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**Hot Topics in Fraud and Abuse Enforcement
Involving Health Care Providers**

Stephen C. Payne (moderator)
Winston Y. Chan
John D. W. Partridge
Jonathan M. Phillips

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Agenda

- **Applicable Law**
- **Enforcement Trends**
- **Enforcement Theories**
- **Recent Legal Developments**
- **Questions**

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Applicable Law

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 (except in declined *qui tam* cases).



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

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

FCA – Key Provisions

31 U.S.C. § 3729(a)(1)	Statutory Prohibition	Summary
(A)	Knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval	False/Fraudulent Claim
(B)	Knowingly makes, uses or causes to be made or used, a false record or statement material to a false or fraudulent claim	False Record/Statement
(C)	Knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government	“Reverse” False Claim
(G)	Conspires to violate a liability provision of the FCA	Conspiracy

FCA – Overview of Key FCA Theories

Factual Falsity

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

Legal Falsity / False Certification

- Express certification of compliance with legal requirements
- Submission of claim with representations rendered misleading as to goods / services provided

Promissory Fraud / Fraud in the Inducement

- Obtaining a contract through false statements or fraudulent conduct
- *U.S. ex rel. Marcus v. Hess*, 317 U.S. 537 (1943) (claims by contractors who colluded on bids)

Reverse False Claims

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

The False Claims Act (FCA) – *Qui Tam* Provisions

- ***Qui Tam* Provisions**

- Enable so-called “relators” to bring cases in the government’s name and recover as much as 30% of favorable judgment or recovery
- Allow government to intervene
 - An increasing number of whistleblower cases are pursued without government intervention (but often with government statement of interest)

- **FCA Whistleblower Protections (31 U.S.C. § 3730(h))**

- Protects employees and others (e.g., contract workers)
- Relief may include:
 - Double back pay and interest on back pay;
 - Reinstatement (at seniority level); and
 - Costs and attorneys’ fees



“In short, sir, I have based the [*qui tam* provision] upon the old-fashioned idea of holding out a temptation and ‘**setting a rogue to catch a rogue,**’ which is the safest and most expeditious way I have ever discovered of bringing rogues to justice.”

Statement of Senator Howard, Cong. Globe,
37th Cong. 955-56 (1863)

The Anti-Kickback Statute (AKS)

- The AKS, 42 U.S.C. § 1320a-7b(b), criminalizes
 - **knowing and willful**
 - **payment (or offers) 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.
- **DOJ** and **HHS OIG** are the dual enforcers of the AKS and the CMP equivalent.



The Anti-Kickback Statute (AKS)

- **Remuneration** includes anything of value, such as:
 - Cash, gifts, hospitality
 - Free or discounted rent
 - Compensation for medical directorships
- **Statutory exceptions** and **regulatory safe harbors** protect certain payment and business practices that could otherwise implicate the AKS from criminal and civil prosecution, including certain:
 - Discounts
 - Payments to bona fide employees
 - Personal services / management contracts
 - Equipment / space rental contracts
- To be protected by a safe harbor, the arrangement must satisfy all of its requirements.



“In some industries, it is acceptable to reward those who refer business to you. **However, in the Federal health care programs, paying for referrals is a crime.**”

- HHS OIG, *A Roadmap for Physicians, Fraud and Abuse Laws*

Physician Self-Referral Law (Stark Law)

- The Stark Law, 42 U.S.C. § 1395nn, prohibits:
 - Physicians who have a financial relationship with a health care entity from referring patients to that entity to receive “designated health services” reimbursed by federal health care programs; and
 - The health care entity from submitting claims to federal health care programs for those services resulting from a prohibited referral.
- **DOJ** and **HHS OIG** are the dual enforcers of the Stark Law.



Physician Self-Referral Law (Stark Law)

- The Stark Law contains **multiple exceptions**.
- **Fair market value** compensation—so long as the value is independent of the value or volume of referrals—is generally permissible.
- **Designated health services** include:
 - Clinical laboratory services
 - Physical / occupational therapy services
 - Radiology / radiation services
 - DME / prosthetics / orthotics
 - Parenteral / enteral nutrients, equipment and supplies
 - Home health services
 - Inpatient and outpatient hospital services



“The Stark Law is ***intended to prevent overutilization of services by physicians who [stand] to profit*** from referring patients to facilities or entities”

U.S. ex rel. Drakeford

v. Tuomey Healthcare Sys.,

792 F.3d 364, 373 (4th Cir. 2015)

Applicable Law – Relationship of the Statutes

- The government and relators often pursue alleged AKS and Stark violations in tandem in FCA cases involving providers.
- Since PPACA, claims “**resulting from**” violations of the AKS are false for purposes of the FCA.
 - 42 U.S.C. § 1320a–7b(g)
 - *See, e.g., U.S. ex rel. Kester v. Novartis Pharms. Corp.*, 41 F. Supp. 3d 323, 331-33 (S.D.N.Y. 2014)
- Claims resulting from Stark Law violations also may be false for FCA purposes.
 - *See, e.g., U.S. ex rel. Drakeford v. Tuomey Healthcare Sys.*, 792 F.3d 364, 382 (4th Cir. 2015)

FCA – Damages and Penalties

- **Simple Damages Calculation**

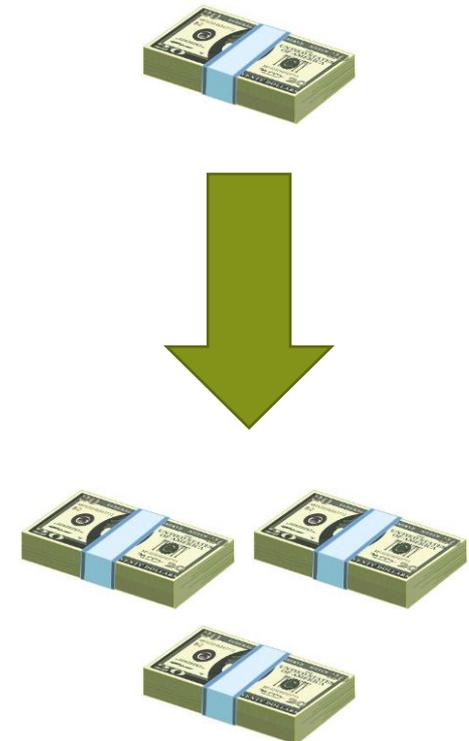
- Treble damages are traditionally calculated by multiplying the government's loss by three (e.g., if defendant charged government \$100 for goods not received, damages would be \$300).

- **Complex, Contested Damages Calculation**

- Calculations are more complicated (and less certain) when the government receives goods or services it considers deficient or when there is a “false certification” or “promissory fraud.”

- **Civil Per Claim Penalty**

- Previously \$5,500 to \$11,000
- Nearly doubled effective August 1, 2016 (~\$10,700 to ~\$21,500)



