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US Qui Tam Actions against Foreign Pharma and Device Companies doing Business in the US

13th Annual International Pharmaceutical and Medical Device Compliance Conference

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What We'll Talk About Today

- False Claims Act Investigations
- Current Enforcement Landscape
- Takeaways – What Do DOJ/OIG/FDA/CMS/State AGs Expect From Compliance Programs

The Health Care System

- Total U.S. Health Care Spending
  - $3.5 trillion (2017) – 17.9% of GDP
    - 34% private
    - 37% public
      - 20% Medicare
      - 17% Medicaid & CHIP
    - 10% out of pocket/private pay
- 2018 DOJ civil frauds recoveries
  - Total: $ 2,880,520,711
  - Health Care: $ 2,513,335,647
- 2016-18: $11.3 billion ($7.4 billion from health care fraud)

By The Numbers - 2018

- Investigative Recoveries - $2.88 billion
  - Criminal Actions: 1,938
  - Indictments: 2,498
  - Over $3 billion at issue
- 15,205 – Medicaid Fraud Control Unit investigations
- 2,712 Exclusions from participation in federal health care programs

- ~$7 Returned to Medicare Trust Fund for Every $1 Spent
  - By Some Estimates The Number Is Closer To 15 To 1

Current Enforcement Priorities

- Record FCA Numbers
  - Number of Cases Is At Record High
- More Follow-On Investigations
  - Cooperation Obligations – DPAs/CIAs
  - Cases Against Individuals
- More Criminal Enforcement
- More Contract Auditors = More Referrals
- Medicare Fraud Strike Force Expansion to Corporate Matters

Anatomy of an Investigation

- *Qui Tam* Complaints
  - Employees; Media; Public; Competitors; Vendors; Referrals
- Criminal or Civil – How Does DOJ Decide?
- Role of Agencies
  - FBI
  - OIG
  - FDA
  - CMS
  - Auditors
  - State AGs
- DOJ Use of Contractors and Experts

Enforcement Resources

- Fraud and abuse enforcement authorities:
  - Health Care Fraud Statute, 18 U.S.C. § 1347
  - Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b)
  - Stark Law, 42 U.S.C. § 1395nn
  - False Claims Act, 31 U.S.C. §§ 3729-3733
  - Exclusion, 42 U.S.C. § 1320a-7
  - Civil Monetary Penalties Law, 42 U.S.C. § 1320a-7a
  - Other Criminal Laws, 18 U.S.C. §§ 287, 1001, 1035

False Claims Act

- *Qui tam* action – suit by a private party brought on behalf of the United States.
  - Under the False Claims Act private party is called a "relator"

- *Qui tam* – shorthand for *Qui tam pro domino rege quam pro se ipso in hac parte sequitur*
  - "Who as well for the King as for himself sues in this matter"

- U.S. Code contains Five other *qui tam* provisions – also referred to as Private Attorney General laws

