Focus on Fraud in Pharma and Medical Devices
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Agenda

• Hot Areas of Enforcement/Government Scrutiny
  • False Claims Act – off-label promotion
  • Anti-kickback Statute – relationships with health care professionals and providers
  • Executive Liability
  • Physician-owned Distributorships
  • Foreign Corrupt Practices Act

• Corporate Integrity Agreements and Settlements

• Compliance Programs

• Additional Recent Developments
  • Advisory Opinions
  • Open Payments (“Sunshine Act”)

Hot Areas of Enforcement/Government Scrutiny
Enforcement and Recovery

- Department of Health and Human Services ("HHS"), Department of Justice ("DOJ") reported $4.2 billion in health care fraud recoveries for FY 2012
  - FY 2011: $4.1 billion in recoveries
- HHS/DOJ – settlements/judgments of more than $3 billion in FY 2012 under the False Claims Act ("FCA")
  - Biggest Case – July 2012, GlaxoSmithKline ("GSK") paid $3 billion plus interest
    - Criminal and civil liability for: unlawful promotion of certain prescription drugs, failure to report certain safety data, and false price reporting practices
    - Of the $3 billion about $2 billion was for the civil FCA settlement
Enforcement and Recovery (ctd.)

• 3rd straight year of over $2 billion in recoveries by HHS/DOJ for FCA health care matters

• Fraud enforcement occurs at state and federal levels
  • e.g., November 2, 2010 – July 18, 2012, federal/state governments and pharmaceutical manufacturers reached settlements totaling $10.2 billion in financial penalties

• Fraud and Abuse enforcement areas of focus are:
  • Unlawful pricing by pharmaceutical manufacturers;
  • Noncompliant sales and marketing practices (e.g., sales to fee schedule providers where the product is not separately billed, e.g., lab equipment; off-label promotion); and
  • Self-referrals/Kickbacks (anti-kickback discount cases, e.g., manufacturer sales to providers)
Paying Rebates under Medicare Part B

• September 2013 – OIG released a study examining the potential of Medicare to collect billions of dollars if pharmaceutical manufacturers were required to pay rebates for Part B drugs
  • Currently under Medicaid there are statutorily mandated rebates to recoup a percentage of money spent on prescription drugs annually
  • OIG estimated that if similar rebates were to exist under Medicare Part B it would result in the collection of billions of dollars
    • e.g., in 2010 Medicare could have collected $2.4 billion (26% of expenditures for 20 high-end expenditure Part B brand-name drugs)
  • Centers for Medicare and Medicaid (“CMS”) is not yet onboard
  • It would require legislative action to establish a prescription drug rebate program under Medicare
Issues with Off-Label Promotion/Use

- Under the Food, Drug and Cosmetic Act (“FDCA”) a manufacturer must first obtain approval by the Food and Drug Administration (“FDA”) before it promotes a new drug for sale.
- “Off-label” – the promotion of the sale or use of pharmaceuticals for uses not approved by the FDA (“off-label” can apply to devices too).
  - Promotion for sale or use beyond the scope of what is approved has potentially significant criminal and civil penalties, e.g., Pfizer case (see later slide).
  - To determine whether there is “off-label” activity, the FDA/OIG considers, for example:
    - Approved/intended use; and
    - Actual marketing and distribution of the devices/drugs by the manufacturer.
Issues with Off-Label Promotion/Use (ctd.)

• Industry-wide belief that civil FCA off-label cases are no longer a fraud and abuse focus by the Federal government subsequent to a December 2012 appeals court decision
  • Conviction of a pharmaceutical sales representative for allegedly violating FDCA for promoting off-label drug use was overturned
    • Basis for overturning the conviction – trial judge’s conviction was based solely on the representative’s Constitutionally-protected right to free speech
• Industry’s response is misguided – focus in this case was on speech misconduct but most civil FCA off-label cases are based upon FDCA misbranding violations
  • The FCA off-label cases are “a major priority of the department, [Attorney General] Eric Holder and the Obama Administration”, United States Attorney for the Eastern District of Pennsylvania
Who pays when fraudulent pharmaceutical promotion has its intended effect?

- April 2013 – First Circuit issued three decisions for three cases involving Pfizer
  - Third-party payers sought compensation from Pfizer for damages as a result of fraudulent pharmaceutical promotion
  - Application by the Court of Appeals of the First Circuit of a causal chain of injury as follows
    - Pharmaceutical company’s fraudulent promotion → prescribing decisions of thousands of physicians → prescriptions for which a third-party payer paid
Who pays when fraudulent pharmaceutical promotion has its intended effect (ctd.)?

- *Kaiser v. Pfizer* Case (the lead case of the three)
  - Involved Pfizer’s marketing and sales of Neurontin, an anti-seizure medication
  - Jury found that Pfizer promoted the anti-seizure drug as a safe and effective treatment for indications (e.g., bipolar disorder, migraine or headache, neuropathic pain) for which Pfizer knew it was no more effective than a placebo
  - Pfizer did not contest the jury’s finding of fraud on appeal
  - Upheld verdict – $142 million (after trebling damages)
Who pays when fraudulent pharmaceutical promotion has its intended effect (ctd.)?

