False Claims Act Enforcement, Policy Updates, and Trends in Patient Support

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2018 DOJ Policy Updates

- Granston Memo (1/10/18)
  - Addressed use of Department's dismissal authority under 31 U.S.C. § 3730(c)(2)(A) and outlined a number of factors to consider in non-intervened *qui tam* matters, including dismissal of "meritless" *qui tam* cases
- Brand Memo (1/25/18)
  - DOJ "may not use its enforcement authority to effectively convert agency guidance documents into binding rules"
- Rosenstein Speech (11/29/18)
  - DOJ redefined policy previously set forth in the "Yates Memo" regarding cooperation credit

Revised DOJ Policy on Corporate Settlements

2015 Yates Memo – Key Principles:

- Corporations must provide all relevant facts relating to the individuals responsible for the misconduct in order to qualify for cooperation credit
- Focus on individuals from the inception of criminal or civil corporate investigation
- Close coordination between DOJ criminal and civil attorneys
- DOJ will not release culpable individuals from civil or criminal liability when resolving a matter (absent extraordinary circumstances or DOJ policy)
- Resolution with corporation should not occur without clear plan to resolve related individual cases
- Civil attorneys should focus on individuals and evaluate whether to bring suit against individual based on consideration beyond individual's ability to pay

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Revised DOJ Policy on Corporate Settlements

New policy statement on cooperation:

- Companies must identify all individuals "substantially involved in or responsible for" the alleged wrongdoing in order to get "maximum" cooperation credit
- "Restored" discretion for DOJ attorneys to award some credit for companies that "meaningfully assist" the government's investigation
  - "In a civil False Claims Act case, for example, a company might make a voluntary disclosure and provide valuable assistance that justifies some credit even if the company is either unwilling to stipulate about which non-managerial employees are culpable, or eager to resolve the case without conducting a costly investigation to identify every individual who might face civil liability in theory, but in reality would not be sued personally."
    - Remarks of Deputy Attorney General Rod Rosenstein, Nov. 29, 2018
- Companies that conceal senior officials' wrongdoing or fail to make good faith representations to DOJ will be ineligible or cooperation credit.

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Revised DOJ Policy on Corporate Settlements

New policy statement on individuals:

- DOJ attorneys generally to avoid pursuing civil litigation "that is unlikely to yield any benefit"
- "Return[ed]" discretion for DOJ attorneys to give releases for individuals in corporate settlements, depending on the facts and circumstances
- Civil releases are again possible for those individuals "who do not warrant additional investigation in corporate civil settlement agreements"
- DOJ attorneys may again consider an individual's ability to pay in deciding whether to pursue a civil case against that individual

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DOJ Policy on FCA Dismissal Authority

- Granston Memo: "Factors for Evaluating Dismissal Pursuant to 31 U.S.C. 3730(c)(2)(A)"
  - "Even in non-intervened cases, the government expends significant resources in monitoring these cases and sometimes must produce discovery or otherwise participate. If the cases lack substantial merit, they can generate adverse decisions that affect the government's ability to enforce the FCA."
  - "3730(c)(2)(A) . . . Remains an important tool to advance the government's interests, preserve limited resources, and avoid adverse precedent"
  - Enumerated factors:
    - "Curbing meritless *qui tams*"
    - "Preventing parasitic or opportunistic *qui tam* actions"
    - "Preventing interference with agency policies and programs"
    - "Controlling litigation brought on behalf of the United States"
    - "Safeguarding classified information and national security interests"
    - "Preserving government resources"
    - "Addressing egregious procedural errors"

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Case Developments on Materiality

- *United States ex rel. Campie v. Gilead*
  - Supreme Court had called for the Solicitor General's views
  - In amicus brief, the Solicitor General stated "If this case is remanded to the district court, the government will move to dismiss . . . based in part on the government's thorough investigation of [the] allegations and the merits thereof"
  - DOJ did not provide any elaboration on its view of the merits of the case
  - Noted its decision took into consideration the possibility that "both parties might file burdensome discovery and Touhy requests for FDA documents and FDA employee discovery (and potentially trial testimony), in order to establish 'exactly what the government knew and when,' which would distract from the agency's public-health responsibilities"
  - This pronouncement from the DOJ is the most high-profile invocation of the Granston Memo since it was issued in January

Case Developments on Materiality

- *United States ex rel. Harman v. Trinity Industries, Inc.* (5th Cir. 2017)
  - Petition for a writ of certiorari pending
  - Circuit Court reversed district court's denial of motion for judgment as a matter of law based on materiality
    - Overturned a $663 million jury verdict
  - "When the government, at appropriate levels, repeatedly concludes that it has not been defrauded, it is not forgiving a found fraud—rather it is concluding that there was no fraud at all."