FCA History

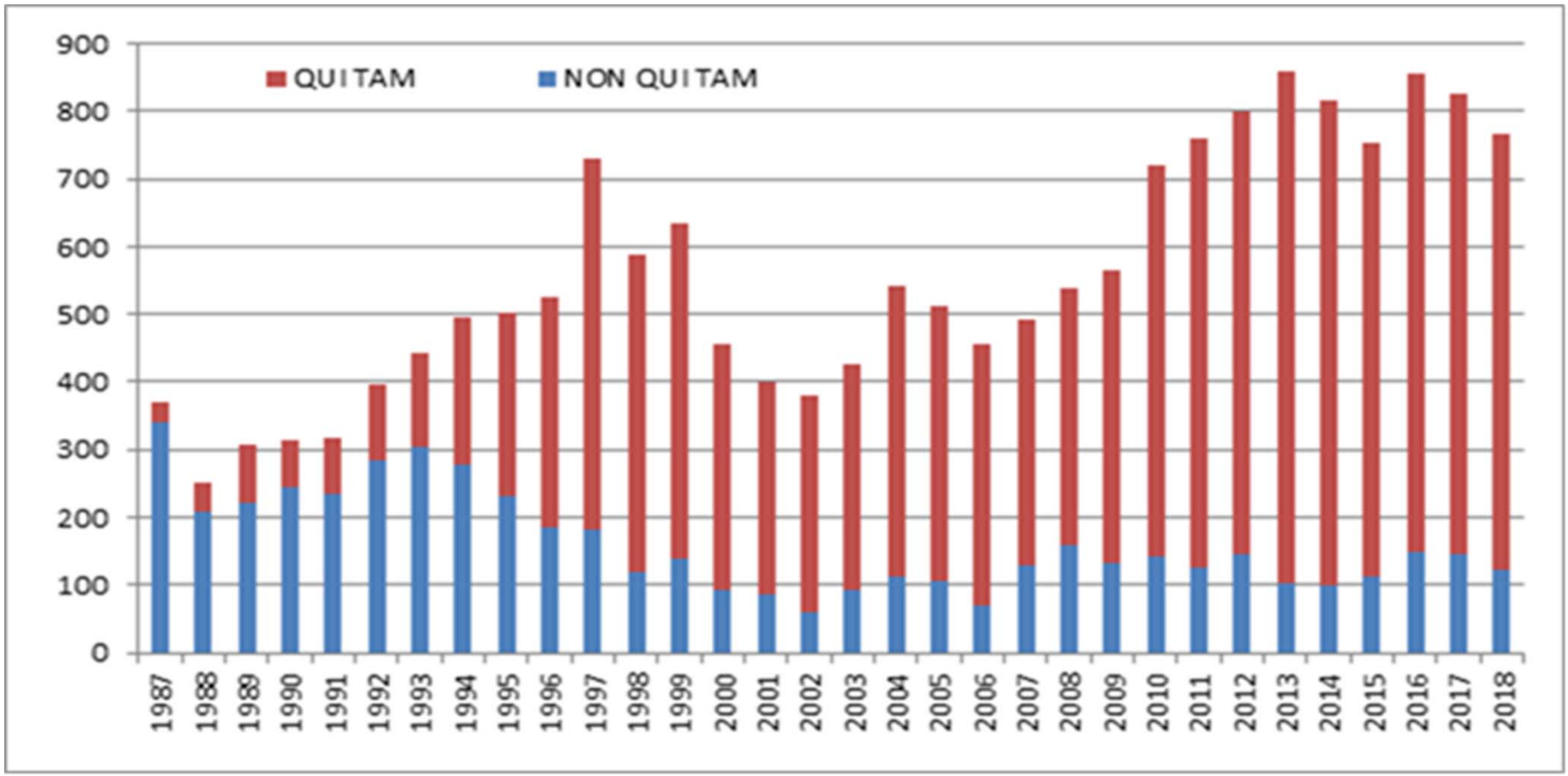
- Originally enacted during the Civil War (1863) to combat war profiteering
  - Delivering boxes of sawdust instead of "guns"
  - Selling same horses more than once
  - "You can sell anything to the government at almost any price you've got the guts to ask" – Profiteer

- Key Features:
  - Prohibits false claims involving U.S. funds
  - Treble damages
  - Penalties for each false claim or statement
  - Joint and several liability for defendants

