Twelfth Annual Pharmaceutical Regulatory and Compliance Congress

Pre-Conference I: The Legal Framework

Sean P. Fahey | November 2, 2011

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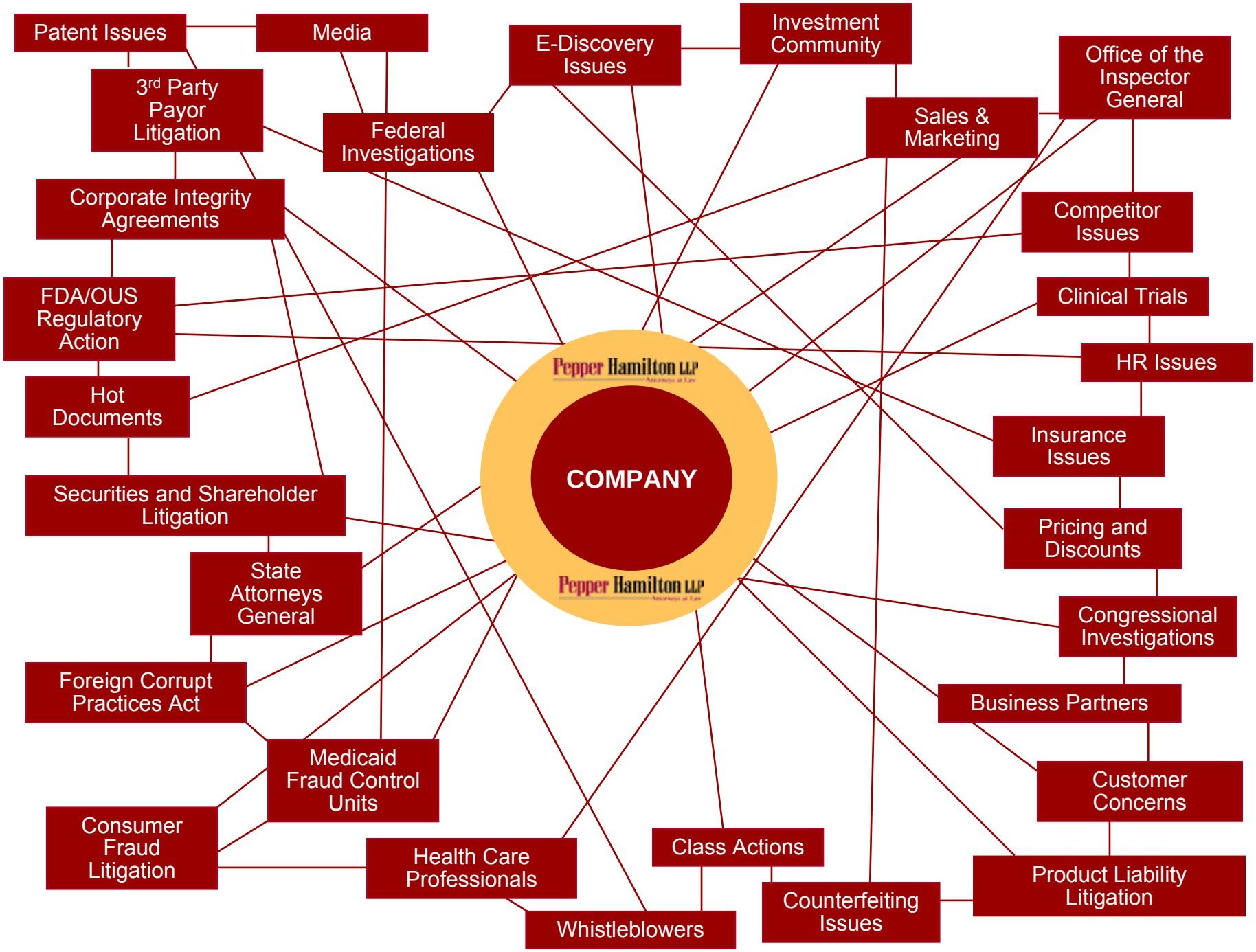
The Legal Framework

- Federal Food, Drug, and Cosmetic Act ("FDCA" or "FD&C Act"), 21 USC §§ 301 et seq.
  - OPDP
  - RCO or Park Doctrine
- False Claims Act ("FCA"), 31 U.S.C. §§ 3729-3733
- Anti-Kickback Statute ("AKS"), 42 U.S.C. §1320a-7b
- Physician Payment Sunshine Provision, § 1128G of Social Security Act, 42 U.S.C. 1301 et seq.
- The Foreign Corrupt Practices Act, 15 U.S.C. §§ 78dd-1, et seq. ("FCPA")
- Corporate Integrity Agreements


Patent Issues
Media
E-Discovery Issues
Investment Community
Office of the Inspector General
3rd Party Payor Litigation
Federal Investigations
Sales & Marketing
Corporate Integrity Agreements
Competitor Issues
FDA/OUS Regulatory Action
Clinical Trials
HR Issues
Hot Documents
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Insurance Issues
Securities and Shareholder Litigation
Pricing and Discounts
State Attorneys General
Congressional Investigations
Foreign Corrupt Practices Act
Business Partners
Medicaid Fraud Control Units
Customer Concerns
Consumer Fraud Litigation
Health Care Professionals
Class Actions
Product Liability Litigation
Counterfeiting Issues
Whistleblowers

