Morgan Lewis

webinar

Medical Device Industry – Government Investigations

Tuesday, April 24

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Today's Presenters

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Agenda

- Responsible corporate officer doctrine and individual liability
- False Claims Act and qui tam
- Foreign Corrupt Practices Act
- Q&A

Responsible Corporate Officer Doctrine And Individual Liability

RESPONSIBLE CORPORATE OFFICER DOCTRINE
Vicarious Liability for Regulatory Violations

- Criminal liability under theory historically used for civil disputes
- Key Elements
  - No requirement for awareness of wrongdoing
  - Typically applied to misdemeanor crimes
  - Underlying statute intended to protect public welfare
  - Applies to any person with a "responsible relation" to the violation
  - Affirmative defense that individual was "powerless to prevent or correct the violation"

US v. DOTTERWEICH
320 U.S. 277 (1943)

- Supreme Court approved in a 6-3 vote, and 7-page majority opinion
- Dotterweich was President and General Manager of pharmaceutical distributor
- Jury convicted Dotterweich with shipping misbranded and adulterated drugs in violation of the FDC&A, but acquitted the corporation
- Declined to define or illustrate the class of employees that counts as standing in “responsible relation” to a given violation—decision left to jury or prosecutor

US v. PARK
421 U.S. 658 (1975)

- Park was CEO of a national food chain with 36,000 employees and 874 retail outlets
- Park pled guilty to shipping adulterated food in violation of the FDC&A
- Park admitted to awareness of FDA letter regarding unsanitary conditions that led to the conviction
- Court rejected Park's defense that he justifiably delegated responsibility to qualified subordinates
- Court acknowledged an affirmative defense that official was powerless to prevent the underlying violation
- Dissenting Justices criticized the failure to require proof of duty of care as amounting to a charge that "you must find the defendant guilty if you conclude that he is guilty"

Enforcement Examples
Synthes

- Misdemeanor FDC&A guilty pleas in connection with promotion and clinical testing of bone cement
- 4 corporate officers pled guilty
  - President, North America
  - President, Spine
  - VP of Operations
  - Director of Regulatory and Clinical Affairs
- Prison terms from 5 months to 9 months
- Operating subsidiary excluded and OIG agreement required divestiture from Synthes

Enforcement Examples
Purdue Frederick

- Misdemeanor guilty pleas to FDC&A violations in connection with marketing of OxyContin
- 2 corporate officers pled guilty
  - President and CEO
  - EVP of Medical and Scientific Affairs
  - Chief Legal Officer
- OIG exclusion for 12 years upheld in District Court

Enforcement Examples
Vitamin Company

- Violation of “books and records” requirement under FCPA
- $25,000 fine
- 2 corporate officers entered settlement
  - CEO
  - CFO
- No knowledge of underlying misconduct

Criminal *Park/RCOD* Jury Instructions

7.07 Personal Criminal Responsibility Of A Corporate Agent

A person is personally responsible under the criminal law for acts *(he) (she)* **performs or causes to be performed on behalf of a corporation, just the same as if** *(he) (she)* **performed those acts on** *(his) (her)* **own behalf.**

However, a person who is a *(state the type of agent alleged to have committed the acts)* **of a corporation is not criminally responsible for illegal acts committed by another agent on behalf of that corporation merely because of** *(his) (her)* **status as an** *(type of agent)* **of the corporation** *[, unless the defendant had, by reason of (his)(her) position in the corporation, responsibility and authority either to prevent in the first instance, or promptly correct, the violation complained of, and failed to do so]*.

Comment

See 1A O'Malley et al., supra, § 18.04. For other Circuit instructions on the point, *see* Eighth Circuit §5.04.

(Type of agent) requires the trial judge to state the particular type of agent or agents – director, officer, employee, etc – who is or are alleged to have acted on the corporate defendant's behalf.

Responsible Corporate Agent Doctrine; Liability for Failure to Prevent Violations of the Law. The bracketed language at the end of the Instruction should be used in those cases in which the "responsible corporate agent" doctrine applies. The Supreme Court recognized in *United States v. Park*, 421 U.S. 658 (1975), and *United States v. Dotterweich*, 320 U.S. 277 (1943), that with respect to certain federal statutes that impose criminal liability without any mental state requirement, responsible corporate officers or agents may be held criminally liable without performing any acts, but instead for failing to prevent violations of the law. Thus, in *Park* the Court observed:

[T]he principle had been recognized that a corporate agent, through whose act,

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Third Circuit Criminal Model Jury Instruction

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[, unless the defendant had, by reason of (his)(her) position in the corporation, responsibility and authority either to prevent in the first instance, or promptly correct, the violation complained of, and failed to do so].

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FDA Guidance

U.S. Department of Health & Human Services

U.S. Food & Drug Administration

Inspections, Compliance, Enforcement, and Criminal Investigations

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6-5 - PROSECUTION

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- 6-5-1 - Purpose
- 6-5-2 - Referral of Criminal Matters to the Office of Criminal Investigations
- 6-5-3 - Special Procedures and Considerations for *Park* Doctrine Prosecutions
- 6-5-4 - Communication Between OCI and Other FDA Components
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- 6-5-6 - Criminal Prosecution after Section 305 Notice
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- 6-5-11 - Information And Indictments
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- 6-5-13 - Preparation Of Summary And Recommendation
- 6-5-14 - Submission of Summary and Recommendation Documents

6-5 - PROSECUTION

6-5-1 - Purpose

This section establishes guidelines for the uniform submission and review of prosecution recommendations, including referrals for criminal investigation. A number of different procedures, depending upon the distinguishing case features, are included in order to eliminate unnecessary review and to expedite the case review process.

As described below, all criminal referrals, whether initiated by the District, the Center, or another FDA Headquarters component, must be sent to OCI for initial review in accordance with Section 6-5-2 and 6-5-3. If OCI declines the referral, the Center or District may pursue the matter through the preparation of a Summary and Recommendation in accordance with Section 6-5-5 et seq.

6-5-2 - Referral of Criminal Matters to the Office of Criminal Investigations

The Office of Criminal Investigations (OCI) is responsible for reviewing all matters in FDA for which a criminal investigation is recommended, and is the focal point for all criminal matters. FDA personnel must refer all criminal matters, regardless of their complexity or breadth, to OCI. This includes criminal search warrants, misdemeanor prosecutions, felony prosecutions, referrals for criminal investigation, and Section 305 meetings.

District management must communicate with the local OCI office before pursuing any criminal matter. Designated center and ORA and FDA Headquarters points of contact must communicate with their respective OCI Senior Operations Manager (SOM). This communication is absolutely essential to preclude potential interference with other on-going criminal investigations and to prevent confusion among the components of the Office of Chief Counsel and the Department of Justice that are responsible for handling FDA's criminal cases.

During this communication, OCI is to be provided with all of the facts of the potential case and any additional information that is relevant to, or could impact, the case in any way. In accordance with SMG 9111, district management should notify the local Special Agent in Charge, Assistant Special Agent in Charge, or Resident Agent in Charge of the referral via telephone. For referrals of Park Doctrine prosecutions, see the procedures below.