Case Developments on Materiality

- *United States ex rel Prather v. Brookdale Senior Living Communities, Inc.* (4th Cir. 2018)
  - Petition for a writ of certiorari pending
  - Circuit Court reversed district court's dismissal for failure to sufficiently allege materiality and scienter
    - Applied a 'holistic' approach to assess materiality
    - Held that continued payment did not render claims immaterial where "the government did not know that the claims the defendants submitted were false"
    - Rejected defendants' argument that relators must provide allegations of past government action to overcome a motion to dismiss

Case Developments on Materiality

- *United States ex rel. Rusckh v. CMC II LLC* (M.D. Fla. 2018)
  - District Court vacated $350 million jury verdict and granted defendants' motion for judgment as a matter of law
  - *"Escobar* rejects a system of government traps, zaps, and zingers that permits the government to retain the benefit of a substantially conforming good or service but to recover the price entirely — multiplied by three — because of some immaterial contractual or regulatory non-compliance"
  - Further held that relators must prove that defendants were aware at the time of payment that their claims for payment were false *and* that compliance was material to the government
  - Currently on appeal to the 4th Cir.

Case Developments: Statute of Limitations

- *Cochise Consultancy v. United States ex rel. Hunt*
  - Supreme Court poised to settle deepening circuit split involving the statute of limitations for the False Claims Act
    - Petition for a writ of certiorari to the 11th Cir. granted on November 16, 2018
  - Questions presented are whether a relator (as opposed to only the United States) can take advantage of Section 3732(b)(2) when the United States declines to intervene in an FCA action and, if so, whether the relator constitutes an "official of the United States" under the statute
  - Analysis hinges on government's knowledge of allegations

Case Developments: AKS and False Claims

- ***U.S. ex rel. Greenfield v. Medco Health Solutions, Inc.***, 880 F.3d 89 (3d Cir. 2018)
  - Relator, a former Area VP for a specialty pharmacy (Accredo) alleged that the company made donations to hemophilia charities that then recommended the company to hemophilia patients; according to relator, this violated the AKS and FCA
  - The district court granted Accredo's SJ motion because relator did not show that the charities' referrals "resulted from" the donations
  - DOJ filed a brief on appeal arguing that the district court erred in requiring relator to show that patients chose the company because of the charities' recommendations

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Case Developments: AKS and False Claims

- ***U.S. ex rel. Greenfield v. Medco Health Solutions, Inc.***, 880 F.3d 89 (3d Cir. 2018)
  - The Third Circuit affirmed, holding that **relator must show, at a minimum, that at least one patient for whom the company submitted reimbursement claims was exposed to a referral from a charity that received a donation**
  - The court stated that it would be "too exacting" to "require a relator to prove that federal beneficiaries would not have used the relevant services absent the alleged kickback scheme"
  - "**A kickback does not morph into a false claim unless a particular patient is exposed to an illegal recommendation or referral and a provider submits a claim for reimbursement pertaining to that patient**"

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Case Developments: AKS and False Claims

- ***U.S. ex rel. King v. Solvay Pharmaceuticals, Inc.***, 871 F.3d 318 (5th Cir. 2017)
  - Relators, former sales and marketing employees, alleged that Solvay engaged in off-label marketing and improper promotion of three drugs in violation of, *inter alia*, the AKS and the FCA
  - The Fifth Circuit affirmed summary judgment in favor of Solvay
    - Relators offered **no credible evidence that payments to physician-consultants caused those physicians to write prescriptions that were reimbursed by Medicaid**
    - Rather, the evidence showed that physicians participated in Solvay speaker programs and were compensated for consulting or presenting

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Case Developments: AKS and False Claims

