

Healthcare Fraud: Individual Liability for Executives and High-Level Employees

Identifying and Addressing Risks for Executives; Avoiding OIG Exclusion Sanctions

THURSDAY, MARCH 22, 2012

1pm Eastern | 12pm Central | 11am Mountain | 10am Pacific

Today's faculty features:

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Healthcare Fraud: Individual Liability for Executives and High-Level Employees

Thomas E. Zeno

Kimberly J. Donovan

Elizabeth E. Trende

WANTED

- **PRESIDENT AND CEO –
PURDUE FREDERICK**
- **EXECUTIVE VICE
PRESIDENT – PURDUE
FREDERICK**
- **CHIEF LEGAL OFFICER
– PURDUE FREDERICK**
- **CHIEF EXECUTIVE
OFFICER – FOREST
LABS**

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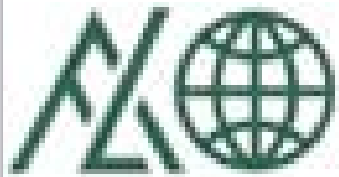
Exclusions

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Forest Laboratories, Inc.

- ❑ **Corporate guilty plea to a felony**
- ❑ **\$313 million fine**

NOT ENOUGH

- ❑ **Solomon was NOT CONVICTED of a health care fraud offense**
- ❑ **Solomon was NOT CHARGED with a health care fraud offense**

Dear Mr. Solomon:

Re: OIG File Number H-11-40460-9

You were previously advised that an exclusion action was being proposed under section 1128(b)(15) of the Social Security Act based on your relationship to Forest Pharmaceuticals, Inc.

Based on a review of the information in our file and consideration of the information that your attorneys provided to us, both in writing and during an in-person meeting, we have decided to close this case. We anticipate no further action related to this matter.

Sincerely,

/s/ Peter Clark

Peter Clark

Exclusions Director

Office of Investigations

Responsible Corporate Officer doctrine

US v. Park, 421 US 658 (1975)

Inadequate Defense

- ❑ Park conferred with the VP of legal affairs about the letter
- ❑ VP of legal affairs informed him that the Baltimore division VP “was investigating the situation immediately and would be taking corrective action and would be preparing a summary of the corrective action to reply to the letter”
- ❑ Park stated that he did not “believe there was anything [he] could have done more constructively than what [he] found was being done”

US v. Park, 421 U.S. at 663-4

NOT ENOUGH

Park was convicted

Park Doctrine

“Defendant had, by reason of his position in the corporation, responsibility and authority either to:
(1) prevent in the first instance, or
(2) promptly to correct the violation complained of,
and that he failed to do so.”

Park, 421 US at 674

Park Doctrine (cont.)

The government did not have to prove knowledge or intent, only that the individual could have prevented or corrected the violation

OIG Controls Exclusion

- ❑ **Not the DOJ**
- ❑ **Preponderance standard**
- ❑ **Court review only at the end**

Two Types of Exclusions

- ❑ **Mandatory**
- ❑ **Permissive**

[42 USC 1320a-7]

Mandatory Exclusions [42 USC 1320a-7(a)]

- ❑ **Criminal offense related to the delivery of an item or service to Medicare or any state health care program**
- ❑ **Offense in connection with the delivery of an item or service or with respect to any act or omission in a health care program operated by or financed in whole or in part by any federal, state, or local government agency**
- ❑ **Criminal offense relating to neglect or abuse of patients in connection with the delivery of a health care item or service**
- ❑ **Felony conviction related to fraud, theft, embezzlement, breach of fiduciary responsibility or other financial misconduct**
- ❑ **Felony conviction relating to the unlawful manufacture, distribution, prescription or dispensing of a controlled substance**

Permissive Exclusions [42 USC 1320a-7(b)(1)-(16)]

Programmatic

- Making false statements or misrepresentations of material facts or omissions in any application, agreement, bid or contract to participate or enroll as a provider of services or supplier under a federal health care program – (b)(16)**
- Failure to provide certain information – (b)(9, 10, 11)**
- Failure to grant immediate access – (b)(12)**
- Conviction relating to interference with or obstruction of any health care investigation or audit – (b)(2)**

