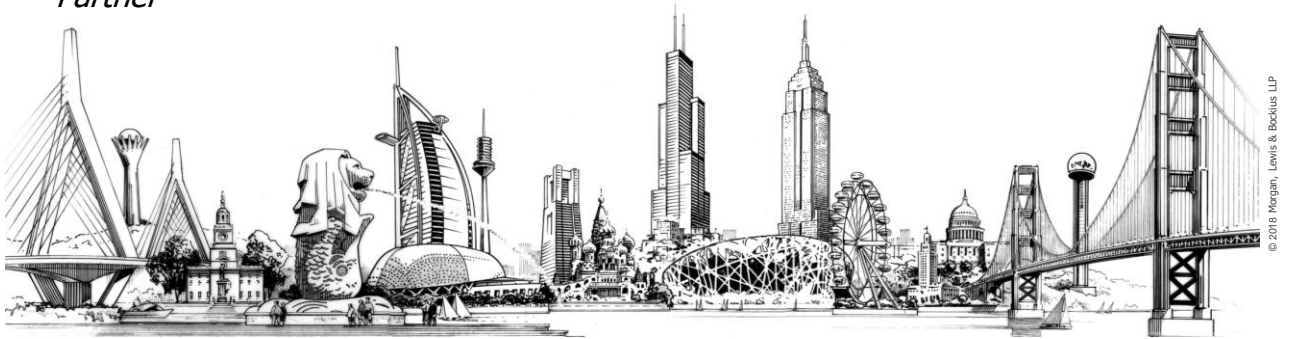


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INTERNAL INVESTIGATIONS

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Partner



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Internal Investigations

- There are many different things that can trigger an internal investigation.
- Internal investigations of perceived misconduct or questionable issues may be:
 - Prompted by a Government investigation (CID, subpoena, raid, or lawsuit);
 - Discovered through internal compliance reviews and/or routine audits;
 - Reported by employees or third parties (may be reported anonymously);
 - Discovered through industry reports; or
 - Reported externally by competitors or the media.

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2

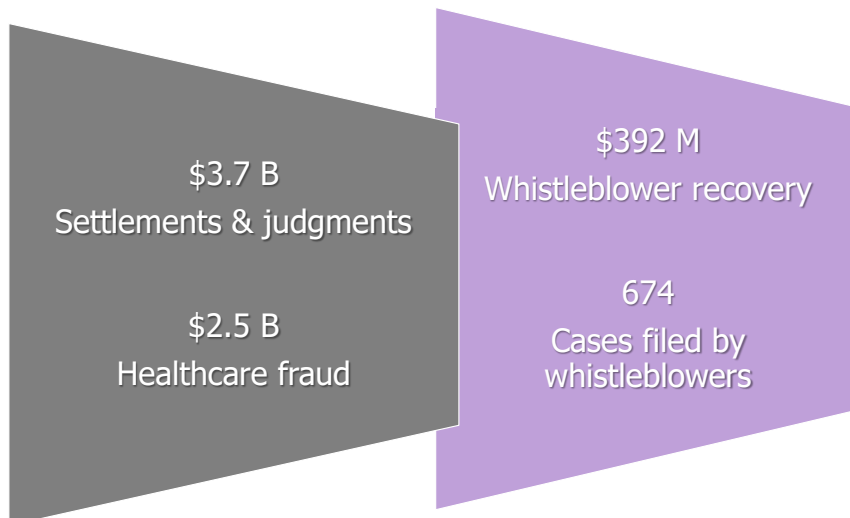
Internal Investigations

- Enforcement and industry activities may also be considerations in conducting internal investigations.
 - Federal False Claims Act
 - State False Claims Act
 - Civil Monetary Penalties
 - Whistleblowers or Hot Line Reports
 - Self Disclosures and Reporting Obligations
 - Corporate Integrity Agreement or other compliance obligations
 - Industry Reports
 - Individual Accountability

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FCA Enforcement Stats – FY 2017



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FCA Enforcement Landscape



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Parallel Investigations

- **DOJ policy statement**

"We in the Criminal Division have recently implemented a procedure so that all new *qui tam* complaints are shared by the Civil Division with the Criminal Division as soon as the cases are filed. Experienced prosecutors in the Fraud Section are immediately reviewing the *qui tam* cases when we receive them to determine whether to open a parallel criminal investigation."

