Drinker Biddle

Hot Topics in Government Enforcement for Life Sciences Companies

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Jesse Witten
Jesse.Witten@dbr.com
(202) 230-5146

Antonio Pozos
Antonio.Pozos@dbr.com
(215) 988-3327

False Claims Act

Enforcement Policy Developments - The "Yates Memo"

- Issued by Deputy Attorney General Sally Yates in September 2015
  - Instructed prosecutors and civil enforcement attorneys to focus on bringing cases against individuals, and not just against their employers
  - Also required companies to provide DOJ with all relevant facts about individuals involved in misconduct as condition of cooperation
  - Guidance Incorporated into "Principles of Federal Prosecution of Business Organizations"
- October 6, 2017: Deputy Attorney General Rosenstein Announced Broad Review of DOJ Policies
  - Criticized DOJ "[m]anagement-by-memo" and announced that DOJ's Individual Accountability Initiative for corporate executives was "under review"

False Claims Act

Enforcement Policy Developments - The "Yates Memo" (Cont.)

- Appears to Have Continued Under the New Administration
  - Yates Memo Remains a Part of the U.S. Attorney's Manual
  - New FCPA Corporate Enforcement Policy (Nov. 2017)
    - Adopted Yates Memo's requirement that company must disclose all relevant facts about all individuals involved in violation
  - FCA Settlements Continue to Include Individuals
    - $65 million Settlement with Prime Healthcare Services - $3.25 million Contribution from CEO (Aug. 2018)
    - $428,700 Settlement with Physician and Wife for Prescribing Unapproved Drugs (Aug. 2018)
    - $124,440 Settlement With Former CFO of Mission Support Alliance, LLC (Aug. 2018)

False Claims Act

Enforcement Policy Developments - The "Granston Memo"

- Issued by DOJ Civil Fraud Section Director Michael Granston in January 2018
- Directs DOJ Attorneys to More Formally Consider Dismissing *Qui Tams*
  - False Claims Act Gives DOJ Authority to Dismiss *Qui Tams* Over Objections of Relator
    - 31 U.S.C. § 3730(c)(2)(A)
  - Circuit Split:
    - Unilateral Authority to Dismiss (5th, 11th, D.C. Circuits)
    - "Valid Purpose" Test (9th and 10th Circuits)

False Claims Act

Enforcement Policy Developments - The "Granston Memo" (Cont.)

- Factors to Consider:
  - Whether the "*qui tam* complaint is facially lacking in merit, either because the relator's legal theory is inherently defective, or the relator's factual allegations are frivolous."
  - Whether the *qui tam* action "duplicates a pre-existing government investigation and adds no useful information to the investigation."
  - Whether the relevant government agency "has determined that a *qui tam* action threatens to interfere with an agency's policies or the administration of its programs and has recommended dismissal to avoid those effects."
  - Whether dismissal is "necessary to protect the Department's litigation prerogatives."
  - Whether dismissal will help to "safeguard classified information."
  - Whether costs of litigation "are likely to exceed any expected gain."
  - Whether there are "problems with the relator's action that frustrate the government's effort to conduct a proper investigation."

False Claims Act

Enforcement Policy Developments - The "Granston Memo" (Cont.)

- The Granston Memo in Practice
  - From 1986 to 2013, DOJ Unilaterally Dismissed 30 Known Cases Out of Approximately 4,000
    - Engstrom, *Public Regulation of Private Enforcement*, 107 Nw. U. L. Rev. 1689 (2013)
  - Post-Granston Memo
    - *United States ex rel. Maldonado v. Ball Homes*, LLC, 2018 U.S. Dist. LEXIS 109127 (E.D. Ky. Jun. 29, 2018)
      - Granting DOJ motion to dismiss based on weakness of case.
    - *United States ex rel. Manchester v. Purdue Pharma, Inc., et al.*, No. 1:16-cv-10947 (D. Mass. Aug. 22, 2018)
      - DOJ has moved to dismiss case against opioid pharmaceutical manufacturers on the basis that relator was not an "original source," and "has no inside information concerning any of the defendants."
      - Note: Did not rely on 31 U.S.C. § 3730(c)(2)(A); Relied on Rule 16.