FDCA

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FDCA

- FDCA, 21 USC §§ 301 et seq.
  - Passed by Congress in 1938 giving authority to FDA to oversee the safety of food, drugs, and cosmetics
  - Replaced the earlier Pure Food and Drug Act of 1906, following the death of more than 100 people after consumption of “Elixir Sulfanilamide“ in 1937
    - Company paid a minimum fine under the 1906 Act, which prohibited labeling the preparation an "elixir" when it had no alcohol in it

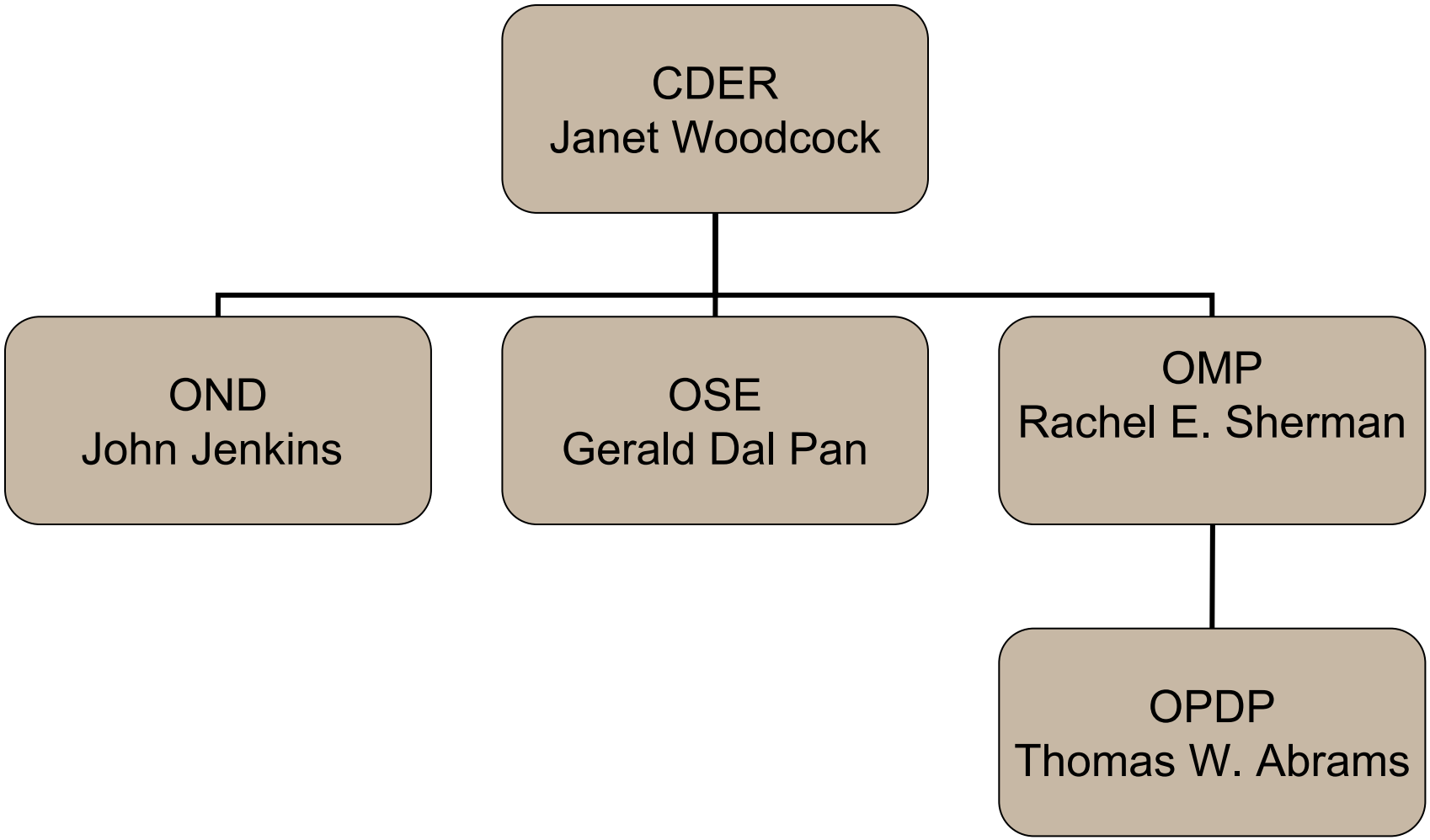
FDCA – Key Amendments

- Food and Drug Administration Modernization Act (FDAMA) of 1997
  - Permitted dissemination of peer-reviewed journal articles if certain conditions met; sunset in 2006
    - 2009 Guidance on Good Reprint Practices
- Food and Drug Administration Amendments Act (FDAAA) of 2007
  - Expansion of clinicaltrial.gov
  - FDA given increased power to regulate DTC ads and require post marketing studies, safety-related labeling changes and Risk Evaluation Mitigation Strategy (REMS) programs

