November 7, 2024

FALSE CLAIMS ACT ENFORCEMENT IN THE LIFE SCIENCES & HEALTH CARE SECTORS

Presented by John D. W. Partridge, Jonathan M. Phillips, Katlin McKelvie, and James L. Zelenay Jr.

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TODAY'S PRESENTERS

John D. W. Partridge

Partner; Co-Chair, FDA and Health Care, Denver; Washington, D.C.

John Partridge, a *Chambers*-ranked white collar defense and government investigations lawyer, focuses on government and internal investigations, white collar defense, and complex litigation for clients in the life science and health care industries, among others.

John has particular experience with the Anti-Kickback Statute, the False Claims Act, the Foreign Corrupt Practices Act, and the Federal Food, Drug, and Cosmetic Act, including defending major corporations in investigations pursued by the U.S. Department of Justice (DOJ) and the U.S. Securities and Exchange Commission (SEC).

Jonathan M. Phillips

Partner; Co-Chair, FDA and Health Care; False Claims Act/Qui Tam Defense; Washington, D.C.

Jonathan M. Phillips is a partner who focuses on compliance, enforcement, and litigation in the health care and government contracting fields, as well as other white collar enforcement matters and related litigation.

A former Trial Attorney in DOJ's Civil Fraud section, he has particular experience representing clients in enforcement actions by the DOJ, Department of Health and Human Services, and Department of Defense brought under the False Claims Act and related statutes.

Katlin McKelvie

Partner, Washington, D.C.

With over two decades of experience in food and drug law, including as Deputy General Counsel of the Department of Health and Human Services (HHS), Katlin McKelvie offers clients expansive knowledge of the complex legal and policy issues associated with FDA regulation of food, drugs, medical devices, and cosmetics.

As Deputy General Counsel at HHS, Katlin was responsible for advising senior HHS officials on FDA-related regulatory, enforcement, and litigation matters. Prior to joining HHS, she served as Deputy Health Policy Director and Senior FDA Counsel to the Senate Committee on Health, Education, Labor, and Pensions for Chair Patty Murray.

James L. Zelenay Jr.

Partner, Los Angeles

Jim Zelenay, a partner in Gibson Dunn's Los Angeles office, practices in the firm's Litigation Department and has extensive experience in defending clients involved in white collar investigations, assisting clients in responding to government subpoenas, and in government civil fraud litigation.

Jim also has substantial experience with the federal and state False Claims Acts and whistleblower litigation, in which he has represented a breadth of industries and clients, including educational institutions, financial institutions, insurers, pharmaceutical companies, construction companies, telecommunication clients, emergency services personnel, and accounting firms, among others.

AGENDA

01	FCA / AKS Overview
02	Recent Jurisprudence
03	Enforcement Priorities and Trends
04	Hot Topics for Drug and Device Companies
05	Compliance Best Practices

FCA / AKS OVERVIEW

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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 (e.g., federal health care 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)

FCA BASICS

Elements of a False Claims Act Case

- **Falsity**: A request for payment (claim) that is false or fraudulent.
- **Materiality**: The falsity of the claim was material to the government's payment of the claim.
- **Scienter**: The false claim was submitted with knowledge of its falsity—in the form of "actual knowledge," "deliberate ignorance," or "reckless disregard."
- **Causation and Harm**: The false claim caused the government to suffer financial harm (i.e., payment of the claim).

To succeed, the plaintiff—either the government or a whistleblower—must prove each of the above by a ***preponderance of the evidence***.

FCA BASICS (cont'd)

Factual Falsity

- False billing (e.g., goods or 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
- *United States ex rel. Marcus v. Hess*, 317 U.S. 537 (1943) (claims by contractors who colluded on bids)

Reverse False Claims

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

FCA BASICS (cont'd)

Damages and Civil Penalties

- **Treble damages** are traditionally calculated by multiplying the government's loss by three (e.g., if the government was charged $100 for goods not received, damages would be $300).
- But the damages calculation can be much 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."
- In addition to damages, there is **a per-violation civil penalty**:
  - Current range: **$13,946 to $27,894** per violation occurring after November 2, 2015, and assessed after February 12, 2024.
  - For violations occurring on or before November 2, 2015: **$5,500 to $11,000** per violation.

The Anti-Kickback Statute (AKS)

- The AKS, 42 U.S.C. § 1320a-7b(b), is a **criminal statute** that proscribes:
  - Knowing and willful;
  - Payment, offer, solicitation, or receipt of remuneration;
  - To induce patient referrals, reward referral sources, or generate business;
  - Involving any item or service payable by federal health care programs.
- The **willful** element does not require specific knowledge of the AKS, but does require intent to do something the law forbids.
- The AKS covers those who **provide (or offer) remuneration** and those who **receive (or solicit) remuneration.**
  - **Remuneration** means anything of value; if "one purpose" of the remuneration is to secure referrals, there is **inducement**.
- 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)).

RECENT JURISPRUDENCE

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RECENT JURISPRUDENCE: *Chevron* Doctrine's Demise

FCA Impacts

- In the Supreme Court's 1984 ruling in ***Chevron U.S.A. v. Natural Resources Defense Council***, U.S. federal courts were instructed to defer to agencies' interpretations of the laws or statutes they administered.
- The 2024 decision in ***Loper Bright Enterprises v. Raimondo*** overruled *Chevron*, holding that courts must independently interpret agency statutes without deference to agency readings of those statutes.
- Falsity in FCA cases often hinges on questions of statutory interpretation. For example:
  - Stark Law and AKS exceptions / safe harbors established by statute and interpreted via HHS regulations.
  - Medicaid rebate requirements established by statute and interpreted via HHS "best price" regulations.
  - What constitutes "reasonable and necessary" services for Medicare and Medicaid reimbursement.

Citations: Chevron U.S.A. v. Natural Resources Defense Council, 467 U.S. 837 (1984); *Loper Bright Enterprises v. Raimondo*, 144 S. Ct. 2244 (2024)

RECENT JURISPRUDENCE: *Chevron* Doctrine's Demise (cont'd)

U.S. ex rel. Sheldon v. Forest Labs., LLC, 2024 WL 3555116 (D. Md. July 23, 2024)

- Courts are already grappling with ***Loper Bright*** in the FCA context, interpreting foundational statutory provisions where they previously would have deferred to agency interpretation.
- In ***Forest Labs***, the district court granted the defendant's motion to dismiss, holding that the relator had not adequately pleaded falsity or scienter.
- The court independently interpreted the Medicaid Drug Rebate Statute, 42 U.S.C. § 1396r-8, noting that it was not relying on CMS's interpretation of that statute, as required by ***Loper Bright***.

RECENT JURISPRUDENCE:

FCA Scienter

U.S. ex rel. Schutte v. SuperValu Inc., 143 S. Ct. 1391 (2023)

- The Supreme Court unanimously held that FCA scienter turns on a defendant's subjective knowledge at the time of the relevant conduct.
  - Before ***SuperValu***, some lower courts permitted defendants to advance scienter defenses based on objectively reasonable interpretations of ambiguous legal requirements (from which they were not "warned away" by existing legal authority).
  - Other courts rejected this approach, concluding that it prioritized post hoc litigation positions over contemporaneous facts.
  - Under *SuperValu*, an FCA defendant can negate scienter by putting the ambiguity of a particular legal requirement at issue, but only with evidence of contemporaneous subjective belief in a particular interpretation of the requirement—not with post hoc arguments.
- In future cases, if DOJ or a relator presents evidence of a defendant's awareness of agency guidance to demonstrate the defendant's subjective interpretation of a statute or regulation, ***Loper Bright*** could provide a new defense. Can a defendant knowingly violate a regulation that was not a valid interpretation of the governing statute?

