

# FDA and the Park Doctrine

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# Hyman, Phelps & McNamara, P.C.

- Largest dedicated food and drug law firm in the country.
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# Presenters

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# What is the Park Doctrine?

- A criminal liability theory named after the United States Supreme Court decision in United States v. Park, 421 U.S. 658 (1975).
- Also called the “Responsible Corporate Officer” (RCO) Doctrine.

# What is the Park Doctrine?

- The Government can seek to obtain misdemeanor convictions of a company official for alleged violations of the Federal Food, Drug, and Cosmetic Act (FDCA) – even if the corporate official was *unaware of the violation* – if the official was in a position of authority to prevent or correct the violation and did not do so.
- “[T]he [FDCA] imposes the highest standard of care and permits conviction of responsible corporate officials who, in light of this standard of care, have the power to prevent or correct violations of its provisions.” Park, 421 U.S. at 676.

# Statutory Basis for Criminal Prosecutions Under the FDCA

- 21 U.S.C. § 333(a)(1) – “Any person who violates a provision of [21 U.S.C. § 331 (“prohibited acts”)] shall be imprisoned for not more than one year or fined . . . or both.”
- No “knowledge” or “intent” requirement.
- Compare with 21 U.S.C. § 333(a)(2) – “if any person . . . commits such a violation with the intent to defraud or mislead, such person shall be imprisoned for not more than three years or fined . . . or both.”

# Committing an FDCA “Prohibited Act”

- The “prohibited acts” are enumerated in 21 U.S.C. § 331.
- E.g., § 331(a): “The introduction or delivery for introduction into interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded.”
- FDCA defines more than two dozen prohibited acts.

## Examples of “Adulterated”

- § 342 – A food or dietary supplement is deemed adulterated if, e.g., it:
  - Contains poisonous, insanitary or deleterious/unsafe ingredients; or
  - Was prepared, packed or held under insanitary conditions.
- § 351 – A drug or device is deemed adulterated if, e.g., it:
  - Was prepared, packed or held under insanitary conditions or inadequate controls; or
  - Is a device subject to premarket approval but does not have such approval.



## Examples of “Misbranded”

- § 343 – A food or dietary supplement is deemed misbranded if, e.g., it:
  - Contains false or misleading labeling;
  - Makes unauthorized health claims.
- § 352 – A drug or device is deemed misbranded if, e.g., it:
  - Contains false or misleading labeling;
  - Contains inadequate directions for use/warnings;
  - Is a device subject to 510(k) premarket notification/clearance but does not have such clearance.

## **Genesis of the Park Doctrine – United States v. Dotterweich, 320 U.S. 277 (1943)**

- Issue: Whether the manager of a corporation, as well as the corporation itself, may be prosecuted under the FDCA for introducing misbranded and adulterated articles into interstate commerce.
- Holding: Yes, because the Supreme Court concluded that the FDCA is of “a now familiar type” of legislation which “dispenses with the conventional requirement for criminal conduct – awareness of some wrongdoing. In the interest of the larger good it puts the burden of acting at hazard upon a person otherwise innocent but standing in responsible relation to a public danger.” 320 U.S. at 280-81.

## United States v. Park, 421 U.S. 658 (1975)

- John Park was the President of Acme Markets, Inc., a large national retail food chain with approximately 36,000 employees, 874 retail outlets, and 16 warehouses.
- In 1970, FDA observed and advised Mr. Park of insanitary conditions including rodent infestation at Acme's Philadelphia warehouse.
- In 1971, FDA found similar conditions at Acme's Baltimore facility, and so informed Mr. Park by letter in January 1972.

## United States v. Park

- Mr. Park consulted with Acme's legal counsel who advised that the employee in charge of the Baltimore warehouse was investigating and taking all appropriate remedial action.
- In March 1972, FDA re-inspected the Baltimore facility and, despite some improvements, found evidence of rodent infestation.