FDA

- Center for Drug Evaluation and Research (CDER)
  - Office of New Drugs (OND)
    - Approves new medicines, ensures accurate labeling of medicines once approved
  - Office of Surveillance and Epidemiology (OSE)
    - Identify drug safety concerns and recommend actions to improve product safety and protect the public health
  - Office of Medical Policy (OMP)
    - Office of Prescription Drug Promotion (OPDP) - formerly Division of Drug Marketing, Advertising and Communications or DDMAC
      - Division of Professional Promotion (DPP), and the Division of Direct-to-Consumer Promotion (DDTCP)

CDER Organizational Chart



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FDCA

- Prohibited Acts - 21 U.S.C. § 331
  - misbranding
  - adulterated products
  - cGMP violations
  - many other things (a through nn)

FDCA

- All violations of the act are civil violations
- Repeated, intentional and fraudulent violations can also be criminal violations
- FDCA incorporates concepts of “strict liability” (through the Park doctrine)
- States using consumer protection actions to enforce FDCA (and PhRMA Code)

FDCA

- Penalties - 21 U.S.C. § 333
  - Injunctive relief
  - Seizure
  - Fines
  - Misdemeanor
  - Felony
    - Prior misdemeanor conviction
    - Intent to defraud or mislead
  - Exclusion (permissive or mandatory)

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OPDP

OPDP

- Mission
  - Assure information is truthful, balanced, and accurately communicated
  - Stop false and misleading advertising and promotion through surveillance, enforcement, and educational programs
- Implementation
  - Surveillance and enforcement
  - Advice to industry
  - Guidance and policy development

OPDP

- Some Key Regulations
  - 21 CFR 202.1 (Prescription drug advertisements)
  - 21 CFR 312.7 (Preapproval promotion)
  - 21 CFR 314.550, Subpart H, Accelerated Approval for Drugs (submission of promotional materials)
  - 21 CFR 314.81(b)(3) (submission at time of first use)

OPDP

- Prescription drug promotion
  - Must not be false or misleading
  - Must have fair balance
  - Must be consistent with the approved product labeling/package insert (PI)
  - Must only include claims substantiated by adequate and well-controlled clinical studies

OPDP - What They are Looking For

- Accurately communicate indication, including any limitations on the indication (patient population/concomitant therapies/efficacy)
- Communicate most important risks in a manner comparable to benefits (presentation and language)
- Do not omit important information
- Use plain language and communicate an accurate and balanced picture of the drug product

OPDP – Words to Avoid

- New
- Now approved
- Introducing
- Drug of choice
- Gold standard
- Standard of care
- Next-generation
- Novel
- Breakthrough
- Well-tolerated
- Only
- Rapid
- Faster
- More Potent
- Unique
- Preferred
- Convenient
- Easy
- Simple
- Targeted

OPDP – Types of Materials

- Pre-approval
  - OPDP usually considers pre-approval promotion to be violative
  - Exceptions:
    - *Institutional promotion* - state that company is conducting research in a therapeutic area to develop new/important drugs. May not mention any drug name.
    - *"Coming Soon" promotion* - announce the name of a new product that will soon become available. May not include written, verbal or graphic representations regarding safety, efficacy or use. Not available with boxed warning.
    - *Scientific Exchange*

OPDP – Types of Materials

- After approval:
  - Reminder Ads – mentions the pharmaceutical brand name, but not the indication or medical condition it treats. No balance required. Not available with boxed warning.
  - Disease Awareness – no mention of pharmaceutical brand name. No balance required.
  - Product Claims – must include information about the drug in "brief summary"
- Draft Guidance on Presentation of Risk Information, May 2009
- http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM155480.pcf

Off Label Guidance

What is "Off-Label"?

- Traditional definition: Uses for treatment of disease state and/or symptoms that are not indicated in the product's label.
- Broader definition:
  - Overstating safety claims
  - Drawing claims from clinical data that may be considered an overstatement
  - Dismissing certain warnings in the label
  - Comparative/superiority claims without H2H studies
  - Symptoms vs. disease states (expanding potential treatment population)
  - Dosing

Off Label Guidance

Condition	FDAMA Section 401	2009 Guidance
Drug approval	Information must concern a drug or device that has received FDA approval for some use.	Drug-approval status not mentioned.
Commitment to file a supplemental New Drug Application	Manufacturer must have submitted a supplemental New Drug Application for a proposed new use or completed required studies and certified that this application will be submitted within 6 months after initial dissemination (or within 36 months if supporting	Not mentioned; companies [are] encouraged to seek approval for new uses of a drug.
Advance provision to the FDA	Manufacturer must submit copy of article and other safety and efficacy information concerning unapproved use 60 days before dissemination.	Not mentioned
Source of underlying clinical data	Information must not be derived from another manufacturer's clinical research (unless [the] other manufacturer gives permission) and must be from "scientifically sound" clinical investigation.	Information should be based on adequate and well-controlled clinical investigations.
Accuracy	Information must not be false or misleading, must not involve inappropriate conclusions, and must not pose significant risk to public health if relied on. Company may need to include other safety and efficacy information to ensure objectivity and balance.	Information should be truthful and not misleading and should not pose a significant public health risk if relied on.