RECENT JURISPRUDENCE: Scope of Actionable "Claims"

U.S. ex rel. Heath v. Wis. Bell, Inc.
92 F.4th 654, 657 (7th Cir. 2024), *cert. granted*, 2024 WL 3014477 (U.S. June 17, 2024)

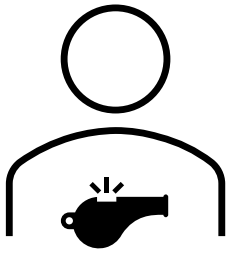
- The Supreme Court will determine in ***Wisconsin Bell*** if reimbursement requests to the FCC's E-rate program are "claims" under the FCA.
- The E-rate program, a $4.5B initiative under the Telecommunications Act of 1996, provides discounted telecommunications and internet services to eligible schools and libraries. Service providers competitively bid to offer these services at subsidized rates. The program is funded by private contributions and administered by a non-profit.
- Relator accused Wisconsin Bell of overcharging, causing excess federal payments. Wisconsin Bell argued that the E-rate program doesn't involve government funds and that reimbursement requests aren't "claims" under the FCA. Wisconsin Bell contended that since the funds are privately sourced and managed by a non-profit, the FCA does not apply.
- The Court's ruling will shape the scope of actionable FCA claims.

RECENT JURISPRUDENCE:

Constitutionality of *Qui Tam* Provisions

Constitutionality of Qui Tam Provisions

- Over the years, defendants have argued that the FCA's *qui tam* provisions improperly grant private parties the authority to pursue cases on behalf of the United States, a responsibility exclusively vested in the Executive Branch by Article II of the Constitution.
- Every circuit court that has addressed this issue has concluded that the *qui tam* provisions are constitutional, primarily because the government retains ultimate authority and control over the litigation, even after it ceases to be a party.
  - *See United States ex rel. Stone v. Rockwell Int'l Corp.*, 282 F.3d 787 (10th Cir. 2002); *Riley v. St. Luke's Episcopal Hospital*, 252 F.3d 749 (5th Cir. 2001); *United States ex rel. Taxpayers Against Fraud v. Gen. Elec. Co.*, 41 F.3d 1032 (6th Cir. 1994); *United States ex rel. Kelly v. Boeing Co.*, 9 F.3d 743 (9th Cir. 1993).
- Federal district courts in other circuits also have upheld the constitutionality of the FCA's *qui tam* provisions. *See, e.g., United States ex rel. Lagatta v. Reditus Laboratories, LLC*, No. 1:22-CV-01203-SLD-JEH, 2024 WL 4351862 (C.D. Ill. Sept. 30, 2024).



RECENT JURISPRUDENCE: Constitutionality of *Qui Tam* Provisions (cont'd)

U.S. ex rel. Polansky v. Executive Health Resources, Inc., 599 U.S. 419, 449 (2023)

- The Supreme Court issued an 8-1 ruling in ***Polansky***, affirming the government's authority to dismiss *qui tam* lawsuits in non-intervened cases.
- Justice Thomas dissented, flagging Article II concerns about the *qui tam* provisions:
  - "*The FCA's* qui tam *provisions have long inhabited something of a constitutional twilight zone. There are substantial arguments that the* qui tam *device is inconsistent with Article II and that private relators may not represent the interests of the United States in litigation*"
- Justice Kavanaugh, joined by Justice Barrett in concurrence, expressed agreement and encouraged the Court to "consider the competing arguments on the Article II issue in an appropriate case."
- Defendants are now regularly advancing constitutional challenges to the FCA's *qui tam* provisions. These challenges include arguments that relators in declined cases can enforce or promote statutory interpretations not endorsed by the government.

RECENT JURISPRUDENCE: Constitutionality of *Qui Tam* Provisions (cont'd)

U.S. ex rel. Zafirov v. Florida Medical Associates, LLC, No. 8:19-CV-01236-KKM-SPF (M.D. Fla. Sept. 30, 2024)

- A relator alleged that defendants falsified patients' medical conditions in claims to Medicare. DOJ declined to intervene. Defendants moved for judgment on the pleadings, arguing that the FCA's *qui tam* provisions are unconstitutional.
- Judge Kathryn Mizelle, a former Justice Thomas clerk, concluded that (1) relators act as officers of the United States, (2) historical examples of *qui tam* provisions do not exempt a relator from the Appointments Clause of Article II, and (3) because relators are not constitutionally appointed, their execution of litigating powers is unconstitutional because *qui tam* provisions "permit[ ] unaccountable, unsworn, private actors to exercise core executive power with substantial consequences to members of the public."
- *Zafirov* conflicts with a ruling from another Florida district court issued the same month. That court rejected a defendant's constitutional argument and denied the motion to dismiss, noting that "the Eleventh Circuit has yet to squarely consider the issue." *United States ex rel. Butler v. Shikara*, No. 20-CV-80483, 2024 WL 4354807, at *11 (S.D. Fla. Sept. 6, 2024).
- DOJ and relator are appealing Judge Mizelle's decision to the Eleventh Circuit.

AKS and Case Law Developments

Causation Standard: "[A] claim that includes items or services ***resulting from*** a violation" of the AKS constitutes a false or fraudulent claim for purposes of the FCA.
42 U.S.C. § 1320a-7b(g)

Knowing and willful

Payment, offer, solicitation, or receipt of remuneration

Induce patient referrals, reward a referral source, or generate business

Involving any item or service payable by federal health care programs

RECENT JURISPRUDENCE:

AKS Willfulness

U.S. ex rel. Hart v. McKesson Corp., 96 F.4th 145 (2d Cir. 2024)

- In October 2024, the U.S. Supreme Court declined to hear a case about the "willfulness" element of the AKS. This decision leaves in place the Second Circuit's ***Hart*** ruling.
- In ***Hart***, a relator filed a lawsuit claiming that the company violated the FCA through a kickback scheme by giving free business tools to oncology centers to induce drug purchases.
- The district court dismissed the relator's complaint because the relator did not adequately plead that McKesson acted "willfully." The principal issue before the Second Circuit was whether the term "willfully" requires proof that a defendant knew that its conduct was unlawful.
- The Second Circuit affirmed the district court's dismissal, holding that:
  - "[A] defendant [must] act understanding that his conduct is unlawful (if not necessarily under the AKS)."
  - This requires an analysis of specific individuals' intent.

RECENT JURISPRUDENCE:

Causation Standard

Stop Illinois Health Care Fraud, LLC v. Sayeed, 100 F.4th 899 (7th Cir. 2024)

- In *Sayeed*, the defendant paid a health care consortium for "management services" and "administrative advice." The consortium allegedly provided access to its clients' health data, which the defendant used to solicit patients directly. The district court found the defendant liable under the FCA based on the AKS theory, ruling that all Medicare claims submitted after the alleged data-mining agreement were false. The defendant appealed both the liability and damages findings.
- The Seventh Circuit acknowledged the circuit split over the causation standard but did not take a position on it. Instead, it rejected the notion that every claim after an AKS violation is automatically false. The court concluded, however, that the district court erred in calculating damages based on Medicare claims that might not be related to the kickback scheme and remanded the case for further proceedings.
- The Supreme Court declined to review the Seventh Circuit's decision.

RECENT JURISPRUDENCE: Causation Standard (cont'd)

United States v. Regeneron Pharmaceuticals, Inc., No. 23-2086 (1st Cir.)

- DOJ alleged that Regeneron violated the AKS by using a third-party foundation to subsidize patients' copays, inducing providers to prescribe its drug.
- Both parties moved for summary judgment as to causation. The district court held that the "resulting from" language requires but-for causation (following the Sixth and Eighth Circuits).
- During the July 2024 oral argument, the First Circuit panel scrutinized the government's argument on the causation standard, noting the absence of a historical analog for its proposed standard—"the factual connection is: 'is the claim for the items or services that the kickback was given to induce.'"
- This suggests that the First Circuit may align with the Sixth and Eighth Circuits in adopting a "but-for" causation standard. This standard contrasts with the Third Circuit's more lenient standard, which only requires some connection between the kickback and the subsequent reimbursement claim.

