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The Government's Attack on Drug and Device Executives

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Apr. 21, 2011
2:00 – 3:30pm EST
Thompson Publishing Group

Overview of Our Discussion Today

- A “Perfect Storm” for Executives
- OIG’s Permissive Exclusion Authority and the October 2010 Guidance
- The Park Doctrine and FDA’s Publication of Referral Criteria for Executives in February 2011
- Other Sources of Executive Liability under the Federal Healthcare Laws
- Recent Cases Involving Prosecution and/or Exclusion of Executives
- Considerations for Navigating Enforcement Actions
- Q&A

A "Perfect Storm" for Executives

- Pressure by Congress to combat fraud/waste
- Previously unseen level of coordination by agencies empowered to enforce the federal Food, Drug, and Cosmetic Act (FDCA), fraud/abuse laws, the Foreign Corrupt Practices Act, and other healthcare-related laws against corporations and individuals
  - Clear indication that tools such as permissive exclusion authority and Park Doctrine will be used to pursue individuals
  - Convergence in prosecution theories

Convergence of Enforcement Approach

- Recent enforcement actions have resolved as multi-agency settlements at the state and federal level involving several converging areas of government scrutiny:
  - Sales and marketing practices
  - Publication and dissemination of clinical research
  - Consulting relationships with HCPs
  - Product manufacturing and distribution
  - Government reporting requirements (*e.g.*, adverse event reports, product pricing, securities filings)

OIG EXCLUSION AUTHORITY

What is "Exclusion"?

- The Office of Inspector General of the Department of Health and Human Services (OIG) is authorized to exclude an individual or company from participation in Medicare, Medicaid and other Federal health care programs
  - *See* 42 U.S.C. § 1320a–7; 42 C.F.R. Part 1001

- Mandatory vs. Permissive Exclusion
  - Grounds relate to the kind of misconduct associated with the program (*e.g.*, conviction in connection with providing services, bribery, fraud, illegally dispensing controlled substances, etc.)
  - No payment for items or services furnished by excluded individuals or entities or directed by excluded physician
  - May be permanent or temporary

- Adjudicated in an administrative proceeding; final decision subject to judicial review

- Civil money penalties may be imposed on excluded individuals who provided services while excluded and on companies who knowingly employ such individuals

Permissive Exclusion Under (b)(15)

- Section 1128(b)(15) of the Social Security Act provides OIG with discretionary authority for strict liability exclusion of individuals who:
  - Have an ownership interest in a sanctioned entity and knew or should have known of the conduct giving rise to sanctions; or
  - Are executives and managers who are deemed responsible parties by virtue of their positions within a sanctioned entity, irrespective of actual knowledge of the conduct giving rise to sanctions.

Permissive Exclusion Under (b)(15) (cont'd)

- Where there is evidence that an owner, officer, or manager **knew or should have known** of the sanctioned conduct, OIG will apply a rebuttable presumption of exclusion
- Presumption may be overcome where OIG finds that "**significant factors** weigh against exclusion"
  - These "mitigating" factors are undefined

The Latest OIG Guidance

- October 20, 2010, OIG released its Guidance for Implementing Permissive Exclusion Authority under (b)(15)
- The Guidance signals a shift to **proactively use exclusion as a punitive tool to achieve deterrence**
  - OIG exclusion authority traditionally functioned as a remedial tool to protect the Medicare program from individual bad actors
- Stated purpose of Guidance was to (a) improve investigations, (b) establish a framework for exclusions, and (c) to "positively influence individuals' future behavior and compliance with Federal health care program requirements."
- Stirs debate about whether OIG decision to exercise (b)(15) exclusion authority is subject to administrative or judicial review

Factors Driving the Exercise of Authority

1. **Circumstances surrounding the misconduct** and the seriousness of the sanctioned offense, including the nature and scope of the misconduct, the level at which the conduct occurred, the sanctions leveled against the entity, the harm to beneficiaries and federal health care programs, and whether the misconduct was an aberration or part of a greater pattern. OIG will factor-in the conduct of related entities, a corporate parent or subsidiary, and the scope of its review will include "all allegations in criminal, civil, and administrative matters."
2. **Executive's role** in the company. OIG is concerned with an individual's degree of control or authority at the time of the underlying misconduct.

