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Executive Liability: Beyond the Park Doctrine

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Vernessa T. Pollard

Agenda

- Individual Liability
  - Recent Cases
  - The Park Doctrine
- Individual Liability under the Federal Food, Drug and Cosmetic Act (FFDCA)
  - Basic violations
  - FDA's enforcement options and approaches
- Liability Beyond the FFDCA
  - Enforcement of other healthcare laws
- Considerations for Navigating Enforcement Actions
- Best Practices

Recent Cases

- *AbTox (2006)*
  - Two executives received ten-year and six-year prison sentences, respectively, for felony FFDCA 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)

- *Purdue Pharma (2007)*
  - Company and three executives pleaded guilty to misdemeanor FFDCA violations relating to the promotion and marketing of the painkiller OxyContin
  - Company agreed to pay $634.5 million in fines

- *Advanced Bionics (2008)*
  - Company and executive agreed to pay civil money penalties of $1.1 million and $75,000, respectively, for FFDCA violations relating to failure to comply with 510(k) requirements relating to Cochlear Implants

- *InterMune (2008)*
  - Former executive indicted for wire fraud and felony FFDCA violations relating to the promotion and marketing of Actimmune
  - In 2006, Company agreed to pay more than $36.9 million to resolve related criminal charges

The Park Doctrine

- *United States v. Dotterweich (1943)*
  - US Supreme Court held that the FFDCA 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.”

The Park Doctrine continued

- *United States v. Park* (1975)
  - US Supreme Court held that individuals who have authority to prevent violations can be held vicariously liable for the illegal acts of subordinates or agents
  - Responsible corporate officers 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

Who is a responsible corporate officer?

- Anyone with authority to prevent or 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)

Individual Liability Under the FFDCA

- Judicial Remedies
  - Injunctions
    - Restitution
    - Disgorgement
  - Criminal prosecution
- Administrative Remedies
  - Civil Money Penalties
  - Debarment due to ANDA activities
  - Disqualification from research activities
  - Adverse publicity

Prohibited Acts are Violations

- Section 301 of the FFDCA lists "prohibited acts"
- Committing prohibited acts or "causing" such acts to be committed constitutes a violation of the FFDCA
- Prohibited acts under Section 301 also form the basis of criminal violations under Title 18 of the U.S. Code (*e.g.*, mail and wire fraud, false statements, conspiracy, etc.)

FDA's Judicial Enforcement Options for Prohibited Acts

- Three basic options under FFDCA
  - Seizure of violative products (action against products not individuals)
  - Injunctions to prevent further violations
  - Criminal prosecution
- Each option requires FDA to go to court
  - FDA is represented by the U.S. Department of Justice (DOJ)
  - FDA has the burden of establishing statutory violation
- FDA may collaborate with other government agencies (*e.g.,* SEC, DEA, OIG, etc.)

Injunctions

- Section 302 of the FFDCA 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 continued

- 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 continued

- 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

Criminal Prosecution

- Section 303(a) of the FFDCA imposes criminal sanctions against persons who commit a prohibited act or cause such acts to be committed
  - Felony if done with intent to defraud or mislead, or a second offense without intent
  - Misdemeanor without a showing of intent
- 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 continued

- 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 under-cover 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 FFDCA violations
- Evidence of actual harm or injury to the public as a result of FFDCA violations

FDA's Administrative Enforcement Options for Prohibited Acts

- Four basic options under FFDCA
  - 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 FFDCA 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 continued

- 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

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 FFDCA 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 continued

- "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 FFDCA 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 FFDCA

- Several statutes prescribe individual liability for other health care-related violations
  - Anti-kickback Act
    - 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

Exclusion from Federal Programs

- The Department of Health and Human Services Office of Inspector General (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
- Adjudicated in an administrative proceeding; final decision subject to judicial review
- May be permanent or temporary
- Civil money penalties may be imposed on excluded individuals who provided services while excluded and on companies who knowingly employ such individuals

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 continued

- **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
- Corporate officers increasingly becoming targets
- Penalties are increasing
- Greater settlement pressure
- Adverse publicity increasingly being used as enforcement/settlement strategy

Questions and Discussion

If you have additional questions, contact me:

Vernessa.Pollard@aporter.com
202.942.5811

Arnold & Porter LLP
555 12th St., NW
Washington, DC 20004