PRE-CONFERENCE I: COMPLIANCE BASICS

WHAT IS AN 'EFFECTIVE' CORPORATE COMPLIANCE PROGRAM?

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SESSION OVERVIEW

I. Corporate Compliance Program Requirements
   - Federal Sentencing Guidelines
   - OIG Compliance Guidance
   - Corporate Integrity Agreements
   - Defining “Effective”

II. Key Health Care Laws Relevant to Corporate Compliance Programs

III. Representative Settlements

I. CORPORATE COMPLIANCE PROGRAM REQUIREMENTS

I. CORPORATE COMPLIANCE PROGRAMS

- An effective compliance and ethics program is a mitigating factor that may reduce an organization's fine under the United States Federal Sentencing Guidelines
  - Created in 1984 under the Sentencing Reform Act
  - Effective in 1991
  - Most recent updates take effect 11/1/10
- Guidelines define a "compliance and ethics program" as "a program designed to prevent and detect criminal conduct"
- Guidelines originally included 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

I. CORPORATE COMPLIANCE PROGRAMS

- OIG has no specific statutory authority to issue industry guidance, but OIG has issued compliance guidance for all major sectors of healthcare
- OIG historically had issued 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
- Now, Health Reform requires as a condition of enrollment that certain "providers and suppliers" develop and maintain compliance programs with certain "core elements"
  - Regulations from the Secretary pending

I. CORPORATE COMPLIANCE PROGRAMS

- OIG Voluntary Compliance Guidance for Pharmaceutical Manufacturers (Guidance)
  - OIG issued request for input in 2001
  - Ad Hoc Coalition responded with comments in August 2001
  - OIG issued draft Guidance in October 2002
  - Final Guidance issued in May 2003

I. CORPORATE COMPLIANCE PROGRAMS

- Stated purpose of Guidance (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."

I. CORPORATE COMPLIANCE PROGRAMS

- 7 Elements of the Guidance
  1. Implement written policies and procedures
  2. Designate a compliance officer and compliance committee
  3. Conduct effective training and education
  4. Develop effective lines of communication
  5. Conduct internal monitoring and auditing
  6. Enforce standards through well-publicized disciplinary guidelines
  7. Respond promptly to detected problems and undertaking corrective action

I. CORPORATE COMPLIANCE PROGRAMS

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
     - Develop under the direction of the compliance officer (CO), committee and managers
   - Written standards to guide employees in their conduct of duties in all compliance risk areas including --
     - Use of prescribers as consultants
     - Grants for research and education
     - Gifts
     - Samples
     - Customer grants
     - Discounts, free goods, product or formulary support services
     - Data integrity
     - Sales agent compensation
     - Billing for samples

I. CORPORATE COMPLIANCE PROGRAMS

2. Put Someone in Charge
   - Designate a CO and other bodies, such as a corporate compliance committee
   - CO should be a high-level employee who has direct access to Board, CEO and senior management
     - OIG believes that it generally is not advisable for the compliance function to be subordinate to the manufacturer's [GC], or comptroller or similar financial officer
       - Independent and objective legal reviews and financial analysis
       - System of checks and balances
     - Responsible for the implementation and day-to-day compliance activities
     - Sufficient funding, resources and staff
   - CO serves as the focal point for compliance activities
   - Compliance Committee should be a cross-functional task force with high integrity
     - Serves as an extension of CO for oversight
   - Board of Directors oversight (CIAs)

I. CORPORATE COMPLIANCE PROGRAMS

3. Develop a Training Program and Train Employees
   - Develop and implement an effective employee education and training program
   - Training should include employees and contractors, where appropriate
   - New employees should receive training soon after they commence work
   - All employees should be required to complete certain training hours
   - Participation in training should be a condition of employment and non-compliance should result in discipline
   - Training topics should cover
     - General compliance program, policies and applicable laws
     - Specific areas relevant to job functions
     - Issues identified in Guidance
     - Issues from auditing and monitoring activities
   - CO should maintain records of all training

I. CORPORATE COMPLIANCE PROGRAMS

4. Create a Hotline
   - Create and maintain an effective line of communication between the CO and all employees that provides mechanism that allows them to ask questions and report problems
   - Open door policies should be considered to foster dialogue between supervisors and employees
     - Use of hotlines, e-mail box, newsletters, exit interviews, surveys are encouraged
     - Open lines between CO and employees are equally important
   - Confidentiality and non-retaliation policies should be adopted and distributed
   - Rewards for employees for use of reporting systems should be considered
   - CO should maintain detailed logs of reports and CEO and Board should be informed