Factors Driving the Exercise of Authority (cont'd)

3. **Executive's response** to the misconduct. That is, OIG will look to what steps the individual took to mitigate the harm caused by the violation and to whether the individual disclosed the misconduct to the appropriate authorities.
4. OIG will consider **characteristics of the entity**, including its size, corporate structure, and past conduct.

Factors Driving the Exercise of Authority (cont'd)

- Another example of convergence:

  "These factors were derived from multiple sources, including: (1) the regulations governing exclusions under sections 1128(b)(15) and 1128A of the Act (42 CFR parts 1001 and 1003); (2) the factors for implementation of permissive exclusion under section 1128(b)(7) (62 Fed. Reg. 67392 (Dec. 17, 1997)); (3) **the responsible corporate official doctrine established in case law, including *U.S. v. Park*, 421 U.S. 658** (1975); and (4) decisions of the Departmental Appeals Board in exclusion matters. (emphasis added)"

THE PARK DOCTRINE

Recently Published FDA Referral Criteria

- February 2, 2011, FDA published non-binding criteria in its Regulatory Procedures Manual (RPM) for referrals of Park Doctrine cases for prosecution
- The RPM comes a year after FDA notified Senator Charles Grassley of its intention to put forth definitive referral criteria
  - Provides that actual knowledge of and participation in a violation are relevant facts to be considered for purposes of evaluating whether a referral for prosecution is merited
  - However, once again reiterates that knowledge and participation are **not prerequisites** to Park Doctrine prosecution

What is the Park Doctrine?

- In *United States v. Park* (1975), the U.S. Supreme Court held that individuals who have the authority to prevent and/or detect and correct violations of the FDCA are vicariously liable for the violative acts of their subordinates or agents
  - Responsible corporate officers (RCOs) have an **affirmative duty** to seek out and remedy violations and implement measures to prevent violations
  - Failure to exercise proper care in carrying out duties creates liability
  - Delegation to subordinates does not negate liability
  - Potential defenses very limited (*e.g.*, impossibility)

Roots of the Park Doctrine

- Strict vicarious liability of individuals under the FDCA is nothing new
- *United States v. Dotterweich (*1943)
  - U.S. Supreme Court held that the FDCA imposes strict liability on corporations and individual defendants
  - The government is not legally required to show that an individual defendant knowingly committed the violations
  - A “responsible corporate officer” is an executive who stands in “responsible relation” to public danger
  - Decisions regarding who is the “responsible corporate officer” are left to “the good sense of prosecutors, the wise guidance of trial judges, and the ultimate judgment of juries.”

Who Can Be an RCO?

- Anyone with authority to prevent or detect and correct violations
- Most often:
  - Highest ranking corporate officer (*e.g.*, president or CEO)
  - Executive with direct authority to implement corrective actions (*e.g.*, director of regulatory affairs or director of corporate compliance)
  - Legal staff

FDA Referral Key Considerations

1. The executive's position and relationship to the alleged violation;
2. Whether the executive had authority to correct or prevent the alleged violation;
3. Whether the alleged violation itself posed actual or potential public harm;
4. The extent to which the alleged violation was obvious to the executive;
5. Whether the alleged violation reflects a pattern of behavior and whether there had been prior warnings;

FDA Referral Key Considerations (cont'd)

6. The extent and breadth of the alleged violation;
7. The seriousness of the alleged violation;
8. The quality and quantity of the available evidence; and
9. Whether prosecution is a prudent use of government resources

- Noteworthy omission from the Criteria is any contemplation that efforts by executives to discover and prevent misconduct should be countervailing considerations that favor a declination of referral

