The False Claims Act – 2020 Update: Drug and Device Industries

October 22, 2020

Panelists

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John Partridge is a Co-Chair of Gibson Dunn's FDA & Health Care Practice. He represents corporate and individual clients facing government investigations and associated litigation. He has particular experience defending pharmaceutical, medical device, and dietary supplement companies in investigations and litigation involving the federal Anti-Kickback Statute, the FCA, the FCPA and related state and federal laws.

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 CLE@gibsondunn.com

Agenda

1	**FCA / AKS Overview and Recent Jurisprudence**
2	**Enforcement Trends and Developments**
3	**Hot Topics for Drug and Device Companies**
4	**FCA / AKS Compliance Best Practices**
5	**Questions**

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FCA / AKS Overview and Recent Jurisprudence

The False Claims Act (FCA)

- The FCA, 31 U.S.C. §§ 3729–3733, is the federal government's **primary weapon to redress fraud** against government agencies and programs
- The FCA provides for recovery of **civil penalties and treble damages** from any person who knowingly submits or causes the submission of false or fraudulent claims to the United States for money or property
- Under the FCA, the Attorney General, through DOJ attorneys, investigates and pursues FCA cases
- DOJ devotes substantial resources to pursuing FCA cases—and to considering whether *qui tam* cases merit parallel criminal investigations

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

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

The Anti-Kickback Statute (AKS)

- The AKS, 42 U.S.C. § 1320a-7b(b), criminalizes
  - Knowing and willful
  - Payment, offer, solicitation, or receipt of remuneration
  - To induce patient referrals, reward a referral source, or generate business
  - Involving any item or service payable by federal health care programs
- The AKS covers those who **provide (or offer) remuneration** and those who **receive (or solicit) remuneration**
- Since the Affordable Care Act, a "claim that includes items or services **resulting from**" a violation of the AKS is a false claim for purposes of the FCA (42 U.S.C. § 1320a-7b(g))

Post-*Escobar* Materiality – Government Knowledge

***United States ex rel. Janssen v. Lawrence Mem. Hosp.*, 949 F.3d 533 (10th Cir. 2020)**

- The case concerned alleged certifications to Medicare regarding patient arrival times, and the district court granted summary judgment to defendants on materiality
- The Tenth Circuit affirmed, finding it significant that CMS's third-party investigative service had investigated relator's allegations after she raised them via CMS's hotline prior to filing suit—and that CMS did "nothing in response and continue[d] to pay [defendant's] Medicare claims"
- "Although CMS may not have independently verified [defendant's] noncompliance—and thus may not have obtained 'actual knowledge' of the alleged infractions—**its inaction in the face of detailed allegations from a former employee suggests immateriality**"

Post-*Escobar* Scienter

United States ex rel. Complin v. North Carolina Baptist Hosp., 818 F. App'x 179 (4th Cir. 2020)

- The court rejected relator's argument that scienter could be "inferr[ed] from the alleged regulatory violation itself . . . because **the FCA does not punish 'honest mistakes or incorrect claims submitted through negligence'**"
- The court emphasized the **ambiguity of the regulation at issue** in the case, including the open question of whether the rule "even . . . applies in the first place to the transactions in question"
- In the course of its analysis, the court cited favorably to FCA case law applying the Safeco rule that reckless disregard cannot exist where the alleged fraud "turns on a **disputed interpretive** question" and the defendant has not been "**warned away**" from its interpretation

Recent Jurisprudence – Scienter

***United States ex rel. Silva v. VCI Marketing, LLC*,**
361 F. Supp. 3d 1245 (M.D. Fla. 2019)

- The government alleged that a pharmacy and its owner engaged in a kickback scheme to defraud TRICARE by paying commissions to marketers and sales representatives in exchange for prescriptions sold and filled through that pharmacy, and that the president of the pharmacy negotiated a commission agreement
  - The individual defendant moved to dismiss on the grounds that he did not submit the claims himself and did not knowingly submit a false claim because he consulted with attorneys to draft agreements that would not violate federal law
- The court allowed the case to proceed, holding that a party "can be held liable under the FCA if he **caused the submission of false claims even if he did not submit the claims himself**"
- The court also rejected the argument that the government failed to plead scienter because the "United States has clearly alleged that Smith knew that paying commissions per prescription to marketers regarding government-funded claims was illegal because of **his research into anti-kickback statutes and his experience in the health care industry**"

Recent Jurisprudence – Scienter

United States ex rel. Strunck v. Mallinkrodt Ard LLC, No. 12-175 (E.D. Pa. Jan. 22, 2020)

- The government alleged that the defendant raised the price of a drug (from $50 per vial to over $30,000 per vial) and then worked with a nonprofit to establish a copay assistance fund limited to copays for the drug and to those with private insurance
  - The government asserted that the company indirectly paid remuneration to patients in the form of copay subsidies, that defendant marketed the drug as free to doctors and patients regardless of its actual high price, and that defendant created the copay assistance program specifically for patients with government insurance and excluded Medicare patients from its free drug program
- The court denied defendant's motion to dismiss, holding that the government had sufficiently alleged facts to plead a violation of the AKS (and the FCA)
- The court also held that the government included sufficient facts that defendant knew the scheme was illegal because defendant had **training programs that reflected an understanding of the AKS** and a **reimbursement manager emailed articles regarding the illegality of copay subsidies for Medicare Part D patients to the Commercial VP during the relevant time period**

Recent Jurisprudence – Remuneration

United States ex rel. Purcell v. Gilead Scis., Inc., No. 17-3523 (E.D. Pa. Feb. 13, 2020)

- *Qui tam* relator alleged that defendant provided health care providers with thousands of dollars in speaker payments, travel, and other remuneration to induce them to prescribe Gilead's Hepatitis B Virus drugs
- Sales directors alleged that speaker programs "offered excessive cumulative payments to healthcare providers to participate in 'sham' speaker programs and advisory board meetings offering little education value" and that the sales and marketing teams "**selected paid invitees based on data about prescription volume and habits**"
- The court acknowledged that industry speaker programs may provide educational benefits, but that the sales directors pleaded facts "questioning the legitimacy of the speaker programs"

United States ex rel. Hartnett v. Physicians Choice Lab. Servs., No. 3:17-CV-00037 (W.D.N.C. Feb. 5, 2020)

- The government alleged that diagnostic laboratory grew its business by (1) **providing medical diagnostic equipment to physicians**; (2) paying a co-defendant to send referrals to the laboratory from the two physician practices he managed; and (3) **inducing referrals through loans to two physicians**
- The court denied defendants' motion to dismiss, holding that the allegations "plainly provide[d the defendant] with enough detailed information on the alleged wrongful conduct to allow him to defend against the allegations"
- The court also reasoned that it was "readily apparent that this case is neither frivolous nor an improper fishing expedition in search of facts to support a speculative claim"

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/she is an "original source" of the allegations, meaning he/she either:
    - voluntarily disclosed them to the government prior to the public disclosure; or
    - voluntarily disclosed them to the government 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 was jurisdictional and contained 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**"
- The first-to-file and public disclosure bars do not apply to DOJ

Recent Jurisprudence – Public Disclosure Bar

United States ex rel. Banigan v. PharMerica, Inc.,

950 F.3d 134 (1st Cir. 2020)

- Applying the pre-2010 version of the public disclosure bar, the First Circuit held that, for purposes of the original source exception, a relator's "independent knowledge" need not be based on actual participation in or observation of the alleged conduct; rather, the relator need only have **direct and independent knowledge "of the information on which the allegations are based"**
- The court held **the fact that the relator learned about the alleged conduct from other people did not disqualify him as an original source**
  - Relator was "a corporate insider" who learned of the underlying conduct during his employment, and via communications with the primary participants in the conduct and "documents . . . that he obtained through his own investigative efforts"
  - There was no "intervening agency, instrumentality, or influence" between the sources of relator's knowledge and the knowledge itself

Recent Jurisprudence – Public Disclosure Bar

***United States ex rel. Holloway v. Heartland Hospice, Inc.*,**

960 F.3d 836 (6th Cir. 2020)

- The Sixth Circuit held that **a qui tam relator is the government's "agent" for purposes of the prong of the public disclosure bar requiring disclosure in a federal proceeding** in which the government or its agent is a party