• Responses to First Circuit decisions
  • Pfizer petitioned for certiorari
    • Issues with (1) proper test for proximate cause under RICO and (2) use of aggregate statistical proof in collective fraud cases
    • Plaintiff’s responses due November 4, 2013
  • Amici briefs filed by BIO, PhRMA and the Washington Legal Foundation
    • Concern that the decisions will lead to an increase in lawsuits against pharmaceutical companies regarding alleged off-label promotion
    • Concern that the decisions chill “truthful and constitutionally protected speech concerning beneficial off-label uses of FDA-approved drugs”
• Debatable as to whether decisions open floodgates
Relationships with health care professionals and providers: Kickbacks

• Kickbacks to sales agents
  • Providing rewards to pharmaceutical sales representatives based on volume of sales, e.g., GlaxoSmithKline (see later slide)
  • How are they being paid, and do the payments fit within a Federal Anti-kickback statute (“AKS”) safe harbor?
    • e.g., contracted sales agents, personal services, or employee safe harbor

• Speaking Programs and Consultant Meetings
  • Payments of illegal remuneration to physicians to participate at speaker programs/consultant meetings with the intention of inducing physicians to use certain products, e.g., Baxano Surgical, Inc. (see later slide)
Relationships with health care professionals and providers: Kickbacks (ctd.)

- Discounts/Rebates
  - Entering into written agreements to pay rebates in return for the recommendation, promotion and selling of pharmaceuticals to health care providers
  - Potential to implicate Best Price Requirements
  - Who is remuneration offered to and for what purpose?
  - Do payments (rebates/discounts) fit within an AKS safe harbor?
    - e.g., the discount safe harbor (see advisory opinion later slide)

- Payments for consulting services
  - Payments to health care facilities for consultant services at rates below cost and below fair market value for the purpose of inducing referrals to pharmaceutical manufacturers for pharmacy services, e.g., Omnicare (see later slide)
Executive Liability: A new Focus in 2012-2013

- Co-prosecutions of companies and their executives
- Increase in use of corporate settlements to place greater compliance responsibilities on executives/board members
  - e.g., DOJ requires executives to personally certify their companies’ compliance with corporate integrity agreements (“CIA”)
- Inclusion of recoupment provisions related to executives in CIAs/settlement agreements
  - e.g., companies required to recover bonuses paid to certain executives if either the executives or their subordinates subsequently violate the agreements
- Industry response – creation of corporate governance principles: *The Principal Elements of a Leading Recoupment Policy*
Industry Developed Recoupment Policy

- Principal Elements of a Leading Recoupment Policy

  - Created in 2013 by working group of investors and pharmaceutical companies to deter unethical and inappropriate behavior

  - Key principles include
    - Providing full discretion to a board compensation committee to ascertain
      - If there are any material violations of company policies related to sales/manufacturing/marketing of health care services
      - If any such violations caused significant financial harm to the company
      - Whether such violations should trigger consideration of possible recoupment of incentive compensation

  - Development of this Policy indicates companies are willing to develop robust compliance programs in response to heightened federal/state government scrutiny
Monetary Settlements Not Enough

• In FY 2012, DOJ and U.S. Attorneys obtained 14 criminal convictions and $1.5 billion in criminal fines and forfeitures under the FDCA

• Renewed focus on prosecuting individuals for misdemeanor FDCA violations under the Park Doctrine related to marketing practices within the health care industry
  • OIG recognizes that billion/million dollars settlements are not sufficient deterrents to pharmaceutical companies
  • Settlements viewed as the cost of doing business
The Park Doctrine

• Use of exclusion of corporate executives in the life sciences industry from Federal health care programs
  • Allows for the misdemeanor prosecution of “responsible corporate officers” that violate the FDCA
  • Referred to as the Corporate Officer Doctrine or Park Doctrine
• Based on two Supreme Court Cases: Dotterweich & Park
  • U.S. v. Dotterweich (1943)
    • Misdemeanor conviction of a general manager of a store that sold repackaged drugs
    • Without general manager’s knowledge/involvement a shipment was sent to a physician that contained less potent drugs than indicated on the label
    • General manager was found to have a “responsible share in furtherance of the transaction which the statute outlaws”
The Park Doctrine (ctd.)

- **U.S. v. Park** (an expansion of *Dotterweich*) (1975)
  - President/CEO (Park) of a national grocery chain with 900 stores charged with a misdemeanor for selling adulterated food
  - Park claimed he was not “personally concerned with the violations”
  - The FDA presented testimony that it informed Park of the unsanitary conditions at a store warehouse
  - Park was found to violate the FDCA
    - “A corporate agent, through whose act, default, or omission the corporation committed a crime” violates the FDCA and may be held criminally liable for
      - The wrongdoing of the corporation or lower-level corporate employees
  - Criminal liability under the FDCA does not require “awareness of some wrongdoing” or “conscious fraud”
Implications of the Park Doctrine

• Individuals are responsible for the corporation
  • High standard of care for corporate executives
  • Did corporate official have power to prevent/correct violation?
  • Criminal liability extends “not only to those corporate agents who themselves committed the criminal act, but also to those who by virtue of their managerial positions or other similar relation to the actor could be deemed responsible for its commission”
• Potential Defense under Park
  • Corporate executives are not expected to do the “objectively impossible” by remedying/preventing a wrongdoing
• The Park Doctrine was infrequently used until 2010/2011
  • 2011 – FDA updated its Regulatory Procedure Manual to add a section on Park Doctrine prosecutions
OIG Permissive Exclusion and Park Doctrine

