Materiality

Panelists

- Paul S. Chan, Principal, Bird Marella
- David Finkelstein, Trial Attorney, U.S. Department of Justice, Civil Frauds Division
- Lesley C. Reynolds, Partner, Reed Smith LLP
- Tejinder Singh, Partner, Goldstein & Russell, P.C.

- Moderator: Kate Seikaly, Partner, Reed Smith LLP

Agenda

- The Statute and *Escobar*
- Pleading Materiality – Complaints and Motions to Dismiss
- Discovering Materiality
  - Intervened / Non-Intervened
  - Touhy Regulations
- Proving Materiality – Summary Judgment and Trial

Materiality – the FCA statute

- 2009 FERA amendments added materiality to statute:
  - any person who knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim; knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government. 31 U.S.C. § 3729(a)(1)(B) and (G).
  - "the term 'material' means having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property." 31 U.S.C. § 3729(b)(4).

***Universal Health Services, Inc. v. United States ex rel. Escobar*, 136 S. Ct. 1989 (2016)**

- "A misrepresentation about compliance with a statutory, regulatory, or contractual requirement must be material to the Government's payment decision in order to be actionable under the False Claims Act."
- The materiality requirement is "rigorous" and "demanding."

Universal Health Services, Inc. v. United States ex rel. Escobar, 136 S. Ct. 1989 (2016)

- "Whether a provision is labeled a condition of payment is relevant to but not dispositive of the materiality inquiry."
- "A misrepresentation cannot be deemed material merely because the Government designates compliance with a particular statutory, regulatory, or contractual requirement as a condition of payment. Nor is it sufficient for a finding of materiality that the Government would have the option to decline to pay if it new of defendant's noncompliance."
- Rejects view "that any statutory, regulatory, or contractual violation is material so long as the defendant knows that the Government would be entitled to refuse payment were it aware of the violation."

Universal Health Services, Inc. v. United States ex rel. Escobar, 136 S. Ct. 1989 (2016)

- "[P]roof of materiality can include, but is not necessarily limited to, evidence that the defendant knows that the Government consistently refuses to pay claims in the mine run of cases based on noncompliance with a particular statutory, regulatory, or contractual requirement."
- "Conversely, if the Government pays a particular claim despite actual knowledge that certain requirements were violated, that is very strong evidence that those requirements were not material."
- "Or, if the Government regularly pays a particular type of claim in full despite actual knowledge that certain requirements were violated, and has signaled no change in position, that is strong evidence that the requirements are not material."

Pleading Materiality

- *Escobar* rejects "that materiality is too fact intensive for courts to dismiss False Claims Act cases on a motion to dismiss or at summary judgment."
- "And False Claims Act plaintiffs must also plead their claims with plausibility and particularity under Federal Rules of Civil Procedure 8 and 9(b) by, for instance, pleading facts to support allegations of materiality."

Pleading Materiality: *United States ex rel. Campie v. Gilead Sciences, Inc.*, 862 F.3d 890 (9th Cir. 2017)

- Relator allegations that defendants made false statement about compliance with FDA regulations regarding HIV drugs, making them ineligible for payment and resulting in false claims
- DOJ declined intervention
- Defendants argued materiality lacking because FDA continued to approve drugs after becoming aware of non-compliance

Pleading Materiality – *United States ex rel. Campie v. Gilead Sciences, Inc.*, 862 F.3d 890 (9th Cir. 2017)

- 9th Circuit found materiality sufficiently pled
  - Many reasons FDA may choose not to withdraw approval, unrelated to concerns about payment
  - Defendants ultimately came into compliance: "Once the unapproved and contaminated drugs were no longer being used, the government's decision to keep paying for compliant drugs does not have the same significance as if the government continued to pay despite continued noncompliance"
  - The "parties dispute exactly what the government knew and when, calling into question its 'actual knowledge.'"

