

Best Practices to Manage Whistleblower Claims and Perform Effective Investigations

Agenda

- False Claim Act Trends
- Managing and Investigating Whistleblower Claims
- Prevention Through Effective Compliance Programs
- Q&A

False Claim Act Trends

FCA Filing and Recovery Trends

- The number of lawsuits filed under the *qui tam* provisions of the FCA have grown significantly since 1986
 - **2016:** 702 suits filed, an average of 13.5 new cases every week
 - **2017:** 669 suits filed, an average of 12 new cases every week
- 2017 was the eighth straight year in which the government recovered more than \$3 billion in FCA cases
- FCA recoveries are increasingly driven by *qui tam* lawsuits and shared with relators
 - **2016:** \$4.7 billion recovered, \$2.9 billion related to *qui tam* lawsuits, \$519 million paid to relators
 - **2017:** \$3.7 billion recovered, \$3.4 billion related to *qui tam* lawsuits, \$392 million paid to relators
- A majority of the government's FCA recoveries involve the healthcare industry
 - **2016:** \$4.7 billion recovered, \$2.5 billion involved the healthcare industry
 - **2017:** \$3.7 billion recovered, \$2.4 billion involved the healthcare industry

FCA Intervention Trends

- Recent DOJ intervention decisions reflect that a variety of circumstances may give rise to FCA exposure for any player in the healthcare industry
- The government's precedent-setting 2017 settlement with eClinicalWorks ("ECW"), one of the nation's largest vendors of electronic health records ("EHR"), may be sign that it will pursue intervention in FCA lawsuits against other vendors of EHR technology
- Earlier this year, the DOJ intervened in a FCA lawsuit involving a military healthcare contract held by one of the firm's portfolio companies
 - The case, *United States ex rel. Medrano v. Diabetic Care Rx, LLC*, may suggest increased FCA enforcement efforts against PE firms
 - In a press release touting its intervention decision, DOJ explained: "We will hold pharmacies *and those companies that manage them*, responsible for using kickbacks to line their pockets at the expense of taxpayers and federal healthcare beneficiaries

FCA Settlement Trends

- Compared to 2016, the number of settlements and settlement amounts in 2017 increased for healthcare providers, but decreased for pharmaceutical and medical device manufacturers
- Settlements were not necessarily accompanied by a corporate integrity agreement (CIA), reflecting the HHS OIG's April 2016 criteria that governs its decision-making in settlements with the DOJ under the FCA and other statutes
- Settlements reflect the government's continued focus on unlawful sales and marketing practices, including off-label marketing and the provision of kickbacks, and expanded interest in:
 - Patient assistance programs
 - Patient support programs
 - Drug pricing
 - Privacy issues
 - FDA's requirements regarding risk evaluation and mitigation strategy (REMS)

FCA Enforcement & Individual Liability

- DOJ-led FCA investigations can result in individual civil and/or criminal liability for company executives and employees
- Since the DOJ's issuance of the Yates Memo in 2015, there have been a number of notable settlements with and actions against individuals stemming from *qui tam* lawsuits, including:
 - Agreement by owner of Life Care Centers to joint and several liability for the \$145M settlement (10/24/16)
 - Agreement by three founders of eClinical Works (CEO, CMO and COO) to joint and several liability for the \$155M settlement; separate agreements with prgm. dev. (\$50K) and proj. mgrs. (\$15K) (5/31/17)
 - Sentencing of Warner Chilcott managers to forfeiture, fines and home confinement based on HIPAA violations (10/28/16)
 - Criminal charges against INSYS founder and former executives for sales and marketing of Abstral
- DOJ's decision to bring criminal charges against an individual does not guarantee victory
 - Acquittal of now-former Vascular Solutions CEO (2/26/16)
 - Acquittal of former Warner Chilcott executive (6/17/16)

Leaked Memo Provides DOJ Enforcement Insight

- On January 10, 2018, Michael D. Granston, Director of the Civil Fraud Section, issued an internal memorandum encouraging DOJ attorneys to consider using the government's authority to dismiss FCA *qui tam* cases that “lack substantial merit”
- The memo, which was leaked to the press, lists seven factors for government lawyers to consider when evaluating whether to seek dismissal of a *qui tam* case:
 - Meritless *qui tams*
 - Parasitic or opportunistic *qui tams*
 - Actions interfering with agency policies and/or programs
 - Controlling litigation brought on behalf of the United States
 - Safeguarding classified information and national security interests
 - Preserving government resources
 - Addressing egregious procedural errors
- While it is too early to measure the impact of the memo, defendants in non-intervened *qui tam* suits should consider a request for dismissal to the DOJ, using one or more of the seven factors

Managing and Investigating Whistleblower Claims

Who are the Whistleblowers?