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Off Label Guidance

Condition	FDAMA Section 401	2009 Guidance
Provision of countervailing scientific findings	Information must be disseminated along with approved labeling and comprehensive bibliography of publications related to off-label use (including unfavorable studies) and other available information about risks of this use.	Information should be disseminated with approved labeling and comprehensive bibliography of publications related to off-label use, plus representative publications (if any) reaching conclusions regarding this use that are contrary or different.
Required disclosures	Must include prominent disclosure stating that use is not FDA-approved and identifying other products (if any) approved for that use.	Should include prominent disclosure statement regarding unapproved use that identifies study sponsors, discloses relevant financial interests, and mentions any known significant risks not discussed in the publication.
Presentation of journal article	Must provide entire, unabridged article or section of reference publication; no promotional materials may physically accompany it, and company representatives may not verbally promote the new use.	Should provide entire, unabridged article or reference. It should not be marked, highlighted, summarized, or characterized in any way.
Journal requirements	Information must be published in peer-reviewed scientific or medical journal (listed in *Index Medicus*) and must not have appeared in industry-funded special supplement or publication; unabridged reference texts may also be distributed (including non–peer-reviewed)	Information should be published by an organization with [an] editorial board that involves experts with demonstrated expertise in subject of article and objectively reviews proposed articles, adhering to standard peer-review procedures;

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Off Label Guidance

Condition	FDAMA Section 401	2009 Guidance
Distribution	Distribution must be limited to health care practitioners, pharmacy benefit managers, issuers of health insurance, group health plans, and federal and state agencies (no distribution to consumers).	Information should be provided separately from promotional information; distribution should be limited to health care practitioners and entities such as pharmacy benefit managers, health insurers, and government agencies (no distribution to consumers).
Other avenues of dissemination	Manufacturers may still disseminate information about off-label uses in response to unsolicited requests from health care practitioners.	Manufacturers may still disseminate information about off-label uses in response to unsolicited requests from health care practitioners.

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OPDP – 2011 Warning/Untitled Letters

Warning Letters

- Bromday – omission of risk information and dosing limitations; references prior WL for related compound
- Multikine – promotion of investigational compound prior to approval
- Vyvanse – magnet submitted through “Bad Ad” program; sales rep business card covered risk information

Untitled Letters

- Acanya
- Atelvia
- Chantix/Caduet/Norvasc - *references previous Untitled Letter regarding sponsored links*
- Focalin XR
- KRX-0401
- Mephyton Vitamin K1 Tablets
- Pexeva
- Solaraze
- Trisenox

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OPDP – 2011 Warning/Untitled Letters

- Omission/Minimization of Risk
- Unsubstantiated Claims
- Broadening of Indication
- Overstatement of Efficacy
- Omission of Material Facts
- Promotion of an Investigational Drug
- Misleading Claims (dosing, compliance)
- Failure to Submit Under Form FDA 2253

OPDP Resources

- OPDP Homepage
  - http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm
- Warning Letters/Untitled Letters (1997-2011)
  - http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/WarningLettersandNoticeofViolationLetterstoPharmaceuticalCompanies/default.htm
- Guidance Documents
  - http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm

RCO or Park Doctrine

The RCO Doctrine

- The “Responsible Corporate Officer” or “*Park*” Doctrine
- Employees can be held strictly liable for a corporate violation of a public welfare statute if they had the power, by virtue of their position, to prevent or correct the violation but failed to do so—*regardless of their awareness of the violation*

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The RCO Doctrine

- Doctrine developed in two Supreme Court cases:
  - *United States v. Dotterweich*, 320 U.S. 277 (1943)
  - *United States v. Park*, 421 U.S. 658 (1974)

"The prosecution…is based on a now familiar type of legislation whereby penalties serve as an effective means of regulation. Such legislation dispenses with the conventional requirement for criminal conduct—awareness of some wrongdoing. In the interest of the larger good, it puts the burden of acting at hazard upon a person otherwise innocent but standing in responsible relation to a public danger."

Dotterweich, 320 U.S. at 280-81; quoted in *Park*, 421 U.S. at 668-69.

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The RCO Doctrine

- 1960s-1980s: FDA requested DOJ to bring *Park* cases arising out of:
  - Persistent violations observed during successive FDA inspections that were not remedied despite FDA notice to the company; or
  - Instances where a regulatory violation caused injury to consumers or animals

The RCO Doctrine

- Fell into disuse:
  - Little DOJ interest in misdemeanors
    - Labor-intensive investigation
    - Small fines
  - Judges impatient with clogging up the courts with matters that should be handled by civil penalties

The RCO Doctrine

- Revived in ***Purdue Pharma*** case in 2007:
  - Government charged that Purdue falsely claimed that OxyContin was less addictive, less subject to abuse, and less likely to cause withdrawal symptoms that other pain medications
  - Company pleaded to felony misbranding with intent to defraud or mislead
  - CEO, GC and VP of Worldwide Medical Affairs each pleaded to a one-count misdemeanor
  - Disgorgement of $19M, $8M, $7.M, respectively; $5000 criminal fine, 3 years probation; 400 hours community service
  - In accepting plea, court noted absence of proof of knowledge

The RCO Doctrine

- Used again in 2010 in ***Synthes/Norian*** case:
  - Company charged with having conducted unauthorized clinical trials for off-label use of bone cement
  - Companies pleaded to conspiracy to impede functions of FDA, false statements, shipping misbranded/adulterated products
  - President, SVP, VP and Director of Regulatory pleaded guilty to misdemeanor violations
  - Synthes agreed to divestiture of Norian to avoid exclusion

