COMPLIANCE 101

Pharmaceutical Regulatory and Compliance Congress and Best Practices Forum

Pre-Con I

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PURDUE

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EPSTEIN BECKER GREEN

SESSION OVERVIEW

1. Current Environment
2. Program Requirements
   - Federal Sentencing Guidelines
   - OIG Compliance Guidance
   - Corporate Integrity Agreements
3. Practical Tips to Building a Program
   - Key Questions
   - Tips
4. Break
5. Test your Knowledge

“CHANGE”

“The dogmas of the quiet past are inadequate to the stormy present. The occasion is piled high with difficulty, and we must rise with the occasion. As our case is new, so we must think anew and act anew.”

- Abraham Lincoln

PART 1: CURRENT ENVIRONMENT

HIGH SCRUTINY AND ENFORCEMENT

- Hostile environment for the pharmaceutical industry
- 49 pharmaceutical CIA's since 1999
- Close to $10B in settlements
- Prosecutors and plaintiffs focusing on kickbacks and illegal payments, sampling, off-label promotion, integrity of pricing data
- False Claims Act, Anti-Kickback Statute, Food Drug & Cosmetic Act
- OIG Pharma Compliance Guidance
- 2010 OIG Work Plan
- U.S. Sentencing Guidelines

Compliance programs are important to the financial health of a pharmaceutical company

SELECT RECENT SETTLEMENTS

COMPANY	$ PENALTY	YEAR
Pfizer	$2.3 Billion	2009
Eli Lilly	$1.4 Billion	2009
Cephalon	$425 Million	2008
Purdue	$634.5 Million	2007
Eli Lilly	$36 Million	2005
GSK	$150 Million	2005
Serono	$704 Million	2005
Pfizer	$427 Million	2004
Bayer	$257 Million	2003
GSK	$88 Million	2003
TAP	$875 Million	2001

HIGHEST OVERALL RISK AREAS

- Sales and Marketing
- Policies and training materials for field and home office personnel
- Adverse Event reporting
- Medical Education programs / Grant Activities
- Prescription Drug Marketing Act Compliance (Sampling)
- Government Price Reporting
- Promotional Material Reviews
- Brand Plans
- PhRMA Code
- DHHS Office of Inspector General Compliance Guidance

HIGHEST OVERALL RISK AREAS

- Manufacturing
  - Quality
  - GMP
- DEA and Diversion
- Environmental, Safety and Health
- Integrity of Clinical Research and Trials
- Human Subject Protection
- Patient Privacy

PART 2: PROGRAM REQUIREMENTS

UNITED STATES SENTENCING GUIDELINES

- An effective compliance and ethics program is a mitigating factor that may reduce an organization's fine under the United States Federal Sentencing Guidelines ("USFG")
  - Created in 1984 under the Sentencing Reform Act
  - Effective in 1991
- The Guidelines define a "compliance and ethics program" as "a program designed to prevent and detect criminal conduct."
- The Guidelines previously had set forth 7 minimum criteria of an effective compliance and ethics program only in its commentary.
- When the Guidelines were revised, effective 11/1/04, these criteria were "elevated" into a separate, enumerated guideline that:
  - Elaborated on the 7 minimum criteria including written standards; compliance infrastructure; training; background checks; hot-line; auditing and monitoring; corrective action
  - Imposed significantly greater responsibilities on the organization's governing authority and executive leadership

DHHS 2003 OIG GUIDANCE FOR PHARMACEUTICAL MANUFACTURERS

- OIG has no specific statutory authority to issue industry guidance. OIG has issued compliance guidance for all major sectors of healthcare
- OIG issues voluntary compliance program guidances to encourage the industry to develop effective internal controls that detect, prevent and reduce the potential for fraud and abuse.
- Controls are intended to promote adherence to applicable laws relevant to the Federal health care programs.
- Non-binding direction to the industry for procedural and structural guidance.
- Identifies the risk areas that the OIG believes to be ripe for misconduct.

DHHS 2003 OIG GUIDANCE FOR PHARMACEUTICAL MANUFACTURERS

- OIG issued request for input in 2001
- Ad Hoc Coalition responded with comments in August 2001
- OIG issued draft guidance in October 2002
- Ad Hoc Coalition responded in December 2002
- Final guidance issued April 2003

DHHS 2003 OIG GUIDANCE FOR PHARMACEUTICAL MANUFACTURERS

- Stated Purpose of 2003 OIG Final Compliance Program Guidance for Pharmaceutical Manufacturers:

  (http://www.oig.hhs.gov/authorities/docs/03/050503FRCPGPharmac.pdf)

  - "Guidance is intended to assist companies…in evaluating and …refining existing compliance programs."
  - "This guide is not a compliance program. Rather, it is a set of guidelines that pharmaceutical manufacturers should consider when developing and implementing a compliance program."
  - "For those manufacturers with an existing compliance program, this guidance may serve as a benchmark or comparison against which to measure ongoing efforts."

