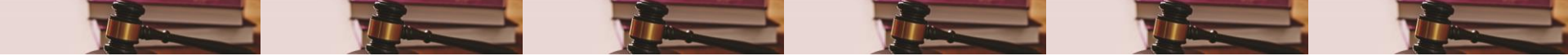

Top Legal Threats and Trends Facing FDA-Regulated Companies

Hannah Bornstein *Nixon Peabody LLP*
Lauren Misztal *Mallinckrodt Pharmaceuticals*
Michael Paddock *Sheppard Mullin Richter & Hampton LLP*
Jonathan Phillips *Gibson Dunn & Crutcher LLP*

FDLI

Agenda

- Continuing Trends in Post-*Escobar* Case Decisions
- Anti-Kickback Statute Enforcement Trends
- *Allina* and Implications
- DOJ Cooperation Credit Guidance
- “Granston Memo” Updates
- Opioid Litigation and Enforcement Update

False Claims Act: Post-*Escobar* Trends

Universal Health Services v. Escobar, 136 S. Ct. 1989, 2016

- Affirmed validity of implied certification as a theory of liability in certain circumstances:
    - 1) "[T]he claim does not merely request payment, but also makes specific representations about the goods or services provided," and
    - 2) "[T]he defendant's failure to disclose noncompliance with material statutory, regulatory, or contractual requirements makes those representations misleading half-truths"
- Alleged statutory, regulatory, or contractual violation, or misrepresentation regarding compliance, must be "material" to the government's payment decision
- *Escobar* identified relevant, non-dispositive factors, for lower courts to use in deciding materiality:
    - 1) Has the government expressly identified compliance with a provision or regulation a condition of payment
    - 2) Would the government deny payment if it had known of the alleged noncompliance
    - 3) Was the noncompliance minor or substantial

3.5 years post-*Escobar*: where do we stand?

- No further definition or clarification provided by SCOTUS as to "materiality" standard

- No bright-line or "easy" definition or rule for lower courts to follow when ascertaining whether a relator's allegation(s) of noncompliance satisfies the "materiality" standard set forth in *Escobar*

- Potential for materiality question to become a fact-intensive, discovery-focused question

Sampling of 2019 case highlights:

- Eleventh Circuit review of *United States ex rel. Ruckh v. Salus Rehabilitation, Inc.*, No. 18-10500, 11th Cir.
    - Following *Escobar*, trial court set aside a $347M jury verdict on the grounds that *Escobar*'s rigorous and demanding standard was not met
    - Oral argument (held on Nov. 20, 2019) addressed whether *Escobar* can apply to factually false and legally false claims
- *United States ex rel. Lemon et al v. Nurses to Go, Inc*., 924 F.3d 155 (5th Cir. 2019) (reversing the district court and finding that Medicare regulations tie hospice service to certifications made by the provider and HHS had previously taken enforcement action against hospice providers that have submitted bills for ineligible patients)
- *United States ex rel. Castillo-Baier v. Walgreen Co.*, No. 14-cv-1558, 2019 WL 4749904 (N.D. Ill. 2019) (finding that relator failed to satisfy *Escobar*'s two-part test and show that there was any 'specific misrepresentation' made by Walgreens leading to a 'misleading half truth' in connection with automatic prescription refills)
- *United States ex rel. Marsteller v. Tilton*, No. 5:13-cv-00830-AKK (N.D. Ala. Sep. 30, 2019)(allowing relators to replead to show a more 'holistic' standard toward materiality rather than adopting an explicit standard that continued payment demonstrates immateriality)

Practical Considerations

- Potential sources for proving materiality (or lack thereof)
    - Discovery from the relators
    - Discovery from the government
        - Implications of seeking discovery from the FDA or CMS
        - Implications of issuing *Touhy* requests
- Impact of materiality evidence on the public disclosure bar and original source requirements set forth in 31 U.S.C. § 3730(e)(4)
- **Remember: the heart of the False Claims Act – and the materiality inquiry – is always about the *claim for payment* and not, for example, a product approval decision, a recall, a potential injury or adverse effect, etc.