False Claims Act

Enforcement Policy Developments - The "Brand Memo"

- November 16, 2017: Attorney General Issued "Prohibition on Improper Guidance Documents"
  - "Effective immediately, Department components may not issue guidance documents that purport to create rights or obligations binding on persons or entities outside the Executive Branch (including state, local, and tribal governments)"
  - Must go through notice and comment rulemaking
- January 25, 2018: Associate Attorney General Rachel Brand Issues Memo Entitled "Limiting Use of Agency Guidance Documents in Affirmative Civil Enforcement Cases" (the "Brand Memo")
  - "Guidance documents cannot create binding requirements that do not already exist by statute or regulation"
  - "Department litigators may not use noncompliance with guidance documents as a basis for approving violations of applicable law in [civil enforcement] cases"
  - "That a party fails to comply with agency guidance expanding upon statutory or regulatory requirements does not mean that the party violated those underlying legal requirements."

False Claims Act

Enforcement Policy Developments - The "Brand Memo" (Cont.)

- But….
  - "The Department may continue to use agency guidance for proper purposes … For instance, some guidance documents simply contain or paraphrase legal mandates from existing statutes or regulations, and the Department may use evidence that a party read such a guidance document to help prove that the party had the requisite knowledge of the mandate."
  - Nothing prevents the DOJ from taking the same positions in litigation that an agency took in a guidance document.
  - Memo "is not intended to, does not, and may not be relied upon to, create any rights, substantive or procedural, enforceable at la by any part in any matter civil or criminal."
- Takeaways
  - Tone is Encouraging
  - Difficult to Know Whether the Brand Memo Will Actually Affect False Claims Act Litigation

False Claims Act

Enforcement Policy Developments - Policy Against "Piling-On"

- May 9, 2018 - Deputy Attorney General Rosenstein Announced Policy Against "Piling-On"
  - "Our new policy discourages 'piling on' by instructing Department components to appropriately coordinate with one another and with other enforcement agencies in imposing multiple penalties on a company in relation to investigations of the same misconduct."
  - Fact that companies in highly regulated industries may be accountable to multiple regulators "creates a risk of repeated punishments that may exceed what is necessary to rectify the harm and deter future violations."
  - Also encouraged DOJ attorneys to consider the affect of penalties "on innocent employees, customers, and investors who seek to resolve problems and move on."

False Claims Act

Enforcement Policy Developments - Policy Against "Piling-On" (Cont.)

- Policy Incorporated into the U.S. Attorney's Manual, § 1-12.100
  - DOJ attorneys handling parallel civil and criminal matters "should remain mindful of their ethical obligation not to use criminal enforcement authority unfairly to extract or to attempt to extract additional civil or administrative monetary payments."
  - DOJ attorneys from different components should coordinate with one another "to avoid the unnecessary imposition of duplicative fines, penalties, and/or forfeiture against the company."
  - DOJ attorneys should also, "as appropriate," coordinate with "other federal, state, local, or foreign enforcement authorities that are seeking to resolve a case with a company for the same misconduct."
  - Lists factors that DOJ may consider when determining whether multiple penalties are in the interests of justice, including the egregiousness of the wrongdoing, statutory mandates, risk of delay finalizing a resolution, and the adequacy and timeliness of disclosures to the Department (as opposed to other agencies)

False Claims Act

Enforcement Policy Developments - Policy Against "Piling-On" (Cont.)

- June 14, 2018 – Acting Associate Attorney General Jesse Panuccio Delivered Remarks at ABA False Claims and *Qui Tam* Enforcement Institute
  - Reaffirmed Application of Policy in FCA Cases
  - Recognized that "repeated and unwarranted punishment for the same conduct has the potential to undermine the spirit of fair play and the rule of law," and that "[m]ultiple punishments can also deprive a company, as well as its employees, customers and investors, of the benefits of certainty and finality ordinarily available through a full and final settlement."
  - Policy designed "to ensure that defendants are subject to the appropriate, not just the highest, level of punishment that is available."