- October 2010 – new OIG guidance on permissive exclusion
  - Application of executive exclusion in larger corporations (e.g., drug or device manufacturers)
  - Presumption in favor of exclusion
    - When “there is evidence that an executive knew or should’ve known of underlying criminal misconduct of the organization”; and
    - Unless significant factors weigh against such exclusion
  - OIG examines
    - Circumstances of misconduct;
    - The seriousness of the offense;
    - An individual’s action in response to misconduct; and
    - Information about the entity
  - OIG Guidance contains similar criteria to the FDA Procedures Manual
Park Doctrine: Synthes, Inc.

• Synthes, Inc. executives (October 2012)
  • OIG excluded four executives one year after they were sentenced to prison
  • The executives allegedly ran unauthorized trails of certain bone cement devices used in surgeries to treat vertebral compression fractures of the spine.
  • The executives allegedly marketed the products without first conducting clinical trials.
  • The guilty pleas were made under the Responsible Corporate Officer Doctrine
    • Without conceding they were directly involved in any crime, the executives accepted responsibility for running the unauthorized trials and promoting the product for unapproved uses.
Park Doctrine: *Friedman v. Sebelius*

  - Court upheld the convictions of three former company executives for misdemeanor misbranding under the Park Doctrine
  - Their exclusions were upheld because the misdemeanors were fraud related
    - Case was subsequently remanded to OIG, which excluded the executives for 20 years – essentially a lifetime ban from the pharmaceutical industry
      - Later reduced to 15 years because executives assisted authorities to “combat abuse of OxyContin”
  - Executives disgorged approximately $34.5 million in compensation
  - Executives admitted responsibility/authority to prevent or promptly correct the misbranding
  - Executives admitted guilt as to misdemeanor misbranding
  - Judge/U.S. Attorney recognized an absence of proof that the executives had personal knowledge of the misbranding or personal intent to defraud
Physician-owned Distributorship ("POD")

- Business arrangements involving physician ownership of a medical device distributor or company
- An entity that sells medical devices and that is owned in whole or in part by physicians
  - Result is distribution to physician owners of profits resulting from the purchase by hospitals of medical devices, including devices that are implanted by the physician investors
- Physician-owned entities that produce revenue from selling or arranging the sale of, implantable medical devices ordered by the physician-owners that are then used in procedures performed by the physician-owners in hospitals or ambulatory surgical centers ("ASC") (OIG’s definition)
Physician-owned Distributorship ("POD")

- PODs are one of several types of physician-owned implant companies ("POC")
  - POCs take several forms, including manufacturers, GPOs, and PODs
- Prevailing POD model is a “stocking distributor” (buys and resells inventory)
- Focus of PODs tends to be in the surgical arena, with a particular emphasis on orthopedic implants (spine and joint) and cardiac implants (pacemakers and defibrillators)
  - October 2013 OIG Report found that in FY2011 roughly 20% of all spinal fusion surgeries used devices supplied by PODs (discussed on later slide)
Are PODs legal?

- Little regulatory guidance currently exists for PODs
  - It remains unclear whether certain POD models are legal
- Over the past year there has been a sharp increase in the government’s scrutiny of PODs
  - Both the 2012 and 2013 OIG Work Plans identified PODs of Spinal Implants as an area that OIG plans to carefully review
  - OIG is monitoring these business arrangements and has promised that guidance will be issued
    - 2013 - OIG is focused on the high-utilization of orthopedic implant devices used in spinal-fusion procedures
    - March 26, 2013 –OIG issued a Special Fraud Alert on PODs (discussed on later slide)
    - October 24, 2013 –OIG issued a report on PODs (discussed on later slide)
Do PODs violate the AKS?

- AKS prohibits any remuneration to induce physicians to purchase or order (or arrange for purchase or order of) products, or refer patients for a procedure, for which payment may be made under Medicare/Medicaid/Other Federal health care programs
  - Orthopedic/spinal implants used in federal patients are deemed paid for in the payment to the hospital or ASC
  - Remuneration includes return on investment and the opportunity to earn a profit
  - AKS is violated if one purpose is to induce the prohibited purchase, order or referral, even if there are other legitimate purposes
PODs and Risk under the AKS

- Is one purpose of the investment opportunity to induce physicians to order a manufacturer’s implantable devices?
  - If yes, the physician owners and the POD’s other investors are at risk for receiving the investment return; and
  - The manufacturer is at risk for creating the profit opportunity by selling to the POD

- Is one purpose of the investment opportunity to induce physicians to refer their patients to hospitals that agree to buy through the POD?
  - If yes, the hospital is also at risk for creating the profit opportunity by purchasing from the POD
PODs and AKS Violations

- AKS prohibits any remuneration to induce physicians to purchase or order (or arrange for purchase or order of) products, or refer patients for a procedure, for which payment may be made under Medicare/Medicaid/Other Federal health care programs
  - Orthopedic/spinal implants used in federal patients are deemed paid for in the payment to the hospital or ambulatory surgical center
  - Remuneration includes return on investment and the opportunity to earn a profit
  - AKS is violated if one purpose is to induce the prohibited purchase, order or referral, even if there are other legitimate purposes
Do PODs violate the AKS?