Anti-Kickback Statute Enforcement Trends

Anti-Kickback Statute

- The federal Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b), criminalizes offering or paying remuneration to induce or reward referrals of any item or service which may be reimbursed by federal health programs

- “Remuneration” has been defined very broadly as anything of value including cash, gifts, and in-kind services or compensation

- “One-purpose test”: The government takes the position that if even “one purpose” of the remuneration is to induce referrals, reward a referral source, or generate business, the AKS applies notwithstanding other valid purposes for the remuneration

2019 AKS Resolutions

- The alleged remuneration at issue in AKS-based resolutions announced in 2019 has taken a variety of forms:
  - Gifts and luxury expenses (x7)
  - Excessive or sham speaking, ad board, and consulting fees (x8)
  - Agreements on price (x2)
  - Payments to third-party marketers to solicit patients regardless of need (x2)
  - Payment of co-pays for government beneficiaries through charitable foundations/PAPs (x6)
  - Practice development and marketing support services
  - Providing free product to HCPs

Patient Assistance Programs

- DOJ has continued to pursue allegations that manufacturers' donations to PAPs violated the AKS by defraying patients' co-payment obligations for drugs offered by those manufacturers
  - Theories have largely been tied to HHS OIG 2005 and 2014 guidance emphasizing importance of PAP's independence

- Key risk factors:
  - Disease definitions: where the charity allows donors to influence the identification of disease categories
  - Data: where the charity provides disaggregated or patient-specific data to donor
  - Product: special considerations where the manufacturer donates product to the charity

- Sens. Warren and Whitehouse recently called on HHS OIG to update PAP guidance by (1) prohibiting donations to disease-specific funds, (2) requiring PAP coverage disclosure, and (3) requiring PAPs to cover generic alternatives

Reimbursement/Patient Support Services

- Widespread *qui tam* and DOJ investigative activity pertaining to reimbursement and product support services
  - Examples: benefits investigation/verification; coding advice/assistance; insurance coverage and claims submission support; adherence and compliance programs; physician locator services

- Government has recognized some level of patient or reimbursement support is desirable and permissible
  - 2003 OIG guidance: manufacturer can provide "limited" reimbursement support in connection with sale of products without violating AKS
  - DOJ motion to dismiss *U.S. ex rel. Health Choice Group v. Bayer Corp.*: "basic product support" such as patient educational services are consistent with "important policy and enforcement perogatives of the federal government's healthcare programs"

Reimbursement/Patient Support Services

- Product support service risk factors to watch for:
  - Volume-based criteria for offerings or compensation to HCPs/pharmacies
    - E.g. withdrawing or denying support due to declining or insufficient volumes of prescribing
  - Establishing or quantifying the financial gain an HCP could realize from the services
  - Heightened level of service that creates independent value for HCP
    - HCPs who can eliminate staff or reduce salaries on account of receiving the services
    - Reimbursement guarantees that eliminate normal financial risks
  - Offer of product support results in skewed clinical judgment or overutilization
  - HCPs charging patients or charging E/M codes for free or below-FMV admin services

Agreements on Price

- AKS is also being employed to combat drug prices
  - E.g. proposed (but withdrawn) rule to remove safe harbor protection for rebates to government program payors
- Recent DOJ Antitrust Division activity
  - Ongoing investigation of generic drug prices
  - Procurement Collusion Strike Force announced to focus on conduct that "undermine[s] competition in government procurement, grant and program funding"
- Recent settlements with manufacturers based on AKS theory that they allegedly "paid remuneration through arrangements on price, supply and allocation of customers"
- Relevant traditional antitrust risk factors include low barriers to entry; commoditized products; significant opportunities for industry interactions (e.g. trade shows/meetings, employee turnover to competitors)

