Compliance 101

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The Fourteenth Pharmaceutical Compliance Congress and Best Practices Forum

Audience Poll

How long have you worked in compliance?

A. I do not work in compliance

B. Less than one year

C. 1- 5 years

D. 5-10 years

E. More than 10 years

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Audience Poll

What is your current role in compliance?

A. Chief Compliance Officer (CO), deputy CO, associate CO

B. Compliance Auditor/Monitor

C. Compliance Trainer

D. Compliance Investigator

E. In-house lawyer supporting compliance

F. Other

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Audience Poll

How would you describe your organization?

A. Pharmaceutical manufacturer/biotech company
B. Medical device manufacturer
C. Technology company
D. Lawyer- private practice
E. Compliance vendor
F. Press
G. Government
H. Other

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Audience Poll

Is your organization currently subject to a consent decree, a corporate integrity agreement or similar obligations?

A. Yes

B. No

C. The company has completed such obligations

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Session Agenda

I. Where Do the Rules Come From?
   1. Introduction to State & Federal Laws
   2. Promotional Rules
   3. International Issues

II. How Have the Rules Been Enforced?
   1. Summary of Recent CIAs

III. What are the Seven Elements of an Effective Compliance Program?

Case studies will be interwoven for audience participation

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Hot Compliance Topics

- French Sunshine on October 1 (too late already!)
- US Sunshine on August 1! Get prepared for March 31!
- States are acting . . . and reacting
- Off-label promotion focus continues
- Safety: a top priority
- Manufacturing: a (relatively) new focus
- Individual Liability continues
- 1st Amendment issues: in flux
- Impact of sequestration?
- Social media

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Case Study Introduction

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WHERE DO THE RULES COME FROM?

- Introduction to Federal & State Laws
  - Federal healthcare program Anti-Kickback Statute
  - Civil Monetary Penalties
  - False Claims Acts
  - Physician Payment Sunshine Act
  - Health Insurance Portability & Accountability Act (HIPAA)
  - Government Program Pricing Programs

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Audience Poll

What is the organizational and reporting relationship between the Legal Department and Compliance Department in your Organization?

A. Full -time Legal and Compliance personnel overlap completely, reporting to the CEO and/or BoD

B. Full-time Legal and Compliance personnel overlap in part, dual reporting to the General Counsel CEO/BoD

C. Compliance Department reports to General Counsel

D. Compliance Department has a dual report to General Counsel and CEO /BoD

E. Other

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Anti-Kickback Statute

- It is a felony to:
  - Knowingly and willfully
  - Offer, pay, solicit or receive
  - Remuneration (such as a kickback, bribe or rebate)
  - Directly or indirectly
  - Overtly or covertly
  - In cash or in kind
  - In exchange for inducing the ordering or prescribing of products or services
  - That are reimbursed, in whole or in part, by a Federal health care program

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Anti-Kickback Statute

- Under the Affordable Care Act (or ACA), the Anti-Kickback Statute was changed so that a person need not have actual knowledge of the Anti-Kickback Statute or specific intent to commit a violation of the Anti-Kickback Statute
- Statute implicated if any one purpose of the remuneration is to induce or reward the referral
- Penalties
  - Criminal fines up to $25,000
  - Imprisonment up to 5 years
  - Civil monetary penalties
  - Exclusion
  - Basis for False Claims Act violation

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Anti-Kickback Statute

- There are statutory exceptions and regulatory safe harbors to the Anti-Kickback Statute that, if strictly complied with, will protect against liability
- Some of the most common for the industry include:
  - Discounts
  - Personal Services and Management Contracts
  - GPO Administrative Fees

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Anti-Kickback Statute

- "Discount" Safe Harbor
  - "Public policy favors open and legitimate price competition in health care. Thus, the anti-kickback statute contains an exception for discounts offered to customers that submit claims to the federal health care programs, if the discounts are properly disclosed and accurately reported.... However, to qualify for the exception, the discount must be in the form of a reduction in price of the good or the service based on an arms-length transaction. In other words, the exception covers only reductions in the product's price. Moreover, the regulations provide that the discount must be given at the time of sale or, in certain cases, set at the time of sale, even if finally determined subsequent to the time of sale (i.e., a rebate).
  - ...To fulfill the safe harbor requirements, manufacturers will need to know how their customers submit claims to the federal health care programs (e.g., whether their customer is a managed care, cost-based, or charged-based biller). Compliance with the safe harbor is determined separately for each party."

- Final OIG Compliance Program Guidance for Pharmaceutical Manufacturers (68 Fed. Reg. 23731,23735 (May 5, 2003)

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Anti-Kickback Statute

- "Discount" Safe Harbor (cont'd)
  - A "discount" is defined as a reduction in the amount a buyer (who buys either directly or through a wholesaler or a group purchasing organization) is charged for an item or service based on an arms-length transaction"
  - A "discount" is not, for example:
    - Cash payment or cash equivalents (except that rebates may be in the form of a check)
    - A reduction in price applicable to one payer but not to Medicare, Medicaid or other FHCPs
    - Services provided in accordance with a personal or management services contract
  - A "rebate" is defined as "any discount the terms of which are fixed and disclosed in a writing to the buyer at the time of the initial purchase to which the discount applies, but which is not given at the time of sale."

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Anti-Kickback Statute

- "Discount" Safe Harbor requires different responsibilities for "buyers", "sellers" and "offerors"
  - Specifically, in the case of a buyer that is an HMO or CMP acting in accordance with its risk contract with the Government
    - A discount will not violate the Anti-Kickback Statute or serve as a basis for exclusion from participation in FHCPs if the HMO/CMP reports the discount if such reporting is required under the HMO/CMP's risk contract with the Government
    - The seller and offeror have no obligation to report the discount

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Anti-Kickback Statute

- "Personal Services Safe Harbor" requires
  1. Written Agreement (not less than 1-year term) specifying: (i) all of the services to be provided for the term of the agreement, (ii) exact schedule of services if the services are to be provided on a periodic, sporadic or part-time basis, and (iii) compensation.
  2. Compensation must be set in advance, consistent with fair market value in arms-length transactions and is not determined in a manner that takes into account the volume or value of any federal health care program referrals.
  3. The services must be bona fide and may not involve the counseling or promotion of a business arrangement or other activity that violates any State or Federal law.
  4. The aggregate services contracted for may not exceed those which are reasonably necessary to accomplish the commercially reasonable business purpose of the services.

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Anti-Kickback Statute

- Group Purchasing Organization (GPO) Safe Harbor
  - Protects payments by vendors of goods/services to GPOs if:
    - Written agreement with each member providing that either—
      1. States that participating vendors will pay a fee to the GPO ≤3% of the purchase price, or
      2. If fee is not fixed at ≤3% of the purchase price, the agreement specifies the amount (or if not known, the max amount) the GPO will be paid by each vendor (amount may be a fixed sum or a fixed % of the value of purchases made from the vendor by the members)
    - If the purchaser is a health care provider of services, GPO must disclose in writing to the purchaser at least annually, and to the HHS Secretary upon request, the amount received from each vendor with respect to purchases made by or on behalf of the entity
  - GPO= entity authorized to act as a purchasing agent for a group of individuals or entities who are furnishing services for which payment may be made in whole or in part under Federal health care programs,
    - neither wholly-owned by the GPO nor
    - subsidiaries of a parent corporation that wholly owns the GPO (either directly or through another wholly-owned entity)

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Anti-Kickback Statute

- Conduct that does not fit within a statutory exception or a safe harbor will be analyzed based on the cumulative "facts and circumstances" to determine whether a violation exists
  - Final OIG Voluntary Compliance Program Guidance for Pharmaceutical Manufacturers (68 Fed. Reg. 23731, 23734-23735 (May 5, 2003)
- OIG Advisory Opinions and Special Fraud Alerts

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Anti-Kickback Statute

- OIG Voluntary Compliance Program Guidance for Manufacturers provides factors to consider in evaluating the risks associated with the identified relationships
  - Potential to interfere with, or skew, clinical decision-making
  - Potential to undermine the clinical integrity of a formulary process
  - If the arrangement involves providing information to decision-makers, prescribers or patients, complete and accurate that is not misleading
  - Potential to increase costs to FHCP, beneficiaries, enrollees
  - Potential to be a disguised discount used to circumvent the Medicaid Rebate Program Best Price calculation
  - Potential to increase the risk of over- or inappropriate utilization
  - Potential for patient safety or quality of care issues

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Anti-Kickback Statute

- Many states have adopted laws similar to the federal Anti-Kickback Statute
  - Some state laws may be broader in scope
    - May extend to all payors (including third-party payors)
    - May extend to professionals
    - May not contain comparable exceptions

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Civil Monetary Penalties Law

- Civil Monetary Penalties Law was enacted in 1981 as part of the Social Security Act relevant to certain activities
- Provides procedures for the OIG to follow to initiate action such as a 6 year SOL from the state a claim was presented, request for payment made or other occurrence occurred
- Claim is “improper” if offeror “knew” or “should have known” that it was false or fraudulent
- Activities include, with some exceptions:
  - Dealing with excluded individuals or entities
  - Beneficiary inducements

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Civil Monetary Penalties Law

- Specifically , and by way of example, –
  - knowingly presents, or causes to be presented, claims to a federal healthcare program that the person knows, or should know, is for an item or service that was not provided as claimed or is false or fraudulent;
  - knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim for payment for items and services furnished under a federal healthcare program; and
  - arranges or contracts with an individual or entity that the person knows, or should know, is excluded from participation in a federal healthcare program

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Civil Monetary Penalties Law

- Maximum imposed CMP amounts vary based on violation committed
- The following factors are considered to determine the actual amount or scope of any penalty, assessment or exclusion imposed:
- the nature of claims and the circumstances under which they were presented;
- the degree of culpability, history of prior offenses, and financial condition of the person presenting the claims; and
- such other matters as justice may require.