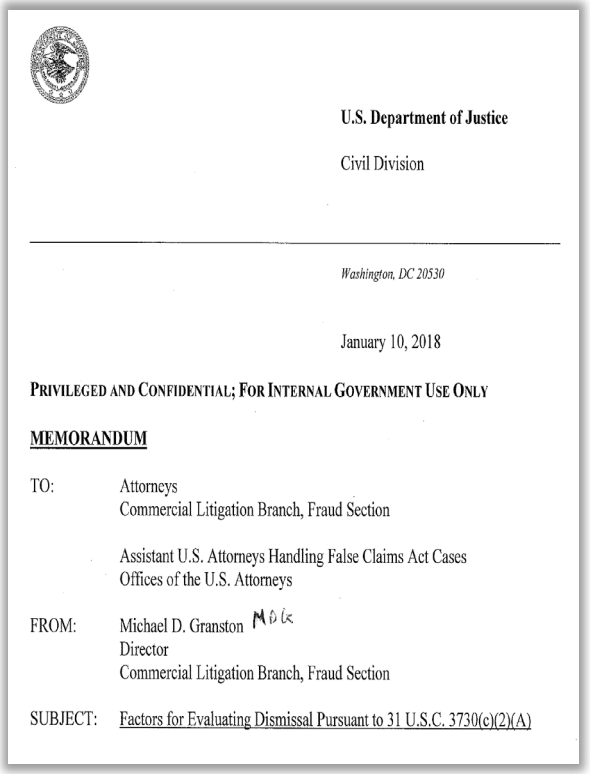
Recent Jurisprudence – First-to-File Bar

***In re Plavix Marketing, Sales Practice & Prods. Liability Litig. (No. II)*, --- F.3d ---, 2020 WL 5200681 (3d Cir. Sept. 1, 2020)**

- Deepening a Circuit split, the Third Circuit joined the First, Second, and D.C. Circuits 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
- In contrast, the Fourth, Fifth, Ninth, and Tenth Circuits have held that the bar is jurisdictional
- 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

FCA – DOJ Dismissal Authority

- Recent DOJ focus on use of its **dismissal authority** (31 U.S.C. § 3730(c)(2)(A))
- Principles in Granston Memo incorporated into DOJ Justice Manual at Section 4-4.111 in September 2018
- DOJ attorneys should **consider dismissal** for:
  - Facially meritless or duplicative qui tam suits
  - Cases seen as interfering with agency policy/programs
  - Suits that threaten DOJ's litigation positions
  - Cases that might reveal classified information
  - Low expected-value suits
  - Actions that frustrate investigative efforts
- Courts divided over which standard applies – the *Swift* (deferential) standard or the *Sequoia Orange* (less deferential)



U.S. Department of Justice

Civil Division

Washington, DC 20530

January 10, 2018

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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 – DOJ Dismissal Authority

United States v. UCB, Inc., 970 F.3d 835 (7th Cir. 2020)

- The Seventh Circuit called the choice between the *Sequoia Orange and Swift* standards "a false one, based on a misunderstanding of the government's rights and obligations under the False Claims Act"
- The court held that DOJ's exercise of its dismissal authority should be evaluated under the Federal Rule of Civil Procedure 41 standard concerning voluntary dismissals
- In the Seventh Circuit, **the voluntary dismissal right conferred by Rule 41 is "absolute" provided the notice of dismissal is served before the opposing party moves for summary judgment**
- The court also held, however, that **the government must intervene before it can move for dismissal—and so the "good cause" standard in the FCA still governs in the event that DOJ decides to dismiss a case** after initially declining to intervene
- The court characterized its holding as lying "much nearer to *Swift* than *Sequoia Orange*"

FCA – DOJ Dismissal Authority

United States v. Academy Mortgage Corp., 968 F.3d 996 (9th Cir. 2020)

- The Ninth Circuit considered the district court's denial of the government's motion to dismiss the case under Section 3730(c)(2)(A)
- The district court's decision in June 2018 held that **the government's cost-benefit justification was insufficient to satisfy the *Sequoia Orange* standard; the government claimed that discovery would be burdensome, but according to the court the government's limited investigation meant its justification was based on an incomplete understanding** of the potential recovery in the case
- The government appealed under the collateral order doctrine rather than seeking to have the issue certified for interlocutory review
- The Ninth Circuit held that **the collateral order doctrine does not apply to denials of motions to dismiss under Section 3730(c)(2)(A), "at least in cases where the Government has not exercised its right to intervene"**
- The court thus dismissed the appeal for lack of jurisdiction

FCA – DOJ Dismissal Authority

- Outcomes in Circuits that have not yet adopted a standard of review remain mixed, but also highlight the ultimate similarities in the standards

Court	Circuit	Approach
D.R.I.	First	Declined to choose, but found *Sequoia Orange* satisfied
S.D.N.Y.	Second	Declined to choose, but found *Sequoia Orange* satisfied
S.D.N.Y.	Second	*Sequoia Orange*
E.D. Pa.	Third	Declined to choose, finding both standards satisfied
E.D. Pa.	Third	Declined to choose, but applied *Sequoia Orange* and found it satisfied
E.D. Va.	Fourth	*Swift* (but found *Sequoia Orange* satisfied)
S.D. Miss.	Fifth	*Swift*
N.D. Ala.	Eleventh	Predicted Circuit Court would apply *Swift*, but found both standards satisfied
S.D. Ala.	Eleventh	Applied *Sequoia Orange* "in abundance of caution" and found it satisfied

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Enforcement Trends and Developments

By the Numbers: 2019 Federal Fiscal Year

> $3 Billion

Civil settlements and judgments under the FCA

782

New FCA cases filed

81%

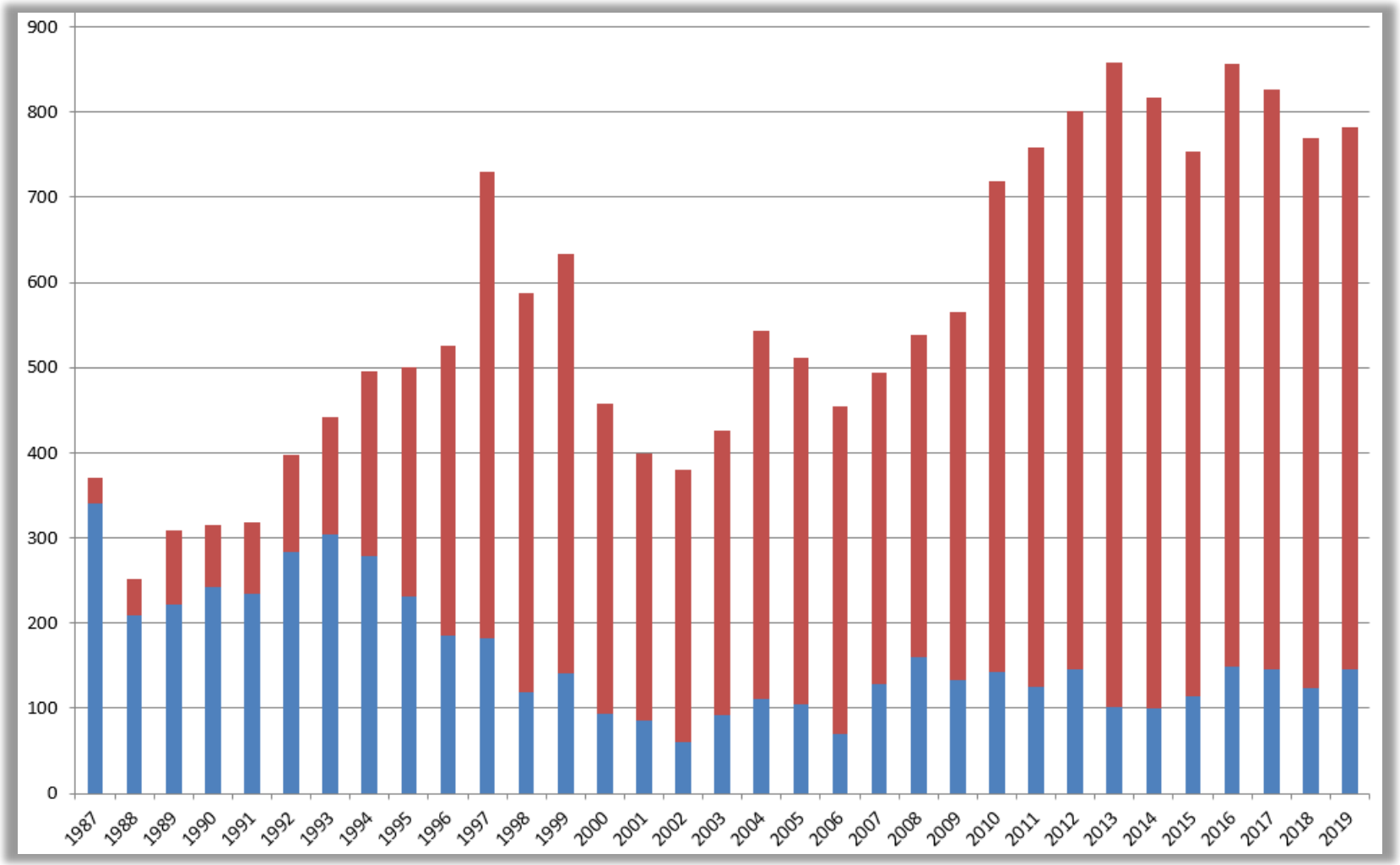
New FCA cases initiated by a whistleblower