False Claims Act

Notable Recent Pharma FCA Decisions

- *United States ex rel. Streck v. Allergan, Inc.*, No. 17-1014, 2018 U.S. App. LEXIS 22762 (3d Cir. Aug. 16, 2018)
  - Drug companies allegedly reported false "average manufacturer price" data to CMS by applying certain credits, thereby lowering the reported AMPs.
  - Relator alleged that wholesalers bought excessive supplies of drugs and held them until drug companies raised prices, and then wholesalers would resell at a higher price. To prevent this, the drug companies entered into price-appreciation credit agreements with wholesalers, and these credits were applied to payments under services agreements that manufacturers paid to wholesalers. The drug companies did not apply the price-appreciation credits to AMP calculation, which had the effect of lowering AMP and therefore Medicaid rebates.
  - Third Circuit affirmed dismissal for failure to allege "knowing" conduct: (i) the relevant law was ambiguous; (ii) defendants' conduct was consistent with an objectively reasonable interpretation of law; (iii) defendants were not warned away from their conduct by administrative or judicial guidance. "Although we are not prepared to say that this is the best interpretation of the statute," it was not objectively unreasonable.

False Claims Act

Notable Recent Pharma FCA Decisions

- *Carrel v. AIDS Healthcare Found., Inc.*, ___ F.3d ___, 2018 U.S. App. LEXIS 21901 (11th Cir. 2018).
  - AKS employee exception applied to payments by AIDS foundation to employees "tasked with referring HIV-positive patients to healthcare services offered by the foundation."
  - Statutory exception protects "any amount paid by an employer by an employee … for employment in the provision of ***covered services***." Affirms summary judgment on grounds that, under the Ryan White Act, making referrals are "covered services."
  - Safe harbor states that "remuneration" "does not include any amount paid by an employer to an employee, who has a bona fide employment relationship with the employer, for employment in the furnishing of any item or service for which payment may be made in whole or in part under [a federal health care program]." Eleventh Circuit calls this a "parallel exemption."
  - But OIG states that employed salespersons of a pharma company fit within the employee safe harbor, and payments to non-employed salespersons can be permissible if they present low risk of abuse. (OIG Compliance Guidance for Pharmaceutical Manufacturers (2003)).

False Claims Act

Applying *Universal Health Services v. Escobar* in life sciences context

- *Escobar* authorized implied certification theory, but also explained that any falsity must have been "material" to the government's decision to pay claims.
- What is necessary to allege an implied certification? Must there by "specific representations about the goods and services" provided, as well as regulatory noncompliance? *United States ex rel. Rose v. Stephens Institute*, No. 17-15111 (9th Cir. Aug. 24, 2018).
- Over 100 decisions dealing with materiality, post-*Escobar*:
  - Motion to dismiss versus motion for summary judgment?
  - What has government done in other situations when faced with similar regulatory noncompliance?
  - How much weight should be given to the Government's continuing to pay claim or not taking enforcement action?
  - What is the significance of the Government's decision not to intervene?

False Claims Act

Cases of Note – Post Escobar

- *D'Angostino v. ev3, Inc.* (1st Cir. 2016) – Affirmed dismissal.
  - Relator alleged that medical device manufacturer made misrepresentations to FCA to obtain approval to market a device (regarding the intended use of the device, overstating training that was later provided, omitting safety information).
  - The government's decision to continue to reimburse, and FDA's failure to withdraw approval for the device, indicated that any misstatements were not material to the CMS decision to continue reimbursement for procedures using the device.
  - "FDA's failure actually to withdraw its approval … in the face of [relator's] allegations precludes [realtor] from resting his claims on a contention that the FDA's approval was fraudulently obtained. To rule otherwise would be to turn the FCA into a tool with which a jury … could retroactively eliminate the value of FDA approval and effectively require that a product largely be withdrawn from the market even when the FDA itself sees no reason to do so."
  - *United States ex rel. Nargol v. DePuy Orthopaedics, Inc.* (1st Cir. 2017) (same).