ENFORCEMENT PRIORITIES AND TRENDS

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ENFORCEMENT PRIORITIES & TRENDS

DOJ's 2024 Enforcement Priorities

DOJ's FCA enforcement priorities for 2024, as stated by PDAAG Boynton at a February 2024 conference, have been:

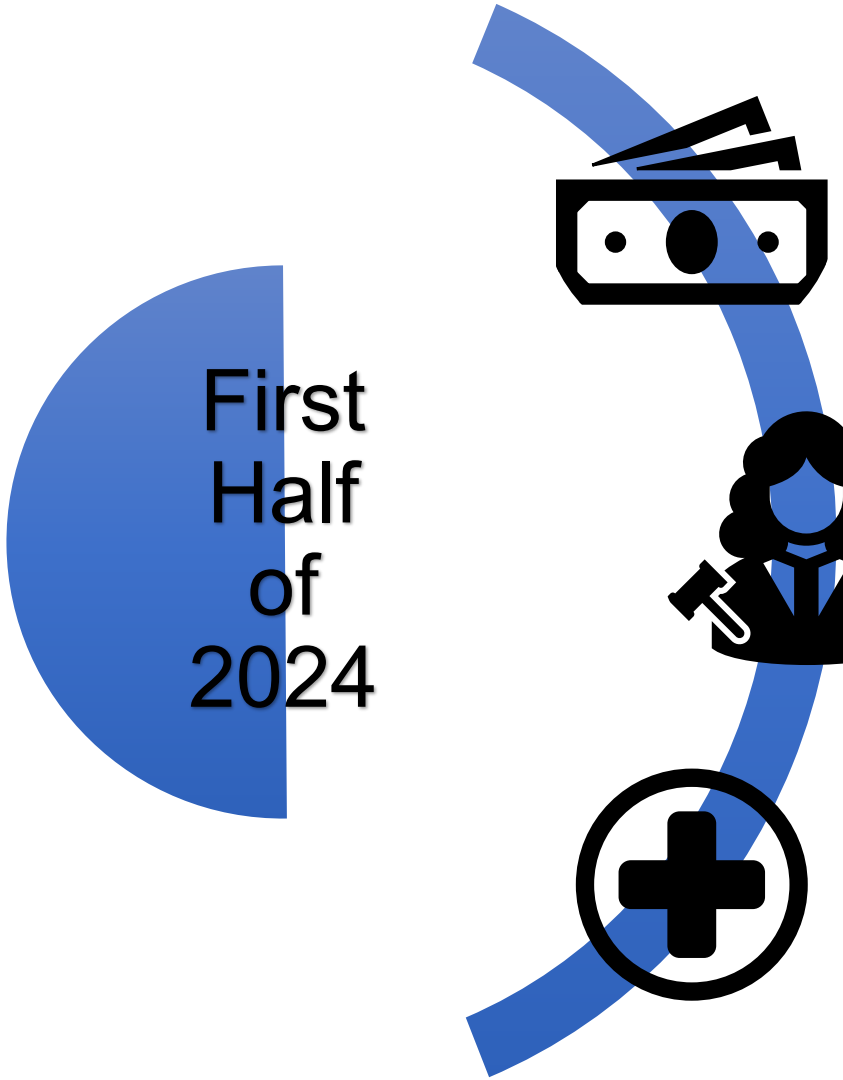
- Cybersecurity fraud;
- COVID-19 pandemic fraud;
- Health care fraud, specifically illegal inducements and schemes involving nursing homes (echoing DOJ's stated focus on elder fraud more broadly); and
- Accountability for third parties that cause the submission of false claims, including private equity firms.

"We continue to encourage companies to take advantage of the government's False Claims Act cooperation policy. It offers companies an opportunity to mitigate their potential liability. It is also the right thing to do for our security."

- PDAAG Brian Boynton

ENFORCEMENT PRIORITIES & TRENDS

Enforcement Data



Through June 30, 2024, the government entered into resolutions totaling **over $1 billion** in recoveries—the highest in recent memory for the first half of a year.

A jury verdict of **~$150 million** in mid-June, in a case in which DOJ **declined to intervene**.

Recoveries in the **health care** and **life sciences industries** continue to dominate enforcement activity.

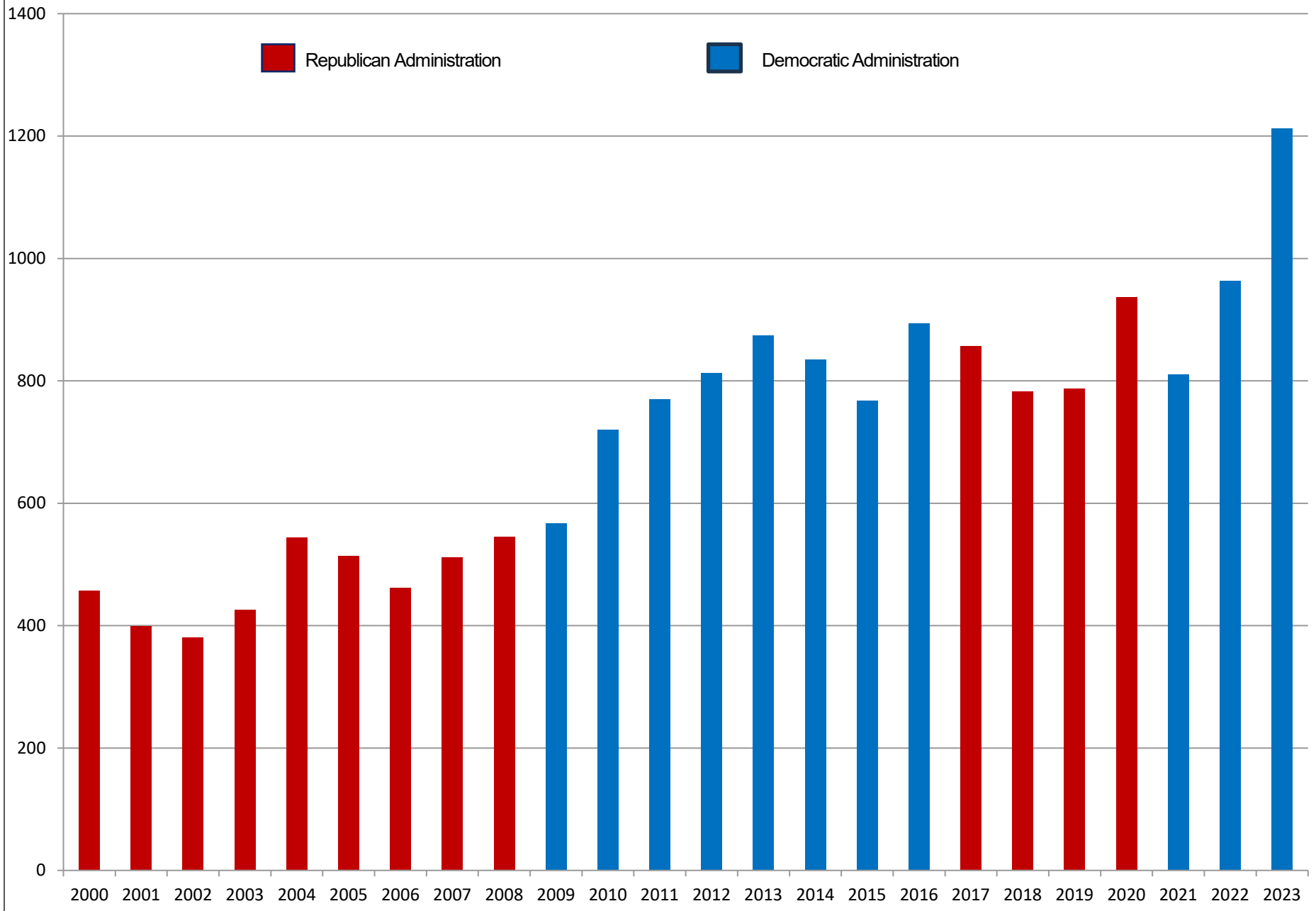
ENFORCEMENT PRIORITIES & TRENDS

FCA Activity Outlook

The presidential election is unlikely to cause significant change in the level of FCA enforcement.

