

IDENTIFYING AND RESPONDING TO POTENTIAL VIOLATIONS

David Anderson

*Healthcare Compliance Office, Internal Investigator
Genentech, Inc.*

Dan Dovdavyan

*Senior Corporate Counsel, US Litigation and Investigations
Sanofi-Aventis*

Elizabeth A. Lewis

*Vice President, Deputy General Counsel
Millennium Pharmaceuticals, the Takeda Oncology Company*

Wendy C. Goldstein (Moderator)

*Shareholder
Epstein Becker & Green, P.C.*

OCTOBER 2008

DISCLAIMER

The Statements Made By the Panelists during this Session Represent His/Her Individual Views and Should Not Be Construed to Represent those of his/her organization.

OVERVIEW

1

IDENTIFYING POTENTIAL VIOLATIONS

2

RESPONDING TO POTENTIAL VIOLATIONS

3

DETERMINING CORRECTIVE ACTION



Audience Polling Question

In your opinion, what is the largest source of compliance reports that require an internal investigation?

1. Compliance hotline
2. Walk-ins / direct reports
3. Monitoring & auditing
4. External touches



Audience Polling Question

What do you believe is the biggest challenge facing Compliance departments for maintaining open lines of communication?

1. Overcoming employee resistance to report
2. Developing new ways to advertise the Compliance hotline
3. Convincing employees that the hotline is anonymous
4. Convincing employees that the company enforces a non-retaliation policy

1

IDENTIFYING POTENTIAL VIOLATIONS

DISCUSSION



Audience Polling Question

What do you believe is the biggest challenge facing Compliance departments when conducting an internal investigation?

1. Buy-in to the process from Management / Brand
2. Coordination between Compliance, Legal, HR, Business
3. Training employees to be effective investigators
4. Analyzing the legal implications to decide whether outside reporting is required



Audience Polling Question

True or False:

Investigations of senior management should be handled differently?

1. True
2. False



Audience Polling Question

Fill in the Blank:

Anonymous reports are _____ difficult to investigate than those reports in which the caller identifies him/herself.

1. More
2. Less
3. Equally



Audience Polling Question

Yes or No:

A different protocol should be used for an internal investigation that is triggered by an “outside touch” than one that is triggered by an inside report.

1. Yes
2. No

DISCUSSION



Audience Polling Question

What do you believe is the biggest challenge facing Compliance departments when determining corrective action?

1. Ensuring consistency
2. Exercising discretion
3. Managing the interests of various parties
4. Deciding on appropriate corrective action for senior management



Audience Polling Question

What department should be responsible for ensuring that consistent corrective action is determined?

1. Compliance department
2. Legal department
3. Human Resources department
4. Business
5. Other

DISCUSSION

IDENTIFYING AND RESPONDING TO POTENTIAL VIOLATIONS

David Anderson

*Healthcare Compliance Office, Internal Investigator
Genentech, Inc.*

Dan Dovdavyan

*Senior Corporate Counsel, US Litigation and Investigations
Sanofi-Aventis*

Elizabeth A. Lewis

*Vice President, Deputy General Counsel
Millennium Pharmaceuticals, the Takeda Oncology Company*

Wendy C. Goldstein (Moderator)

*Shareholder
Epstein Becker & Green, P.C.*

OCTOBER 2008