False Claims Act

Cases of Note – Post Escobar

- *United States ex rel. Petratos v. Genetech, Inc.* (3d Cir. 2017) – Affirms dismissal.
  - Relator alleged that drug company suppressed data that would have shown that a drug's side effects for certain patients were more common and more severe than reported. This allegedly caused physicians to submit claims that were not "reasonable and necessary" and, therefore, not covered by Medicare.
  - No factual allegations that CMS would not have reimbursed the claims had the alleged reporting deficiencies been cured. No allegation that CMS consistently refuses to pay claims like those alleged; Relator "essentially concedes that CMS would consistently reimburse these claims with full knowledge of the purported noncompliance." FDA continued its approval for the drug for the at-risk populations that Related claimed were adversely affected by the undisclosed data.
  - FDA did not initiate any proceedings to enforce its adverse-event reporting rules or require a change to the drug's label.
  - DOJ took no action and *declined to intervene*.
  - Court rejected argument that drug company's conduct was material to physician decisions to prescribe because that issue pertains to causation, not the materiality of the alleged falsity.

False Claims Act

Cases of Note – Post Escobar

- *Cyone v. Amgen, Inc.* (2d Cir. 2017).
  - Relator alleged that drug manufacturer made misrepresentations when it changed labels for its drug.
  - Second Circuit affirmed dismissal.
  - "Yet armed with [Relator's] information, [the Government] did not alter its reimbursement practices or exercise any independent discretion from the presumption of FDA approval."

False Claims Act

Cases of Note – Post Escobar

- *United States ex rel. King v. Solvay Pharmaceuticals, Inc.* (5th Cir. 2017).
  - Dictum: "We think it unlikely that prescribing off-label is material to Medicaid's payment decision under the FCA." Parties agreed that Medicaid pays claims without asking about the purpose of the drug prescription.

False Claims Act

Cases of Note – Post Escobar

- *Gilead Sciences, Inc. v. United States ex rel. Campie* (9th Cir. 2017) (Pending Pet.)
  - Relator alleged that Defendant manufactured its drugs using an active ingredient manufactured in a non-FDA-approved Chinese facility and then allegedly made false statements to FDA to obtain approval of the facility, in alleged violation of FDA's good manufacturing practices regulations.
  - District court granted motion to dismiss due to lack of materiality because FDA never withdrew approval of the drugs.
  - Ninth Circuit reversed, holding that Relator alleged materiality, given the significance of FDA approval for drugs. It stated that FDA's non-withdrawal of approval could be due to multiple different reasons, and may also lack significance because the Defendant replaced the drugs with compliance drugs.
  - "To read too much into the FDA's continued approval – and its effect on the government payment decision – would be a mistake." Relator alleged "more than the mere possibility that the government would be entitled to refuse payment if it were aware of the violations" and disputed "exactly what the government knew and when."

False Claims Act

Cases of Note – Post-Escobar Criminal Cases

- Lower Courts Resistant to Applying *Escobar's* Materiality Standard in Criminal Cases
  - *United States v. Lindsey*, 850 F.3d 1009 (9th Cir. 2017)
  - *United States v. Palin*, 874 F.3d 418 (4th Cir. 2017)
  - *United States v. Raza*, 876 F.3d 604 (4th Cir. 2017)
- Resistance is at Odds with *Escobar*
  - FCA "defines materiality using language that we have employed to define materiality in other federal fraud statutes," including the mail, bank and wire fraud statutes
  - *Escobar*'s materiality requirement descends from 'common-law antecedents'" and, "[u]nder any understanding of the concept, materiality 'look[s] to the effect on the likely *or actual behavior* of the recipient of the alleged misrepresentation.'"