63%

Overall federal recovery from cases in which the government intervened

Source: U.S. Dep't of Justice, "Fraud Statistics – Overview" (Jan. 9, 2020)

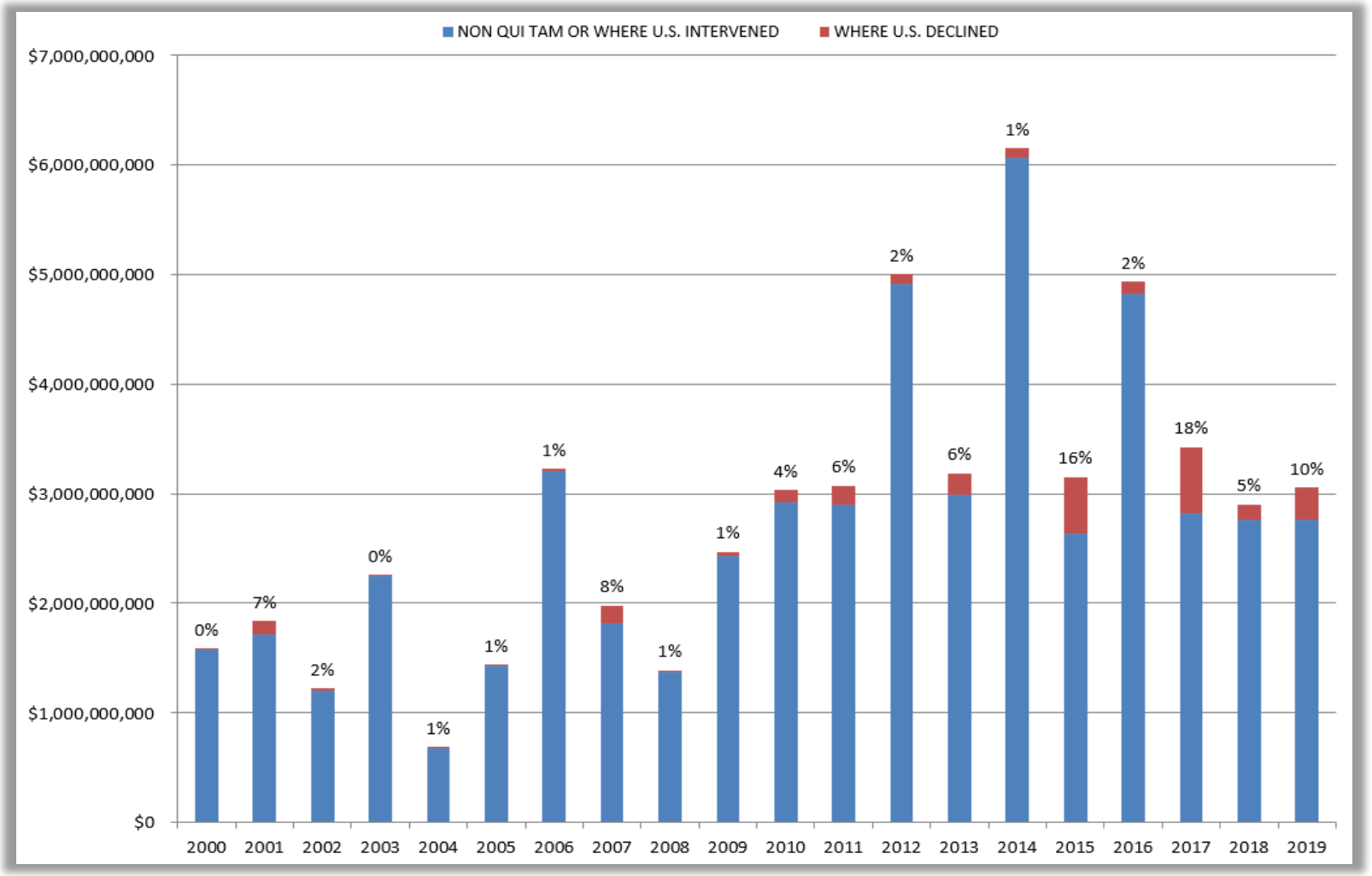
Number of New FCA Suits (FFY 1987–2019)



FFY 2019: 782 new FCA suits • 636 *qui tam* • 146 non-*qui tam*

Source: DOJ, "Fraud Statistics – Overview"

Recoveries through Settlements & Judgments (FFY 2000–2019)



FFY 2019: >$3B • $2.74B intervened & non-*qui tam* • $293M declined

Source: DOJ, "Fraud Statistics – Overview"

By the Numbers: 2020 Year to Date

$1.1 billion

FCA civil recoveries from *settlements* with drug and device companies in the 2020 to date, according to Gibson Dunn calculations

>$890 million

from civil *AKS settlements* with drug and device companies in the first half of 2020, according to Gibson Dunn calculations

1st?

2020 on pace to *exceed* 2019 in FCA civil recoveries from drug and device companies after 2018 dip