## United States v. Park

- The Government charged Acme and Mr. Park with misdemeanors under 21 U.S.C. §§ 331(k) and 333(a), for causing food shipped in interstate commerce to become adulterated while it was held at Acme's Baltimore warehouse.
- § 331(k) “prohibited act” – “The alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of, or the doing of any other act with respect to a food . . . , if such act is done while such article is held for sale . . . and results in such article being adulterated or misbranded.”

## United States v. Park

- Acme pleaded guilty.
- Mr. Park went to trial, was convicted on all five counts, and was fined \$50 per count.
- Mr. Park testified that he did not “believe there was anything [he] could have done more constructively than what [he] found was being done.” 421 U.S. at 664.

## United States v. Park

- A Court of Appeals reversed Mr. Park's conviction. However, the United States Supreme Court reversed, and ordered Mr. Park's conviction to be reinstated, clarifying the principles announced in Dotterweich.
- The Court ruled that: "The [FDCA] imposes not only a positive duty to seek out and remedy violations when they occur but also, and primarily, a duty to implement measures that will insure that violations will not occur." 421 U.S. at 672.

## United States v. Park

- It also concluded that: “The requirements of foresight and vigilance imposed on responsible corporate agents are beyond question demanding, and perhaps onerous, but they are no more stringent than the public has a right to expect of those who voluntarily assume positions of authority in business enterprises whose services and products affect the health and well-being of the public that supports them.” 421 U.S. at 672.
- The Court did not impose on the Government a duty to prove that the defendant had a consciousness of wrongdoing.



## United States v. Park

- The Court did recognize that the FDCA “does not require that which is objectively impossible.” Thus, “[t]he theory upon which responsible corporate agents are held criminally accountable for ‘causing’ violations of the Act permits a claim to be raised defensively that a defendant was ‘powerless’ to prevent or correct the violation.” 421 U.S. at 673.

## United States v. Park

- However, it stated in footnote 19: “Assuming, *arguendo*, that it would be objectively impossible for a senior corporate agent to control fully day-to-day conditions in 874 retail outlets, it does not follow that such a corporate agent could not prevent or remedy promptly violations of elementary sanitary conditions in 16 regional warehouses.” 421 U.S. at 677.
- The Court ruled that an executive cannot be convicted solely because of the person’s title at the company.
- Lower courts have subsequently ruled that a defendant demonstrates that compliance is objectively impossible when he shows that he took “extraordinary care” to comply with the FDCA.

## Early Use of Park Doctrine – “Bottom Up” Prosecutions

- 1960s – mid 1980s, FDA requested the Department of Justice (DOJ) to prosecute numerous cases based on Dotterweich and Park.
- Most such cases arose from:
  - Persistent violations observed during a series of FDA inspections, where those violations were not, in FDA’s view, remedied despite FDA notice to the firm concerning such violations; or
  - Instances where a regulatory violation had allegedly caused injuries to consumers or animals.

## Early Use – “Bottom Up” Prosecutions

- FDA publicly stated that its decision about whether to seek initiation of a prosecution depended on whether:
  - The violations were of a continuing nature;
  - Management must have known of violations occurring or could have prevented them;
  - The violations were life threatening or resulted in injuries;
  - A prosecution would likely affect future compliance by the company and other similarly-situated companies; and
  - FDA had enough resources to bring a case.

## Early Use – “Bottom Up” Prosecutions

- “Bottom Up” pathway to prosecution:
  - FDA inspectors found violations and reported those violations to the relevant FDA Center.
  - The FDA District Office and/or the relevant Center decided that a criminal prosecution was appropriate.
  - The matter was presented to FDA’s Chief Counsel.
  - The Chief Counsel referred the matter to DOJ’s Office of Consumer Litigation (OCL).
  - After obtaining the necessary approvals, OCL asked the local U.S. Attorney to file the case.