Pleading Materiality: *United States ex rel. Petratos v. Genentech Inc.*, 855 F.3d 481 (3rd Cir. 2017)

- Grant of motion to dismiss affirmed for failure to plead materiality.
- Allegations that defendant concealed information about health risks associated with drug Avastin.
- District Court noted: "there are no factual allegations showing that CMS would not have reimbursed that these claims had these alleged reporting deficiencies been cured" and relator did not dispute this finding, "which dooms his case."
- Rejected relator's argument that physicians would have prescribed less or no Avastin and the government would have paid less claims or the concealment was material to the physicians' decision to prescribe.

Pleading Materiality: *United States ex rel. Petratos v. Genentech Inc.*, 855 F.3d 481 (3rd Cir. 2017)

- Relator "not only fails to plead that CMS 'consistently refuses to pay' claims like those alleged, but essentially concedes that CMS would *consistently reimburse* these claims with full knowledge of the purported noncompliance. Nor has he cited to a single successful claim under [the relevant statute] involving drugs prescribed for their on-label uses or a court decision upholding such a theory."
- Notes that after Relator disclosed information to FDA and DOJ, FDA did not initiate proceedings or require change to drug label and DOJ took no action and declined intervention.

Pleading Materiality: *D'Agostino v. ev3, Inc.*, 845 F.3d 1 (1st Cir. 2016)

- Upheld dismissal of relator's claims that a medical-device subsidiary engaged in improper conduct by making fraudulent misrepresentation to the FDA when seeking marketing approval, thus knowingly causing health care providers to submit false reimbursement claims to government entities.
- "The fact that CMS has not denied reimbursement for [the medical device] in the wake of [relator's] allegations casts serious doubt on the materiality of the [alleged] fraudulent misrepresentations."

Pleading Materiality: *United States ex rel. Dresser v. Qualium Corp*., 5:12-cv-1745-BLF, 2016 WL 3880769 (N.D. Cal. July 18, 2016)

- Intervened *qui tam* alleging false claims for diagnostic sleep studies and sleep disorder-related medical devices based on allegations that defendants conducted tests at locations not approved by Medicare, employed unqualified personnel to conduct the tests, and dispensed DME from those unapproved locations by unapproved personnel.
- Implied certification theory based on certifications in Medicare enrollment forms that defendants would abide by Medicare laws, regulations, and program instructions, and that they understood payment of claims was conditioned on being compliant

Pleading Materiality: *United States ex rel. Dresser v. Qualium Corp*., 5:12-cv-1745-BLF, 2016 WL 3880769 (N.D. Cal. July 18, 2016)

- Complaint "alleges in several places that the government would not have paid Defendants' claims had they known of Defendants' fraudulent conduct, but does not explain why. This does not meet [*Escobar*'s] heightened materiality standard: While [*Escobar*] held that payment being conditioned on compliance with regulations could be evidence that a misrepresentation was material, it also explained that this did not necessarily make a misrepresentation material."
- Granted motion to dismiss implied certification theory with leave to amend.

Pleading Materiality: *United States ex rel. Kietzman v. Bethany Circle of King's Daughters of Madison, Ind., Inc.*, 305 F. Supp. 3d 964 (S.D. Ind. 2018)

- Allegations of overbilling for medical services
- Motion to dismiss granted
- "[T]he complaint does not contain a single nonconclusory allegation of materiality. [Relator] either alleges baldly that a certain alleged act of non-compliance was 'material,' or, restating the concept, that the government 'would not have paid' had it known of the Hospital's alleged noncompliance."

Pleading Materiality: *United States ex rel. Kietzman v. Bethany Circle of King's Daughters of Madison, Ind., Inc.*, 305 F. Supp. 3d 964 (S.D. Ind. 2018)

- "No facts are alleged as to what types of claims the government usually did or did not pay, nor as to what the government's compliance priorities were, nor as to the degree of severity of the Hospital's alleged breaches of regulations. For example, does Medicare usually refuse to pay claims for treatment where any order issued in the course of the treatment was entered into 'the electronic medical system' either 'by a licensed healthcare professional nor a credentialed medical assistant'? We have no way of knowing because the complaint is utterly silent on the issue."