Drug and Device Companies – Key Legal Theories

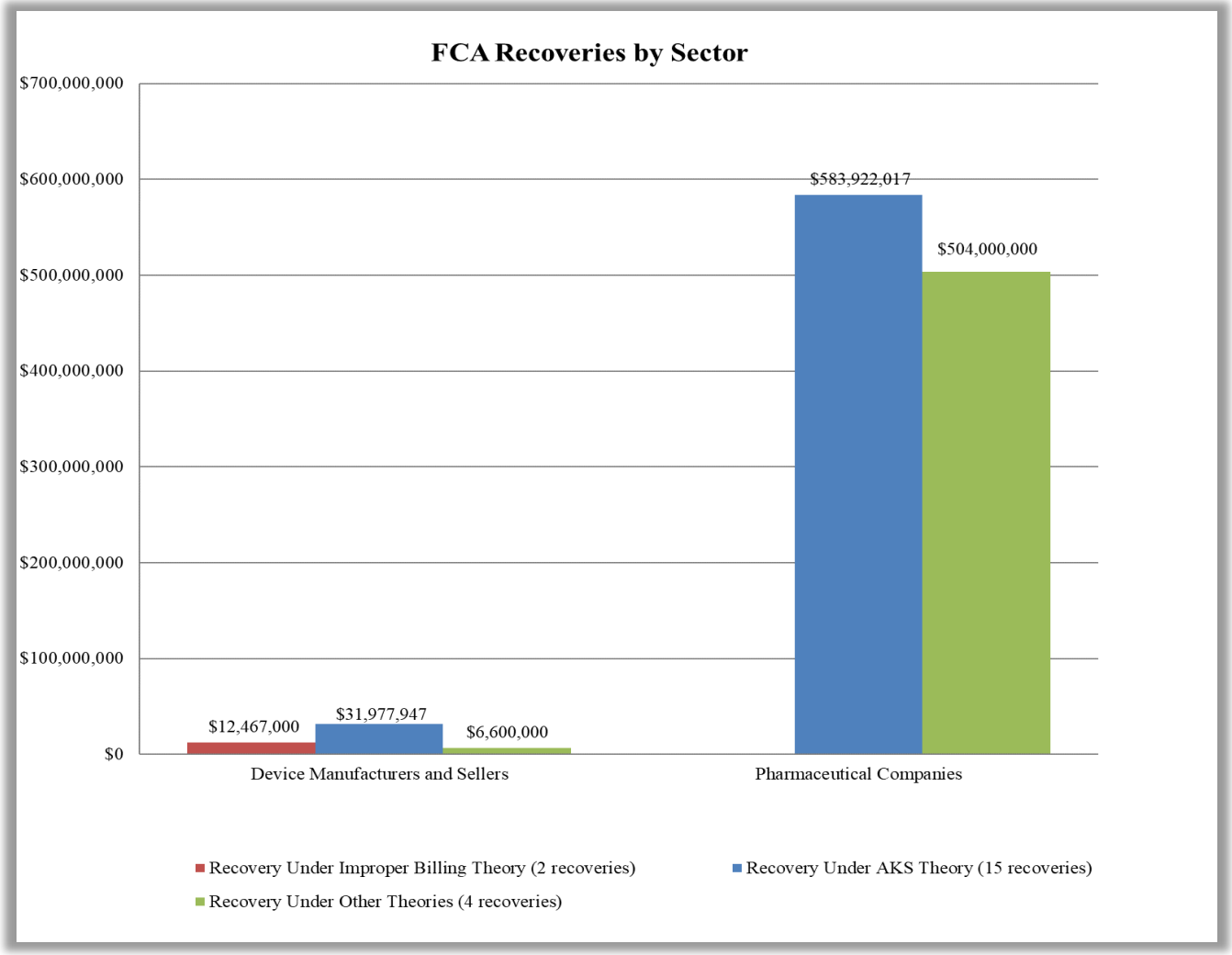
FCA allegations against drug and device companies typically are based on one (or more) of the following legal theories:

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
5. **Improper Billing.** Allegations that the company submitted claims for services or materials that were not provided and/or were not medically necessary, or "upcoded" to a higher-reimbursement service or material than what was actually provided

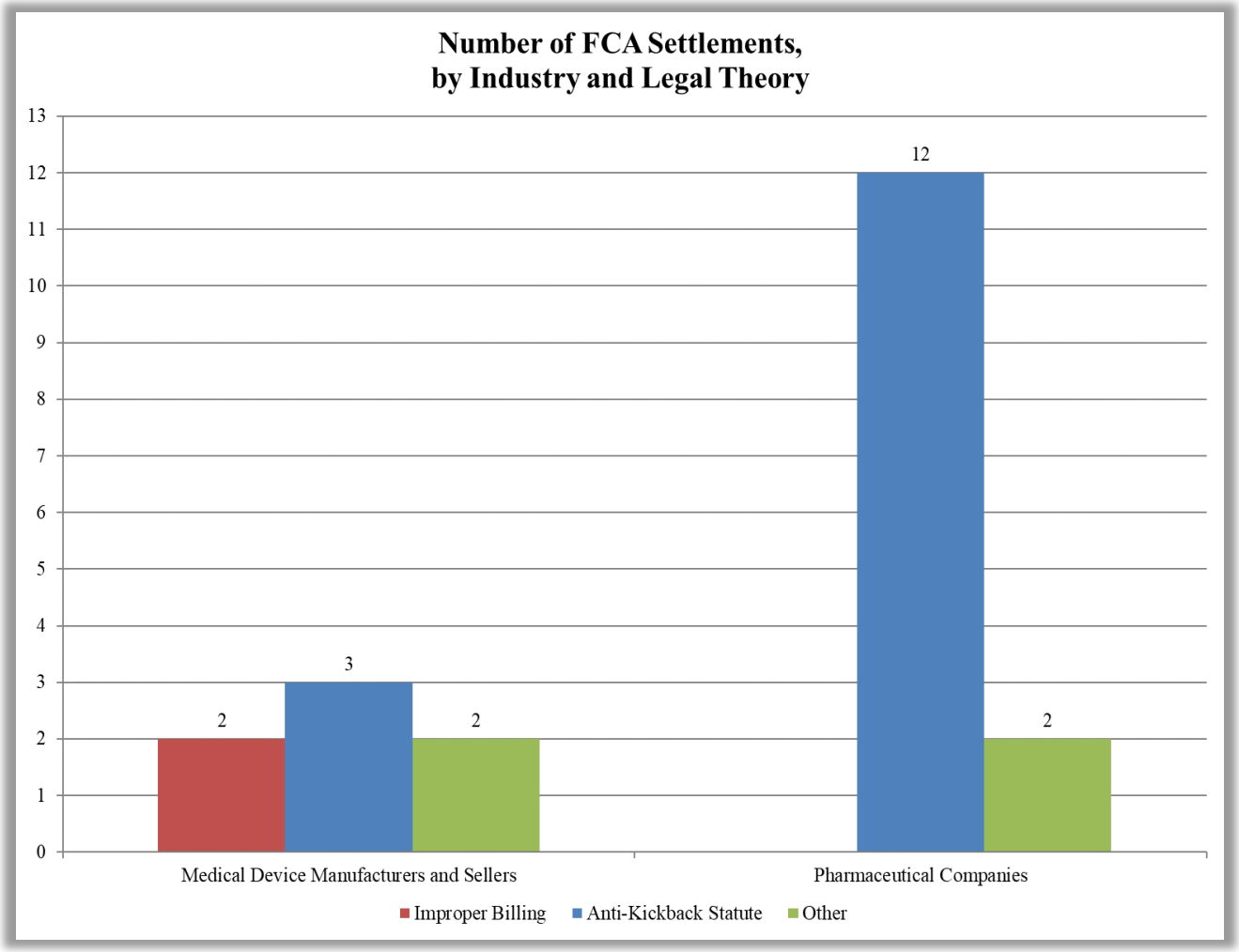
Drug and Device Companies – 2019 FCA Recoveries

~$1.14 billion in civil recoveries from drug and device companies in 2019

- AKS: $615.9m
- Off-Label Promotion and Other Allegations: $510.6m
- Improper Billing: $12.5m



Drug and Device Companies – 2019 FCA Recoveries



In 2019, DOJ cited the **AKS as the recovery theory in the vast majority** of settlements with drug and device companies

Substantive Risk Areas

Substantive AKS Risk Areas Based on Recent Enforcement Actions

Key Risk Areas

- Speaker Programs, Advisory Board, and Consulting Relationships
- Product / Practice Support
- Find-a-Doctor / Surgeon Locator Tools
- Free Equipment / Free Goods / Demo and Evaluation Products
- Fraudulent Billing / Miscoding
- Clinical Decision Support and In-App Advertising
- FDA Regulatory Issues

Speaker Programs, Advisory Board, and Consulting Relationships

- **HHS OIG "Roadmap for New Physicians."** HHS OIG advises physicians that "some pharmaceutical and device companies have used sham consulting agreements and other arrangements" to induce use of products, including "opportunities to work as a consultant or promotional speaker for the drug or device industry"
- **PhRMA Guidelines.** PhRMA Code advises that consultants may receive "reasonable compensation for" services and "reimbursement for reasonable travel, lodging, and meal expenses incurred as part of providing those services"
- ***United States ex rel. Arnstein v. Teva Pharm.* (S.D.N.Y. Feb. 27, 2019).** According to the court (which applied the Third Circuit's *Greenfield v. Medco Health Solutions* decision), relators "need not demonstrate that the providers would not have prescribed those drugs absent" the speaker fees; instead, "**Relators need only show that the speakers' referral of [] drugs 'actually sat in the causal chain.'**"