## Early Use – “Bottom Up” Prosecutions

- FDA’s referral of cases for prosecution was guided by its Regulatory Procedures Manual:
  - Referrals to be based on “all the facts.”
  - Recommendation for prosecution required FDA to “present the evidence of each element of the offense to be charged.”
  - Recommendation for prosecution required concurrence from multiple FDA offices.

## Early Use – “Bottom Up” Prosecutions

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- The Park cases were generally brought as, and ended as, misdemeanor prosecutions.
- Few cases were referred to DOJ as potential felony cases because FDA generally did not have evidence to support a charge that a potential defendant acted with the intent to defraud or mislead.

## Post-Park RCO Cases

- Most Park Doctrine defendants pleaded out, with sentences that generally involved small fines and no jail time. The small number of cases that did go to trial tested the boundaries of the “objective impossibility” defense, e.g.:
  - United States v. Y. Hata & Co., 535 F.2d 508 (9<sup>th</sup> Cir. 1976) (rejecting defense because “One maintaining far less than the requisite ‘highest standard of foresight and vigilance’ would have recognized . . . that implementation of a wire cage system would substantially, if not completely, prevent access by thieving and untidy birds.”).
  - United States v. Starr, 535 F.2d 512 (9<sup>th</sup> Cir. 1976) (rejecting impossibility of avoiding mouse infestation because anyone with “minimum foresight” would anticipate the migration of rodents from newly plowed fields; rejecting impossibility based on delegation to a janitor because the defendant failed to follow up and could have anticipated and remedied the failure of his subordinate).



## Post-Park Cases

- Generally, the Government charged the company and very high level company officials. However, there were exceptions where low level people were charged, and senior people were not necessarily charged.
- United States v. General Nutrition, Inc., 638 F. Supp. 556 (W.D.N.Y. 1986) (retail managers and store clerks who had no role in choosing claims or devising promotional materials for a dietary supplement alleged by FDA to be a drug may be prosecuted for misbranding because “[t]he Act provides that ‘[a]ny person’ who violates section 331 shall be liable . . . [and] ‘Any’ means any.”).

## Post-Park Cases

- Eli Lilly prosecution in 1985 for failure to report four fatalities and six illnesses relating to Orflex. Lilly's Director of Medicine, Research and Development in the U.K. pleaded *nolo contendere* under Park.
- SmithKline Beckman Corp. prosecution in 1984. Three officials in its Medical Affairs Division pleaded guilty under Park for failing to report to FDA side effects from the drug Selacryn.

## 305 Hearings

- 21 U.S.C. § 335 –

“Before any violation . . . is reported . . . to any United States attorney for institution of a criminal proceeding, the person against whom such a proceeding is contemplated shall be given appropriate notice and an opportunity to present his views.”

## 305 Hearings

- Almost all criminal prosecutions during the height of use of the Park Doctrine were preceded by a “305 hearing.”
- In some instances, based on the hearing, the potential defendants convinced FDA that no case should be filed.

## 305 Hearings

- Thus, the Government and industry both valued the usefulness of such hearings because they gave targets and their attorneys a direct opportunity to argue to FDA why a case should not be brought.
- Courts have held that FDA is not required to hold “305 hearings.”
- In the past 20 years, such hearings have been rare – if not nonexistent.

# Disappearance of Park – Reasons

- By the late 1980s, use of the Park Doctrine was in steep decline.
- There were staffing limitations at DOJ.
- U.S. Attorneys often declined to bring Park cases:
  - Those brought typically settled with guilty pleas.
  - The prosecutor had to devote considerable resources to determine if the case had merit.
  - Many prosecutors were frustrated by what they believed were limited sanctions imposed on the defendants by the courts.
  - Many judges believed the cases unnecessarily clogged up the courts with matters that should have been handled with civil sanctions.

# Disappearance of Park – Reasons

- Prosecutors had a rising interest in prosecution of felony cases under the FDCA and alleged violations of Title 18 of the United States

Code:

- Criminal conspiracy;
- Mail fraud;
- Wire fraud;
- False statements to Government;
- Obstruction of justice.