Allina and Implications

Allina and Implications

- *Azar v. Allina Health Services, et al.*, No. 17-1484 (June 3, 2019)
- At issue: CMS' method of calculating payments to hospitals that serve disproportionate share of low income patients
- 'Medicare Fraction': days providing care to Part A eligible patients who are also eligible for SSA income support / days providing care to Part A eligible patients
- 2004 CMS final rule: Part C days to be included in fraction
  - Hospitals complained, rule vacated
- 2013 CMS proposed rule: prospectively adopted rule of including Part C patients
- 2014: CMS posts the 2012 fraction on its website, notes that fraction included Part C patients
  - Hospitals: $4 billion reduction in DSH payments

Allina and Implications

- Hospitals' lawsuit: CMS violated Medicare Act requirement of 'notice and comment' for any "rule, requirement or other statement of policy… that establishes or changes a substantive legal standard governing… the payment of services." 42 USC 1395hh(a)(2).
- HHS: while decision to include Part C patients was a "statement of policy", it did not create a "substantive legal standard"… no need for 'notice and comment'
- District Court: calculus was an "interpretive rule" which did not require notice and comment (~APA analysis)
- Court of Appeals for D.C. Circuit (Kavanaugh): reversed
  - Including Part C patients was not an "interpretive rule"; it established a "substantive legal std."
  - Medicare Act requires N&C for <u>anything</u> that establishes a "substantive legal std."

Allina and Implications

- Supreme Court decision (June 2019) (7-1)
- Distinguishes between APA and Medicare Act notice & comment requirements
- APA analysis: if a “substantive rule”, need N&C; if an “interpretive rule”, no need
- Medicare Act analysis: forget labels
  - If a guidance document establishes a “substantive legal standard”, it must undergo N&C… even if
    - An interpretive rule
    - A statement of policy
    - Takes any form or name
- Is an APA “substantive rule” something different from a Medicare Act “substantive legal standard”? Supreme Court: Yes
- What is the difference? Supreme Court: Future cases will decide

Allina and Implications

- Further branching of Medicare administrative law from traditional APA law
- What has happened since June 3, 2019?
- August 22: *Select Specialty Hosp.-Denver, Inc. v. Azar*, 391 F. Supp. 3d 53 (D.C. D.C.)
  - At issue: when providers could seek reimbursement from Medicare for dual eligibles' bad debt
  - Where statute or regulation did not speak to reimbursement rule, and CMS policy "filled a gap" and established a requirement for a provider to obtain reimbursement, the policy established a 'substantive legal standard'
  - Court ordered CMS to determine whether hospitals entitled to reimbursement, ignoring CMS policy
- October 29: *Agendia, Inc. v. Azar*, U.S. Dist. LEXIS 191877 (C.D. Cal.)
  - Local Coverage Decisions (LCDs) establish when services – here, molecular diagnostic testing – will be covered by Medicare, thus establish a "substantive legal standard"
  - Furthers distinction between APA and Medicare Act – an interpretive rule exempt from N&C under APA may still require N&C under Medicare Act
  - Enforcement action cannot be based on 'gap-filling' LCDs because they didn't go through N&C

Allina and Implications

- November 5: *Polansky v. Exec. Health Res.,* 2019 U.S. Dist. LEXIS 192332 (E.D. Pa.)
  - FCA matter based on designation of patients as inpatients (2-midnight)
  - DOJ moved to dismiss and court granted it… but still addressed summary judgment on *Allina* and other grounds
  - Held: CMS' 2-midnight rule established a "substantive legal standard" re when an inpatient service would be deemed "reasonable and necessary" and thus reimbursed
  - Held: because Medicare Manual provisions don't undergo N&C, FCA actions based on them cannot stand
- October 31: HHS OCG letter re *Allina* and implications
  - HHS cannot bring enforcement actions based on violations of payment policies w/o N&C
  - "If CMS intends for a particular guidance document to be used in enforcement actions, then the guidance must [undergo N&C]"
  - Ability to rely on guidance turns on whether guidance document is "closely tied" to statute or regulation
  - "Critical question": Can the enforcement action be brought absent the guidance document? If not…
  - However, guidance documents may still speak to materiality and scienter