Consequences of the Park Doctrine

- Under *Park* a medical product company executive who fails to meet her duty of care to prevent or detect and correct FDCA violations from occurring can be charged with a **strict liability misdemeanor** if a violation occurs under her watch
- Recall that the FDCA provides for strict misdemeanor criminal liability for corporations and individuals that commit enumerated prohibited acts
- The FDCA also provides for **strict felony liability** for recidivists

OTHER SOURCES OF INDIVIDUAL LIABILITY UNDER THE FEDERAL HEALTHCARE LAWS

The FDCA

- FDA is empowered to pursue enforcement actions against individuals under a wide range of criminal, civil, and administrative theories
  - As inter-agency cooperation increases, Congress' broad enforcement mandate under the FDCA, as well as its strict liability provisions for "prohibited acts", make it an attractive enforcement tool
  - Prosecutions under related theories (wire fraud, obstruction, civil False Claims Act, etc.) are supported by favorable case law

Individual Liability Under the FDCA

- Section 301 of FDCA – "Prohibited Acts"
  - Can be basis of violations of Title 18 of the U.S. Code (*e.g.*, mail and wire fraud, false statements, conspiracy, etc.)
- Judicial Remedies (FDA goes to court)
  - Criminal prosecution
  - Injunctions
    - Restitution
    - Disgorgement
- Administrative Remedies (FDA acts on its own)
  - Civil Money Penalties
  - Debarment due to ANDA activities
  - Disqualification from research activities
  - Adverse publicity

Criminal Prosecution

- Section 303(a) of the FDCA imposes criminal sanctions against persons who commit a prohibited act or cause such acts to be committed
  - Misdemeanor without a showing of intent (*i.e.,* strict liability)
  - Felony if done with intent to defraud or mislead
  - Strict felony liability for a second offense
- Fines and prison sentences determined by Federal Sentencing Guidelines
- Courts may order restitution for violations of Title 18 of the U.S. Code
  - *See* 18 U.S.C. §§ 3663 and 3663A

Criminal Prosecution (cont'd)

- FDA's Office of Criminal Investigations (OCI) is responsible for initiating criminal investigations and recommending criminal matters to DOJ in consultation with FDA's Office of Chief Counsel
- Investigations may be initiated based on tips and complaints from company whistle blowers, competitors, or consumers
- Evidence may come from undercover investigations or routine FDA inspections

When are Criminal Prosecutions Recommended?

- Manufacturing and sale of counterfeit and unapproved drugs
- Illicit prescription drug diversion
- Product substitution and product tampering crimes
- Schemes involving fraudulent health treatments
- Fraud involving NDAs, PMAs, or clinical investigations
- Fraud involving FDA regulated products
- Continuous, repeated, gross, flagrant, or intentional FDCA violations
- Evidence of actual harm or injury to the public as a result of FDCA violations

Injunctions

- Section 302 of the FDCA authorizes injunctions to restrain most violations of Section 301
  - Action against an individual or company or both
  - Evidence of actual injury or harm not required

- Two types of Injunction
  - Prohibitive
    - Defendant may not engage in designated activity “unless or until” FDA finds that defendant has come into compliance
  - Mandatory
    - Defendant may continue to engage in designated activity, but must take specific actions, pursuant to specific timetable, or be subject to penalties or other sanctions

When are Injunctions Recommended?

- Evidence of recent violations with prior history of same
- Cessation of operations is needed to halt the flow of violative products in interstate commerce
- Health hazard or gross consumer deception requiring immediate action
- Failure to correct pre-existing violations
- Significant amounts of violative products owned by the same person or company in several different locations

What is the Scope of Executive Liability in an Injunction?