I. CORPORATE COMPLIANCE PROGRAMS

5. Monitor and Audit
   - Monitor compliance and identify problem areas through audits and/or other risk evaluation techniques
   - Monitoring and auditing activities should cover all departments that have involvement with risk areas identified in the Guidance and in OIG Fraud Alerts
     - Also consider settlement agreements, CIAs, SEC filings, OIG Work Plans, public pronouncements of enforcement officials, trade groups
   - Reviews may include processes or actual practices
     - Manager approvals
     - Certifications
     - Home office reviews
     - Employee surveys
     - Audits

I. CORPORATE COMPLIANCE PROGRAMS

6. Discipline Employees
   - Develop policies and procedures to: (1) enforce disciplinary actions against violators and (2) 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
     - "Each situation must be considered on a case-by-case basis, taking into account all relevant factors, to determine the appropriate response"
   - Clear and specific disciplinary policies should be established and enforced
   - Intentional and material infractions should result in significant sanctions
     - Discipline also may 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
     - Note CMP laws

I. CORPORATE COMPLIANCE PROGRAMS

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
       - OIG, DoJ, FDA, FTC, FBI, MFCU, U.S. Attorney's Office
     - Prompt voluntary reporting will demonstrate good faith and be a mitigating factor if there is enforcement
     - Note - OIG Voluntary Disclosure Protocol, Open Letters, Health Reform

POLLING QUESTION

The “hardest” element to implement as part of an effective corporate compliance program is the following:

1. Written Standards
2. Corporate Compliance Infrastructure
3. Training
4. Open Lines of Communication
5. Auditing and Monitoring
6. Discipline
7. Corrective Action and Self-Reporting
8. All of the Above

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The “easiest” element to implement as part of an effective corporate compliance program is the following:

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I. CORPORATE COMPLIANCE PROGRAMS

- A Corporate Integrity Agreement (CIA) is an agreement with the OIG that is entered into in exchange for the OIG not exercising its "permissive exclusion" authority
- CIAs are included in almost all civil settlements and provide a "probation" period of generally 5 – 7 years
- Generally CIAs include
  - Requirements relating to each of the 7 elements
  - Stipulated penalties for breach (e.g., $2,500 per day) and may include exclusion for non-compliance
  - A focus on obligations relating to "Covered Persons" (CPs)
  - Significant reporting obligations
    - Typically 150 days after execution an implementation report is required
    - Annual reports thereafter
  - CO certification

I. CORPORATE COMPLIANCE PROGRAMS

- 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 DHHS within certain time frames:
    - All existing and new employees
    - All contractors
  - Maintain and publicize confidential hotline
  - 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

I. CORPORATE COMPLIANCE PROGRAMS

- Typical CIA provisions (continued)
  - Maintain CO:
    - Oversee implementation of policies, procedures and practices
    - Monitor daily 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

I. CORPORATE COMPLIANCE PROGRAMS

- OIG does not define “effective” in its guidances despite the repeated use of the word
  - “In order for a compliance program to be effective, it must have the support and commitment of senior management and the company’s governing body”
- Merriam-Webster Dictionary definition of “effective”
  - “Having the power to produce a decided, decisive, or desired effect”
- OIG recent developments relevant to “effectiveness”
  - BoD Involvement
  - Management and employee certifications

I. CORPORATE COMPLIANCE PROGRAMS

- Board Of Directors Involvement
  - Obligations of Board of Directors now include:
    - "[B]e responsible for the review and oversight of matters related to compliance with Federal health care program requirements, FDA requirements, and the obligations of [the] CIA"
    - Meet at least quarterly to review and oversee the Compliance Program, which may require the Board to:
      - Arrange for a review of the effectiveness of the organization's Compliance Program for each reporting period that is provided to the OIG in each annual report
      - Retain a Compliance Expert to create a work plan for the Compliance Program Review, oversee the performance of the Compliance Program Review and prepare a written report about the Compliance Program Review
    - Adopt a resolution for each CIA reporting period that summarizes its review and oversight of the Organization's compliance program
    - See, e.g., Ortho (2010), Pfizer (2009), Eli Lilly (2009)