DHHS 2003 OIG GUIDANCE FOR PHARMACEUTICAL MANUFACTURERS

- 7 Elements of the OIG Guidance Program:
  1. Put it in Writing: develop and distribute written standards of conduct and policies, procedures and protocols.
     - Code of Conduct with general principles regarding compliance and ethics developed with management involvement.
     - Written standards to guide an employee in their conduct of duties in all compliance risk areas:
       - Use of prescribers as consultants; grants for research/education; gifts; samples; customer grants, discounts, free goods, product or formulary support services; data integrity, sales agent compensation; billing for samples
     - Developed under the direction of the compliance officer (CO), committee and managers.
     - Adherence to policies and procedures and training requirements should be a factor in the annual employee evaluation.

DHHS 2003 OIG GUIDANCE FOR PHARMACEUTICAL MANUFACTURERS

- 7 Elements of the OIG Guidance Program:
  2. Put Someone in Charge: designate a compliance officer and other bodies, such as a corporate compliance committee.
     - CO should be high-level with direct access to Board, CEO, and senior management. CO serves as the focal point for compliance activities. Must have sufficient funding, resources, and staff.
     - Compliance Committee should be a cross-functional task force with high integrity. Serves as an extension of compliance officer for oversight.

DHHS 2003 OIG GUIDANCE FOR PHARMACEUTICAL MANUFACTURERS

- 7 Elements of the OIG Guidance Program:
  3. Develop a Training Program and Train Employees: develop and implement an effective employee education and training program.
     - Training should cover employees and contractors where appropriate.
     - New employees should receive training soon after they start.
     - All employees should be required to complete certain training hours.
     - Training should cover compliance program, policies, and applicable laws, as well as issues identified in Guidance and from audits or monitoring.
     - Participation in training should be a condition of employment and non-compliance should result in discipline.
     - CO should “ensure that independent contractors and agents … are aware of company’s compliance program …”

DHHS 2003 OIG GUIDANCE FOR PHARMACEUTICAL MANUFACTURERS

- 7 Elements of the OIG Guidance Program:
  4. Create a Hotline: create and maintain an effective line of communication between the compliance officer and all employees. Employees must be able to ask questions and report problems.
     - Open door policies should be considered to foster dialogue between supervisors and employees.
     - Confidentiality and non-retaliation policies should be adopted and distributed.
     - Open lines between compliance officer and employees are equally important.
     - Rewards for employees for use of reporting systems should be considered.
     - Use of hotlines, e-mail box, newsletters, exit interviews, surveys are encouraged.
     - CO should maintain detailed logs of reports and summaries should be shown to CEO and Board.

DHHS OIG GUIDANCE FOR PHARMACEUTICAL MANUFACTURERS

- 7 Elements of the OIG Guidance Program:
  5. Monitor and Audit: monitor compliance and identify problem areas through audits and/or other risk evaluation techniques.
     - Should cover all departments that have involvement with risk areas identified in guidance and in fraud alerts.
     - Reviews may include processes or actual practices (e.g., manager approvals, certifications, home office reviews, employee surveys and audits).

DHHS OIG GUIDANCE FOR PHARMACEUTICAL MANUFACTURERS

- 7 Elements of the OIG Guidance Program:
  6. Discipline Employees: develop policies and procedures to enforce disciplinary actions against violators and to ensure that individuals who have been excluded from participation in Federal health care programs are not employed or retained. Reasonable indications of misconduct should be investigated and root causes should be identified.
     - Clear and specific disciplinary policies should be established and enforced.
     - Intentional and material infractions should result in significant sanctions.
     - Discipline may also be appropriate for negligent or reckless failure to detect a violation.
     - CO should “ensure that the List of Excluded Individuals/Entities has been checked” with respect to all independent contractors, and the company should “carefully consider” whether to do business with excluded individuals/entities.