- There are two essential elements for an AKS violation
  - Is there remuneration to a referring physician?
  - Is one purpose of giving the physician the remuneration to induce the physician to order a covered product or make a covered referral?
- If these elements are present, then the participants are solely in the realm of prosecutorial discretion as to whether they are subjected to the AKS’s sanctions
  - Civil money penalty and exclusion by OIG
  - Direct criminal proceeding by DOJ
  - Qui Tam lawsuit under FCA
OIG Special Fraud Alert on PODs

- March 26, 2013 – OIG issued a special fraud alert on PODs
  - PODs are “inherently suspect” under the AKS
  - PODs have a high risk of fraud and abuse
  - PODs may be unlawful even if they do not have suspicious characteristics
  - Prior fraud alert in 1989 on joint venture arrangements included a discussion of PODs, but OIG did not declare PODs unlawful or “inherently suspect”

- October 8, 2013 – Reliance Medical Systems, LLC ("Reliance"), a manufacturer of spinal implant devices and surgical tools filed a lawsuit against HHS/OIG alleging that OIG’s characterization of PODs infringes the First Amendment rights of small business and physicians
OIG Special Fraud Alert on PODs (ctd.)

- Reliance’s complaint further alleges
  - OIG Special Fraud Alert on PODs alerts both hospitals and ASCs of AKS risk if they enter into such POD arrangements
  - The POD model is lawful under the AKS and existing legal precedent, e.g., *Hanlester Network v. Shalala* (9th Circuit 1995)
    - e.g., the complaint alleges, among other things, that the *Hanlester* Court found it legal under the AKS for a company to recruit physician investors that would be in a position to refer business to a company
  - OIG Special Fraud Alert is part of an aggressive lobbying campaign by larger medical device manufacturers that face competition from small physician-owned companies to pressure the government to take action against PODs
- Reliance asks the court to declare OIG Special Fraud Alert “invalid, incorrect and/or inaccurate” and that PODs that comply with the precedent it cites are not suspect
- Lawsuit is ongoing
OIG October 2013 POD Report

- OIG sampled 589 hospitals and found
  - 34% purchased spinal devices from PODs
  - Surgeries that used PODs did not have lower device costs (despite claims to the contrary by advocates)
  - OIG did not make any recommendations based on report findings

- Implications
  - Potential increase in cost of spinal surgery to Medicare overtime
    - Based on findings of OIG Report and another report that found between FY 2004 and FY 2012 hospitals that purchased POD devices witnessed a 21% increase in spinal fusion surgeries
  - PODs continue to be a focus of OIG
    - Are physicians that invest in PODs acting on inappropriate financial incentives?
    - Are there potential abuses?

- Congressional responses to OIG Report - support for increased scrutiny of PODs because of their potential to drive up health costs
The Foreign Corrupt Practices Act ("FCPA")

- FCPA was enacted in 1977 and amended in 1998 to stop U.S. companies from bribing foreign officials
  - Enforced by DOJ and Securities Exchange Commission ("SEC")
  - Comprises anti-bribery provisions and accounting provisions
  - Either one or both of the provisions may be implicated in a health care FCPA case
- Anti-bribery provisions prohibit
  - Paying or offering to pay anything of value
    - directly or indirectly
    - to a foreign official or to any other person while knowing that all or part of the thing of value will be paid or offered to a foreign official
  - corruptly
  - for the purpose of influencing the official in some official act or to secure any improper advantage
  - in order to obtain or retain business
The Foreign Corrupt Practices Act ("FCPA") (ctd.)

- The accounting provisions
  - Require issuers (defined as companies required to register their securities with SEC) to adhere to certain enumerated record keeping and disclosure requirements, and to adopt internal account controls
  - The purpose of the accounting provisions is to prevent
    - failure to record illegal transactions;
    - falsification of records to conceal illegal transactions; and
    - creation of records that are quantitatively accurate, but fail to specify qualitative aspects of the transaction

- Penalties
  - Health care entities that violate the FCPA may be subject to significant criminal and civil penalties in accordance with the FCPA and U.S. Federal Sentencing Guidelines
    - May also include Medicare/Medicaid exclusion
General Considerations: FCPA

• DOJ/SEC construe FCPA provisions broadly
  • e.g., “foreign official” includes many individuals that hospitals/manufacturers interact with abroad because many foreign healthcare providers are either in whole or in part operated and/or owned by the government
• In an affiliation, e.g., a joint venture between a U.S. manufacturer and a foreign entity, the U.S. partner can be held liable for corrupt payments made by a foreign partner because the knowledge element does not require actual knowledge of the corrupt payment and the corrupt payment need not be directly made to result in liability
  • Improper payments in order to obtain or retain business include payments
    • Made for regulatory approvals
    • Made for favorable licensing terms
    • To doctors to use medical devices or to steer them to certain laboratories, prescribe certain drugs, etc.
General Considerations: FCPA