AKS and Stark Law – Penalties

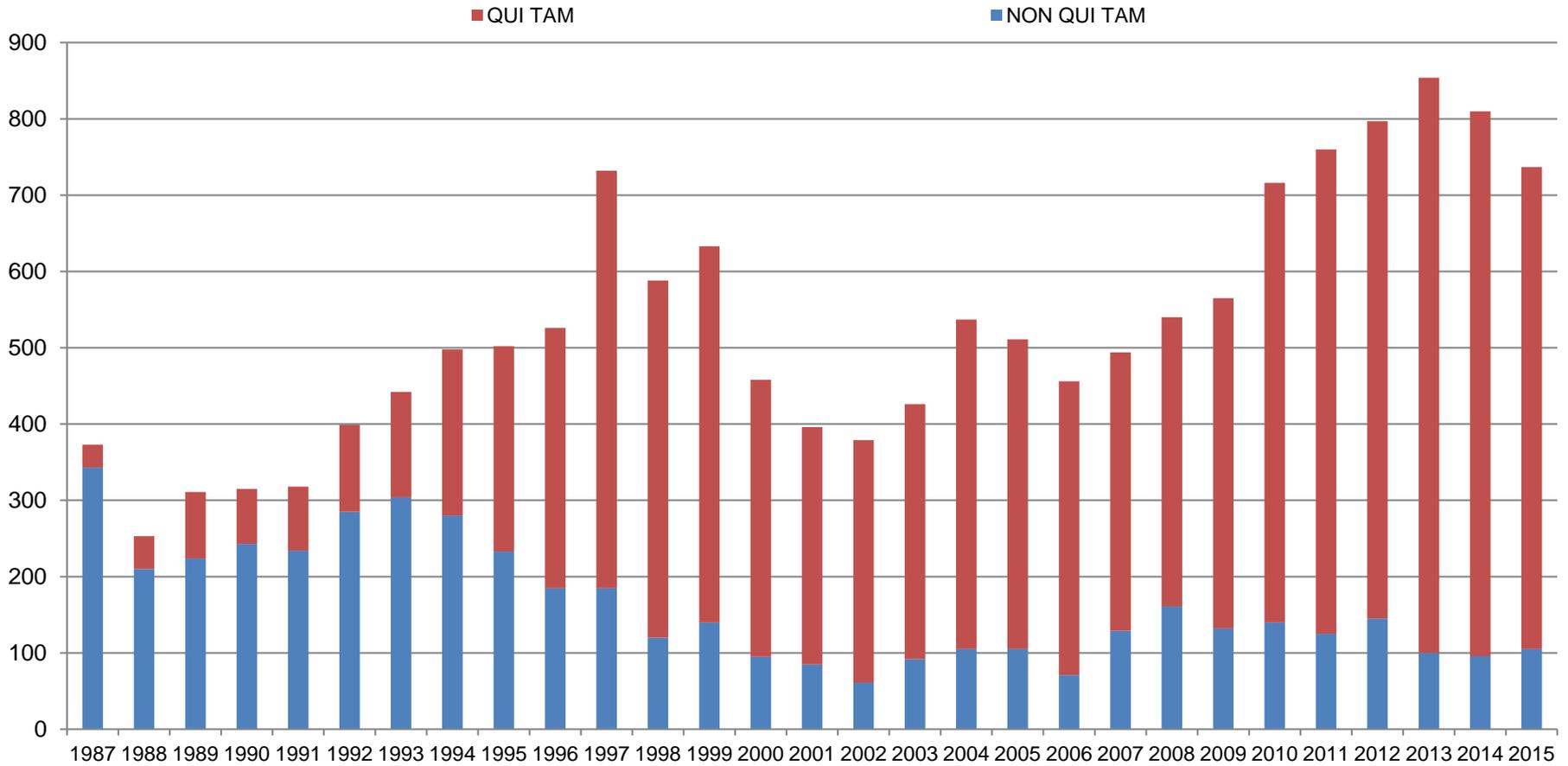
- **Potential consequences of AKS violation:**
 - Jail terms of up to five years
 - Fines of up to \$25,000 per violation or twice the alleged gain or loss
 - Exclusion from participation in federal health care programs
 - Civil penalties of up to \$50,000 per kickback plus three times the amount of remuneration
- **Potential consequences of Stark Law violations:**
 - Denial of payments
 - Refund of payments
 - Civil penalties of \$15,000 per service
 - Civil assessments of as much as three times the amount claimed

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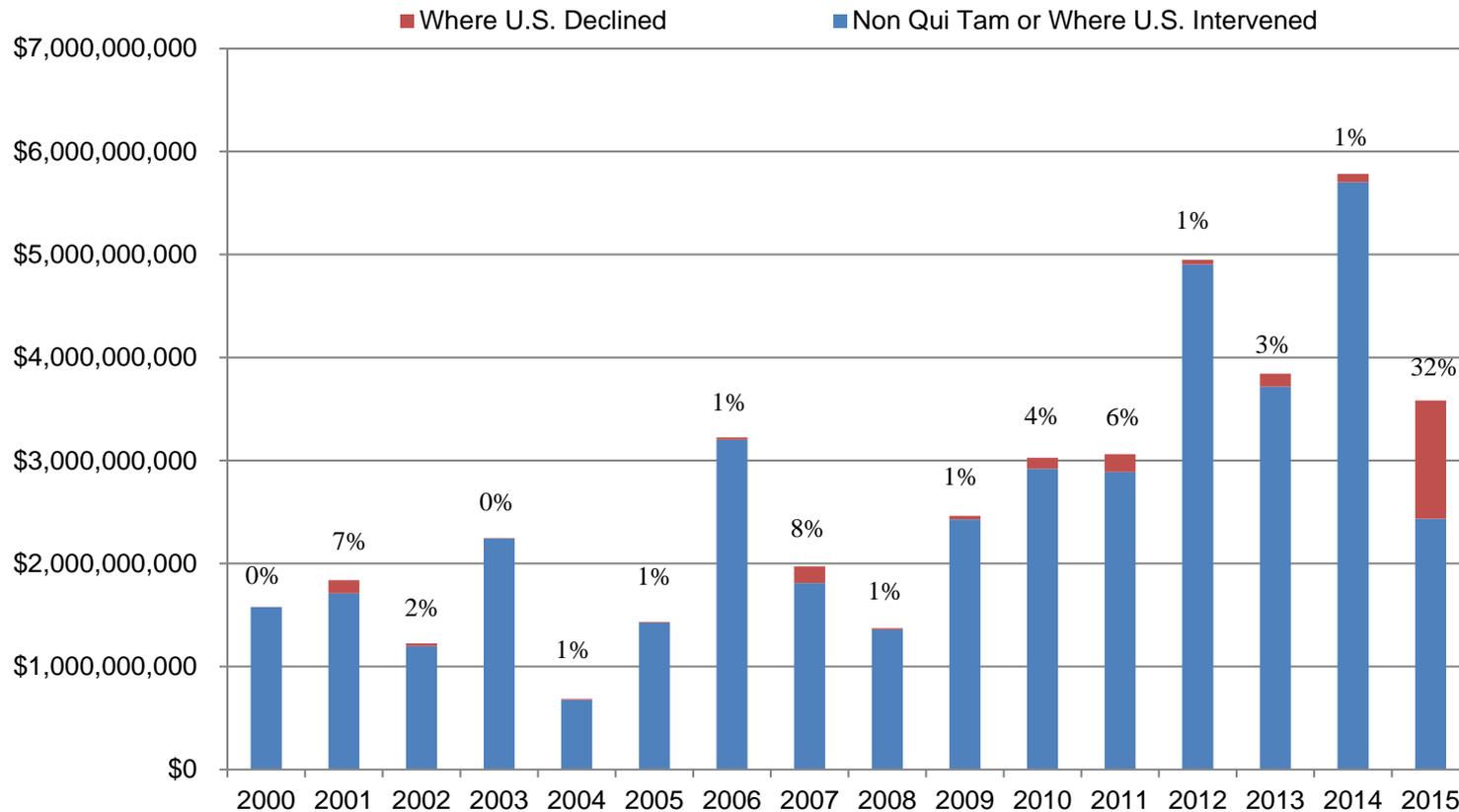
Enforcement Trends



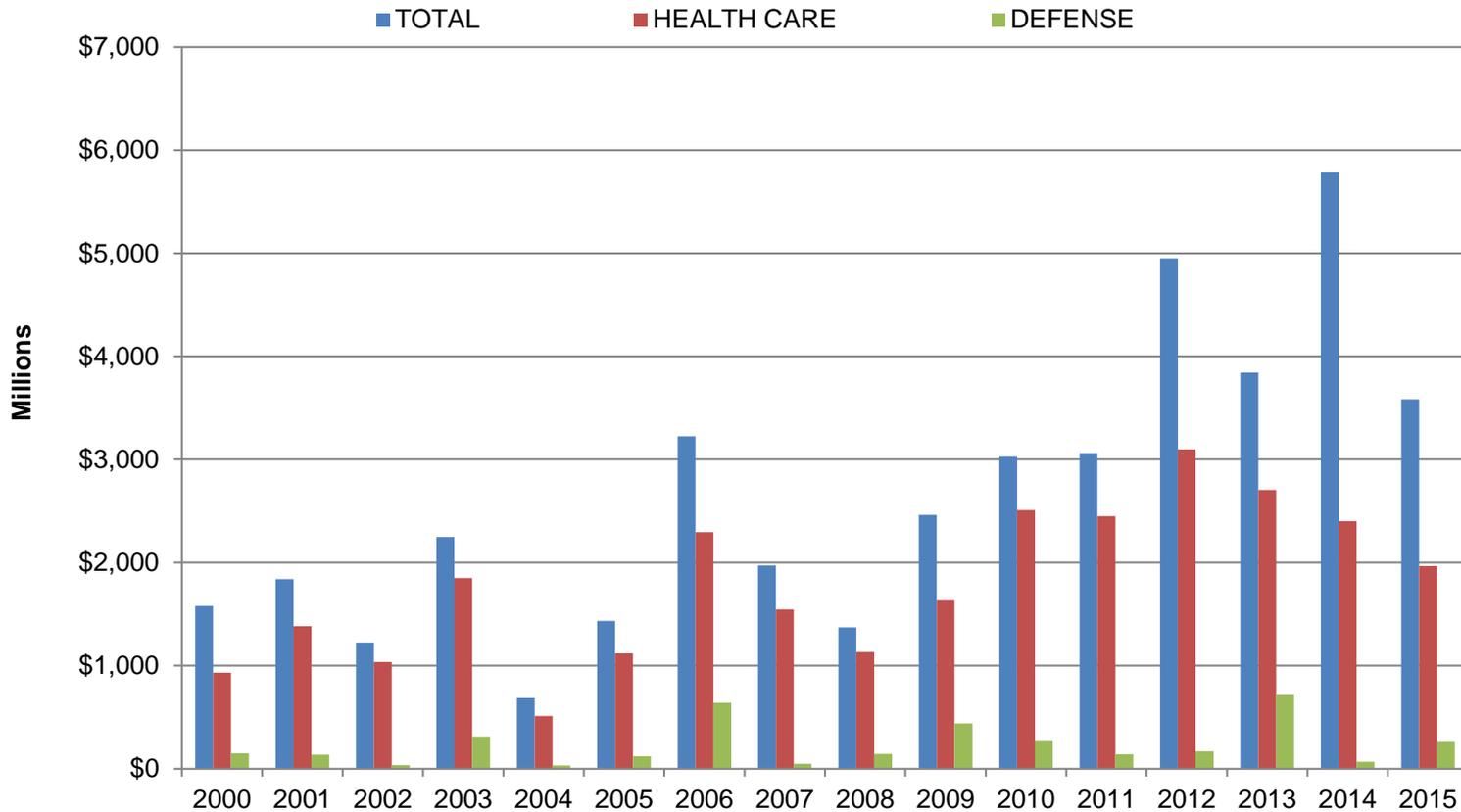
Number of New FCA Suits (1987 – 2015)