DHHS OIG GUIDANCE FOR PHARMACEUTICAL MANUFACTURERS

- 7 Elements of the OIG Guidance Program:
  7. Find It and Fix It: develop policies and procedures for the investigation of noncompliance or misconduct, including self-reporting to the OIG if required.
     - Where credible evidence of violations of law are discovered, it should be reported to authorities within 60 days.
     - Prompt voluntary reporting will demonstrate good faith and be a mitigating factor if there is enforcement

CORPORATE INTEGRITY AGREEMENTS

Generally -

- A CIA is an agreement with the Office of Inspector General (OIG) of DHHS that is entered into in exchange for the OIG not exercising its permissive exclusion authority
- CIA is included in almost all civil settlements and provides a "probation" period of generally 5 – 7 years
- A CIA includes stipulated penalties for breach (e.g., $2,500 per day) and may include exclusion for non-compliance
- There is a focus on obligations relating to "Covered Persons" ("CPs")
- CIAs require significant reporting obligations
  - Typically 150 days after execution an implementation report is required
  - Annual reports thereafter
  - CO certifies compliance

CORPORATE INTEGRITY AGREEMENTS

- Other typical CIA provisions -
  - Maintain Compliance Officer to:
    - Oversee implementation of policies, procedures and practices
    - Monitor day-to-day compliance activities
    - Report regularly to the BoD Committee
  - Maintain Compliance Committee
  - Distribute Code of Conduct, policies and procedures within defined time periods to CPs and to new hires who are CPs
  - Make compliance an element of performance plans for CPs
  - Provide certain number of hours of general training on health care laws and specific training on certain policies and procedures within certain time periods
    - Repeat training annually – can be computer based

CORPORATE INTEGRITY AGREEMENT

- Other typical CIA provisions -
  - Retain Independent Review Organization (IRO) to perform:
    - Systems Review
    - Transaction Reviews
  - Screen against List of Excluded Parties by Government Accountability Office ("GAO") and Department of Health and Human Services ("DHHS") within certain time frames:
    - All existing and new employees
    - All contractors
  - Maintain and publicize confidential hot-line
  - Review and conduct investigations where sufficient information is provided
  - Notify OIG in writing within a certain period if government investigation or legal proceeding alleging a crime or fraud
  - Report to OIG within a certain time period any matter that a reasonable person would consider a probable violation or potential violation of health care laws

PART 3: PRACTICAL TIPS TO BUILDING A PROGRAM

KEY QUESTIONS

- What is the scope of the business?
- What is the scope of compliance function?
- What areas of risk should the compliance program address?
- Which employees or groups play a material role in contributing to or controlling the exposure to risk?
- Do we have systems that can identify potential problems?
- What financial resources are available to help implement the program?
- What human resources are available to help implement the program?

KEY QUESTIONS

- What elements should be included in an effective compliance program?
- How will compliance requirements be disseminated to employees?
- How will we measure the success of the program?
- How will we secure compliance performance information?
- How will we report compliance information upward?
- What will we do when we detect potential violations?
- What are our reporting relationships?
- How do we interact with other departments?

COMPLIANCE OFFICER ROLE

- DO consider the job description and tailor the role of the CO to meet organizational needs
  - Identify focus areas
  - Define expectations
  - Understand organization
  - Be up front regarding resources
  - Define compliance organization and identify sources of support

ROME WASN'T BUILT IN A DAY

- Rome wasn't built in a day – your compliance program shouldn't be either
  - If the foundation is flawed, cracks will eventually form
  - Do a survey to start, it's invaluable for design and measuring improvement
  - Test plans with senior managers, middle managers and staff
    - It's both a Top Down and Bottom Up process
    - Build it into the business process where possible
    - "After the Drexel thing exploded, there was a push to codify ethics. A big policy book came out. No one read it." (Anonymous Harvard MBA Alumnus)

LOVE YOUR LAWYERS

- Communicate and interact with the lawyers
  - You need to know and understand the legal requirements
  - Your compliance program, while laudable, is still discoverable
    - Attorney-client privilege should be considered for sensitive matters
    - Self-evaluative privilege available in some jurisdictions
    - Work product doctrine

GIVE COMPLIANCE A FAMILIAR FACE

- Build credibility within your organization by staying connected internally:
  - Learn your organization
  - Learn your departments
  - Learn your products
  - Attend sales training meetings
  - Attend product training meetings
  - Ride with representatives
  - Work with the Government pricing program Departments
  - Tour the facilities often, including international sites
- Participate in industry compliance associations

YOU ARE YOUR BROTHER'S KEEPER

- Contract with vendors based upon demonstrated commitment to compliance -- they are your agents
- Conduct thorough due diligence on your vendors' compliance infrastructures
- Do not approve programs with vendors who are non-compliant or lax about corporate compliance
- Update vendor contracts:
  - Ensure compliance with your corporate compliance program requirements
  - Reserve audit rights
- Exercise audit rights