- Individual defendants liable for future violations and failure to implement adequate corrective actions
- Individual defendants subject to contempt action, liquidated damages, disgorgement or restitution
- Burden for lifting permanent injunction can be difficult to satisfy (*e.g.*, 5-7 years of continuous compliance or no significant violations)

Consent Decrees

- Consent Decrees
  - Negotiated settlements between FDA and a defendant
  - Can result from seizure action, money penalties, or criminal action
  - Violations of decree can result in liquidated damages

- FDA is currently including liquidated damages provisions in consent decrees
  - Baxter (2006)
  - GE Healthcare (2007)
  - Medtronic/Physio-Control (2008)

Equitable Remedies: Restitution and Disgorgement

- Equitable Remedies
  - According to FDA, a court "sitting in equity" in an injunction proceeding can order ancillary equitable relief
  - FDA typically recommends equitable remedies in cases involving fraud on consumers or where there are repeated or systemic violations
  - Restitution requires the defendant to make its victims "whole" for losses suffered
  - Disgorgement strips the defendant of "ill-gotten gains"

Equitable Remedies: Restitution and Disgorgement (cont'd)

- FDA first sought restitution in *Universal Management* (1999)
  - Defendant sold $1 electric gas grill starters for $90 as pain relieving medical devices
  - US Court of Appeals for the 6th Circuit upheld restitution in *Universal Management* (1999)
- FDA includes restitution and disgorgement in enforcement Actions
  - Abbott Laboratories (1999)
  - Wyeth (2000)
  - Schering-Plough (2002)
- Subsequent cases
  - *Lane-Labs-USA* (3rd Cir. 2005) (restitution)
  - *Rx Depot* (10th Cir. 2006) (disgorgement)

Equitable Remedies: Restitution and Disgorgement (cont'd)

- Court has broad discretion in determining the amount of restitution or amounts to be disgorged
  - Calculation need only be a "reasonably approximation" of the amount of customers' net losses or defendant's profits gained from violation
  - Court takes into account the financial resources of the defendant, the financial needs and earning ability of the defendant and the defendant's dependants, and such other factors as the court deems appropriate
  - Defendants may be ordered to provide gross revenues of company, revenues associated with product involved, corporate and individual tax records, customer lists and payment information

FDA's Administrative Enforcement Options for Prohibited Acts

- Four basic options under FDCA
  - Civil Money Penalties
  - Debarment due to ANDA activities
  - Disqualifications
  - Adverse publicity

- FDA does not have to go to court for most administrative actions
  - FDA Center or Commissioner is represented by Office of Chief Counsel (in most cases)
  - FDA has the burden of establishing statutory violation
  - Most cases are adjudicated by FDA Administrative Law Judge (ALJ)
  - Final decision subject to judicial review

Civil Money Penalties (CMPs)

- The FDCA contains specific statutory provisions that permit FDA to impose CMPs through an administrative process
  - No general CMP authority for all violations
  - Notice and opportunity for hearing before an ALJ
  - Right to seek judicial review of ALJ decision
  - CMPs may be sought separately from, or in connection with, another civil or criminal action under the FFDCA
- Maximum penalty for each violation depends on the authorizing statute and is adjusted periodically for inflation
- Procedures governed by 21 C.F.R. Part 17

Drug-Related CMPs

- Prescription Drug Marketing
  - Applies to companies if a sales representative is convicted of selling or trading drug samples, or if company fails to report such convictions to FDA
- Direct-to-Consumer Drug Advertising
  - Applies to DTC ads for Rx drugs and biologics that are false and misleading
- Risk Management and Mitigation Strategies (REMS)
  - Applies to failures to conduct mandated post-approval studies, to implement FDA-ordered labeling changes, and to develop and implement REMS programs as directed by FDA

Drug-Related CMPs (cont'd)

- Clinical Trial Registry and Results Data Bank Requirements
  - Applies to failure to submit (or submitting false or misleading) information on drug trials to NIH's clinical trials website
- Generic Drugs (Misconduct Relating to ANDAs)
  - Applies to false statements, failure to disclose material information, destruction of evidence, bribery, obstruction of FDA inspections

When are CMPs Recommended?

