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# Individual Culpability and Liability in the Pharmaceutical Industry

Presentation to the Pharmaceutical Compliance Forum

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# Individual Culpability/Liability

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- Criminal prosecution of individuals – such as corporate executives, managers, physician contractors, or customers – either for personal misconduct or because of status
- Civil actions for compliance failures
- Exclusion actions against individuals

UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS

**UNITED STATES OF AMERICA**

**V.**

- 1. VP for SALES**
- 2. VP for MARKETING**
- 3. NAT'L SALES DIRECTOR**
- 4. NAT'L SALES DIRECTOR**
- 5. NAT'L ACCOUNT MANAGER**
- 6. DISTRICT MANAGER**
- 7. DISTRICT MANAGER**
- 8. DISTRICT MANAGER**
- 9. DISTRICT MANAGER**
- 10. DISTRICT MANAGER**
- 11. DISTRICT MANAGER**
- 12. HOSPITAL ACCOUNT EXEC.**
- 13. PHYSICIAN**

Defendants

CRIMINAL NO. 01-CR-10350-DPW

VIOLATION:

18 U.S.C. 371

Conspiracy to Violate:

42 U.S.C. 1320a-7b(b)(1) and  
(b)(2)

21 U.S.C. 331(T) and 333(b)

42 U.S.C. 1320a-7b(b)

Illegal Remuneration

21 U.S.C. 333(b)

Sale of Drug Samples

18 U.S.C. 2

Aiding and Abetting

**SUPERSEDING INDICTMENT**

# Early Prosecutions

Company	Individuals	Charge	Outcome
TAP	4 Physicians	AKS violations	Guilty plea
	11 Executives & Managers	AKS violations	Acquitted
	1 District Sales Manager	Conspiracy	Guilty plea vacated
	1 Account Manager	Obstruction of justice	Convicted
AstraZeneca	2 Physicians	PDMA violations	Guilty plea
Serono	1 Sales Representative	AKS violations	Guilty plea
	2 Vice Presidents & 2 Regional Sales Managers	AKS violations	Acquitted

# Recent Prosecutions

Company	Individuals	Charge	Outcome
Purdue	President and COO	<ul style="list-style-type: none"> <li>▪ Misbranding (<i>Park</i> liability)</li> </ul>	Guilty pleas
	EVP and Chief Legal Officer		
	EVP, Worldwide Medical Affairs		
Jazz	Physician	<ul style="list-style-type: none"> <li>▪ Conspiracy to misbrand</li> </ul>	Guilty plea
	Sales Representative	<ul style="list-style-type: none"> <li>▪ Conspiracy to misbrand</li> <li>▪ Misbranding</li> </ul>	Convicted of conspiracy charge; acquitted of all other charges
InterMune	Chief Executive Officer	<ul style="list-style-type: none"> <li>▪ Wire fraud</li> <li>▪ Misbranding</li> </ul>	Convicted of wire fraud; acquitted of misbranding charge
Pfizer	District Manager	<ul style="list-style-type: none"> <li>▪ Obstruction of justice</li> </ul>	Convicted

# Recent Prosecutions

Company	Individuals	Charge	Outcome
Synthes / Norian Corp.	President	<ul style="list-style-type: none"> <li>▪ Introduction of adulterated and misbranded medical devices (<i>Park</i> liability)</li> </ul>	Guilty pleas
	President / SVP, Global Strategy		
	VP, Operations		
	Director of Regulatory & Clinical Affairs		
Stryker	President	<ul style="list-style-type: none"> <li>▪ Wire fraud</li> <li>▪ Aiding and abetting</li> <li>▪ Conspiracy</li> <li>▪ False statements</li> </ul>	<i>Pending</i>
	National Sales Director	<ul style="list-style-type: none"> <li>▪ Wire fraud</li> <li>▪ Aiding and abetting</li> <li>▪ Conspiracy</li> </ul>	<i>Pending</i>
	Regional Manager	<ul style="list-style-type: none"> <li>▪ Wire fraud</li> <li>▪ Aiding and abetting</li> <li>▪ Conspiracy</li> <li>▪ Misbranding</li> </ul>	<i>Pending</i>
	Regional Manager	<ul style="list-style-type: none"> <li>▪ Wire fraud</li> <li>▪ Aiding and abetting</li> <li>▪ Conspiracy</li> <li>▪ Misbranding</li> </ul>	<i>Pending</i>