# Disappearance of Park – Reasons

- Felony cases were more interesting and challenging to prosecutors.
- Congress pressured FDA/DOJ to bring felony cases when it believed companies and officials had intentionally violated the law.
- Judges understood Title 18 offenses far better than the complicated provisions of FDCA.
- Charging violators with a Title 18 offense made them appear to judges/juries like ordinary criminal defendants, whereas FDCA violations sounded too “technical,” as if there were merely a regulatory dispute between FDA and the defendant.



## Disappearance of Park – Paradigm Shift in Prosecution Pathway

- 1992 – FDA’s Office of Criminal Investigations (OCI) was established to conduct and coordinate criminal investigations for the agency.
- No more “bottom up” prosecutions. Instead, criminal cases began with referrals from OCI to U.S. Attorneys’ offices. OCI received its information from FDA’s Districts and Centers, whistleblowers, and other federal and state agencies.

## Disappearance of Park – Paradigm Shift in Prosecution Pathway

- OCI focused almost entirely on fraud investigations, not Park cases.
- Those cases ending in misdemeanor convictions generally have been settlements where OCI investigated each case as a potential felony prosecution, often seeking and getting an individual's cooperation in a felony case to be brought against others.

# Resurrection of the Park Doctrine

2009 cases applying RCO theory:

- Two corporate officers at Chemnutra, Inc., pleaded guilty to one count of selling adulterated food and one count of selling misbranded food for shipping wheat gluten tainted with melamine, destined for pet food. These counts were for strict liability misdemeanors.

# Resurrection of the Park Doctrine

- Synthes, Inc., a wholly-owned subsidiary of Norian Corporation, and four executives were indicted for the off-label promotion of a bone void filler. The Government charged the executives with a single misdemeanor count of shipping adulterated and misbranded product. They pleaded guilty under the RCO Doctrine. The company also recently pleaded guilty.

# Resurrection of the Park Doctrine

- March 4, 2010 letter from FDA Commissioner Hamburg to Senator Charles Grassley:
  - In response to a Government Accountability Office report (requested by Senator Grassley) raising concerns about OCl oversight.
  - Commissioner Hamburg announced that an FDA senior leadership committee had been formed to recommend strategies for enhanced coordination and alignment between OCl and other FDA components.

# Resurrection of the Park Doctrine

- March 4, 2010 FDA correspondence with Senator Grassley:
  - Committee recommendations included: “***increase the appropriate use of misdemeanor prosecutions, a valuable enforcement tool, to hold responsible corporate officials accountable.***”
  - Commissioner Hamburg also announced that criteria had been developed for selection of misdemeanor prosecution cases and these would be incorporated into revised policies and procedures addressing appropriate use of misdemeanor prosecutions.

# Resurrection of the Park Doctrine

- April 22, 2010 – Eric M. Blumberg, FDA Deputy Chief Counsel for Litigation, warned company officials about impending misdemeanor prosecutions in a speech to the Food and Drug Law Institute.
  - He is quoted as saying: ***“Very soon, and I have no one particular[ly] in mind, some corporate executive is going to be the first in a long line.”***
  - He indicated that FDA’s new criteria for Park prosecutions may not be different from the criteria historically used by FDA (discussed herein on Page 17).
  - Mr. Blumberg was one of the authors of the Government’s briefs to the Supreme Court in the Park case.

# Resurrection of the Park Doctrine

- May 27, 2010 – Deborah Autor, Director of CDER’s Office of Compliance, testified before Congress that FDA is heading toward greater use of criminal prosecution as an enforcement tool: ***“The agency is working to increase our enforcement on the criminal side and to connect carefully what we do on the criminal side with what we do on the civil side.”***
- April 20, 2010 – John Taylor Jr., Counselor to FDA’s Commissioner, stated that Park prosecutions are another arrow in FDA’s quiver.