- Seizure, injunction, or criminal prosecution is not appropriate or adequate
- Policy or regulation is reasonably clear (e.g., Federal Register notice, guidance, warning letter)
- In most cases, FDA has given prior notice (e.g., FDA form 483, Warning Letter or other correspondence, or regulatory meetings with company)
- Evidence of chronic violations over a short period of time
- Repeated failures to comply with the same or similar requirements more than once

The Intersection of Criminal, Civil, and Administrative Penalties under the FDCA

- *AbTox* (2006)
  - Two executives received ten-year and six-year prison sentences, respectively, for felony FDCA violations relating to the introduction of adulterated and misbranded sterilizers into interstate commerce
  - Ordered to pay over $17 million in restitution
  - Sentences were affirmed, but restitution order vacated by US Court of Appeals for 7th Cir (2008)

- *Advanced Bionics* (2008)
  - Company and executive agreed to pay civil money penalties of $1.1 million and $75,000, respectively, for FDCA violations relating to failure to comply with PMA requirements relating to Cochlear Implants

Debarment Due to ANDA Activities

- Section 306 allows FDA to prohibit individuals from participating in certain aspects of the drug approval process as a result of misconduct involving ANDAs

- Mandatory vs. Permissive Debarment
  - Grounds relate to the kind of misconduct associated with ANDA (*e.g.*, prior convictions for FDCA violations, bribery, fraud, etc.)
  - FDA will not accept or review any ANDA or NDA submitted by a company or individual that has been debarred or submitted by a company that has been assisted by an individual or company that has been debarred
  - May be permanent or temporary

- Civil money penalties may be imposed against individuals or companies who knowingly employ debarred individuals or against individuals or companies who provide services while debarred

Debarment Due to ANDA Activities (cont'd)

- "High managerial agents" may be debarred if they:
  - worked for the same company as another individual convicted of felony that resulted in debarment
  - had actual knowledge of the conduct or took steps to avoid actual knowledge
  - knew that debarred individual's actions violated the law, and failed to report
  - failed to take other appropriate action that would have ensured that the process for the regulation of drugs was not undermined

Disqualification from Research Activities

- FDA regulations deny access to investigational drugs to clinical researchers found to have been engaged in "deliberate or repeated" violations of IND requirements
  - *See* 21 C.F.R. §§ 312.70 (drugs); 812.119 (devices) and 511.1(animal drugs)
  - Applies to violations of good laboratory practice requirements
  - Applies to violations of IRB rules
- Disqualification proceedings filed by FDA's Office of Chief Counsel
- Governed by 21 C.F.R. Part 16

Adverse Publicity

- Section 705 of the FDCA allows FDA to disseminate information "in situations involving, in the opinion of [FDA], imminent danger to health or gross deception of the consumer"

- FDA routinely issues press releases upon filing of enforcement actions
  - Announcements may affect stock prices
  - May adversely affect reputation of company and individual officers

Individual Liability Beyond the FDCA

- Several statutes prescribe individual liability for other health care-related violations
  - Anti-Kickback Statute
    - Prohibits knowingly seeking or paying remuneration in exchange for referral of services or products covered by federal health care programs
  - Stark Law
    - Prohibits physicians from referring services to entities in which they or their immediate family members have a financial interest
  - False Claims Act (*qui tams*)
    - Allows whistle-blowers to bring a suit on behalf of the government against individual or company responsible for the alleged fraud
  - Controlled Substances Act
    - Prescribes criminal liability for various violations relating to the sale, distribution, and dispensing of Rx drugs
- Violations may lead to exclusion from federal programs

RECENT CASES

Overview

- The government's recent enforcement actions against Forest Labs, KV Pharmaceutical, and Purdue Pharma are important examples of cross-agency cooperation in pursuing aggressive prosecution of individuals under the FDCA and related theories