False Claims Act

Pharma Developments

- AstraZeneca (2018)
  - $110 million to settle Texas *qui tam* action alleging off-label promotion of an antipsychotic medication to Texas Medicaid providers who primarily treated children and adolescents but the medication was not FDA-approved for children. Also allegedly marketing a cholesterol-lowering medication while downplaying the risk of diabetes in certain patient groups.
- Numerous Relators alleging that product support, such as assisting with insurance verification and prior authorizations, violate the Anti-Kickback Statute.
  - *E.g.*, *Di Donato v. Insys Therapeutics Inc*. (D. Ariz. 2017); *Health Choice Alliance, LLC v. Eli Lilly and Co*. (E.D. Tex. 2018); *DAC Surgical Partners, P.A. v. United Healthcare Services, Inc*. (S.D. Tex. 2016); *Health Choice Group, LLC v. Bayer Corp*. (E.D. Tex. 2018); *United States v. Boston Scientific Neuromodulation Corp*. (D.N.J. 2013).
  - Relevant guidance – Advisory Opinion 12-10 (among others) and OIG Compliance Guidance for Pharmaceutical Manufacturers (2003).

Notable Enforcement Areas

Patient Copayment Assistance Programs

- OIG special advisory bulletins and advisory opinions
  - Pharmaceutical company cannot use charity as a mere conduit to pay money to patients. Charity must be independent and bona fide.
  - Disease funds must be defined in accordance with widely recognized clinical standards.
  - Broad formulary (e.g., all FDA-approved drugs).
  - Pharmaceutical company cannot “influence” charity.
  - Charity cannot provide data to donors to enable them to correlate donations with support for their particular drugs.

Notable Enforcement Areas

Patient Copayment Assistance Programs

- Settlements
  - Aegerion - $29M plus CIA (Sept. 2017) (Along with criminal misbranding and other FCA theories)
  - United Therapeutics - $210M plus CIA (Dec. 2017)
  - Pfizer - $24M plus CIA (May 2018)
  - Jazz Pharmaceutical – announced tentative $57M settlement (May 2018)
  - Lundbeck - announced $52M tentative settlement (June 2018)
- Rescission of Advisory Opinion for Caring Voice Coalition (Nov. 2017)

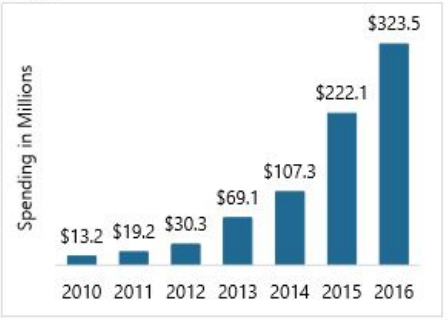
Notable Enforcement Areas

Compounding Pharmacies

- OIG Report: *Questionable Billing for Compounded Topical Drugs in Medicare Part D* (August 2018)
  - Increase in Part D spending for compounded drugs increased from $13.2 million in 2010 to $323.5 million in 2016
  - "[T]his explosive growth raises fraud, waste and abuse concerns about whether compounded topical drugs are being billed appropriately"
  - Identified: 550 pharmacies that "warrant further scrutiny," and

    124 prescribers who "raise particular concern."

Part D spending for compounded topical drugs grew exponentially from 2010 to 2016.



Source: OIG analysis of Part D data, 2017.

- May signal evolution from TRICARE centric-cases.