The RCO Doctrine

- New Provision of FDA Regulatory Procedures Manual (February 2011) on “Recommending Park Doctrine Prosecutions”
  - Nonbinding, no different from usual criteria for deciding whether to prosecute, provide no illustrative examples
  - Relevant factors:
    - Whether violation involves actual or potential harm to the public
    - Whether the violation is obvious
    - Whether the violation reflects a pattern of illegal behavior and/or failure to heed prior warnings
    - Whether the violation is widespread
    - Whether the violation is serious
    - The quality of the legal and factual support for the prosecution
    - Whether the proposed prosecution is a prudent use of agency resources

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RCO Consistent With Crusade Against Individuals

Congress

"This prison time is critical as a deterrent…. This focus on ensuring real prison sentences must continue."

Senator Patrick Leahy, January 2011

"If potential fraudsters view the lenient sentences being handed down as merely the cost of doing business, efforts to combat fraud will be undermined."

Senator Chuck Grassley, January 2011

RCO Consistent With Crusade Against Individuals

FDA

"It's clear we're not getting the job done with large, monetary settlements…. Unless the government shows more resolve to criminally charge individuals at all levels in the company, we cannot expect to make progress in deterring off-label promotion."

Eric Blumberg, FDA Deputy Chief for Litigation, 10/14/2010

There will be an "increase in the appropriate use of misdemeanor prosecutions, a valuable enforcement tool, to hold responsible corporate officials accountable."

Letter from FDA Commissioner Hamburg to Sen. Grassley, 3/4/2010

RCO Consistent With Crusade Against Individuals

DHHS OIG

There "is definitely a renewed emphasis, maybe a new emphasis, on holding individuals accountable."

Robert DeConti, chief of OIG administrative and civil remedies branch, October 2010

"A better pressure point is to go after responsible employees. Law enforcement's focus over the next year will be on the individual...."

Lewis Morris, Chief Counsel to the Inspector General, February 2010

"We think there needs to be increased accountability for compliance both at the board level and at the level of individual managers within a company."

Mary Riordan, OIG Senior Counsel, October 2010

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RCO Consistent With Crusade Against Individuals

DOJ

"The department is intent on identifying and, where appropriate, prosecuting the individuals who are responsible for illegal off-label marketing…. Our emphasis is going to be much increased in this area."

Ann Ravel, Deputy Assistant Attorney General, October 2010

Prosecutors are "zealously fighting for jail time"…the average prison sentence in a health care fraud case is approximately 40 months.

Assistant Attorney General Lanny Breuer, January 2011

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False Claims Act

FCA

- False Claims Act ("FCA"), 31 U.S.C. §§ 3729-3733
  - Enacted in 1863, after contractors defrauded government during Civil War
  - FCA includes a "*qui tam*" provision that allows people ("whistleblowers") who are not affiliated with the government to file actions on behalf of the government
  - Key amendments in 1986, 2009 and 2010

FCA

- FCA establishes liability when any person or entity improperly receives from or avoids payment to the Federal government
- Prohibits:
  - Knowingly presenting, or causing to be presented a false 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 claim;
  - Conspiring to commit any violation of the FCA;
  - Knowingly making, using, or causing to be made or used a false record to avoid, or decrease an obligation to pay or transmit property to the Government.

FCA

- 2010 FCA Amendments
  - Patient Protection and Affordable Care Act ("PPACA")
  - More difficult to dismiss "qui tam" actions based on public disclosures
  - Expansion of "original source" definition
    - "Direct" knowledge no longer required; independent and material
  - No longer considered "jurisdictional" so more difficult to limit discovery
  - Anti-Kickback Statute violation now automatic violation of FCA

FCA

- Penalties
  - Civil penalty of not less than $5,500 an not more than $11,000 for each false claim
  - Triple the amount of actual damages sustained by the Government
- DOJ recovered approximately $3 billion in civil FCA settlements in 2010, including $2.5 billion in health care fraud recoveries (largest single-year in history)
  - $385 Million to *Qui Tam* Relators
- States AGs also extremely active; incentivized (10% increase in recoveries) if state false claims act is “at least as effective” in rewarding and facilitating *qui tam* actions

Anti-Kickback Statute

Anti-Kickback Statute

- Anti-Kickback Statute, 42 U.S.C. §1320a-7b
- Criminal statute that prohibits the exchange (or offer to exchange), of anything of value, in an effort to induce (or reward) the referral of federal health care program business
- Establishes penalties for individuals and entities on both sides of the prohibited transaction

Anti-Kickback Statute

- Covers a wide variety of activities:
  - Consulting fees
  - Samples (potentially to be billed to government)
  - Retreats, conference attendance
  - Meals
- Amended in 2010 by PPACA:
  - Government no longer has to prove defendants had knowledge of the law and specific intent to violate it
  - Violation automatically constitutes a false claim for FCA purposes

Anti-Kickback Statute

- Certain enumerated safe harbors (42 C.F.R. § 1001.952), all other transactions evaluated by OIG on case-by-case basis
- Examples of safe harbors
  - Space and equipment rental
  - Physician recruitment
  - Discounts
  - Personal services and management contracts
  - Managed care risk sharing