For all criminal referrals, OCI will decide promptly whether or not to pursue the case. OCI will communicate its decision back to the referring Office. If OCI declines to pursue a referral, OCI will promptly convey its decision to the referring office, which may then proceed with the case and submit a formal summary and recommendation for prosecution in accordance with sections 6-5-5 and 6-5-13 of this chapter.

6-5-3 - Special Procedures and Considerations for Park Doctrine Prosecutions

Recommending Park Doctrine Prosecutions

The Park Doctrine, as established by Supreme Court case law, provides that a responsible corporate official can be held liable for a first time misdemeanor (and possible subsequent felony) under the Federal Food, Drug, and Cosmetic Act ("the Act") without proof that the corporate official acted with intent or even negligence, and even if such corporate official did not have any actual knowledge of, or participation in, the specific offense. A Park Doctrine prosecution, for the purposes of this section, refers to a recommended prosecution of a responsible corporate official for a misdemeanor violation of the Act.

Misdemeanor prosecution under the Act can be a valuable enforcement tool. Such prosecutions are referred to the Department of Justice. Once a person has been convicted of a misdemeanor under the Act, any subsequent violation of the Act is a felony, even without proof that the defendant acted with the intent to defraud or mislead. Misdemeanor prosecutions, particularly those against responsible corporate officials, can have a strong deterrent effect on the defendants and other regulated entities. In some cases, a misdemeanor conviction of an individual may serve as the basis for debarment by FDA.

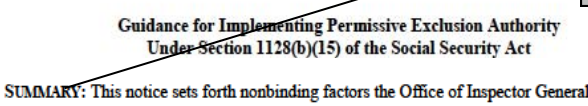
When considering whether to recommend a misdemeanor prosecution against a corporate official, consider the individual's position in the company

[T]hese factors are intended solely for the guidance of FDA personnel, do not create or confer any rights or benefits for or on any person, and *do not operate to bind FDA.*

- Individual's position in the company
- Relationship to the violation
- Whether the official had the authority to correct or prevent the violation
- Knowledge or actual participation in the violation
- Actual or potential harm to the public
- Whether the violation is obvious
- Pattern of illegal behavior and/or failure to heed prior warnings
- Widespread or seriousness
- Legal and factual support
- Agency resources

OIG Guidance

This notice sets forth *nonbinding factors the OIG will consider* in deciding whether to impose permissive exclusion in accordance with section 1128(b)(15)(A)(ii) of the Social Security Act (the Act), which authorizes OIG to exclude an officer or managing employee of an entity that has been excluded or has been convicted of certain offenses.



Guidance for Implementing Permissive Exclusion Authority Under Section 1128(b)(15) of the Social Security Act

SUMMARY: This notice sets forth nonbinding factors the Office of Inspector General (OIG) will consider in deciding whether to impose permissive exclusion in accordance with section 1128(b)(15)(A)(ii) of the Social Security Act (the Act), which authorizes OIG to exclude an officer or managing employee of an entity that has been excluded or has been convicted of certain offenses.

SUPPLEMENTARY INFORMATION

I. Purpose and Rationale

Section 1128(b)(15) of the Act authorizes the Secretary, and by delegation the Inspector General, to exclude an individual owner, officer, or managing employee of a sanctioned entity, as defined in section 1128(b)(15)(B) (i.e., an entity that has been convicted of certain offenses or excluded from participation in the Federal health care programs). Exclusions under section 1128(b)(15) of the Act are derivative in nature and are based upon the individual's role or interest in a company that is excluded or is convicted of certain offenses. Exclusions under section 1128(b)(15) are permissive, that is, the Secretary has the discretion whether to exclude or not to exclude. OIG's exercise of this discretion is not subject to administrative or judicial review.

Section 1128(b)(15) of the Act provides two different bases for exclusion. Individuals who have an ownership or a control interest in a sanctioned entity may be excluded under section 1128(b)(15)(A)(i) if they knew or should have known of the conduct that led to the sanction. Officers and managing employees, as defined in section 1126(b) of the Act, may be excluded under section 1128(b)(15)(A)(ii) based solely on their position within the entity.

Because the elements of these two provisions are so different, our exclusion analysis differs depending on whether the individual in question is: (1) an owner or (2) an officer or a managing employee.

The statute sets a higher standard for exclusion of an owner, requiring evidence that the owner knew or should have known of the conduct that formed the basis for the sanction. In general, if the evidence supports a finding that an owner knew or should have known of the conduct, OIG will operate with a presumption in favor of exclusion. This presumption may be overcome when OIG finds that significant factors weigh against exclusion.

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Individual's Role in Sanctioned Entity

- What is the individual's current position?
- What positions has the individual held with the entity throughout his or her tenure, particularly at the time of the underlying misconduct?
- What degree of managerial control or authority is involved in the individual's position?
- What was the relation of the individual's position to the underlying misconduct?
- Did the misconduct occur within the individual's chain of command?

Individual's Actions in Response to the Misconduct

- Did the individual take steps to stop the underlying misconduct or mitigate the ill effects of the misconduct (e.g., appropriate disciplinary action against the individuals responsible for the activity that constitutes cause for the sanction or other corrective action)?
- Did these actions take place before or after the individual had reason to know of an investigation?
- If the individual can demonstrate either that preventing the misconduct was impossible or that the individual exercised extraordinary care but still could not prevent the conduct, OIG may consider this as a factor weighing against exclusion.
- Did the individual disclose the misconduct to the appropriate Federal or State authorities?
- Did the individual cooperate with investigators and prosecutors and respond in a timely manner to lawful requests for documents and evidence regarding the involvement of other individuals in a particular scheme?

Practice Pointers

- Assess Compliance of Subsidiaries
- Disassociate from Bad Actors
- Train Management on Compliance Responsibilities
- Monitor and Audit in Risk Areas
- Encourage Employees to Report Problems Internally

False Claims Act and Qui Tam

Enforcement Landscape – Healthcare Industry

- Healthcare industry remains a focus of the Government
  - "The era of getting away with Medicare fraud is over… [t]he government as a whole is coordinating like never before to take on the problem of health care fraud." Asst. AG Lanny Breuer, 2011
  - "From Day One, President Obama and Attorney General Eric Holder have been focused like a laser beam on tackling health care fraud in all of its many forms." Asst. AG Tony West, 2011

Enforcement Landscape – Healthcare Industry

- Sustained legislative anti-fraud agenda with focus on healthcare industry
  - Patient Protection and Affordable Care Act
- Increased funding to DOJ for investigation and prosecution of health care fraud
- Increased coordination and collaboration among federal agencies – HEAT
  - HEAT Compliance Training Initiative
- Increased involvement and collaboration between federal state and local agencies
  - USAO and State AGs
- New and expansive theories of liability
  - Regulatory violations enough

Enforcement Landscape – Healthcare Industry

- Recent FCA amendments part of seminal anti-fraud measures – key amendments in the Patient Protection and Affordable Care Act
- 25th Anniversary of the 1986 amendments to the FCA
- Healthcare industry has been dominant FCA focus since 1986
- FCA recoveries since 1986 are $30.3 billion
- Over 20 billion of that (about 70%) from the from healthcare industry.
- For FY 2011, $3.03 billion recovered, of which more than $2.4 billion was from healthcare industry; skewed focus on one industry sector in last decade
- First quarter of FY 2012 already in the billions in FCA recoveries
- Predicting up to $ 9 billion in recoveries in FY 2012 based on pipeline – majority will be healthcare industry

