Jurisprudence – AKS and "Scienter" (cont.)

- ***United States v. Nerey***, 877 F.3d 956 (11th Cir. 2017)
  - The court held that ***the government sufficiently demonstrated willful conduct in light of its evidence that the defendant attempted to hide illegal kickbacks***
  - The "overwhelming" evidence included proof that the defendant:
    - explicitly sought cash payments to avoid a paper trail,
    - attempted to hide kickbacks by masking them as therapy services,
    - referred to kickbacks by code names, concocted a fallback story in the event of an audit, and
    - was caught stating that it would be nice to "break [a suspected confidential informant's] head"

GIBSON DUNN

Questions?

GIBSON DUNN

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