

American Conference Institute's 11<sup>th</sup> National Forum on:  
Fraud and Abuse in the Sale and Marketing of Drugs

**MANAGING, DEFENDING AND CURTAILING WHISTLEBLOWER AND RELATOR  
ALLEGATIONS UNDER AN EXPANDED FALSE CLAIMS ACT**

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# Introduction of the Panelists

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\* The views expressed today, in this oral and PowerPoint presentation and in conversation with you, are those only of Wendy Weiss personally and are not and should not be taken as official positions of either the Office of the US Attorney's or the US Department of Justice.

# Agenda

- Overview of presentation
- Why this is important
- Basic theories of liability
- Role of the whistleblower in bringing evidence of fraud to the government
- How investigations commence
- Purpose of anonymity
- How to assess the allegations
- Ascertaining the identity, motives and credibility of the whistleblower
- How both parties treat the whistleblower
- How best to respond to the government
- Best Practices

# Why This is Important to You

- Fraud Recovery Statistics
  - For past two years the government has recovered almost \$7 billion in False Claims Act matters
    - Approximately \$4 billion of that amount is related to whistleblower claims
  - 574 qui tam lawsuits were filed in 2010 alone
  - \$2 billion dollars recovered for healthcare qui tams in 2010
- New whistleblower statutes that provide bounties
  - IRS
  - Dodd-Frank
- Fulbright survey indicated that 20% of the corporate respondents anticipate an increase in whistleblower allegations this year
- Number of qui tam suits filed over the last few years appear static, per DOJ statistics

# Basic Liability

- The Amended False Claims Act – The Fraud Enforcement and Recovery Act of 2009 (“FERA”) – Enacted May 20, 2009 – First significant revision of FCA in more than 20 years.
- Elements Required to Prove a Case:
  - Claim for payment to the government
  - Falsity
  - Materiality
  - Required state of mind (“Scienter”)
    - Actual knowledge OR
    - Deliberate ignorance OR
    - Reckless disregard of the truth or falsity of the information

# Basic Liability (con't)

- Pursuant to FERA/PPACA can prove liability through a scheme
  - The Anti-Kickback Statute
  - Off-Label Promotion
- Damages and Penalties
  - Treble Damages
  - Penalties of \$5,500 to 11,000 Per False Claim (Adjusted for inflation)
  - Relator Gets 15 – 25%
  - Relator's Attorney Gets Statutory Attorneys Fees

# Role of the Whistleblower

- Reactive Discovery of Possible Problems

- Notice of government investigation
- Government subpoena
- Press reports
- Competitor
- Whistleblower notification

- Proactive Discovery of Possible Problems

- Self Assessments and certification
- Compliance review
- Due diligence (acquisitions/mergers)
- Internal and external audits

# Why Whistleblower Cases Have Increased

- Media reports regarding huge recoveries and relator share
- Publicity by the government that healthcare enforcement is a priority
- Bad economy
- More publicity due to more statutes with bounty provisions
- Increased awareness by plaintiff's bar



# New Benefits to Whistleblowers under FERA

- Sharing of CID Information
- Enhanced retaliation provisions
- Public disclosure bar changes

# Mechanics of a Whistleblower Action

- Suit is Filed Under Seal for 60 days (Confidential)
- Government Investigates
  - Review Relator’s Allegations and Evidence Provided
    - Federal Agents assigned (i.e., HHS, FBI)
    - Interview the Whistleblower
      - Warnings to Relator about conduct going forward
        - Tell Us Everything You Know Now
        - Give Us Everything You Have Now
        - 4<sup>th</sup> Amendment/Agency Issues
  - Conduct Witness Interviews
  - Issue Agency Subpoenas
  - Hire Experts (i.e., medical consultants, accountants)