Enforcement Landscape – Healthcare Industry

- DOJ informed Senator Charles E Grassley in 2011 that:
  - 885 qui tam cases under seal involving heath care fraud
  - No decision on intervention or whether to investigate fully
  - 98% involve Medicare or Medicaid dollars
  - An unspecified percentage of these cases are against multiple pharmaceutical and medical device companies

Medical Device Enforcement

- Government policies/programs: e.g., FDA's Bad Ad program – seeks physician assistance in monitoring and policing advertising and promotion of medical devices and drugs
- Medical device industry open FCA/qui tam investigations based on securities disclosures
  - Most common allegations:
    - *Sales and marketing practices – off-label*
    - *Interactions/Kickbacks to HCPs – consulting payments, clinical trials, contributions to charities, gifts, advisory boards, speaker programs*
    - *Safety issues/Defective products*
    - *Reimbursement advice to HCPs – improper codes, upcoding*
    - *Often in tandem with alleged FDCA and AKS violations*

Medical Device Enforcement

- Mary Riordan, Senior Counsel, HHS, OIG, said of the "OIG Work Plan" for 2012:
  - Continued large numbers of cases alleging improper promotion
  - Continued large numbers of cases against drug and device manufacturers
  - Exclusion, criminal, civil, and monitoring

False Claims Act – It Is Still the One

- Civil War era statute to protect against fraud in government contracting
- Civil statute – but is the origin of criminal and administrative fraud investigations and prosecutions under DOJ parallel proceeding policy
- Can affect any corporation, institution or individual doing business directly or indirectly with the government
  - 2009 amendments expanded potential for third-party or downstream liability for manufacturers, vendors and suppliers, banks, investment firms, and consultants
  - Significant litigation battleground
- Potential for substantial damage and penalties
  - Provides for mandatory treble damages plus a mandatory civil penalty of between $5,500 and $11,000 per claim
- Joint and several liability with no right of contribution or indemnity

False Claims Act – It Is Still the One

- Actions filed under seal in U.S. District Court
  - Not served on defendant
- DOJ – mandatory duty to investigate allegations under seal and decide to take over case
  - 60 days to investigate but often extended by years
  - How far must they go? How many years can they take? When does defendant party get to protect its rights?
- Qui tam whistleblower bounty provisions added in 1986 – became the driver of FCA cases
  - Whistleblower shares from 10-30%
  - Mandatory award of attorney fees and costs
  - If allegations publicly disclosed in news media, federal hearing or proceeding, must be an original source and have provided material information to the government prior to filing suit
    - *Area of great challenge*
    - *Balance of reporting fraud v. parasitic and opportunistic suits*

False Claims Act – It Is Still the One

- Civil preponderance of the evidence standard; 51% weight of evidence
- No specific intent requirement; reckless disregard or deliberate ignorance will do; smidge over negligence? Gross negligence?
  - But mere negligent or innocent mistakes are not actionable
- Retaliation provisions – separate provision with different damages
  - Qui tam driver
  - Expanded in 2009 amendments from employees to include non-employee agents and contractors

FCA Theories of Liability Against Medical Device Industry

- Sales and marketing practices
  - Off-label marketing
- Financial arrangements/Payments to HCPs – AKS violations
  - Consulting agreements
  - Honoraria/speaker programs/samples/gifts
  - Royalty payments on new devices
  - Unrestricted grants/fellowships
- Substandard product manufacturing, product substitution, quality deficiencies
- Manipulated price reporting
- Specialty pharmacy relationships/other customer relationships

FCA Theories of Liability Against Medical Device Industry

- Regulatory violations: any will do? Failure to disclose a known defect in connection with the FDA approval process
- Conflicts of interest, industry codes of ethics – AdvaMed - and corporate compliance program deficiencies
- Certifications of compliance
- Current good manufacturing practice violations
- Promoting surgical procedures when less invasive pressures are appropriate
- Reimbursement advice – upcode to inflate reimbursement
- Charging government entity a higher rate than commercial customers
- Inflation of cost of replacement devices by failing to grant warranty credits and rebates for devices explanted while covered under a product warranty
- Invoices for equipment for patients who did not qualify for procedures and for equipment that was not medically necessary
- Retaliation claims

False Claims Act/ Qui Tam Trends

- In FY 2011, 762 new FCA cases were initiated; 638 (84%) of which were qui tam actions
  - Whistleblowers initiated more new matters ever before
  - Recent study: 90% of all heath care fraud case are qui tam actions by these with direct knowledge
- Qui tams driver of FCA cases and recoveries – $2.8 million of $3.03 billion recovered in FY 2011 from matters initiated under qui tam provisions
- More than 7,800 qui tam actions since 1986
- DOJ increasingly relying on whistleblowers to initiate matters

False Claims Act/ Qui Tam Trends

- DOJ Declination is approximately 75 to 80% of cases
- Relator recoveries significantly higher in DOJ-intervened cases
  - $532 million in whistleblower awards – highest yearly recovery on record
  - $490 million in cases where DOJ intervened
  - $42 million in cases where DOJ declined to intervene

False Claims Act/ Qui Tam Trends

- Trend to national initiatives and industry qui tams.
  - Medical device industry: Cardiac ICD investigation, Biliary stents investigation
- Fewer settlements and more litigation, even in parallel criminal and administrative proceedings
- Judicial impatience with length of DOJ investigations under seal in some jurisdictions
- Consortiums of relator's counsel banding together – willing to go it without DOJ
- Professional whistleblowers – Ven-a-Care
- More USAOs getting involved

Rise of State and Local FCAs

- Over 30 states, cities, counties have own FCAs
- Most modeled almost exactly after Federal FCA
- Most have qui tam provisions
- Some limited to Medicaid fraud
- Enforcement and recoveries under State FCAs increasing
  - CA: 241 million settlement announced in 2011
- More sophisticated attorneys, more aggressive, more willing to fight at state and local level
- Increases investigative and legislative complexity

Dominant Legal Issues

- More than 300 reported decisions involving the FCA in 2011 – many circuit splits
- Issues common to medical device FCA actions
  - Implied certification
  - Regulatory violations
  - Downstream liability/causation
  - Public disclosure bar

FCA: Selected Case Law Developments – Public Disclosure Bar

- *US ex rel. Jamison v. McKesson Corp.* (5th Cir. Aug. 2011)
  - Even where public disclosures do not disclose allegations specifically relating to defendant named in qui tam suit, they may bar a suit where the complaint's allegations are also generalized and contain no allegations specific to named defendant
  - Relator in this case named almost 450 defendants and provided no evidence regarding the selection of the defendants.
  - Court rejected relator's claim; held that relator may not merely synthesize generalized public disclosures and then arbitrarily list a large group of possible perpetrators "in hopes that his allegations will prove true for at least a few defendants." Such relator lotteries are no more than "parasitic suits by opportunistic late-comers who add nothing to the exposure of fraud"

