

GOVERNMENT INVESTIGATIONS:
RESPONDING TO REQUESTS FOR
INFORMATION INCLUDING
E-DISCOVERY

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PANELISTS

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GOVERNMENT INVESTIGATION SCENARIO

Easytarget Pharmaceutical Co. is a U.S.-based pharmaceutical company based in New Jersey that sells its products throughout the world. Its largest selling product is a statin product called "Save Your Heart." That product grosses the company over \$1 billion per year and has been on the market for five years.

In August 2005, Easytarget conducted a Good Clinical Practices Audit of a number of its products. That audit, which was conducted under the auspices of Easytarget's Quality Assurance Department reviewed preapproval clinical studies that were conducted on those products.

Bill Whistleblower had been the Director of Quality Assurance for Easytarget from 2003 until September 1, 2005. On that date, he was fired by Easytarget because he had made inappropriate advances to one of his subordinates. On his last day, Mr. Whistleblower went through the exit interview that is standard for all Easytarget employees. That interview was conducted by Easytarget's Human Resources Department. Several days later, Colby Justsayno, Easytarget's Head of Regulatory Affairs, receives a written report of that exit interview. That report states that Mr. Whistleblower is bitter about his termination. It also states that during his exit interview, Mr. Whistleblower indicated that the recently conducted audit had concluded that Dr. Profit, the clinical investigator who had enrolled the greatest number of patients in the major study used by Easytarget to get FDA to approve Save Your Heart, had falsified the results of that study, used the names of fictitious persons as participants in the study, withheld crucial safety information from his report that cast doubt on the safety of the product, and falsified important documents regarding that study. Mr. Whistleblower also told Mr. Justsayno that Dr. Profit's cousin, Laura Flybynight, had received a profitable distributorship with Easytarget for "Save Your Heart." Mr. Whistleblower expressed doubts about Ms. Flybynight, a new distributor with no other customers, and raised concerns that the products were being shipped to a warehouse that Easytarget had rented for Ms. Flybynight. Not sure of what to do, Mr. Justsayno has not spoken to anyone about the report or sought confirmation as to whether Mr. Whistleblower's allegations are true.

Concerned about the report, Mr. Justsayno schedules a meeting with Rosemary Cautious, the company's General Counsel, and with John Hearnoevil, the company's CEO.

RELEVANT TRENDS IN GOVERNMENT INVESTIGATIONS

- What is the current outlook on federal, state local government investigations?
 - False Claims Act cases
 - Health care fraud prosecutions
 - Securities fraud cases
 - Government seeking disgorgement and restitution
- Implications for document retention, disclosure and e-discovery

HOW SHOULD THE THREAT OF A GOVERNMENTAL INVESTIGATION IMPACT YOUR DOCUMENT RETENTION POLICY?

- Upon first learning of facts that may give rise to a governmental inquiry or litigation
- Upon receipt of formal or informal notice of investigation
- Upon receipt of government demand not to destroy records
- Upon receipt of a subpoena
- Documenting what you have done
- Negotiating with government officials regarding record retention policy

HOW SHOULD YOUR APPROACH TO GOVERNMENTAL INVESTIGATIONS DIFFER DEPENDING ON WHO IS CONDUCTING THE INVESTIGATION?

- FDA or other regulatory agency
- DOJ
- SEC
- FTC
- Department of Labor
- EEOC
- OSHA
- An Inspector General
- State or local government

HOW SHOULD YOUR APPROACH TO GOVERNMENTAL INVESTIGATIONS DIFFER DEPENDING ON WHO IS CONDUCTING THE INVESTIGATION?

(CONTINUED)

- Relevant questions for retention efforts
 - Which documents need be retained
 - Whose documents need be retained
 - How to communicate retention requirements
 - How to implement retention efforts
 - Role of IT personnel; counsel; others
 - How to enforce retention requirements

HOW SHOULD YOUR APPROACH TO GOVERNMENTAL INVESTIGATIONS DIFFER DEPENDING ON WHO IS CONDUCTING THE INVESTIGATION? (CONTINUED)

- What enforcement tools do they have?
 - Criminal Prosecutions
 - Injunction Cases
 - Civil Seizures
 - Civil Penalties
 - Debarment and Disqualification
 - Cease and Desist Orders
 - Warning Letters
 - Negative Inferences

THE NEED TO GET COUNSEL INVOLVED EARLY

- Having written corporate document retention plan before investigation begins
- Role of outside counsel
- Role of in-house counsel
- Documenting role of counsel to protect privilege (if such protection is possible)
- “Representation” of company employees
- Coordinating with securities disclosure counsel and investor or public relations efforts

PRACTICAL STRATEGIES FOR DIFFERENT TYPES OF INVESTIGATIONS AND DIFFERENT STAGES OF THE INVESTIGATION

- The government's right to information.
 - phone calls to employees
 - home visits to employees
 - letters requesting information
 - regulatory inspections
 - subpoenas
 - search warrants
 - grand jury subpoenas
 - wiretaps and wires
 - examining garbage

PRACTICAL STRATEGIES FOR DIFFERENT TYPES OF INVESTIGATIONS AND DIFFERENT STAGES OF THE INVESTIGATION

- The corporation's response.
 - Meeting with the Government
 - Internal investigation
 - Use of experts and consultants
 - Dealing with corporate employees
 - Interviewing
 - Firing and disciplining
 - Providing counsel
 - Whistleblowers
 - Preserving the privilege
 - Joint defense agreements
 - When and how to disclose to the government
 - Contacting ex-employees and third parties

PRACTICAL STRATEGIES FOR DIFFERENT TYPES OF INVESTIGATIONS AND DIFFERENT STAGES OF THE INVESTIGATION

- Proactively taking remedial action
 - Document production, including Grand Jury secrecy rules and confidentiality of records
 - Witness production
 - Voluntary disclosure of other wrongdoing
 - Speaking to customers, suppliers and media about investigation
- The False Claims Act angle

WHAT STEPS CAN YOU TAKE TO INCREASE THE GOVERNMENT'S WILLINGNESS TO NEGOTIATE?

- Understanding expectations for cooperation and their implications for document retention, production and e-discovery
 - DOJ's Thompson Memorandum
 - SEC's Seaboard Ruling
- Potential benefits of a global resolution
- Importance of voluntary corrective actions
- Approaching the right agency/person
- Offering evidence against other persons

EFFECTIVE NEGOTIATING STRATEGIES:

- When you know there is something amiss internally
- When you believe your company is not culpable in any way

IN WHAT SITUATIONS MUST
WRONGDOING OR
POTENTIALLY DAMAGING
CONDUCT OR
COMMUNICATIONS BE
DISCLOSED AND WHAT ARE
THE RISKS OF DISCLOSURE (OR
NON-DISCLOSURE)?

ENSURING THAT YOU COMPLY WITH ETHICS REQUIREMENTS THROUGHOUT THE INVESTIGATIVE PROCESS

- Consult applicable ethics rules
- Sarbanes-Oxley requirements
 - Gatekeeper issues
- Document actions taken

QUESTIONS AND ANSWERS