Declined Cases in FCA Settlements / Judgments



Health Care Industry FCA Settlements / Judgments



Enforcement Trend 1 – DOJ and HHS Resources

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

“Through [DOJ’s Criminal Division’s] Fraud Section, [DOJ] will be **committing more resources to this vital area, so that we can move swiftly and effectively to combat major fraud involving government programs.**”

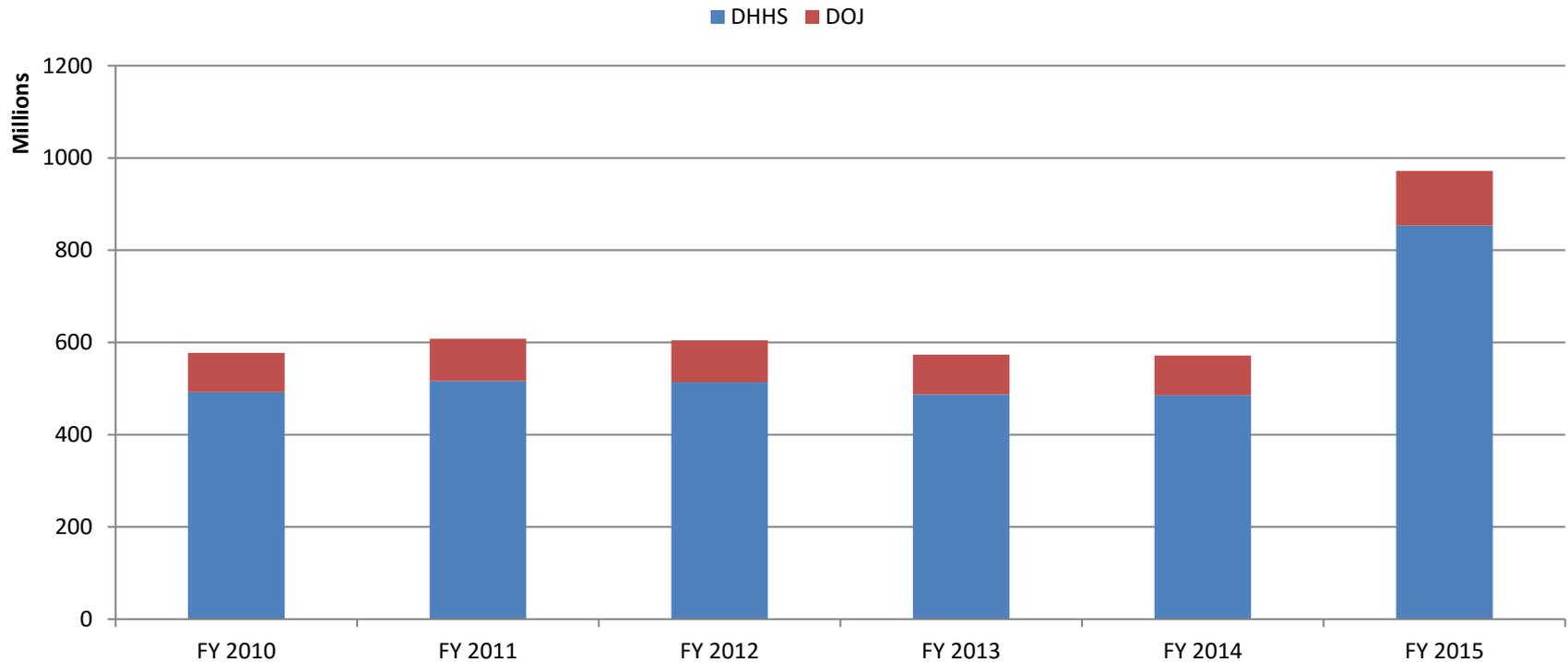
AAG for the Criminal Division Leslie R. Caldwell (Sept. 2014)



- New HHS OIG litigation team will focus on CMPs and exclusions in FCA-related cases DOJ opts not to pursue and in response to other referrals.

Enforcement Trend 1 – DOJ and HHS Resources

Expenditures by HHS and DOJ for Health Care Fraud and Abuse Control



Enforcement Trend 2 – Parallel Criminal & Civil Investigations

- In September 2014, DOJ announced that **all** *qui tam* complaints would be reviewed by criminal prosecutors for potential parallel criminal actions.

“We in the Criminal Division have **recently implemented a procedure** so that all new *qui tam* complaints are **shared by the Civil Division with the Criminal Division** as soon as the cases are filed.”

AAG for the Criminal Division Leslie R. Caldwell (Sept. 2014)



- As a result, more companies now face simultaneous investigations by civil and criminal investigators.

Enforcement Trend 2 – Parallel Criminal & Civil Investigations

- Two of the largest FCA settlements of 2016 so far resulted from **parallel criminal and civil** investigations of kickback allegations (\$646 million & \$514 million).
- **Effects of parallel criminal and civil investigations:**
 - Navigating DOJ requests for joint meetings
 - Potential implications for settlement
 - Effects on ability to litigate civil cases
 - Concerns about individual liability for officers and executives

Enforcement Trend 3 – Individual Liability – Enforcement

- **The focus on individual liability – and recent results:**
 - *Miami Facilities* (July 22, 2016)
 - The owner of more than 30 Miami-area skilled nursing and assisted living facilities, a hospital administrator, and a physician's assistant were charged with conspiracy, obstruction, money laundering, and health care fraud in connection with a \$1 billion scheme involving numerous Miami-based health care providers.
 - *Prime Healthcare Services Inc.* (May 25, 2016)
 - DOJ intervened in FCA suit against Prime and its CEO and founder, who allegedly pressured emergency department doctors to raise inpatient admission rates (regardless of medical necessity) and thereby caused the submission of false claims to federal health care programs.

Enforcement Trend 4 – Active *Qui Tam* Bar

- Record number of *qui tam* suits filed four years in a row
- In 2015, 32% of total *qui tam* suit recoveries came in cases in which the government declined to intervene.
- Bigger, more sophisticated firms representing relators
 - Application of big firm resources to investigations allows relators to drive up fees.
- DOJ attorneys often use relators' counsel to advance pre-election investigations more quickly and efficiently, which results in more access to investigative findings for relators' counsel.



Enforcement Trend 5 – Efforts to Erode the Scierter Standard

- Increasing number of cases that lack the “badges of fraud” previously required for liability, including cases targeting technical violations of:
 - Contractual requirements
 - Agency rules and regulations
 - Policies and procedures
- Result of increase in cases brought by relators’ counsel who are incited to lower the scierter threshold and the difficulty of defining and providing culpable scierter
- Efforts to impose corporate liability based on subsidiary conduct (despite scierter requirement)



“Strict enforcement of the FCA’s scierter requirement will also help to ensure that ordinary breaches of contract are not converted into FCA liability.”

United States v. Sci. Applications Int’l Corp., 626 F.3d 1257, 1271 (D.C. Cir. 2010)

Enforcement Trend 6 – Corporate Integrity Agreements

- HHS OIG continues to insist on CIAs as a condition for settling administrative actions.
- CIAs are rigorous and may contain terms requiring a provider to:

- | | |
|--|--|
| • establish a compliance program with board and executive oversight | • provide periodic reports regarding compliance |
| • retain independent monitors to oversee and audit compensation agreements | • train board members, executives, employees, and third parties |
| • retain independent advisors to assess effectiveness of compliance programs | • and other terms as necessary to target provider's alleged violation(s) |

Enforcement Trend 6 – CIA Trends

- **Actions to enforce terms of CIAs**

- In 2016, a hospice and home health provider paid a record \$3 million for violations of its CIA.
- In 2015, a renal dialysis provider agreed to pay \$450,000 for alleged violations of its CIA.