FCA: Selected Case Law Developments – Certification Theory

- Implied false certification theory allows the government to hold medical device companies and others liable for FCA violations even absent express false statements to the government
- Theory is: requests for payment implicitly represent compliance with requirements that are preconditions to payment
- Circuit splits on this theory are emerging

FCA: Selected Case Law Developments – Certification Theory

- *US ex rel. Steury v. Cardinal Health, Inc.* (5th Cir. Nov. 2010)
  - A false certification, implicit or explicit, does not give rise to liability under the FCA unless certification is required as a prerequisite to payment
- *US ex rel. Vigil v. Nelnet, Inc.* (8th Cir. May 2011)
  - If certification of compliance with program terms is a condition of program participation, rather than payment, a false certification is not actionable under the FCA
- *US ex rel. Hutcheson v. Blackstone Medical, Inc.* (1st Cir. June 2011)
  - Broad implied false certification framework
  - A suit against a party that did not submit any claims to the government survived a 12(b)(6) challenge where the non-submitting party was alleged to have caused the party submitting the claim to falsely certify compliance with a precondition of payment (compliance with the AKS)
  - Supreme Court denied Petition for Certiorari in Dec., 2011

FCA: Selected Case Law Developments – First-to-File Bar

- When a person brings an action, no person other than the government may intervene or bring a related action based on the facts underlying the pending action
- Reduces copy cat litigation
- *United States ex rel. Batiste v. SLM Corp.*, 659 F.3d 1204 (D.C. Cir. 2011)
  - First filed complaints need not meet the heightened pleading standard of Rule 9(b) to bar later complaints – must only provide sufficient notice for the government to investigate claims
  - Court did not agree with government position in amicus brief that the first-to-file bar should be limited to situations in which prior complaints survived a rule 9(b) challenge
  - Stops bootstrapping similar facts or claims from previous actions into new actions

FCA: Selected Case Law Developments – Enforceability of Releases

- *US ex rel. Radcliffe v. Purdue Pharma L.P.* (4th Cir. Mar. 2010)
  - A pre-filing release is enforceable with respect to a subsequent *qui tam* action under the FCA when the government had knowledge of the alleged fraudulent conduct before the suit was filed
- *Radcliffe* has been cited by subsequent decisions
  - Emerging Circuit Court view that pre-filing releases bar subsequent qui tam claims if the release can be fairly interpreted to encompass qui tam claims and public policy does not otherwise outweigh enforcement of the release
  - Relator's claims were barred by waiver signed months before FCA action was filed. *US ex rel. Nowak v. Medtronic Inc*. (D. Mass July 2011)
  - But see: Waiver may not be enforceable if executed before the Government has knowledge of the allegedly fraudulent conduct. Enforcement of such a waiver would frustrate the FCA's goals of incentivizing individuals to reveal fraudulent conduct to the Government. *US ex rel. McNulty v. Reddy Ice Holdings, Inc.* (E.D. Mi. Dec. 2011)

FCA: Selected Case Law Developments – Government Authority to Unilaterally Dismiss Qui Tams

- Broad discretion to government to unilaterally dismiss qui tam action over whistleblower objections
- Almost uniformly, if the government wishes to dismiss a suit, Courts will uphold
- *United States ex rel. Nicholson v. Spiegelman, M.D.*, 2011 WL 2683161 (N.D. Ill. July 8, 2011)
  - DOJ declined to intervene and moved to dismiss qui tam action alleging submission of false claims to Medicaid for a drug ineligible for reimbursement
  - Circuit split over whether DOJ's ability to dismiss a qui tam action is unlimited or whether DOJ must satisfy a valid purpose and rational relation between dismissal and that purpose
  - Court upheld dismissal without choosing between circuits

Potential Collateral Consequences

- Severe penalties– substantial fines
- Different government agencies may investigate the same allegations
- Follow on civil litigation
- Exclusion
- Corporate Integrity Agreements/CCAs
- Monitors

Defense Strategies

- Goal #1: Manage company's credibility dividend in all communications and strategic actions from first call to government
- Define strategy early
  - Goal is always DOJ declination and relator dismissal under seal-most FCA cases resolved that way. How to get there? What about criminal? What about exclusion and debarment?
- Determine what to fight about substantively on legal issues; never housekeeping on document production, unless there is abuse and harassment - watch the CID process

Defense Strategies

- FCA Amendments confirm that proactive defense strategies are necessary preintervention
  - Routine processing is not a defense advantage
- Global approaches
  - Should states be dealt with first in multidistrict matters?
- CIDs and information sharing preintervention will require defense interaction with Court
  - How to position company?
  - Cost Sharing

Defense Strategies

- Whistleblowers are the driver of FCA litigation - assess each complaint
- Compliance program effectiveness reviews must extend beyond 7 elements to program or contract review; training and auditing key
- Audit work plan should take into account contract or program requirements
- Encourage employees, agents, and contractors to use internal channels to address concerns or issues