## Predictions for Future Use of the Park Doctrine

- Off-label use cases
  - September 21, 2010 – Ann Ravel, Deputy Assistant Attorney General, who oversees DOJ’s OCL, stated at an FDLI conference: ***“The Department is intent on identifying and, where appropriate, prosecuting the individuals who are responsible for illegal off-label marketing.”***
  - The speech suggests that DOJ may bring cases without a referral from FDA.

## Predictions for Future Use of the Park Doctrine

- Health scares which generate publicity
  - Food cases
  - Drugs containing contaminants
- GMP violations involving alleged patterns of non-compliance.
- The Government singles out one company for prosecution involving allegations regarding violations that others in industry are also committing.
- Failure to report adverse events to FDA.

## Predictions for Future Use of the Park Doctrine

- OCl agents are being trained on the Park Doctrine.
- Cases generally will begin as felony investigations and end as misdemeanor prosecutions of certain individuals.
  - Whistleblower involvement.
  - Difficulty developing enough evidence to convict on felony charge(s).
  - May involve misdemeanor charges of individuals independent of, or as part of larger deals with, companies.

## Consequences of Park Misdemeanor Convictions – Then

- Early Park cases – resulted in what prosecutors and FDA considered to be mere “slaps on the wrists”
  - Minimal fines
    - Dotterweich – \$500 (about \$6,300 in today’s dollars)
    - Park – \$250 (about \$1,000 in today’s dollars)
  - Almost never jail time
    - Dotterweich – 60 days probation
    - Park – no jail time; no probation
  - No exclusion or debarment

# Consequences of Park Misdemeanor Convictions – Now

- Much larger fine – 21 U.S.C. § 333(a) and 18 U.S.C. § 3571 allow:
  - \$100,000 per count for individuals (\$250,000 if death occurs)
  - \$200,000 per count for corporations (\$500,000 if death occurs)
  - Fines can be increased to up to double the amount of defendants' pecuniary gain or victims' pecuniary loss
- Jail time up to a year (and certainly probation) is more likely.
- OIG exclusion from participation in federal health care programs.
- FDA debarment from working in or for the pharmaceutical industry.

## Consequences of Conviction – Role of Sentencing Guidelines

- 1987 Sentencing Guidelines for individuals
  - Section 2N2.1 for FDCA misdemeanor violations.
- Application of 2N2.1 typically has resulted in probation, but not jail time.

## Consequences of Conviction – Role of Sentencing Guidelines

- 2008 changes to 2N2.1 Guideline:
  - Increased likelihood that misdemeanors will result in jail time.
  - Sentencing court to consider “upward departure” in any case where the offense created “a substantial risk of bodily injury or death.”
  - FDA historically seems to have taken the position that any FDCA violation creates such risk.

## Consequences of Conviction – Role of Sentencing Guidelines

- On two occasions, FDA has tried to persuade the Sentencing Commission to strengthen the FDCA-related guidelines:
  - 1997 attempt was unsuccessful;
  - 2008 attempt was also largely unsuccessful;
  - FDA has almost certainly not given up on seeking amendments to the guidelines.



## Consequences of Conviction – Role of Sentencing Guidelines

- Under the recently enacted health care legislation, the Sentencing Commission must establish new guidelines for health care offenses.
- The new statute (which amended 18 U.S.C. § 1347) increased sentencing levels for these offenses.
- “Health care offenses” includes any FDCA violation.
- The Sentencing Commission recently announced that implementing the changes to the health care guidelines is a “priority” by May 2011.

## Consequences of Conviction – OIG Exclusion of Individuals

- 42 U.S.C. § 1320a-7 “exclusion” – federal Government will not pay – through Medicare, Medicaid or any other directly- or indirectly-funded federal program – for any items or services furnished, ordered, or prescribed by the excluded individual, anyone who employs or contracts with the excluded individual, and any hospital or provider where that person provides services.