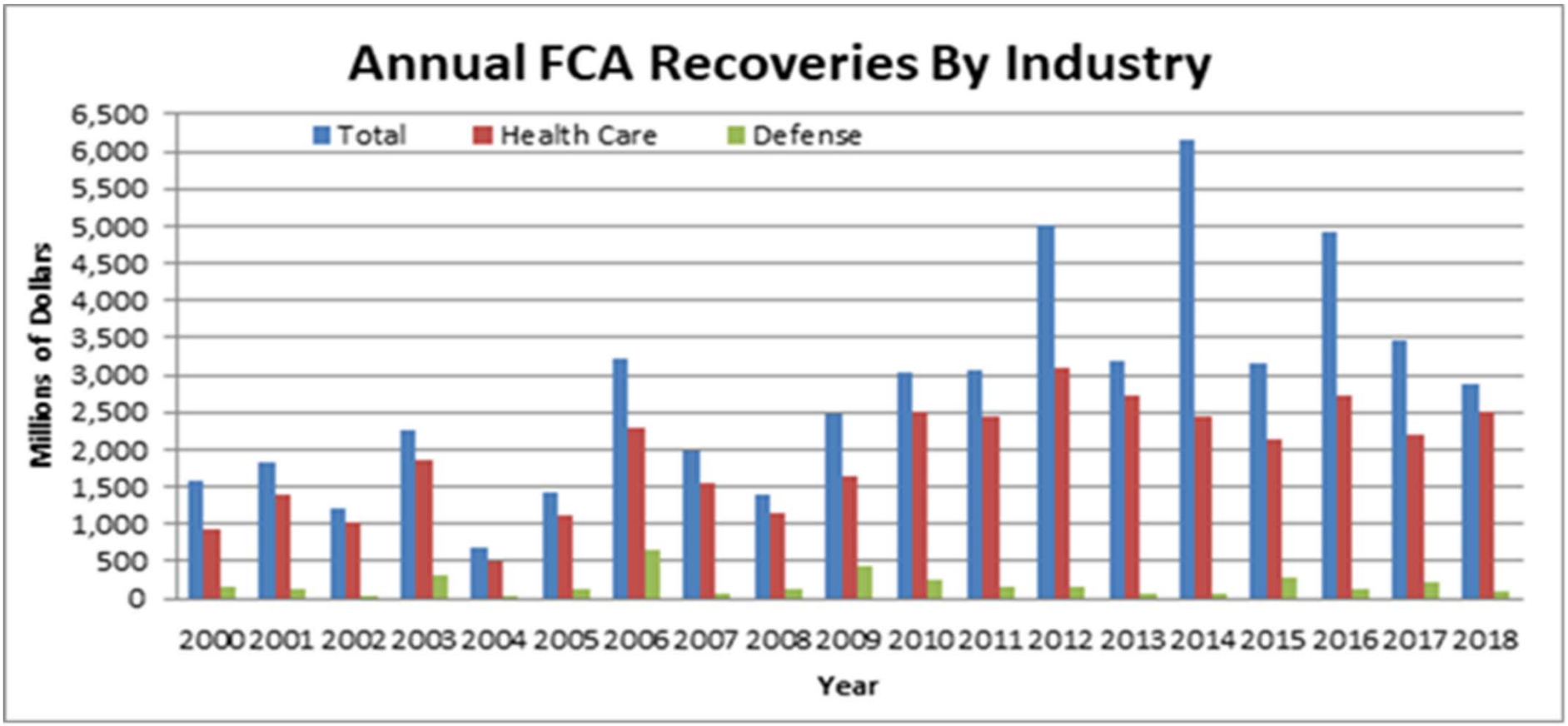
History

- A qui tam provision was included in the original 1863 version of the False Claims Act
  - Relator was entitled to half of any recovery
- Congress amended qui tam provisions in 1943
  - Reduced relator share
  - Added public disclosure bar
- Congress again amended qui tam provisions in 1986
  - Amendments designed to encourage more qui tam actions
- Congress amended False Claims Act in 2009
  - Significant expansion of False Claims Act
- PPACA Amendments in 2010