Enforcement Trend 7 – Data Mining

- Use of data mining and quantitative analysis to develop leads and expand existing cases.
- DOJ may use early data analysis to probe whether and how allegations should be investigated further.
- DOJ and HHS have
 - **expanded data sharing;**
 - improved information-sharing procedures; and
 - **used advanced data analysis techniques** to identify aberrant billing levels in health care fraud “hot spots”—cities with high levels of billing fraud—and target suspicious billing patterns.
- This “get[s] ***critical data and information into the hands of law enforcement*** to track patterns of fraud and abuse”



Enforcement Trend 8 – RICO Suits

- Private companies and competitors are increasingly turning to RICO lawsuits to address private sector false claims.
- The Racketeering Influenced and Corrupt Organizations Act (RICO), 18 U.S.C. §§ 1961 *et seq.*, takes aim at racketeering and organized crime.
 - RICO prohibits conducting the affairs of an enterprise through a “pattern of racketeering activity” (and conspiring to do so).
 - RICO defines “racketeering activity” by reference to a series of federal and state crimes.
- Under the statute, “[**a**]ny **person injured in his business or property** by reason of a violation” of RICO may sue in federal district court and recover treble damages, costs and attorneys’ fees.



RICO – FCA-Like Provider Suits

- *Aetna Life Ins. Co. v. Behar (S.D. Tex.)*
 - Aetna sued Houston-based hospital based on alleged kickbacks to providers.
 - Aetna seeks as much as \$120 million.
- GEICO goes on a tear, and sues (among others):
 - Massachusetts chiropractic / sports injury clinic, alleging that it overbilled for services provided by unlicensed staff and provided kickbacks to patients (D. Mass. Oct. 2015).
 - New York medical companies, alleging that they fraudulently billed for medical / physical therapy (E.D.N.Y. Aug. 2015; E.D.N.Y. Feb. 2015).
 - New Jersey physician and his practice, alleging that they paid referring providers kickbacks and billed for tests that were unnecessary (or were never provided) (D.N.J. Nov. 2012).
- *Liberty Mut. Fire Ins. Co. v. Acute Care Chiropractic Clinic, P.A. (D. Minn.)*
 - Denied providers' motion to dismiss claim that they fraudulently billed while violating state corporate practice of medicine doctrine.
 - Akin to implied certification theory.

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Enforcement Theories



Overview of Key Enforcement Theories

1. Improper Financial Relationships

- AKS / Stark Law
- Providing anything of value to induce referrals or other business

2. Billing / Coding / Coverage

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

3. Medical Necessity

- Providing services that are not medically necessary
- Inflating volume or value of services provided (e.g., inpatient rather than outpatient care)

4. Quality of Care

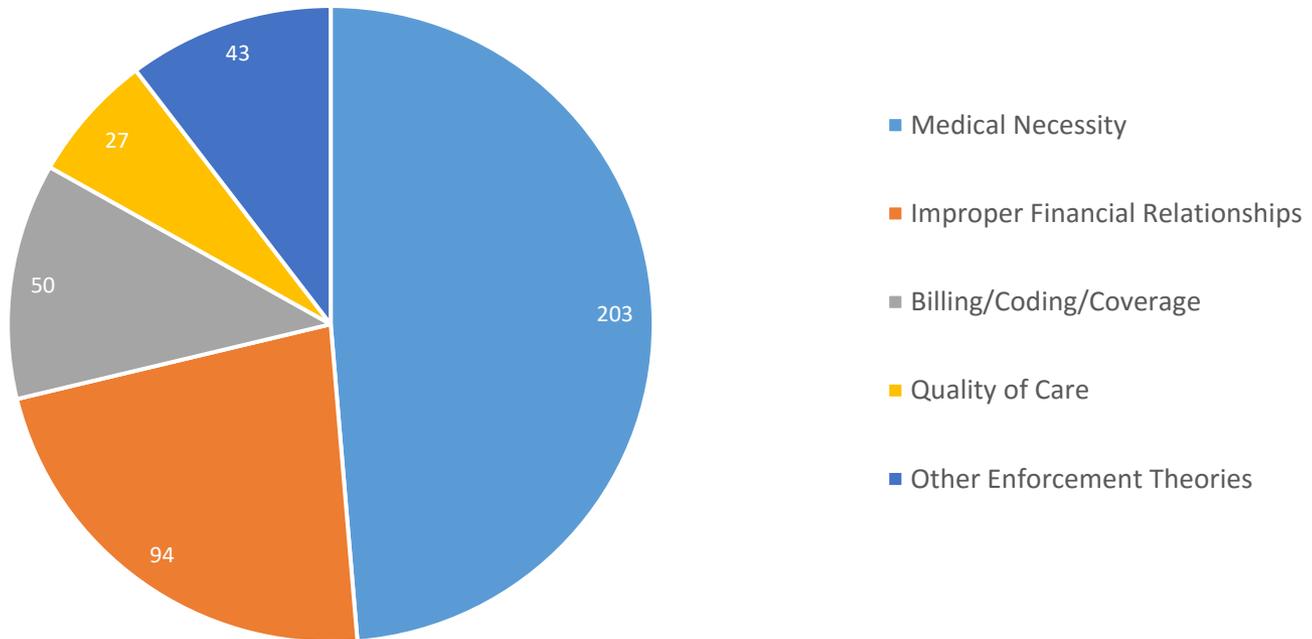
- Providing substandard care (e.g., using unqualified personnel)
- Charging the government for “worthless” services

