



# Focus on Investigations: Government Trends and Best Practices for Internal Investigations

*Food and Drug Law Institute Conference*

*May 3, 2019*

# Panel Members

- **Beth Weinman, Ropes & Gray LLP**  
his own, and are not intended to impart
- **John Bentivoglio, Skadden, Arps, Slate, Meagher & Flom LLP**  
Justice.
- **John Claud**, Assistant Director, Consumer Protection Branch, US Department of Justice
- **William Gould**, Holland & Knight LLP

# Key Topics for Discussion

- **Enforcement Priorities**
- **Best Practices for Internal Investigations**
- **Individual Accountability**
- **Strategies for Interacting with DOJ during Enforcement Actions**

# *Discussion: Enforcement Priorities*

***What are the current DOJ and FDA enforcement priorities regarding FDA regulated products?***

# Recent Enforcement Priorities

- Opioids
- Youth Vaping
- Poor manufacturing practices
- Unapproved stem cell injections
- Safety Reporting
- Dietary Supplements (e.g., undisclosed ingredients)
- Misleading marketing



# ***Discussion: Best Practices for Internal Investigations***

***What are the goals and best practices for conducting an internal investigation?***

# Goals of Internal Investigations

- **Uncover Facts**
- **Preserve Information**
- **Establish Independence**
- **Take Action to Prevent Repeat**
  - **Review Response/Policies/Procedures/Training**
  - **Address wrongdoing/wrongdoers**
- **Respond to Government Investigation/Render it Redundant**

# Investigation Checklist

- Determine the goal(s) and scope of the investigation.
- Identify who should conduct the investigation – no interested parties.
- Determine and analyze applicable laws and regulations.
- Develop a plan of action and timeline for completion.
- Preserve documents appropriately.
- Review and analyze key documents.
- Interview key witnesses – ask for honesty.
- Provide *Upjohn* Warning with witness present.
- Provide clear explanation for purpose of interview.
- Document interviews.
- Communicate results in a manner that protects the privilege.
- Consider disclosure obligations & corrective action.



# Build and Plan

- **Who's in charge?**
- **Who's on the team?**
  - **Inside or Outside.**
- **Who do we need to help?**
  - **Forensic investigative services.**
  - **IT: Litigation holds/records searches.**
  - **Financial: Follow the money.**
- **Who represents the witnesses?**
- **Who gets what reports?**



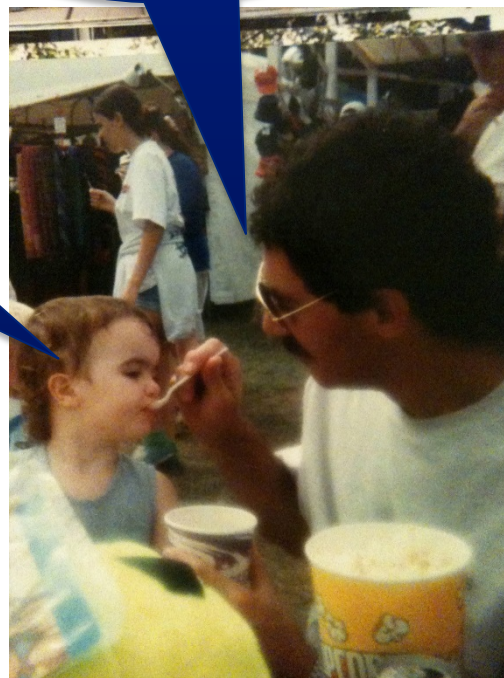
# Witnesses

- **Basic Principles**

- Prioritize.
- Chose interview team.
- Prepare/Plan.
- Provide *Upjohn* warnings.
- Ask for honesty.
- Discuss troubling / exculpatory documents.
- Prepare interview memorandum.
- Go back to witnesses when necessary as investigation develops.

One more scoop, then we'll talk!

We have fulfilled your request. Now please tell us what you saw!



# ***Discussion: Witness Interviews and Upjohn Warnings***

- ***When and how should you provide an Upjohn warning?***
- ***What could go wrong if an Upjohn is poorly executed?***
- ***What are important considerations in choosing when to offer witnesses counsel?***

# Witnesses

## Individual Considerations:

Pros	Cons
Avoids Conflict	Expense
Avoids Bias/Appearance	Time
“Pool” More Efficient	Learning Curve
Gives Government Comfort	

## Tough Questions:

“Should I Agree to This Interview?”

“Should I Have My Own Lawyer?”

“Am I in Trouble?”