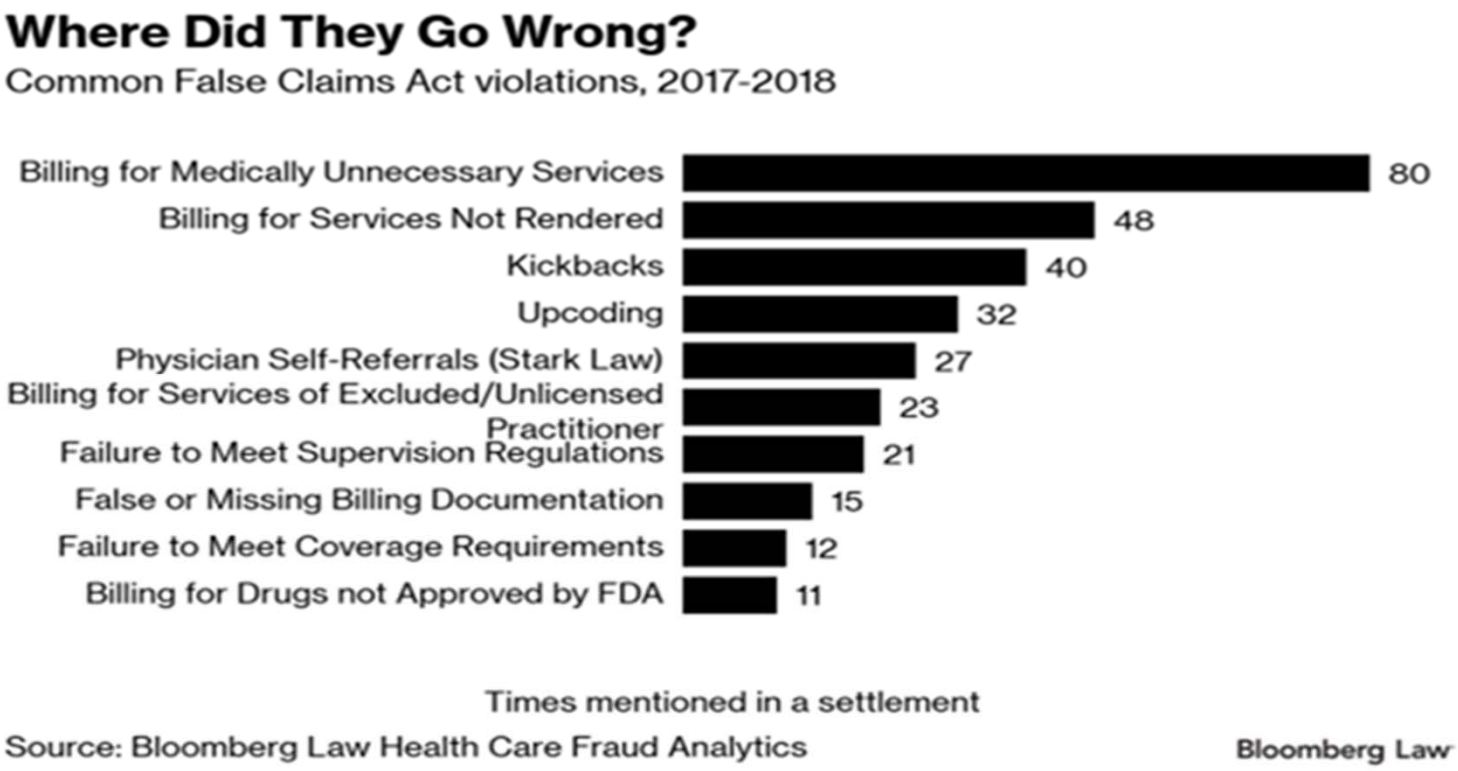
New FCA Cases – Investigations and Qui Tams



FCA Recoveries



Basis for Liability



Resolution Amount

Ongoing Federal Oversight: Corporate Integrity Agreements

- Most Pharma and Device Settlement Agreements Require CIAs
  - Almost every top pharma company has had a CIA
- CIAs Evolve
  - Over 1,000 CIAs since mid-1990s
  - Early CIAs focused on Training and Education Requirements
  - Over 240 Active CIAs at close of 2018
- Current State-of-Art CIAs
  - Aegerion Pharmaceuticals, Inc.