# Public Sentiment in Favor of Aggressive Action

- On July 31, 2007, following the Purdue Pharma settlement, the Senate Judiciary Committee held a hearing to investigate why the executives did not receive prison sentences in connection with their convictions

**Senator Patrick Leahy:** “Nothing makes high executives think twice about malfeasance” than the possibility of receiving a prison sentence.

**Senator Arlen Specter:** “I don’t see that [the Purdue executives] weren’t wrongdoers who deserve jail.”



# Public Sentiment in Favor of Aggressive Action

- **“The eye-popping total [of \$2.3 billion] is unlikely to end the sometimes-dangerous practice of promoting drugs for unapproved uses. The penalty pales compared with the billion dollars or more in annual revenue that blockbuster drugs generate.”**  
- Associated Press (Sept. 5, 2009)
- **“What might help are a few well-publicized ‘perp walks’ for executives charged with pursuing profits over patients—not to mention cheating the taxpayers by overcharging Medicare and Medicaid.”**  
- The Philadelphia Inquirer (Sept. 18, 2009)
- **“Government critics say Pfizer represents a glaring example of what’s wrong with the U.S. criminal justice system when it deals with big business. Federal prosecutors seem especially impotent against Big Pharma and the vital health care industry.”**  
- Corporate Counsel Online (Feb. 1, 2010)
- **“You’re shooting a .22 caliber short round into the ass of a rhino . . . It may make him move a little bit, but it won’t change the quality of his life.”**  
- Corporate Counsel Online (Feb. 1, 2010)



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# Response By Enforcers

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- In response to criticism by GAO, FDA on March 4, 2010 announced that a senior committee had recommended that it “increase the appropriate use of misdemeanor prosecutions, a valuable enforcement tool, to hold responsible corporate officials accountable.”

– FDA Letter to Senator Grassley, March 4, 2010

- Did not specify criteria for application of new policy, (e.g. whether it would apply only in egregious cases), whether DOJ agreed, whether it would provide prior notice, etc.

# Response By Enforcers

- Other Government officials have publicly stated that they will pursue responsible employees and utilize the CIA management certifications, if necessary.

**Ann Ravel, Deputy Assistant Attorney General:**  
“The department is intent on identifying and, where appropriate, prosecuting the individuals who are responsible for illegal off-label marketing.”  
- *The Gray Sheet* (Oct. 4, 2010)

# Response By Enforcers

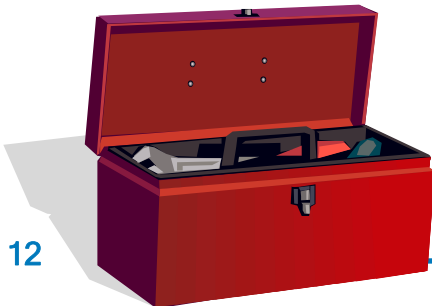
**Lewis Morris, Chief Counsel to the Inspector General:** A better pressure point is to go after responsible employees. Law enforcement's focus over the next year will be on the individual, and HHS attorneys will be emphasizing “why we think those individuals shouldn’t continue to operate in those companies that want a corporate integrity agreement” to avoid criminal charges. OIG lawyers are “aggressively looking” at opportunities to debar individuals.  
- *Corporate Counsel Online* (Feb. 1, 2010)

**OIG Senior Attorney Mary Riordan:**  
CIA management certifications are “a way for people to be held personally accountable for compliance in their area.”  
- *BNA Health Care Fraud Report* (Jan. 28, 2009)

**Assistant U.S. Attorney Sara Bloom:**  
Prosecutors are “looking forward” to having the CIA management certifications to facilitate identification of responsible individuals within the corporation, particularly when the misconduct was widespread and widely acquiesced to by corporate officials.  
- *Rx Compliance* (Oct. 16, 2009)