• There are limited exceptions to the FCPA
  • e.g., Payments made for expenses that benefit foreign officials that are directly related to the promotion/demonstration of a health care entity’s services
  • Payments include – travel and expenses related to visiting a company facility for training or for meetings with a legitimate business purpose
• Having an FCPA compliance program is important when a U.S. health care entity expands overseas and important compliance program elements include
  • A code of conduct
  • Compliance policies and procedures
  • Risk assessment
  • Third-party due diligence
  • Compliance enforcement measures
Recent Corporate Integrity Agreements and Settlements
Corporate Integrity Agreements

• What is a Corporate Integrity Agreement?
• Typically last 5 years

• Standard Provisions:
  • Written Standards
  • Training and Education to Covered Persons
  • Disclosure Program
  • Ineligible Persons Screening Requirement
  • Independent Review Organization
  • Reporting requirements

• In 2012 and 2013 – specific focus to place heightened compliance responsibilities on executives and board members
Settlement and CIA: Johnson & Johnson

Johnson & Johnson ("J&J") entered into a 5 year CIA (2013)

- J&J and its subsidiaries agreed to pay more than $2.2 billion to resolve criminal and civil liability arising from allegations of off-label drug promotion and payment of kickbacks to physicians and to a long-term care pharmacy provider (Omnicare, Inc.)

- Specific allegations included:
  - Bonuses to sales representatives
  - Payment of speaker fees to physicians
  - Urging doctors/hospitals to setup outpatient clinics to administer Natrecor as serial outpatient infusions, providing funds to defray costs to setup clinics, and providing resources/support to providers to bill Medicare for outpatient infusions
  - Paying “kickbacks” to Omnicare, Inc. in the form of market share rebate payments, “grants”/educational funding
CIA: GlaxoSmithKline ("GSK")

GSK entered into a 5 year CIA (2012)

- GSK agreed to pay $3 billion plus interest to resolve its criminal and civil liability arising from its alleged unlawful promotion of certain prescription drugs, its failure to report certain safety data, and its civil liability for alleged false price reporting practices.
  - Alleged use of misleading medical journal article.
  - Alleged sponsorship of dinner/spa programs to promote off-label use.
  - Alleged payments to doctors to speak at/attend meetings.
  - Alleged use of sham advisory boards, and “independent “ CME programs to promote drugs for unapproved uses.
  - Alleged failure to include safety data about Avandia, a diabetes drug, in reports to the FDA.
  - Alleged false drug price reporting, which resulted in GSK’s underpaying rebates owed under the Medicaid Drug Rebate Program.
CIA: Par Pharmaceutical, Inc.

Par Pharmaceutical, Inc. (“Par”) entered into a 5 year CIA (2013)

- Par agreed to pay $45 million to resolve its criminal and civil liability for allegedly promoting its prescription drug Megace ES for uses not approved as safe and effective by the FDA and not covered by federal health care programs.

- Par allegedly promoted Megace ES for off-label uses, including launching a long-term care sales force to market off-label uses, while aware of adverse events associated with the use of Megace ES in geriatric patients.

- Par allegedly made unsubstantiated/misleading representations to geriatric patients about Megace ES’s superiority over its generic
CIA: Baxano Surgical, Inc.

- Baxano Surgical, Inc. (“Baxano”) (formerly TranS1, Inc.) entered into a 5 year CIA (2013) as part of a settlement agreement that stemmed from a qui tam lawsuit.

- Baxano agreed to pay $6 million to resolve false claims allegations for allegedly:
  - Causing providers to submit claims with incorrect diagnosis/procedure codes for minimally invasive spine fusion surgeries using its AxiaLIF System
    - Resulted in greater reimbursement than entitled for performing minimally-invasive AxiaLIF procedures.
  - Knowingly paid illegal remuneration to physicians to participate at speaker programs/consultant meetings with intention of inducing physicians to use certain Baxano products
  - Promoted the sale/use of its AxiaLIF System for “off-label” uses
CIA: Amgen, Inc.

Amgen, Inc. entered into a 5 year CIA (2012)

• Amgen agreed to pay $762 million to resolve civil and allegations that Amgen:
  • Promoted certain drugs for off-label uses and doses that were not approved by the FDA and not properly reimbursable by federal insurance programs.
  • Offered illegal kickbacks in an effort to influence health care providers to select its products for use.
  • Engaged in false price reporting practices involving several of its drugs.

• April, 2013 – Amgen agreed to pay $24.9 million to resolve FCA allegations that Amgen paid kickbacks to long-term care pharmacy providers in return for implementing “therapeutic interchange” programs designed to switch Medicare/Medicaid patients beneficiaries from a competitor drug.
Settlement Agreement: Omnicare

- Omnicare entered into a settlement agreement (October 2013)
  - Stems from a sealed qui tam lawsuit filed in 2010/unsealed in 2011
  - Omnicare agreed to pay $120 million to resolve allegations that it violated the AKS
  - Omnicare allegedly gave prescription drug discounts to certain nursing homes for their Medicare Part A patients in order to induce referrals of their non-Medicare Part A patients
    - Omnicare allegedly charged non-Medicare Part A patients full price for pharmaceutical services
    - Omnicare’s pharmaceutical supply costs were allegedly above what it charged a certain nursing home
  - Not yet finalized/approved by DOJ civil division
Settlement Agreement: Mallinckrodt LLC