5. Overpayments

- Nexus of “reverse FCA” and the ACA 60-Day Rule

Recent Recoveries – Providers

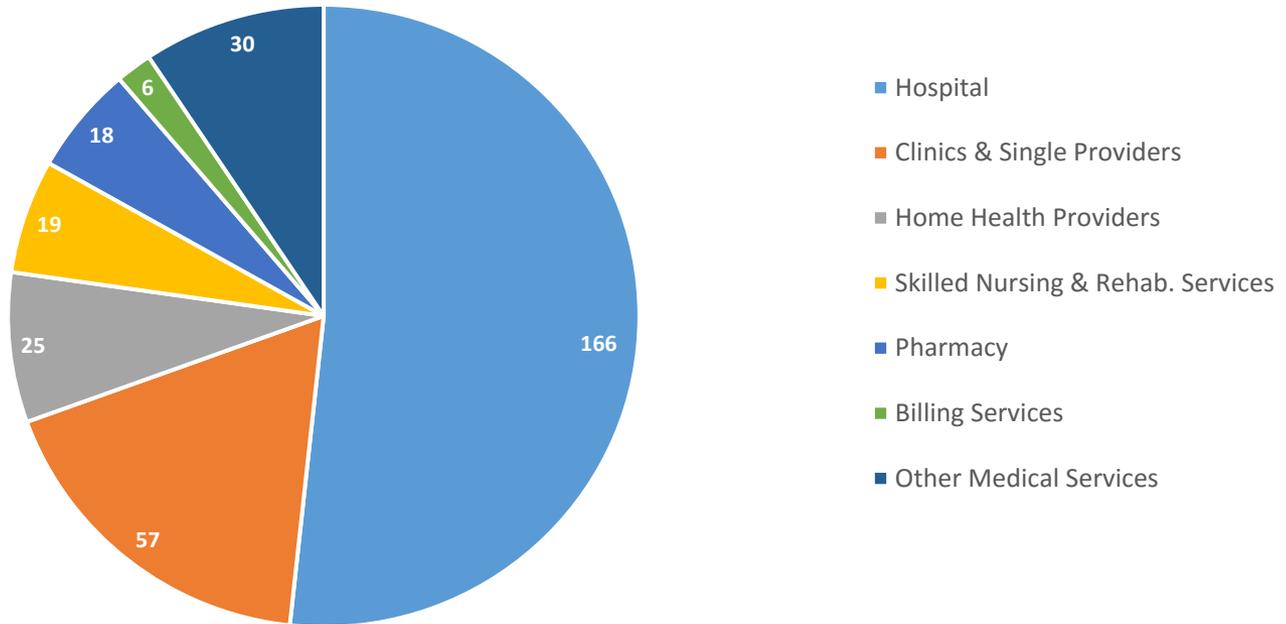
Recent Recoveries by Enforcement Theory



* Data from January 2014 through June 2016

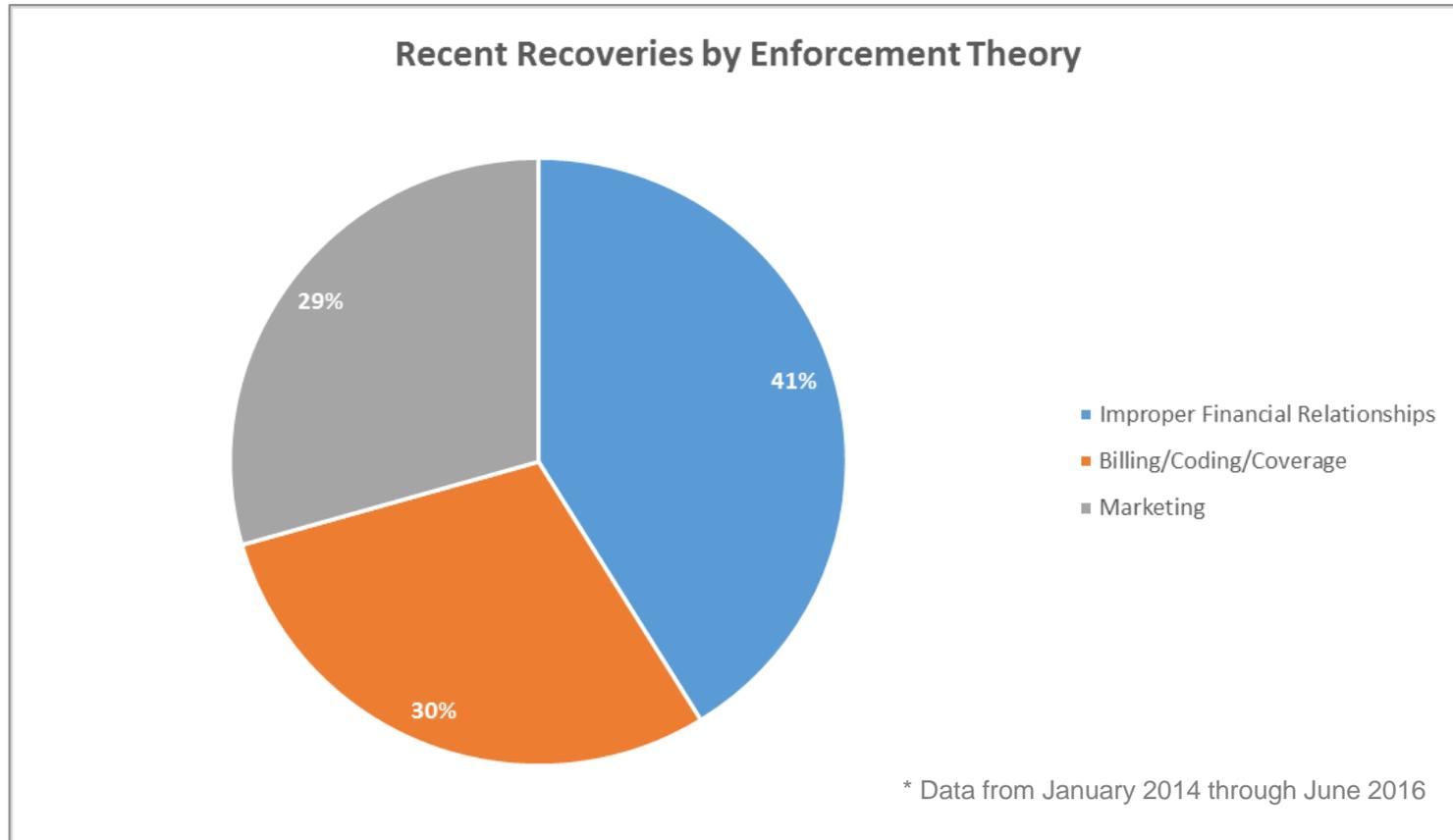
Recent Recoveries – Providers (cont'd)

Recent Recoveries by Provider Type

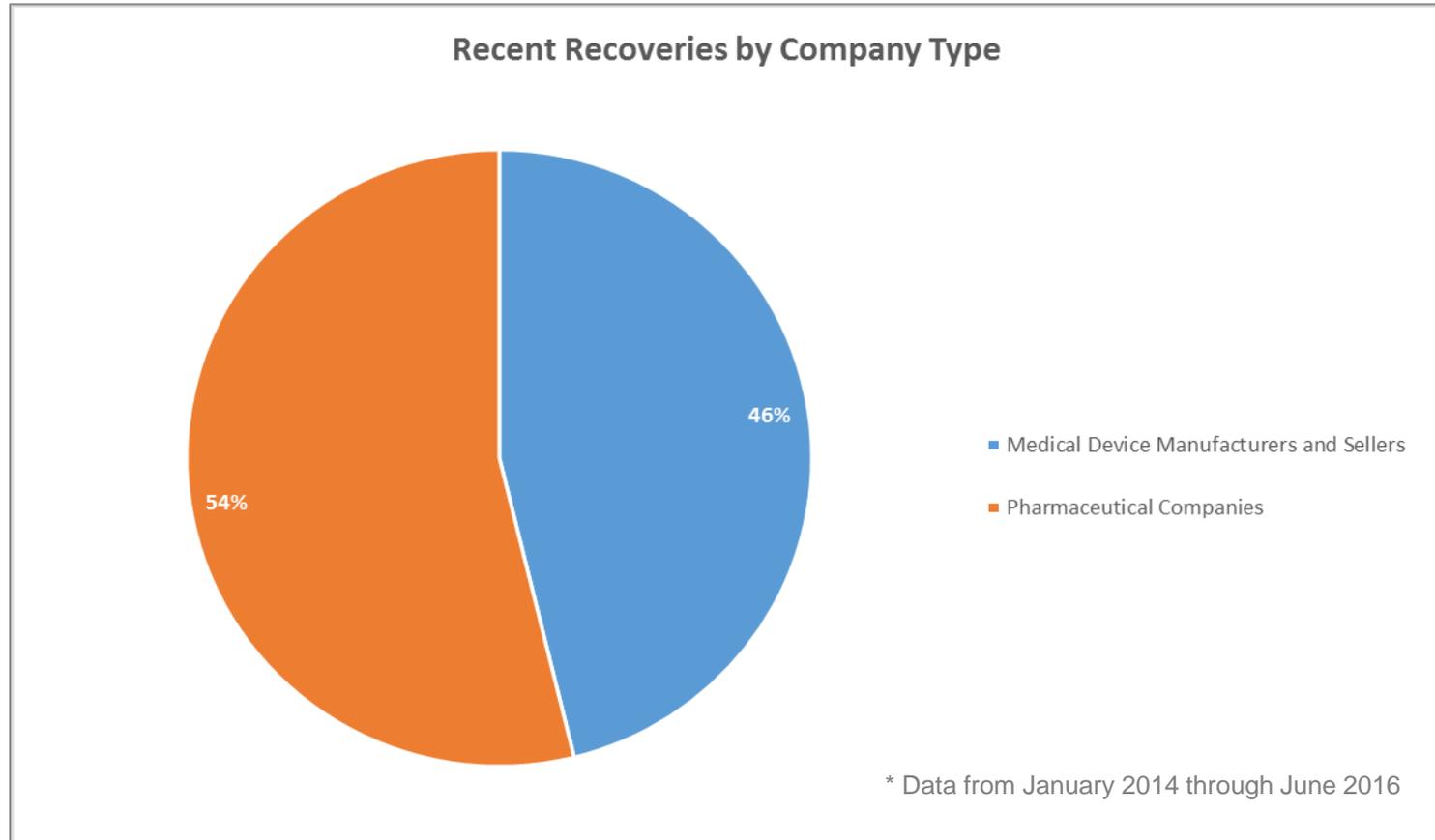


* Data from January 2014 through June 2016

Recent Recoveries – Pharma & Device

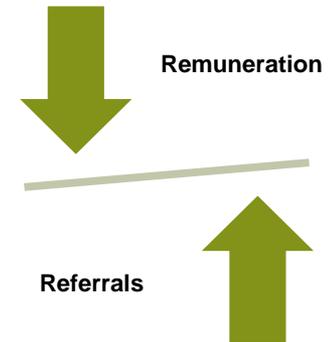


Recent Recoveries – Pharma & Device (cont'd)



Enforcement Theory 1 – Improper Financial Relationships

- Approximately **14** settlements under the AKS with providers and drug and device companies in 2016 so far, resulting in recoveries ranging from **\$245,000** to **\$513.8 million**.
- The government and relators take an extremely broad view of what counts as remuneration.
 - **The obvious**: cash payments, paid vacations
 - **The less obvious**: speaker fees, physician compensation, joint venture investments
 - **The even less obvious**: targeted advertising, electronic health record integrations, urine testing cups, opportunities to make money



“Health care providers that attempt to profit by providing illegal inducements will be held accountable We have pursued many . . . kickback matters [and] ***we will continue to make these cases a top priority.***”

- Principal Deputy Assistant AG
Benjamin C. Mizer

Enforcement Theory 1 – AKS / FCA Enforcement

- The potential for criminal AKS liability *and* civil FCA penalties increases risk to companies facing AKS allegations.
- In August 2016, one of the largest hospital operators in the U.S. announced an agreement to pay almost **\$514 million**, comprised of a civil monetary payment of \$368,000,000 and a criminal monetary payment of \$145,788,345.
- Two subsidiaries also agreed to **plead guilty** to criminal offenses.



