

# Government Investigation Preparedness for PHARMA

Developing the playbook for new domestic  
and international challenges

**January 23-24, 2007**

New York Marriott East Side, New York City

Industry Insights from:

- Baxter Healthcare Corporation
- Eisai, Inc.
- Johnson & Johnson
- Pfizer Inc.
- Schering-Plough Corp.

- Indemnification after KPMG
- Preparing for FCPA investigations
- Preserving attorney client privilege
- Implementing better internal investigation procedures

## Plus Don't Miss

**A Step-By-Step Guide to Conducting Internal Investigations  
for the Pharmaceutical Industry**

January 22, 2007 from 1:15 p.m. – 5:15 p.m.

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## Stop being a target for government investigations!

Learn new strategies to meet the government head on.

Despite companies' best efforts to comply with government regulations, the pharmaceutical industry continues to be the focus of government investigations. Pharma companies routinely pay hundreds of millions of dollars to settle government claims, and the consequences can be devastating.

## Changes in the way the government conducts investigations may be underway

While it doesn't seem that the targeting of pharmaceutical companies will end any time soon, the tide may be turning. The government suffered a setback with the recent KPMG decision and is now on the defensive. A new game in the world of compliance and government investigations is evolving and it's time for pharma companies to seize this opportunity.

## Reassess and refine your client's investigations playbook

Learn to navigate your way through the variables and intricacies of a government investigation in the drug industry with firsthand accounts by attorneys who have been through it before. Seats at this unique event are sure to go quickly. Don't delay – register now by calling 1-888-224-2480, fax your registration form to 1-877-927-1563, or register online at [www.americanconference.com/pharmainvestigations](http://www.americanconference.com/pharmainvestigations)

## Agenda at a Glance

- Indemnifying Employees: Where the Government Stands & Where the Corporation Should Stand
- FCPA and International White Collar Crime Basics That Every Pharma Company Needs to Know
- Trends in FCPA and Foreign Government Investigations
- Implementing Anti-Bribery Compliance Programs: Keys to Meeting New FCPA Compliance Standards
- Ensuring FCPA Compliance for Foreign Operations
- Aftermath of an Enforcement Action: Appointing & Working with Special Compliance Monitors
- Determining When – If Ever – the Attorney/Client Privilege Should Be Waived
- The Key to a Successful Investigation: An Integrated Records Management and Preservation Notice Program
- Assessing Your Options Once a Government Investigation is Initiated – It's Not Necessarily Time to Throw in the Towel!
- Bulletproofing Your Sales and Marketing Practices from Government Scrutiny
- Internal Investigations: Controlling Costs & Directing the Investigation
- Weighing the Pros and Cons of Voluntary Disclosures



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- In-house counsel responsible for:
  - investigations
  - compliance
  - litigation
- Compliance officers
- Regulatory affairs officers
- Attorneys with practice areas in:
  - pharmaceutical, food and drug, and healthcare law
  - fraud, false claims, and qui tams
  - healthcare fraud & abuse
  - white collar
  - internal and government investigations
  - corporate investigations
  - litigation

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## Interactive Workshop

### A Step-By-Step Guide to Conducting Internal Investigations for the Pharmaceutical Industry

Monday, January 22, 2006

1:15 p.m. – 5:15 p.m. (Registration Opens at 12:45 p.m.)

One of the most important steps in preparing for a government investigation is conducting a well-planned internal investigation. Effectively dealing with violations and complaints as they happen can head off a government investigation or mitigate damages if one should occur. Knowing how to handle problems from the moment the phone rings to when the government comes knocking is a vital aspect of every general counsel and compliance officer's job.

This hands-on workshop will provide you with a step-by-step guide for every phase of an internal investigation. The workshop will be tailored to the unique concerns of the pharmaceutical industry, and workshop leaders will lead you through the intricacies of the investigation process. This focus on the fundamentals of an internal investigation will help you fully appreciate the more detailed aspects of government and internal investigations presented in the main conference.

