Anatomy of a False Claims Act Case INVESTIGATION, NEGOTIATION AND RESOLUTION	
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Investigation	
Relator's Pre-Filing Investigation	
and Considerations Knowledge of facts involving clear FCA violation? Documentary evidence, other proof of fraud? Sufficient evidence of "who, what, when, where and why" supporting fraud and damages? Specific examples of the fraud? Requisite scienter/knowledge evidence for Defendant? Damages large enough to justify risks to the relator? Level of Government interest in specific area of law and type of fraud? Is it material to the government?	

4 Investigation – DOJ's Perspective ► Government investigates qui tams, non qui tams, agency referrals, self disclosures ▶ Goal is to decide whether to intervene (qui tams) or pursue ▶ Considerations ► Evidence that a violation of 31 U.S.C. § 3729(a)(1) has occurred ▶ Evidence that violation was "knowing" as defined in § 3729(b)(1) $\blacktriangleright\,$ Evidence and arguments regarding materiality ▶ Damages (amount and provability) Agency policies and prioritiesStrength of likely defenses Investigation – DOJ's Perspective 5 (cont'd) ► Sources of evidence: ▶ Applicable statutes, regulations, and policies ▶ Relators and other witnesses with knowledge ▶ Internal and external/third party audits ▶ Agency subpoenas and Civil Investigative Demands ▶ Presentations by, and discussions with, counsel ▶ Other considerations: ▶ OIG ▶ Responsibility of individuals Recent Supreme Court Escobar Precedent 6 Universal Health Servs., Inc. v. United States ex rel. Escobar, 136 S. Ct. 1989 (2016) ► Key Issues: Implied Certification & Materiality Implied certification liability does not depend on whether a requirement is labeled a condition of payment (overruling United States ex rel. Mikes v. Straus, 274 F.3d 687 (2d Cir. 2001) and similar cases) "What matters is not the label the Government attaches to a requirement, but whether the defendant knowingly violated a requirement that the defendant knows is material to the Government's payment decision." Id. at 1996.

Recent Supreme Court Escobar Precedent 7 Universal Health Servs., Inc. v. United States ex rel. Escobar, 136 S. Ct. 1989 (2016) ▶ Reaffirms "'material' means having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property" Id. at 2002 ► Materiality can be objective OR subjective: Would a reasonable person attach importance to it in deciding whether to pay? ▶ Would the government attach importance to it in deciding whether to pay even if a reasonable person would not? Investigation - OIG's Role 8 ▶ OCIG attorney assigned when OIG notified of ▶ OCIG attorney coordinates with defrauded agency, Main DOJ attorney and/or AUSA assigned ▶ Evaluate merits of case ▶ Consult with counsel and agent regarding investigative steps ► Individual liability issues Investigation - Defense Perspective ▶ Indicators that you might be under investigation ▶ When to retain expert counsel ▶ Steps to take when you receive a subpoena/CID/request letter ▶ What you can learn from the subpoena ▶ Responding to the subpoena ▶ Consider how proactive a role to take ▶ Missteps to avoid ► Attempt to negotiate resolution or litigate? ▶ Individuals and Impact of Yates Memo ▶ Impact of the Granston Memo

Self - Disclosures	
 Intersection of self-disclosure under HHS-OIG Self- Disclosure Protocol and qui tam filing alleging related facts 	
 Impact of self-disclosure on civil and administrative resolution to the case 	
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Negotiation	
Overview - Negotiation	
 ▶ Timing can vary ▶ Objectives of the various parties (DOJ, OIG, MFCU, relator, defendant) ▶ Key negotiating issues 	
► Civil monetary damages► Scope of release	
Administrative remedyRelators' shareAttorneys' fees	

Negotiation – DOJ Priorities 13 ▶ Make government whole ▶ Deter fraud ▶ Consider and address views of victim agency ▶ Identify individual wrongdoers and proceed accordingly ▶ Fairly reflect strengths and weaknesses of case ▶ Provide a release tailored to damages recovered OIG Objectives 14 Appropriate prospective program safeguards in exchange for forbearance of exclusion authority ► Evaluation of Risk Risk Categories Highest Risk - Exclusion High Risk - Heightened Scrutiny Medium Risk - CIAs Lower Risk - No Further Action Low Risk - Self-Disclosure Relator Objectives 15 ► Monetary resolution of FCA claims ▶Intervened ▶ Non-intervened ▶ Relator's share percentage ▶ Resolution of any retaliation claims ▶ Resolution of attorneys' fee claims ▶ Coordination with DOJ