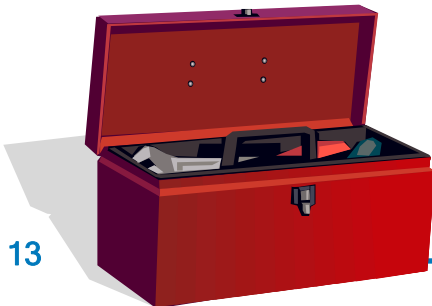
# The Government's Toolbox: Theories of Individual Liability

	“Direct” Liability	“Indirect” Liability
Criminal Actions	<ul style="list-style-type: none"><li>• Anti-kickback statute</li><li>• Food, Drug, and Cosmetic Act</li><li>• False statements</li><li>• Mail/wire fraud</li><li>• Conspiracy</li></ul>	<ul style="list-style-type: none"><li>• Violation of the FDCA as a “responsible corporate officer” (i.e., <i>Dotterweich/Park</i> liability)</li></ul>
Civil Actions	<ul style="list-style-type: none"><li>• Failure to maintain an adequate compliance program</li></ul>	
OIG Exclusion	<ul style="list-style-type: none"><li>• Mandatory or permissive exclusion based on a prior conviction or other personal conduct</li></ul>	<ul style="list-style-type: none"><li>• Permissive exclusion under a “responsible corporate officer”-like theory</li></ul>



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# “Direct” Liability for Criminal Misconduct

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- Government is pursuing individuals – including corporate executives, managers, employees, contractors, and other related parties – for participation in underlying misconduct at issue.
- Prosecutions have included charges of:
  - Kickbacks
  - FDCA violations
  - False statements
  - Mail/wire fraud
  - Conspiracy
- Potential for false statement liability has expanded due to the management certification requirement imposed in the recent generation of Corporate Integrity Agreements.

# “Indirect” Criminal Liability As A “Responsible Corporate Officer”

- Under certain circumstances, an employee may be held strictly liable for corporate violations of a “public welfare” statute such as the FDCA.
- The manager may be liable, even if the corporation itself is not convicted of a crime.
- The government may prosecute a “responsible corporate officer” for a misdemeanor violation of the FDCA regardless of the officer’s awareness of misconduct if, by reason of the officer’s position in the company, he/she had the responsibility and authority either (1) to prevent the misconduct in the first instance, or (2) promptly to correct the violation, and failed to do so.



# “Indirect” Criminal Liability As A “Responsible Corporate Officer”

- Doctrine primarily developed in two Supreme Court cases:
  - *United States v. Dotterweich*, 320 U.S. 277 (1943)
  - *United States v. Park*, 421 U.S. 658 (1974)

“The prosecution to which Dotterweich was subjected is based on a now familiar type of legislation whereby penalties serve as an effective means of regulation. Such legislation 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.”

*Dotterweich*, 320 U.S. at 280-81, 284-85; *quoted in Park*, 421 U.S. at 668-69.

# “Indirect” Criminal Liability As A “Responsible Corporate Officer”

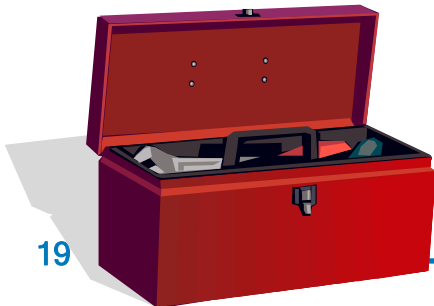
- Historically, the doctrine has been rarely invoked.
- Revived in 2007 against three Purdue Pharma Company executives.
  - Executives:
    - Michael Friedman (President and Chief Operating Officer)
    - Howard Udell (Executive VP and Chief Legal Officer)
    - Paul Goldenheim (VP of Worldwide Medical Affairs)
  - Each pled guilty to a one-count misdemeanor violation of the FDCA, based on Purdue Frederick’s guilty plea for felony misbranding of OxyContin.
  - Sentenced to:
    - Disgorgement of \$19 million, \$8 million, and \$7.5 million, respectively, to the Virginia AG’s Medicaid Fraud Control Unit
    - \$5,000 criminal fine
    - Three years probation
    - 400 hours of community service

# “Indirect” Criminal Liability As A “Responsible Corporate Officer”

- Two key limitations of the “responsible corporate officer” doctrine:
  1. Liability does not extend to all executives and managers of a company that violates the FDCA. Individuals whose job responsibilities placed them in “responsible relation” to the criminal acts may be held responsible.
  2. Liability does not extend to all corporate compliance violations. In the context of health care compliance, it has been applied only to violations of the FDCA.