Healthcare Compliance Programs: Building Blocks

1978	Inspector General Act
1980s	Defense Industry Scandals - Packard Commission Report
1991	Federal Sentencing Commission Business Organizations Chapter
1997	HHS Health Care Fraud and Abuse Control Program
1998	OIG Compliance Program Guidance for Hospitals
2002	Fraud scandals (Enron, Tyco, etc.), then SOX
1998 - 2008	Additional and Supplemental OIG Compliance Program Guidances
2005	Medicaid Integrity Program – Mandatory Compliance
2000s	OIG Dashboards and Roundtables; Proliferation of CIAs
2000s	Manufacturing Industry Compliance Guidance – PhRMA & AdvaMed
2010	ACA makes compliance programs a Medicare condition of enrollment
2010s	Post-Resolution Enhancements: Board Experts, External Monitors, Probation, ???

Recent Enforcement – Free Product, No-Charge Equipment

Olympus (March 2016)

- Olympus Corp. paid $646 million to resolve civil and criminal allegations that it paid kickbacks to doctors and hospitals
  - Whistleblower worked at Olympus for 18 years
    - Appointed Chief Compliance Officer in Feb. 2009
    - Alleges harassment and retaliation in response to efforts to correct alleged wrongdoings
- Olympus allegedly obtained business and rewarded doctors and hospitals by giving kickbacks
  - Kickbacks included: consulting payments, foreign travel, lavish meals, millions of dollars in grants, and free product
  - Examples:
    - **"Permanent loan" of expensive equipment at no charge**
    - Tying of grant money for research or education to future sales
    - Extravagant trips to Olympus facilities in Japan and California

U.S. ex rel. Slowik v. Olympus America, Inc.
Case No. 10-cv-5994 (D.N.J. 2010)

Recent Enforcement – Improper Discounts

Coloplast (December 2015) and *Hollister* (April 2016)

- Three whistleblowers brought suit against ostomy and continence supply manufacturers and suppliers
  - $3.16 million and $11.4 million settlements, respectively
- Allegations included:
  - **Price concessions contingent on "conversion" campaigns**
  - Manufacturer "spiff" payments to supplier employees
  - Excess payments for catalogues
  - Violation of MediCal Best Price reporting rules
  - Violation of telephone solicitation laws
  - Manufacturer provision of patient leads to suppliers

U.S. ex rel. Herman v. Coloplast Corp.
Case No. 11-cv-12131 (D. Mass. 2011)

Recent Enforcement – Discounts Tied to "Conversion"

Coloplast and *Hollister*

- Government alleged discounts paid by manufacturers to suppliers/ distributors were actually kickbacks to **induce/reward participation in product conversion campaigns**
  - Discounts were transparent and properly reported under the safe harbor, but were accompanied by a requirement (i) to run a promotional campaign for the manufacturer's product, or (ii) as a reward for sales or conversions by the supplier's sales reps
  - Note that the allegations did not involve market share requirements tied to discounts
- Cases suggest that government tends to read safe harbor very narrowly
  - Government may exclude payments from safe harbor protection if not made in connection with or contingent upon any other requirement (e.g., promotional efforts)
    - **More than a "mere reduction in price"**
  - One supplier currently in trial over its role in case

Recent Enforcement – Debt Forgiveness

U.S. ex rel. Derrick v. Roche (N.D. Ill.)