Permissive Exclusions [42 USC 1320a-7(b)(1)-(16)]

Quality of Care

- Claims for excessive charges or unnecessary services and failure of certain organizations to furnish medically necessary services – (b)(6)**
- Misdemeanor conviction relating to manufacture or dispensing of a controlled substance – (b)(3)**
- License suspension or revocation – (b)(4)**
- Exclusion or suspension from health care programs – (b)(5)**
- Failure to take required corrective measure – (b)(13)**

Permissive Exclusions [42 USC 1320a-7(b)(1)-(16)]

Miscellaneous

- Individual is owner, executive or manager of a sanctioned entity – (b)(15)
- Conviction of misdemeanor relating to fraud – (b)(1)
- Fraud, kickbacks, or other prohibited activity as determined by the Secretary – (b)(7)
- Failure to repay health care scholarship or loan – (b)(14)
- Entity is controlled by a sanctioned individual – (b)(8)

Misdemeanor Fraud [42 USC 1320a-7(b)(1)]

An individual or entity that has been convicted of a misdemeanor criminal offense, under Federal or State law relating to fraud, theft, embezzlement, breach of fiduciary responsibility or other financial misconduct in connection with the delivery of a health care item or service or with respect to any act or omission in a local, State or Federal health care program.

Park Doctrine Imperils Executives

- **President/CEO**
- **Executive VP**
- **Chief Legal Officer**



- ❑ **Corporate guilty plea to a felony**
- ❑ **\$600 million in criminal fines and civil monetary penalties**
- ❑ **Misdemeanor guilty pleas by executives as responsible corporate officers**

NOT ENOUGH



The video player displays a woman with dark hair, wearing a grey blazer over a purple top, smiling. She is positioned in front of a dark wood-paneled wall. To her left is an American flag. To her right is a screen showing the text "Provider Compliance Training" and the OIG logo. The video player interface includes a play/pause button, a volume icon, a progress bar showing 0:02 / 4:25, and icons for CC, settings, and YouTube. The video title "Video 2: Exclusion Authorities & Effects of Exclusion" is displayed in a rounded rectangle below the player.

Video 2: Exclusion Authorities & Effects of Exclusion

http://oig.hhs.gov/newsroom/video/2011/heat_modules.asp

Sanctioned entity is an entity

- ❑ Excluded from participating in any federal or state health care programs OR
- ❑ Convicted of offenses that would give rise to mandatory exclusion OR
- ❑ Convicted of offenses giving rise to the first three grounds permissive exclusion (b)(1, 2, 3)

42 USC § 1320a-7(b)(15)

Who controls sanctioned entity?

Any individual who –

- has direct or indirect ownership or control and who knows or should know of the action causing conviction or exclusion OR
- is an officer or managing employee of the entity (no requirement of knew or should have known)

42 USCS 1320a-7(b)(15)

Managing Employee

“an individual, including a general manager, business manager, administrator, and director, who exercises operational or managerial control over the entity or who directly or indirectly conducts the day-to-day operations of the entity.”

42 U.S.C. § 1320a-5(b).

Factors considered for exclusion pursuant to (b)(15):

- 1. Circumstances of the misconduct and seriousness of the offense**
- 2. Individual's role in the company**
- 3. Individual's actions in response to the misconduct**
- 4. Information about the company**

<http://oig.hhs.gov/exclusions/advisories.asp>



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List by Exclusion Type

TYPE	DESCRIPTION		
SECTION 1128(a)(1)	Program-related conviction	12691	
SECTION 1128(a)(2)	Patient abuse/neglect conviction	5299	
SECTION 1128(a)(3)	Felony health care fraud conviction	2375	
SECTION 1128(a)(4)	Felony controlled substance conviction	1986	
SECTION 1128(b)(1)	Conviction relating to program or health care fraud	571	
SECTION 1128(b)(11)	Failure to provide payment information	11	
SECTION 1128(b)(12)	Failure to grant immediate access	1	
SECTION 1128(b)(14)	Default on health education loan or scholarship obligation	2303	
SECTION 1128(b)(15)	Individual controlling excluded/convicted entity	36	
SECTION 1128(b)(2)	Obstruction of an investigation conviction	41	
SECTION 1128(b)(3)	Misdemeanor controlled substance conviction	292	
SECTION 1128(b)(4)	License revocation/suspension/surrender	22637	
SECTION 1128(b)(5)	Federal/state health care program exclusion/suspension	546	
SECTION 1128(b)(6)	Quality of care violation	75	
SECTION 1128(b)(7)	Fraud/kickbacks	520	