Case Study: Speaker Programs

Relators' Assertions in Opposition to Motion for Summary Judgment

Teva eliminated Speakers from its Speaker Bureau to punish them for declining prescriptions, CS, ¶ 4, and Teva's National Sales Director circulated a request for promotion to senior management at Teva in which the sales representative was recommended for promotion on the basis that he had removed a Speaker and then reinstated him (stating "[redacted] and later approached the physician about reinstating him, thereby obtaining increased prescription writing of the Drugs, which resulted in the sales representative being promoted, CS, ¶ 4; Ex. ¶¶ 98, 99;

Dr. Tim Turner, the former Professional Education Scientific Mana explained that "[d]uring my tenure with Teva, it was clear to me tha chosen to speak on behalf of Teva and were compensated for speaki of Teva for the specific purpose of influencing their prescribing hab respect to Azilect and Copaxone." CS, ¶ 5; Ex. 137 at ¶ 13;

On numerous occasions, sales representatives repeatedly reported t managers about Speakers increasing their prescriptions of the Drug their speaking, CS, ¶ 2, and Teva sales representatives reported to t that they were eliminating Speakers who were not able to prescribe were training Speakers based upon their prescription volume, even were poor presenters, and were scheduling Speakers for patient pro patients to the Speakers' practice. CS, ¶¶ 2, 4;

A Regional Sales Manager requested additional dollars for Speaker Programs from an Area Sales Director in order to schedule Speaker Programs to drive patients to a specific Speaker, whose prescriptions of Azilect were being carefully tracked. CS, ¶ 4; Ex. 141;

The materials presented at the Speaker Programs were rudimentary in nature and highly repetitive and would be of little or no interest to practicing neurologists or MS and PD patients, as Teva's own Speakers confirmed. CS, ¶¶ 11, 41, 143-167, 169-178; Ex. 142; and

The evidence also reflects over 1,300 examples in which Speakers served as attendees at Speaker Programs on the same drug for which they spoke, CS, ¶ 74, Ex. 172; over 2,400 examples in which there was only one legitimate attendee at a Speaker Program, Ex. 173; almost 2,000 examples of Speaker Programs with no legitimate attendees, Ex. 175; over 1,500 examples in which an attendee attended a program on the same drug more than three times in a six month period, Ex. 177; and over 5,000 examples in which there was excessive money spent on food and alcohol at a Speaker Program, thereby violating the requirement that only a modest meal be served at Speaker Programs, Ex. 174; over 600 Speaker Programs with no venue, Ex. 178; over 650 instances in which Speakers were overpaid in terms of fair market value, based upon Teva's own policies, Ex. 179; all of which Relators' experts, in addition to other specific instances, have opined constitute sham Speaker Programs. Ex. CS, ¶¶ 75-76, 179-187, 197-206; Exs. 162, 161.

Case Study: Speaker Programs

	Nature of Case	Key Government Allegations
NOVARTIS	In July 2020, Novartis agreed to pay $678 million to resolve allegations about speaker programs	• Between 2002 and 2011, Novartis allegedly hosted thousands of speaker programs and related events • Novartis allegedly spent hundreds of millions of dollars on these programs, including speaking fees and meals • Some events were allegedly largely social gatherings, while others never occurred
Shire	In January 2017, Shire agreed to pay $350 million to settle allegations that it violated the FCA by paying kickbacks to providers to use or "overuse" its FDA-approved human skin substitute	• DOJ alleged that company sales reps induced physicians and clinics to use the product with cash and rebates, "lavish" dinners and entertainment, medical supplies, and payments for "purported speaking engagements and bogus case studies" • The settlement, a record recovery for a kickback case against a device company, resolved six *qui tams* against Shire and a predecessor company • Three executives who supervised the alleged kickback scheme, and some providers who received kickbacks, were criminally convicted

Product / Practice Support

Medical device makers and pharmaceutical companies often provide certain **product or practice support** in connection with the sale of their products, including:

- Assistance with seminars and other patient scheduling
- Find-a-doctor websites that connect patients with physicians qualified to use the companies' products

There is no statutory exemption or regulatory safe harbor for practice support services, but HHS OIG has endorsed companies' ability to offer product support services with "**no substantial independent value**"

- But the guidance cautions against providing support "**in tandem with another service of program that confers a benefit**" on the referring provider
- The guidance also states that the AKS "would be implicated if a manufacturer were to **couple a reimbursement support service with a promise** that a purchaser will pay for ordered products only if the purchaser is reimbursed by a Federal health care program"

> "[Certain support services] may include **billing assistance tailored to the purchased products**, **reimbursement consultation**, and other programs **specifically tied to support of the purchased product**. Standing alone, services that have **no substantial independent value** to the purchaser may not implicate the [AKS]."
>
> - OIG Compliance Program Guidance for Pharmaceutical Manufacturers
> 68 Fed. Reg. 23,735 (May 5, 2003)

Product / Practice Support

In assessing the appropriateness of providing practice and product support services, device companies should consider:

Value and scope of support	What services have "substantial independent value" and what services are "limited"?
Connection between support and the relevant product and/or other services	What services are "tied" to the product or provided "in tandem" with other, valuable services?

Enforcement authorities and whistleblowers also may argue that certain practice support provides independent value to physicians by:

- **Relieving the practices of expenses** they otherwise would have to incur; and/or
- **Presenting the practices with opportunities** to make more money (e.g., by gaining efficiency or more patients)

Product / Practice Support

As to seminar and/or other scheduling assistance and find-a-doctor websites, device makers should consider the value of:

- **All connected or packaged support** (e.g., with other coding, billing, and reimbursement assistance; educational assistance; or other practice support or practice assessment tools, features, and resources)
- Whether the services involve **pure product support** or a **FMV-based service**
- **Channeled referrals** or **additional advertising** benefits from seminar listings and find-a-doctor websites

Device makers also should consider the rationale behind (and optics of) any mechanisms in place for selecting physicians to receive the support, including:

- Fixed, objective **criteria** connected to product performance; inclusion of volume- or usage-based criteria; and consistency of applying said criteria
- **Method of communicating** the availability and benefit of the support in question to physicians (e.g., quantifying a potential financial gain)
- Use of **dedicated, specialized personnel** (e.g., third-party consultants or practice advisors)
- Interaction between any such personnel and **company sales representatives** and/or sharing of **sales-related information** or conducting other **ROI analyses**

Case Studies: Practice Support

Inform Diagnostics **(formerly Miraca Life Sciences Inc.) (M.D. Tenn.)**

- DOJ pursued AKS-based claims focused on the provision of free or discounted technology and consulting services to physicians
- Settled in January 2019 for $63.5 million

United States ex rel. Health Choice Group, LLC v. Bayer Corp. **(E.D. Tex.)**

- *Qui tam* action alleged that defendant provided remuneration in the form of "free nurse services" to patients and assistance to providers with benefit verifications and prior authorization forms

United States ex. rel. Nevyas v. Allergan, Inc. **(E.D. Pa.)**

- *Qui tam* action alleged that the company's entire eye care business advisor program (and associated business unit) amounted to kickback to physicians, despite fees charged by company for the services

Find-a-Doctor / Surgeon Locator Tools

DOJ and whistleblowers have been pursuing AKS theories based on "find a doctor" websites and related tools, especially where companies spend marketing / advertising budget to direct consumers to such sites

- "Find a Doctor" tools are **common within the industry**
- The sites increase otherwise limited **information available to public** regarding qualified providers and practices
- But DOJ views as problematic where being listed has "**value**" and the listing is **tied to use of company's products**

There are concerns with (and potential barriers to) DOJ pursuing these theories:

- **Referral Services Safe Harbor.** "'[R]emuneration' does not include any payment or exchange of anything of value between an individual or entity . . . and another entity serving as a referral service," so long as four standards are satisfied. Sites are often analogous to, even if not technically within, the safe harbor
- **First Amendment.** Sharing of truthful, non-misleading information regarding providers who perform procedures is protected by the First Amendment (under *Sorrell v. IMS Health Inc.*, 131 S. Ct. 2653 (2011))

Clinical Decision Support and In-App Advertising

EHR vendors have been the subject of an industry-wide sweep for alleged FCA and AKS violations; thus, companies' **relationships with EHR vendors** have come under scrutiny