Case Study: Anti-Kickback Statute



Millennium Health

- In late October 2015, Millennium Health, a large urine drug testing lab, agreed to pay \$256 million to resolve allegations that it violated the AKS, the Stark Law, and the FCA by paying doctors in return for referrals of lab testing business and billing federal health care programs for excessive drug testing (purportedly caused by promoting physicians to adopt standing orders for drug testing).
- Millennium allegedly provided free urine drug test cups to physicians on the condition that the physicians would return those cups to Millennium for testing.
- As part of the settlement, Millennium entered into a CIA with HHS OIG.

Case Study: Anti-Kickback Statute (cont'd)



“The Department of Justice is committed to ensuring that laboratory tests ... are ordered based on each patient’s medical needs and not just to increase physician and laboratory profits. ... **We will not tolerate ... the provision of inducements to physicians that lead to unnecessary costs being imposed upon our nation’s health care programs.**”

Principal Deputy Assistant AG Benjamin C. Mizer, Head of DOJ Civil Division

\$256 million resolution

\$19.2 million additional payment to CMS

Case Study: Stark Law



Tuomey Healthcare System

- In October 2015, South Carolina-based Tuomey Healthcare System settled FCA claims relating to alleged violations of the Stark Law.

The government alleged that:

- To avoid losing lucrative outpatient procedure referrals to a new surgery center, Tuomey contracted with 19 specialist physicians that required the physicians to refer their outpatient procedures to Tuomey in exchange for compensation that exceeded FMV.
- Tuomey ignored its attorneys' warnings that the physician contracts were "risky" and raised "red flags."

Case Study: Stark Law (cont'd)



“This case demonstrates the United States’ commitment to ensuring that doctors who refer Medicare beneficiaries to hospitals for procedures, tests and other health services do so **only because they believe the service is in the patient’s best interest**, and not because the physician stands to gain financially from the referral. . . . **[DOJ] is determined to prevent the kind of abuses uncovered in this case, and we are willing to take such cases to trial to protect the integrity of the Medicare program.**”

Principal Deputy Assistant AG Benjamin C. Mizer, Head of DOJ Civil Division

\$237 million judgment

\$72.4 million settlement

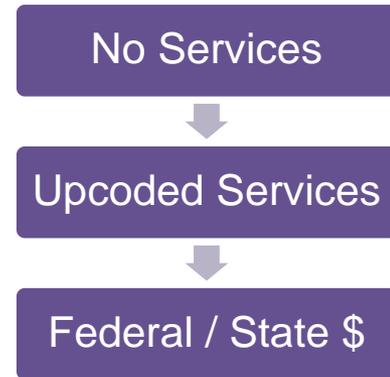
Enforcement Theory 1 – AKS – Pharma / Device

- The government is just as actively pursuing AKS-based FCA cases against pharma and device manufacturers:
 - March 2016: Record DOJ AKS/FCA settlement with Olympus Corporation, a manufacturer and distributor of endoscopes, for **\$623.2 million** (plus **\$22.8 million** to settle alleged FCPA violations).
 - November 2015: **\$390 million** resolution of claims against Novartis Pharmaceuticals Corp. relating to its allegedly improper financial relationships with specialty pharmacies.



Enforcement Theory 2 – Billing / Coding / Coverage

- These cases involve a wide range of legal theories, but tend to involve facts that include:
 - Billing for services not provided; or
 - “Upcoding” services that were provided.



“Our prosecutors and in-house analysts and our law enforcement partners have become . . . fluent in the complexities of Medicare billing, and we are working hard to identify those engaged in these new schemes and to bring them to justice.”

AAG Leslie R. Caldwell (May 2015)

Case Study: Billing / Coding / Coverage



Kindred Healthcare Inc.

- In January 2016, Kindred Healthcare Inc. and its subsidiary, RehabCare, agreed to pay \$125 million to resolve allegations that they violated the FCA by causing SNFs to submit false claims to Medicare for rehabilitation therapy services that were not reasonable, necessary and skilled, or that never occurred.
- The company's alleged policies and practices (e.g., setting unrealistic financial goals and scheduling therapy to achieve the highest reimbursement level regardless of patients' clinical needs) allegedly resulted in unreasonable and unnecessary services.

Case Study: Billing / Coding / Coverage (cont'd)



“All providers, whether contractors or direct billers of taxpayer-funded federal healthcare programs, **will be held accountable when their actions cause false claims for unnecessary services.**”

Principal Deputy Assistant AG Benjamin C. Mizer, Head of DOJ Civil Division

\$125 million settlement

\$24 million whistleblower reward

Enforcement Theory 2 – Skilled Nursing Facilities

- **SavaSeniorCare LLC**
 - The government has alleged that SavaSeniorCare improperly maximized reimbursement rates by delaying patient discharges and pressuring staff to meet unrealistic financial goals.
- **HCR ManorCare**
 - The government has alleged that ManorCare inappropriately maximized reimbursement rates by pressuring staff to provide unnecessary treatment, keeping patients longer than necessary, and setting unrealistic financial goals.
- **Life Care Centers of America**
 - The government has alleged that Life Care improperly maximized reimbursement rates for patient stays by encouraging staff to keep patients for the maximum length of time and pressuring therapists to provide therapy to patients regardless of whether they needed it.

Case Study: Billing / Coding



George Hepburn and Dynasplint Systems, Inc.

- In December 2015, Dynasplint Systems, Inc. and owner George Hepburn agreed to pay approximately \$10.3 million to resolve allegations of false claims.
- The government alleged that the defendants knowingly, and improperly, charged Medicare for splints provided to patients in skilled nursing facilities. Patients in skilled nursing facilities should have received the splints as part of their bundled services. To submit these claims, the defendants allegedly represented that the patients were located outside of skilled nursing facilities.

Case Study: Billing / Coding (cont'd)



“The civil False Claims Act is a valuable weapon in our office’s arsenal to combat abuse of federal healthcare funds here in the Eastern District of Louisiana and nationwide.”

Kenneth Allen Polite, Jr., U.S. Attorney, E.D. Louisiana

\$10.3 million

\$1.98 million to go to qui tam relator

Case Study: Billing / Coding



Covenant Hospice, Inc.

- In June 2015, hospice care provider Covenant Hospice, Inc. agreed to pay more than \$10.1 million to settle allegations of false claims.
- The government alleged that Covenant Hospice, Inc. submitted claims to Medicare, Tricare, and Medicaid for general inpatient care that should have instead been submitted as routine home care.
- The federal government will receive \$9.6 million of the settlement and Alabama and Florida will receive more than \$552,000.

Case Study: Billing / Coding (cont'd)



“Careful and correct claims for reimbursement from critical federal health care programs are essential to the health of our economy. . . . We will continue our efforts to ensure that federal dollars intended for compassionate care and legitimate patient needs are protected.”

Pamela C. Marsh, U.S. Attorney, N.D. Florida

\$10.1 million

3 government payors
subject to false claims

Case Study: Billing / Coding



Community Health Network

- In June 2015, CHN, an Indiana-based non-profit health system, agreed to pay more than \$20 million to resolve allegations that it submitted false claims to the Medicare and Medicaid programs.
- CHN contracted with ASCs to provide outpatient surgical services to CHN patients. CHN allegedly represented that the surgeries were performed in the outpatient department of CHN's hospitals, rather than in an ASC, thereby resulting in higher reimbursement.

Case Study: Billing / Coding (cont'd)



“This recovery sends the message that health care providers must comply with all applicable state and federal regulations **when billing the United States Government for services, or they will face consequences.**”

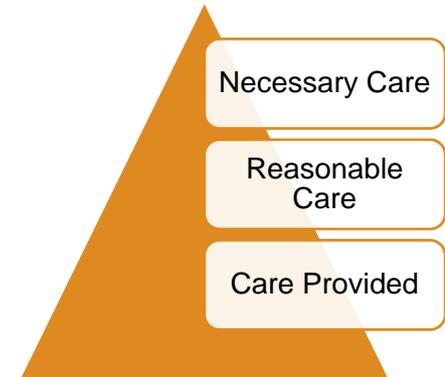
Josh Minkler, U.S. Attorney, S.D. Indiana

\$20 million

4 government agencies involved in investigation

Enforcement Theory 3 – Medical Necessity

- Primary Theories
 - **Unnecessary Procedures:** Large-scale, complex approach to medical necessity cases
 - **Inpatient vs. Outpatient:** Cases indicate broader scrutiny of this issue
 - **Long-term Care Facilities:** Current DOJ sweep looking for unnecessary lengths of stay
- These theories demonstrate DOJ’s skepticism of hospitals’ pursuit of profit and potential abuse of federal health care programs.