ORGANIZE CLUTTER

- Develop and implement appropriate document retention policies for all business units and departments
- Teach appropriate documentation to employees
  - Electronic mail
  - Business records
- Establish systems to ensure the retention of control documents and program documents
- Centralize records

USE THE NEWS

- Use public documents to identify gaps and update corporate compliance programs and policies:
  - Settlement agreements and Corporate Integrity Agreements (our “case law”)
  - (http://oig.hhs.gov/fraud/cias.html)
  - DHHS OIG Work Plans (http://oig.hhs.gov/publications/docs/workplan/2005/2005%20Work%20Plan.pdf)
  - Enforcement officials public pronouncements
  - Trade press, periodicals,
  - Corporate security filings
  - Medicare Modernization Act
  - (http://www.cms.hhs.gov/mmu/)

IDENTIFY THE “GIMME” AUDIT TOPICS

- Use public documents to identify audit topics
- Use reports prepared for state reporting laws as audit topic:
  - State gift reporting laws such as MN, DC, VT, ME, WV
- Use the risk assessments
  - Provides for focus of limited resources in the right place
  - Good risk assessment is efficient and effective
  - Conduct Interviews and benchmarking

ALIGN THE REWARD SYSTEM WITH COMPLIANCE

- Review compensation structure and determine whether it promotes compliance or non-compliance:
  - Incentives for “doing the right thing” ?
  - Recognition for saying “no” ?
  - Objective standards
  - Subjective standards
- Consider a compensation structure that includes compliance components at all levels

TRAINING TO PREVENT COMPLAINING

- Understand your audience - make it practical and simple
  - Use methods and language that matches the internal customer
    - Safety instructions in English when the work force speaks Spanish makes no sense
  - Truck safety was greatly improved with the banner on a truck: Call 1-800- XXX- XXXX if I am driving badly
- Test training on focus groups
- Keep training simple and interactive
- Focus training on what should be done -- not what could be done
- Quiz, quiz, quiz
- Ask for feedback
- Repeat, repeat, repeat

KEEP THE “SENIORS” PRESENT

- Ensure that senior management consistently demonstrates publicly its commitment to compliance
  - Training and retraining sessions
  - Newsletter articles
  - “Compliance Days”
- Publicize open door of senior management along with hot-line
- Do not ignore the executives and the board
  - Bigger risks are usually approved by executives and Board; e.g., Enron, WorldCom, Anderson
    - Most of this group are untrained in ethical decision-making
    - Most companies overlook this group

BACK TO BASICS

- Compliance is rules oriented - ethics is values based
- Teach corporate morals to employees
- Teach common sense to employees
- Train on how to do the “right” thing versus knowing the policies and procedures
  - Use Company Code of Conduct as a tool
- Discuss how “wrong” in your organization, may be “right” in another organization
- It’s better to teach good judgment than blind adherence
  - “Use your good judgment in all situations. There will be no additional rules.” (Nordstrom, Inc., Employee Handbook)

BRAND NAME COMPLIANCE

- Brand your compliance program
  - Compliance should be sold to the employees with the same style and class as the product line
- Wear a marketing hat and make it fun and effective
- Avoid long memoranda in dry legalese
- Use humor and trinkets if possible: Dilbert; baseball caps, fortune cookies, post-its

BRAND NAME COMPLIANCE

- Personalize the program
  - Do not buy it off the shelf
  - Customize to your company size and structure
  - Make it fit in your culture
  - Tailor to your infrastructure
    - Centralized
    - De-centralized
    - Globalized, in part or in whole

DOCUMENT WISELY

- It’s not a “paper program,” -- but it must be a program on paper
  - If the program, or its elements are not documented, it is almost like it/they didn’t happen
- Be thoughtful on how to track all compliance related activities that are implemented
  - It’s not the gloss, but the content that counts:
    - Military historians contend that you can tell which army is more effective by looking at their uniforms. The best dressed is usually the least effective.

KEYS TO SUCCESS

1. Tone from the Top - Role of Management
   - Senior managers regularly emphasizing message
   - All managers are compliance monitors
     - Compliance is everyone's job… compliance officers just get paid for it.
2. Compliance is a Journey, Not a Destination
   - Good faith to build a culture with values and good judgment
   - Responsive to internal and external developments
3. Making Ethics a Key
   - It's not just the legality, but also the propriety
   - Appearance issues can attract enforcement

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