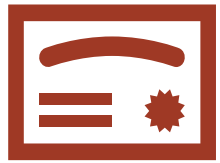
Practice Fusion (2019)

In a *criminal* resolution, Practice Fusion admitted that it solicited and received kickbacks (in the form of "sponsorship" payments) from pharma companies (particularly, a major opioid manufacturer) that paid Practice Fusion to implement **clinical decision support (CDS) alerts** in its EHR software

- The pharma companies were involved in designing the CDS alerts, which were intended to increase the number of prescriptions that HCPs wrote for the companies' medications
- DOJ alleged that the CDS alerts "did not always reflect accepted medical standards"

In a *civil* settlement, Practice Fusion agreed to pay approximately $118.6 million to the federal government and states related to:

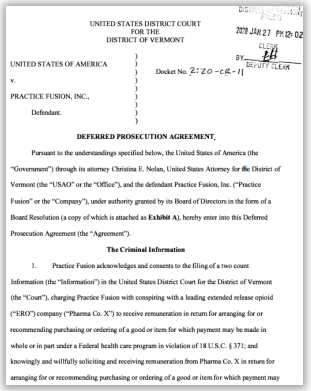
- The submission of false claims to federal health care programs affected by the types of kickback arrangements described above; and
- Allegations that Practice Fusion caused EHR users to submit false claims for federal incentives payments because Practice Fusion misrepresented the capabilities of various versions of its EHR software to receive ONC certification



Case Study: Clinical Decision Support and In-App Advertising

practicefusion

Deferred Prosecution Agreement



UNITED STATES DISTRICT COURT
FOR THE
DISTRICT OF VERMONT

2019 JAN 27 PM 12:02

CLERK
BY
DEPUTY CLERK

UNITED STATES OF AMERICA
v.
PRACTICE FUSION, INC.,
Defendant.

Docket No. 2:20-cr-11

DEFERRED PROSECUTION AGREEMENT

Pursuant to the understandings specified below, the United States of America (the "Government") through its attorney Christina E. Nolan, United States Attorney for the District of Vermont (the "USAO" or the "Office"), and the defendant Practice Fusion, Inc. ("Practice Fusion" or the "Company"), under authority granted by its Board of Directors in the form of a Board Resolution (a copy of which is attached as **Exhibit A**), hereby enter into this Deferred Prosecution Agreement (the "Agreement").

The Criminal Information

1. Practice Fusion acknowledges and consents to the filing of a two count Information (the "Information") in the United States District Court for the District of Vermont (the "Court"), charging Practice Fusion with conspiring with a leading extended release opioid ("ERO") company ("Pharma Co. X") to receive remuneration in return for arranging for or recommending purchasing or ordering of a good or item for which payment may be made in whole or in part under a Federal health care program in violation of 18 U.S.C. § 371; and knowingly and willfully soliciting and receiving remuneration from Pharma Co. X in return for arranging for or recommending purchasing or ordering of a good or item for which payment may

1. Beginning in or around Fall 2013 Defendant PRACTICE FUSION solicited remuneration from a pharmaceutical company ("Pharma Co. X") in exchange for creating and embedding an alert, known as a clinical decision support ("CDS") alert, in PRACTICE FUSION's electronic health record ("EHR") to prompt doctors to take certain clinical actions for purposes of increasing Pharma Co. X's extended release opioid ("ERO") prescriptions. This CDS alert ("the Pain CDS") suggested doctors focus on assessing and treating a patient's pain symptoms, and provided the healthcare provider a list of potential care plan treatment options. The Pain CDS suggested treatments, including the prescription of opioid medications, without discussing the medical appropriateness of each option.

2. The remuneration offered and paid by Pharma Co. X and solicited and received by PRACTICE FUSION in return for PRACTICE FUSION designing the Pain CDS with a

…ich were paid for by federal …1320a-7b(b)(1)(B) & (2)(B).

34. Employee #5 modelled the "commercial impact" that would accrue to Pharma Co. X as a result of the Pain CDS causing an increase in ERO prescriptions. PRACTICE FUSION calculated that Pharma Co. X would obtain a return on investment ("ROI") of between 5.8 and 7.8 times its cost if it implemented the PRACTICE FUSION Pain CDS.

35. The model, as revised in an internal April 24, 2015 PRACTICE FUSION email from Employee #5, estimated that Pharma Co. X would achieve a "patient gain" of two thousand seven hundred seventy-seven (2,777) and between $8,458,232 and $11,277,643 in additional opioid revenue by implementing the CDS.

Free Equipment / Goods / Demo and Evaluation Products

Provision of **free equipment, goods, or evaluation products** has long attracted FCA and AKS scrutiny.

Nature of Case	Key Government Allegations

In January 2020, ResMed Corp., a California-based DME supplier agreed to pay $37.5 million to resolve FCA and AKS allegations	• Among other things, ResMed allegedly provided:
	  • Sleep labs with free and below-cost positive airway pressure masks and diagnostic machines, as well as free installation of these machines; and
	  • Non-sleep specialist physicians free home sleep testing devices referred to as "ApneaLink"
	• ResMed entered into a Corporate Integrity Agreement with HHS OIG

Scientific Research Grants and Financial Disclosures

- In coordination with other federal authorities, NIH is investigating the sources of undue foreign influence in NIH-funded research and the failure of NIH grantees to disclose financial ties
- **The Scripps Research Institute settlement (September 2020)**
  - $10 million to settle FCA allegations relating to improperly charging NIH-funded grants for time spent on non-grant related activities
  - Failed to have system in place for faculty to account for time spent on activities that could not be charged directly to NIH-funding projects
  - Whistleblower was a TSRI professor
- **Van Andel Research Institute settlement (December 2019)**
  - $5.5 million settlement to resolve allegations that it violated the FCA by submitting federal grant applications and progress reports to NIH in which the institute failed to disclose foreign grants to two researchers
  - Foreign funding allegedly included support from China's Thousand Talents Program
  - Institute failed to take adequate steps to investigate foreign funding sources, according to DOJ

FDA Regulatory Issues

DOJ and *qui tam* relators are increasingly pursuing **FCA theories premised on interactions with FDA** and alleged **noncompliance with FDA regulations**

Recent High-Profile Examples

- 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

- In *United States ex rel. Campie v. Gilead Scis., Inc.*, 862 F.3d 890 (9th Cir. 2017), the Ninth Circuit allowed the case to move forward where the purported fraud in the FDA approval process was material to the government's decision to pay for the drugs at issue, even though FDA did not rescind approval after learning of the alleged violations and CMS continued reimbursement

FDA Regulatory Issues – Off-Label Promotion

DUSA Pharmaceuticals (August 2020)

- DUSA paid $20.75 million and entered into a Corporate Integrity Agreement to resolve allegations that it knowingly promoted an administration process for the drug Levulan Kerastick that contradicted the product instructions
- Levulan Kerastick is a prescription topical solution approved by the FDA for the treatment of minimally to moderately thick actinic keratosis (AKs) of the face or scalp
- The drug's FDA-approved instructions described a two-stage process involving application of the topical solution to the target lesions and then, following an incubation period, illumination of the target lesion with blue light
- DOJ alleged that DUSA used physician speaker programs and other promotional methods to encourage physicians to use demonstrably less effective, shorter incubation periods (1–3 hours)
- The case was brought by a whistleblower, who received $3.5 million as part of the resolution

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Hot Topics for Drug and Device Companies

The CARES Act

- The **Coronavirus Aid, Relief, and Economic Security Act (CARES Act)**
  - Largest emergency stimulus package in history – $2.2 trillion in government funds to mitigate effects of COVID-19
  - Key programs:
    - Paycheck Protection Program (PPP) – Small Business Administration (SBA) loan program
    - Main Street Lending Program (Federal Reserve)
  - Created Pandemic Response Accountability Committee (PRAC) and Special Inspector General for Pandemic Recovery (SIGPR)
    - SIGPR empowered to conduct audits and investigations into CARES Act relief programs