The Forest Labs Case

- On September 15, 2010 DOJ announced that Forest agreed to plead guilty to charges relating to obstruction of justice in connection with an FDA inspection, the distribution of Levothroid, an unapproved new drug used to treat hypothyroidism, and the illegal promotion of Celexa, an anti-depressant drug for use in treating children and adolescents.
- Forest paid more than $313MM in criminal and civil fines and penalties
- Last week, Forest Labs CEO and Chairman Howard Solomon announced that he had received an exclusion notice from OIG and that he intended to vigorously challenge the decision
  - Though the letter is not yet posted online, it is likely connected to Mr. Solomon's role as an RCO during the allegedly violative activities at Forest Labs

The KV Pharmaceutical Case

- In March 2010, KV Pharmaceutical and its subsidiary, Ethex Corporation, resolved a criminal investigation into the failure of Ethex to file field reports to FDA to alert the Agency of manufacturing irregularities with the drugs propafenone and dextroampthetamine sulfate
- To resolve the investigation, Ethex pleaded guilty to a two-count Information charging the company with two felony counts of failing to maintain records or reports required under 21 U.S.C. § 355(k) with an intent to defraud or mislead and paid approximately $27.6 MM in fines, forfeiture, and restitution
- As part of its agreement with OIG, KV agreed to dissolve Ethex
- The criminal settlement followed a 2009 FDA investigation into manufacturing and recordkeeping irregularities which resolved in KV entering into a Consent Decree for Permanent Injunction with FDA

The KV Pharmaceutical Case (cont'd)

- Marc Hermelin (then the CEO), was named along with several other KV Pharmaceutical executives in the 2009 Consent Decree which prohibited KV Pharmaceutical, its subsidiaries, and certain of its officers and directors, including Mr. Hermelin, from manufacturing drugs pending FDA review of KV Pharmaceutical's manufacturing practices
- The 2010 Information named but did not charge an individual known as "KV [Pharmaceutical] corporate executive A", an "agent of Ethex" who "was also a corporate executive at KV" who "chose" to "do nothing" when presented with evidence that further manufacturing irregularities were occurring at Ethex and allegedly tried to limit an Audit Committee inquiry

The KV Pharmaceutical Case (cont'd)

- On November 15, 2010, OIG posted notice that it intended to exclude Mr. Hermelin under (b)(15) (less than a month after it announced its Guidance); Mr. Hermelin did not challenge his exclusion
- On March 10, 2011, Mr. Hermelin, pleaded guilty to two misdemeanor violations of the FDCA for his role as failing to discharge his duties as an RCO during the violative activities at Ethex, and was ordered to pay a $1 MM fine, forfeit $900,000, and serve a 30-day jail sentence

The Purdue Pharma Case

- In May 2007, the government announced that it had reached a settlement with Purdue Fredrick Company, Inc. and its parent, Purdue Pharma, L.P. to resolve a multi-year criminal and civil investigation into alleged off-label promotion of OxyContin
  - In public criminal and civil filings, the government argued that Purdue illegally promoted OxyContin as “less addictive, less subject to abuse and diversion, and less likely to cause tolerance and withdrawal than other pain medications.”
  - Purdue Pharma paid approximately $600 MM in criminal and civil penalties
  - Purdue Fredrick pleaded guilty to a felony

The Purdue Pharma Case (cont'd)

- Purdue Fredrick's President, General Counsel, and Chief Medical Officer each pleaded guilty to one misdemeanor count of distribution of misbranded OxyContin by virtue of their positions as RCOs; paid over $35MM in fines and penalties
- After the settlement, OIG notified the executives of its intention to exclude
- Upon considering the executives' responses to the exclusion letters, OIG elected to exclude the executives for 20 years based on two aggravating factors: (1) the duration of the conduct exceeded one year; (2) the conduct allegedly resulted in significant financial harm to program beneficiaries
- OIG agreed to reduce term from 20 to 15 years, and DAB further reduced from 15 to 12 years

The Purdue Pharma Case (cont'd)