#### 1:15 Organizing and Managing Your Compliance Program

*Mark Lurie*

Vice President, Chief Ethics & Compliance Officer  
Eisai Corporation of North America (Teaneck, NJ)

*Christopher Myers*

Partner, Holland & Knight LLP (McLean, VA)

*Sue Seferian*

Senior Counsel, Corporate Law Department  
Johnson & Johnson (New Brunswick, NJ)

Learn from top pharmaceutical companies how their compliance programs are organized, as well as best practices for maintaining an effective compliance program. This panel discussion will address:

- Understanding the OIG guidelines
- Examining the Federal Sentencing Guidelines
- Creating different departments to address compliance issues
  - what departments should you have?
  - what are the duties and responsibilities of each department?
- Having a centralized system for reporting complaints
- Tracking problem areas and doing a risk assessment
  - creating mitigation plans to deal with potential problems

#### 2:00 Initial Steps for Dealing with Complaints and Violations

*Lisa C. Dykstra*

Partner, Morgan, Lewis & Bockius LLP (Philadelphia, PA)

*Paul A. Weismann*

Staff Vice President, Schering-Plough Corporation  
(Kenilworth, NJ)

- Identifying triggering events
  - hot line calls
  - findings in routine monitoring and other information-gathering exercises
  - findings and discrepancies in formal and mandated audits
  - government inquiries
- Defining a referable issue
  - determining whether an issue or finding is referable
- Notifying the proper people
- Making the decision to investigate, not investigate, or wait
- Considerations for publicly traded companies

#### 2:45 Afternoon Refreshment Break

#### 3:00 Structuring the Investigation Process

*Katherine A. Lauer*

Partner, Latham & Watkins LLP (San Diego, CA)

*Nicholas C. Theodorou*

Partner, Foley Hoag LLP (Boston, MA)

- Determining who will conduct the investigation
  - preventing multiple people from multiple departments from working on the same investigation
- Assessing whom to interview
- Dealing with senior management and the BOD
- Being consistent with your investigations
- Ensuring that your investigation process is comprehensive
- Reporting your findings
  - who should you report your findings to?
  - will the results of the investigation be presented verbally or in writing?

#### 4:00 Interacting with Employees

- Interviewing employees and providing them with notices
  - corporate Miranda warnings
- Determining whether to treat employees equally

#### 4:30 Dealing with Whistleblowers in the Course of an Investigation

*Carrie Valiant*

Member of the Firm, Epstein Becker & Green, P.C.  
(Washington, DC)

- Determining what you do with whistleblowers in the course of the investigation
  - do you know who the whistleblower is?
  - when should you try to find out if you don't know?
- How to best position yourself to defend possible civil employment actions
- Assessing a company's obligations to the employee when the government ultimately chooses not to join the whistleblower suit

#### 5:15 Workshop Concludes

**Tuesday, January 23, 2007**

#### 7:30 Registration & Continental Breakfast

#### 8:30 Co-Chairs' Opening Remarks – The Case for a Global View of Government Investigations

*Brien T. O'Connor*

Partner, Ropes & Gray LLP (Boston, MA)

*Carlton E. Wessel*

Senior Corporate Counsel, Pfizer, Inc. (New York)

#### 8:45 Indemnifying Employees: Where the Government Stands & Where the Corporation Should Stand

*Steven M. Bauer*

Partner, Latham & Watkins LLP (San Francisco, CA)

*Paul W. Butler*

Partner, Akin Gump Strauss Hauer & Feld LLP  
(Washington, DC)

*Lisa C. Dykstra*

Partner, Morgan, Lewis & Bockius LLP (Philadelphia, PA)

- Examining the recent KPMG decision
- Including indemnification language in your corporate by-laws
  - determining when employees should be indemnified by the corporation

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- controlling costs associated with indemnification
- when – if ever – should the indemnification be discontinued?
  - factors to consider in deciding when to terminate indemnification
- Maintaining control of a case through indemnification
- Understanding the benefits and disadvantages of entering into joint defense agreements (JDAs)
  - compelling employee cooperation
  - structuring JDAs to protect the company
  - recognizing potential consequences of JDAs

## PREPARING FOR THE GOVERNMENT'S FORAY INTO FCPA INVESTIGATIONS

### 9:45 FCPA and International White Collar Crime Basics that Every Pharma Company Needs to Know

*Michael Kendall*

Partner, McDermott Will & Emery LLP (Boston, MA)