Allina and Implications

- Unclear if / when a court will extend *Allina* concepts outside of Medicare Act, apply to traditional APA analyses applicable to other regulated industries
- Gradation of difference (if any) between “substantive rule” (APA) and “substantive legal standard” (Medicare Act)
- Does this decision portend other, more direct attacks on agency ‘deference’?
- Additional weapon in FCA defendant’s arsenal when confronted with allegations of falsity based in any part on non-compliance with guidance documents – regardless of industry
- Already impacting counseling around conduct that implicates guidance documents, particularly those that are ‘gap fillers’, those that are not ‘closely tied’ to the terms of statutes and regulations

DOJ Cooperation Credit Guidance

DOJ Guidance re Cooperation Credit

- In May 2019, DOJ released a formal policy identifying cooperation eligible for credit, which is codified in Justice Manual Section 4-4.112
- Effort to scale back "all or nothing" approach to cooperation credit in 2015 Yates Memo and to describe the bases for cooperation credit
- Belief that "all or nothing" approach deprived DOJ of the "flexibility" needed "to accept settlements that remedy the harm and deter future violations"
- Former AG Rosenstein made clear in late-2018 that DOJ will focus on individual defendants' ability to pay as deciding factor in whether to pursue civil action
- Guidance clarifies DOJ's overall approach **BUT** lacks specificity regarding several critical issues (e.g., what constitutes cooperation and how to assess the value that cooperation provides to DOJ)

DOJ Guidance re Cooperation Credit

- Defendants may receive varying levels of cooperation credit depending on their efforts in cooperation categories including:
    - "[i]dentifying individuals substantially involved in or responsible for the misconduct";
    - making individuals available who have "relevant information";
    - "[a]dmitting liability or accepting responsibility for the relevant conduct"; and
    - "[a]ssisting in the determination or recovery" of losses
- Guidance notes that cooperation must have value for DOJ, measured by:
    - "timeliness and voluntariness" of cooperation
    - "truthfulness, completeness, and reliability" of information provided
    - "nature and extent" of the cooperation
    - "significance and usefulness of the cooperation" to DOJ
- Full credit requires self-disclosure of all those involved in misconduct, full investigation cooperation, and remedial steps to prevent and detect similar wrongdoing
- Unlike criminal case cooperation guidance, no percentage reductions in penalties or damages; instead, DOJ may reduce the multiple sought

“Granston Memo” Updates

31 U.S.C. § 3730(c)(2)(A): “The Government may dismiss the action notwithstanding the objections of the person initiating the action if the person has been notified by the Government of the filing of the motion and the court has provided the person with an opportunity for a hearing on the motion.”

1/10/2018 “Granston Memo:” Addressed the government’s use of its (c)(2)(A) authority in non-intervened False Claims Act matters

Key Reminder: The United States is the real party of interest in a non-intervened False Claims Act matter

“Granston Memo” principles incorporated into the Justice Manual (“JM”) at Section 4-4.111

"Granston Memo" described the government's (c)(2)(A) authority as "an important tool to advance the Government's interests, preserve limited resources, and avoid adverse precedents."

"Granston Memo" and JM Section 4-4.111 identify "non-exhaustive" factors to be considered in connection with the government's decision to seek a dismissal of a non-intervened *qui tam* action. These include:

1) "Curbing meritless qui tams that facially lack merit (either because the relator's legal theory is inherently defective, or the relator's factual allegations are frivolous)"

2) "Preventing parasitic or opportunistic qui tam actions that duplicate a pre-existing government investigation and add no useful information to the investigation"

3) "Preventing interference with agency policies or the administration of its programs"

4) "Controlling litigation brought on behalf of the United States, in order to protect the Department's litigation prerogatives"

5) "Safeguarding classified information and national security interests"