# The Government's Toolbox: Theories of Individual Liability

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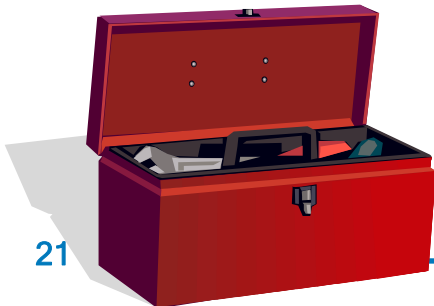


# “Direct” Liability In Shareholder Lawsuits

- In re Caremark International Inc. Deriv. Litig. – Delaware Supreme Court held that corporate directors have fiduciary duty to implement and monitor compliance programs effectively
  - Liability for sustained or systematic failures
  - Delaware Supreme Court has not extended case to corporate officers, but one other court has done so
- Louisiana Municipal Police Employees Retirement System v. Pyott et al. – shareholder suit to force members of Allergan’s Board of Directors to shoulder the burden of the company’s \$600 million settlement with the DOJ
  - Filed in September 2010
  - Theory that Board members breached their fiduciary duty by permitting the conduct that led to Allergan’s settlement

# The Government's Toolbox: Theories of Individual Liability

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# “Direct” or “Indirect” Liability Through OIG Exclusion

- Depending on the nature of the underlying misconduct, the OIG may be required or authorized to exclude an individual from participation in the Federal health care programs under 42 U.S.C. § 1320a-7.
- “Exclusion” means that the Federal health care programs may not pay for any items or services furnished, ordered, or provided by that individual.
- As a practical matter, an individual who has been “excluded” cannot work for an entity that directly or indirectly supplies products or services to federal health care program beneficiaries.



## “Direct” Liability — Mandatory Exclusion Based On A Prior Conviction Or Other Personal Conduct

- 42 U.S.C. § 1320a-7(a)(1) – Program-related conviction
  - Mandates exclusion if an individual is convicted of an offense (misdemeanor or felony) related to Medicare or any State health care program.
- 42 U.S.C. § 1320a-7(a)(3) – Felony conviction for health care fraud
  - Mandates exclusion if an individual is convicted of a (felony) offense “relating to” (*inter alia*) fraud or breach of fiduciary duty in connection with:
    - the delivery of a health care item or service; or
    - any act or omission in a health care program (other than those specifically described in paragraph (a)(1)) operated by or financed in whole or in part by any Federal, State, or local government agency.
  - Convictions need not be for fraud, if they “relate to” fraud – a very broad standard capturing offenses that have a “nexus or common sense connection” to fraudulent conduct.

# “Direct” Liability — Permissive Exclusion Based On A Prior Conviction Or Other Personal Conduct

- **42 U.S.C. § 1320a-7(b)(1) – Conviction for health care or other fraud**
  - Authorizes exclusion if an individual is convicted of an offense “relating to” (*inter alia*) fraud or breach of fiduciary duty that is –
    - A misdemeanor in connection with the delivery of a health care item/service;
    - A misdemeanor with respect to an act or omission in a health care program that is operated or financed (in whole/part) by any government agency; or,
    - A criminal offense (misdemeanor or felony) with respect to any act or omission in a non-health care program that is operated or financed (in whole/part) by any government agency.
  - Was the basis for the OIG’s exclusion of Purdue executives Friedman, Udell, and Goldenheim for 15 years.
- **42 U.S.C. § 1320a-7(b)(7) – OIG finding of fraud, kickbacks, false claims**
  - Authorizes exclusion if the OIG determines that an individual has violated the Civil Monetary Penalties laws or the Anti-kickback statute.
  - Unlike the (a)(1), (a)(3), or (b)(1), exclusion is not based on a predicate conviction.