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Federal Civil False Claims Act

- Federal Civil False Claims Act (FCA)
  - 31 USC § 3279-3733
  - Enacted in 1863 to combat fraud by government contractors
  - Used extensively to combat fraud in government health care programs
  - Includes "qui tam" provisions that allow private whistleblowers a/k/a relators to sue violators on behalf of the government (including non-retaliation protections)
- Prohibits, among other things:
  - knowingly presenting, or causing to be presented, a false or fraudulent claim for payment or approval
  - knowingly making, using, or causing to be made or used, a false record or statement material to a false or fraudulent
  - possession, custody, or control of property or money used, or to be used, by the Government and knowingly delivering, or causing to be delivered, less than all of that money or property
  - knowingly making, using, or causing to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly concealing or knowingly and improperly avoiding or decreasing an obligation to pay or transmit money or property to the Government
  - conspiring to commit a violation of the FCA
- A company need not directly submit claims to the government to be liable

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Federal Civil False Claims Act

- The FCA provides several circumstances in which a relator cannot file or pursue a qui tam action including where the action is based upon information that has been disclosed to the public through any of several means: Federal criminal, civil, or administrative hearings in which the government is a party, government hearings, audits, reports, or investigations, or through the news media (this is known as the "public disclosure bar.") §3730(e)(4)(A)
  - There is an exception to the public disclosure bar where the relator was the original source* of the information
  - *This concept has been broadened, as discussed below…

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Federal Civil False Claims Act

- Health Reform Changes
  - Expansion of False Claims Act (under ACA 2010 and FERA 2009)
    - Public Disclosure Bar Narrowed
      - Whistleblower having independent knowledge that materially adds to public disclosed allegations
      - Limits "public disclosure" to disclosures made in a Federal setting (disclosures in state reports or proceedings no longer qualify)
      - Permits US to waive application of the bar so that Whistleblower can proceed
  - Violations of Anti-Kickback Statute trigger FCA claims
    - Some jurisdictions already permitted this, but now statutory
  - FCA liability for failure to return overpayment
  - Claims made by, through, or in connection with a health insurance "Exchange" that involve federal funds are within scope of FCA

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Federal Civil False Claims Act

- Penalties/Legal Sanctions for FCA Violations
  - Civil
    - Possible exclusion from Federal health care programs; and
    - Significant monetary penalties
  - Criminal (felony – separate statute)
    - Monetary fine and/or up to 5 years imprisonment
    - Mandatory exclusion from Federal health care programs
  - Possible sanctions under similar state laws

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Sunshine Act

- CMS Open Payments website
  - http://www.cms.gov/Regulations-and-Guidance/Legislation/National-Physician-Payment-Transparency-Program/index.html
- CMS FAQs
  - https://questions.cms.gov/faq.php?isDept=0&search=%22third+party+payment%22&searchType=keyword&submitSearch=1&id=5005
- Cooley FAQs
  - http://thebeatatcooleyhealth.files.wordpress.com/2013/08/cms-sunshine-faqs-by-topic.pdf
  - http://thebeatatcooleyhealth.files.wordpress.com/2013/08/cms-sunshine-faqs-by-date.pdf

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Sunshine Act

- Section 6002 of the Affordable Care Act (PPACA or ACA) signed into law by President Obama on March 23, 2010
- Final Rule implementing the Sunshine provisions was published on February 8, 2013

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Sunshine Act

- Sunshine provisions require:
  - "Applicable Manufacturers" to report annually to the Centers for Medicare & Medicaid Services (CMS) certain "payments or other transfers of value" provided to "covered recipients"; and
  - Applicable Manufacturers and Applicable Group Purchasing Organizations ("GPOs") to report annually certain physician ownership and investment interests

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Sunshine Act

- Key Definitions:
  - "Applicable Manufacturers"
    - Manufacturer of a "covered" drug, device, biological or medical supply for which payment is available under Medicare, Medicaid or CHIP operating in the US
    - Certain related entities under "common ownership" (e.g. parent, sister companies, subsidiaries, etc.) that provide "assistance or support" to an Applicable Manufacturer

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Sunshine Act

- Key Definitions:
  - "Payments or other transfers of value"
    - Anything of value, unless specifically excluded
    - Includes transfers to an entity or individual at the request of or designated on behalf of a covered recipient
  - "Covered recipients"
    - Physicians
    - Teaching hospitals

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Sunshine Act

- Key Dates:
  - Data collection began August 1, 2013
  - Registration with CMS in early 2014
  - First report due to CMS by March 31, 2014
  - First publication of data by CMS by September 30, 2014

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Sunshine Act

- Reporting Payments/Transfers of Value
  - Name of covered recipient
  - Business address of covered recipient
  - Physician specialty
  - National provider identifier / teaching hospital tax ID number
  - State professional license information
  - Total amount of payment(s) or transfer(s) of value; number of payments
  - Date of payment(s) or other transfer(s) of value
  - Form of payment
  - Nature of payment
  - Name(s) and NDC(s) of related covered drug, device, biological, medical supply
  - Third party recipient, if applicable
  - Payments or transfers of value to physician owners or investors
  - Additional information or context (optional)

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Sunshine Act

- Reporting Related to Research Payments
  - Name of research institution/other entity or individual receiving payment
  - Names, primary business address for direct payments
  - NPI, state professional license information, specialty for HCPs
  - Total amount, date, and form of research payment
  - Study name
  - Name(s) of related covered product and NDC (if any)
  - Principal investigator information
  - Context of research and/or ClinicalTrials.gov identifier (optional)
  - Delayed publication eligibility

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Sunshine Act

- Reporting Ownership/Investment Interests
  - Name of physician
  - Business address of physician
  - Physician's specialty
  - National Provider Identifier
  - State professional license information
  - Dollar amount invested by each physician or immediate family member of the physician
  - Value and terms of each ownership or investment interest

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Sunshine Act

- Form of Payment

Cash or Cash Equivalent

In-kind items/ Services

Stock, Options, Dividends, Profits

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Sunshine Act

- Nature of Payment

Consulting Fees

Compensation: Other Services

Honoraria

Gifts

Entertainment

Food

Travel

Funding for Education

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Sunshine Act

- Nature of Payment (cont'd)

Research

Charitable Contributions

Royalties/ Licenses

Space Rental/ Fees

Ownership/ Investment Interest

Faculty/Speaker Compensation

Grants

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Sunshine Act

- Third Party Payments
  - Payments or transfers of value provided to a third party at the request of, or designated on behalf of, a physician or teaching hospital
    - Example: charitable donation

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Sunshine Act

- Indirect Payments
  - Payments or transfers of value made by a manufacturer or GPO to a physician or teaching hospital through an intermediary where the manufacturer or GPO requires, instructs, directs, or otherwise causes the third party to make the payment or transfer
    - Examples: vendor, CRO

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Sunshine Act

- Exclusions
  - Anything with a value of less than $10 but only if the aggregate amount provided to a covered recipient by the manufacturer does not exceed $100 per calendar year
  - Free product samples intended for patient use
  - Educational materials that directly benefit patients or intended for patient use
  - Buffet meals, snacks, soft drinks, coffee made generally available at conferences
  - Covered recipient is a patient/research subject and not acting in professional capacity
  - Discounts and rebate

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Sunshine Act

- Exclusions
  - In-kind items provided for charity care
  - Loan of a covered device for a short term trial period (up to 90 days)
  - Certain items or services provided under a contractual warranty
  - Dividend or other profit distribution from, or ownership or investment interest in, a publicly traded security or mutual fund
  - CE program funding, if all specified requirements are met
  - Certain other limited applicability exclusions

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Sunshine Act

- Attestation
  - Each report and any subsequent corrections to a filed report must include an attestation by the CEO, CFO, CCO or other Officer of the Applicable Manufacturer or Applicable GPO that the information reported is timely, accurate, and complete to the best of his or her knowledge and belief

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Sunshine Act

- Civil Monetary Penalties
  - CMPs of $1,000 - $10,000 for each failure to timely, accurately, completely report a payment/ transfer of value or ownership or investment interest, up to $150,000 annually
  - CMPs of $10,000 - $100,000 for each “knowing failure” to timely, accurately or completely report a payment or other transfer of value or ownership or investment interest, up to $1 million annually

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Sunshine Act

- Dispute/Correction Process
  - 45-day review period for covered recipients before information made public
  - Covered recipients that register with CMS will be notified when information is reported
  - Disputed payments that are not resolved will be posted by CMS with notation

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Sunshine Act

- Assumptions Document
  - Applicable Manufacturers and Applicable GPOs may submit an assumptions document that explains the reasonable assumptions made and methodologies used to report payments or other transfers of value
    - Will not be posted on public website or provided to Covered Recipients
      - FOIA requests
      - Enforcement authorities

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Sunshine Act

- Preemption
  - Same "type of information regarding the payment or other transfer of value required to be reported"

	Compliance Program	Code of Conduct/Ethics	"Gift" Restrictions	Annual Disclosure Report	Annual Compliance Certification
California	X		X		X
Connecticut	X	X			
DC (3 laws)		X	X	X	X
Mass.		X	X	X	X
Minnesota			X	X	
Nevada		X			X
Vermont			X	X	
West Virginia				X	

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HIPAA Privacy Rule

- The Health Insurance Portability and Accountability Act (HIPAA) was signed into law by President Clinton on August 21, 1996.
- HIPAA required Congress to enact a medical privacy statute. However, if Congress failed to do so, the Act gave the Secretary of HHS the authority to promulgate regulations.

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HIPAA Privacy Rule

- Privacy Rule:
  - Contains general principles for uses and disclosures of Protected Health Information (PHI)
  - Gives patients rights regarding their PHI including rights to access and amend
- Security Rule:
  - Requires entities to implement appropriate administrative, physical and technical safeguards to ensure the confidentiality, integrity, and security of PHI
- Breach Notification Rule (Interim):
  - Defines a “Breach” of HIPAA
  - Requires entities to notify individual, HHS, and in certain cases the media regarding a Breach
- Enforcement Rule:
  - Describes the imposition of civil monetary penalties for violations of HIPAA

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HIPAA Privacy Rule

- The HIPAA Privacy Rule establishes a fundamental presumption that all “Protected Health Information” is confidential, and can only be disclosed with appropriate authorization from the individual.
- Exceptions to this presumption are described in the Privacy Rule.

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HIPAA Privacy Rule

- Who is subject to HIPAA Privacy Rule?
  - "Covered Entities"
  1. Health care providers: providers of medical or health services who transmit health information in electronic form
  2. Health plans:
     - Health insurers and HMOs
     - Insured and self-funded employee welfare benefit plans that have 50 or more participants or are administered by an entity other than the sponsor
  3. Health care clearinghouses: billing services, repricing companies and others that engage in data translation

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HIPAA Privacy Rule

- Who is subject to HIPAA Privacy Rule?
  - "Business Associates"
    - Entity or person that provides services for a Covered Entity involving Protected Health Information, such as accounting, legal services, consulting services, or practice management.