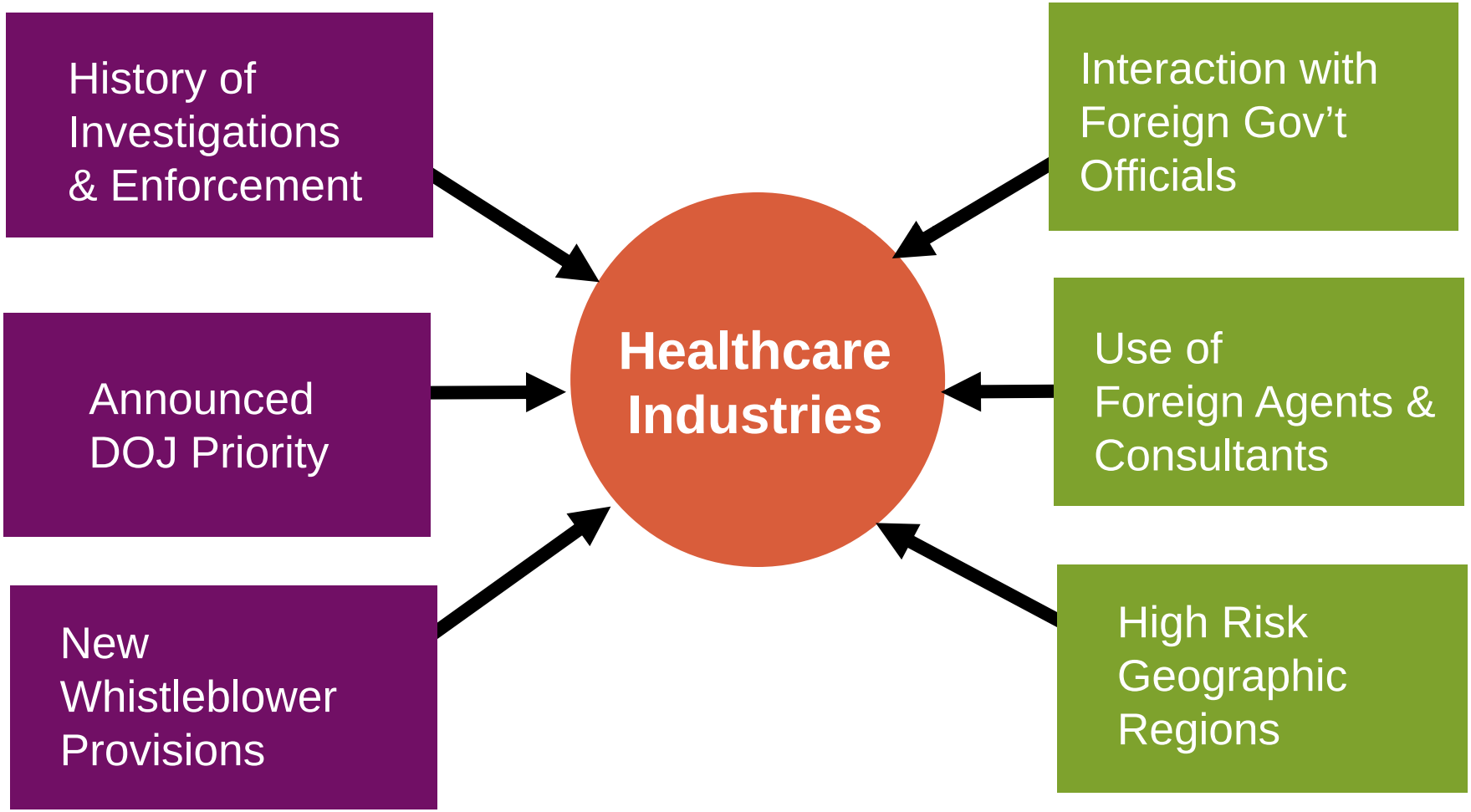
CLE

- If you registered noting that you need CLE for:
  - **NY – The Code is C1603.25. Please save this number; you will need this to receive a Certificate of Attendance. You will be contacted within 30-60 days by our CLE administrative team.**
  - We will process your credits for other states where this program has been approved.
  - Questions? Please email Claire Sherin at csherin@morganlewis.com

Note: If you requested CLE when registering, your request will be processed and there is no need to do anything further.

Foreign Corrupt Practices Act Enforcement

FCPA Enforcement Risk – Healthcare Industries



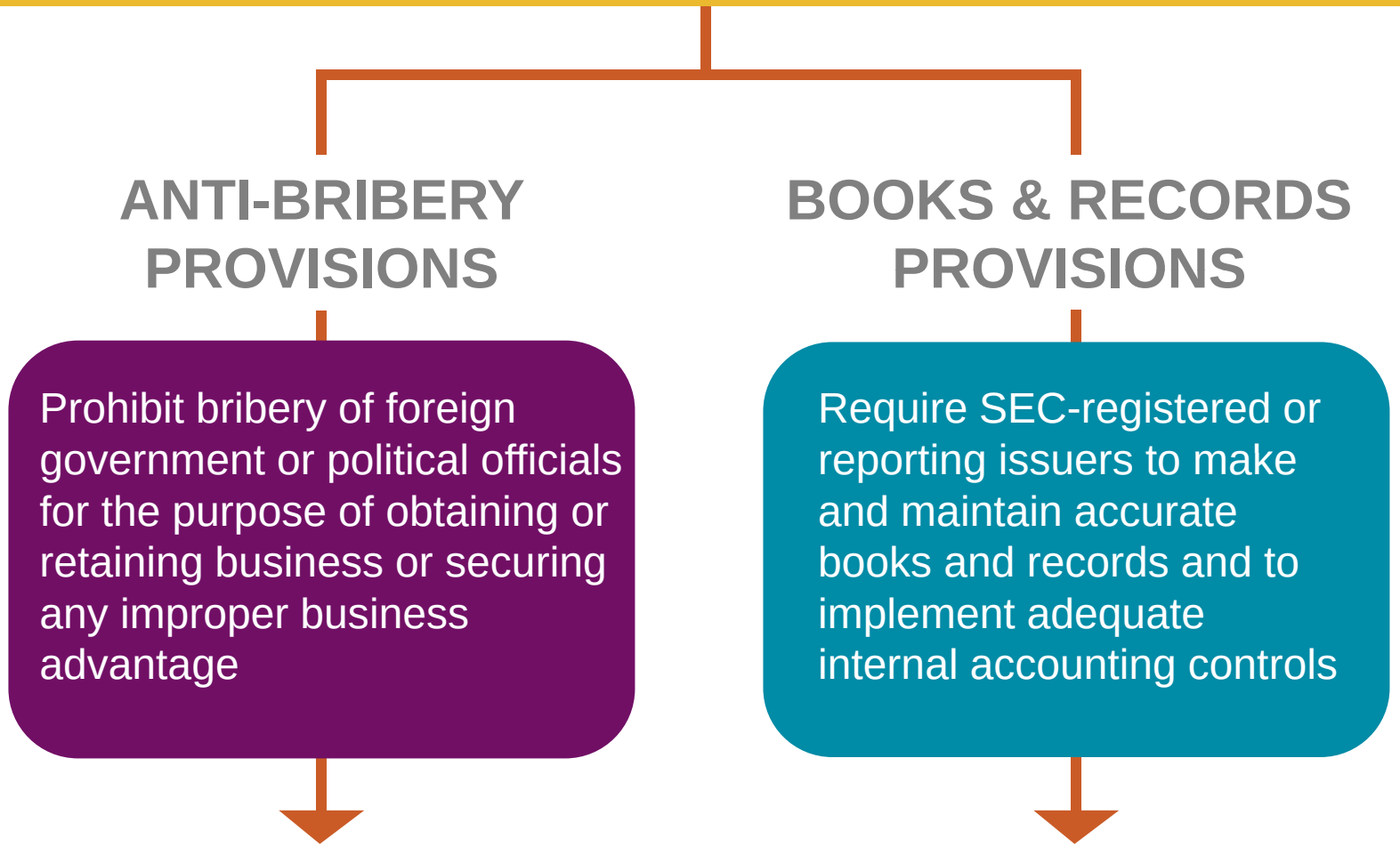
Medical Device FCPA Enforcement

2008	2011	2012
AGA Medical Corp. (June 3, 2008) - China - $2 million penalty	**Johnson & Johnson and Dupuy Inc.** (April 8, 2011) - Greece, Poland, Romania, Iraq - $70 million penalty	**Smith & Nephew** (February 15, 2012) - Greece - $22 million penalty **Biomet, Inc.** (March 26, 2012) - Argentina, Brazil, China - $23 million penalty

Example of Multi-Jurisdiction Enforcement: Johnson & Johnson Settled Charges (April 8, 2012)

- Two principal allegations
  - Improper payments to publicly employed doctors, hospital administrators and pharmacists in Greece, Poland, and Romania
  - Kick-backs to Iraqi government officials by J&J subsidiaries in connection with the U.N. Oil for Food Program
- Multi-jurisdiction enforcement
  - $70.0 million (U.S. – DOJ and SEC)
  - $7.9 million (U.K. Serious Fraud Office)
  - $8.3 million (asset freeze) (Greece)
- Self-disclosure, settlement, and cooperation (U.S. and non-U.S. authorities)