Pleading Materiality: *United States ex rel. Prather v. Brookdale Senior Living Cmtys.*, 892 F.3d 822 (6th Cir. 2018), *petition for cert. filed*, No. 18-699 (U.S. Nov. 20, 2018)

Questions presented:

(1) Whether the failure to plead facts relating to past government practices in an FCA action can weigh against a finding of materiality.

(2) Whether an FCA allegation fails when the pleadings make no reference to the defendant's knowledge that the alleged violation was material to the government's payment decision

Discovering Materiality – Government Privileges

- Attorney-Client / Work Product – agency counsel and DOJ
- Deliberative process privilege –agency communications that are pre-decisional and deliberative
- Law enforcement / investigative files privilege – law enforcement techniques, sources and investigations
- Informant privilege – identity of persons who furnish information to law enforcement
- Military / state secrets privilege –information that, if disclosed, would harm national security

Discovering Materiality – Non-intervened Cases

- Where it declines to intervene, DOJ considers the United States to be a third party for discovery purposes.
  - Requests for documents or deposition testimony should comply with the agency rules for serving third party discovery requests, including *Touhy* regulations.
  - Government will object to requests for admission and interrogatories.

Discovering Materiality – Non-intervened Cases
Granston Memo

U.S. Department of Justice

Civil Division

Washington, DC 20530

January 10, 2018

PRIVILEGED AND CONFIDENTIAL; FOR INTERNAL GOVERNMENT USE ONLY

MEMORANDUM

TO: Attorneys
Commercial Litigation Branch, Fraud Section

Assistant U.S. Attorneys Handling False Claims Act Cases
Offices of the U.S. Attorneys

FROM: Michael D. Granston MDG
Director
Commercial Litigation Branch, Fraud Section

SUBJECT: Factors for Evaluating Dismissal Pursuant to 31 U.S.C. 3730(c)(2)(A)

6. *Preserving Government Resources*

The Department should also consider dismissal under section 3730(c)(2)(A) when the government's expected costs are likely to exceed any expected gain.[4] *See, e.g.*, *Swift v. United States*, 318 F.3d 250, 251 (D.C. Cir. 2003) (the government moved to dismiss the complaint, arguing that the amount of money involved did not justify the expense of litigation even if the allegations could be proven); *United States ex rel. Nicholson v. Spigelman, et al.*, No. 1:10-cv-03361, 2011 WL 2683161, at *2 (N.D. Ill. July 8, 2011) (explaining that the estimated government losses, even with statutory penalties and damages multiplier, were less than the costs of monitoring the litigation and responding to discovery requests). Examples of potential costs may include, among other things, the need to monitor or participate in ongoing litigation, including responding to discovery requests. *See, e.g.*, *United States ex rel. Sequoia Orange Co.*, 151 F.3d at 1146 (holding that district court "properly noted that the government can legitimately consider the burden imposed on taxpayers by its litigation, and that, even if the relators were to litigate the FCA claims, the government would continue to incur enormous internal staff costs"); *United States ex rel. Levine v. Avnet, Inc.*, No. 2:14-cv-17-WOB-CJS, 2015 WL 42359 (E.D. Ky.

Discovering Materiality – Non-intervened Cases

United States ex rel. Campie v. Gilead Sciences, Inc., 862 F.3d 890 (9th Cir. 2017)

- Defendants petitioned SCOTUS for cert; SCOTUS requested Solicitor General express the views of the U.S.
- In amicus brief, U.S. argued against cert, supporting the 9th Circuit's decision. U.S. noted its authority to dismiss *qui tam* suits and stated that if the case was remanded, it would move to dismiss.
  - "That determination is based in part on the government's thorough investigation of respondents' allegations and the merits thereof. In addition, if the suit proceeded past the pleading stage, 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. . . . Based on all those considerations, the government has concluded that allowing this suit to proceed to discovery (and potentially a trial) would impinge on agency decision making and discretion and would disserve the interests of the United States."