“Providers who waste taxpayer dollars by ***billing for unnecessary services***, including services that are not used or improperly performed, ***will face serious consequences.***”

Principal Deputy Assistant AG
Benjamin C. Mizer

Case Study: Medical Necessity



21st Century Oncology, South Florida Radiation Oncology LLC

- In March 2016, 21st Century Oncology and subsidiary South Florida Radiation Oncology LLC agreed to pay \$34.7 million to resolve allegations of false claims.
- The government alleged that the providers performed and billed for procedures that were not medically necessary. Specifically, the government alleged that Gamma function procedures, intended to measure the radiation emitted by a patient following radiation treatment, were (1) performed and billed by physicians and physicists not trained to review and utilize the results, (2) billed even when results were not read for a week following a patient's last treatment, and (3) billed even when technical failures prevented a result from being obtained.
- The suit was initially filed by qui tam relator Joseph Ting, a former physicist at South Florida Radiation Oncology.

Case Study: Medical Necessity (cont'd)



21st Century Oncology

“Providers who waste taxpayer dollars by billing for unnecessary services, including services that are not used or improperly performed, will face serious consequences.”

Principal Deputy Assistant Attorney General Benjamin C. Mizer, DOJ – Civil Division

\$ 34.7 Million recovered

\$7 Million to be paid to qui tam relator

Case Study: Medical Necessity



Cardiac Industry Sweep

- Since October 2015, DOJ has reached **81 settlements** involving more than 450 hospitals nationwide for more than **\$250 million** related to cardiac devices that were implanted in Medicare patients in violation of coverage requirements.
- The NCD for ICDs (1) provides that they generally should not be implanted in patients who have recently suffered a heart attack or recently had heart bypass surgery or angioplasty and (2) generally prohibits implantation of ICDs during specified waiting periods.
- DOJ alleged that from 2003 to 2010, each settling hospital implanted ICDs during the prohibited periods.

Case Study: Medical Necessity (cont'd)



“Working as a team with the Department of Justice to **investigate and settle false billing claims of this magnitude has resulted in substantial recoveries to Medicare and the successful enforcement of Medicare’s coverage requirements** for these procedures.”

Inspector General Daniel Levinson of the Department of Health and Human Services’ Office of Inspector General (HHS-OIG).

~500 hospitals

\$250 million recovered

Enforcement Theory 4 – Quality of Care

- Claims for reimbursement of inpatient care are false if the services were “grossly” deficient or substandard, such as to make them essentially “worthless.”
- Quality-of-care allegations are sometimes used as a vehicle to plead theories not actionable in themselves, such as:
 - Regulatory violations, e.g. violations of Medicare conditions of participation or state licensure rules
 - Failure to meet the “standard of care” in the field
 - Pursuit of profit goals by management and/or corporate parent
- Investigations focus on management pressure to sacrifice patient care in favor of the bottom line.
- FCA theories based on deficient quality of care have faced resistance in the courts.



“It is not enough to offer evidence that the defendant provided services that are worth some amount less than the services paid for. . . .
Services that are ‘worth less’ are not ‘worthless.’
U.S. ex rel. Absher v. Momence Meadows Nursing Ctr., Inc., 764 F.3d 699, 710 (7th Cir. 2014)

Case Study: Quality of Care



Extendicare Health Services

- In October 2014, Extendicare and a subsidiary agreed to pay \$38 million to the United States and eight states to resolve allegations that Extendicare billed Medicare and Medicaid for nursing services that the government contended were “so deficient that they were effectively worthless.”
- The government alleged, *inter alia*, that Extendicare failed to (1) have a sufficient number of skilled nurses to adequately care for its skilled nursing residents; (2) provide adequate catheter care to some of the residents; and (3) follow the appropriate protocols to prevent pressure ulcers or falls.

Case Study: Quality of Care (cont'd)



“This case demonstrates that the government will **aggressively pursue allegations of . . . grossly deficient care.**”

Inspector General Daniel Levinson of the Department of Health and Human Services' Office of Inspector General (HHS-OIG)

\$38 million settlement

5 year Corporate Integrity Agreement

Case Study: Quality of Care – Recent Complaint



Vanguard Healthcare LLC and Six Vanguard Facilities

- A September 7, 2016 DOJ civil complaint against Vanguard Healthcare LLC, six of its subsidiary facilities, and its Director of Operations, alleging false claims based on “nonexistent, grossly substandard, and/or worthless nursing home services.”
- DOJ is pursuing the corporate parent based on:
 - “Alter ego” theory;
 - Alleged corporate knowledge (based on termination of employees); and
 - Theory that the parent caused the facilities to be materially deficient by failing to provide adequate resources.

Enforcement Theory 5 – Overpayments

- Amendments to the FCA in 2009 created liability for the retention of any “overpayment” by federal health programs. 31 U.S.C. § 3729(a)(1)(G), (b)(3).
- Knowing—including reckless—violations of the PPACA’s “60-day Rule” can violate this “reverse False Claims Act.”
- Opens up providers to fraud liability in broader contexts, including where they lacked the requisite knowledge at the time they originally submitted the claim.
- Overpayment cases under the FCA emphasize the importance of robust compliance programs.



“Repaying Medicaid for false claims is not only vital to the integrity of the program, but it is also the law.”

NY AG Eric Schneiderman (Aug. 2016)

Enforcement Theory 5 – 60-Day Rule

- The 60-day Rule requires that a provider who received an overpayment must repay it within 60 days of the time it is “identified.”
- On February 12, 2016, CMS issued final guidance on the 60-Day Rule:
 - ***When the 60-day period begins to run***
 - The clock begins when a provider “has or should have, through the exercise of reasonable diligence, determined” that it has received an overpayment.
 - ***Required diligence***
 - Providers must use “reasonable diligence,” which includes proactive compliance activities and reactive investigations.
 - Timely, good-faith investigations should generally be completed within six months of receiving credible information regarding an overpayment.
 - ***Look-back period***
 - A provider must look back and investigate all similar payments received in the six years prior to the overpayment.

Case Study: Overpayments



Pediatric Services of America, Inc., Pediatric Healthcare Inc., Pediatric Home Nursing Services, and Portfolio Logic LLC

- In August 2015, Pediatric Services of America, Inc., Pediatric Healthcare Inc., Pediatric Home Nursing Services, and Portfolio Logic LLC agreed to pay \$6.88 million to settle allegations of false claim in a “precedent-setting” FCA settlement.
- DOJ alleged that defendants violated the FCA by maintaining or writing off credit balances on their books without investigating whether those credit balances were the result of government overpayments.

Case Study: Overpayments (cont'd)



“Participants in federal health care programs are required to actively investigate whether they have received overpayments, and if so, promptly return the payments. **This settlement is the first of its kind and reflects the serious obligations of health care providers to be responsible stewards of public health funds.**”

John Horn, U.S. Attorney, N.D. Georgia

\$6.88 million settlement

\$1.1 million to be paid to *qui tam* relators

Case Study: Overpayments



Continuum
Health Partners

Healthfirst / Continuum Health Partners Inc.

- In August 2016, Continuum Health Partners, Inc. (Continuum) agreed to pay \$2.95 million to the federal government and New York State to resolve False Claims Act allegations.
- The alleged that defendants identified hundreds of overpayments from Medicaid as a secondary payor, but failed to timely repay them even after state auditors identified the issue.
- Prior to settlement, the District Court had recognized the viability of this FCA theory in denying defendants' motion to dismiss. See *U.S. ex rel. Kane v. Healthfirst et al.*

\$2.95 million settlement

\$800k In alleged overpayments

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Legal Developments



Recent Legal Developments – Implied Certification

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

- Relator brought FCA suit against leading nation-wide provider of mental health services, alleging that hospital provided inadequate care to a teenage patient by using underqualified personnel to deliver counseling services.
- The Court held that the implied certification theory can provide a basis for FCA liability where:
 1. “the claim does not merely request payment, but also makes **specific representations about the goods or services provided**,” and
 2. “the defendant’s failure to disclose noncompliance with material statutory, regulatory, or contractual requirements makes those representations **misleading half-truths**.”
- The Court declined to decide “whether **all** claims for payment **implicitly** represent that the billing party is legally entitled to payment.”

Recent Legal Developments – Materiality

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

- The Court also concluded that “[a] misrepresentation about compliance with a statutory, regulatory, or contractual requirement must be material to the Government’s payment decision.”
- The Court characterized the materiality requirement as “rigorous” and “demanding,” and confirmed that materiality can be a basis for dismissing a case on a MTD.
 - The relevant question is not whether the alleged underlying legal violation was “capable” of affecting payment, but whether the government actually “would not have reimbursed the claims had it known that it was billed for . . . services that were performed [in violation of the statute or regulation at issue].”
- Government knowledge of violations paired with continued payment can be “very strong evidence” that requirements are not material.

