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## Lessons of Forest and Purdue

Presentation to the Pharmaceutical Regulatory and Compliance Congress

Paul E. Kalb, M.D., J.D.

November 3, 2011

# Exclusion of Individuals: The Set-Up

“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.”

Lewis Morris, Chief Counsel to  
the Inspector General

*Corporate Counsel Online* (Feb. 1, 2010)

# Exclusion of Individuals: The Forest Case

**THE WALL STREET JOURNAL.**

WSJ.com

HEALTH INDUSTRY : APRIL 26, 2011

## U.S. Effort to Remove Drug CEO Jolts Firms

By ALICIA MUNDY

A government attempt to oust a longtime drug-company chief executive over his company's marketing violations is raising alarms in that industry and beyond about a potential expansion of federal involvement in the business world.



Forest Labs CEO Howard Solomon

Bloomberg

blamed for wrongdoing rather than simply punishing companies. The government has tried to prosecute Wall Street executives in connection with the 2008 financial crisis, but with limited success.

The Health and Human Services department startled drug makers last year when the agency said it would start invoking a little-used administrative policy under the Social Security Act against pharmaceutical executives. This policy allows officials to bar corporate leaders from health-industry companies doing business with the government, if a drug company is guilty of criminal misconduct. The agency said a chief executive or other leader can be banned even if he or she had no knowledge of a company's criminal actions. Retaining a banned executive can trigger a company's exclusion from government business.

The "action against the CEO of Forest Labs is a game changer," said Richard Westling, a corporate defense attorney in Nashville who has represented executives in different industries against the government.

According to Mr. Westling, "It would be a mistake to see this as solely a health-care industry issue. The use of sanctions such as exclusion and debarment to punish individuals where the

government is unable to prove a direct legal or regulatory violation could have wide-ranging impact." An exclusion penalty could be more costly than a Justice Department prosecution.

He said that the Defense Department and the Environmental Protection Agency, for example, have debarment powers similar to the HHS exclusion authority.

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# Exclusion of Individuals: The Forest Case

- 42 U.S.C. §1320a-7 (b)(15) provides:
  - (b) Permissive exclusion:** The Secretary may exclude the following individuals and entities from participation in any Federal health care program :
    - (15) Individuals controlling a sanctioned entity
      - (A) Any individual—
        - (i) who has a direct or indirect ownership or control interest in a sanctioned entity and who knows or should know (as defined in section 1320a-7a(i)(6) 1 of this title) of the action constituting the basis for the conviction or exclusion described in subparagraph (B); or
        - (ii) who is an officer or managing employee (as defined in section 1320a-5(b) of this title) of such an entity.

# Exclusion of Individuals: The Forest Case

THE WALL STREET JOURNAL  
WSJ.com

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WSJ.com

HEALTH INDUSTRY      AUGUST 6, 2011

## U.S. Drops Effort to Oust Forest Labs CEO

By ALICIA MUNDY

WASHINGTON—The U.S. government dropped efforts to force the resignation of a prominent pharmaceutical-company chief executive, reversing course after protests from the company and major business groups.

The about-face on Forest Laboratories's longtime leader, Howard Solomon, represents a significant retreat by the Department of Health and Human Services, which has said it wants to step up punishments against drug-company executives when wrongdoing happens on their watch.

In a letter to Mr. Solomon on Friday, the office of the inspector general of the Department of Health and Human Services said, "Based on a review of information in our file, and consideration of the information your attorneys provided to us both in writing and in an in-person meeting, we have decided to close this case."

Forest called the decision a vindication of its contention that the move against Mr. Solomon was unfair because he wasn't named in the criminal action. "We are gratified," said Forest's lead independent director, Kenneth Goodman.

The action came as a dispute between Forest and billionaire investor Carl Icahn heated up. Mr. Icahn has demanded four seats on Forest's board and recently increased his holdings of the company to roughly 7%, ahead of Forest's Aug. 18 annual shareholder meeting.

Mr. Icahn has criticized the company's governance and alleged lack of succession planning for Mr. Solomon, who is 83 years old. Forest said it has a detailed succession plan.

Forest posted sales of \$4.4 billion in its most recent fiscal year. Celexa became one of the best-selling antidepressants in the world in the late 1990s, but later questions were raised about the safety of Celexa and similar drugs for use by teenagers and children.