- Mallinckrodt entered into a settlement agreement (July 2013)
  - Stems from a qui tam lawsuit filed in 2008
  - Mallinckrodt agreed to pay $3.5 million to resolve improper physician payment allegations
    - $3.2 million will go to the Federal government and the remainder will go to eight states
    - Mallinckrodt also entered into additional settlement agreements with certain states and commonwealths
  - Mallinckrodt allegedly made improper payments to physicians that led to false claims being submitted to Medicare/Medicaid
    - Mallinckrodt's allegedly improper behavior included paying physicians to participate in speaker programs, clinical trials, meetings, and completing forms in order to induce them to write prescriptions for their drug products
Enhanced CIA Provisions

• Board of Directors Obligations and Resolution

• Management Accountability and Certifications

• Compliance Experts/Outside Consultants

• Compensation Policies and Recoupment (“Claw Back”) Provisions
Enhanced CIA Provisions – Board of Directors Obligations and Resolution

- Baxano CIA, Section III.A.3. \textit{Bd. of Directors Compliance Obligations}

- Board shall be responsible for review and oversight of matters related to compliance with Federal health care program requirements, FDA requirements, and obligations of this CIA.

- Board must include independent (i.e., non-executive) members.

- Board shall meet at least quarterly to review and oversee Baxano Surgical’ s Compliance Program, including evaluating its effectiveness and receiving updates about activities and performance of Compliance Officer and Compliance Committee.

- For each Reporting Period of the CIA, the Board shall adopt a resolution, \textit{signed by each individual member of the Board}, summarizing its review and oversight of Baxano Surgical’ s compliance with Federal health care program requirements, FDA requirements, and obligations of this CIA.
The Board of Directors has made a reasonable inquiry into the operations of Baxano Surgical’s Compliance Program, including the performance of the Compliance Officer and the Compliance Committee. Based on its inquiry and review, the Board has concluded that, to the best of its knowledge, Baxano Surgical has implemented an effective Compliance Program to meet Federal health care program requirements, FDA requirements, and the obligations of the CIA.

Baxano shall report to OIG, in writing, any changes in the composition of the Board, or any actions or changes that would affect the Board’s ability to perform the duties necessary to meet the obligations in this CIA, within 15 days after such a change.
Enhanced CIA Provisions – Management Accountability and Certifications

Amgen CIA, Section III.A.4. *Management Accountability and Certifications*

- Certain Amgen officers or employees (“Certifying Employees”) are specifically expected to monitor and oversee activities within their areas of authority and shall annually certify that the applicable Amgen business unit is compliant with applicable Federal health care program and FDA requirements and with the obligations of this CIA.

*Certifying Employees* shall include, at a minimum, the following: Executive Vice President, Global Commercial Operations; Executive Vice President, Research & Development; Senior Vice President, U.S. Commercial Operations; Senior Vice President, Global Marketing & Commercial Development; Senior Vice President & Chief Medical Officer, Global Development; Senior Vice President, Global Value & Access; Senior Vice President, Global Regulatory Affairs & Safety; Vice President, Scientific Affairs; the general managers of Amgen U.S. commercial business units; and, to the extent that an Amgen business unit performs Covered Functions and is not covered by the certifications of one of the above-listed individuals, such other Amgen executives, vice-presidents, or leaders of business units as would be necessary to ensure that there is a Certifying Employee from each such business unit engaged in Covered Functions.
Enhanced CIA Provisions – Management Accountability and Certifications (ctd.)

Amgen CIA, Section III.A.4. (ctd.)

- Certification
  
  “I have been trained on and understand the compliance requirements and responsibilities as they relate to [name of department/functional area], an area under my supervision. My job responsibilities include ensuring compliance with regard to the [name of department/functional area] with all applicable Federal health care program requirements, FDA requirements, obligations of the [CIA], and Amgen policies, and have taken steps to promote such compliance. To the best of my knowledge, except as otherwise described herein, the [name of department/functional area] of Amgen is in compliance with all applicable Federal health care program requirements, FDA requirements, and the obligations of the [CIA]. I understand that this certification is being provided to and relied on by the United states.”

- A Stipulated Penalty of $2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Amgen fails to establish and implement, among other things, the management accountability and certification obligations. Section X.A. of Amgen CIA.
Enhanced CIA Provisions – Compliance Experts/Outside Consultants

J&J CIA, Section 3
The Compliance Obligations of the North American Leadership Board of J&J’s pharmaceutical affiliates, include:

- Arranging for the performance of a review of the effectiveness of the J&J Pharmaceutical Affiliates’ Compliance Program by a Compliance Expert who shall create a work plan for the Compliance Program Review, and prepare a written report about the Compliance Program Review and the results of the review.

- The written Compliance Program Review Report shall include a description of the review and shall include recommendations with respect to the Compliance Program.

  - Compliance Expert - an independent individual or entity with expertise in compliance with Federal health care program and FDA requirements.

Par CIA, Section III.H. Employee and Executive Incentive Compensation Restriction Program.

Par agrees that Par will maintain policies and procedures that shall (1) be designed to ensure that financial incentives do not inappropriately motivate sales representatives or their direct managers to engage in improper promotion, sales, and marketing of Par’s pharmaceutical products; and (2) include mechanisms, where appropriate, to exclude from incentive compensation any sales that may indicate off-label promotion of Par’s pharmaceutical products.