Whistleblowers in Recent FCA Recoveries

- Although whistleblowers come from different backgrounds, the allegations in their underlying complaints contain a common theme –companies were aware of purported fraud, but did nothing
 - In many cases, whistleblowers personally reported the purported fraud to internal stakeholders who then failed to take corrective action
 - In other cases, whistleblowers became aware of the purported fraud but did not specifically alert the company or ask that it take corrective action before filing suit
- Whistleblowers have every incentive to document both the corporate failure to remediate and any affirmative steps a company has taken to conceal the fraud
- Companies have every incentive to fully investigate, remediate, and document its findings with respect to whistleblower allegations made before a lawsuit is filed

Notice of Whistleblower Claims

- Historically, companies become aware of FCA investigations/potential *qui tam* actions through subpoenas
 - Requires assumptions about conduct at issue
 - Extensive document production often required
 - Underlying lawsuit remains under seal for months or years while conduct is investigated
- Recent trend of more informal notice by the government
 - Often involves a greater level of information sharing by the government
 - Often signals that the government is willing to make an intervention decision more quickly

Internal and External Strategic Considerations

Internal Considerations

- ✓ Messaging with current and former employees
- ✓ Compliance documentation on issue at hand
- ✓ Identification of internal resources that can assist with the investigation
- ✓ Identification of insurance policies that may offset investigative and prospective settlement costs
- ✓ Identification of outside counsel team to handle investigation
- ✓ Drafting and monitoring of budget

External Considerations

- ✓ Interactions with government on matter at issue
- ✓ PR strategy for investors, customers, partners, press, and public
- ✓ Lender/bondholder/rating agency relations
- ✓ Prospect of other litigation
- ✓ Prospect of administrative action
- ✓ Prospect of legislative or other political action

Strategy for Managing Investigation

- **Initial Communication with Government**
 - Scope of investigation
 - Company's status in investigation
 - Status of investigation
 - Prospective narrowing of government requests
 - Timing of productions
 - Method of productions
 - Company's commitment to compliance/cooperation with government's investigation
 - Agreement to continue dialogue

Strategy for Managing Investigation (Cont'd)

- **Establish Internal Investigation**
 - Scope of investigation
 - Under privilege
 - Internal and external personnel responsible for investigation
 - Personnel within the scope of privilege

Strategy for Managing Investigation (Cont'd)

- **Document Preservation through Legal Hold**
 - Identify employees who should receive the legal hold
 - Document preservation policy and/or historic practices will likely dictate the universe of information available for retrieval
 - Legal hold should cover all company-issued devices and all responsive documentation regardless of form
- **Document Collection and Production**
 - Identification of custodians (both current and former employees) whose documents should be collected
 - Use of third parties to collect, upload, host and possibly help review documentation
 - Prepare, distribute and discuss summary of each production before

Strategy for Managing Investigation (Cont'd)

- **Conduct Internal Investigation**
 - Key issues analysis based on document review
 - Conduct interviews of key current and former employees
 - Determine possible exposure
 - Consider use of experts to further support analysis
 - Present prospective next steps to internal stakeholders
 - Preserve privilege by marking documentation appropriately and limiting distribution to individuals who are within the scope of privilege

Cooperation Considerations

- **Extent of Cooperation**
 - Meetings to discuss facts at issue
 - More fulsome cooperation required to obtain credit in any settlement
- **Potential Benefits of Cooperation**
 - Limit scope and cost of investigation
 - Control narrative in the light most favorable to company
 - Persuade the government not to intervene and, possibly, to seek to affirmatively dismiss the case
 - Persuade the government and relator(s) to agree to a settlement favorable to company
- **Potential Risks of Cooperation**
 - Waiver of work product
 - Requirement to identify individual misconduct
 - Cooperation will fail to sway the government