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HIPAA Privacy Rule

- Key Definition
  - Protected Health Information ("PHI") is information
    - in any medium (including electronic, paper, oral);
    - that is created, received, maintained or transmitted by a Covered Entity;
    - that relates to an individual's health, healthcare treatment, or payment; and
    - that identifies an individual in any way
  - Broader concept than traditional focus on medical record information
  - Information properly de-identified under HIPAA is no longer PHI

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HIPAA Privacy Rule

- HIPAA Privacy Rule contains requirements that fall into 3 basic categories:
  1. Administrative Requirements
  2. Use and Disclosure of PHI
  3. Individual Rights – Rights regarding PHI that Covered Entities must respect

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HIPAA Privacy Rule

- Administrative Requirements
  - Policies and Procedures
  - Privacy Officer
  - Document Retention
  - Notice of Privacy Practices

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HIPAA Privacy Rule

- Uses and Disclosures
  - General Rule: All PHI is confidential, and may only be disclosed with appropriate authorization from the individual
  - Exceptions ALL governed by the minimum necessary standard
    1. Treatment - provision, coordination, or management of health care and related services by one or more health care providers (such as: referral from one provider to another)
    2. Payment - coverage decisions, adjudicating claims, performing risk adjustment, billing, eligibility, or conducting utilization management activities
    3. Healthcare Operations - performing Quality Assurance or Quality Improvement, credentialing, achieving accreditation or licensure, conducting or arranging for medical review, legal services

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HIPAA Privacy Rule

- Uses and Disclosures
  - PHI may be disclosed without individual's authorization in the following circumstances:
    - Required by Law
    - To Public Health Agencies
    - Victims of Abuse or Neglect
    - Health Oversight Activities
    - Judicial and Administrative Proceedings
    - Law Enforcement
    - Worker's Compensation
    - About Decedents to Coroners and Funeral Directors
    - Organ, Eye or Tissue Donation
    - Serious Threat to Health or Safety
    - Special Government Functions

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HIPAA Privacy Rule

- Uses and Disclosures
  - Sale of PHI
    - Selling PHI without authorization is almost always prohibited
  - Marketing
    - Strong restrictions on use of PHI for purposes of marketing
  - Research
    - Individual's authorization required for PHI to be used in research
    - IRB governs research confidentiality
    - De-identified health information is not PHI
- Disclosures to Business Associates
  - HIPAA requires that there be an agreement (a "Business Associate Agreement" or "BAA") between every Covered Entity and its Business Associates that establishes the permitted uses and disclosures of PHI, and sets forth other safeguards to PHI

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HIPAA Privacy Rule

- Individual Rights
  - Individuals have the rights to:
    - Access their PHI
    - Request amendments to their PHI
    - Receive an accounting of disclosures of their PHI
      - Individuals have the right to request an accounting of disclosures, and therefore, it is necessary to keep a record of such disclosures
    - Request restrictions on disclosures of their PHI
      - Entity does not have to abide by such a request unless (1) it relates to a disclosure to a health plan for purposes of payment or healthcare operations; and (2) the PHI relates to a health care service or product for which the individual paid out of pocket and in full

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HIPAA Privacy Rule

- State Privacy Laws
  - State Privacy Laws that afford greater protections to individuals are not preempted by HIPAA
  - New York has privacy laws that are more stringent with respect to:
    - Mental health records (MHL Section 33.13)
    - HIV/AIDS (PHL Article 27-F)
    - Drug and alcohol treatment records (42 CFR Part 2)
    - Genetic testing information (CRL 79-L)
    - Minors (PHL sections 17 & 18)

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Government Program Pricing

- Federal Programs
  - Medicaid Drug Rebate Program
    - Rebate program with amount of post-sale rebate based on lowest includible price
  - 340B Drug Discount Program
    - Procurement program with ceiling price derived from rebate paid on prescription unit (for example, single tablet)
  - FSS
    - Procurement program with ceiling price derived from average price of same item sold to wholesalers
    - Also includes rebate-like refund for TRICARE retail
  - Medicare ASP
    - Manufacturer calculation used to determine reimbursement to Part B providers
- State Programs

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Government Program Pricing

- Medicaid Drug Rebate Program (MDRP) Generally
  - If a manufacturer wants to participate in a State Medicaid program, manufacturer must participate in the Medicaid Drug Rebate Program
  - Program requires certain prescription drugs, defined as "covered outpatient drugs," purchased through a state Medicaid program, to be subject to rebates to be paid by the manufacturers
    - Effective March 23, 2010, Medicaid MCO utilization qualifies for federal rebate (unless dispensed by 340B covered entities)

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Government Program Pricing

- Manufacturers Obligations Generally (cont'd)
  - Must report to CMS (1) monthly: "Average Manufacturer Price" (AMP); (2) quarterly: Best Price (BP), AMP, value of customary prompt pay discounts, and value of nominally priced sales
    - AMP = "the average price paid to the manufacturer for the drug in the United States by wholesalers for drugs distributed to the retail pharmacy class of trade, after deducting customary prompt pay discounts"
    - Best Price = generally, "the lowest price available from the manufacturer during the rebate period to any wholesaler, retailer, provider, [HMO], nonprofit entity or governmental entity within the United States. . . ."

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Government Program Pricing

- Manufacturers Obligations Generally (cont'd)
  - Must certify pricing reports
  - CEO, CFO, individual other than a CEO/CFO with equivalent authority; or individual with the directly delegated authority to perform the certification
  - Must keep records of the data and any other material used in calculating rebates for 10 years

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Government Program Pricing

- Calculating Rebates Generally
  - CMS generally calculates the "unit rebate amount" or "URA" for each drug after receiving the manufacturer-reported data
  - Post-health reform, CMS has been "temporarily" requiring manufacturers to calculate URAs
  - As of January 1, 2010, the rebate for covered outpatient drugs is:
    - For non-innovator ("N") products – 13% of the AMP per unit
    - For single source ("S") and innovator multiple source ("I") products
      - The larger of
        - 23.1% of the AMP per unit (17.1 % for clotting factor with separate furnishing fee and for exclusively pediatric products); or
        - The difference between AMP and the Best Price per unit
      - Plus, "additional" rebate based on the percentage by which the AMP of the drug increased in comparison to the increase in the CPI-U since base period (first full Q or sales)

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Government Program Pricing

- Calculating Rebates Generally (cont'd)
  - Maximum Rebate
    - The URA for "S" and "I" products capped at 100% of AMP
      - States can claim more than 100% of drug *reimbursement* payments in rebates
  - "Additional" rebate calculation for "new formulations" of existing drugs
  - Calculation changes for new formulations/"line extensions" of "oral solid dosage forms" of S or I products such as extended-release formulations
  - "Additional" rebate = greater of (1) the "additional" rebate amount calculated under the statutory formula; and (2) the product of (i) the new formulation's AMP for the current rebate period, (ii) the highest "additional" rebate for any strength of the original "S" or "I" drug, calculated as a percentage of the new formulation's AMP for the current rebate period, and (iii) the number of units for the new formulation invoiced for rebate

Government Program Pricing

- "In the absence of specific guidance in section 1927 of the Act, Federal regulations and the terms of this agreement, the Manufacturer may make reasonable assumptions in its calculations of AMP and Best Price, consistent with the intent of section 1927 of the Act, Federal regulations and the terms of this agreement. A record (written or electronic) outlining these assumptions must also be maintained."

  -Section II(i) of the CMS Rebate Agreement

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Government Program Pricing

- 340B Drug Discount Program
  - Program was created by Section 602 of the Veterans Health Care Act of 1992
  - Requirements are codified at Section 340B of the Public Health Service Act (42 U.S.C. § 256b)
  - Purpose is to ensure that certain hospitals and PHS Grantees obtain mandatory price discounts a/k/a Covered Entities
    - Medical "safety net providers" who enroll
    - 17000+ (and growing) entities registered in HRSA's database (http://opanet.hrsa.gov/opa)
  - Response to price increases that resulted from OBRA 90
  - Program is administered by the Healthcare Resources and Services Administration, Office of Pharmacy Affairs (HRSA or OPA)

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Government Program Pricing

- Manufacturer Obligations Generally
- New Drugs
  - HRSA requires mfrs to estimate ceiling prices "until sufficient data is available to calculate the AMP and BP of the new drug"
  - Any adjustments necessary to reconcile differences between the first and second quarter estimated ceiling price and the third quarter ceiling price will be in the form of a retroactive charge back or rebate
- Because 340B price uses a data lag, mfr would estimate the new drug ceiling price for three quarters
- Under 340B Pharmaceutical Pricing Agreement (PPA), mfr agrees to sell "covered outpatient drugs" to "covered entities" at a price determined by a statutory formula
- 340B sales are excluded from the Medicaid Best Price

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Government Program Pricing

- Manufacturer Obligations - new obligations (post-Health Reform)
  - Report 340B prices quarterly (to HRSA?)
  - "Must sell" to CEs if such drug is made available to any other purchaser at any price
  - Compliance obligations regarding how to the refund overcharges to CEs

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Government Program Pricing

- VA Federal Supply Schedule
  - Program was created by Section 603 of the Veterans Health Care Act of 1992
  - Requirements are codified at 38 U.S.C. § 8126
  - Mandates manufacturer participation in the VA Federal Supply Schedule (FSS)
  - Medicaid Best Price excludes FSS sales
  - Response to price increases and withdrawal from FSS that resulted from OBRA 90

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Government Program Pricing

- VA Federal Supply Schedule (continued)
  - Authority to administer the FSS for pharmaceuticals and medical devices has been delegated by GSA to VA
  - FSS authorized purchasers include:
    - Executive agencies and other Federal agencies
    - Mixed ownership government corporations
    - The District of Columbia
    - Government contractors authorized in writing by a Federal agency
    - Other activities and organizations authorized by statute or regulations to use GSA as a source of supply (including State Veterans Homes with sharing agreements)

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Government Program Pricing

- Manufacturer Obligations Generally
  - Must enter into FSS contract, Master Agreement and Pharmaceutical Pricing Agreement with VA
  - Agrees to sell to the Big Four purchasers (VA, DoD, Coast Guard and PHS) through the FSS or a depot at not more than the Federal Ceiling Price (FCP)
  - FCP equals 76% of the Non-Federal Average Manufacturer Price (non-FAMP) minus any additional discount
  - May sell to other authorized purchasers at a higher FSS price
  - Report annually and quarterly the non-FAMP and FCP on each package unit of a covered drug

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Government Program Pricing

- TRICARE Retail Pharmacy Rebates
  - 10 U.S.C. 1074g(f) provides that the TRICARE Retail Pharmacy Program shall be treated as an element of DoD for purposes of procurement at or below FCP
  - Effective with respect to any prescription filled on or after January 28, 2008
  - DoD has implemented through refund requirement for scripts provided by network retail pharmacies to TRICARE beneficiaries
  - DoD's PBM provides sales data to DoD's Pharmacy Benefit Office
  - PBM distributes data to manufacturer to calculate "refund"
  - DoD/VA maintain this is a "virtual" depot

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Promotional Rules

- Lucy Rose

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WHERE DO THE RULES COME FROM?