U.S. Foreign Corrupt Practices Act



Antibribery Provisions

- It is unlawful for:
  - an issuer, domestic concern, or anyone acting within the jurisdiction of the United States
  - with “corrupt intent”
  - to directly or indirectly
  - offer, pay, promise to pay, or authorize payment
  - of “anything of value”
  - to a “foreign official”
  - for the purpose of obtaining or retaining business or securing any improper advantage

The FCPA's Third-Party Payment Provisions

- The FCPA's broad definition of knowledge means that a company can be liable for the actions of its agents and third-party representatives
  - Anti-bribery provisions cover improper payments made to "any person, while ***knowing*** that all or a portion of such money or thing of value will be offered, given, or promised, directly or indirectly to any foreign official"
  - Knowledge is established "if a person is aware of a ***high probability*** of the existence of such circumstance, unless the person ***actually believes that such circumstance does not exist***"
- More than 50% of FCPA prosecutions involve liability based on the use of agents and representatives
- Due diligence and monitoring agents and third-party representatives is increasingly important

Books & Records Provisions

- Books and records
  - Must be in reasonable detail that accurately and fully reflect transactions
  - Payments, gifts, and entertainment
- Effective internal accounting controls
  - company policies and procedures
  - documentation (e.g., expense forms)
  - reporting
  - certifications
  - corrective actions

Potential FCPA Fines & Penalties

Business Organizations

- $25 million criminal fine per violation (books & records and internal control violations)
- Up to $2 million criminal fine per violation (anti-bribery violations)
- $10,000 civil penalty or disgorgement of gross gain
- Alternative Fines Statute, 18 U.S.C. § 3571(d) (twice the gain or loss)

Individuals

- 20 years in prison and/or $5 million per violation (books & records and internal control violations)
- 5 years in prison and/or $250,000 fine per violation (anti-bribery violations)
- $10,000 civil penalty or disgorgement of gross gain
- Alternative Fines Statute, 18 U.S.C. § 3571(d) (twice the gain or loss)

Potential FCPA Collateral Consequences

- Investigation Costs
- Business Disruption
- Foreign Enforcement Actions
- Reputational Harm
- Deferred Prosecution Agreements
- Independent Compliance Monitors
- Civil Litigation
- Exclusion from Government Contracting ("Corporate Death Penalty")
- Recission of Contracts, Permits

The FCPA: Broad Jurisdictional Reach

Anti-Bribery Provisions

- U.S. persons
- FCPA issuers
- Domestic concerns
- Any officer, director, employee, or agent of an FCPA issuer or domestic concern, or any stockholder "acting on behalf of" an FCPA issuer or domestic concern that does any act outside of the United States
- Any persons, including organizations, wherever located, that, while in U.S. territory, performs any act in furtherance of the prohibited conduct

Books & Records Provisions

- FCPA issuers (direct liability)
- Aiders and abettors
- Control persons (civil liability only)
- Any person who willfully makes or causes to be made false statements in a required filing

Extraterritorial and Territorial Jurisdiction

Extraterritorial Jurisdiction	Territorial Jurisdiction
• U.S. persons • FCPA issuers • Domestic concerns • Officer, director, etc. (can be a non-U.S. person)	• Non-U.S. persons • Non-FCPA issuers • Non-domestic concerns
Any act outside of the United States in furtherance of a prohibited act	Use of any means or instrumentality of interstate commerce while in the United States

Healthcare Industries Targeted

- The application of the FCPA to the pharmaceutical industry **"will be a focus for the Criminal Division in the months and years ahead."**

  – Lanny A. Breuer, Assistant Attorney General, Criminal Division Address *to the Pharmaceutical Regulatory and Compliance Congress November 12, 2009*

Healthcare Industries Targeted

"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. **The Criminal Division stands ready to ferret out this illegal conduct and we are uniquely situated to do so.**"

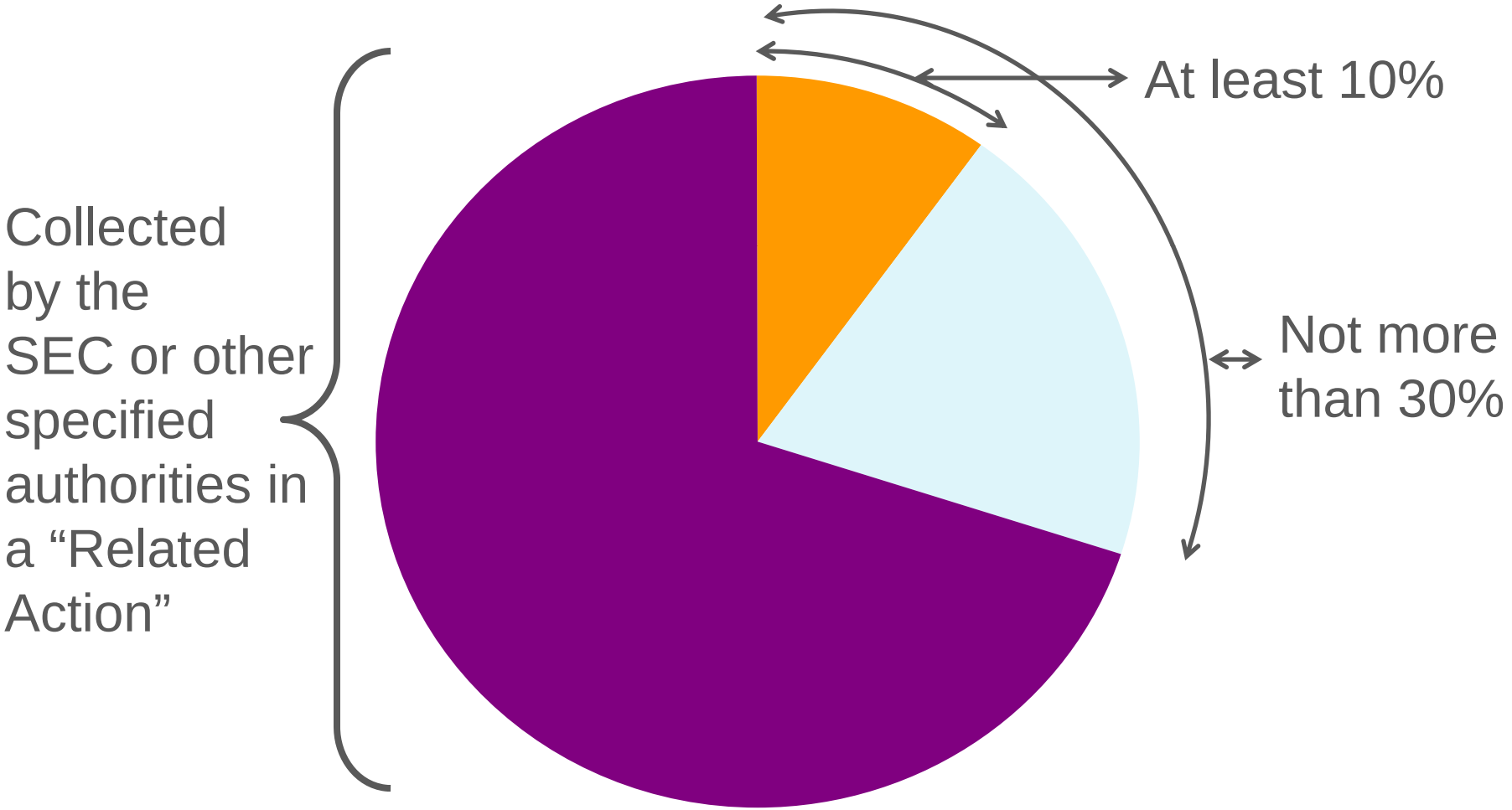
– Lanny A. Breuer, *Assistant Attorney General, Criminal Division*
November 12, 2009