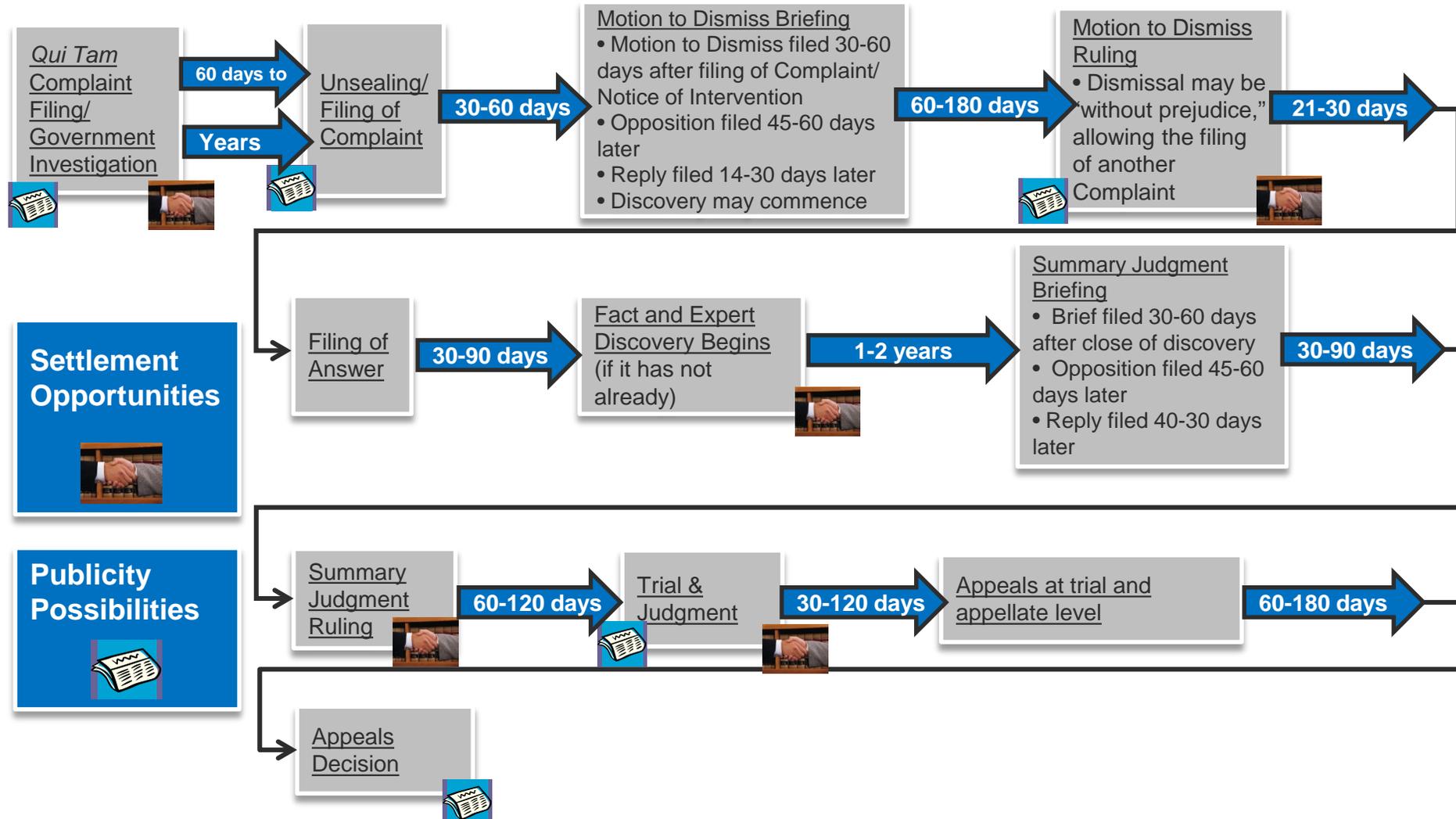
Potential FCA Defenses

- No evidence to support factual allegations
- No violation of underlying state/federal regulations
- Complaint lacks required specificity under FRCP 9(b)
- Ambiguity in regulations precludes FCA “falsity” and “scienter”
- No false statements in any submitted claims
- No false certification of condition of payment
- No injury to government

Resolution of Investigation

- **Negotiated Settlement**
 - Each side performs analysis of litigation risks
 - May involve waiver of attorney-client privilege
- **Typical Settlement Terms**
 - May require criminal pleas and fines
 - May require civil damages and/or penalties
 - May require administrative civil monetary penalties
 - May require Corporate Integrity Agreement (“CIA”) in order to avoid exclusion from Government programs

Investigative and Litigation Process



Prevention Through Effective Compliance Programs

Prevention Through Effective Compliance

- The Office of the Inspector General for the Department of Health and Human Services (“OIG”) maintains a website with extensive compliance resources
- At the heart of OIG’s guidance are the Seven Fundamental Elements of An Effective Compliance Program
 - Written standards of conduct, policies and procedures
 - Designated compliance officer and compliance committee
 - Effective training and education
 - Effective lines of communication
 - Internal monitoring and auditing
 - Enforcement of standards through well-publicized disciplinary guidelines
 - Prompt response to detected problems through corrective action

Measuring Compliance Program Effectiveness

- In January 2017, a group of compliance professionals from the Health Care Compliance Association (“HCCA”) and staff from the OIG held a roundtable, known as the HCCA-OIG Compliance Effectiveness Roundtable, to discuss ways to measure the effectiveness of compliance programs
- The Roundtable’s efforts resulted in the March 2017 publication of “Measuring Compliance Program Effectiveness – A Resource Guide,” a detailed, 54 page document listing many individual compliance program metrics as they relate to the seven elements of an effective compliance program
 - The Roundtable made clear that the list **is not a “checklist”** to be applied wholesale to assess a compliance program
 - Rather, the utility of any suggested measure listed in the report will be dependent on the organization’s individual needs

Creating a Culture of Compliance

- Tone from the top is key – stakeholders should be internally and externally visible and committed to ethics and compliance
- Companies can best reduce the likelihood of external whistleblowing by advocating for and acting upon internal whistleblowing
 - Training on policies and procedures, with emphasis on compliance
 - Promotion of internal reporting through various channels, including the use of an anonymous compliance hotline
 - Demonstration that the company will quickly and seriously act upon information provided through these channels
 - Use of auditing and monitoring measures to ensure compliance
 - Contemporaneous documentation of efforts

Q&A