- Lucy Rose

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International Issues

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Bribery and Corruption

Simple Definitions

- Corruption – “the abuse of entrusted power for private gain”
- Bribery - “to offer or give something of value with the intention of gaining or retaining an unfair or improper advantage”
- Facilitation Payment – “small payment to facilitate or expedite the performance of a routine action”

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Corruption in Healthcare

- US$ 4.1 trillion is spent globally on health services every year, with US$ 750 billion spent in the pharmaceutical market.
- 10 to 25% of public procurement spending (including on pharmaceuticals) is lost to corrupt practices.
- In developed countries, fraud and abuse in health care is estimated to cost individual governments as much as US$ 23 billion per year.
- Countries with a higher incidence of corruption have higher child mortality rates.
- To reduce corruption, thorough checks and balances are required at each step in the medicine chain.

Source: WHO Factsheet 335, December 2009

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Anti-Corruption Landmarks

- **1977 - Foreign Corrupt Practices Act**
- 1996 - Inter-American Convention against Corruption
- **1997 - OECD Convention on Bribery of Foreign Public Officials**
- 1999 - Council of Europe Criminal Law Convention on Corruption
- 1999 - Council of Europe Civil Law Convention on Corruption
- 2000 - United Nations Convention against Transnational Organised Crime
- 2003 - African Union Convention on Preventing and Combating Corruption
- **2003 - United Nations Convention against Corruption**
- 2009 - Recommendation of the Council for Further Combating Bribery
- 2010 - Good Practice Guidance on Internal Controls, Ethics and Compliance
- **2010 – UK Bribery Act**

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Transparency International

TI is the “global civil society organisation leading the fight against corruption”; publications include:

- Bribe Payers Index
- Corruption Perceptions Index
- Global Corruption Barometer
- Progress Report (Enforcement of the OECD Anti-Bribery Convention)

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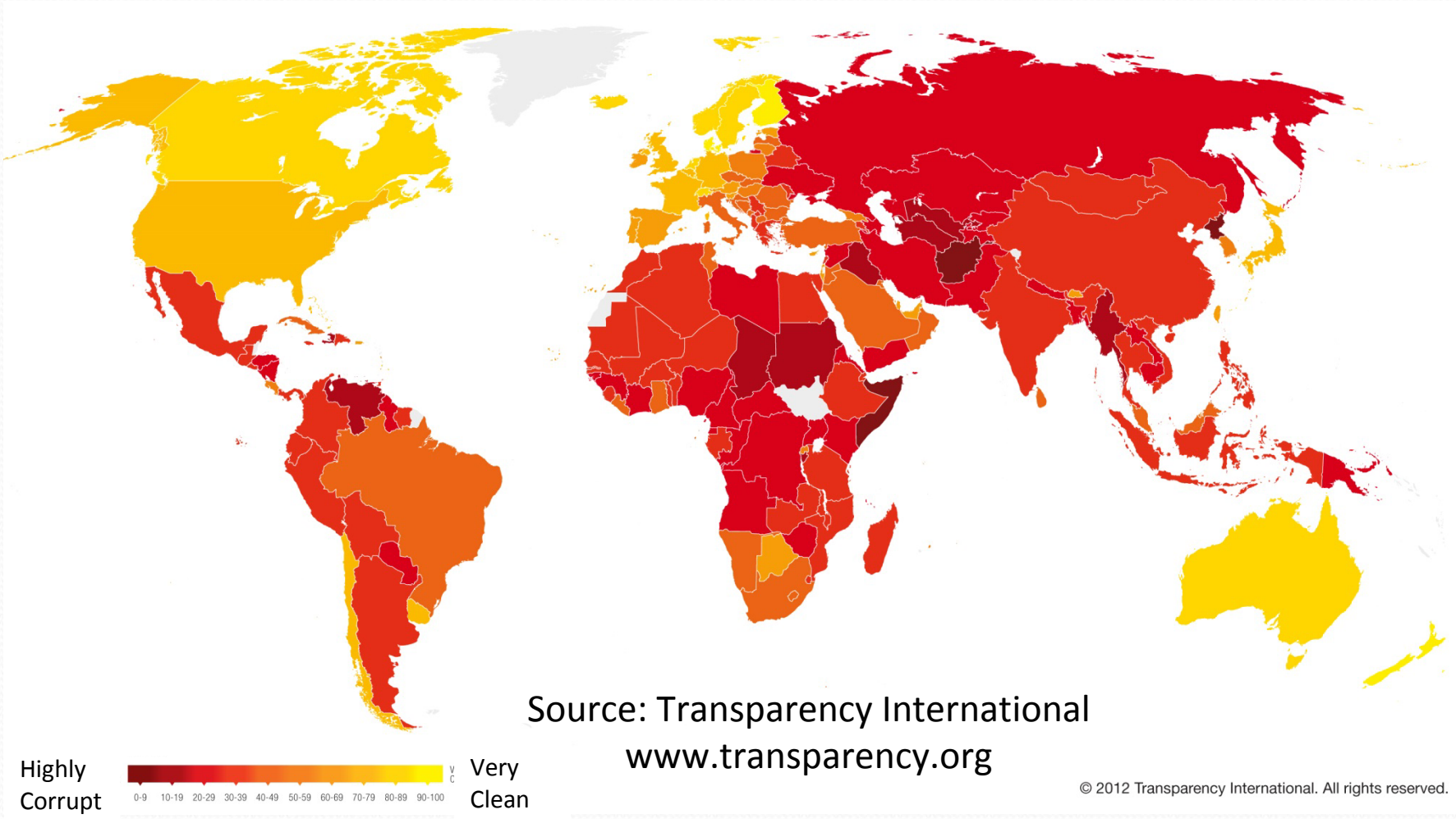
Transparency International



Source: Transparency International
www.transparency.org

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TI Corruption Index 2012 Scores

Scores out of 100 (higher is better)

- Denmark, Finland, NZ (90)
- Switzerland (86)
- Germany (79)
- Japan (74)
- USA (73)
- Spain (65)
- Sweden (88)
- Australia (85)
- Belgium (75)
- UK (74)
- France (71)
- South Korea (56)

- Brazil (43)
- China (39)
- Mexico (34)
- Italy (42)
- India (36)
- Russia (28)

Scores below 50 "indicate a serious corruption problem"

Source: Transparency International
www.transparency.org

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Bribe Payers Index 2011

Scores out of 10 where 10 corresponds to the view that companies never pay bribes and 0 corresponds to the view that companies always pay bribes

Rank	Sector	Score
19	Public works contracts and construction	5.3
17	Utilities	6.1
17	Real estate, property, legal and business services	6.1
16	Oil and gas	6.2
15	Mining	6.3
13	Power Generation and Transmission	6.4
13	**Pharmaceutical and Healthcare**	**6.4**
12	Heavy Manufacturing	6.5
10	Fisheries	6.6
10	Arms, Defence and Military	6.6

Source: Transparency International: www.bpi.transparency.org/bpi2011/results/

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OECD* Principles (1)

- Criminal offense to:
  - offer, promise or give any undue advantage
  - directly or through intermediaries
  - to a foreign public official, in order to
  - obtain or retain business or other improper advantage
- Includes incitement, aiding and abetting, or authorisation
- Attempt and conspiracy to bribe equally serious
- Statute of limitations to enable sufficient time for investigation and prosecution
- "Small facilitation payments" are excluded

*OECD = Organisation for Economic Cooperation and Development www.oecd.org

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OECD Principles (2)

- Prohibits:
  - off-the-books accounts,
  - inadequately identified transactions,
  - recording of non-existent expenditures,
  - entry of liabilities with incorrect identification of their object
  - use of false documents
- Requires:
  - co-operation in carrying out a programme of systematic follow-up to monitor and promote the full implementation of the convention

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OECD Principles (3)

- "foreign public official" means any person holding a legislative, administrative or judicial office of a foreign country, whether appointed or elected; any person exercising a public function for a foreign country, including for a public agency or public enterprise; and any official or agent of a public international organisation
- "public function" includes any activity in the public interest
- "public agency" is an entity constituted under public law to carry out specific tasks in the public interest
- An official of a public enterprise shall be deemed to perform a public function

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Foreign Corrupt Practices Act

"In general, the FCPA prohibits offering to pay, **paying**, promising to pay, or authorizing the payment of money or **anything of value** to a **foreign official** in order to **influence any act or decision** of the foreign official in his or her official capacity or to secure any other **improper advantage** in order to **obtain or retain business**."

Source: A Resource Guide to the U.S. Foreign Corrupt Practices Act; http://www.sec.gov/spotlight/fcpa/fcpa-resource-guide.pdf

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UK Bribery Act 2010

- Came into force July 2011
- Replaced the fragmented and complex offences at common law and in the Prevention of Corruption Acts 1889-1916
- Created two general offences covering:
  - the offering, promising or giving of an advantage, and
  - requesting, agreeing to receive or accepting of an advantage
- Created a discrete offence of bribery of a foreign public official
- Created a new offence of failure by a commercial organisation to prevent a bribe being paid for or on its behalf (it will be a defence if the organisation has adequate procedures in place to prevent bribery)
- Includes bribes paid to or received by anyone, not just "public officials"
- Does **not** allow facilitation payments

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Quotes

- European prosecutor involved in Siemens case, speaking at International Pharmaceutical Compliance Forum May 2009:

  "We know that there are some countries where if you're doing business, it is highly likely that there is corruption involved; that is the logical place to look next"

- US Assistant Attorney General, speaking at US Pharmaceutical Compliance Forum November 2009:

  "The depth of government involvement in foreign health systems, combined with fierce industry competition and the closed nature of many public formularies, creates a significant risk that corrupt payments will infect the process…In the pharmaceutical context, we have additional expertise that significantly enhances our ability to proactively investigate and prosecute these often complex cases… "

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Challenges

- Healthcare professionals (HCPs), pharmacists, etc. as foreign public officials
- Other foreign public officials, e.g. health ministers, customs officials, lab technicians, other politicians and decision makers
- 3rd Parties interacting with foreign public officials

- Ongoing / historical relationships

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Interactions with HCPs

- Advisory Boards
- Clinical Trials
- Lunch / Dinner
- Product launches
- Conferences / Continuing Medical Education
- Ghost writing
- Grants
- Scholarships
- Donations
- Speaking engagements
- Consulting agreements
- Sales rep 1:1 discussions
  - gifts, gadgets, etc.
  - product information

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Interactions with Others

- Patient Groups / Organisations
- Politicians / Ministers
- “Think Tank” Groups
- Government / Regulatory Consultants
- Industry Body Representatives
- Decision Makers
  - Pricing
  - Reimbursement
  - Pharmacoeconomics, e.g. NICE in UK
  - Formularies
  - Payers

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Third Parties

- Distributors / Wholesalers
- Sales Agents
- Import Agents
- Export Agents
- Customs Agents
- Regulatory Consultants
- Contract Manufacturers
- Co-promotion Partners
- Travel Agents
- Conference Organisers
- Contract Sales Organisations
- Contract Research Organisations
- Market Research Consultants
- Continuing Medical Education (CME) Providers

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Anti-Corruption Compliance

- Develop and implement clear anti-corruption policies and procedures, including third party interactions and due diligence
- Ensure **all** staff are adequately trained (not just reps)
- Ensure third parties are adequately trained and contractually bound to comply with your anti-corruption policy (or theirs if sufficiently similar to yours)
- Actively manage third party relationships, including audits
- Conduct effective internal monitoring and auditing

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Warning Signs to Look For

- Cash payments of any kind
- Third party fees above the “norm” (even as little as 1%)
- Few influential HCPs receiving higher than average payments
- Inadequate documentation of payments to HCPs
- Expensive lunches, dinners, drinks with HCPs / public officials
- Single supplier used for key supplies to reps
- Expensive gifts / reps able to purchase items to give to HCPs
- Inadequate recording and management of medical samples
- Sudden increases in sales for a particular territory / region / country

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Bribery and Corruption Summary

- Understand potential abuse areas, both internal and external
- Manage financial relationships well (follow the money!)
- Think about how your company rewards its staff, especially bonus payments
- Think about what opportunities might arise for people to abuse the system, both internal and external
- Manage third party relationships appropriately, and use your audit rights!