Defendant Objectives 16 ▶ Appropriate monetary resolution covering all claims ► Attorneys' fees ▶ Release of **all** potential claims ▶ Least onerous compliance requirements possible going forward ▶ Minimize reputational/business impacts ► Appropriate consideration of individual liability/indemnification Negotiation – Getting Started 17 ▶ Initiation of discussions ▶ When? ▶ By whom? ▶ Mediation ▶ Who is at the table? ► Intervened cases ▶ Declined cases ► Relators ▶ OIG 18 Alternative Dispute Resolution ► Federal government committed to ADR in "appropriate civil cases" ► http://www.jamsadr.com/files/Uploads/Documents/Articles/ Stevens-False-Claims-Act-2012-11-20.pdf ▶ Benefits of mediation ▶ Objective neutral gives all parties an important reality check ▶ Use of an impartial intermediary can change the personal dynamics ▶ Non-binding

Monetary Negotiations 19 ▶ Damages assessment ► Each party's principled assessment of damages (which may include use of sampling and extrapolation) ► Each party's principled quantification of false claims at issue ▶ Realistic assessment of the respective litigation risks of each party ▶ Debate over the appropriate multiplier and calculation of penalties ▶ Realistic assessment of resources required for, and risks associated with, continued pursuit 20 Resolution Settlement Agreement 21 ▶ DOJ sends initial draft ▶ Standard language (including re: restitution) Key terms to negotiate (ideally <u>before</u> handshake agreement reached): ▶ Covered conduct ▶ Released parties ▶ (Mostly) Non-negotiable terms, including: ▶ Post-handshake interest ▶ Definition and treatment of "unallowable costs" ▶ Agreement to cooperate with investigation of individuals

Settlement Agreement – Key Issues 22 Regarding the Scope of Release ▶ Defining the "Covered Conduct" to be released ▶ Defining released parties ▶ Express reservation of unreleased claims, including: ► Criminal liability Mandatory (and/or permissive) exclusion from government programs Liability of individuals ➤ Dismissal of complaint with prejudice as to Covered Conduct but without prejudice as to remainder ▶ Handling of non-intervened claims Resolution: Other Key Issues 23 ▶ Impact of state law claims ▶ State FCAs ▶ States as parties ▶ Role of NAMFCU ► Parallel criminal investigations ▶ Relationship to other litigation with Relators ▶ Issues that may arise from increased focus on individual liability Clarity of rules going forward: "Leveling the playing field" for all like providers Resolution: Defense-Specific Issues 24 ightharpoonup Cooperation ► Individuals ▶ Impact of Yates Memo ▶ Limitation on Releases ▶ Indemnification ▶ Who signs ▶ Confidentiality ▶ Press release

Resolution: OIG-Specific Issues 25	
 ▶ Administrative Remedies ▶ Negotiated Exclusion ▶ Corporate Integrity Agreement ▶ OCIG sends initial draft ▶ Standard language ▶ Also specific terms based on conduct and provider ▶ Negotiated between OCIG and defendant ▶ Timing issues 	
Key Issues Relating to Corporate Integrity Agreements • Overarching issues • Effectiveness of existing compliance program • Track record of provider • CIA vs. Reservation of Rights • Scope of CIA • Definition of issues covered by CIA • IRO? • Legal IRO? • Monitor?	
Defining to Enter Into a Cornerate	
Refusing to Enter Into a Corporate Integrity Agreement Beginning October 1, 2018, OIG is posting the names of any entities that refuse to enter into a CIA on its website.	

Resolution: Relator-Specific Issues 28 ▶ Relator's right to object to settlement as unfair, inadequate, unreasonable \blacktriangleright Declined vs. intervened cases and claims within cases ▶ Attorney fees—between Relator and Defendant ► Retaliation claims ► Releases ▶ Relator's share—between Relator and DOJ Contact Information 29 Katherine A. Lauer Latham & Watkins LLP San Diego, CA 858.523.5451 katherine.lauer@hv.com Amy L. Easton Phillips and Cohen LLP Washington, DC 202.833.3618 Laura E. Ellis Amy D. Kossak Commercial Liftgation Branch, Civil Frauds United States Department of Justice Washington, DC 202.616.2856 Amy D.Kossak@usdoj.gov Laura E. Ellis United States Department of Health and Human Services—Office of Inspector General Washington, DC 202.834.1665 Laura.Ellis@oig.hhs.gov