Anti-Kickback Statute

- Penalties
  - Violation is felony
  - Criminal fines of up to $25,000 per violation
  - Imprisonment for up to five years
  - Exclusion from Medicare, Medicaid and other Federal or State health care programs
  - Civil monetary penalties
- OIG Compliance Guidance Documents
  - http://oig.hhs.gov/compliance/compliance-guidance/index.asp

Physician Payment Sunshine Act

Physician Payment Sunshine Act

- The Sunshine Act requires that as of Jan. 1, 2012, firms begin tracking all payments or transfers of value to all U.S. based physicians and teaching hospitals and report aggregate spend on or before March 31, 2013, for the 2012 calendar year.
- Reports will be available to the public and states as of Sept. 30, 2013.

Physician Payment Sunshine Act

- Required to report every payment of any kind (over $10) made to physicians.
- “Payment” is any “transfer of value” including all consulting fees, compensation, entertainment, food, travel, and more.
- Report aggregated and filed electronically, along with the physicians’ National Provider Identifier (NPI)
- Submitted annually

Physician Payment Sunshine Act

- Penalties for non-compliance.
  - If a manufacturer *unknowingly* fails to report a single instance, there will be a $1000 to $10,000 fine that is limited to $100,000 annually.
  - If a manufacturer *knowingly* fails to report a transfer of value, there will be a $10,000 to $100,000 fine that is limited to $1,000,000 annually and an investigation will be opened by the federal government.

Sunshine 2.0

- May 5, 2011 - Senator Grassley urged voluntary disclosure by “influential disease and medical advocacy groups”
  - American Academy of Family Physicians, American Cancer Society, the American College of Obstetricians and Gynecologists, the American College of Surgeons, the American Hospital Association, Inc., the American Medical Association, the American Psychological Association, the American Society of Anesthesiologists, the American Society of Health-System Pharmacists, the American Society of Nephrology, the American Society of Plastic Surgeons, the Infectious Diseases Society of America, the National Association of Chain Drug Stores, and Screening for Mental Health, Inc.

FCPA

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FCPA

- Enforcement authorities around the world are increasing anti-corruption investigations and prosecutions
- U.S. prosecutors have been particularly active:
  - Siemens - $800 million (2008)
  - KBR-Halliburton - $579 million (2009)
  - BAE - $400 million (2010)
  - More cases in past five years than in the prior history of the statute
  - Over 120 current open cases

FCPA - Enforcement Expands Outside U.S.

- OECD Convention on Combating Bribery of Foreign Public Officials in International Business now in 38 countries
- Some countries aggressively enforcing
  - **Germany**: more open cases than U.S.
  - **Canada**: first anti-corruption case in 2010 and two new specialized RCMP anti-corruption units
  - **UK**: new legislation (effective 4/11) applies to companies incorporated in, or doing business in, the UK. Will reach conduct anywhere in the world.
    - Strict liability for failing to prevent bribery, including by employees and agents
    - Affirmative defense to show credible evidence of "adequate procedures" to prevent bribery offenses

What is the FCPA?

- Federal statute passed by post-Watergate Congress in 1977 to prohibit bribery of foreign government officials for the purpose of obtaining or retaining business
- Contains two core components:
  - Anti-bribery provisions
  - "Books and records" provisions
- Enforced by Justice and SEC

Anti-Bribery Elements

- *Corruptly* offering or paying;
- a thing of value
- to a "foreign government official;"
- directly or
- indirectly, with knowledge;
- for purpose of influencing an official act or omission, or
- securing an improper advantage

Myth

- We don’t work for foreign governments, and we never deal with any foreign officials. So I’ve got nothing to worry about. Right?

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Myth Buster

- Customs
- Environmental regulators
- Immigration
- Tax offices
- Freight forwarders
- Zoning
- Health care systems
- Telephone
- Deed recorders
- Utilities
- Product Safety
- Airlines

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Myth

- We have some local agents who are responsible for getting us business in foreign markets. We pay them for their services, and what they do with that money is just not our business.

Myth Buster

- Liability can arise from actions of your agents
- FCPA jurisdiction follows your company
- Bourke trial – jury instruction on "turning a blind eye" to warning signs
- Due diligence and compliance is key

Books and Records

- Make and keep records, "which, in reasonable detail, accurately and fairly reflect the transactions . . ."
- Devise and maintain "system of internal accounting controls" to assure:
  - Transactions executed in accordance with management's authorization
  - Transactions recorded in accordance with GAAP
- "Control Person"
- No materiality requirement
- No scienter requirement

Exposure Points

- Interaction with Regulators
  - *AGA Medical* – Chinese business agent says must "sponsor" persons in the Patent Protection Bureau to get approval:
    - "Any action in China I must pay money to do."
- Use of Agents
  - *Akzo Nobel* – Dutch pharmaceutical company listed on U.S. exchanges admitted that its agents made corrupt payments to Iraqi government under the U.N. Oil-for-Food Program