Notable Enforcement Areas

Compounding Pharmacies

- DOJ Intervention in *United States ex rel. Medrano v. Diabetic Care Rx* (Feb. 2018)
  - DOJ complaint asserts claims against Los Angeles private equity firm, compounding pharmacy portfolio company, and two portfolio company executives.
    - Alleges that Florida compounding pharmacy paid kickbacks to marketing companies to target TRICARE beneficiaries, and that those marketing companies in turn paid telemedicine doctors to prescribe creams without seeing patients.
    - Also alleges pharmacy used a related charity to pay patients to accept prescriptions by covering hefty copayments through a related charitable organization.
  - Claims against private equity firm: Alleges that private equity firm assumed active control over pharmacy, including appointing two of its partners as pharmacy officers and directors responsible for pharmacy's strategic direction.
    - DOJ asserts that this active management is evidence that the private equity firm know or should have known about the illegal marketing arrangements.

Notable Enforcement Areas

Opioids

- Criminal Enforcement
  - August 2, 2017 – Attorney General Announces Criminal Opioid Fraud and Abuse Detection Unit
    - Emphasis on data analytics to identify and prosecute individuals contributing to opioid epidemic
  - June 28, 2018 – Annual DOJ Health Care Fraud & Opioid "Takedown"
    - 601 individuals charged: 162 defendants charged with illegally distributing opioids & other narcotics
    - Exclusions: 587 individuals, including 67 doctors and 402 nurses, for opioid diversion and abuse in prior year

Notable Enforcement Areas

Opioids

- Civil Enforcement Under Controlled Substances Act
  - January 17, 2017 – DOJ Announces $150 Million Settlement with McKesson Corporation for Alleged Failure to Report Suspicious Orders
  - July 11, 2017 – DOJ Announces $35 Million Settlement with Mallinckrodt LLC for Alleged Failure to Report Suspicious Orders of Pharmaceutical Drugs and for Recordkeeping Violations
- False Claims Act as Opioid Enforcement Tool
  - February 27, 2018: Attorney General Sessions Announces “Prescription Interdiction & Litigation Task Force”
    - New initiative to “deploy and coordinate all available criminal and civil law enforcement tools to reverse the tide of opioid overdoses in the United States”

Notable Enforcement Areas

Opioids

- Insys Criminal Litigation
  - *United States v. Babich, et al.*, No. 16-cr-10343 (D. Mass.) – Trial set for January 2019
    - Defendants Include Founder John Kapoor, former CEO Michael Babich, and five other former executives.
    - Charges include Racketeering, Wire Fraud, Mail Fraud and Conspiracy
  - Notable Guilty Pleas:
    - Several managers and sales reps., including former CEO's wife, have pleaded guilty to various charges
  - Cases Reported in Michigan, Alabama, New Hampshire, Rhode Island, New York, Florida, Ohio, and other jurisdictions
- Insys False Claims Act Litigation
  - Government has intervened in 5 *qui tams*
  - Company announced $150 million settlement in principle; up to $75 million more, depending on unspecified contingencies

Notable Enforcement Areas

Opioids

- Additional False Claims Act Developments
  - Galena Biopharma Settlement (Sept. 8, 2017) (D.N.J.)
    - $7.7 million to resolve allegations the company paid kickbacks to doctors, in the form of free meals, speaking fees and expenses, and improper performance rebates to induce prescriptions of fentanyl based drug Abstral.
    - According to DOJ, also cooperated with criminal prosecution of two physicians in Alabama.
  - *United States ex rel. Manchester v. Purdue Pharma, Inc., et al.*, No. 1:16-cv-10947 (D. Mass. Aug. 22, 2018)
    - DOJ has moved to dismiss, contends relator not an "original source," and "has no inside information"
  - *United States ex rel. Sheoran v. Wal-Mart Stores East LP*, No. 4:13-cv-10568 (E.D. Mich)
    - Company has moved to dismiss claims by former pharmacist accusing company of improper opioid prescriptions on grounds that relator did not identify any actual false claims in his complaint.
    - DOJ and Michigan declined to intervene.