Discovering Materiality – Scope of Discovery

- ***United States ex rel. Dean v. Paramedics Plus, LLC*, 2018 WL 620776 (E.D. Tex. 2018)**
  - Government partially intervened in relator action.
  - Defendants sought discovery into how government actually handled the disputed issue in this case and others.
  - Government objected as outside scope of discovery because the requests involved a different contractor, contract, and time period.
  - Defendant's motion to compel granted. Agreed with defendant that "the issue of materiality goes beyond [the defendant's] alleged misconduct," and includes the time period after the suit was filed.

Discovering Materiality – Touhy Regulations

Department of Agriculture – 7 CFR Subtitle A, Pt. 1, Subpart K

- Responsibility is on employee to notify his or her agency head and provide any additional information (if known) about the nature of the testimony or documents requested.
- To determine whether the employee's appearance is in the interest of the USDA, the authorizing official should consider:
  - What USDA interest would be promoted by the testimony;
  - Whether the appearance would unnecessarily interfere with the employee's duties; and
  - Whether the testimony would appear to improperly favor one litigant.
- Subpoenas duces tecum are deemed to be FOIA requests and handled accordingly.

Discovering Materiality – Touhy Regulations

Department of Commerce – 15 CFR Subtitle A, Pt. 15, Subpart B

- Testimony or production of documents must first be approved by the General Counsel, appropriate agency counsel, or the Solicitor for the Patent and Trademark Office.
- Every demand for testimony or documents shall be accompanied by an affidavit or a statement (if an affidavit is not feasible) setting forth: the title of the proceeding; the forum; the requesting party's interest in the proceeding; the reason for the demand; a showing that the desired testimony or document is not reasonably available from any other source; the intended use of the testimony; a general summary of the desired testimony; and a showing that no document could be used in lieu of testimony.

Discovering Materiality – Touhy Regulations

Department of Defense – 32 CFR Part 516, Appendix C, DoD Directive 5405.2

- DoD policy is "that official information should generally be made reasonably available for use in Federal and state courts . . . ."
- The person requesting the testimony or information must also submit, in writing, "with as much specificity as possible, the nature and relevance of the official information sought."

Discovering Materiality – Touhy Regulations

Department of Education – 34 CFR Subpart A, Part 8

- Demand for testimony or documents must also include:
  - Why the information sought is unavailable by any other means; and
  - Why the release of the information would not be contrary to an interest of the Department or the United States.
- An employee may not give testimony or produce documents without prior written consent of the Secretary.

Discovering Materiality – Touhy Regulations

Department of Energy – 10 CFR Chapter II, Subchapter A, Part 202, Subpart B

- No employee shall testify or produce documents without prior approval of the General Counsel.
- If oral testimony is sought, an affidavit (or a statement when an affidavit is not possible) must also be submitted by the Regional Counsel to the General Counsel setting forth a summary of the desired testimony.

Discovering Materiality – Touhy Regulations

Department of Health and Human Services – 45 C.F.R. §§ 2.1-2.6

- No employee or former employee may testify or provide documents in any proceedings concerning information acquired in the course of performing official duties without authorization from the Agency head.
- Requests for employee testimony must be in writing, addressed to the agency head and must state:
  - The nature of the requested testimony;
  - Why the information sought is unavailable by other means; and
  - The reasons why the testimony would be in the interest of HHS or the federal government.

Discovering Materiality – Touhy Regulations

Department of Homeland Security – 6 CFR Chapter I, Part 5, Subpart C

- All summonses must be served on the General Counsel otherwise the receiving employee may decline to accept, this includes summonses issued to specific employees.
- No employee may testify or provide documents without authorization from Office of the General Counsel.
- The requesting party must also provide in writing:
  - For testimony, the nature and relevance of the official information sought with as much specificity as possible.
  - For documents, as much identifying information as possible such as date, title or name, author, recipient, subject matter of the record, case number, file designation, or reference matter.
- Provides a list of considerations the Department will use when deciding whether to comply.

