What Keeps You Up At Night?

Issues of Fraud and Abuse Compliance Series
WANTED

- President and CEO - Purdue Frederick
- Executive Vice President - Purdue Frederick
- Chief Legal Officer - Purdue Frederick
- Chief Executive Officer - Forest Labs
What Keeps You Up At Night?

Issues of Fraud and Abuse Compliance Series
Today’s Speakers

David W. Grauer
Chair, Healthcare

Thomas E. Zeno
Healthcare; White Collar Defense & Investigations

Kimberly J. Donovan
Healthcare & Litigation

Elizabeth E. Trende
Healthcare
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

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”
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
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
## List by Exclusion Type

<table>
<thead>
<tr>
<th>TYPE</th>
<th>DESCRIPTION</th>
<th>COUNT</th>
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<tbody>
<tr>
<td>SECTION 1120(a)(1)</td>
<td>Program-related conviction</td>
<td>12691</td>
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<td>SECTION 1120(a)(2)</td>
<td>Patient abuse/neglect conviction</td>
<td>5299</td>
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<tr>
<td>SECTION 1120(a)(3)</td>
<td>Felony health care fraud conviction</td>
<td>2375</td>
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<tr>
<td>SECTION 1120(a)(4)</td>
<td>Felony controlled substance conviction</td>
<td>1986</td>
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<tr>
<td>SECTION 1120(b)(1)</td>
<td>Conviction relating to program or health care fraud</td>
<td>571</td>
</tr>
<tr>
<td>SECTION 1120(b)(11)</td>
<td>Failure to provide payment information</td>
<td>11</td>
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<tr>
<td>SECTION 1120(b)(12)</td>
<td>Failure to grant immediate access</td>
<td>1</td>
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<tr>
<td>SECTION 1120(b)(14)</td>
<td>Default on health education loan or scholarship obligation</td>
<td>2393</td>
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<td>SECTION 1120(b)(15)</td>
<td>Individual controlling excluded/convicted entity</td>
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<tr>
<td>SECTION 1120(b)(2)</td>
<td>Obstruction of an investigation conviction</td>
<td>41</td>
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<tr>
<td>SECTION 1120(b)(3)</td>
<td>Misdemeanor controlled substance conviction</td>
<td>292</td>
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<td>SECTION 1120(b)(4)</td>
<td>License revocation/suspension/surrender</td>
<td>22837</td>
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<td>SECTION 1120(b)(5)</td>
<td>Federal/state health care program exclusion/suspension</td>
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<td>SECTION 1120(b)(6)</td>
<td>Quality of care violation</td>
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</tr>
<tr>
<td>SECTION 1120(b)(7)</td>
<td>Fraud/kickbacks</td>
<td>529</td>
</tr>
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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”
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, 63 years old and the chief
corporate officer of Forest Laboratories since 1977, pro-
vided over the company’s manufacture of a maker
of vitamins into a $4 billion global pharmaceutical annu-
ual. Solomon was not convicted of a health care fraud
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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
OIG 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*
Fostering 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

Join us for future calls in this series:

- May 24: How to Handle the Bad Email or Social Media Post
- Attorney-Client Privilege: Keeping It and Using It Wisely
- Use of Outside Counsel: When Inside Counsel Is Not Enough
- Proper Recordkeeping in a Heightened Enforcement Environment
Thanks For Joining Our Webinar

Contact us with other questions or issues:

- Tom Zeno: thomas.zeno@squiresanders.com
- Kimberly Donovan: kimberly.donovan@squiresanders.com
- Emy Trende: elizabeth.trende@squiresanders.com
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