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Relationships That Drive Results

Health Care and Life Sciences

After The Implementation - Next Steps For Building An Effective Compliance Program

Speakers:

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Presentation Overview

1. Introduction to Compliance Environment
2. Risk Assessment
3. Auditing and Monitoring
4. Conducting Internal Investigations
5. Questions

Introduction To The Current Compliance Environment

- Increased Enforcement Activity
  - U.S. Department of Justice (DOJ)
  - Securities and Exchange Commission (SEC)
  - Federal Trade Commission (FTC)
  - Office of Inspector General of the Centers for Medicare and Medicaid Services (OIG)
  - Food and Drug Administration (FDA)

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Huge Corporate Costs For Compliance Failures

- Examples:
  - Hoffman-La Roche paid a $500 million dollar fine in the vitamins antitrust investigation
  - Pfizer recently announced a $2.3 billion dollar settlement in the Bextra off-label marketing probe
  - Zimmer, DePuy Orthopaedics, Biomet, and Smith & Nephew paid $311 million in total fines and were required to implement significant compliance initiatives in orthopedic joint replacement industry investigation

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Example: DOJ Criminal Statistics Antitrust Division

	2001	2002	2003	2004	2005	2006	2007	2008
Cases	44	33	41	42	32	33	40	54
Persons Fined	20	19	16	15	22	17	25	23
Total Fined	$2.02 M	$8.89 M	$470,000	$644,000	$4.48 M	$3.65 M	$15.11 M	$1.49 M
Avg. Fine	$100,950	$457,105	$29,375	$42,933	$203,773	$214,706	$604,400	$64,782
Persons Jailed	11	19	15	20	18	19	34	19
Avg. Months	14.55	18.42	20.76	12.22	24.36	9.44	30.78	25.14
Corporations Fined	14	17	17	13	18	18	12	12
Total Fined	$270.8 M	$93.8 M	$63.8 M	$140.6 M	$595.9 M	$469.8 M	$615.7 M	$695.0 M
Avg. Fine	$19.3 M	$5.5 M	$3.75 M	$10.8 M	$33.1 M	$ 26.1 M	$51.3 M	$57.9 M

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Personal Liability For Managers And Officers

- Two Stryker Biotech sales representatives pleaded guilty to allegations of off-label promotion of a Stryker Biotech product.
- A former Bristol-Myers Squibb Co. senior executive pleaded guilty to a charge of making false statements to the federal government with respect to a patent deal involving generic versions of Plavix.

New AdvaMed Code of Ethics

- Revised Code of Ethics effective June 1, 2009 - http://www.advamed.org/MemberPortal/About/code/
- OIG Compliance Guidance for Pharmaceutical Manufacturers[5] - http://oig.hhs.gov/authorities/docs/03/050503FRCPGPharmac.pdf
- Many companies have implemented AdvaMed Code of Ethics revisions and trained on the Code
- Code and OIG Compliance Guidance is a starting point for a global compliance program

Footnote 5 – "In addition, the compliance program elements and potential risk areas addressed in this compliance program guidance may also have application to manufacturers of other products that may be reimbursed by federal health care programs, such as medical devices and infant nutritional products."

Minimum Requirements To Build And Maintain An Effective Compliance Program

- Clearly established written policies
- Executive oversight
- Careful delegation of responsibility
- Effective training and communication
- Auditing and monitoring
- Consistent enforcement
- Prompt response to violations

Three Drivers For Internal Investigations

1. Conduct Discovered Internally
2. Government Announced or Self-Identified Focus Areas (i.e., OIG Work Plan)
3. Governmental Investigation Commenced or Announced

What Is An "Internal Investigation"?

"Internal"

- Conducted within the organization
- Often conducted with assistance of outside counsel, investigators, consultants and auditors

"Investigation"

- What are the relevant statutes, rules, regulations, etc.?
- What are the facts?
- How do you find them?
  - Interviews
  - Document gathering

Why Conduct An Internal Investigation?

- **Pro-active:** before involvement of government or existence of litigation

  For example:

  - Information obtained by compliance officer or submitted to compliance hotline
  - Information uncovered during internal or external auditing or monitoring efforts
  - Focus on a regulatory risk area: i.e., assist in determining whether sales force tactics are consistent with regulatory requirements
  - OIG Work Plan project announcement or other public statement by regulatory body

Why Conduct An Internal Investigation?

- **Reactive:** In response to governmental involvement or threatened or pending litigation

  For example:

  – FBI raid or grand jury subpoena

  – False Claims Act case filed by government or by *qui tam* relator

Who Conducts The Investigation?