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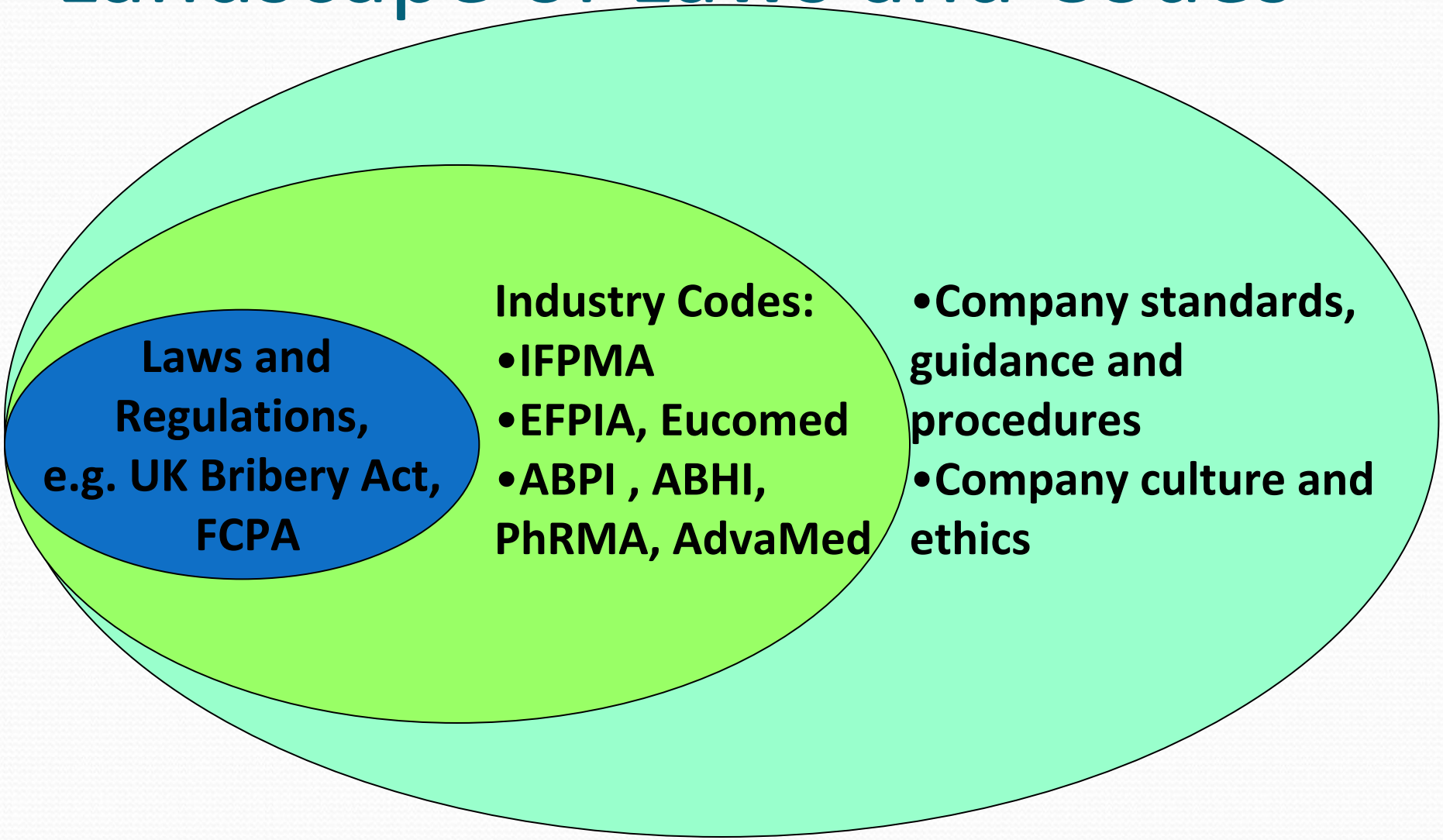
Landscape of Laws and Codes



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Landscape of Laws and Codes

- Complex and growing regulatory framework
  - EU Directives and Regulations
  - National laws and regulations, e.g. to implement EU Directives
  - IFPMA
  - EFPIA
  - Local industry body codes

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EU Regulations

- Immediately applicable in all member states
- 726/2004 (Authorisation and Supervision of Medicines)
- 488/2012 (Financial Penalties)
- 1901/2006 (Medicines for Paediatric Use)
- 1394/2007 (Advanced Therapy Medicines)
- 1647/2003 amending 2309/93 (Authorisation Precodeures)

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EU Directives

- State what must be achieved and by when member states must implement local laws
- 2001/83/EC (Medicinal Products for Human Use)
  - amended by 2002/98/EC, 2003/63/EC, 2004/24/EC, 2004/27/EC, Regulation 1901/2006, Regulation 1394/2007, 2008/29/EC, 2009/53/EC, 2009/120/EC, 2010/84/EU, 2011/62/EU, 2012/26/EU
- 2001/20/EC (Good Clinical Practices)
- 2003/94/EC (Good Manufacturing Practices)
- 2005/28/EC (GCP – Investigational Medicines)
- 2010/84/EU (Pharmacovigilance)
- 2011/62/EC (Prevention of Falsified Medicines)

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There is hope…

- Complex and growing regulatory framework
  - Changes recently introduced, e.g. UK Human Medicines Regulations 2012 has simplified UK law
  - Growing co-operation between EMA, FDA and others to simplify inspection regime and share information
  - Increased use of risk-based approaches by regulators has positive impact overall

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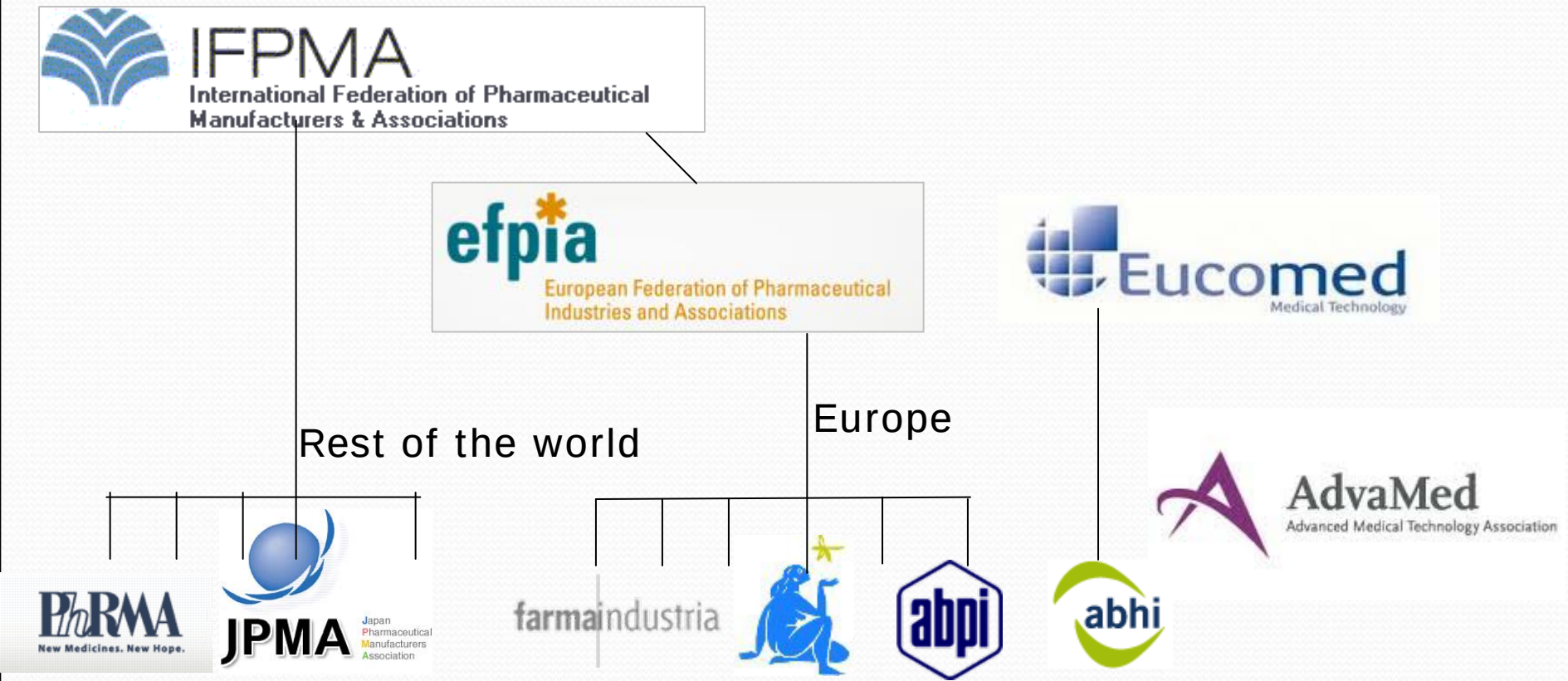
Alignment of international and national industry codes



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China Developments

- July 2007 Former SFDA Head executed for corruption
- May 2013 GSK cut prices in emerging markets to boost sales
- June 2013 GSK conducted internal enquiry into China corruption allegations – concluded allegations unfounded
- June 2013 GSK fired its head of R&D in China – misrepresentation of study results
- July 2013 Chinese authorities investigate GSK allegations and arrest senior local employees
- August 2013 other multi-nationals (Sanofi, Novartis, AZ, UCB, Eli Lilly, Novo Nordisk, Lundbeck, Bayer) brought into scope of Chinese corruption investigation
- August 2013 local companies also included in corruption probe
- August 2013 British adviser hired by GSK (Peter Humphrey of ChinaWhys) arrested in China for allegedly gathering information illegally
- September 2013 RDPAC recognises corruption as a "systemic challenge" in Chinese healthcare system
- September 2013 Chinese official ("Brother Watch") sentenced to 14 years in prison for corruption (not related to life science industry)