# Mechanics of a Whistleblower Action (con't)

- Issue Civil Investigative Demands (for documents, interrogatories, depositions)
  - Previously used sparingly because pre-FERA only AG could authorize
  - Post-FERA: “[T]he Attorney General or a designee [now been delegated to US Attorneys]” can authorize CIDs
  - Result: Increased Use of CIDs
  - FERA allows sharing of information obtained by CIDs with Relators (whistleblowers) “if the Attorney General or designee determine it is necessary as part of any false claims act investigation.” §3733(a)(1)
  - Allows greater Relator participation in investigation and potentially larger share of recovery for Relator

# Mechanics of a Whistleblower Action (con't)

- If Parallel Investigation with Criminal Division
  - Consensual monitorings
  - Undercover operations
- Government Intervenes or Declines Intervention
  - Case Settles or Proceeds to Trial
    - Gear Up for Trial
    - Conduct Discovery (again)
    - Motions (dismissal, summary judgment)
    - Trial

# Mechanics of a Whistleblower Action (con't)

- What Information Does the Government Share with the Whistleblower?

# The Investigation

- Private party's reasons to investigate
  - How does the investigation proceed?
  - What steps does it take to identify the problem to remediate?
  - What does it intend to do with the information?

# Why Ascertain the Identify of the Whistleblower?

- How to assess the credibility of the whistleblower
- How to treat the whistleblower
- What are the civil ramifications
  - Remedies and damages

# Sharing Information between the government and defense in light of the seal and anonymity of the whistleblower.

- When to disclose the identity of the whistleblower
- Reasons not to share the identity of the whistleblower
  - Need for lifting of seal



# What is the whistleblower's share of any recovery?

- Strategy for limiting the recovery – does one exist?
- When does the government ascertain his share during the investigation?
- Wild expectations on both sides.
  - Whistleblower – lottery fever
  - Target – nominal payment or declination

# The Government's Decision

- What will drive the government's determination in declining or intervening; What Separates the Good Cases from the Bad?
  - Egregiousness of Behavior
  - Complexity of Issues
  - Evidence of Scierter (Bad Intent)
  - Amount of Loss to the Government from Defendant's Actions
  - Assets of Defendant

# The Government's Decision

- Pitfalls the government has observed by the company.
  
  
  
  
  
  
  
  
  
  
- Pitfalls the government has observed by the whistleblower.

# Why the corporation should cooperate.

- “It always gets worse”
- “You know more than we do.”

# How the corporation can demonstrate investigation and remediation to the government.

- Enhanced training and certifications
- Expertise employed
- Updated policies and procedures
- Monitoring procedures to ascertain reliability

# How to Best Protect The Corporation

- Self Disclosure: Whether to Voluntarily Disclose
- Why Disclose?
  - Minimize punishment/  
avoid criminal charges
  - Limit civil charges
  - Limit adverse administrative  
results
  - Reduce Litigation Risk
  - Part of Proactive Strategy
- Why Not Disclose?
  - Allegation not yet  
substantiated
  - Trigger government  
investigation
  - Negative publicity
  - Waiver of privilege

# Government's view of compliance programs in making an intervention/settlement decision

- Good compliance plans that you adhere to including hotline and internal investigation
  - Know/follow letter & spirit of laws
  - Work with agencies
  - Do not risk liability, reputational harm
  - Despite economic concerns, not a good idea to cut resources dedicated to compliance as more government resources will likely be dedicated to enforcement

## Government's view to compliance programs in making an intervention/settlement decision (con't)

- Vet Subcontractors carefully
  - Include them in your compliance program
- Reassess and update your program
- Employee Training
- Self-policing
- Government will focus on relationships – who is designing, endorsing, promoting medical devices – be careful about fraudulent relationships with physicians and study authors



# Government's view to compliance programs in making an intervention/settlement decision (con't)

- Evaluate types of activities that have gotten other companies in trouble
- Consider how the government will assess your response to non-compliance
- Intent behind compliance program
  - Incentive structure within company that encourages non-compliant conduct
    - Recent CIAs – HHS requires Board members to certify that company is in compliance with federal regulations

# Compliance Best Practices

- Benefits of compliance
- How they help

Questions?