“Effective April 1, 2013, Par agrees that it will not provide financial reward (through compensation, including incentive compensation or otherwise) or discipline (through tangible employment action) its prescribing-customer-facing field sales professionals (pharmaceutical sales representatives) or their direct managers based upon the volume of sales of any non-generic megestrol acetate product within a given employee’s own territory or the manager’s district (Employee and Executive Incentive Compensation Restriction Program).”

Par CIA, Section III.H. Executive Financial Recoupment Program
Requires Par to recoup performance pay, including bonuses, in the event of significant misconduct by the executives or employees under the executives’ supervision where the misconduct is not isolated and is of a nature that the executive knew or should have known was occurring.

Specifically, the Par CIA requires:
“Par shall establish and maintain throughout the term of the CIA a financial recoupment program that puts at risk of forfeiture and recoupment an amount equivalent to up to 3 years of annual performance pay for an executive who is discovered to have been involved in any significant misconduct. This financial recoupment program shall apply to Covered Executives who are either current Par employees or who are former Par employees at the time of a Recoupment Determination.”

Covered Executives – all senior Par executives at the level of Vice President or above
Living Under a CIA

- What is it like?
- Working with the OIG?
- Using an Independent Review Organization?
Compliance Programs
What can we learn from CIAs?
Compliance Programs

- Guidance for effective compliance programs is found in:
  - The U.S. Federal Sentencing Guidelines
  - CIAs between the Federal government and manufacturers

- An effective compliance program is structured to promote a culture that encourages ethical conduct and compliance with the law.
Compliance Programs

• Seven elements of 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;
  and
  7. Responding promptly to detected problems and undertaking corrective action
Key Areas of Compliance Programs

- Boards of Directors’ Oversight of and Participation in Compliance-Related Activities
  - Board training and education
  - General assessments of a pharma/device company’s compliance program
  - Review of compliance issues pertaining to particular business initiatives
  - Review and oversight of audits and identified risks
  - Periodic interaction with compliance officers/third-party compliance experts who may access a pharma/device company’s compliance program
  - Compliance-related certifications and passage of compliance-related resolutions
Board Oversight

“The best boards are active, questioning, and even skeptical about the [companies] they oversee. They don’t make assumptions, they don’t view their jobs narrowly, and they don’t shy away from asking some very tough questions.”

~ Daniel R. Levinson, HHS-IG
Key Areas of Compliance Programs (ctd.)

- Integration of Compliance Activities into Business Functions Beyond the Compliance Department
  - Appoint deputy compliance officers within individual business units
  - Imbed compliance representatives in individual business units
  - Use training, communications, technology and compliance personnel and field-based managers to disseminate compliance messages and activities in the field
  - Require business unit managers to incorporate compliance considerations in business decision-making
  - Increase individual accountability by requiring compliance-related certifications from senior management in key business units
  - Include compliance-related requirements as an element in performance plans for all employees
  - Staff compliance committees with individuals from varied business units and disciplines
Key Areas of Compliance Programs (ctd.)

• Risk Identification and Monitoring Activities

  • CIAs usually do not explicitly require companies to engage in specific processes to identify compliance risk

    • Provide compliance training for management and field representatives in order to create an effective risk-identification program

    • Give compliance personnel a “seat at the table” when sales/marketing activities are planned or discussed

  • CIAs usually require companies to have compliance personnel annually monitor specified types of activities

    • Includes review of – sales representative call notes, speaker program activities, and activities of the medical information department (includes responses to inquiries about off-label uses of drugs)

    • Certain monitoring activities are to be undertaken by compliance department personnel only

    • Compliance/other personnel also attend speaker programs and go on “ride-along” with sales representatives

    • Certification requirements for board members/managers
Key Areas of Compliance Programs (ctd.)

• Policies, Procedures and Training Activities

  • Establish written policies/procedures re: business operations (e.g., sales, marketing, interactions between companies and providers)
    • Participation by business unit personnel/other affected stakeholders
    • Collaboration between compliance officers/other compliance personnel and business unit personnel
    • Creation of straightforward, simple policies to maximize compliance
    • Creation of policies that are easily accessible by employees and available in different, useful formats (e.g., electronic, paper)

  • Provide general training and job-function-specific training to persons covered by the CIAs
    • In-person, tailored training for specific job functions of employees
    • Include specific relevant examples and role-playing in trainings
    • Conduct training for employees of contractors as well
      • Presents challenges for companies, e.g., same contractor may work with multiple companies
FCPA and Compliance Programs

• For purposes of FCPA, DOJ/SEC recommend FCPA specific compliance programs if such entities do business overseas
  • Existence of an FCPA compliance program is a factor that DOJ/SEC consider when they decide whether or not to bring charges

• Considerations for FCPA compliance programs include
  • Ensuring there are FCPA specific policies and procedures
    • e.g., prevention of unlawful corrupt payments, etc.
  • Providing FCPA education for relevant employees within an entity
  • Creating a mechanism for reporting possible FCPA violations
  • Monitoring high-risk activity in which corrupt payments may be made
Additional Recent Developments
Stark Advisory Opinion (No. CMS-AO-2013-01)

• Requestor – a for profit limited liability company that provides clinical lab services to health care providers

• Proposed Arrangement – provide to referring physicians, without charge, liquid-based Pap smear collection kits
  • Requestor tracks the number of kits provided
  • Requestor uses monitoring procedures to ensure the number of kits received approximates the number of specimens sent back to the Requestor