Assistant Attorney General, Leslie Caldwell
Sept. 17, 2014

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Parallel Investigations

• **Olympus Corp. of the Americas**

- Allegations: Kickbacks to doctors and hospitals to induce them to purchase Olympus products
- \$646 M global settlement
 - Civil penalties
 - \$310.8 M – To resolve whistleblower allegations in connection with a qui tam action
 - Criminal penalties
 - \$312.4 M – Violation of Anti-kickback Law
 - \$22.8 M – Violation of Foreign Corrupt Practices Act

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Individual Accountability for Corporate Wrongdoing

• **DOJ policy statement (Yates Memo)**

“One of the most effective ways to combat corporate misconduct is by seeking accountability from the individuals who perpetrated the wrongdoing . . . [accountability] it deters future illegal activity, it incentivizes changes in corporate behavior . . . and it promotes the public’s confidence in our justice system.”

Deputy Attorney General, Sally Quillian Yates

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Yates Memo – 6 Key Principles

1. To qualify for cooperation credit – “corporations must provide all relevant facts relating to the individuals responsible for the misconduct.”
2. Criminal and civil corporate investigations “should focus on individuals” from inception.
3. Criminal and civil attorneys handling corporate investigations “should be in routine communication.
4. Culpable individuals will not be released from civil or criminal liability when resolving a matter with a corporation, absent “extraordinary circumstances.”
5. No resolution of the corporate investigation “without a clear plan to resolve related individual cases.”
6. “Civil attorneys should consistently focus on individuals” as well as the company and “evaluate whether to bring suit against an individual based on considerations beyond that individual's ability to pay.”

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Yates Memo in Action

- **Biodiagnostic Lab Services, et al.**
 - 41 convictions include the lab’s owner, employees and 27 physicians; \$12 M recovery
- **Insys Therapeutics, Inc.**
 - Indictment and arrest of 6 former pharmaceutical executives for their involvement in an alleged racketeering scheme to defraud insurers
 - Includes CEO, VPs and sales directors

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Compliance Programs – DOJ Guidance

Evaluation of Corporate Compliance Programs

Topics and questions for organizations to review when designing and / or improving compliance programs.

- Analysis and remediation of underlying misconduct
- Senior and middle management
- Autonomy and resources
- Policies and procedures
 - Design and accessibility
 - Operational integration
- Risk assessment
- Training and communications
- Confidential reporting and investigation
- Incentives and disciplinary measures
- Continuous improvement, periodic testing and review
- Third party management
- Mergers and acquisitions

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Compliance Programs – DOJ Guidance

- **Evaluating compliance – key focus areas**
 - Conduct and oversight of senior leadership
 - Concrete actions demonstrating compliance and remediation efforts
 - Content and effectiveness of training programs
 - Resources available to employees when seeking guidance on corporate compliance policy
 - Available funding, resources and experienced personnel
 - Appropriate autonomy for compliance officers and program
 - Effectiveness of the risk assessment process
 - Methods and metrics for information gathering and analysis
 - Reporting mechanisms through which the organization may assess allegations of misconduct
 - Internal audits and control testing
 - Continuing review of compliance policies, procedures, practices

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Refund Reporting

- ACA enacted Section 1128J(d)
(42 U.S.C. § 1320a-7k(d))
 - Must “report and return” overpayment and notify government of the reason for the overpayment
 - Must make repayment:
 - within “60 days after the date on which the overpayment was identified;” or
 - at time of cost report filing (if applicable)
 - Overpayments may require “reconciliation” before due

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Identification

- Part A/B provider has “identified” an overpayment when it “has, or should have, through the exercise of reasonable diligence, determined that [it] has received an overpayment and quantified the amount of the overpayment”
 - Includes proactive compliance activities; and
 - Responses to “credible information”

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Identification

- “We advise those providers and suppliers [that do not have active compliance programs] to undertake such efforts to ensure they fulfill their obligations under section 1128J(d) of the Act.”
- “We believe that undertaking no or minimal compliance activities to monitor the accuracy and appropriateness of a provider or supplier’s Medicare claims would expose a provider or supplier to liability under the identified standard articulated in this rule. . .”

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Identification

- A person has, or should have through the exercise of reasonable diligence, determined that the person has received an overpayment and quantified the amount of the overpayment.
- Overpayment is identified “if the person fails to exercise reasonable diligence and the person in fact received an overpayment.”

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Credible Information

- Responding to “credible information” is a subset of “reasonable diligence,” which includes proactive monitoring and reactive investigating.
- “Credible information” is not the same as “identification” – it is what triggers the duty to investigate.
- “Credible information” includes information that supports a reasonable belief that an overpayment may have been received.

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Credible Information

- Acting on “credible information”
 - Providers have 6 months from receipt of credible information to investigate and decide if in fact they have an overpayment or not.
 - Providers that receive credible information but do not have proactive measures to monitor for such credible information, and therefore do not know that they have credible information, have liability 60 days after receipt.
 - “Credible information” is credible information, no matter who in the organization receives it.