Discovering Materiality – Touhy Regulations

Department of Housing and Urban Development – 24 CFR Subtitle A, Part 15, Subpart C

- No employee may testify or produce materials without prior approval of the Authorized Approving Official.
- Any demand may be submitted to the department or specific employee but a copy must also go to the Appropriate Associate General Counsel or Regional Counsel no later than 30 days prior to the date the material or testimony is required.
- The demand must state numerous specific requirements set forth in § 15.203.
- The Authorizing Official must consider the standards set forth in § 15.204 when deciding whether or not to give approval.

Discovering Materiality – Touhy Regulations

Department of the Interior – 43 CFR Subtitle A, Part 2, Subpart L

- General policy "not to allow its employees to testify or to produce Department records either upon request or by subpoena."
- No employee may testify or produce records without authorization from the Department.
- Both subpoenas for testimony and subpoenas duces tecum must be accompanied by a written request covering the information set forth in § 2.284.
- The request will be considered under the criteria set forth in § 2.288**.**

Discovering Materiality – Touhy Regulations

Department of Justice – 28 CFR Chapter I, Part 16, Subpart B

- No employee may provide testimony or materials without prior approval of the appropriate Department official.
- If oral testimony is sought, the party seeking testimony must set forth a summary of the testimony sought and its relevance to the proceeding to the responsible U.S. Attorney.
- The demand or request may be granted if it complies with the procedures and requirements set forth in 28 § 16.26.

Discovering Materiality – Touhy Regulations

Department of State – 22 CFR Chapter I, Subchapter R, Part 172

- Only the Executive Office of the Office of the Legal Adviser is authorized to receive and accept summonses.
- No employee may respond to a request or summons without prior authorization from the Director General of the Foreign Service and Director of Personnel or the Legal Adviser or the Assistant Secretary of State for Consular Affairs, or the delegates of them.
- Accompanying any request or demand must be an explanation, in writing, with as much specificity as possible, the nature and relevance of the official information sought.
- Department officials must consider the factors set forth in 22 CFR § 172.8 when evaluating a request or demand.

Discovering Materiality – Touhy Regulations

Department of Transportation – Title 49, Subtitle A, Part 9

- There are limitations on an employee's testimony set forth in 49 CFR § 9.9.
- Employees may not testify at a trial or hearing. Testimony may only be provided in a single deposition, affidavit, or set of interrogatories. If any further testimony is desired, the request must be submitted to agency counsel. The request must set forth why the information was not obtained in the first opportunity.
- All demands and requests must comply with the requirements set forth in 49 CFR Part 7.
- All demands and requests must be accompanied by the information set forth in 49 CFR § 9.15.

Discovering Materiality – Touhy Regulations

Department of the Treasury – 31 CFR § 1.11

- No employee may testify or provide materials without prior authorization from the General Counsel or appropriate agency counsel.
- The request must include an affidavit (or statement if affidavit is not feasible) setting forth: the title of the proceeding; the forum; the requesting party's interest in the proceeding; the reason for the demand; a showing that the desired testimony or document is not reasonably available from any other source; the intended use of the testimony; a general summary of the desired testimony; and a showing that no document could be used in lieu of testimony.
- Section (e) sets forth the factors the agency counsel will use when considering the request.

Discovering Materiality – Touhy Regulations

Department of Veterans Affairs – 38 CFR Chapter I, Subpart 14

- In determining whether to authorize testimony or disclosure, an authorizing official will consider the factors set forth in 38 CFR § 14.804.
- The request or demand shall be accompanied by an affidavit (or a statement if an affidavit is unavailable) containing sufficient information for the responsible VA official to determine whether the individual should testify or produce the requested materials.