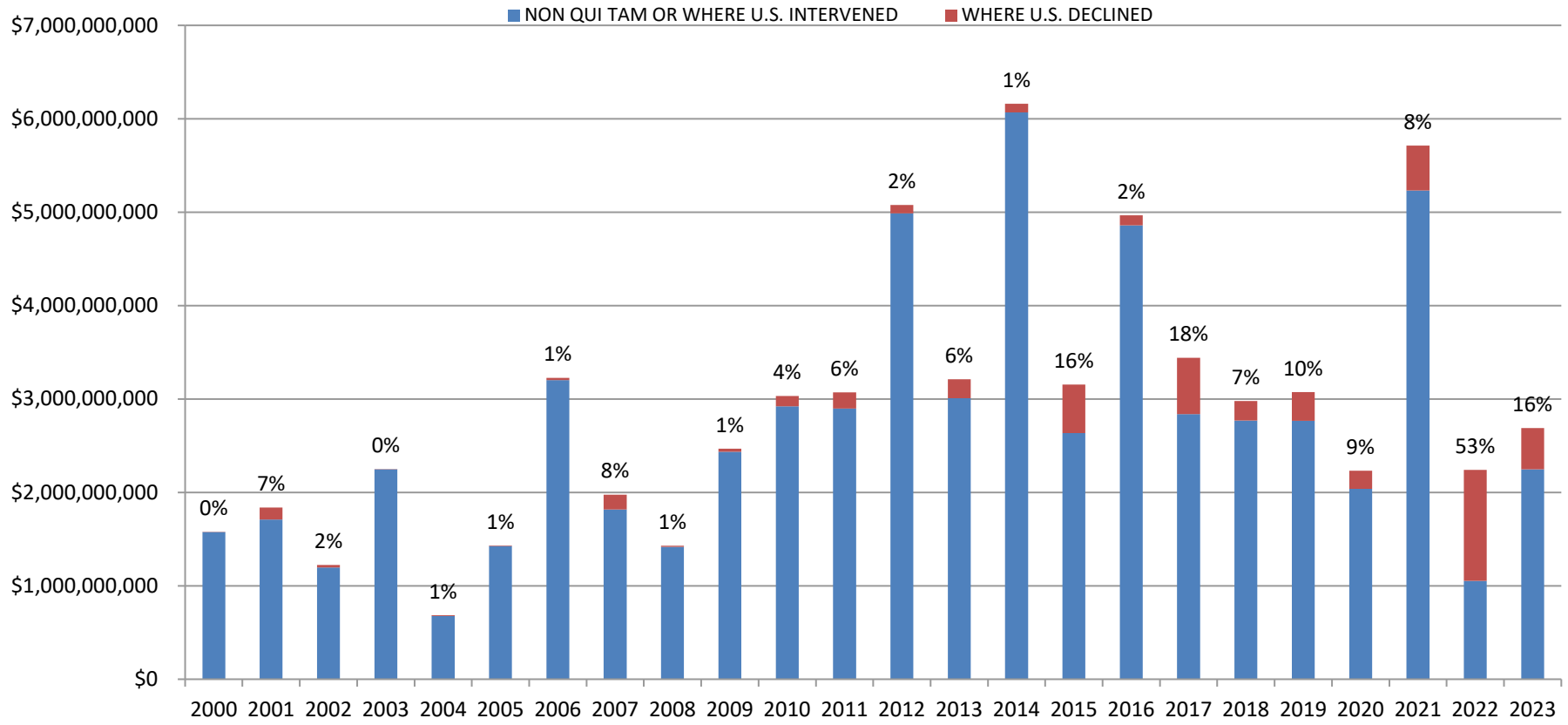
- DOJ's vigorous enforcement efforts show no signs of slowing; DOJ issued a record number of Civil Investigative Demands in FCA matters last year (more than 1,500).
- Main Justice and USAOs have a deep bench of enforcement attorneys and investigators who are not political appointees.
- Many U.S. enforcement attorneys have freed up from years spent on investigations and cases stemming from the opioid epidemic.
- The Civil Fraud unit (which handles FCA matters) has more than 125 enforcement attorneys.

Number of FCA New Matters 2000-2023 by Presidential Party



Source: DOJ "Fraud Statistics – Overview" (Feb. 22, 2024)

Settlements or Judgments 2000-2023



Source: DOJ "Fraud Statistics – Overview" (Feb. 22, 2024)

ENFORCEMENT PRIORITIES & TRENDS

DOJ's Cooperation Credit Policy

In May 2019, DOJ issued a policy regarding the circumstances under which it would award cooperation credit in FCA cases.

- For several years thereafter, DOJ's settlement agreements did not explicitly discuss cooperation credit.
- A recent cybersecurity-related FCA resolution heralds greater transparency but leaves some questions unanswered:
  - DOJ's press release highlighted the company's self-disclosure, and while the settlement agreement identified other forms of cooperation, it did not specify which factors, if any, carried more weight than others in the credit determination.
- DOJ press releases have credited companies for other forms of cooperation, including:
  - Affirmative acceptance of responsibility
  - Proactive disclosures of key evidence
  - Engaging experts to conduct analyses
  - Conducting an internal compliance review
  - Conducting and disclosing internal investigation results
  - Remediation

Key Legal Theories in Life Sciences and Health Care

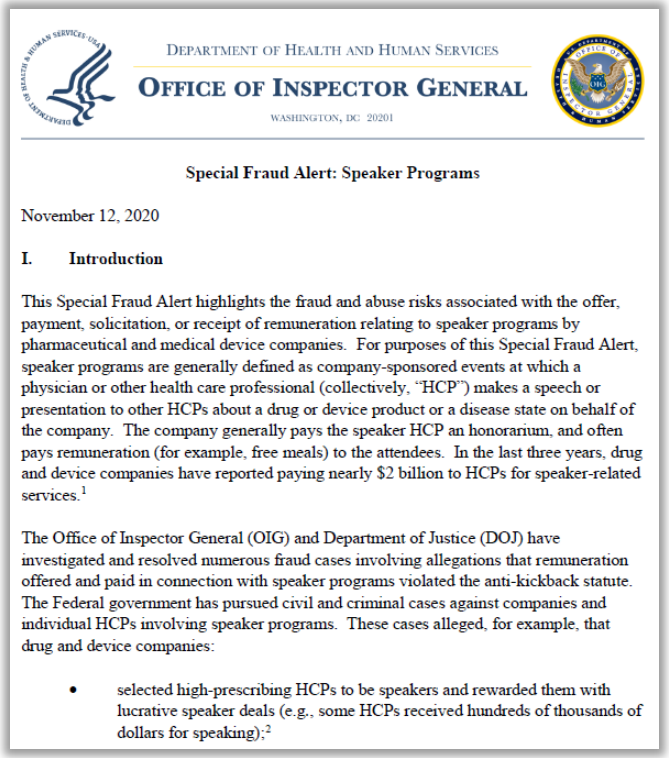
FCA allegations against health care, drug and device companies typically are based on one (or more) of the following legal theories:

- **AKS / Stark Law.** Payment of remuneration to providers in a position to prescribe the company's drug or device violates the AKS and, in turn, the FCA.
- **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 may render reimbursement claims for scripts "false."
- **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.
- **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.
- **Medical Necessity / Coding.** 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.

AKS Legal Theory: Speaker Programs

The Fraud Alert on Speaker Programs lists the following illustrative "suspect characteristics" that heighten the risk of **AKS violations**:

- Little or no substantive information presented
- Alcohol / meal above modest value
- Venue not conducive to educational exchange
- Many programs on the same / similar topic or product
- Stale medical or scientific information
- Repeat attendance / attendance after speaking on same topic
- Attendance by friends, family, members of the speaker's practice, and/or staff of facilities where the speaker is a medical director
- Influence by sales / marketing in selecting speakers (or analyzing ROI)
- Compensation greater than FMV



DEPARTMENT OF HEALTH AND HUMAN SERVICES
OFFICE OF INSPECTOR GENERAL
WASHINGTON, DC 20201

Special Fraud Alert: Speaker Programs

November 12, 2020

I. Introduction

This Special Fraud Alert highlights the fraud and abuse risks associated with the offer, payment, solicitation, or receipt of remuneration relating to speaker programs by pharmaceutical and medical device companies. For purposes of this Special Fraud Alert, speaker programs are generally defined as company-sponsored events at which a physician or other health care professional (collectively, "HCP") makes a speech or presentation to other HCPs about a drug or device product or a disease state on behalf of the company. The company generally pays the speaker HCP an honorarium, and often pays remuneration (for example, free meals) to the attendees. In the last three years, drug and device companies have reported paying nearly $2 billion to HCPs for speaker-related services.[1]