- ***U.S. ex rel. King v. Solvay Pharmaceuticals, Inc.***, 871 F.3d 318 (5th Cir. 2017)
  - "There was **nothing illegal about paying physicians for their participation in these types of [marketing] programs and there is no evidence that participation was conditioned upon prescribing Solvay's drugs to Medicaid patients**"
  - Acknowledging that Solvay likely "intended these programs to boost prescriptions[,]" the Fifth Circuit nonetheless concluded that "it would be speculation to infer that compensation for professional services legally rendered actually caused the physicians to prescribe Solvay's drugs to Medicaid patients"

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Case Developments: Off-Label False Claims

- ***U.S. ex rel. Ibanez v. Bristol-Myers Squibb Co.***, 874 F.3d 905 (6th Cir. 2017)
  - The district court dismissed employees' FCA suit alleging that pharmaceutical companies engaged in a nationwide scheme to promote an anti-psychotic drug for off-label uses and to improperly induce physicians to prescribe the drug
  - The Sixth Circuit affirmed because ***relators failed to plead a specific, representative false claim submitted to the government***
  - A complaint must "adequately allege the entire chain—from start to finish—to fairly show defendants cause[d] false claims to be filed," including any "specific intervening conduct" along the chain
  - As the Sixth Circuit observed, the causal chain issue "***reveals just what an awkward vehicle the FCA is for punishing off-label promotion schemes***"

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Life Sciences Enforcement Trends 2012 – Present*

- Reimbursement Support FCA Settlements: **10** settlements involving reimbursement support allegations from 2012 – present**
  - 2012 – 1 case
  - 2013 – 2 cases
  - 2014 – 1 case
  - 2015 – 1 case
  - 2016 – 0 cases
  - 2017 – 4 cases
  - 2018 – 1 case
- As of December 13, 2018, there are at least **19 ongoing** *qui tams or* investigations involving reimbursement support allegations
  - 14 of these cases or investigations involve nurse or clinical educators
- Other FCA enforcement trends
  - HCP speaker programs, HCP consultant payments
  - Patient Assistance Programs (PAPs)
  - Improper promotional activities

*non-exhaustive; public data; ** cases did not necessarily resolve such allegations

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What are “Reimbursement Support Services”?

- Insurance benefits investigation or verification (BI/BV)
- Prior Authorizations (PAs) / Statements of Medical Necessity (SMNs)
- Billing or coding guides or information (ICD/CPT)
- Insurance Appeals / Medical Exceptions
- Insurance coverage/access process, requirements and information, forms, templates, etc.
- Monitoring, tracking payor/insurer trends in coverage
- Calling insurers directly to facilitate the coverage/access process
- Reimbursement support “hotline” (phone, fax, email, web-portal) to answer questions
- Coordination of specialty pharmacy or dispensing of product
- Refill reminders / Adherence or medication compliance communications
- Adverse event or product safety monitoring
- Field reimbursement personnel / clinical educators or nurses
- Serving as “hub” for all patient support program offerings (e.g., co-pay, bridge program, voucher, etc.)

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OIG Guidance

- Longstanding OIG Guidance (2003 CPG) stated that manufacturers can provide "limited" reimbursement support in connection with the sale of their products without violating the AKS
  - No remuneration, no "independent" value
  - Part of the purchase of a drug
- OIG has never defined "limited" support
  - Several OIG AO's have addressed RSS and related activities
- But, manufacturer cannot:
  - Offer a reimbursement guarantee, or
  - Provide too much service (e.g., providing substantial value to the doctor or staff)
- Services for free or below FMV implicate the AKS
  - Evaluation and management services or "E/M" for Medicare include administrative tasks such as BI, checking formulary lists, seeking coverage determination, PAs, handling prescription refills, etc.
    - HCPs not permitted to directly charge patients for such services; billed indirectly through E/M unit charge

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Enforcement Trend: Reimbursement Support

- Allegations generally include:
  - Comprehensive, instead of limited, reimbursement support providing independent financial value to HCPs
  - Promoting, offering services pre-prescribing decision (selling services)
  - Manufacturer reps. have inappropriate access to patient records, EMR systems (HIPAA/privacy)
  - Manufacturer reps., particularly in sales or managed markets, completing clinical parts of PA, SMN and appeal forms or providing pre-printed forms ("canned" medical justifications or standard "buzzwords")
  - Manufacturer reps., including vendors, purporting to act on behalf of HCPs (misleading identity)
  - Skewed or false clinical information being presented to payors by non-clinically trained commercial personnel (e.g., diagnosis, medical history, tried/failed medications)
  - Providing limited "correct" ICD or CPT codes to HCPs
  - Services encouraging off-label use of products or use of expensive products over generics
  - Incentive compensation tied to reimbursement support (e.g., PA success)
  - Targeting high-prescribers to provide support services to, small offices with inadequate staff
  - Suspect relationships with independent co-pay assistance foundations