Proving Materiality – *United States ex rel. Harman v. Trinity Industries, Inc.*, 872 F.3d 645 (5th Cir. 2017)

- $663MM jury verdict overturned on appeal based on lack of materiality.
- Allegations that approved highway guardrails were modified without proper notification.
- Before and after trial, government agency reaffirmed approval and eligibility for payment of the product at issue.
- “though not dispositive, continued payment by the federal government after it learns of the alleged fraud substantially increases the burden on the relator in establishing materiality”
- “given [the agency’s] unwavering position that the [product] was and remains eligible for federal reimbursement, Trinity’s alleged misstatements were not material to its payment decisions”

Proving Materiality – *United States ex rel. Ruckh v. Salus Rehabilitation, LLC*, 304 F. Supp. 3d 1258 (M.D. Fla. 2018)

- $348MM jury verdict vacated based on lack of materiality.
- Allegations that defendants failed to maintain specific documentation required by Medicare and Medicaid regulations.
- FCA "requires the relator to prove both that the non-compliance was material to the government's payment decision and that the defendant knew at the moment the defendant sought payment that the non-compliance was material to the government's payment decision."

Proving Materiality – *United States ex rel. Ruckh v. Salus Rehabilitation, LLC*, 304 F. Supp. 3d 1258 (M.D. Fla. 2018)

- "both governments were—and are—aware of the defendants' disputed practices, aware of this action, aware of the evidence, and aware of the judgments for the relator—but neither government has ceased to pay or even threaten to stop paying the defendants for the services provided to patients…since long before this action began in 2011."
- "the evidence and the history of this action establish that the federal and state governments regard the disputed practices with leniency or tolerance or indifference …. The evidence shows not a single threat of non-payment, not a single complaint or demand, and not a single resort to an administrative remedy or other sanction for the same practices that result in the enormous verdict at issue."

Proving Materiality – *United States ex rel. Ruckh v. Salus Rehabilitation, LLC*, 304 F. Supp. 3d 1258 (M.D. Fla. 2018)

- "*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."
- ". . . the government that continues to pay full fare for a product or service despite knowledge of some disputed practice, some non-compliance, or some other claimed defect, relentlessly works itself into a steadily tightening bind that at some point becomes disabling because the government [or the relator] must prove that had the government known the facts the government would have refused to pay. In other words . . . that the government would not do exactly what history demonstrates the government in fact did."

Proving Materiality – *United States ex rel. McBride v. Halliburton Co.*, 848 F.3d 1027 (D.C. Cir. 2017)

- Summary judgment granted in favor of defendant.
- Allegations that defendant inflated "headcount" data to overbill government.
- No evidence that headcounts were tied to the amounts billed.
- Relator argued materiality satisfied based on contracting officer's declaration "that he 'might' have investigated further had he known false headcounts were being maintained, and that such an investigation 'might' have resulted in some charged costs being disallowed.
  - "At most, the statement amounts to the far-too-attenuated supposition that the Government *might* have had the 'option to decline to pay.'"

Proving Materiality – *United States ex rel. McBride v. Halliburton Co*., 848 F.3d 1027 (D.C. Cir. 2017)

- "We have the benefit of hindsight and should not ignore what actually occurred: the DCAA investigated McBride's allegations and did not disallow any charged costs. In fact, KBR continued to receive an award fee for exceptional performance under Task Order 59 even after the Government learned of the allegations. This is 'very strong evidence' that the requirements allegedly violated the maintenance of inflated headcounts are not material."

Proving Materiality – *United States ex rel. Rose v. Stephens Institute*, 909 F.3d 1012 (9th Cir. 2018)

- Allegations of violations of incentive compensation ban prohibiting schools from rewarding admissions officers for enrolling higher numbers of students
- On summary judgment, defendant did not establish as a matter of law that its violations were immaterial.
- "A reasonable trier of fact could find materiality here because the Department's payment was conditioned on compliance with the incentive compensation ban, because of the Department's past enforcement activities, and because of the substantial size of the forbidden incentive payments."