- Privilege Issues
  - Who conducts the investigation and is present for interviews?
  - Who communicates with lawyers?
- In-House Counsel versus Outside Counsel
- Corporate Miranda Disclaimer

Timeline For Investigation

1. Obtain authorization for the internal investigation
2. Document hold (including electronic information)
3. Create interview outlines and determine parties to be interviewed
4. Conduct interviews and review provided information
5. Determine whether to create a summary report (depending on circumstances)
6. Determine what to do with results of the investigation
7. Update or improve compliance plan to address any problems identified during investigation

Results Of Internal Investigations

- The outcome of internal investigations and all auditing and monitoring efforts should be used to improve corporate compliance programs
  - *U.S. v. Stolt-Nielsen* (E.D. Penn 2007)
    - DOJ's only attempt to prove breach of immunity agreement
    - Modification of compliance program along with dissemination, documentation, and training provided evidence of "prompt and effective action"

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What To Do With The Results Of An Internal Investigation

- Determining whether to prepare a written report of the internal investigation
  - What is the context?
  - How will the results be used?
- Sharing the results of the internal investigation with the government – key considerations:
  - Oral or written disclosure?
  - How would the results be used by the government or other third-parties?
  - How to manage privilege issues

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Considerations in Making a Voluntary Disclosure

- Depends on circumstances:
  - Does a statute or regulation require disclosure?
- Possible increased exposure to litigation by private litigants
  - Class actions
  - False Claims Act *Qui Tam* suits
- Adversary's use of attorney-client communications and work product as "road map" if you have waived by turning over privileged information to the government

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Benefits Of Voluntary Disclosure

- Reduction in potential criminal fine under Federal Sentencing Guidelines (§ 8C2.5(f) and (g))
- Potential leniency or amnesty
  - Antitrust amnesty program
- Reduced likelihood of substantial civil monetary and non-monetary penalties
  - False Claims Act
  - Antitrust Criminal Penalty Enhancement and Reform Act (ACPERA)
- Opportunity to lay out the facts

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Health And Human Services Self-Disclosure Protocol

- Purpose
  - To disclose fraud affecting Medicare, Medicaid and other federal health care programs
  - Addresses only fraud type conduct
- Requirements include:
  - Initial written submission with basic facts
  - An internal investigation and financial assessment
  - Verification of disclosed information by OIG
  - Payments
  - All submissions must be certified as truthful

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Voluntary Disclosure Protocol Open Letter – April 16, 2008

- Required
  - Accurate and complete disclosures
  - Timely responses for additional information
  - Accurate audits
- Submission indicates effective compliance measures that rule out need for CIAs or Certifications of Compliance in most cases

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Questions?

Please remember to fill out the survey

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Biographies of Speakers

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Amy Manning

Amy Manning focuses much of her practice on antitrust matters and currently co-leads the Life Sciences Industry Group. Ms. Manning has designed and implemented national and international compliance programs. She has spoken on Life Sciences topics, antitrust, compliance, privilege and e-discovery issues. She is a published author on antitrust matters. Ms. Manning has handled criminal and civil antitrust matters for international and national companies, and individuals in federal and state courts and arbitration tribunals in the United States. Her cases have involved international cartels, price fixing, market allocation, bid rigging, tying arrangements, monopolization, attempted monopolization, monopoly leveraging, Robinson-Patman Act claims, and antitrust conspiracies. Ms. Manning's practice also concentrates on complex commercial litigation, including class actions, commodities litigation, multidistrict litigation, health care litigation, civil RICO litigation, and intellectual property disputes. Her responsibilities have included arbitrations, trials, first chair trial experience and appeals.

Ms. Manning was featured in the May 2009 Global Competition Review issue on Women In Antitrust, and The Next Generation of Leaders in the Chicago Lawyer June 2009 issue. She was the 2007-2008 Chairman of the Chicago Bar Association's Antitrust Law Committee. She was named to Lawdragon's 500 New Stars, New Worlds list, and Lawdragon's 3000 Leading Lawyers in America. She received the National Association of Women Business Owners 2006 Corporate Woman of Achievement Award.

Jean Sands

Jean Sands is a Manager out of the Chicago office of PricewaterhouseCoopers with the Pharmaceutical and Life Sciences Advisory Services practice. Her experience capitalizes on almost ten years of pharmaceutical and medical device industry knowledge coupled with an educational background in business and communications. Her healthcare background includes experience with corporate ethics and compliance, marketing (analytical and contracting) and sales. Prior to joining PricewaterhouseCoopers, she worked for Hospira and Abbott Laboratories' Hospital Products Division (HPD).

Jean Sands' compliance experience includes implementing global compliance programs with corporate policies, procedures and training programs for interactions with healthcare professionals, the Foreign Corrupt Practices Act (FCPA), anti-bribery / anti-corruption laws and anti-kickback laws. In addition, her experience includes streamlining complex compliance policies, developing innovative ethics and compliance training programs and working with federal and state marketing disclosure requirements. Because of her commercial experience, she has a particular compliance focus on the Commercial Organization and the Global Medical Affairs Organization, specializing in the key risk areas of Sales and Marketing, Medical Education and the Clinical Grant-in-Aid process.