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Competition Law / Anti-trust

- EU Competition Law penalties include fines up to 10% of global turnover
- European Commission Pharmaceutical Sector Inquiry 2008/9 and further investigations 2012/3
- EU Director General Competition issued brochure "Compliance Matters"* for antitrust programmes
- Pay-for-delay allegations still appearing

*Available at http://ec.europa.eu/competition/antitrust/compliance/

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Third Party Oversight

- Risk based approach
  - What are the third parties doing on your behalf?
  - What are the risks involved in those activities?
  - How could you mitigate those risks?
  - What has already been done to mitigate those risks?
- Some suggestions
  - Have clear, written rules for third parties, depending on what they do for you
  - Include auditing rights in contracts and use them
  - Check training records and training effectiveness

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Off-Label Promotion

Higher risk areas include:

- Scientific discussions where a healthcare professional may express views about using your product for an unapproved use – especially if speaking for your company
- Distribution of journal papers about using products for unapproved uses – pay attention to circulation methods
- Reps (internal and third party) who may not fully understand the limits of the label – mitigated by training
- Promotional materials and advertisements – ensure these go through a rigorous review process

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Transparency Requirements

- French Sunshine
- EFPIA and local industry codes now include requirements for transparency relating to:
  - Payments to physicians / healthcare professionals (HCPs)
  - Sponsorship to attend conferences
  - Support for Patient Organisations
  - Results of Non-Interventional Studies

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Use of Social Media

- Growing trend in many industries to use Social Media
- Guidance from industry bodies still being developed
- Understand the “risk appetite” of your company
- Write a pragmatic Social Media policy based on current guidance and future risk
- Ensure employees understand where to draw the line between personal and professional posts on Social Media

- Remember – if it’s not normally allowed, it won’t be allowed via Social Media

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Summary of Recent CIAs

Retta Riordan

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PHARMACEUTICAL MANUFACTURER SETTLEMENTS I

COMPANY	Year	$M	Kickbacks	False Claims	Samples	Off-Label Promotion	Pricing	Unapproved Ineffective	Manufac-turing
TAP	2001	875	X	X	X				
Bayer I	2001	14		X			X		
Pfizer I	2002	49					X		
AstraZeneca I	2003	600	X		X				
Bayer II	2003	257					X		
GSK I	2003	87.6					X		
Pfizer II	2004	430		X		X			
Schering I	2004	345					X		
Serono I	2005	704	X			X			
King I	2005	124					X		
Eli Lilly I	2005	36				X			
Schering II	2006	435	X	X		X	X		
Intermune	2006	36				X			
Pfizer III	2007	34.7	X			X			
Cell Therapeutics	2007	10.5	X	X		X			
Purdue	2007	634.5				X			
Medicis	2007	9.8		X		X			
Jazz	2007	20		X		X			
Sanofi-Aventis I	2007	190	X	X					

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PHARMACEUTICAL MANUFACTURER SETTLEMENTS 2

COMPANY	Year	$M	Kickbacks	False Claims	Samples	Off-Label Promotion	Pricing	Unapproved Ineffective	Manufac-turing
BMS	2007	515	X	X		X	X		
Merck I	2008	650	X	X			X		
Otsuka	2008	4		X		X			
Biovail	2008	22	X						
Cephalon	2008	425		X		X			
Eli Lilly II	2009	1400		X		X			
Sanofi-Aventis II	2009	95.5		X				X	
Pfizer IV	2009	2300	X	X		X			
Novartis I (Eon)	2010	3.5		X				X	
Schwarz	2010	22		X				X	
King II (Alpharma)	2010	42.5	X	X					
AstraZeneca II	2010	520	X	X		X			
J&J I-Ortho-McNeil	2010	81		X		X			
Novartis II -Vaccines	2010	72		X		X			
Allergan	2010	600		X		X			
Forest	2010	313	X	X		X		X	

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PHARMACEUTICAL MANUFACTURER SETTLEMENTS 3

COMPANY	Year	$M	Kickbacks	False Claims	Samples	Off-Label Promotion	Pricing	Unapproved Ineffective	Manufac-turing
Novartis III	2010	422	X	X		X			
Abbott I	2010	126.5		X					
Roxane	2010	280		X					
B.Braun	2010	14.7		X					
Abbott II (Kos)	2010	41	X	X		X			
Eisai	2010	11		X		X			
Elan	2010	203.5	X	X		X			
Dey	2010	280		X					
GSK II	2010	750		X					X
Serono II	2011	44	X	X					
UCB	2011	35		X		X			
Novo Nordisk	2011	25		X		X			
Genentech	2011	20	X	X		X			
KV Pharma (Ethex)	2011	28					X		X
Pfizer V	2011	14.5		X		X			
GE Healthcare (Amersham)	2011	30		X			X		
J&J II (Scios)	2011	85		X		X			

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PHARMACEUTICAL MANUFACTURER SETTLEMENTS 4

COMPANY	Year	$M	Kickbacks	False Claims	Samples	Off-Label Promotion	Pricing	Unapproved Ineffective	Manufac-turing
Dava	2012	11		X			X		
Merck II	2012	950		X		X			
Cypress	2012	2.8		X					
Abbott III	2012	1500	X	X		X			
GSK III	2012	3000	X	X		X	X		
Boehringer Ingelheim	2012	95	X	X		X			
Pfizer VI	2012	55				X			
Amgen	2012	762	X	X		X	X		
Sanofi-aventis III	2012	109	X	X	X		X		
Victory	2012	11.4	X	X					
Par	2013	45		X		X			
Ranbaxy	2013	500		X					X
ISTA (B&L)	2013	33.5	X	X		X			
Pfizer VII	2013	490.9		X		X			

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MEDICAL DEVICE MANUFACTURER SETTLEMENTS I

COMPANY	Year	$M	Kickbacks	False Claims	Off-Label Promotion	Adverse Events	Other
Boston Scientific (Guidant) I	2003	94				X	
Orthofix I	2003	1.6		X	X		
Medtronic	2006	40	X				
Adv Neuromodulation Systems	2007	3					
Zimmer Inc.	2007	169.5	X				
Depuy Orthopaedics	2007	84.7	X				
Smith & Nephew Inc.	2007	28.9	X				
Biomet Orthopedics	2007	26.9	X				
Stryker Orthopedics	2007	0	X				
AbTox (went to trial)	2008	17			X	X	
Medtronic Spine	2008	75		X			
RJL Sciences	2008	.005		X	X		
Bayer	2008	97.5	X				
Neurometrix	2009	3.7	X	X			
Endoscopic	2009	1	X	X	X		
Quest Diagnostics	2009	302		X			X
Spectranetics	2009	5.0		X	X		X
Boston Scientific (Guidant) II	2009	22	X				

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MEDICAL DEVICE MANUFACTURER SETTLEMENTS 2

COMPANY	Year	$M	Kickbacks	False Claims	Off-Label Promotion	Adverse Events	Other
St. Jude I	2010	3.9	X	X			
Cochlear Americas	2010	.880	X	X			
AtriCure	2010	3.8	X	X	X		
Synthes	2010	23.2		X	X	X	X
Wright Medical	2010	7.9	X				
Exactech	2010	3	X				
Boston Scientific (Guidant) III	2011	296				X	
Boston Scientific (Guidant) IV	2011	9		X			
St. Jude II	2011	16	X				
Medtronic II	2011	23.5	X	X			
Hill-Rom	2011	41.8		X			
Globus	2012	1			X		
Stryker II	2012	15			X	X	
Orthofix II	2012	42	X	X			
Baxano (TranS1)	2013	6	X	X	X		

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7 Elements of an Effective Compliance Program

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OIG's "Seven Elements"*

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. Take disciplinary actions
7. Conduct investigations and take corrective actions

OIG Compliance Program Guidance for Pharmaceutical Manufacturers (April 2003)
http://www.oig.hhs.gov/compliance/compliance-guidance/index.asp

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Seven Elements Overview

- U.S. Federal Sentencing Guidelines ("USFSG")
  - USFSG defines an "Effective Compliance and Ethics Program" as "a program designed to prevent and detect criminal conduct"
  - 7 minimum criteria for an Effective Compliance and Ethics Program:
    1. Standards and procedures
    2. Compliance infrastructure and oversight
    3. Background checks
    4. Training and other communication
    5. Monitoring and auditing; compliance hotline and publication
    6. Appropriate incentives and disciplinary action
    7. Corrective action

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Seven Elements Overview

- OIG Compliance Program Guidance for Pharmaceutical Manufacturers
  - ". . . 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 . . . "
  - 7 elements "fundamental" to an Effective Compliance Program:
    1. Implementing written policies and procedures
    2. Designating a compliance officer and compliance committee
    3. Conducting effective training and education
    4. Developing effective lines of communication
    5. Conducting internal monitoring and auditing
    6. Enforcing standards through well-publicized disciplinary guidelines
    7. Responding promptly to detected problems and undertaking corrective action

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Policies and Procedures

1. Written Standards, Policies and/or Procedures
   - Corporate Code of Conduct with general principles regarding compliance and ethics
   - Written standards to guide an employee in the performance of duties related to compliance risk areas:

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Compliance Officer / Committee

2. Compliance Officer and Compliance Committee
   - CO should be high-level employee with direct access to Board, CEO and other senior management
     - "OIG believes it is generally 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
       - Maintain a system of checks and balances
     - Responsible for the implementation and day-to-day compliance activities
     - Sufficient funding, resources and staff
   - Compliance Committee should be a cross-functional task force
     - Should serve as an extension of compliance officer for oversight
   - Board of Directors oversight

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Training and Education

- Training should cover employees and contractors, where appropriate
  - Independent contractors and agents should be made aware of the company's compliance program
- New employees should receive training soon after they start
- All employees should be required to complete certain training hours
- Participation in training should be a condition of employment
- Training should cover compliance program policies and procedures, applicable laws, risk areas addressed in industry guidance or settlements, issues identified in auditing and monitoring
- CO should maintain records of all training

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Lines of Communication

- Clarify that talking with line managers, HR, and / or legal is the preferred route to report / discuss problems
- Be accessible (e.g. via newsletters, intranet) and communicate openly with employees
- Maintain an anonymous “hotline” to report issues (where this is allowed by local laws)
- Enforce a non-retaliation policy for employees who report potential problems
- Communicate directly with the Board - regular briefings
- Use surveys or other tools to get feedback on compliance programme effectiveness