• Issues
  • Does the provision of free kits constitute “remuneration” giving rise to a “compensation arrangement” under Stark law?
Stark Advisory Opinion (No. CMS-AO-2013-01)

• Analysis – Nature and Use of Kits
  • Remuneration does not include the “provision of items, devices or supplies that are used solely to . . . . collect, transport, process, or store specimens for the entity providing the item, devices or supply.”
  • “Surgical items, devices or supplies” do not qualify for the exception.
  • CMS concluded the kits are not “surgical items, devices, or supplies” for purposes of the Stark law (used for screening exam not surgical proc.)
    • The kits are used solely to collect, transport, process or store specimens for Requestor and composed exclusively of single-use collection tools
    • Requestor took steps to avoid providing excessive devices by tracking the number of specimens sent to the Requestor
  • CMS determined the provision of free Pap smear collection kits
    • Would not result in remuneration to physicians; and therefore
    • Would not constitute a compensation arrangement under Stark law
Stark Advisory Opinion (No. CMS-AO-2013-02)

- Requestor – a for profit corporation that provides clinical lab services to health care providers
- Proposed Arrangement – provide to referring physicians, without charge, disposable biopsy brushes
  - Requestor certified that the device cannot be reused because its tip is broken off subsequent to use and sent as a specimen to the lab
    - It is used as an alternative to a punch biopsy
- Issues
  - Does the provision of free biopsy brushes constitute “remuneration” giving rise to a “compensation arrangement” under Stark law?
Stark Advisory Opinion (No. CMS-AO-2013-02)

- Same Analysis – Nature and Use of Brushes
  - Fall under the exception to “remuneration”?

- Conclusion – the brushes are “surgical items, devices, or supplies” for purposes of the Stark law
  - Brushes are routinely used as part of a surgical procedure, biopsies are surgical procedures, brushes are used to routinely obtain a biopsy, and the surgical procedure for which the brush is used is substantially different from and goes beyond “mere scraping of surface cells seen in a Pap smear”

- CMS determined the provision of free brush biopsies
  - Would result in remuneration to Physicians; and therefore
  - Would create a compensation arrangement under Stark law
OIG Advisory Opinion – Rebates (No.13-07)

- Requestor – manufacturer of ophthalmological surgical products
- Proposed Arrangement – grant rebates under a tiered rebate program
  - Customers can earn a percentage rebate based on the customer’s total annual purchases of surgical products (calculation based on federally reimbursable and non-federal reimbursable products).
- OIG determined:
  - Proposed arrangement would not result in administrative sanctions
  - Proposed arrangement would not violate the AKS
    - Protection under the AKS’s discount safe harbor
OIG Advisory Opinion – Rebates (No.13-07)

• OIG determined the tiered rebate constituted a “discount” under the discount safe harbor

• Discount safe harbor
  • This exception protects “a discount or other reduction in price obtained by a provider of services or other entity under a Federal health care program if the reduction in price is properly disclosed and appropriately reflected in the costs claimed or charges made by the provider or entity under a Federal health care program”
    • Not a bundled discount – discount on one product is contingent on the purchase of another product
    • Not a reward program where items provided in return for purchases
OIG Advisory Opinion – Rebates (No.13-07)

- Requestor would provide a program description to customers
  - Describing the terms of the rebate program
  - Including a notification that the customer may have obligations under the discount safe harbor to report the portion of the rebate applicable to Federally reimbursed products
- Requestor would provide invoices to customers participating in the program
  - Stating items included on the invoice may be subject to a later rebate and may trigger reporting obligations to Federal health care programs
- Requestor would send each participating customer a year-end report
  - Including an explanation of the rebate program tier for which the customer qualified
  - Including a summary of the customer’s total qualifying purchases
  - Including a calculation of the total rebate to which the customer is entitled
Open Payments ("Sunshine Act") ~ Potential Enforcement Impact?

- March 2014 – applicable manufacturers (including devices and drugs) will be required to report payments or transfers of value to physicians or teaching hospitals on an annual basis to CMS
  - Manufacturers are required to begin collecting and tracking payment, transfer, and ownership information (August 1, 2013 – December 31, 2013)
  - Annual, calendar year, reporting thereafter
  - Anticipated that CMS will release most of the data on a public website on September 30, 2014

- New pool of data for investigators to data mine
  - Data will be aggregated and searchable across multiple fields, and available for download.
The Sunshine Act: Potential Enforcement Impact

• Federal government will use the database to:
  • Expose potential conflicts of interest/inappropriate financial ties
  • Identify suspect/unusual billing patterns
    • Reporting payments will not protect parties from potential AKS or FCA liability

• Taxing authorities may also view the information in the database and compare it to what individual physicians report as income

• Congressional Action – identify future areas for investigation?
The Sunshine Act: Potential Enforcement Impact

• Whistleblowers/private citizens may also access the database in order to gather data to bring qui tam lawsuits against providers and manufacturers

• Unlikely to be very useful for individuals without insider knowledge – the pleading requirements are such that allegations of fraud and abuse must be stated “with particularity”

• However, individuals with insider knowledge (e.g., an employee) may be able to use the database information and their knowledge to state a viable claim