- Roche and Humana facing FCA suit alleging that Roche regained formulary status for its diabetes products with Humana by forgiving large debt that Humana had incurred
  - Relator alleges that, after Humana dropped Roche's drugs from its formulary, she discovered that Roche had paid Humana $45 million in rebates it was not required to pay
  - Roche and Humana allegedly negotiated a deal in which Roche was returned to the formulary and Humana paid $11 million to settle the debt
- DOJ declined to intervene in May 2017, but court denied motion to dismiss in June 2018

Derrick v. Hoffman-La Roche LTD
Case No. 1:14-cv-04601 (N.D. Ill. 2018)

Case Examples

U.S. ex rel. Giddarie v. Sanofi-Aventis (2012)

- Whistleblower filed suit, government joined
- Sanofi provided "samples" of its drug, Hyalgan, to induce physicians to order Hyalgan over its less expensive competitor, Supartz.
  - Allegedly illegal sampling arrangements using free units as kickbacks (termed "value adds" by sales representatives)
  - Examples:
    - 25 samples for every 100 purchased
    - Also referenced practice-wide dinners considered "lavish"
- Settled for $109 million

New Targets and Theories: Private Equity

- On February 16, 2018, government intervened in *United States ex rel. Medrano and Lopez v. Diabetic Care Rx, LLC d/b/a Patient Care America, et al.*, No. 15-CV-62617 (S.D. Fla.), naming a private equity firm as an FCA co-defendant.
  - DOJ alleged that the compounding pharmacy Patient Care America (PCA) paid illegal kickbacks to induce prescriptions for drugs reimbursed by TRICARE.
  - PCA allegedly implemented a scheme to manipulate the compounding formula for pain and scar creams that resulted in the submission of false claims to TRICARE .
  - The complaint names as defendants PCA, two of its senior executives (one of which has since left the company), and PCA's private equity sponsor.

New Targets and Theories: Individuals

- In 2o17 Aegerion settled for $36 million an FCA case alleging off-label promotion of its drug Juxtapid. The relators have pursued non-intervened claims, and the court denied motions to dismiss filed by individuals, including the former CEO, CFO, COO, VP of Global Marketing, National Sales Director, and sales employees. The court granted the motion to dismiss regarding a board member who was part of a private equity fund.

New Targets and Theories: REMS

- Government alleged Novo Nordisk failed to comply with the FDA-mandated Risk Evaluation and Mitigation Strategy (REMS) for its Type II diabetes medication Victoza. At the time of Victoza's approval in 2010, the FDA required a REMS to mitigate the potential risk in humans of a rare form of cancer called Medullary Thyroid Carcinoma (MTC) associated with the drug. The REMS required Novo Nordisk to provide information regarding Victoza's potential risk of MTC to physicians. Matter resolved for $46.5 million.

New Targets and Theories: Meals

- In 2018, Abiomed settled with the Boston U.S. Attorney's Office for $3.6 million to resolve allegations that in promoting its line of heart pumps, it provided meals to physicians with a value inconsistent with legitimate scientific and educational discussions.
- Novartis case involving speaker programs and lunch-and-learns recently moved past summary judgment and is scheduled for trial in May.
- Lead civil AUSA in Boston USAO has stated that government perceives "modest" value of meals very differently than does industry.

New Targets and Theories: Patient Assistance Programs

- A number of manufacturers have settled with DOJ to resolve allegations that participation in patient assistance programs with third-party charities violated the Anti-Kickback Statute
  - Resolutions announced by Jazz, Lunbeck, Alexion, Accredo, United Therapeutics, Aegerion, Pfizer, Celgene
  - Other subpoenas issued and more settlements expected
- In 2017 OIG rescinded previous guidance issued to one of the charities
- In 2014 OIG issued new guidance regarding compliant operation of patient assistance programs
- In 2018, charity Patient Services Inc. filed a challenge to OIG's regulatory guidance, arguing the guidance restricted its interactions with manufacturers

The Business Case For Compliance

- Benefits of Effective Compliance
  - Creates Centralized Source of Information
  - Reveals Operational Gaps
  - Insurance: Compliant Culture May Prevent Criminal and Unethical Conduct

- CEOs of Health Care Providers Report That Under CIAs:
  - Reputation Improves
  - Problems Decrease
  - Staff Retention Increases

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