The Office of Inspector General (OIG) and Department of Justice (DOJ) have investigated and resolved numerous fraud cases involving allegations that remuneration offered and paid in connection with speaker programs violated the anti-kickback statute. The Federal government has pursued civil and criminal cases against companies and individual HCPs involving speaker programs. These cases alleged, for example, that drug and device companies:

- selected high-prescribing HCPs to be speakers and rewarded them with lucrative speaker deals (e.g., some HCPs received hundreds of thousands of dollars for speaking);[2]

Speaker Programs – Case Studies

In October 2020, **Medtronic** agreed to pay **~$9.2M** to settle allegations that it violated the FCA by sponsoring social events at a restaurant owned by an HCP.	• Between 2019 and 2020, Medtronic allegedly paid over $87,000 for more than 130 events at a physician's restaurant from 2010 to 2019. • Sales reps allegedly described events in expense reports as for discussion of educational content or business information, when they were actually social gatherings in inappropriate venues. • Settlement included $1.11 million to resolve allegations that Medtronic violated transparency requirements of the Open Payments Program by failing to accurately report the payments.
In September 2022, **Biogen** agreed to pay **$900M** to settle allegations that it paid kickbacks to providers through speaker programs to induce them to prescribe Biogen drugs.	• The government alleged that between 2009 and 2014, Biogen offered and paid remuneration, including in the form of speaker honoraria, speaker training fees, consulting fees, and meals, to health care professionals who spoke at or attended Biogen's speaker programs, speaker training meetings, or consultant programs to induce them to prescribe more drugs. • Allegedly paid its speakers above fair market value by, for instance, automatically compensating them for travel time even when it was unnecessary.

Alleged Agreements with Physicians – Case Studies

1. Proctoring, Data Analysis, Research **U.S. ex rel. Chao v. Medtronic PLC (C.D. Cal. Feb. 23, 2022)**	• Non-intervened case where an HCP / relator alleged that Medtronic violated the AKS and the FCA by paying HCPs for: proctoring; data analysis services; uploading patient and procedure data to registries; and research (e.g., grants). • The HCP / relator also alleged that Medtronic purchased entities in which other HCPs had ownership interests for inflated amounts. • The court denied Medtronic's motion to dismiss: "A payor violates the [AKS] whenever one purpose of the remuneration is to induce future referrals or orders, even if the payments were also intended to compensate for professional services."
2. Training-Related Payments **U.S. ex rel. Bell v. Biotronik, Inc. (C.D. Cal. 2022)**	• Biotronik resolved AKS-based FCA enforcement action for $12.95M, with $2.1M going to two former sales reps who filed a *qui tam* complaint. • DOJ alleged that the device company improperly paid "favored" surgeons training fees associated with a new employee training program, even where the training events did not occur or provided little to no educational value, during the period between 2013 and 2017.
3. Royalty Arrangements **U.S. ex rel. Shea v. Arthrex, Inc. (D. Mass. 2021)**	• Arthrex resolved FCA enforcement action for $16M. • DOJ alleged that the device company paid a surgeon improper, inflated royalty payments. According to DOJ, the surgeon, after being denied royalties in 2006, threatened to shift to an Arthrex competitor, which led the company to enter a 2010 royalty arrangement under which it back paid royalties and agreed to a higher-than-normal royalty percentage for future sales. IP or royalty arrangements to preserve a customer relationship or ward off competitors are likely to generate scrutiny.

Product | Practice Support – Key Risks

Relators and DOJ have asserted a wide variety of AKS theories based on the provision of "free" or low cost product support services and equipment, such as:

- Reimbursement and coding support
- Specialized training or practice consulting
- Find-a-doctor websites or similar marketing support (e.g., pharmaceutical companies' telehealth platforms linking patients to prescribers)
- Free computers or devices to facilitate use of patient care software or services
- Clinical support (e.g., nursing services)

OIG guidance focuses on whether the product support service or item has independent value from the purchased service or item. OIG evaluates the intent of the parties in a variety of ways, including looking at:

- Conditions or criteria for using the free service or equipment
- Procedures used by either party to monitor for unauthorized use
- Comparative value of item/service to the core item/service that is purchased
- Availability of the arrangement to other customers

"[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)

Discount and Rebate Arrangements – Key Issues

Manufacturers may offer purchasers (e.g., distributors / wholesalers, GPOs) price concessions, discounts, and rebates, but can be scrutinized for adherence to the discount AKS exception and/or safe harbor.

DOJ is leveraging the FCA to target manufacturers that induce product purchases with discounts, rebates, or prebates that fall outside the safe harbor's protection.

Discount arrangements that could draw scrutiny without necessary safeguards include:

- Upfront discounts / prebates / signing bonuses
- Exclusivity or utilization-based commitments
- Product (and/or service) bundles / discounts contingent on other purchases

Service Contracts with AKS Violations – Case Studies

1. Wrap-Around Physician Support **ChristianaCare (2024)**	• The hospital system paid $47.1M to resolve FCA allegations. The relator alleged that ChristianaCare provided prohibited remuneration in the form of free services from ancillary support providers (including nurse practitioners, hospitalists, and physician assistants) to private physicians with contracts to manage care in the system's neonatal unit. • The lawsuit claimed that the free ancillary services were intended to induce physicians to refer patients to ChristianaCare hospitals, thereby creating improper financial relationships with the non-employee providers.
2. Commission-Based Payments **Admera Health (2024)**	• Admera agreed to pay ~$5.3M to resolve allegations that it violated the FCA by paying commissions to third party independent contractor marketers. • DOJ alleged that from Sept. 2014 through May 2021 Admera—a biopharmaceutical research and laboratory testing provider—made commission-based payments to contractor marketers in return for recommending or arranging for the ordering of genetic testing services reimbursable by Medicare and Medicaid. • Admera admitted to paying millions in commissions to marketers to induce health care providers to order and refer clinical laboratory services, despite being informed that these payments violated the AKS.
3. Flawed Fair Market Value Analysis **Cardiac Imaging Inc. (CII) (2023)**	• The PET scan provider and its CEO resolved AKS-based FCA and Stark Law enforcement action for $85M. • DOJ alleged that CII paid kickbacks to referring cardiologists by offering fees of $500 or more per hour, which exceeded fair market value, for supervising PET scans. CII relied on a consultant's flawed fair market value analysis that the government alleges CII knew was premised on inaccuracies and was later withdrawn.

Medical Necessity and Physician Decision-Making – Case Studies

1. Independent Physician Evaluations **Cape Cod Hospital (2024)**	• The hospital paid $24.3M to resolve FCA allegations that it knowingly submitted non-compliant claims to Medicare for transcatheter aortic valve replacement (TAVR) procedures. • At the time, Medicare required specific clinical personnel to independently evaluate patients' suitability for TAVR, document their clinical judgment, and share it with patients' medical team. • From 2015 to 2022, the hospital allegedly submitted hundreds of claims that did not meet these requirements. Issues included insufficient physician evaluations and failure to document and share clinical judgments.
2. Default Testing **Gamma Healthcare Inc. (2024)**	• The laboratory and three owners paid $13.6M to resolve allegations of violating the FCA by submitting claims to Medicare for lab tests that were neither ordered by healthcare providers nor medically necessary. • Gamma allegedly submitted claims for unnecessary polymerase chain reaction (PCR) urinalysis tests that were not ordered by treating physicians. When a physician ordered a urinalysis (UA) with culture and sensitivity (C&S) or just a C&S, Gamma allegedly automatically performed and billed for a urinary tract infection (UTI) panel of tests by PCR. • Gamma's requisition forms allegedly did not allow physicians to opt out of the UTI PCR Tests.
3. Requisite Documentation **Appalachian Regional Healthcare, Inc. (2023)**	• The Kentucky hospital system and one of its physicians paid $3M to resolve allegations that they violated the FCA by submitting claims for non-covered procedures. • The government alleged that the hospital and physician billed federal healthcare programs for reimbursement of services without the requisite documentation to support medical necessity of those services. This included billing for medically unnecessary appointments in the days preceding patients' diagnostics and admission to the hospital. • This was a self-disclosure case, and the government stated that its recovery was limited to 1.5 times the amount of monetary loss caused by the alleged false claims.