A statement from the HHS inspector general's office Friday said: "We remain committed to investigating and, when

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# Exclusion of Individuals: The Purdue Case

## Purdue General Counsel Fights For His Career

By Ed Silverman // December 23rd, 2009 // 8:53 am

[6 Comments](#)

The HHS, however, took the additional step of debarring the execs. As the paper notes, this appears to be the first time the federal government has imposed such an exclusion based on a "responsible corporate officer" misdemeanor. The move also

The case stems from the May 2007 settlement between the US Attorney for Western Virginia and three top execs at Purdue Frederick - including Udell and Friedman - over the misbranding of the OxyContin painkiller. The government claimed Purdue Frederick misled patients, regulators and doctors about the drug's addictive risks. All totaled, Purdue and the three execs paid \$634 million in fines ([background here](#)).

The Purdue Frederick subsidiary pled guilty to felony misbranding as part of the settlement and was automatically debarred from winning new government contracts, the paper notes. The parent company, which avoided criminal charges by striking a nonprosecution agreement and paying the fines, can receive contracts. The three execs pled guilty and, in exchange for no jail time, also paid fines.

The HHS, however, took the additional step of debarring the execs. As the paper notes, this appears to be the first time the federal government has imposed such an exclusion based on a "responsible corporate officer" misdemeanor. The move also affects science chief Paul Goldenheim. All three appealed and [this is the lawsuit Udell and Friedman filed against the HHS](#).

Udell's attorney, Andrew Ceresney, tells Corporate Counsel that "the decision to exclude Udell and two others based on strict liability, no intent misdemeanors, resulting solely from their status as officers of Purdue at a time when others engaged in conduct of which they were unaware, was arbitrary, unfair, and exceeded the inspector general's statutory powers." What do you think?

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# Exclusion of Individuals: The Purdue Case

- 42 U.S.C. §1320a-7 (b)(1) (A)
  - (b) Permissive exclusion:** The Secretary may exclude the following individuals and entities from participation in any Federal health care program:
    - (1) Conviction relating to fraud** Any individual or entity that has been convicted for an offense which occurred after August 21, 1996, under Federal or State law—
      - (A) of a criminal offense consisting of a misdemeanor relating to fraud, theft, embezzlement, breach of fiduciary responsibility, or other financial misconduct—
        - (i) in connection with the delivery of a health care item or service, or
        - (ii) with respect to any act or omission in a health care program (other than those specifically described in subsection (a)(1) of this section) operated by or financed in whole or in part by any Federal, State, or local government agency;

# Exclusion of Individuals: The Purdue Case

Case 1:09-cv-02028-ESH Document 38 Filed 12/13/10 Page 1 of 30

UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF COLUMBIA

MICHAEL FRIEDMAN, *et al.*,

Plaintiffs,

v.

KATHLEEN SEBELIUS, SECRETARY,  
DEPARTMENT OF HEALTH AND HUMAN  
SERVICES, *et al.*,

Defendants.

Civil Action No. 09-2028 (ESH)

MEMORANDUM OPINION

Plaintiffs Michael Friedman, Paul Goldenheim, and Howard Udell seek review of a final decision of the Secretary of the Department of Health and Human Services ("the Secretary" or "the Department") excluding them from participation in Medicare, Medicaid, and all other federal health care programs for twelve years. The Secretary's exclusion decision was based on plaintiffs' misdemeanor guilty pleas to charges that they served as "responsible corporate officers" of the Purdue Frederick Company during a five-and-a-half-year period in which that company has admitted to marketing misbranded drugs with "the intent to defraud or mislead" in violation of the Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 331(a), 333(a). Plaintiffs seek reversal of the Secretary's exclusion decision, arguing that their pleas under the "responsible corporate officer" doctrine do not reflect any personal wrongdoing and that excluding them from participation in all federal health care programs is therefore inconsistent with the text and purpose of the exclusion statute. For the reasons set forth below, the Court disagrees and affirms the Secretary's decision.

ORAL ARGUMENT NOT YET SCHEDULED

No. 11-5028

UNITED STATES COURT OF APPEALS  
FOR THE DISTRICT OF COLUMBIA CIRCUIT

MICHAEL FRIEDMAN, PAUL GOLDENHEIM, AND HOWARD UDELL,

*Plaintiffs-Appellants,*

v.