# ***Discussion: Responding to Government Inquiries***

***How do best practices change if you are investigating because the government has issued a CID or subpoena?***

# Investigation Best Practices Post-Subpoena

- **Goal of discovering facts never changes.**
- **Steps taken—especially if no prior investigation has been conducted—are the same.**
- **The key difference is how government engagement can change the course of fact development.**
  - **Credibility is key and requires cooperation and disclosure.**
  - **Primary goals are to keep investigation narrowly focused and provide relevant context for facts disclosed.**
  - **Stay three steps ahead.**

# ***Discussion: Managing Documents***

***What tips do you have regarding:***

- Document collection and e-discovery?***
- Production?***
- Getting the government to narrow the subpoena, or permit collection and production to unfold in phases?***

# Communicate Management Strategy

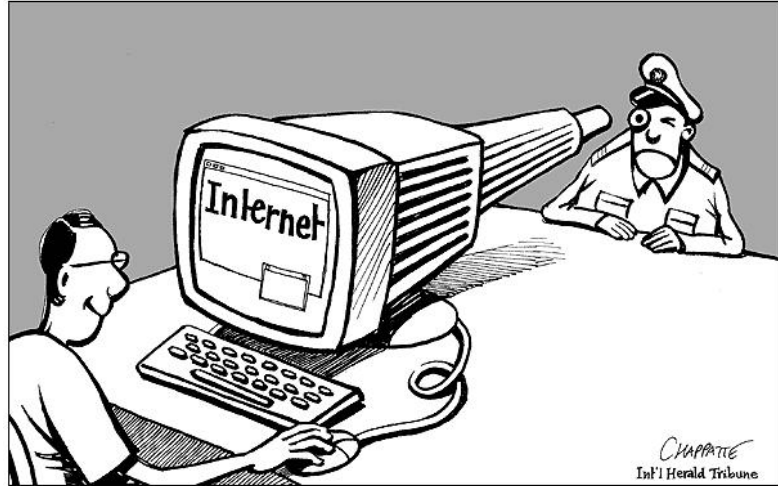
- **Litigation Hold**
  - “Zubulake Duty” 229 FRD 422 (SDNY, 2004).
  - Requires **Counsel** to ensure:
  - All potentially relevant documents:
    - Identified.
    - Placed on hold.



# Communicate Management Strategy

- **ELECTRONIC WORLD**

- Emails.
- Documents on System.
- Texts.
- Social Media.
- Et Cetera.



# *Discussion: Best Practices in Specific Contexts*

*Are there any best practices that are unique to specific types of investigations?*

- cGMP/ data integrity
- marketing practices
- safety reporting
- changes without appropriate clearances

# *Best Practices: Specific Contexts*

- **Each type of investigation is going to involve different policies and procedures.**
  - **Figure out where those documents (historical and current) are housed.**
  - **Figure out who are the best people to explain policy changes over time.**
- **Some investigations will involve a high volume of technical, scientific records (cGMP/data integrity).**
  - **Find someone who understand which records will be relevant, and can assist with attempts to narrow the government requests for technical documents.**
  - **Find an expert who is also a good educator and can explain to you (and the government if necessary) relevant scientific concepts that are particularly complex.**

## ***Best Practices: Specific Contexts***

- **While required formal documentation is critical, emails will still reveal where the biggest problems are.**
- **For reporting cases, if a specific required report was not filed, search for other ways the information may have been disclosed.**

# ***Discussion: Individual Accountability***

***Where is the government on individual accountability?***

***Is the Yates Memo still relevant?***

***How has DOJ's approach changed?***

# Individual Accountability: Yates Memorandum

- **Focuses on the need for accountability by individuals for corporate misconduct.**
- **Addresses “steps that should be taken in any investigation of corporate misconduct,” and applies to civil enforcement actions.**

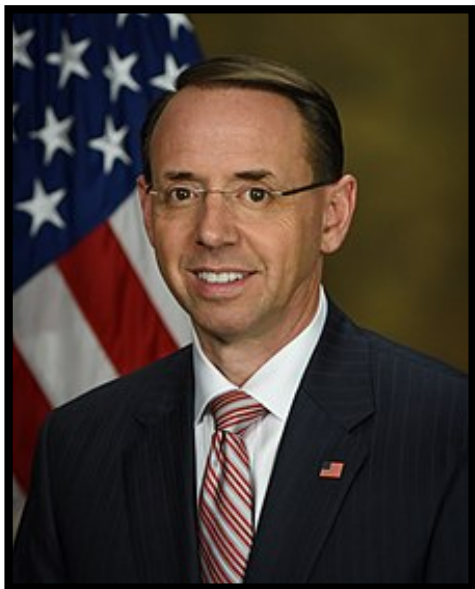
# Individual Accountability

- **Corporations must provide all relevant facts about the individuals involved in corporate misconduct**
- **Investigations should focus on individuals from the inception of the investigation**
- **Criminal and civil attorneys should be in routine communication with one another**
- **Absent extraordinary circumstances, no corporate resolution will provide protection from criminal or civil liability for any individuals**
- **Corporate cases should not be resolved without a clear plan to resolve related individual cases**
- **Civil attorneys should consistently focus on individuals as well as the company**

# Edit to Yates Policy

## Individual Accountability: Updated

Remarks on November 29, 2018



Rod Rosenstein  
Deputy Attorney General

### JUSTICE NEWS

Deputy Attorney General Rod J. Rosenstein Delivers Remarks at the American Conference Institute's 35th International Conference on the Foreign Corrupt Practices Act

Oxon Hill, MD ~ Thursday, November 29, 2018

#### *Remarks as prepared for delivery*

Thank you, Sandra [Moser]. I appreciate your exceptional work for the Department of Justice. As the chief of the Criminal Division's Fraud Section, Sandra leads our efforts to enforce the Foreign Corrupt Practices Act. And she has helped to develop and implement many policy improvements.