HOT TOPICS FOR DRUG AND DEVICE COMPANIES

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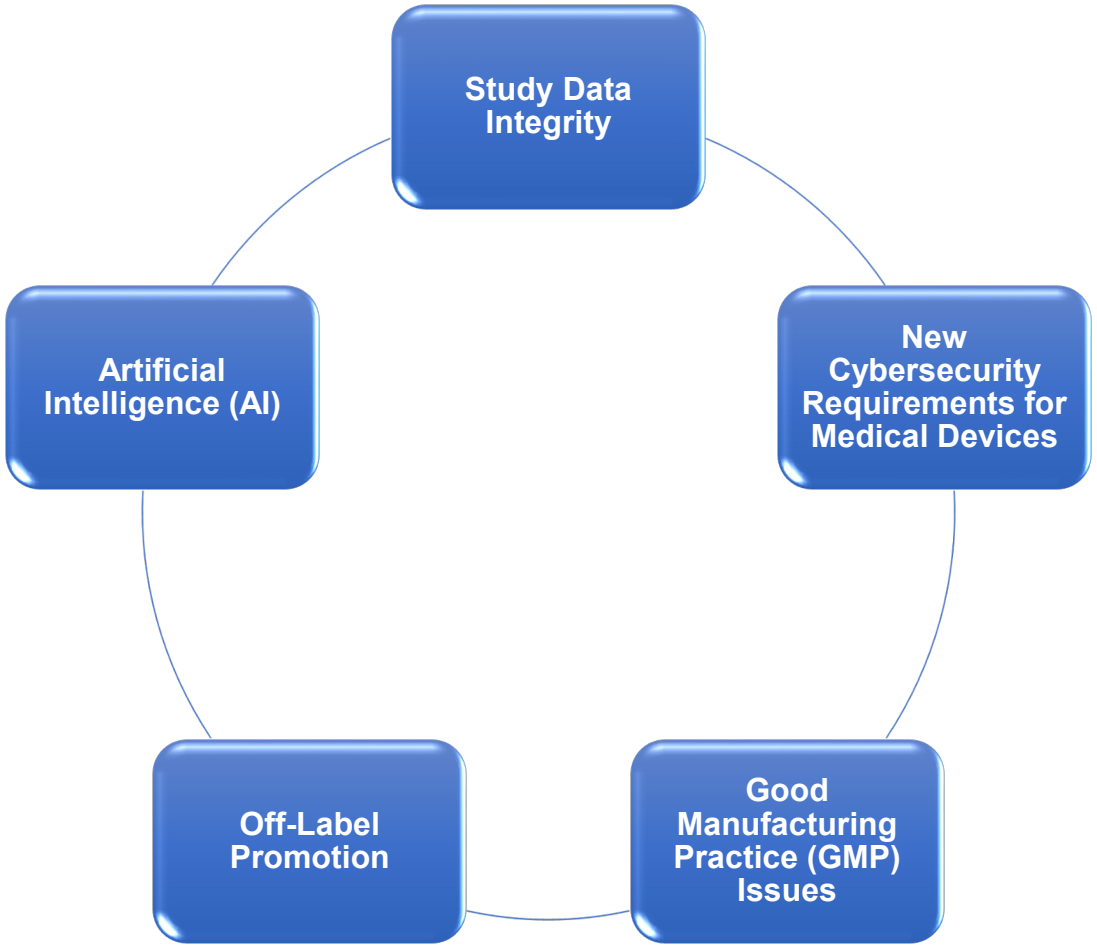
FCA enforcement arising from violations of the FDCA and FDA regulations is a key risk area for life sciences companies.

Areas of FCA risk arising from FDCA violations include:



STUDY DATA INTEGRITY

Identifying and addressing **fraud in clinical trials and other studies submitted to FDA** remains a top priority for FDA and DOJ.

- DOJ "has been aggressive" in the space, prosecuting dozens of clinical investigators.
- DOJ is considering a "leniency" regime to encourage sponsors to report suspect data from CROs or clinical investigators.

Looking Upstream

- FDA's Center for Drug Evaluation and Research (CDER) and DOJ are increasingly focused on CROs and sponsors—four sponsor-directed warning letters in 2023 and numerous criminal investigations opened into sponsors.
  - In February 2024, FDA issued an announcement to medical device study sponsors and manufacturers to "carefully evaluate" third parties used for performance testing and "independently verify all testing results before submitting to the FDA," following an increase in submissions containing unreliable third-party-generated data, particularly from facilities based in China and India.
- While sponsors are encouraged to work with labs that are voluntarily accredited under the Accreditation Scheme for Conformity Assessment (ASCA) program, this is not a substitute for sponsors independently assessing all third-party data.

STUDY DATA INTEGRITY (cont'd)

The FCA Overlay

Study data integrity issues can lead to FCA enforcement, including based on:

- Improper billing for physician services and hospital outpatient and inpatient care for Medicare / Medicaid patients (e.g., for costs already covered by research grants or routine care costs) (Moffitt Cancer Center (2024));
- Failure to disclose an applicant's (e.g., principal investigator) ties to foreign governments in grant applications to NIH, FDA (Cleveland Clinic (2024)); Van Andel Research Institute (2019, 2021)); and
- Alleged incorrect data or statements in grant applications (Purdue University (2023); Duke University (2019); Partners Healthcare / Brigham; and Women's Hospital (2017)).

Potential Fraud-on-the-FDA Hook?

- Fraudulent data submitted in an application could give rise to FCA liability under the "fraud-on-the-FDA" theory, under which a misrepresentation to the FDA in the approval or clearance process renders subsequent claims for payment for the device (e.g., by Medicare and Medicaid) false under the FCA.
- The theory is controversial: The First Circuit rejected it due to lack of a causal link between representations to the FDA and payments by CMS (*D'Agostino v. EV3, Inc.*).
  - But, the Ninth Circuit let two cases proceed on this theory (*Dan Abrams Co. v. Medtronic, Inc.*; *U.S. ex rel. Campie v. Gilead Sciences, Inc.*).

STUDY DATA INTEGRITY (cont'd)

Other Risk Areas with Study Data Integrity

Study data integrity issues could also lead to other consequences for life sciences companies, including:

- Failure to obtain approval or clearances;
- Invocation of FDA's Fraud / Application Integrity Policy (56 Fed. Reg. 46191 (Sept. 10, 1991)), which could result in delays or revocation of approval or clearance for future, pending, or even previously approved or cleared applications or notifications;
- Debarment of companies or individuals by FDA under 21 U.S.C. § 335a; and
- Disqualification of investigators from participating in clinical trials under 21 C.F.R. §§ 312.70 and 812.119.

Cybersecurity in Premarket Submissions

- Under FDCA section 524B, enacted as part of the Food and Drug Omnibus Reform Act in December 2022, premarket submissions for "cyber devices" must contain cybersecurity information.
- Broad definition of "cyber device:" any device that (1) includes software validated, installed, or authorized by the sponsor as a device or in a device; (2) has the ability to connect to the internet; and (3) contains any technological characteristics validated, installed, or authorized by the sponsor that could be vulnerable to cybersecurity threats.
- Premarket submissions (510(k), de novo, PMA) must include plans to address cybersecurity vulnerabilities, processes to provide reasonable assurance that devices are cybersecure, a software bill of materials, and other information as the Secretary requires.
- September 2023 FDA final guidance emphasizes that cybersecurity is part of device system and QSR (future QMSR), and secure product development framework (SPDF) may satisfy QSR / QMSR requirements.
- Guidance also includes recommendations for labeling cybersecurity management plans.
- March 2024 draft guidance provides additional recommendations on documentation and determining when a product modification may impact cybersecurity.