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Operational Considerations

- Engage in proactive auditing and monitoring.
- Train staff to identify and report overpayments.
- Promptly investigate reports of a potential overpayment to determine if it is credible.
- If the information is credible, promptly begin an inquiry and take steps to determine whether an overpayment exists and accurately and efficiently quantify it.

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Benefits of Conducting Internal Investigations

- Early assessment of potential legal exposure.
- Help identify and discipline bad actors.
- Reflection of the company's commitment to ethics/compliance.
- Enhanced credibility with enforcement authorities.
- Protection for directors, officers, and/or senior management.
- May be required by law or advisable under the law.
- Positive reputational impact.

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Conducting Investigations

Steps to Consider

1. Develop an internal investigation plan and scope of review.
2. Consult with legal counsel (Attorney-Client Privilege).
3. Conduct factual due diligence.
4. Understand the legal/regulatory/reimbursement scheme.
5. Analyze and manage the investigation.
6. Take remedial and corrective action as warranted.

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Developing The Internal Investigation Plan

- Internal investigations are key components to crisis-management plans and are the primary means to address and respond to credible allegations of misconduct.
- Trying to identify the nature of the alleged misconduct and who is implicated.
 - Are there any steps that you need to take to identify the misconduct (e.g., high-level complaint without much detail but merits further investigation)?
 - Is the misconduct ongoing?
 - Does the misconduct involve senior management or officers?
 - Where did the misconduct occur (geographical location)?

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Developing The Internal Investigation Plan

- Are there any other issues (consequential or otherwise) related to, or as a result of, the misconduct that you need to consider:
 - Self-reporting to the relevant authorities
 - Other instances of misconduct
 - Disclosure of confidential information
 - CIA obligations

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Developing The Internal Investigation Plan

- Understand who will be ultimate consumers of the investigative work:
 - Senior management and general counsel
 - Board of directors
 - Audit committee
 - Outside auditors
 - DOJ or other government regulators
 - Investors
 - General public

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Developing The Internal Investigation Plan

- Develop a plan that outlines the allegations and the scope of the investigation.
 - Identify players involved in the problematic conduct (e.g., executives, employees, third-party agents, and/or other business partners).
 - Identify internal control deficiencies that may have contributed to problematic conduct.
 - Identify the stakeholders and required expertise that must be a part of the investigation team.
- Advantages to developing and memorializing a work plan at the outset:
 - Enables more efficient management and monitoring of tasks.
 - Assists in managing expectations with respect to timing and costs.
 - Aids in a company's ability to defend the investigative process.

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Developing The Internal Investigation Plan

- Manage the creation of new documentation and consider the security and methods of communications relating to the investigation.
- Whistleblower protection should be considered and taken into account.
- Secure cooperation from employees and business partners.
- Update the investigation plan as the internal review progresses.

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Confidentiality and Attorney-Client Privilege

- Document that outside counsel has been engaged to conduct a confidential investigation for purposes of providing legal advice to the company.
- Advise those working on the investigation that (i) they have been asked to assist with the investigation; (ii) they are to treat all information as privileged and confidential; (iii) they should not discuss their work or findings with others; (iv) they should not make copies of their notes or work papers for sharing with others; and (v) they should mark all investigative notes, reports, documents, and communications, including email correspondence, "Privileged and Confidential."
- Employees assisting with the investigation should be instructed to report to the lawyers directly and not through their usual chain of command.

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Conducting The Factual Investigation

1) Documentary –

- Electronic: computer hard drives (work and personal), shared network drives/folders, email programs, instant messaging programs, databases, portable storage devices, mobile phones, personal digital assistants, etc.
- Paper: Custodial files including documents of an informal nature (diaries, desk calendars, appointment books, etc.)
- Other: physical items (e.g., orthopedic implants)

2) Testimony – statements from witnesses (e.g., interviews).

3) Experts and Consultants – expert opinions or consultant reviews may be helpful.

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Conducting The Factual Investigation

- Witness Interviews
 - Potential for conflict of interest in internal investigations.
 - Company's interest may not align with those of the employee.
 - Provide clear *Upjohn* warnings about whom you represent, who possesses the privilege, and the purpose of the interview (gathering facts to provide legal advice to the client).
 - Responding to "Do I need a lawyer?"
 - What if they bring a lawyer?
 - What if they don't cooperate?

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Understanding the Legal and Payment Issues

- Understand the legal/regulatory/reimbursement issues involved.
- Not all perceived misconduct may result in legal issues.
- Is this a legal issue or an internal policy issue or something else?