# Consequences of Conviction – OIG Exclusion of Individuals

- **Mandatory Exclusion:**
  - OIG must order mandatory, five-year minimum exclusion when an individual is convicted of:
    - Program-related crime;
    - Crime relating to patient abuse/neglect;
    - Felony conviction relating to health care fraud;
    - Felony conviction relating to controlled substances.
  - When an individual is convicted of two mandatory exclusion offenses, minimum exclusion period is ten years.
  - When an individual is convicted of three or more mandatory exclusion offenses, OIG must order permanent exclusion.

## Consequences of Conviction – OIG Exclusion of Individuals

- Permissive Exclusion:
  - OIG has discretion to impose three-year minimum exclusion if an individual is convicted of:
    - Misdemeanor relating to fraud, theft, embezzlement, breach of fiduciary responsibility, or other financial misconduct.
    - Obstructing an investigation of health care program-related misconduct.
    - Offense involving controlled substances.

## Consequences of Conviction – FDA Debarment of Individuals

- 21 U.S.C. § 335a – “debarment” – prohibits individual from “providing services in any capacity” to a company or individual that has an approved or pending drug product application.
- FDA will not accept for filing any drug product applications from companies who hire or contract with a debarred person – even if that person performs work that is unrelated to the FDA regulatory process (e.g., custodial services).
- Applicants for drug approval must certify in their submissions to FDA that they have not used and will not use any services of any debarred individual.

## Consequences of Conviction – FDA Debarment of Individuals

- Mandatory Debarment:
  - FDA must order permanent debarment of an individual if they have been convicted of a felony for conduct relating to the development or approval process of any drug product, or to the regulation of any drug product.

## Consequences of Conviction – FDA Debarment of Individuals

- Permissive Debarment:
  - FDA has discretion to order a maximum five-year period of debarment if individual is convicted of:
    - Federal misdemeanor or felony under state law for conduct relating to the development, approval, or regulation of any drugs or of aiding or abetting such an offense.
    - Felony offense involving, e.g., bribery, fraud, perjury, false statement, obstruction of justice, but not necessarily related to the drug regulatory process.

## Post-Conviction Use of Exclusion and Debarment Remedies Will Increase

- August 2010 – Chief Counsel of HHS OIG, Lewis Morris in an interview with Dan Rather: ***“[O]ne of the tools . . . we’re going to start using more affirmatively is our authority to . . . exclude an executive – or an owner of a sanctioned entity . . . . We’re gonna hold executives personally accountable for what happened on their watch.”***



## Post-Conviction Use of Exclusion and Debarment Remedies Will Increase

- Permissive exclusion and debarment can be initiated at the request of prosecutors who obtain misdemeanor convictions.
- Not simple to succeed on a challenge to proposed permissive exclusion or debarment.
- FDCA requires FDA to provide “opportunity for an agency hearing on disputed issues of material fact,” but very rarely (if ever) has FDA granted a request for such a hearing.

## Avoidance Strategies – What Can Corporate Officers Do?

- Don't violate the law! Really? [Seth Meyers]
- Be more pro-active than reactive in matters of regulatory compliance.
- Hire and retain qualified and competent employees.
- Pay close attention to whistleblowers and potential whistleblowers.
- Make certain there is a corporate compliance program that is monitored to ensure compliance with the program's goals.

# Avoidance Strategies – What Can Corporate Officers Do?

- Document “good faith” attempts to comply with regulatory requirements and to remedy issues that arise. E.g.:
  - Order in writing that SOPs be written.
  - Instruct employees by memorandum that complaints are to be taken seriously.
  - Respond to each internally raised complaint about FDA matters.
  - Executives should demonstrate in writing their commitment to have the company make all reasonable efforts to be in compliance.
- Interact with FDA cautiously – do not give the agency ammunition that could be used against you, personally.

# Questions?



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