I. CORPORATE COMPLIANCE PROGRAMS

- Certifications by "Certifying Employees"
  - "Specifically expected to monitor and oversee activities within their areas of authority"
  - Annual certification that the applicable component is compliant with Federal health care program requirements, FDA requirements and CIA obligations
  - Annual certification that, among other things, he/she has reviewed certain enumerated reports and reported potential issues identified to Compliance and/or Legal
- Certifying Employees may include:
  - President, US Business
  - VPs of Commercial Functions (including sales, marketing, brand)
  - Sales Directors (national, area and regional)
  - Senior Brand Leaders (commercial and development)
  - VP of Medical Affairs and direct reports with responsibilities for Medical Affairs or Field Medical Relations
  - Executive Director of Promotional Regulatory Affairs
  - Finance Directors
- See, e.g., AstraZeneca (2010), Pfizer (2009), Eli Lilly (2009)

II. KEY HEALTH CARE LAWS**

** Lucy Rose will address FDCA

II. KEY HEALTH CARE LAWS

- Federal Health Care Program Anti-Kickback Statute (AKS)
  - It is a felony to knowingly and willfully:
    - Offer, pay, solicit or receive
    - Any remuneration (kickbacks, bribes or rebates)
    - Directly or indirectly
    - Overtly or covertly
    - In cash or in kind
    - In return for:
      - Referring an individual to a person for the furnishing or arranging for the furnishing of an item/service; or
      - Purchasing, leasing, ordering or arranging for or recommending purchasing, leasing or ordering any good, facility, service or item
    - For which a Federal health care program may pay

II. KEY HEALTH CARE LAWS

- AKS (continued)
  - Penalties
    - $25,000 for each offense
    - Imprisonment for up to 5 years
    - Exclusion from the Medicare, Medicaid and/or other Federal or State health care programs
    - Civil monetary penalties

II. KEY HEALTH CARE LAWS

- AKS (continued)
  - There are statutory exceptions and regulatory "safe harbors" for certain financial arrangements that fall outside of the AKS that, if strictly complied with, protect against liability. Relevant examples:
    - Discounts
    - Personal services and management contracts
    - Managed care risk sharing arrangements
    - GPO administrative fees
  - Conduct that does not fit within a "safe harbor" is analyzed based on the cumulative "facts and circumstances" to determine whether a violation exists
    - Potential for increased costs to government payors?
    - Potential for "overutilization" of product?
    - Potential for patient harm/interference with clinical decision-making?

II. KEY HEALTH CARE LAWS

- AKS (continued)
  - Numerous other types of anti-kickback provisions including
    - Medicaid anti-kickback provisions
    - State and local government program anti-kickback provisions
    - State all-payor anti-kickback provisions
    - Healthcare practitioner licensure laws
    - Other insurance law anti-kickback provisions

II. KEY HEALTH CARE LAWS

- SSA permits OIG to assess civil monetary penalties (CMP) against "any person or entity that knowingly offers remuneration to influence choice of provider, practitioner or supplier"
  - Certain exceptions exist including, by way of example
    1. Inexpensive gifts or services (retail value ≤ $10 individually, and ≤ $50 in the aggregate annually per patient)
    2. Waivers of cost-sharing amounts based on financial need
    3. Incentives to promote the delivery of certain preventive care services
    4. Any practice permitted under the AKS exceptions or safe harbors

II. KEY HEALTH CARE LAWS

- CMP (continued)
  - Penalties
    - $10,000 - $15,000 fine for each such act depending on the act
    - Up to three times the amount claimed in lieu of damages incurred by the Government
    - Any other penalty prescribed by law (e.g., permissive exclusion)
  - In August 2002, the OIG said it "does not believe" manufacturers are "providers, practitioners, or suppliers" under the CMP law prohibiting beneficiary inducements, unless they "also own or operate, directly or indirectly, pharmacies, pharmacy benefits management companies, or other entities that file claims for payment under the Medicare or Medicaid programs"

II. KEY HEALTH CARE LAWS

- Federal Civil False Claims Act (FCA)
  - Generally, the FCA prohibits:
    - "any person from knowingly presenting (or causing to be presented) a claim for payment or approval to the Federal government that is false or fraudulent"
  - Examples of actions that may form the basis for liability under the FCA:
    - Presenting or causing to be presented a false or fraudulent claim for payment or approval
    - Making or using or causing to be made or used a false record or statement for payment or approval
    - Conspiring to defraud the government by getting a false or fraudulent claim allowed or paid
    - Making or using or causing to be made or used a false record or statement to conceal, avoid or decrease an obligation to pay money or property to the government