Recent Legal Developments – Post-*Escobar*

U.S. ex rel. Presser v. Acacia Mental Health Clinic, LLC **No. 14-2804 (7th Cir. Sept. 1, 2016)**

- Relator premised FCA claim on alleged “upcoding” and provision of unnecessary medical procedures.
- Allegations that mental health clinic told employees to use code for “full psychological assessment by a therapist” to bill for assessments by receptionists and nurse practitioners was “even more specific than those” presented in *Escobar*, and thus satisfied Rule 9(b). The clinic “allegedly billed Medicaid **for a completely different treatment**,” and thus the relator’s claim “involves an express false statement.”
- But, relator’s medical necessity allegations “provide[d] no medical, technical, or scientific context [that would explain] why Acacia’s alleged actions amount to unnecessary care.”
- “Without additional context providing reason to question the appropriateness of [Acacia’s] policies, the complaint does not present allegations of fraud with sufficient particularity.”

Recent Legal Developments – Post-*Escobar*

***U.S. ex rel. Dresser v. Qualium Corp.* No. 5:12-cv-01745 (N.D Cal. July 18, 2016)**

- Relator and United States brought FCA suit against owner of chain of diagnostic sleep clinics, which treated sleep disorders and dispensed DME, for conducting tests in unapproved locations, using unqualified personnel, and dispensing DME based on improper tests (or from unapproved locations/providers).
- Defendants relied on *Escobar*, but the court held several claims were sufficiently pled under “literally false,” express false certification, or fraudulent inducement theories.
- But, as to implied false certification (an alternative theory), the court rejected the United States’ materiality allegations as insufficient under *Escobar*.
 - Defendants had certified generally that they would “abide by Medicare laws, regulations, and program instructions.”
 - The government “allege[d] in several places that [it] would not have paid Defendants’ claims had they known of Defendants’ fraudulent conduct,” but did “***not explain why.***”

Recent Legal Developments – AseraCare

U.S. ex rel. Paradies v. AseraCare Inc.
No. 2:12-CV-245, 2016 WL 1270521 (N.D. Ala. Mar. 31, 2016)

- The government cannot prove a claim was objectively false when medical experts disagree about whether care was medically necessary and there is no other evidence of falsity.
- “[C]ontradiction based on clinical judgment or opinion alone **cannot constitute falsity** under the FCA as a matter of law.” *Id.* at *4.
- Similar arguments may be gaining traction in other courts around the country.
- See, e.g., *U.S. ex rel. Wall v. Vista Hospice Care Inc.*, No. 3:07-CV-00604, 2016 WL 3449833 (N.D. Tex. June 20, 2016).

Recent Legal Developments – AseraCare (cont'd)

U.S. ex rel. Paradies v. AseraCare Inc.
No. 2:12-CV-245, 2016 WL 1270521 (N.D. Ala. Mar. 31, 2016)

- The government has appealed the decision:
 - “At the heart of the district court’s rulings lies a ***fundamentally flawed interpretation*** of what it means for a claim to be ‘false’ under the False Claims Act.”
- The government contends that conflicting medical opinion is irrelevant because claims are not “reimbursable” – and thus “false” – if they are not supported by adequate documentation.
 - “In a False Claims Act suit concerning eligibility for payment under Medicare, a claim is false if it is not reimbursable under Medicare. And a hospice claim is only reimbursable under Medicare if the hospice provider has sufficient clinical documentation to support a patient’s prognosis of a terminal illness. The jury therefore properly relied upon the relevant patients’ medical records—as elucidated by the competing medical experts—to determine whether AseraCare was entitled to reimbursement under Medicare.”

Recent Legal Developments – Statistical Sampling

- FCA plaintiffs in recent years have been resorting to statistical methods to seek expansive liability for thousands of claims without establishing the falsity of each claim at issue.
- Federal district courts have been divided on whether statistical sampling can be used to prove liability in FCA cases, but several in recent years have approved of sampling.
 - *U.S. ex rel. Martin v. Life Care Ctrs. of Am., Inc.*, No. 1:08-cv-251, 2014 WL 4816006 (E.D. Tenn. Sept. 29, 2014)
- Although **no federal court of appeals has directly addressed this issue yet** in the FCA context, the Fourth Circuit has agreed to hear a case, *United States ex rel. Michaels v. Agape Senior Community, Inc.*, certifying the issue. Oral argument is scheduled for the end of October 2016.

Recent Legal Developments – Statistical Sampling (cont'd)

- The Supreme Court recently approved use of statistical sampling to prove liability in a labor and employment class action suit.

***Tyson Foods, Inc. v. Bouaphakeo*, 136 S. Ct. 1036, 1046 (2016)**



- “Whether and when statistical evidence can be used to establish [] liability will depend on the purpose for which the evidence is being introduced and on ‘the elements of the underlying cause of action.’”
- The government and relators may argue that the Supreme Court’s decision in *Tyson Foods* supports use of sampling in FCA suits.
 - But some courts have interpreted *Tyson Food’s* purpose-specific test to **reject** statistical sampling in FCA cases.

See, e.g., U.S. ex rel. Wall v. Vista Hospice Care Inc., No. 3:07-CV-00604, 2016 WL 3449833 (N.D. Tex. June 20, 2016).

Recent Legal Developments – Sampling and Discovery

- Defendants may obtain discovery from government to counter statistical sampling (or to explore other issues).

Deane v. Dynasplint Sys., Inc.

No. CIV.A. 10-2085, 2015 WL 1638022, at *1 (E.D. La. Apr. 13, 2015)

- Defendants sought more than 17,000 annual cost reports for more than 7,000 nursing homes from the government.
 - The government protested on burden / expense grounds, but the court rejected the government's argument and compelled production:
 - The government “***cannot be permitted to restrict defendant from receiving information its expert believes is necessary to mount an adequate defense.***”
 - “In light of the broad scope of this litigation, as framed by the government itself, the government must commit all resources necessary to comply”
-
- If courts continue to endorse sampling approach, how the parties construct their samples will be critical, especially as nationwide multi-site cases proliferate.

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Questions



Gibson Dunn – Attorneys



Steve Payne

1050 Connecticut Avenue, N.W.
Washington, D.C. 20036-5306
Tel: 202.887.3693
Fax: 202.530.4202
SPayne@gibsondunn.com



Winston Chan

555 Mission Street, Suite 3000
San Francisco, CA 94105-0921
Tel: 415.393.8362
Fax: 415.374.8460
WChan@gibsondunn.com



John Partridge

1801 California Street, Suite 4200
Denver, CO 80202-2642
Tel: 303.298.5931
Fax: 303.313.2857
JPartridge@gibsondunn.com



Jonathan Phillips

1050 Connecticut Avenue, N.W.
Washington, DC 20036-5306
Tel: 202.887.3546
Fax: 202.530.9530
JPhillips@gibsondunn.com

Our Offices

Beijing

Unit 1301, Tower 1
China Central Place
No. 81 Jianguo Road
Chaoyang District
Beijing 100025, P.R.C.
+86 10 6502 8500

Brussels

Avenue Louise 480
1050 Brussels Belgium
+32 (0)2 554 70 00

Century City

2029 Century Park East
Los Angeles, CA 90067-3026
310.552.8500

Dallas

2100 McKinney Avenue
Suite 1100
Dallas, TX 75201-6912
214.698.3100

Denver

1801 California Street
Suite 4200
Denver, CO 80202-2642
303.298.5700

Dubai

Building 5, Level 4
Dubai International Finance Centre
P.O. Box 506654
Dubai, United Arab Emirates
+971 (0)4 318 4600

Hong Kong

32/F Gloucester Tower, The
Landmark
15 Queen's Road Central
Hong Kong
+852 2214 3700

London

Telephone House
2-4 Temple Avenue
London EC4Y 0HB
England
+44 (0)20 7071 4000

Los Angeles

333 South Grand Avenue
Los Angeles, CA 90071-3197
213.229.7000

Munich

Marstallstraße 11
D-80539 München
Germany
+49 89 189 33-0

New York

200 Park Avenue
New York, NY 10166-0193
212.351.4000

Orange County

3161 Michelson Drive
Irvine, CA 92612-4412
949.451.3800

Palo Alto

1881 Page Mill Road
Palo Alto, CA 94304-1125
650.849.5300

Paris

166, rue du faubourg Saint Honoré
75008 Paris France
+33 (0)1 56 43 13 00

San Francisco

555 Mission Street
San Francisco, CA 94105-
0921
415.393.8200

São Paulo

Rua Funchal, 418, 35° andar
Sao Paulo 04551-060
Brazil
+55 (11)3521.7160

Singapore

One Raffles Quay
Level #37-01, North Tower
Singapore 048583
+65.6507.3600

Washington, D.C.

1050 Connecticut Ave., N.W.
Washington, D.C. 20036-5306
202.955.8500