Proving Materiality – *United States ex rel. Rose v. Stephens Institute*, 909 F.3d 1012 (9th Cir. 2018)

- Funds conditioned on compliance through statute, regulation, and contract – had defendant not certified compliance in its contract, it could not have been paid
- "After *Escobar*, that triple-conditioning of . . . funds on compliance . . . may not be sufficient, without more, to provide materiality, but it is certainly probative evidence of materiality."

Proving Materiality – *United States ex rel. Rose v. Stephens Institute*, 909 F.3d 1012 (9th Cir. 2018)

- Past Department Action
  - No evidence that defendant knows the government consistently refused to pay in the mine run of cases, so does not factor into analysis
  - Record does not establish that Department had actual knowledge that Defendant was violating ban, so cannot analyze this factor
  - GAO report identified 32 instances of schools violating the ban
    - 25 were ordered to take corrective action; others had closed, were terminated, or were in safe harbor
    - "There is evidence, then, that the Department *did* care about violations of the . . . ban"

Proving Materiality – *United States ex rel. Rose v. Stephens Institute*, 909 F.3d 1012 (9th Cir. 2018)

- Magnitude of Violation
  - Large monetary awards that constituted violations were not small, occasional perks, but were "precisely the kind of substantial incentive that Congress sought to prevent in enacting the ban on incentive compensation" and "counsel against a finding that Defendant's noncompliance was immaterial"

Proving Materiality – *United States v. Sanford-Brown, Ltd.*, 840 F.3d 445 (7th Cir. 2016)

- Relator allegations of fraudulent conduct in connection with claims for federal subsidiaries under the Higher Education Act; Seventh Circuit affirmed summary judgment in favor of defendants.
- The federal agencies involved "have already examined [Defendant] multiple times over and concluded that neither administrative penalties nor termination was warranted."
- It is not enough to show that the government would have been entitled to decline payment; materiality looks to the "effect on the likely or actual behavior" of the government."

Proving Materiality – *United States ex rel. Miller v. Weston Educational, Inc.*, 840 F.3d 494 (8th Cir. 2016)

- Allegations that college falsely promised to keep accurate student records.
- DOJ declined to intervene
- District Court granted summary judgment to defendants; 8th Circuit affirmed in part, reversed in part; SCOTUS vacated and remanded for further consideration in light of *Escobar*

Proving Materiality – *United States ex rel. Miller v. Weston Educational, Inc.*, 840 F.3d 494 (8th Cir. 2016)

- Defendants argued that falsified grade and attendance records did not cause improper disbursement or retention of funds and so were not material, focusing on the link between individual falsified records and payments
- But "fraudulent inducement examines the false statements that induced the government to enter the contract—liability for the specific claims for payment attaches "so long as the original contract was obtained through false statements or fraudulent conduct."

Proving Materiality – *United States ex rel. Miller v. Weston Educational, Inc.*, 840 F.3d 494 (8th Cir. 2016)

- "Materiality depends on whether Heritage's promise to maintain accurate grade and attendance records influenced the government's decision to enter into its relationship with Heritage."
- Court examined various places where the government expressly conditioned defendant's participation on compliance with recordkeeping requirement and on the government's actions

Proving Materiality – *United States ex rel. Miller v. Weston Educational, Inc.*, 840 F.3d 494 (8th Cir. 2016)

- In addition to this triple conditioning, the significance of the requirement and the government's acts show that the recordkeeping promise was material.
  - The DOE relies on school-maintained records to monitor regulatory compliance;
  - The DOE sometimes terminates otherwise eligible institutions for falsifying student attendance and grade records.
- "To the extent Heritage asserts that its statements, even if false, did not cause any actual harm, this is not an element of materiality."

Government Awareness of Allegations – *United States ex rel. Harman v. Trinity Industries, Inc.*, 872 F.3d 645 (5th Cir. 2017)

- "though not dispositive, continued payment by the federal government after it learns of the alleged fraud substantially increases the burden on the relator in establishing materiality."
- "given [the agency's] unwavering position that the [product] was and remains eligible for federal reimbursement, Trinity's alleged misstatements were not material to its payment decisions."