# “Indirect” Liability — Exclusion Based On Status As An Officer or Managing Employee

- 42 U.S.C. § 1320a-7(b)(15)
  - Conceptually similar to the “responsible corporate officer” doctrine.
  - In pertinent part, provides for exclusion of an individual who is an “officer or managing employee” of a “sanctioned entity”— *i.e.*, a company that has been:
    - Convicted of a mandatory exclusion offense; or
    - Convicted of a permissive exclusion offense (likely, exclusion for an offense relating to fraud in the delivery of a health care item); or
    - Excluded by the OIG.
  - An “officer or managing partner” is someone who exercises operational or managerial control over the entity or who directly or indirectly conducts the day-to-day operations of the entity.
  - Also provides for exclusion of an individual who has a “direct or indirect ownership or control interest in a sanctioned entity and who knows or should know of the action constituting the basis for the conviction or exclusion.”

# “Indirect” Liability — Exclusion Based On Status As An Officer or Managing Employee

- 42 U.S.C. § 1320a-7(b)(15)
  - Covers a significantly wider array of offenses than the “responsible corporate officer” theory of prosecution.
    - *E.g.*, if the company is convicted of mail, wire, or health care fraud; conspiracy; obstruction of justice; false statements; and certain violations of the FDCA.
    - Plus, exclusion authorized if the conviction “related to” fraud.
  - As reported on the OIG website, (b)(15) has not been used to exclude senior pharma executives to date.
  - Nevertheless, based on discussions with the OIG, it appears that the future risk that any individual manager could be excluded under (b)(15) is quite substantive and greater than the risk that the manager will be convicted as a “responsible corporate officer.”
- H.R. 6130
  - Would expand the scope of (b)(15) to:
    - Individuals who previously were officers or managing employees of a sanctioned entity; and
    - Individuals and entities who are or were “affiliated with” sanctioned entities.
  - Passed by the House on September 22, 2010.

# “Indirect” Liability — Exclusion of Entities Based on Exclusion of Individuals

- 42 U.S.C. § 1320a-7(b)(8)
  - Permits derivative exclusion of an entity when an individual:
    - An individual who:
      - Has a direct or indirect ownership or control interest of 5% or more, or an ownership or control interest as defined in 42 U.S.C. § 1320a-3(a)(3) (or who had such interest but transferred it to a family or household member in anticipation of the litigation) in the entity; or
      - Is an officer, director, agent, or managing employee of the entity;
    - Is an individual who:
      - Has been excluded;
      - Has been convicted of certain exclusion-eligible offenses; or
      - Was assessed a CMP under 42 U.S.C. § 1320a-7a or 1320a-8.
- Patient Protection and Affordable Care Act, Section 6502
  - Provision of the health care reform legislation that requires state Medicaid agencies to exclude an entity or individual if, *inter alia*, the individual or entity has been excluded under Title 42 or is “affiliated” with an entity or individual that has been excluded.

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# OIG's Use of Threat of Corporate Exclusion as Leverage over Individuals

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- In some cases, OIG has taken position that it will not waive permissive corporate exclusion unless company agrees to “separate” from specified individuals
- Application, scope of policy very unclear
- Huge policy implications
  - Due process/fairness considerations
  - Public policy considerations - e.g., over-deterrence of people who do not have direct responsibility

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# Implications for Companies

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- Structure and function of compliance programs
- “Company” oversight and direction of defense of government investigations
- Relationship with Board members/senior executives



# Conclusion

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- The government has long been able to prosecute “responsible corporate officers” under *Dotterweich* and *Park* or to exclude these individuals under (b)(15).
- In light of the government’s perception of large-scale, widespread misconduct within the industry, it now appears very interested in pursuing managers and executives personally, even if they did not know of or participate in illegal conduct.
- This shift in focus has important implications for both the structure and function of compliance programs and for the manner in which government investigations are overseen.

The End