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Exposure Points

- Sales and Marketing
  - *Syncor Taiwan* – paid “medicine fees” to doctors at Taiwan public hospitals as reward for using Syncor products; recorded payments as “advertising and promotional expenses”
  - *AGA Medical* – provide a “reward” to doctors who bought AGA devices
  - *Mircus Corporation* – company granted stock options to doctors of publicly-owned hospitals in France, Spain, Turkey and Germany to induce product purchase
  - *Syncor International* - made $23,000 in improper payments to doctors in Mexican hospitals in form of personal loans never repaid and purported reimbursements of personal expenses

Exposure Points

- Travel, Meals and Entertainment
  - *Syncor International* – provided "apoyo" (“support”) to doctors at government-owned hospitals, such as sponsorships for educational seminars and payments for travel, lodging and meals
  - *TAP Pharmaceuticals* – inducements to doctors at government-run hospitals to use prostate cancer medication included golf and ski trips and hosting of office parties

Exposure Points

- Conferences and Symposia
  - *Immucor, Inc.* - company paid for Italian hospital director to participate in medical conference, but paid fees through German subsidiary and falsely booked costs as "consulting fees"
- Charitable Grants
  - *Schering-Plough* - SEC administrative proceeding charged Schering-Plough with making over $75,000 in improper payments through Polish subsidiary to charitable foundation headed by Polish health fund director

Exposure Points

- Gifts
  - *Syncor International* – “apoyo” included gifts in Mexico of computer and office equipment to doctors, as well as sponsorships of social functions and fundraisers
  - *Syncor International* – gift in Belgium, Luxembourg, and France included giving doctors at state-run hospitals generous gifts worth more than $750 each, such as money directly transferred to doctors' bank accounts, computers, digital cameras, expensive wines, wristwatches and leisure travel

Potential Costs of Violations

- Imprisonment
- Criminal fines ($2 million per violation or twice the pecuniary gain from the violation)
- Civil penalties
- Disgorgement of profits
- Retention of monitors to assure future compliance
- Suspension or debarment of ability to contract with governmental agencies
- Civil litigation and shareholder suits
- Damage to business, reputation and goodwill

Corporate Integrity Agreements

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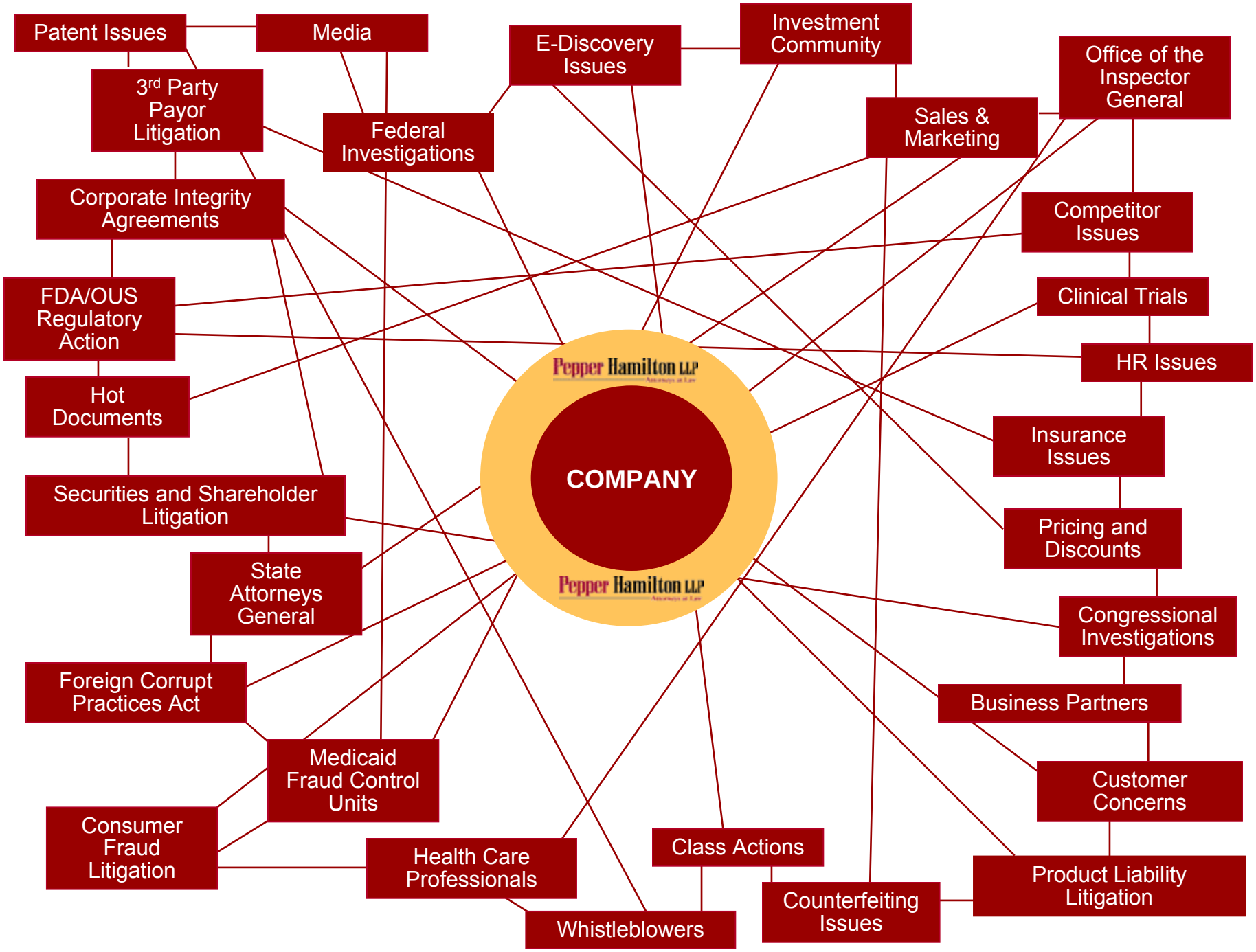
Patent Issues
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Investment Community
Office of the Inspector General
3rd Party Payor Litigation
Federal Investigations
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Competitor Issues
FDA/OUS Regulatory Action
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Insurance Issues
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Health Care Professionals
Class Actions
Product Liability Litigation
Counterfeiting Issues
Whistleblowers