Government Awareness of Allegations - *United States ex rel. Petratos v. Genentech Inc.*, 855 F.3d 481 (3rd Cir. 2017)

- "Petratos admits that he disclosed 'material, non-public evidence of Genetech's campaign of misinformation' to the FDA and [DOJ] in 2010 and 2011. Since that time, the FDA has not merely continued its approval of Avastin for the at-risk populations that Petratos claims are adversely affected by the undisclosed data, but has *added* three more approved indications for the drug.
- Nor did the FDA initiate proceedings to enforce its adverse-event reporting rules or require Genentech to change Avastin's FDA label, as Petratos claims may occur. And in those six years, the [DOJ] has taken no action against Genentech and declined to intervene in this suit."

Government Awareness of Allegations – *Abbott v. BP Expl. & Prod., Inc.*, 851 F.3d 384 (5th Cir. 2017)

- Government's continued activity following investigation into potential fraud is "strong evidence" that materiality is lacking.
  - As a result of *qui tam* suit, agency reviewed Defendant's compliance with regulatory requirements and issued a report concluding that "Abbott's allegations about false submissions by BP to [DOI] are unfounded" and "found no grounds for suspending operations . . . or revoking BP's designation as an operator."
  - DOJ declined to intervene in *qui tam*
- "[W]hen the DOI decided to allow the Atlantis to continue drilling after a substantial investigation into Plaintiff's allegations, that decision represents 'strong evidence' that the requirements in those regulations are not material."

Government Awareness of Allegations - *United States ex rel. Spay v. CVS Caremark Corp*., 875 F.3d 746 (3rd Cir. 2017)

- In 2006, CVS Caremark discovered that its claim submissions to CMS for thousands of prescriptions triggered errors involving prescription IDs. In response, CVS Caremark created "dummy IDs' for the affected prescriptions to facilitate processing. After a 2007 audit, Relator filed this *qui tam* lawsuit.
- Summary judgment for defendants affirmed, the dummy IDs were not material because CMS continued payment of the pharmacy claims in full despite actual knowledge that the dummy IDs were in use.

Government Awareness of Allegations - *United States ex rel. Spay v. CVS Caremark Corp*., 875 F.3d 746 (3rd Cir. 2017)

- "[P]recisely the situation" alluded to in *Escobar*:
  - CMS was well aware of the difficulty many pharmacies and PBMs were having obtaining a proper physician identifier;
  - CMS was concerned with filling valid prescriptions and did not want claims rejected at the point of service for absence of a valid identifier;
  - PDE records could not be submitted without some type of number that satisfied the requisite algorithm in the physician identifier filed;
  - CMS knew that many PBMs were submitting PDEs with dummy numbers in the physician identifier field in 2006 and 2007;
  - CMS could easily recognize dummy prescriber identifier numbers;
  - CMS took no action to deny payment on any such claims during the 2006-2007 time period

Government Awareness of Allegations - *United States ex rel. Spay v. CVS Caremark Corp*., 875 F.3d 746 (3rd Cir. 2017)

- Relator argued that because the government explicitly advised the parties that the individual CMS employees did not speak for CMS and that CMS did not endorse their testimony, the testimony of those CMS employees could not be used at summary judgment to establish that CMS as an agency knew of and affirmatively authorized a general industry use of dummy IDs
- Court disagreed, testimony did not undermine finding that the misstatements were simply not material to the government's decision to pay the claim

Government Awareness of Allegations - *United States v. Triple Canopy, Inc.*, 857 F.3d 174 (4th Cir. 2017)

- Finding of materiality was supported by "common sense and [Defendant's] own actions in covering up the non-compliance."
- Government did not renew the contract and immediately intervened in the litigation, "[b]oth of these actions are evidence that [Defendant's] falsehood affected the Government's decision to pay."