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Understanding the Legal and Payment Issues

- Case Example
 - Investigation of DRG coding for pneumonia patients
 - Client asked physician to review some claims on the side
 - Physician finds errors
 - But physician didn't consider the coding guidelines based on the dates of service

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Understanding the Legal and Payment Issues

False Claims Act Elements

- 1) False statement or fraudulent course of conduct?
- 2) Requisite Scierter—Knowledge of the falsity?
- 3) Material?
- 4) Payment or forfeiture?

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Conditions of Participation

- The quality standards that providers shall meet to participate in the Medicare program.
- CMS explains, “these health and safety standards are the foundation for improving quality and protecting the health and safety of beneficiaries.” – CMS.gov, Conditions for Coverage (CfCs) & Conditions of Participation (CoPs)
- “If during a review, any contractor believes that a provider does not comply with the conditions of participation, the reviewer shall not deny payment solely for this reason.” – Medicare Program Integrity Manual, 100-08, Chapter 3 § 3.1A.

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Conditions of Payment

- Conditions of payment are rules or requirements that must be met in order for the provider to receive reimbursement.
- Two commonly used theories of liability in FCA cases:
 - 1) Express false certification.
 - 2) Implied false certification: the claimant submits a claim that does more than merely request payment. By submitting this claim, the claimant impliedly certifies compliance with federal and state statutes and regulations.

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Payment vs. Participation

- Pre-2016, the courts carefully distinguished the two sets of conditions.
- “Conditions of participation, as well as a provider’s certification that it has complied with those conditions, are enforced through administrative mechanisms, and the ultimate sanction for violation of such conditions is removal from the government program.” – *U.S. ex rel. Hayward v. Sava SeniorCare LLC*

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U.S. ex rel. Escobar v. Universal Health

- Relators were the parents of 17-year-old daughter.
- Parents brought daughter to a counseling center for treatment.
- Most of the staff members who treated daughter were not licensed mental health professionals.
- Daughter died from an adverse reaction to anti-psychotic medications.

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U.S. ex rel. Escobar v. Universal Health

- The relators allegations:
 - 1) The staff members who treated their daughter were unlicensed and unsupervised.
 - 2) The facility's claims used codes corresponding to services that the staff members were not qualified to provide.
 - 3) The facility violated more than a dozen state Medicaid regulations.

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U.S. ex rel. Escobar v. Universal Health

- U.S. Supreme Court affirmed that implied certification "*can be a basis for liability*" "*at least in certain circumstances.*"

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.

- Vacated and remanded to the First Circuit
 - Were the violations in question material to the government's payment decision?

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U.S. ex rel. Escobar v. Universal Health

- U.S. Supreme Court determined that “materiality” *“...cannot rest 'on a single fact or occurrence as always determinative.’”*
 - Condition of payment is itself a “*relevant*” though “*not dispositive*” factor in determining materiality.
 - Materiality must be assessed based on the government’s actual and expected conduct.

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U.S. ex rel. Escobar v. Universal Health

- “The FCA is not an all purpose antifraud statute or a vehicle for punishing garden-variety breaches of contract or regulatory violations.”
- “A misrepresentation cannot be deemed material merely because the Government designates compliance with a particular statutory, regulatory, or contractual requirement as a CoP.”

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U.S. ex rel. Escobar v. Universal Health

- “...proof 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 compliance with the particular statutory, regulatory, or contractual requirement.”
- “Materiality cannot be found where noncompliance is minor or insubstantial.”

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41

Analysis and Management of the Investigation

Analysis

- Objectively assess the facts when making your findings.
- Apply those facts to the relevant law, payment, or policy issues.
- Determine reasonable conclusions.

Reporting

- Reports may vary depending on the nature of the investigation and the preferences of the client.
 - Detailed memorandum
 - Summary conclusion
 - PowerPoint presentation
 - Oral report

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Taking Corrective Actions

- Should be considered at the outset of the investigation (be alert to potential pitfalls and challenges)
- Usually want to make initial recommendations to the client orally (i.e., early case assessment subject to further investigation)
- Examples:
 - Disciplining / terminating employees
 - Revising / enhancing policies
 - Implementing new internal controls
 - Firing vendors or other third parties
 - Conducting training
 - Self-reporting to regulators
 - Making public disclosures

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43

Parting Thought

- You Lost My Dog!



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44

Speaker Profile



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Scott McBride provides legal services to clients throughout the healthcare industry, with a focus on compliance and enforcement issues. Scott represents and advises hospitals, academic medical centers, physician groups, and other healthcare clients in overpayment disputes, False Claims Act (FCA) litigation, internal and external investigations, and regulatory enforcement proceedings. His work spans a variety of matters related to Medicare and Medicaid billing compliance, civil monetary penalties, Stark Law and the Anti-Kickback Statute, corporate oversight, and exclusions from federal and state healthcare programs.

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45

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46