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Monitoring and Auditing

- Understand the differences between auditing and monitoring, and do both!
- Identify key risks and how you would know if they occurred (i.e. what you should check)
- Create monitoring schedules and an audit plan based on those key risks
- Regularly re-evaluate monitoring schedules and audit plan
- Find out what others are doing - use networking and other resources
- Look at root causes, as well as at what happened
- Create corrective action plans to fix problems

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Disciplinary Actions

- Take appropriate disciplinary action against employees who violate laws and policies and procedures
  - Remember: Applies to contractors , too
- Do not hire or retain individuals or entities excluded or debarred
  - Check databases
    - FDA Debarment List:

http://www.fda.gov/ICECI/EnforcementActions/FDADebarmentList

    - OIG List of Excluded Individuals/Entities:

http://oig.hhs.gov/exclusions

    - System for Award Management (formerly General Services Administration List of Parties Excluded):

http://www.sam.gov

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Investigations

- *When?* Conduct an investigation whenever a question of conduct is raised
- *How:* Ensure Investigation is thorough and complete
- *Who?* Assign appropriate person to conduct the investigation:
  - Subject matter expert, skills, level
- *Results?* Close out the investigation
- *Then what?* Take corrective actions

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Corrective Action Plan

- What prompts a corrective action plan?
  - Investigations
  - Monitoring
  - Hot Line/Anonymous Tip/Open Discussion
- If a problem arises
  - Stop the hemorrhaging first!
  - Conduct Root Cause Analysis to determine what the cause of the problem was:
    - Systemic?
    - Individual?
  - Promptly Correct Problem
    - If systemic, develop/revise policies & procedures, training materials
    - If individual, take appropriate personnel action
  - Revisit issue to ensure it has been corrected
  - Report the offense to the government, when appropriate circumstances

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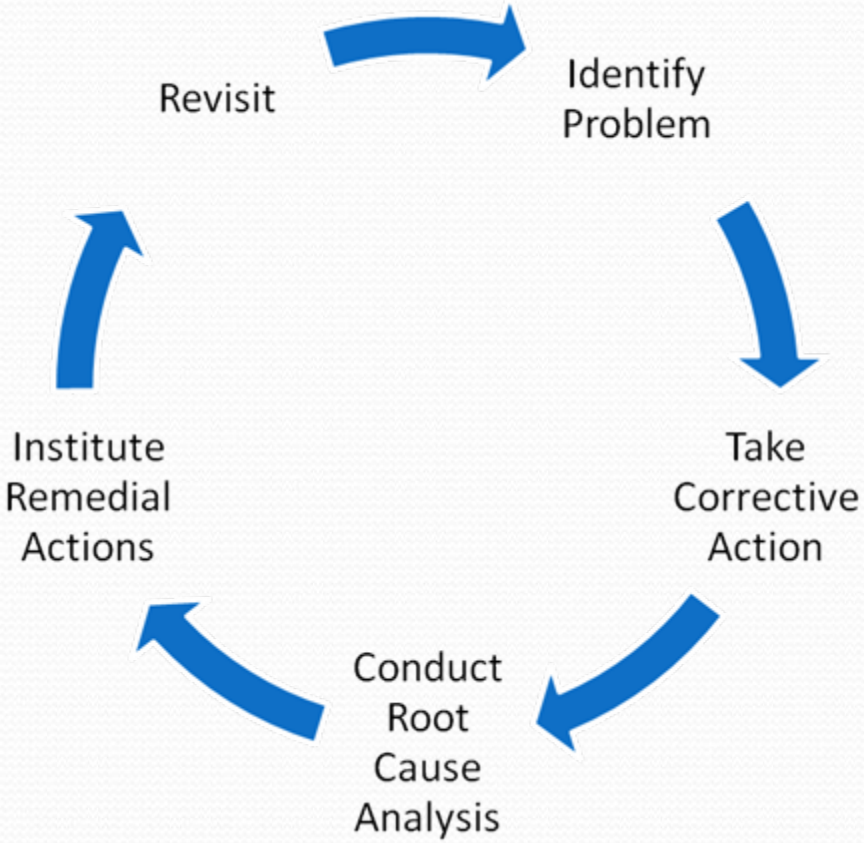
Remedial Steps



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CIAs—Evolution and Trends

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Evolution of CIA Provisions

In the beginning . . .

- CCO/Compliance Committee
- Written Standards
- Training
- Arrangements Database
- IRO
- Disclosure program (including hotline)
- Screening
- Notifications

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CIA Provisions 2

Then Came . . .

- Independence of CCO
- Needs Assessment: consulting services
- Board Oversight
- Senior Manager Certification
- Notification to HCPs
- Website Postings: payments to HCPs
- Website Postings: Research/Clinical Studies
- Inquiries Database
- Monitoring-Promo
- Monitoring—Non-Promo
- Post-marketing Commitments
- Consultant Monitoring

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CIA Provisions 3

And then . . .

- Needs Assessments: Research
- Needs Assessment: Publications
- Publications Monitoring
- Grants Monitoring
- Compliance Expert
- Website Posting: Med Ed Grants
- Compliance with ICMJE Standards
- Disclosures for Formulary Committee Members
- Claw-back provisions
- Rep compensation?

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Recidivism

"Among the factors we considered in calibrating this severe punishment was Pfizer's recidivism."

--Michael Loucks, acting US attorney for the Massachusetts District, who prosecuted the case, at the press conference announcing the settlement

- Companies with multiple CIAs

Pfizer 7
GSK 3
Novartis 3
Bayer 2
AstraZeneca 2
Schering-Plough 2
Lilly 2
Sanofi-aventis 2
Merck 2
King 2
J&J 2
Abbott 2
Serono 2

- Dilemma for Prosecutors

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Individual Liability

- **TAP**: 11 individuals (employees and physicians) indicted (dismissed and acquitted)
- **Serono**: Med. Dir. pled guilty (1 year probation; fined $150,000); VP Sales, VP Marketing, 2 RDs acquitted
- **Purdue**: Pres & COO ($19M), EVP & GC ($8M), and Exec. VP Worldwide R&D ($7.5M) (pled guilty; 12 year exclusions; $500,000 criminal fine; 3 years probation; 400 hours community service. 7/27/12: exclusion upheld, but length = arbitrary and capricious; remanded to dist. ct.)
- **Jazz**: Physician Speaker (arrested, pled guilty to misdemeanor); Rep (convicted of misdemeanor), Rep (pled guilty to felony)
- **RJL**: President (3 years' probation, $10,000 fine)
- **Abtox**: CEO and VP & Chief Compliance Officer (sentenced 10 and 6 years, respectively; plus $17M in restitution to customers)
- **Pfizer**: Sales Mgr (sentenced 6 months' home confinement and electronic monitoring, 3 years' probation); Regional Mgr ($75,000 fine and 24 months' probation)
- **Stryker**: Pres charged, charges dropped; 4 Reps pled guilty; reg sales mgr, natl sales rep, and ex-natl rep charged, charges dropped
- **InterMune**: CEO convicted, sentenced to 3 years' probation, 6 months of home confinement, $20K, 200 hrs comm. service. Conviction upheld. 5 year exclusion. Med license revoked
- **Synthes**: Pres Synthes North America (9 mos jail, $100,000 fine); Pres Synthes Spine (9 mos jail, $100,000 fine); VP Ops (8 mos jail, $100,000 fine); Dir Regulatory and Clinical Affairs (5 mos jail, $100,000)
- **Glaxo:** VP/Assoc GC (indicted on obstruction; indictment dismissed; re-indicted; acquitted)

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Individual Liability 2

- **ExacTech:** Sales Director (5 years' probation, $56K in fines after pleading guilty to 1 criminal count for falsifying surgeons' activities for kickback payments)
- **Spectranetics:** Pres and 3 indvls indicted. Pres convicted on 1 count (lying), acquitted on 11 counts, 1 yr probation, 100 hrs community service; 1 indvl acquitted on all counts. 1 pled guilty (sentencing pending); another indvl awaits trial
- **KV Pharmaceutical:** CEO and Board Chmn (pled guilty; excluded, sentenced to 17 days in jail, fined $1M and forfeited $900,000)
- **Forest:** Chairman, Chief Executive Officer, and President recd exclusion notification, rescinded
- **Wright Medical:** Pres, CEO resigned; CTO fired; GC, SVP EMEA Comm. Ops, VP Clin & Reg Aff resigned
- **OrthoFix:** (1) VP Sales convicted (kickbacks), 8 months' jail, $50,000 fine and forfeiture. (2) Rep pled guilty (fraud), 2 yrs probation, including 5 mos' home detention, $40,000 forfeiture, $4,000 fine. (3) RD pled guilty (perjury to grand jury), 1 yr probation, including 3 mos' home detention, $2,000 fine. (4) Rep pled guilty to falsifying patient medical records: 1 yr probation (first 3 mos home confinement), $10,000 forfeiture, $3,000 fine. (5) Rep pled guilty (fraud), 1 yr probation, fine. (6) pled guilty to healthcare fraud and KBs. Sentencing scheduled 8/9/13. (7) Physician's assistant pled guilty (accepting kickbacks), 6 mos prison, 6 mos home confinement, $10,000 forfeiture and $3,000 fine. (8) Physician: Plea agreement (perjury before grand jury)
- **Glaxo:** Senior execs: Clawback provision
- **Par:** Senior execs: Clawback provision
- **Globus:** CEO $450,000 penalty
- **Sanofi**: Rep/DM excluded for 5 years

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Individual Responsibility

- Board Members
  - Review and oversight of companies' compliance programs
  - Certification to their effectiveness
    - Includes "reasonable inquiry" into effectiveness
  - Quarterly meetings
  - Compliance Expert
  - Annual Work Plans
- Senior Executives
  - Responsible for the compliance issues in their domains
  - Monitor and oversee activities
  - Provide certifications
    - Trained on and understand relevant compliance responsibilities
    - "To best of my knowledge" certification that the domain is compliant
  - Clawback Provisions
- Compliance Officer
  - Develop and implement policies, procedures, and practices
  - Responsible for monitoring the day-to-day compliance activities
  - Member of senior management
  - Report directly to the Chief Executive
  - Make periodic (at least quarterly) reports regarding compliance matters directly to BOD
  - Not be the GC or CFO, or be subordinate to either

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GlaxoSmithKline III (2012)

- **$3 BILLION**
- Government's Allegations:
  - From 1999-2010, GSK engaged in a fraudulent scheme involving
    - repeatedly publishing and promoting false and misleading accounts of studies and treatment guidelines to convince physicians to use GSK drugs
    - misrepresenting clinical evidence, downplaying or ignoring safety risks, and failing to disclose the rejection by FDA of some of the claims GSK was making to physicians
    - promoting products for off-label uses
    - using a wide variety of gifts, payments and other forms of remuneration to induce physicians to prescribe GSK's drugs, including trips to Bermuda and Jamaica, spa treatments and hunting trips, and sham consulting fees
- Products:
  - Paxil: Off-label promotion for children and adolescents
  - Wellbutrin SR: Off-label promotion, kickbacks, and false claims
  - Advair: Off-label promotion, kickbacks, and false claims
- 5 year CIA with novel provisions