DOJ Enforcement Priorities in the COVID-19 Era

- DOJ has made clear that it sees the FCA as a prime tool for addressing fraud in COVID-19 stimulus programs
- Then-Principal Deputy Assistant Attorney General Ethan Davis gave a speech in June that made DOJ's focus on the programs clear:
  - "Going forward, the Civil Division will make it a priority to use the False Claims Act to **combat fraud** in the Paycheck Protection Program"
  - "We will use the False Claims Act to hold accountable those who knowingly attempt to skirt th[e] requirements" of the **Main Street Credit Facility**
  - "Our enforcement efforts may also include, in appropriate cases, **private equity firms** that sometimes invest in companies receiving CARES Act funds. . . . Where a private equity firm takes an active role in illegal conduct by the acquired company, it can expose itself to False Claims Act liability"
  - **But:** "You can rest assured that the Civil Division will not pursue companies that made **immaterial or inadvertent technical mistakes** in processing paperwork, or that **simply and honestly misunderstood** the rules, terms and conditions, or certification requirements"

United States ex rel. Jefferson v. Roche Holding AG, No. GLR-14-3665, 2020 WL 5759779 (D. Md. Sept. 28, 2020)

- Relator alleged that Roche fraudulently induced the federal government to stockpile Tamiflu as part of a its Pandemic Influenza Preparedness Plan
- According to relator, a researcher and clinician, there was scarce evidence to support the effectiveness of Tamiflu, but Roche allegedly misrepresented information about effectiveness to the U.S. Department of Health and Human Services and FDA
- The court denied Roche's motion to dismiss finding that relator adequately pleaded Roche made "factually false statements and engaged in fraud in the inducement" and that the alleged misstatements were material

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.

Purdue Pharma (October 2020)

- Yesterday, Purdue Pharma, the maker of OxyContin, pleaded guilty to a three-count felony indictment and agreed to pay over $8 billion to resolve criminal and civil allegations associated with the marketing of the drug – *the largest-ever resolution in a case brought by the Department of Justice involving an opioid drug*
  - Includes $3.54 billion in criminal fines, $2 billion in criminal forfeiture, and $2.8 billion in civil penalties
  - Company's owners, members of the wealthy Sackler family, will pay $225 million in civil penalties as part of this settlement
- Allegations:
  - Purdue marketed to more than 100 HCP's whom the company had good reason to believe were diverting opioids, while representing to the DEA that Purdue maintained an effective anti-diversion program, therefore defrauding the government;
  - Facilitated the dispensing of drugs without a legitimate medical purpose, and thus without lawful prescriptions; and
  - Violated the AKS through payments to doctors to induce them to write prescriptions of OxyContin; payments to an EHR company to recommend the drug to providers; and contracts with specialty pharmacies to fill prescriptions that were not medically necessary

Opioid Epidemic

Indivior Solutions (July 2020)

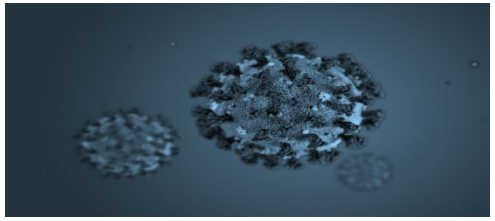
- A joint criminal-civil settlement in which Invidior pleaded guilty to a one-count felony indictment and agreed to pay a total of $600 million to resolve criminal and civil liability associated with the marketing of the opioid-addiction-treatment drug Suboxone
- Together with a 2019 $1.4 billion resolution with Indivior's former parent company, Reckitt Benckiser Group, and a 2020 plea agreement with Indivior's former CEO, the total resolution relating to the marketing of Suboxone is more than $2 billion
- In addition to its financial aspects, the agreement with Indivior Inc. includes novel provisions that, among other things:
  - Require Indivior to disband its Suboxone sales force and not reinstate it;
  - Prohibit Indivior from using data obtained from surveys of health care providers for marketing, sales, and promotional purposes; and
  - Require Indivior to remove health care providers from their promotional programs who are at a high risk of inappropriate prescribing

Telemedicine: Impact – and Possible Legacy – of COVID-19

- **Increased Focus on Telemedicine.** COVID-19 has upended almost every industry, but its effect on pharmaceutical and health care companies has been particularly pronounced
  - The pandemic has increased demand for telehealth services
  - As the number of patients seeking remote care has risen, HCPs have accelerated their efforts to expand and facilitate access to such services, especially for at-risk populations
- **Government Response.** Federal and state regulators have moved to ease—and, in some cases, eliminate—certain restrictions applicable to telehealth services (e.g., restrictions on eligible beneficiaries and services) and to telemedicine generally
- **AKS, FCA, and Other Legal Risks.** Risks remain, and it is not yet clear if (or how) demand for telehealth services will change when COVID-19 is in the rearview mirror, or how regulators will respond once the crisis has passed

Regulatory Efforts to Increase the Use of Telehealth Services

- **FDA is exercising enforcement discretion over various telehealth devices**
- **HHS has waived many Medicare coverage requirements**, vastly expanding the population eligible to receive telehealth services
- **CMS and many states have relaxed licensure requirements**, enabling doctors to render telehealth services across state lines with minimal delays



Telemedicine: FDA Regulation

At the crossroads of medical device regulation, software exemptions, artificial intelligence, cybersecurity, digital/mobile medical apps guidance, and the practice of medicine

- FDA's broad exercise of **enforcement discretion** over telehealth during the COVID-19 pandemic
  - Remote monitoring of patient vitals
  - Digital health devices for treating psychiatric conditions
  - Remote ophthalmic assessment and monitoring
  - Conduct of clinical trials
  - Remote veterinary medicine visits and prescribing
- **Emergency Use Authorization** (EUA) of the KPMAS COVID-19 Test
- **FDA enforcement risks**
  - Focus on products with functionality that could pose a risk to patient safety if the product does not function as intended

Telemedicine: AKS and FCA Risk Areas

Despite the legislative and administrative loosening of certain restrictions in light of the COVID-19 pandemic, telemedicine continues to raise legal risks, including under the AKS and FCA

Anti-Kickback Statute

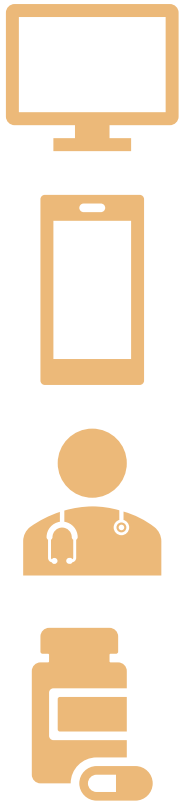
- Telehealth arrangements commonly involve **coordination and potential referrals among multiple parties** (e.g., Party A refers potential patients (or provides IT equipment, or leases retail space) to Party B to facilitate Party B's provision of telehealth services, while Party B may, but is not required to, refer patients back to Party A)
- These arrangements may implicate the AKS, but if structured properly, may present a low risk of fraud and abuse and/or fall under one of the AKS **safe harbors**

False Claims Act

- Recent legislation has (temporarily) waived some restrictions, but **telehealth practices typically present certain FCA risks**
- Federal claims "resulting from" an AKS violation are false post-ACA
- Further, telehealth providers generally may not assess patients by telephone (and must instead) use real-time audio-visual communication to assess patients at specific qualifying sites
- Seeking federal reimbursement for such services typically may violate the FCA if done in violation of legal restrictions or requirements

Telemedicine: Device Fact Patterns and AKS/FCA Risks

- **Potential "Remuneration" / "Inducements"**
  - Payments to telehealth companies
  - Advertising for / referrals to telehealth companies
  - Opportunity to earn telehealth per-visit fees (and other reimbursement)
  - Referrals to specialists / labs
  - Usage of particular devices
  - Patient pricing arrangements
  - Other situations that may be "arranging" for furnishment of health care items or services
- **Potential Intent "to Induce"**
  - In recent advisory opinions, OIG has suggested that one purpose of telehealth relationships "could be to induce referrals of Federal health care program business"
  - AKS/FCA investigation risk factors include patient steering, intrusion on independent clinical decision-making, likelihood of increasing inappropriate utilization / program costs, and analyses of ROI (or leverage, pull-through, etc.)
- **Potential Causation**
  - Provision of information to telehealth HCPs (or efforts to identify HCPs or include them as members of the telehealth platform) could increase risk