CYBERSECURITY REQUIREMENTS FOR DEVICE MANUFACTURERS

FCA Risk from Cybersecurity Disclosures

- FDCA section 524B creates FCA risks in the form of a "fraud-on-the-FDA" theory of liability.
- Cybersecurity disclosures in device applications fall squarely in DOJ's Civil Cyber-Fraud Initiative.
- Uses the FCA to pursue "cybersecurity related fraud by government contractors and grant recipients."
- "Fraud" includes "knowingly providing deficient cybersecurity products or services, knowingly misrepresenting their cybersecurity practices or protocols, or knowingly violating obligations to monitor and report cybersecurity incidents and breaches."
- Statements and representations in applications beyond clinical or other study data could give rise to FCA liability as "fraud on the FDA."
- Advanced Bionics (2022): $12M settlement based on fraudulent statements in PMAs that cochlear implants complied with international radio-frequency testing standards, regardless of whether any safety issues were identified arising from noncompliance with that standard.

GMP ISSUES

Protecting the Public Health

Safety and integrity of drugs and medical devices is a key concern for DOJ and FDA.

- FDA and DOJ are highly reactive to whistleblowers and press reports.
- Most common inspection findings in FDA's Compliance: Devices and Drug Quality Assurance project areas (2009-2024) include inadequate or unwritten required procedures; deficiencies with purchasing controls, process validation, documentation, and laboratory controls; and inadequate quality investigations.

Recent FDA updates for drug and medical device quality and integrity include:

- Feb. 2024 publication of Quality Management System Regulation (QMSR) final rule: largely replaces existing medical device quality requirements with ISO 13485 and comes into effect in Feb. 2026.
- Note: some FDA-specific requirements (e.g., for unique device identification, complaint handling, and servicing) still present.
- Certain notable omissions from prior regulations, including the removal of the exemption from FDA inspection of management review, quality audits, and supplier audit reports, which could increase exposure.

GMP ISSUES (cont'd)

GMP and FCA Liability

Both drug and medical device manufacturers have faced significant FCA liability for GMP issues.

- Claims submitted for products that materially differed from, or fell below, strength, purity, and/or quality standards approved by FDA.
- Stimwave Technologies (2023): alleged implanted nonfunctional device components that, among other things, were marketed in violation of the company's design and document control SOPs.
- GSK (2010): drugs manufactured by GSK subsidiary that allegedly contained issues with, among other things, sterility, contamination, split tablets, and alleged failure to investigate and remediate those issues.
- KVK (2024): KVK Tech agreed to payment to resolve FCA liability arising from the company's failure to exercise appropriate controls as required by GMP.

OFF-LABEL PROMOTION

Significant Liabilities, Broad Exposure

Off-label promotion is a common area of FCA enforcement for drug and medical device manufacturers and can result in significant financial liabilities.

- Bayer (2022): $40M settlement for allegedly promoting Trasylol and Avelox for off-label, unreasonable, and medically unnecessary uses, and for allegedly downplaying safety risks of Trasylol and Baycol.
- Insys (2019): $225M global resolution of criminal and civil investigations relating to alleged sham speaker programs targeting actual or potential high-prescribing HCPs for its opioid therapy Subsys.
- Abbott Laboratories / AbbVie Inc. (2018): $25M settlement for allegedly promoting hypertriglyceridemia drug TriCor for unapproved uses, including reducing CV risk, combination use with statins, and as first-line treatment for diabetic patients.

"Promotion" is a broad concept, which can include, among other things:

- HCP- or patient-facing promotional websites, physical materials, and other content.
- Oral statements by company representatives, including speaker programs and in-person conversations.

Liability under the FDCA—and potentially under the FCA—arises when a manufacturer "promotes" a product for an intended use that is not consistent with the FDA-approved labeling.

OFF-LABEL PROMOTION (cont'd)

October 2023 Revised Draft Guidance on Communications Regarding Scientific Information on Unapproved Uses of Approved / Cleared Medical Products (SIUU)

- SIUU consistent with the draft guidance not considered evidence of intended use.
- New standard for publications that can support SIUU communications: "scientifically sound and provide clinically relevant information."
- Should include disclosures to ensure SIUU communications are truthful and non-misleading (including re: approved / unapproved uses for a product, labeling restrictions and safety information, and material aspects / limitations of study design).
- New recommendations for firm-generated presentations of information from a reprint.

July 2024 Draft Guidance on Addressing Misinformation about Medical Products

- Responsive communications that identify and address misinformation about an approved or cleared medical product not considered subject to labeling / advertising and postmarketing submission / treated as evidence of new intended use if:
- Truthful and accurate;
- Scientifically sound;
- Directly relevant and responsive to identified misinformation; and
- Limited to information necessary to address the identified misinformation and any recommended disclosures (e.g., mechanism to obtain FDA-required labeling, date of response, disclosure that the response is shared by the firm, and disclosures about approved and unapproved uses).

Artificial Intelligence

- AI is a rapidly evolving field with significant implications for drug and device companies. It encompasses potential applications in a wide range of areas, such as clinical research, the development of medical products, and patient care.

- DOJ, federal and state regulators, and relators are keenly focused on the impact of AI-driven decision-making in health care and health sciences to try and identify patterns of claims or conduct suggestive of fraud.

    - DOJ FCA Civil Investigative Demands have asked about algorithms or clinical diagnostic alerts or prompts bolted on to EHR systems.

    - The Colorado Artificial Intelligence Act, effective 2026, requires developers of AI and entities that use it to protect consumers from high-risk AI systems and algorithmic discrimination in health care services (and other areas).

- It is highly likely that a key area of focus will be the use of AI in clinical decision-making, particularly in determining medical necessity.

COMPLIANCE BEST PRACTICES

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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 FDCA violations 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

Proactive Monitoring Strategies Speaker Fee Example

Pharmaceutical manufacturers and other life sciences companies use a range of data to support compliance monitoring activities.

Sources of Data	Controls / Policies	Monitoring Activity
Oracle Financials, SAP, Compass Quality Management System, Salesforce, Internal Trackers, NAVEX Global	Vetting and onboarding of HCPs	HCP-type expenses (e.g. speaker fees) with vendors not identified as HCPs, not vetted
	Fair market value	Expenses outside of norms for engagement type, tracking cumulative spend
	Reasonable venues for events	Mapping of expense and payment locations, repeat venue usage, travel expenses incurred
	Agreement in place prior to service	Alignment of key dates: contract date, event date, purchase orders, invoices, payments
	Attendance sign-in sheets completed	Attendees (including compliance/employees), receipt of information was appropriate, minimum standards met
	Modest meals	Overall meal spend; spend per attendee
	Event relevant to specialty	Event therapeutic area v. HCP specialty

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

Investigation DOJ Expectations

Prosecutors assess the company's processes for handling investigations of complaints.

DOJ's **Evaluation of Corporate Compliance Programs** emphasizes the importance of:

- Appropriately scoping investigations and following up on red flags;
- Ensuring investigations are conducted by qualified, objective personnel;
- Properly documenting investigation findings;
- Applying timing metrics to ensure responsiveness and timely resolution of complaints;
- Monitoring the outcome of investigations and ensuring accountability for the response to any findings or recommendations;
- Providing sufficient funding for reporting and investigation mechanisms;
- Periodically analyzing reports or investigation findings for patterns of misconduct or other red flags;
- Periodically testing the effectiveness of the hotline (i.e., by tracking a report from start to finish).

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Questions?

Upcoming Programs – Fall White Collar Webcast Series

Date and Time	Program	Registration Link
Wednesday, November 13, 2024 **3:00 PM – 4:00 PM ET** **12:00 PM – 1:00 PM PT**	**Government Investigations into AI Systems** Presenters: Eric Vandevelde, Chris Whittaker, Poonam Kumar	Event Details
Thursday, November 14, 2024 **12:00 PM – 1:00 PM ET** **9:00 AM – 10:00 AM PT**	**Criminal Antitrust Enforcement: A Preview of Priorities for the New Administration and Implications for Corporate Compliance Programs** Presenters: Scott Hammond, Jeremy Robison, Alexandra Buettner	Event Details
Thursday, November 21, 2024 **11:00 AM – 12:00 PM ET** **8:00 AM – 9:00 AM PT** **4:00 PM – 5:00 PM BST**	**Investigations: A UK Perspective** Presenters: Allan Neil, Matthew Nunan, Amy Cooke, Marija Brackovic	Event Details
Wednesday, December 4, 2024 **12:00 PM – 1:00 PM ET** **9:00 AM – 10:00 AM PT**	**FARA and CFIUS Enforcement** Presenters: David Burns, Stephenie Gosnell Handler, Amanda Neely	Event Details

1700 M Street, N.W., Washington, D.C. 20036-4504

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Katlin McKelvie is a partner in the Washington, D.C. office of Gibson, Dunn & Crutcher and a member of the firm's Food and Drug Administration (FDA) and Health Care Practice Group. With over two decades of experience in food and drug law, including as Deputy General Counsel of the Department of Health and Human Services (HHS), Katlin offers clients expansive knowledge of the complex legal and policy issues associated with FDA regulation of food, drugs, medical devices, and cosmetics.