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GSK's CIA

- Entered into 5 year CIA
- Maintenance of Compliance Officer and Compliance Committee (chaired by GSK President); Dep. COs, Integrity Champions
- Board of Directors to oversee Compliance Program, evaluate effectiveness, adopt a resolution concluding GSK has implemented an effective Compliance Program
- Management accountability and certifications
  - President, heads of US pharma commercial business units, R&D Chairman, and various VPs of business units must certify that they have "been trained on and understand the compliance requirements responsibilities as they relate to" their functional areas, and certify that "to the best of my knowledge [this department] is in compliance with all applicable Federal health care program requirements, FDA requirements, and the obligations of the CIA."
- Training, including training for management and the Board, with certifications
- Risk Assessment and Mitigation Process (TRACER)
- IRO Review
- Disclosures, including Integrity Helpline, non-retribution, non-retaliation, anonymous, disclosure log
- Screening of Ineligible persons
- Notification Requirement of legal proceeding or investigation
- Notification of Communications with FDA
- Notices to HCPs, HCEs, payers

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GSK's CIA 2

- Field Force Monitoring Program
  - Speaker Programs, field observations of reps
- Non-Promotional Monitoring
  - Consulting arrangements
  - Research
  - Publications
  - Med Ed Grants
- Physician Payment Transparency Program
  - Continue website posting of physician payments for speaking and consulting fees
  - Report cumulative value of payments to each physician quarterly and annually
  - Include all "payments or other transfers of value," as defined in Sunshine Act
  - Other postings
    - Grants
    - Charitable Contributions
    - Requirement that consultants comply fully with applicable disclosure obligations re formulary or P&T committee affiliations
    - Post-marketing commitments

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GSK's CIA 3

Requires policies & procedures in the following areas

- Code of Conduct
- Promotional and product-related activities, e.g., anti-kickback statute and False Claims Act
- Adherence to FDA promotional requirements
- Appropriate ways to conduct payer related functions
- How promotional material, information may be distributed, particularly relating to responses to off-label inquiries
- How reps must respond to off-label requests (must send to Medical Affairs)
- How responses to off-label inquiries may be answered, including appropriate materials and information
- Maintenance of an Inquiries Database to track inquiries
- Materials that may be distributed via social media or via DTC advertising
- Role of medical personnel in meetings with HCPs/HCIs
- Development of target plans for sales personnel to ensure appropriate promotion
- Samples distribution plan
- Consulting arrangements with HCPs (legitimate purposes)
- Use of HCPs to train sales force
- Grants and charitable contributions
- Third party educational funding, sponsorships (no independent med ed companies)
- Promotional materials review
- Financial incentives for all Covered Employees (eliminated territory/individual level sales goals for reps)
- Recoupment or forfeiture of annual performance pay of employees and Covered Execs due to triggering events relating to misconduct by them
- Submission to compendia for coverage of GSK drugs
- Sponsorship of Research including post-marketing clinical trails and post-marketing studies)
- Posting of study results and protocols/registration of studies (including on www.clinicaltrials.gov)
- Publication of clinical trial results
- Reporting of adverse events to FDA
- Authorship requirements

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GSK's CIA: Novel Provisions

- Employee and Executive Incentive Compensation and Recoupment Policies and Practice
  - Patient First Program:
    - No financial rewards or discipline of its sales reps or direct managers based upon volume of sales in rep's or mgr's territory
    - Evaluations based on business acumen, customer engagement, scientific knowledge of products
  - Executives
    - Financial recoupment program: puts at risk forfeiture and recoupment of up to 3 years of annual performance pay (annual bonus, long term incentives) for an exec who is discovered to have been involved in any significant misconduct
    - Applies to current executives or former executives at time of recoupment determination

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GSK's CIA: Novel Provisions 2

- Created a mini-CIA for Manufacturing
  - Separate CCO for global manufacturing and supply (GMS) to develop P&Ps re cGMPs
  - GMS CO to annually certify compliance
  - Development of compliance committee
  - Board to oversee cGMP activities
  - Training
  - Reporting of "manufacturing reportable events" e.g., significant violations of laws re cGMPs
- Clinical Activities
  - Requires steps to ensure full, fair and accurate reporting of scientific data
- Social Media: Development of P&Ps to govern distribution of information via social media, DTC
- Notices: to Payors
- Additional Compliance Personnel: Deputy COs and integrity champions

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Case Study Conclusion

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Acronyms

- ABPI: Association of British Pharmaceutical Industry
- ACCME: Accreditation Council for Continuing Medical Education
- AMA: American Medical Association
- BOD: Board of Directors
- CBER: FDA's Center for Biologics Evaluation and Research
- CCO: Chief Compliance Officer or Corporate Compliance Officer
- CDER: FDA's Center for Drug Evaluation and Research
- CFO: Chief Financial Officer
- cGMP: Current Good Manufacturing Practices
- CIA: Corporate Integrity Agreement
- CME: Continuing Medical Education
- CO: Compliance Officer
- DDMAC: Division of Drug Marketing, Advertising & Communications (now, OPDP)
- DOJ: Department of Justice
- DTC: Direct to Consumer Advertising
- EFPIA: European Federation of Pharmaceutical Industries and Associations
- FDA: Food and Drug Administration
- FDAAA: Food and Drug Administration Amendments Act
- FDASIA: Food & Drug Administration Safety and Innovation Act
- FCPA: Foreign Corrupt Practices Act
- FDCA: Food, Drug & Cosmetic Act

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Acronyms 2

- FTC: Federal Trade Commission
- GC: General Counsel
- GCP: Good Clinical Practices
- GDP: Good Distribution Practices
- GLP: Good Laboratory Practices
- GMP: Good Manufacturing Practices (see also cGMP)
- GxP: Short form encompassing GCP, GDP, GLP and GMP
- HCE/I/P: Healthcare Entity/Institution/Professional
- HHS: Department of Health & Human Services
- HIPAA: Health Insurance Portability & Accountability Act
- IFPMA International Federation of Pharmaceutical Manufacturers & Associations
- IRB: Institutional Review Board
- IRO: Independent Review Organization
- MAH: Marketing Authorisation Holder
- OIG: HHS Office of Inspector General
- OPDP: Office of Prescription Drug Promotion (formerly DDMAC)
- PDMA: Prescription Drug Marketing Act
- PI: Principal Investigator; Product Insert
- PIL: Patient Information Leaflet
- PMCPA: Prescription Medicines Code of Practice Authority
- PPACA: Patient Protection and Affordable Care Act
- REMS: Risk Evaluation and Mitigation Strategy
- SFO: UK Serious Fraud Office
- SmPC or SPC: Summary of Product Characteristics
- UKBA: United Kingdom Bribery Act (2010)

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Resources

- **FDA**: http://www.fda.gov
  - Email Updates: http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/GetEmailUpdates/default.htm
  - FDASIA: http://www.gpo.gov/fdsys/pkg/PLAW-112publ144/pdf/PLAW-112publ144.pdf
  - FDASIA tracker: http://www.fda.gov/AboutFDA/Transparency/track/ucm328907.htm
  - FDA Warning Letters, Notices of Violations: http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/WarningLettersandNoticeofViolationLetterstoPharmaceuticalCompanies/default.htm
  - Sentinel Initiative: http://www.fda.gov/Safety/FDAsSentinelInitiative/ucm2007250.htm
  - Q&A on Opioid shared REMS: http://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm309742.htm
  - FDA Guidances: http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm
    - FDA Guidance for Industry - Good Reprint Practices for the Distribution of Medical Journal Articles and Medical or Scientific Reference Publications on Unapproved New Uses of Approved Drugs and Approved or Cleared Medical Devices. Department of Health and Human Services, Food and Drug Administration, Office of the Commissioner, Office of Policy (January 2009) http://www.fda.gov/RegulatoryInformation/Guidances/ucm125126.htm
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    - Guidance for Industry - Format and Content of Proposed Risk Evaluation and Mitigation Strategies (REMS), REMS Assessments, and Proposed REMS Modifications, http://www.fda.gov/downloads/Drugs/Guidances/UCM184128.pdf (Sept 2009)
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  - REMS Draft Guidance: http://www.fda.gov/downloads/Drugs/Guidances/UCM184128.pdf

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  - CIAs: http://www.oig.hhs.gov/fraud/cias.asp
  - Advisory Opinions: http://www.oig.hhs.gov/fraud/advisoryopinions.asp
  - Fraud Alerts: http://www.oig.hhs.gov/fraud/fraudalerts.asp
  - OIG Work Plans: http://www.oig.hhs.gov/publications/workplan.asp
  - OIG Semi-annual Reports: http://www.oig.hhs.gov/publications/semiannual.asp
  - OIG Mailing List: http://www.oig.hhs.gov/mailinglist.asp
- **GSK Resources**
  - CIA: https://oig.hhs.gov/fraud/cia/agreements/GlaxoSmithKline_LLC_06282012.pdf
  - GSK Settlement Documents, including DOJ Press Release: http://www.justice.gov/opa/gsk-docs.html
- **Pfizer Resources**
  - CIA: http://www.oig.hhs.gov/fraud/cia/agreements/pfizer_inc.pdf
  - Pfizer Settlement Documents, including DOJ Press Release: http://www.usdoj.gov/usao/ma/Pfizer.html
  - DOJ/HHS Pfizer Fact Sheet: http://www.stopmedicarefraud.gov/pfizerfactsheet.html
- **Sunshine Act Information**
  - Home page: http://www.cms.gov/Regulations-and-Guidance/Legislation/National-Physician-Payment-Transparency-Program/index.html
  - Final Rule: http://www.cms.gov/Regulations-and-Guidance/Legislation/National-Physician-Payment-Transparency-Program/Downloads/Final-Rule.pdf
  - Mfr Fact Sheet: http://www.cms.gov/Regulations-and-Guidance/Legislation/National-Physician-Payment-Transparency-Program/Downloads/Applicable-Manufacturer-fact-sheet.pdf
  - FAQs: http://www.cms.gov/Regulations-and-Guidance/Legislation/National-Physician-Payment-Transparency-Program/FAQs-Subpage.html

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Resources 3

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  - Pharmaceutical Research and Manufacturers of America: PhRMA.org
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    - PhRMA Principles on Conduct of Clinical Trials, Communication of Clinical Trial Results: http://phrma.org/sites/default/files/pdf/042009_clinical_trial_principles_final_0.pdf
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