Enforcement Trend: Reimbursement Support (cont'd)

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Reimbursement Support: Compliance Considerations

- In-house or outside vendor for RSS hub?
- Policy, SOPs, Work Instructions, call guides, etc.?
  - Who, what, where, when, how, why?
  - Any risk-based changes or exceptions based on product, label, disease?
- Field reimbursement personnel? (in-house or vendor)
- What can field sales personnel “do”?
- What role does market access play (if any)?
- Is there one lawyer *dedicated* to reviewing all hub/RSS materials?
  - Who is training/communicating with Marketing and Sales leadership about hub/RSS materials?
  - When does Compliance have a role?
- Who is doing oversight/monitoring for legal and healthcare compliance?
- How do you address issues, variations, violations?

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Patient Assistance Programs

- Pharmaceutical companies' relationships with ***charitable organizations*** have come under scrutiny for potential AKS-based FCA violations, with multiple cases resulting in significant FCA settlements in 2017-2018
- Key HHS OIG guidance:
  - ***2005 Special Advisory Bulletin ("SAB"):*** HHS OIG stated that the way for companies to support patients with "few, if any [AKS] concerns" was through "cash donations to independent, *bona fide* charitable assistance programs“
  - ***2014 SAB:*** HHS OIG reiterated the importance of independence of charities and cautioned that limitations on drug choice specified by a patient assistance charity increases the likelihood that such assistance will be viewed as improper
  - ***November 2017 Rescinded Advisory Opinion:*** Citing patient steering risks, HHS OIG rescinded a favorable advisory opinion initially authored in 2006 regarding AKS liability for Caring Voice Coalition's charitable drug subsidy program

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AKS and PAPs – Factors Raising Potential Gov't Concern

- **Disease Definitions** – where the charity allows the donors to directly or indirectly influence the identification of its disease categories.
  - Arrangements that "artificially define their disease categories so narrowly that the earmarking effectively results in the subsidization of one (or a very few) of donors' particular products" may implicate the AKS
- **Data** – where the charity provides disaggregated or patient-specific data to manufacturer or donor.
- **Product** – special considerations where the manufacturer donates product to the charity or patient eligibility is defined with reference to the cost of a particular drug.
  - OIG warned that in-kind donations "have the effect of creating a direct correlation between the donation and use of a particular donor's product."
  - Relatedly, "a disease fund that covers only a single product, or the products made or marketed by only a single manufacturer that is a major donor to the fund, will be subject to scrutiny."

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AKS and PAPs – Factors Tending to Show Independence

- **Independent personnel:** Board members not affiliated with the donor and no board member or employee receives compensation from donor

- **Eligibility criteria:** Charity "determines eligibility according to a reasonable, verifiable, and uniform measure of financial need that is applied in a consistent manner"
  - For example: financial eligibility is based on the federal poverty guidelines; assistance is provided on a first-come, first-served basis; patients are permitted to change providers, drugs, or insurance plans; patients qualify regardless of their current provider, drugs, or insurance plan
  - Detailed policies and procedures should be set out in advance to guide implementation of criteria

- **Scope of coverage:** Charity does not limit its assistance to high-cost or specialty drugs; instead, the charity makes assistance available for all prescription medication, including generics and bioequivalents, approved by the FDA for treatment of the disease states covered by the fund.

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AKS and PAPs – Factors Tending to Show Independence

- **Disease Definitions:**
  - Donors' suggestions are not solicited and are not considered in the delineation of any of the charity's disease funds.
  - Donors may specify that their donations go to a specific disease fund, but they cannot earmark contributions for treatment of a specific disease covered by the fund.
  - Charity does not define its disease funds "by reference to specific symptoms, severity of symptoms, method of administration of drugs, stages of a particular disease, type of drug treatment, or any other way of narrowing the definition of widely recognized disease states"
  - Charity's board defines its diseases according to widely-recognized clinical standards, and it covers a broad spectrum of products

- **Data:** No disaggregated data is provided to donors regarding the patients, and no information is provided to patients regarding the donors.

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Questions?