KATHLEEN SEBELIUS, IN HER OFFICIAL CAPACITY AS SECRETARY,  
DEPARTMENT OF HEALTH AND HUMAN SERVICES AND  
DANIEL R. LEVINSON, IN HIS OFFICIAL CAPACITY AS  
INSPECTOR GENERAL, DEPARTMENT OF HEALTH AND HUMAN SERVICES,

*Defendants-Appellees.*

On Appeal from the United States District Court  
for the District of Columbia (Huvelle, J.)

BRIEF OF APPELLANTS

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June 13, 2011

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# What Will Happen Next?

“The government will continue to ramp up its prosecutions of corporate officers and managers of drug and device companies for health care fraud...”

“The responsible corporate officer doctrine is a broad theme in law enforcement and the exclusion context.”

## **Enforcement** **Health Care Executives Should Expect More** **Prosecutions of Individuals, OIG Official Says**

*By Dana A. Elfin*

The government will continue to ramp up its prosecutions of corporate officers and managers of drug and device companies for health care fraud at their companies, a top government official said Sept. 26.

“I do think we’re going to see an increasing number of cases [brought] against individuals,” Mary E. Riordan, senior counsel at the Administrative & Civil Remedies Branch of the Department of Health and Human Services Office of Inspector General, said.

Speaking at the 2011 Food and Drug Law Institute’s Advertising and Promotion Conference, Riordan also said the government is likely to continue its focus on bringing fraud cases against the drug and device companies themselves in addition to prosecuting individuals.

Riordan predicted that the government will continue to bring large numbers of cases against drug manufacturers as well as an increased number of cases against medical device manufacturers.

“The device industry should not think that they are immune, by a long shot,” she said.

Riordan also said that corporate integrity agreements between the government and companies will require increased corporate transparency, such as requiring companies to post information about payments made to doctors.

## **Individuals Cautioned**

The government is requiring increased accountability from individuals such as members of drug and device companies’ board of directors and key company managers in areas such as sales and accounting, Riordan said.

Under the so-called responsible corporate officer doctrine, certain individuals can be held responsible for fraud and abuse at their companies even if they had no personal knowledge of the fraud.

The responsible corporate officer doctrine also is known as the Park doctrine, named after *United States v. Park*, 421 U.S. 658 (1975), in which the U.S. Supreme Court affirmed a misdemeanor criminal conviction of a company officer whom the agency held responsible for regulatory violations in a food storage warehouse, even though he denied any knowledge of the conditions.

“The responsible corporate officer doctrine is a broad theme in both the law enforcement community and also in the exclusion context,” Riordan said.

The government, Riordan said, is looking to change corporate behavior not by simply imposing fines and penalties on corporations but by holding individuals accountable for illegal actions at their companies “when it’s appropriate to do that.”

## **Excluded From Programs**

That accountability includes the potential exclusion of individuals from participating in government health care programs such as Medicare and Medicaid.

Under current law, the HHS OIG is authorized to permissively exclude individuals who at the time of the proposed exclusion own, control, or direct a sanctioned entity (42 U.S.C. §1320a-7(b)(15)). Individuals with a direct or indirect ownership or control interest must “know or should have known” of the action for which the entity was sanctioned.

Individuals who are officers or managers of the sanctioned entity can be excluded simply on the basis

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“I do think we’re going to see an increasing number of cases [brought] against individuals...”

“The government... is looking to change corporate behavior... by holding individuals accountable for illegal actions...”

# What Should Happen Next?

1. The Government Should Clarify That It's Goal is to Incentivize the Establishment of Effective Corporate Compliance Programs

# What Should Happen Next?

## 2. The Government Should Reevaluate Its Strategy of Prosecuting and Attempting to Exclude Corporate Executives Based on Status

- Unnecessary: What is the evidence that, in 2011, the industry does not “get it”?
- Unfair: Executives are at risk whether or not they have taken diligent steps to address compliance
- Ineffective: There is no marginal deterrent where companies have taken all reasonable steps to be compliant
- Counterproductive: Substantial disincentive to industry service
- Unconstitutional: Deprivation of livelihood raises serious Due Process concerns

# What Should Happen Next?

3. Congress/DOJ/OIG should recognize the “Compliance Program Defense”: If a company has an effective Compliance Program, its executives should be immune from personal culpability and exclusion based on their status.
  - Fair
  - Incentivizes the right conduct
  - Effective: Would enhance the significance of compliance programs
  - Avoid constitutional issues

# END

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