II. KEY HEALTH CARE LAWS

- FCA (continued)
  - Penalties
    - Civil penalty of not less than $5,500 and not more than $11,000 for each false claim; and
    - Up to 3 times the amount of actual damages sustained by the Government
  - Violations of other laws may be "bootstrapped" under a False Claims Act
    - Health Reform
  - State False Claims Acts
    - Under the Deficit Reduction Act of 2005, states are entitled to an increase of 10 percentage points in recoveries for actions brought under the State's respective false claims act if the state false claims act is "at least as effective in rewarding and facilitating *qui tam* actions for false or fraudulent claims as those described in the FCA"

II. KEY HEALTH CARE LAWS

- Federal and State Marketing and Disclosure Laws
  - Currently, there are three "types" of marketing or disclosure laws
    1. Laws that require companies to adopt a compliance program and/or marketing code of conduct that affects payments made to healthcare professionals (HCP)
       - California, Massachusetts, Nevada
    2. Laws that limit the payments that may be provided to HCPs
       - California, District of Columbia, Massachusetts, Minnesota, Vermont
    3. Laws that require certain payments provided to HCPs to be reported on an annual basis
       - Federal, District of Columbia, Maine, Massachusetts, Minnesota, Vermont, West Virginia

II. KEY HEALTH CARE LAWS

	Applicable to Drug Companies	Applicable to Device Companies	Compliance Program	Code of Conduct/ Ethics	"Gift" Limits	Annual Report	Annual Certification
Federal	X	X				X	
California	X	X	X		X		X
District of Columbia (2 laws)	X (2 laws)			X	X	X	
Maine	X					X	
Massachusetts	X	X		X	X	X	X
Minnesota	X				X	X	
Nevada	X	X		X			X
Vermont	X	X			X	X	
West Virginia	X					X	

II. KEY HEALTH CARE LAWS

- Federal Sunshine Act
  - Requires "applicable manufacturers" to report annually certain "payments or other transfers of value" provided to a "covered recipient"
    - "Covered recipient"
      - Physicians and teaching hospitals
    - "Applicable manufacturers"
      - Pharmaceutical, biological, medical device and certain affiliated entities

II. KEY HEALTH CARE LAWS

- Federal Sunshine Act (continued)
  - "Payments or other transfers of value"
    - Transfer of anything of value, unless excluded

Consulting fees	**Compensation other than consulting**	**Honoraria**	**Gifts**
Entertainment	**Food**	**Travel (including specific destination)**	**Education**
Research	**Charitable Contributions**	**Royalties and Licenses**	**Ownership or Investment Interests**
Direct Compensation for Serving as Faculty or as a Speaker for a Med Ed Program	**Grants**	**Other**	

    - Does not include transfers made indirectly to a covered recipient through a third party where the manufacturer is unaware of the identity of the covered recipient
    - Includes transfers to an entity or individual at the request of or designated on behalf of a covered recipient

II. KEY HEALTH CARE LAWS

- Federal Sunshine Act (continued)
  - For each "payment or other transfer of value," the following information must be reported:
    1. Covered recipient's name, business address, specialty and Medicare billing number (if applicable)
    2. Amount
    3. Date of payment or transfer
    4. Description of the form of payment (e.g., cash, cash equivalent)
    5. Description of the nature of payment (e.g., consulting fees, gifts)
    6. Name of the covered drug, device, biological, or medical supply if "related to marketing, education, or research"
    7. Any other categories of information required by the Secretary

II. KEY HEALTH CARE LAWS

- HIPAA
  - Among other things, required DHHS to promulgate regulations regarding the privacy of "individually identifiable health information"
  - The Privacy Rule protects "individually identifiable health information" that is transmitted by or maintained in electronic media or any other form or media ("Protected Health Information" or "PHI") by imposing obligations on "Covered Entities" with respect to such PHI
  - "Individually identifiable health information" is information created or received by a Covered Entity (health plan, provider or clearing house) that:
    1. Relates to the physical, mental health, condition of, provision of health care to, or payment for the provision of health care to, an individual; and
    2. Either identifies the individual or there is a reasonable basis to believe the information can be used to identify the individual

II. KEY HEALTH CARE LAWS

- HITECH Act
  - On August 24, 2009, HHS published regulations clarifying the breach reporting obligations and providing guidance on the meaning of “secured” and “unsecured” PHI
  - Pre-HITECH Act
    - HIPAA only required that Covered Entities “mitigate” the harm of an unauthorized use or disclosure of PHI
    - No requirement to notify individual
  - After the HITECH Act
    - Amends HIPAA to add a requirement that Covered Entities notify individuals if their “unsecured” PHI is “breached” if the “breach” poses a significant risk to the individual