Telemedicine: Key Advisory Opinions

HHS OIG has provided some **insight into how regulators will analyze telehealth fact patterns**

OIG Ad. Op. 18-03

May 31, 2018

Proposed Arrangement

Nonprofit health center to provide equipment / services to facilitate telemedicine visits to County Clinic (located ~80 miles away) for HIV prevention consultations

Risk Mitigation Factors

- Safeguards to avoid inappropriate patient steering (e.g., Clinic's freedom to refer to other centers / HCPs)
- Low likelihood of inappropriate increase in program costs
- Patients as primary beneficiaries
- Public health focus on HIV

OIG Ad. Op. 19-02

January 29, 2019

Proposed Arrangement

Pharma company to loan smartphones to needy patients to receive adherence data from sensor embedded in prescription antipsychotic drug

Risk Mitigation Factors

- Not advertised to patients (but part of HCP education)
- No additional HCP reimbursement
- Low impact on HCP judgment
- Limited functionality smartphone and needy patient population

OIG Ad. Op. 19-04

September 10, 2019

Proposed Arrangement

Tech company to make available to beneficiaries an online HCP appointment directory app (with HCPs paying per-click fees for listing and advertising)

Risk Mitigation Factors

- No filtering of HCPs based on fees paid or "non-user-centric criteria"
- FMV (set in advance) for listing
- Requestor not a provider / supplier (and no promotion of particular items / services)
- Not targeted to federal beneficiaries

Telemedicine: Safe Harbors and Related Good Practices

Several **safe harbors** may permit appropriately structured telemedicine arrangements that otherwise implicate the AKS (and provide general guardrails for arrangements)

- **Leases for Space or Equipment [42 C.F.R. § 1001.952(b)–(c)]**
  - May permit certain arrangements under which one party provides telemedicine equipment, and/or the space to use that equipment, to a second party that provides telehealth services to patients
- **Personal Services and Management Contracts [42 C.F.R. § 1001.952(d); HHS OIG Op. No. 18-03]**
  - May permit certain arrangements under which physicians receive money from an entity, and use equipment provided by the entity, to provide telehealth services to the entity's customers
  - According to HHS OIG, such arrangements may be permissible even where physicians refer patients back to the entity, as long as such referrals are not required under the terms of the contract
- **Promotes Access to Care [81 Fed. Reg. 88,368 (Dec. 7, 2016); HHS OIG Op. No. 17-01]**
  - May permit certain arrangements—with no explicit cost limitation—that "promote[] access to care and pose[] a low risk of harm to patients and Federal health care programs"
    - Such arrangements must, among other things, "improve[] a particular beneficiary's ability to obtain" care by providing tools and/or resources necessary to remove "socioeconomic, educational, geographic, mobility, or other barriers" to care or treatment [81 Fed. Reg. at 88,392]

Telemedicine: Click-Through Telehealth and Good Practices

- Companies with branded drugs are increasingly interested in **click-through telehealth platforms** that link from a drug's website to telehealth entities and/or associated HCPs.

Good Practices	Potential Risk Areas
Adhere to FMV for compensation to telehealth platform (in light of referral stream / advertising)	Steering patients to particular HCPs (e.g., high-decile prescribers)
Insulate individual HCPs / practices and clinical decision-making	Inserting treatment protocols / clinical decision-making tools
Avoid ROI / leverage analyses	Leveraging telehealth data
Consider product donation / AKS guidelines (independence, transparency, documentation, compensation guardrails)	Arming telehealth patients with treatment "asks"
	Conditioning use of telehealth entities / HCPs based on product usage

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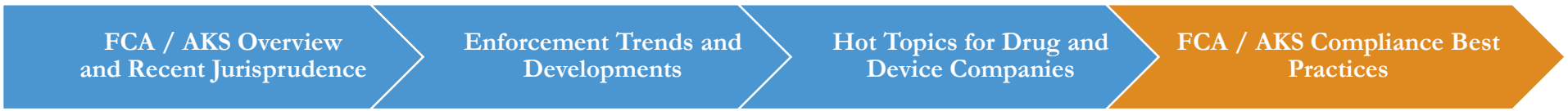
FCA / AKS Compliance Best Practices



Minimizing Exposure

- Set a compliance-focused "**tone from the top**"
- Adopt and implement **reasonable compliance policies and controls**
  - A strong internal compliance program may not prevent a rogue employee from committing fraud, but it may help to defeat scienter
- Ensure **FDA regulatory compliance** to avoid FDA issues giving rise to FCA issues
- Train employees on compliance policies and reporting options
- **Audit, monitor, and test** the compliance program's effectiveness
- **Investigate and remediate**
  - Develop standards and procedures to prevent, detect, and respond to improper conduct

Risk Assessment

- Monitor HCP interactions
- Understand compliance requirements
- Account for internal quality control measures
- Evaluate business partners
- Have a strong HR system in place—most whistleblowers are aggrieved/disgruntled former employees
- Document the government's knowledge, awareness, and ratification of contractual and programmatic deviations
- Take care in responding to billing inquiries, as incorrect explanations may be used as evidence of fraud
- Documentation and transparency are key

Investigation Responsiveness

- Critical to know of FCA complaints as soon as possible
- Foster an environment in which employees and other interested parties report concerns internally
- Separate the message from the messenger, take allegations seriously and follow up
- *Qui tam* warning signs:
  - HR issues;
  - Exit interview statements;
  - Unexpected audits;
  - Requests for billing explanations;
  - Increased web activity; and
  - Former employees contacted
- Proactively engage with and present your case to DOJ and USAO
- The most critical juncture is the government's intervention decision

Questions?

Upcoming Webcasts & Contact Information

Upcoming Gibson Dunn Webcasts

- **October 27 | In-house Guidance for Managing Non-U.S. Antitrust Investigations** | 12:00 – 1:30 pm EDT

  If you are interested in attending, please click here.
- **November 4 | False Claims Act Updates for Health Care Providers** | 12:00 – 1:30 pm EST

  If you are interested in attending, please click here.
- **November 9 | Spoofing: What it is, where it's going** | 12:00 – 1:30 pm EST

  If you are interested in attending, please click here.
- **November 16 | Corporate Compliance and Sentencing Guidelines** | 12:00 – 2:00 pm EST

  If you are interested in attending, please click here.
- **November 18 | SEC Enforcement Focus on COVID-19 Issues and Recent Accounting Cases** | 12:00 – 1:15 pm EST

  If you are interested in attending, please click here.

*** Continued on next page**

Upcoming Gibson Dunn Webcasts (cont.)

- **December 2 | What's next? The Legislative and Policy Landscape After the 2020 Election** | 12:00 – 1:00 pm EST

  If you are interested in attending, please click here.
- **December 7 | FCPA 2020 Case Round-Up** | 2:00 – 3:30 pm EST

  If you are interested in attending, please click here.
- **December 8 | Congressional Investigations and Oversight Post-Election** |12:00 – 1:00 pm EST

  If you are interested in attending, please click here.
- **December 10 | International Anti-Money Laundering and Sanctions Enforcement** | 12:00 – 1:30 pm EST

  If you are interested in attending, please click here.

Publications and Recorded Webcasts

Publications

- 2020 Mid-Year False Claims Update (July 17, 2020): https://www.gibsondunn.com/2020-mid-year-false-claims-act-update/

- Implications of COVID-19 Crisis for False Claims Act Compliance (March 31, 2020): https://www.gibsondunn.com/implications-of-covid-19-crisis-for-false-claims-act-compliance/

Recorded Webcasts

- The False Claims Act: Updates for the Government Contracting Sector (October 13, 2020) https://www.gibsondunn.com/webcast-the-false-claims-act-updates-for-the-government-contracting-sector/

- The False Claims Act: Updates for the Financial Services Sector (October 6, 2020) https://www.gibsondunn.com/webcast-the-false-claims-act-updates-for-the-financial-services-sector/

Contact Information – Today's Panelists

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