<http://exclusions.oig.hhs.gov/ExclusionTypeCounts.aspx>

Civil Monetary Penalties

- Imposed by the OIG
- Preponderance standard
- Up to 3x amount improperly claimed
- Penalties up to \$10,000 per false claim or \$50,000 per act if kickback
- Court review only at the end

42 USC § 1320a-7a; 42 CFR § 1003.102

OIG intends to expand application of (b)(15) to exclude “executives of large complex organizations like a drug or device manufacturer.”

**Congressional testimony of Inspector General Levinson
March 2, 2011**

Future enforcements beyond Pharmaceuticals

- ❑ **Biologics**
- ❑ **Biotechnology**
- ❑ **Medical devices**

What does the Chief Compliance Officer do now?

- ❑ **Tell the executive what is at stake**
- ❑ **Give examples of past OIG actions**
- ❑ **Explain that “it is personal”**

Rx for Fraud

The Feds Get Personal

BY THOMAS E. ZENO AND
KIMBERLY J. DONOVAN

The federal government opened a new front in its war against health care fraud by proposing to ban Howard Solomon from participating in all federal health care programs simply because he was a long-time corporate chairman. Solomon, 83 years old and the chief executive officer of Forest Laboratories since 1977, presided over the company's transformation from a maker of vitamins into a \$4 billion global pharmaceutical company. Solomon was not convicted of a health care fraud offense. In fact, Solomon had not even been notified by the government that he was a target of the proposed ban. Rather, the government waited to announce the ban until its wholly-owned subsidiary of Forest Laboratories was related to marketing its medications.

http://www.squiresanders.com/files/Publication/8fe2d243-8cf0-45bf-9251-d33be521ea26/Presentation/PublicationAttachment/eb2c3a71-bdff-485c-9f96-d43e31a89724/Rx_for_Health_Care_Fraud.pdf

Factors considered for exclusion pursuant to (b)(15):

1. **Circumstances of the misconduct and seriousness of the offense**
2. **Individual's role in the company**
3. ***Individual's actions in response to the misconduct***
4. **Information about the company**

<http://oig.hhs.gov/exclusions/advisories.asp>

OLG guidance regarding third factor:

“If the individual can demonstrate either that preventing the misconduct was impossible or that the individual exercised extraordinary care but still could not prevent the conduct, OIG may consider this as a factor weighing against exclusion.”

Compliance Program Elements

1. **Written policies and procedures**
2. **Compliance professionals**
3. **Effective training**
4. **Effective communication**
5. **Internal monitoring**
6. **Enforcement of standards**
7. **Prompt response**

Key Points about Supplemental Guidance for Hospital Compliance

- ❑ **Has the organization fostered a culture that encourages open communication, without fear of retaliation?**
- ❑ **Has the organization established an anonymous hotline or similar mechanism for medical and clinical staff, contractors, patients and visitors to report potential compliance issues?**
- ❑ **Are all instances of potential fraud and abuse investigated?**

More than a Hotline ...

More than a PowerPoint ...

More than a Manual ...

... It's About the Actions Taken

How to foster a culture of communication

- ❑ **Get compliance officers with the right personality for the job**
- ❑ **Institute transparency**
- ❑ **Talk directly to employees**
- ❑ **Consider a consultant**

Culture of communication

DO NOT:

- ❑ **Let an inbox handle the job (or even play a role)**
- ❑ **Have a “dropped ball” in your records**
- ❑ **Fail to document resolution**

DO:

- ❑ **Build an “Kudos File.” Good strategy is as much about highlighting the positive as defending against the negative**

Questions?

Thanks For Joining Our Webinar

Contact us with other questions or issues:

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