- OIG used permissive exclusion provisions (b)(1) and (b)(3)
  - The case is instructive given that the executives were convicted under the Park Doctrine, which like (b)(15) does not require actual knowledge
  - Subsection (b)(1) allows OIG to exclude individuals convicted of a misdemeanor related to health care fraud
  - Subsection (b)(3) allows exclusion of individuals convicted of a misdemeanor related to the manufacture, distribution, prescription, or dispensing of a controlled substance
- The executives argued on appeal that no there was no "personal wrongdoing," and that excluding them was inconsistent with the remedial purpose of the exclusion statute

The Purdue Pharma Case (cont'd)

- D.C. District Court rejected arguments that they were not guilty of personal wrongdoing and that application of the exclusion penalty was inappropriate where it failed to serve a remedial purpose.
  - Court reasoned that (1) the failure to know and the failure to act where the law imposes a duty constitutes wrongdoing; and (2) application of the exclusion provision to the executives was consistent with the provision's ultimate purpose of protecting federal health care programs and program beneficiaries.
  - Court said that the statute was intended "'to provide a clear and strong deterrent against the commission of criminal acts.'"
  - With respect to the duration of the exclusion period, Court concluded that the aggravating factors cited by the Secretary were supported by the admission during the prior pleas
- Exclusions were ultimately upheld in December 2010

Other Noteworthy Prosecutions

- Former biotech CEO W. Scott Harkonen sentenced last week after a nearly three-year trial for wire fraud in connection with distribution of a clinical press release
- Several Stryker Biotech sales reps and executives are awaiting sentencing for misbranding, false statements, and wire fraud in connection with alleged off-label promotion and falsification of IRB approvals and adverse event reports related to a 2009 investigation
- Settlement earlier this month between SEC and J&J/DePuy for paying bribes to doctors in Greece and elsewhere between 1996 and 2006 to purchase or prescribe J&J devices; follows bribery prosecution of a marketing executive by UK authorities

CONSIDERATIONS FOR NAVIGATING ENFORCEMENT ACTIONS

Considerations for Navigating Enforcement Actions

- **Conduct a due diligence investigation before responding to a subpoena, sign-or-sue letter, or other government communication**
  - Locate relevant documents and employees
  - Scrutinize internal written policies
  - Scrutinize prior public statements, filings, and past communications with government, media, etc.
- **Manage communications**
  - Develop a strategy for communicating with the government, company officials and employees
  - Make sure that employees understand the distinction between lawyers who represent the company and lawyers who represent individuals

Considerations for Navigating Enforcement Actions (cont'd)

- **Determine whether you need separate counsel**
  - Are you the "target" or the "subject" of an investigation?
  - Could your actions be viewed as conflicting with the interests or policies of the company?
  - Were your actions clearly within the scope of your employment?

- **Consider the risks or benefits of waiving attorney-client privilege**
  - Privilege relating to company communications with its attorneys belongs to the company and not the individuals
  - Carefully consider the scope of the company's waiver and the implications of such a waiver on individual's interests

Best Practices

- Proper management oversight
  - Verify, evaluate, document completion/implementation of compliance programs
- Effective compliance and training measures
  - Make sure subordinates know the laws and understand the risks
- Conduct routine internal audits and self-critical analyses
  - Select reputable third-party consultants and auditors
- Select, train, reward or promote motivated employees
  - Make sure QA and compliance employees have meaningful authority, respect, and influence within the corporation
  - Establish procedures for handling employee complaints regarding violations of corporate policies
- Appropriately manage the government's expectations
  - Respond appropriately to warnings or notices from FDA or other agencies
  - Negotiate reasonable timeframes for implementing corrections

The Future

- Increased enforcement by FDA, OIG, and DOJ
- CIAs will continue to require individual compliance certifications and board resolutions
- Corporate officers increasingly becoming targets
- Penalties are increasing
- Greater settlement pressure
- Adverse publicity increasingly being used as enforcement/settlement strategy

Questions?

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