II. KEY HEALTH CARE LAWS

- Foreign Corrupt Practices Act
  - Two primary sets of provisions: anti-bribery provisions and accounting provisions
  - Anti-bribery provision makes it unlawful for
    - U.S. person, U.S. company, or any other person in the U.S.
    - With corrupt intent, to offer, pay, promise to pay, or authorize payment of, directly or indirectly, anything of value
    - To a "foreign official," foreign political party (or official thereof), or any candidate for foreign political office (each a "covered official"), or any person while "knowing" that all or a portion of the payment or thing of value will be offered, given, or promised directly or indirectly to a covered official
    - For the purpose of influencing any official act or decision, inducing any act or omission in violation of a lawful official duty, or securing an improper advantage
    - In order to assist in obtaining, retaining, or directing business to any person

II. KEY HEALTH CARE LAWS

- Foreign Corrupt Practices Act
  - Knowing" means to have actual knowledge, a firm belief that such circumstance exists or that such result is substantially certain to occur, awareness of a high probability of the existence of the circumstance, or willfully blind or consciously disregards the facts
  - "Foreign Official" broadly defined to include any officer or employee of a foreign government or any department, agency, or instrumentality of a foreign government
    - HCPs employed by state owned hospitals and clinics
  - Penalties
    - Criminal fines up to $2 million per violation for business entities
    - Fines up to $100,000 and/or up to 5 years in prison for individuals
    - Civil penalties up to $10,000
    - Debarment and exclusion

III. REPRESENTATIVE SETTLEMENTS

III. REPRESENTATIVE SETTLEMENTS

COMPANY	$ PENALTY	YEAR
Novartis	$422.5 Million	2010
Forest Labs	$313 Million	2010
Pfizer	$2.3 Billion	2009
Eli Lilly	$1.4 Billion	2009
Cephalon	$425 Million	2008
Purdue	$634.5 Million	2007
GSK	$150 Million	2005
Serono	$704 Million	2005
Pfizer	$427 Million	2004
Bayer	$257 Million	2003
GSK	$88 Million	2003
TAP	$875 Million	2001

III. REPRESENTATIVE SETTLEMENTS

- On September 30, 2010, Novartis announced that it had agreed to pay a total of $422.5 million to settle allegations that it had promoted its epilepsy drug Trileptal for uses not approved by the FDA and paid kickback for Trileptal and 4 other products
  - Criminal settlement of $185 million in fines and forfeiture and agreement to plead guilty to a misdemeanor violation of the FDCA was previously announced by Novartis in January 2010
  - Civil settlement of $237.5 million
  - Five year CIA with the OIG
  - Settles four qui tam complaints
- According to the settlement agreement, kickbacks to HCPs included speaker programs, advisory boards, entertainment and travel

III. REPRESENTATIVE SETTLEMENTS

- Also in September 2010, the settlement agreement previously announced by Forest Labs was finalized
  - Forest agreed to pay $313 million to settle allegations that it promoted Levothroid for uses not approved by the FDA and after it received a warning from the agency, misbranded Lexapro and paid kickbacks to HCPs to induce the HCPs to prescribe Lexapro and Celexa
  - Forest Pharmaceuticals pleaded guilty to one felony count of obstruction of justice, one misdemeanor count of distribution of Levothroid for unapproved uses and one misdemeanor count of misbranding Celexa
    - Misdemeanor counts are strict liability violations
  - $313 million settlement amount includes $150 million criminal fine, $14 million forfeiture and $149 million civil FCA penalties
  - 5 year CIA with the OIG

III. REPRESENTATIVE SETTLEMENTS

- Areas
  - Sales (FFS, prescriber, customer, and advocacy groups relationships)
  - Service agreements (bona fide, FMV, commercial reasonable, business need)
  - Marketing (claims)
  - Grant activities
  - CME and Medical Education activities
  - Government program price reporting
  - Manufacturing (quality, GMP)
  - Clinical research and trials
  - Practice guidelines
  - Samples
  - Patient Privacy
  - PhRMA Code topics
- Materials
  - Training materials
  - Brand Plans
  - Promotional materials

PRE-CONFERENCE I: COMPLIANCE BASICS

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