The Dodd-Frank Act

The Dodd-Frank Act Whistleblower's Bounty Provisions

- The SEC will pay an award to one or more whistleblowers who:
  - Voluntarily provide the SEC
  - With original information
  - That leads to the successful enforcement by the SEC in a federal court or administrative action
  - In which the SEC obtains monetary sanctions totaling more than $1,000,000

Dodd-Frank Act Whistleblower Provisions
Amount of Award



SEC Office of the Whistleblower

- Established 2011
- Seven attorneys including Chief and Deputy
- Responsible for handling tips, working with whistleblowers, helping SEC determine award amounts
- SEC announcement, February 18, 2011 – Office to be headed by Sean McKessy, former Corporate Secretary for Altria Group, Inc. and AOL, Inc. and former Securities Counsel for Caterpillar, Inc.
- SEC FY2012 budget calls for creation of 43 new positions for the Whistleblower Program

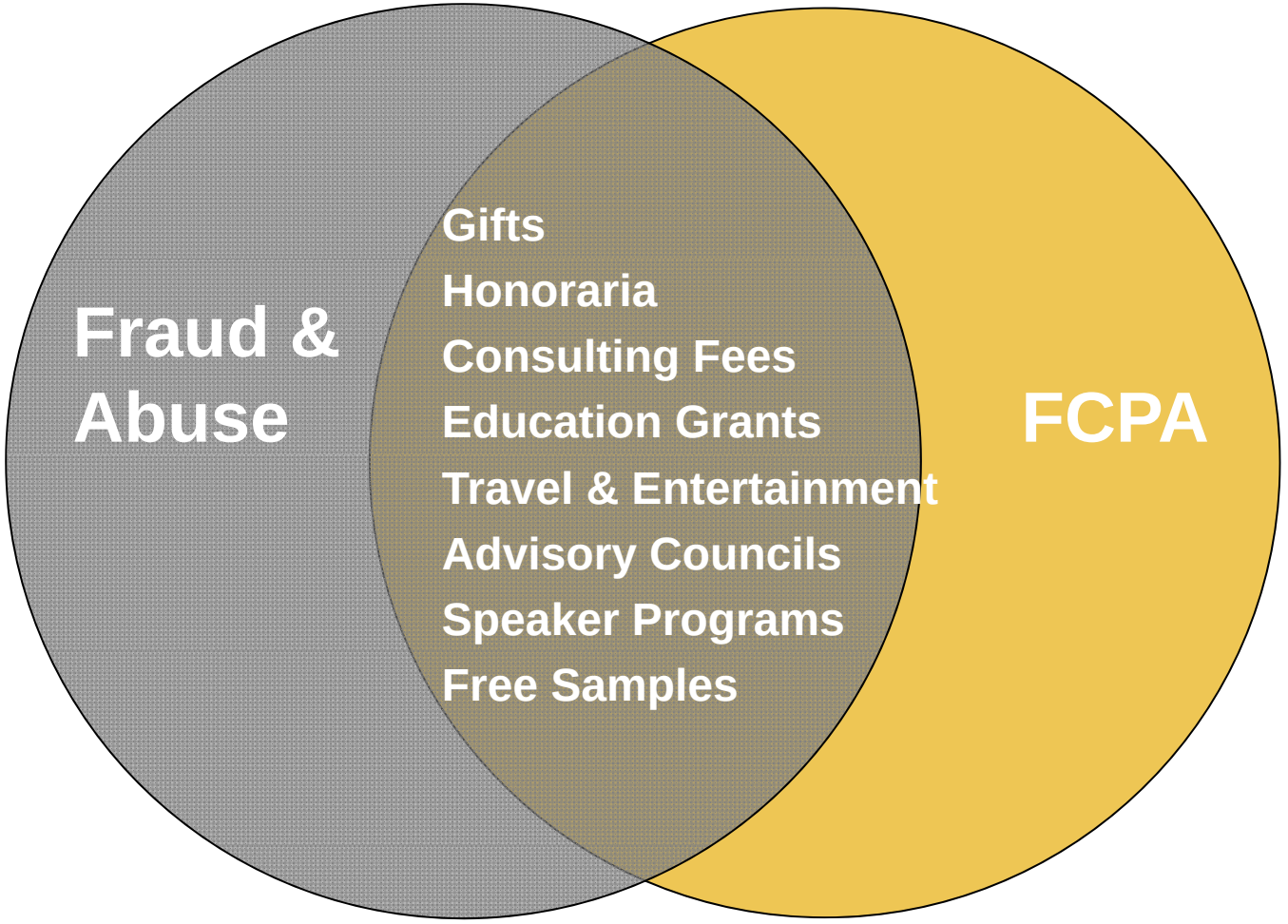
SEC Office of the Whistleblower

- Whistleblower website describes program, explains how to submit a tip and claim an award
  - Includes list of *every* Commission action since 7/21/10 where final judgment resulted in total monetary sanctions exceeding $1 million
    - *More than 200 qualifying actions listed*
    - *Individuals have 90 days from date notice of covered action is posted to apply for an award*

Anticorruption Challenges for Healthcare Companies

- Expanding an international presence is a key long-term growth strategy for many leading health-care companies
- Developing nations are spending more money on healthcare and driving the increase in global demand
- Foreign hospitals, clinics, laboratories, and medical providers frequently are state-owned or state-controlled
- Employees of state-owned or state-controlled entities are “foreign officials” under the FCPA
- Companies work through commercial agents and other third-party representatives