Notable Enforcement Areas

Foreign Corrupt Practices Act – Enforcement Policy Developments

- July 25, 2018 – Deputy Assistant Attorney General Matthew Miner Clarifies DOJ Policy on FCPA Risks Discovered During Mergers & Acquisitions
  - DOJ will apply FCPA Corporate Enforcement Policy to risks discovered during M&A transactions.
    - "Presumption" that DOJ will decline case absent "aggravating circumstances" if company (1) self-discloses violation, (2) fully cooperates, (3) remediates, and (4) disgorges ill-gotten gains
      - 50% fine reduction if DOJ still brings a case for aggravating circumstances (other than recidivism)
    - No Self-Disclosure: At most, 25% fine reduction – even if the company fully cooperates and remediates
  - Also encouraged companies to use DOJ's FCPA Opinion Procedure
    - Clearance through procedures results in "rebuttable presumption" that disclosed conduct complies with FCPA
    - Can take several months, requires certification by senior company official, potentially CEO
    - Last used in 2014.

Notable Enforcement Areas

Foreign Corrupt Practices Act – Resolutions & Declinations

- 2016 and 2017 Saw Significant FCPA Resolutions
  - Zimmer Biomet - $30.5 million Resolution with the DOJ & SEC (Jan. 2017)
    - $17.5 million Resolution with DOJ (Parent DPA, Subsidiary Plea); $13 million with SEC
  - Alere - $13 million Settlement with the SEC (Sept. 2017)
  - Orthofix - $6.1 million Settlement with the SEC (Jan. 2017)
  - Teva - $519 million Resolution with DOJ & SEC (Dec. 2016)
    - $283 million with DOJ (Parent DPA, Subsidiary Plea), $236 million with SEC
  - GSK - $20 million Settlement with the SEC (Sept. 2016)
  - Olympus - $646 million Global Resolution (Mar. 2016)
    - $22.8 million FCPA, $312 million AKS Criminal Resolutions (DPAs, American and Latin American Subs.)
    - $310 million False Claims Act *Qui Tam* Resolution
    - Monitor and CIA

Notable Enforcement Areas

Foreign Corrupt Practices Act – Resolutions & Declinations

- 2018 Resolutions:
  - Sanofi (September 2018)
    - $25 million Settlement with SEC
      - Resolved allegations involving Kazakhstan, Lebanon and the UAE
    - DOJ Declination (March 2018)
      - Declination Announced in Company's Form 20-F
      - Appears to have been traditional declination letter: not listed as a declination with disgorgement under FCPA Corporate Enforcement Policy
        - *See* https://www.justice.gov/criminal-fraud/pilot-program/declinations
- Relative Inactivity Particularly Interesting Due to Announcement of Fraud Section Efforts to Bring Health Care and Life Sciences Cases

Notable Enforcement Areas

Foreign Corrupt Practices Act – Enforcement Policy Developments

- July 25, 2017: DOJ Fraud Section Acting Chief Sandra Moser Announced Partnership Between FCPA and Health Care Fraud Units
  - Objective: coordinate investigation and prosecution of domestic and foreign bribery and kickback cases in the health care industry.
- June 19, 2018: DOJ Fraud Section FCPA Chief Dan Kahn and Health Care Fraud Chief Joe Beemsterboer Reaffirm Partnership at ACI 12th Advanced Forum on FCPA in Life Sciences
  - Kahn cited Olympus resolution (2016) for theory that, if a company lacks sufficient anti-bribery controls overseas to prevent misconduct, there is an "increased chance" that improper payments will occur in the United States
  - Beemsterboer cited reconstruction of Health Care Fraud Corporate Strike Force, expertise with traditional U.S. criminal investigative methods and individual prosecutions
- Impact of Initiative: TBD

Notable Enforcement Areas

Call for Comments re: AKS

- HHS-OIG Has Requested for Comments on Anti-Kickback Statute Safe Harbors
  - Stated Objective: Eliminating "barriers to coordinated care or value based care."
  - Particular focus on identifying "ways in which [the OIG] might modify or add new safe harbors to the anti-kickback statute and exceptions to the beneficiary inducements civil monetary penalty … definition of 'remuneration'"
  - **Deadline to Submit Comments: October 26, 2018**