Evolving Areas of Focus in Corporate Integrity Agreements (CIAs)

System Reviews	Pfizer	Cephalon	Lilly	EMD Serono	Jazz
Promotional and Product Systems Review A review of systems, processes, policies and procedures, including controls, relating to certain promotional and product related functions, such as:					
• Sales - handling of requests for off -label information	X	X	X	X	X
• Medical Information – handling of requests for off-label information	X	X	X	X	X
• Medical Affairs personnel (MSLs) interaction with Health Care Professionals (HCPs)		X		X	X
• Internal review and approval of materials for HCPs or HCIs	X	X	X	X	X
• Compliance procedures related to identifying off label situations		X			X
• Incentive compensation for covered persons	X	X	X		
• Development of Call plans and HCP Targeting	X	X	X		
• Sample distribution planning	X		X		
• Speaking arrangements/Speaker Programs				X	X
• Payments to HCPs and Reporting				X	X

Source: Kathleen Meriwether (Ernst & Young) and Barry Boise (Pepper Hamilton)

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Evolving Areas of Focus in Corporate Integrity Agreements (CIAs)

System Reviews	Pfizer	Cephalon	Lilly	EMD Serono	Jazz
• Materials accessible through detailing system to sales personnel	X				
• Charitable Contributions and Sponsorships				X	
• Funding or sponsoring of Research Support				X	X
• Educational or Informational Activities and Support				X	X
• Expenditures for Third-Party Advice Relating to Reimbursement or Claims Submission and Practice or Patient Support				X	
• Debt Forgiveness and Reduction				X	
• Disciplinary Actions for Compliance Violations		X		X	X

Source: Kathleen Meriwether (Ernst & Young) and Barry Boise (Pepper Hamilton)

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Evolving Areas of Focus in Corporate Integrity Agreements (CIAs)

Transaction Review	Pfizer	Cephalon	Lilly	EMD Serono	Jazz
Off Label Information Inquiries	X	X	X		X
Call Plan Reviews	X	X	X		
Physician (HCPs) payments	X	X	X		
Distribution of Samples Review			X		
Educational grants & sponsorships				X	
Research grants				X	
Charitable contributions				X	

Source: Kathleen Meriwether (Ernst & Young) and Barry Boise (Pepper Hamilton)

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Corporate Integrity Agreements

CIA Certifications

- Increase in number of "Certifying Employees" who must verify that company or individual business units are in compliance
  - **Cephalon (2008):** CEO, EVP WW Medical & Regulatory Operations and EVP WW Pharmaceutical Operations
  - **Lilly (2009):** CEO, EVP Global Marketing & Sales
  - **Bayer (2008):** All affiliate "presidents, chairpersons, CEOs, executive directors, VPs, CMOs, directors of Bayer business units or any affiliate that performs pricing, sales, marketing, contracting, promotion, medical affairs, or medical information functions"
- Board-level certification increasingly required

Corporate Integrity Agreements

- May 4, 2011 – Serono agrees to pay $44.3 million to resolve a False Claims case in connection with the marketing of Rebif
  - OIG extended Serono's existing CIA by three years, and required enhanced provisions requiring that company directors and senior executives take responsibility for ensuring and monitoring compliance with federal law.

"If we can alter the cost-benefit calculus of some directors and executives, OIG can influence corporate behavior without putting access to government health care benefits at risk."

Daniel R. Levinson, Inspector General of the Department of Health and Human Services (HHS-OIG)

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Enforcement Tools

CIA Certifications

CIA certifications are a "way for people to be held personally accountable for compliance in their area."

Eric Blumberg, FDA Deputy Chief for Litigation, 10/14/2010

"There is nothing like signing one's name to get somebody to really pay attention and take something seriously."

Mary Riordan, HHS OIG Senior Attorney, 10/16/09

"I have to confess, we are looking forward to having these certifications…. One of the difficulties of holding people responsible when the conduct has been widespread across the company and acquiesced in is, 'Who do you hold responsible?'"

AUSA Sara Bloom, 10/16/09

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Corporate Integrity Agreements

- OIG Collection of Corporate Integrity Agreements, Certification of Compliance Agreements (CCAs) and Settlement Agreements with Integrity Provisions
- http://oig.hhs.gov/compliance/corporate-integrity-agreements/cia-documents.asp

For more information, visit www.pepperlaw.com.

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