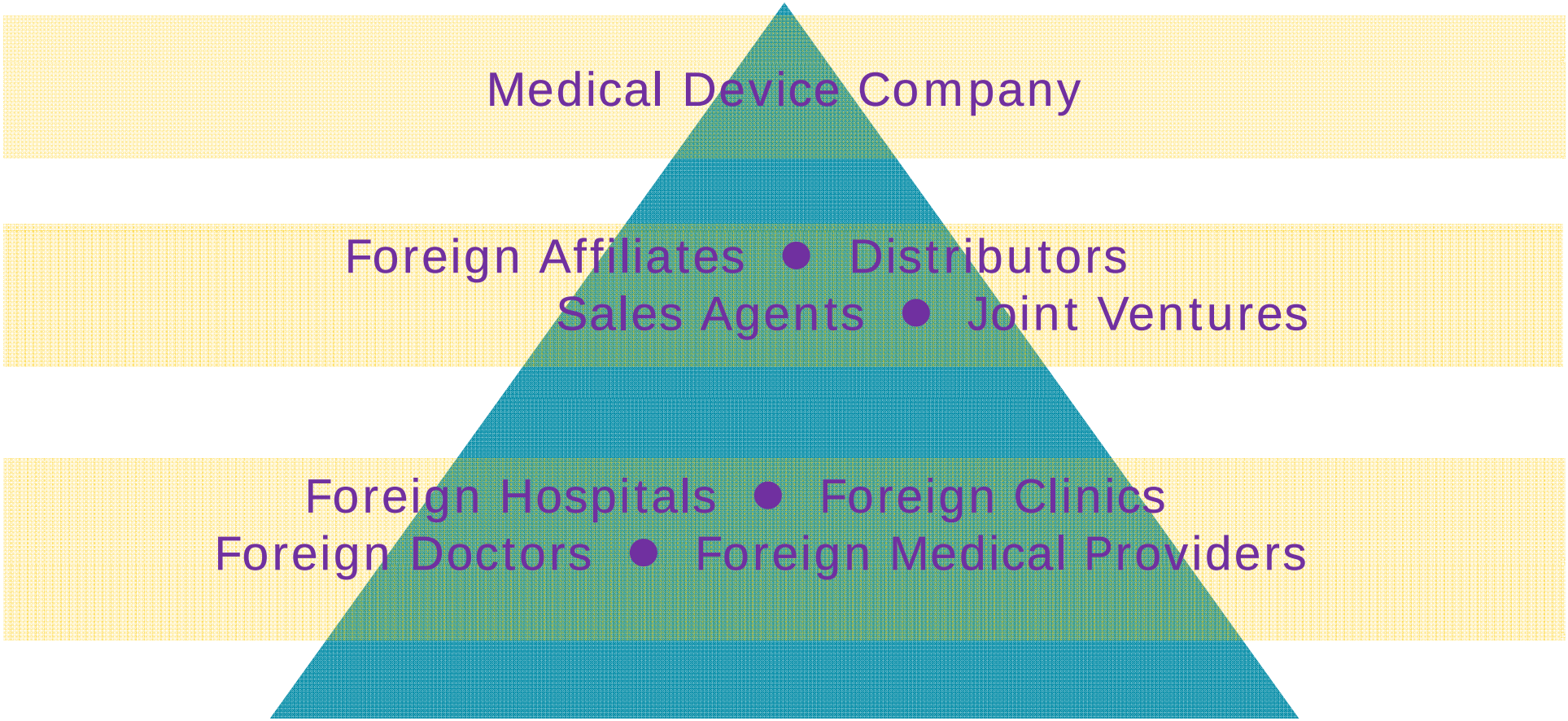
Healthcare Industries – Potential FCPA Issues



The AdvaMed Code Addresses many Potential FCPA Risk Areas

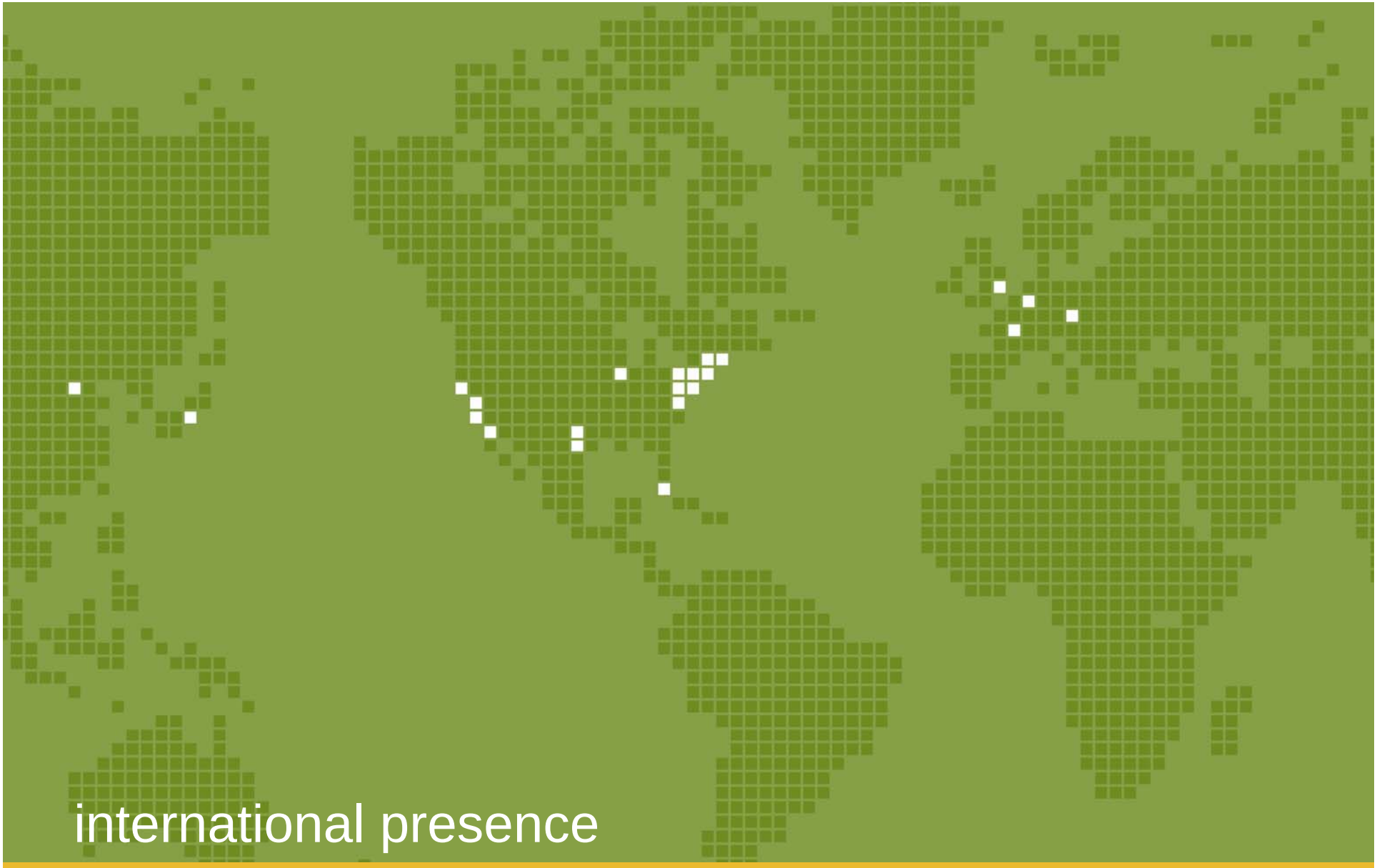
- Supporting third-party educational conferences
- Consulting arrangements with HCPs
- Prohibition on entertainment and recreation
- Modest meals associated with HCP interactions
- Educational items, prohibition on gifts
- Research and educations grants and charitable donations
- Company-conducted product training and education
- Evaluation and demonstration products

Doing Business Through Third-Parties



Third-Party Representatives: Government Expectations

- Due diligence
- Contractual certifications and assurances
- Codes of Conduct for overseas business partners
- Audit rights
- Audits



international presence

Beijing Boston Brussels Chicago Dallas Frankfurt Harrisburg Houston Irvine
London Los Angeles Miami New York Palo Alto Paris Philadelphia Pittsburgh
Princeton San Francisco Tokyo Washington Wilmington