*Mark Lurie*

Vice President, Chief Ethics & Compliance Officer  
Eisai Corporation of North America (Teaneck, NJ)

- Identifying what companies and individuals fall within the jurisdiction of the FCPA
- Avoiding actions that trigger FCPA investigations
  - bribery
  - inadequate record keeping
  - lack of adequate controls
- Recognizing which federal statutes are enforced abroad
  - ITAR
  - wire and mail fraud
  - conspiracy
- International cooperation and Mutual Legal Assistance Treaties (MLATs)

### 10:45 Morning Coffee Break ☕

### 11:00 Trends in FCPA and Foreign Government Investigations

*Richard N. Dean*

Partner, Baker & McKenzie LLP (Washington, DC)

*Stephen J. Immelt*

Partner, Hogan & Hartson LLP (Baltimore, MD)

*Michael S. Kim*

Partner, Kobre & Kim LLP (New York)

- Examining recent FCPA investigations and prosecutions
  - noteworthy investigations
  - significant prosecuted cases and court decisions
  - exploring trends in FCPA enforcement
- Dealing with foreign government investigations
  - identifying key investigations, prosecutions and trends
    - Europe
    - Asia
    - Latin America
    - Middle East
- Best practices for managing a foreign government investigation

### 12:00 Implementing Anti-Bribery Compliance Programs: Keys to Meeting New FCPA Compliance Standards

*Gary Giampetruzzi*

Deputy Compliance Officer, International Investigations and Programs, Pfizer Inc. (New York)

- Protecting the local and parent company against FCPA violations

- what is the type of compliance program the U.S. government wants to see?
- identifying primary risks areas in foreign pharma operations
- going beyond policies and implementing the necessary controls
- undertaking international training programs in an efficient manner
- Reacting when needed -- conducting an internal FCPA investigation
  - what is different about them?
  - where do they begin and where do they end?
  - employee interviews, forensic reviews, and legal considerations

### 12:45 Networking Luncheon



### 2:00 Ensuring FCPA Compliance for Foreign Operations

*R. Christopher Cook*

Partner, Jones Day (Washington, DC)

*Marc W. Farley*

Executive Director, Worldwide Office of Health Care Compliance, Johnson & Johnson (New Brunswick, NJ)

*Michael E. Horowitz*

Partner, Cadwalader, Wickersham & Taft LLP (Washington, DC)

- Working effectively with foreign subsidiaries
  - harmonizing U.S. and local compliance laws and standards
  - overcoming cultural issues
- Conveying the importance of U.S. and foreign anti-corruption compliance obligations
- Controlling day-to-day marketing practices
- Working with state-owned enterprises and government customers
- Ensuring compliance of distributors and joint venture partners
  - evaluating your partner's past compliance history
  - assessing your distributors' FCPA risk profile
- Ensuring compliance in merger situations
  - avoiding antitrust pitfalls
  - examining recent cases

### 3:00 Afternoon Refreshment Break

### 3:15 Aftermath of an Enforcement Action: Appointing & Working with Special Compliance Monitors

*Michael L. Burton*

Member, Arent Fox PLLC (Washington, DC)

- Examining the implications of the increased prevalence of outside monitors
- Assessing the role of an outside monitor – compliance guardian or company-financed probation officer?
  - determining whether the mandate of an outside monitor gives them carte blanche
- Selecting and managing the monitor
- Understanding the effect of the monitoring relationship on privilege
- Exploring the ethical implications of the monitoring relationship

### 4:15 Conference Adjourns to Day Two

 Wednesday, January 24, 2007

### 7:30 Registration & Continental Breakfast ☕

### 8:30 Co-Chairs' Opening Remarks



**8:45 Determining When – If Ever – the Attorney/Client Privilege Should Be Waived**

*Thomas M. Gallagher*

Partner, Pepper Hamilton LLP (Philadelphia, PA)

*David H. Resnicoff*

Associate General Counsel & Vice President, Ethics and Compliance, Baxter Healthcare Corporation (Deerfield, IL)

*Zaldwaynaka (Z) Scott*

Partner, Mayer, Brown, Rowe & Maw LLP (Chicago, IL)