It is nice to be in a room with so many friendly lawyers. As you know, the legal profession prizes collegiality. Once upon a time, there was a small town with just one lawyer who suffered from a lack of business. Then another lawyer moved to town, and they both prospered. So you see, lawyers benefit from collegiality.

I know that many of you have served in the Department of Justice, so you understand our work. In some respects, you serve a law enforcement function even today; you counsel clients about how to comply with the law so that they will not wind up on the wrong side of Sandra and her colleagues.

Prosecuting crime is our tool, but our goal is deterring crime. We want less business. Our Department's 115,000 employees work every day to uphold the rule of law, fulfilling the mission articulated in our name: Justice.

A few months after the creation of our federal government in 1789, President George Washington started the tradition of issuing a Thanksgiving Proclamation. He expressed thanks "for the peaceable and rational manner, in which we have been enabled to establish constitutions of government for our safety and happiness." President Washington prayed that the national government would be "a blessing to all the people, by constantly being a Government of wise, just, and constitutional laws, discreetly and faithfully executed and obeyed."

Almost a century later, in 1863, President Abraham Lincoln issued a Thanksgiving proclamation. In the midst of the Civil War, Lincoln expressed gratitude that the rule of law continued to be observed in most of the country. Outside of the battlefields, "order ha[d] been maintained, the laws ha[d] been respected and obeyed, and harmony ha[d] prevailed." Not even a civil war could extinguish America's commitment to the rule of law.

Another hundred years later, in 1987, President Ronald Reagan celebrated the bicentennial of the Constitution. His Thanksgiving Proclamation declared that "[t]he cause for which we give thanks, for which so many of our citizens through the years have given their lives, has endured 200 years – a blessing to us and a light to all mankind."

The cause continues. Earlier this year, President Donald Trump issued a proclamation explaining that "we govern ourselves in accordance with the rule of law rather [than] ... the whims of an elite few or the dictates of collective will. Through law, we



## ***Discussion: Parallel Investigations***

***When can a company assume there is a parallel government investigation going on? How does that change the course of an investigation from:***

- The government's perspective?***
- The target/defendant's perspective?***

## ***Discussion: Interacting with DOJ***

***What are the best practices for interacting with the government?***

- Do White Papers work? Any dos and don'ts?***
- How do you effectively conduct litigation by PowerPoint in the conference room, thereby avoiding litigation in the courtroom?***

# Interacting with DOJ

## Reporting: Risks and Rewards

Risks	Rewards
Inaccuracies	Tell Your Story
	Limit the Damage
Trigger other actions	Control Momentum
	Slow Speculation

# Interacting with DOJ

## When Reporting, Address:

- **Conduct**
- **Individuals**
- **Policies and procedures**
- **Structures/systems**
- **Compliance program**

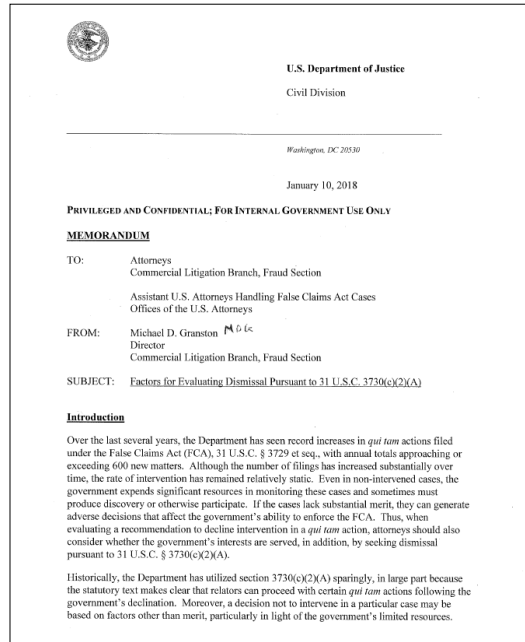
# Interacting with DOJ

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

Department of Justice Memorandum, January 10, 2018



Michael Granston  
Director of Commercial Litigation Branch  
Fraud Section



4/4/19: Pennsylvania federal judge rules DOJ must have a valid purpose for dismissal, and does not have “unfettered discretion” to dismiss.



***Questions?***