6) "Preserving government resources, particularly where the government's costs (including the opportunity costs of expending resources on other matters) are likely to exceed any expected gain"

7) "Addressing egregious procedural errors that could frustrate the government's efforts to conduct a proper investigation"

Circuit Split in Standard of Review Applied to (c)(2)(A) Motion

- *United States ex rel. Sequoia Orange Co. v. Baird-Neece Packing Corp.*, 151 F.3d 1139, 1145 (9th Cir. 1998) (holding that the United States must identify a "valid government purpose" that is rationally related to dismissal)
    - Applied by the Ninth and Tenth Circuits
- *Swift v. United States*, 318 F.3d 250, 252 (D.C. Cir. 2003) (holding that the United States has an "unfettered right" to dismiss a *qui tam* action)
    - "Granston Memo" instructs prosecutors, in jurisdictions where the standard is not clear, to argue for application of the *Swift* standard but also that the government's motion satisfies both standards

- Since issuance of "Granston Memo," thirty-six dismissals sought, only two were unsuccessful
    - 11 of 12 of the "patient support/reimbursement assistance" cases brought by professional relator NHCA-TEV, LLC were either dismissed on the government's motion or were dismissed by the relators
    - Southern District of Illinois decision in *United States ex rel. CIMZNHCA, LLC, et al. v. UCB, Inc., et al.*, Case No. 17-CV-765 (S.D. Ill. Apr. 15, 2019) is on appeal to the Seventh Circuit
- Government's (c)(2)(A) motions to dismiss are often multi-factorial:
    - "Prevent[ing relators] from undermining the considered decisions of FDA and CMS about how to address the conduct at issue here" (*Campie*)
    - "[T]o avoid the additional expenditure of government resources on a case that it fully investigated and decided not to pursue" (*Campie*)
- (c)(2)(A) authority applicable to all False Claims Act matters, regardless of subject matter

9/4/19 Grassley Letter: Expressed concerns regarding the government's cost/burden arguments made in *CIMZNHCA* and *Campie*, as well as the government's reliance on arguments that a case lacks merit or may have little chance of success

United States Senate
COMMITTEE ON FINANCE
WASHINGTON, DC 20510–6200

September 4, 2019

VIA ELECTRONIC TRANSMISSION
The Honorable William Barr
Attorney General
U.S. Department of Justice
Washington D.C., 20220

Dear Attorney General Barr:

I write today with concerns about the Department of Justice's (DOJ) implementation of the Granston Memorandum and its efforts to dismiss greater numbers of *qui tam* cases for reasons that appear primarily unrelated to the merits of individual cases.[1] Those efforts rely at least in part on vague and at times questionable concerns over prerogatives or limited government resources to handle the cases. Such actions could undermine the purpose of the False Claims Act by discouraging whistleblowers and dismissing potentially serious fraud on the taxpayers.

Considerations when approaching government to request (c)(2)(A) dismissal:

- Case-specific advocacy grounded in the facts, the evidence, the case law, and practical implications

- Proactive use of discovery to uncover information, particularly from relators, that government may not have had access to or would not have been aware of during investigation stage

- Consider which stakeholders to involve in discussion, and whether to proactively invite or include FDA into DOJ/USAO analysis

- Implications for potential adverse precedent

    - *Escobar*/materiality
    - First Amendment
    - Statistical sampling/damages

Opioid Litigation & Enforcement

Opioid Litigation & Enforcement Update

- Negotiation class approved by district court
  - "Novel approach" to potential global settlement, which the district court indicated was justified "based on the unique facts of the case and the likelihood it might facilitate a global settlement."
  - Sixth Circuit has taken up interlocutory appeal under Rule 23(f)
  - ~30,000 local governments in play
    - ~98% have agreed to be bound
    - ~541 local governments have opted out, preferring to pursue their own claims in court
- Criminal indictments and subpoenas
  - Government enforcement is becoming more aggressive
  - Not confined to the corporation or C-suite level executives