- What is protected by the privilege?
- What is protected by the work product doctrine?
- Preserving privilege in an internal investigation
  - creating helpful documents without waiving privilege
- Responding to a government demand for waiver
  - determining whether there is room to negotiate
  - assessing whether selective or limited waiver is an option
  - satisfying the government without waiving privilege
- Defending yourself when the government claims that privilege has already been waived
- Parallel proceedings – reserving privilege in the civil and criminal context
- Examining how a privilege waiver could help or hurt your company

**10:00 The Key to a Successful Investigation: An Integrated Records Management and Preservation Notice Program**

*Charlene Allyson Brownlee*

Senior Counsel, Fulbright & Jaworski L.L.P. (Austin, TX)

- Understanding the pharmaceutical industry's unique record retention and document management issues
- Developing and implementing effective document retention management policies
- How to manage the conflict between Sarbanes Oxley whistleblowing requirements and EU data protection laws

**11:00 Morning Coffee Break ☕**

**11:15 Assessing Your Options Once a Government Investigation is Initiated – It's Not Necessarily Time to Throw in the Towel!**

*Arthur E. Brown*

Partner, Kaye Scholer LLP (New York)

*Katherine A. Lauer*

Partner, Latham & Watkins LLP (San Diego, CA)

*Gregory J. Wallance*

Partner, Kaye Scholer LLP (New York)

- Attacking the government's criminal liability and fine theories
  - employing substantive defenses in negotiations with prosecutors
    - technical arguments
    - lack of criminal intent
    - advice of counsel
  - challenging the DOJ's "loss theory" under *U.S. v. Booker*
- Tackling the government's civil liability and damages theories
  - substantive defenses
    - technical arguments
    - lack of "knowing false claims"
    - compliance with underlying statutory/regulatory scheme not a prerequisite to payment
  - challenging DOJ's civil damages theories under the False Claims Act
- Using regulatory ambiguity as a defense to claims of civil or criminal false claims under *U.S. v. Whiteside*

**12:30 Networking Luncheon**



**1:45 Bulletproofing Your Sales and Marketing Practices from Government Scrutiny**

*Ralph F. Hall*

Counsel, Baker & Daniels LLP (Indianapolis, IN)

Visiting Associate Professor, University of Minnesota Law School

*Christopher Myers*

Partner, Holland & Knight LLP (McLean, VA)

This panel will discuss the current leading-edge thinking and practices on reining in your sales force – the most common source of conduct that leads to government investigations. Points of discussion will include:

- Identifying problems arising from a field-based team
- Monitoring these departments, particularly in light of their high turnover rates
- Changing the way your sales force thinks about selling products
  - creating commission incentives for ethical behavior

**2:45 Afternoon Refreshment Break**

**3:00 Internal Investigations: Controlling Costs & Directing the Investigation**

*B. Scott McBride*

Partner, Baker & Hostetler LLP (Houston, TX)

*Nicholas C. Theodorou*

Partner, Foley Hoag LLP (Boston, MA)

*Paul A. Weismann*

Staff Vice President, Schering-Plough Corporation (Kenilworth, NJ)

- Striking a balance between the legal and compliance departments
- Determining when to call in outside counsel
  - using outside counsel as an extension of your in-house legal department
  - defining the role of the corporate counsel
- Addressing the legitimate concerns of employees and management

**3:45 Weighing the Pros and Cons of Voluntary Disclosures**

*Alison M. Duncan*

Partner, Porter Wright Morris & Arthur LLP (Washington, DC)

*Kathleen McDermott*

Partner, Blank Rome LLP (Washington, DC)

*Carrie Valiant*

Member of the Firm, Epstein Becker & Green, P.C. (Washington, DC)

- Determining when you need to disclose a violation to the government
  - when did the incident occur?
  - what employees were involved?
  - what type of violation is it?
  - is there a high risk of prosecution?
  - is there widespread knowledge of the incident?
- Ascertaining who to make the disclosure to
- What to expect in the voluntary disclosure process
- Evaluating the advantages and disadvantages of voluntary disclosure
- Working with the government while still maintaining some protection
  - cooperating without confessing

**4:30 Conference Concludes**

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January 22, 2007 from  
1:15 p.m. – 5:15 p.m.

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