As Deputy General Counsel at HHS, Katlin was responsible for advising senior HHS officials on FDA-related regulatory, enforcement, and litigation matters. Prior to joining HHS, she served as Deputy Health Policy Director and Senior FDA Counsel to the Senate Committee on Health, Education, Labor, and Pensions for Chair Patty Murray. As Committee staff, Katlin played a pivotal role in shaping multiple pieces of legislation the FDA is currently working to implement, most notably the Coronavirus Aid, Relief, and Economic Security (CARES) Act and the Food and Drug Omnibus Reform Act of 2022 (FDORA). Before her time in the Senate, Katlin spent 11 years at FDA, first as Regulatory Counsel in the Office of Prescription Drug Promotion in the Center for Drug Evaluation and Research and then as Associate Chief Counsel for Drugs in the Office of the Chief Counsel.

Katlin received her undergraduate degree, *cum laude*, with honors from Davidson College, and her J.D., *cum laude*, from the Georgetown University Law Center, where she was Executive Editor of *The Georgetown Law Journal*. She clerked for Judge Douglas P. Woodlock on the U.S. District Court for the District of Massachusetts and then worked in private practice with a focus on food and drug law. Katlin is admitted to practice law in the District of Columbia.

Katlin's full biography can be viewed here.

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John Partridge, a Co-Chair of Gibson Dunn's FDA and Health Care Practice Group and *Chambers*-ranked white collar defense and government investigations lawyer, focuses on government and internal investigations, white collar defense, and complex litigation for clients in the life science and health care industries, among others. John has particular experience with the Anti-Kickback Statute, the False Claims Act, the Foreign Corrupt Practices Act, and the Federal Food, Drug, and Cosmetic Act, including defending major corporations in investigations pursued by the U.S. Department of Justice (DOJ) and the U.S. Securities and Exchange Commission (SEC). In its rankings, *Chambers & Partners* has reported that John's clients regard him as a "smart and strategic tactician," "incredibly responsive and thorough," and "extremely knowledgeable." In 2022, John was recognized by *BTI* as a Client Service All-Star.

John has defended clients in criminal and civil enforcement actions relating to alleged health care fraud and abuse, including actions conducted by DOJ, the U.S. Food and Drug Administration's Office of Criminal Investigations, the Department of Health and Human Services Office of Inspector General, and State Attorneys General. His substantive experience includes cases involving allegations tied to, among other things, clinical trials, drug pricing, importation of regulated products, off-label promotion, product manufacturing issues, sampling practices, and anti-kickback issues relating to speaker programs, meals and travel, consulting arrangements, product support activities, patient support programs, physician locators, royalties, and investment interests.

John received his J.D., with distinction, from Stanford Law School in 2007. While there, he served as an Executive Editor of the *Stanford Law Review* and was awarded the Law Review's Board of Editors' Award. John graduated *magna cum laude* and Phi Beta Kappa from Dartmouth College in 2002 with a B.A. in History and Psychology. Before joining Gibson Dunn, John clerked for the Honorable David M. Ebel of the United States Court of Appeals for the Tenth Circuit from 2007 to 2008.

John serves as a member of Gibson Dunn's Pro Bono and Hiring Committees-and as a Hiring Partner for Gibson Dunn's Denver office. He also is a member of the Board of Directors of KIPP Colorado, a network of six college-preparatory public charter schools serving students in several neighborhoods in Denver. In the past, he has served on the Board of Trustees of the Legal Aid Foundation of Colorado, a non-profit dedicated to supporting access to justice for low-income residents of Colorado.

John's full biography can be viewed here.

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Jonathan Phillips is a partner in the Washington, D.C. office of Gibson, Dunn & Crutcher, where he is a member of the firm's litigation department and Co-Chair of the FDA and Health Care Practice Group and False Claims Act/Qui Tam Defense Practice Group. A former DOJ Trial Attorney, his practice focuses on FDA and health care enforcement, compliance, and litigation, as well as other white collar enforcement matters and related litigation. Jon is ranked nationally as a leading False Claims Act practitioner by *Chambers USA*.

Jon has substantial experience representing health care, pharmaceutical, and medical device clients in civil and criminal enforcement actions by the Department of Justice, Food and Drug Administration, Department of Health and Human Services Office of Inspector General, State Attorneys General, and other federal and state agencies, as well as related whistleblower litigation. He has particular experience representing clients in health care enforcement matters brought under the False Claims Act, the Anti-Kickback Statute, the Stark Law, and the Federal Food, Drug, and Cosmetic Act, and their state analogues on a wide variety of theories. He also regularly counsels clients on health care fraud and abuse compliance matters and conducts related internal investigations and risk assessments, including counseling Boards of Directors on health care compliance oversight matters and related government and shareholder litigation. Jon also has extensive experience defending government contractors and their affiliates in government investigations under the False Claims Act and related breach-of-contract theories, and in related government and whistleblower litigation. Jon has been recognized by *The Best Lawyers in America*® for his work in Health Care and Qui Tam Law (2023 - 2025) and named by *Washingtonian Magazine* as a "Top Lawyer" for Criminal Defense-White Collar (2022).

Prior to joining Gibson, Dunn & Crutcher, Jon served as a Trial Attorney in the Civil Division, Fraud Section of the U.S. Department of Justice, where he investigated and prosecuted allegations of fraud against the United States under the False Claims Act and related statutes. His work at DOJ included handling a variety of health care enforcement cases including allegations of pharmaceutical and device fraud, such as off-label promotion, adulterated products, and Anti-Kickback Statute violations, as well as a variety of other types of alleged Medicare and Medicaid provider fraud. Jon also investigated and tried cases involving bid rigging and other allegations of fraud by government contractors while at the DOJ.

Jon's full biography can be viewed here.

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Jim Zelenay is a partner in the Los Angeles office of Gibson, Dunn & Crutcher where he practices in the firm's Litigation Department. Jim has extensive experience in defending clients involved in white collar investigations, assisting clients in responding to government subpoenas, and in government civil fraud litigation.

Jim has been named as one of the Top 50 Litigators in Los Angeles by the *Los Angeles Business Journal* (2018), a list that highlights “50 of the very best litigators in the business.” He was selected by *Super Lawyers* as a “Rising Star” in the area of Business Litigation (2013-2018). Jim is also a recipient of the prestigious Burton Award for Distinguished Legal Writing and has written extensively on the False Claims Act.

Jim has represented clients in connection with alleged violations of environmental regulations, regulations governing trade with sanctioned countries, Department of Education rules and regulations, Food and Drug Administration regulations, Federal Emergency Management Agency regulations, government construction contracting matters, patent and telecommunication proceedings, and other administrative matters.

Jim also has substantial experience with the federal and state False Claims Acts and whistleblower litigation, in which he has represented a breadth of industries and clients, including educational institutions, financial institutions, insurers, pharmaceutical companies, construction companies, telecommunication clients, emergency services personnel, and accounting firms, among others. In addition to his white collar and False Claims Act practice, Jim has assisted clients in defending against class action complaints and legal malpractice claims, served as plaintiff’s counsel in actions alleging fraud and breach of contract, assisted clients with patent and other intellectual property matters, and advised and assisted clients in matters involving claims asserted under the First Amendment and other constitutional provisions.

Jim has also been recognized within Gibson Dunn for his pro bono work, including the work performed on assisting the California Science Center Foundation with the acquisition and transportation of the Space Shuttle Endeavour. Jim served on the Executive Committee and Board of Directors for Pasadena Heritage, California’s second largest historical preservation organization.

Jim’s full biography can be viewed here.

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