The First International Medical Device Compliance Congress
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Track 3.01
Managing Investigations and Compliance Programs in Connection with Corporate Transactions - Acquisitions and Divestitures

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Outline of Remarks

I. Introductions
   – Bronwen R. Taylor
   – Lynn Shapiro Snyder, Esq.

II. Acquisitions and Divestitures
   – Private Equity/Strategic Partners (examples)
   – Payors; Providers; Manufacturers (examples)

III. Understand the Framework for Compliance Programs

IV. Understand the Legal Landscape
   – Example: USA Health Care Fraud Enforcement
     • Brief Overview
     • Key Laws
     • Recent Settlements

V. Examples of Key Issues that Arise Managing Health Care Fraud Investigations and Compliance Programs in Connection with Acquisitions and Divestitures

VI. Best Practices Going Forward
I. Introductions

• Bronwen R. Taylor
  Vice President,
  Internal Audit & Compliance
  Stryker

• Lynn Shapiro Snyder, Esq.
  Senior Member
  Epstein Becker & Green P.C.
II. Acquisitions and Divestitures

• Global
  – Substance of the Transaction
    • Shares ➔ History and baggage
    • Assets ➔ No history + some or no baggage
  – Cross Border Challenges
  – Business Practices

• USA
  – Private Equity/Strategic Partners
  – Payers; Providers; Manufacturers
III. Understand the framework for Compliance Programs

- Global
  - International Standards

- USA
  - Laws
  - Rules and Regulations
    - New York Stock Exchange (NYSE) Corporate Governance Rules
    - United States Sentencing Commission’s Guidelines (Chapter 8, 2.1)
    - Compliance Program Guidance for Pharmaceutical Manufacturers Published by the U.S. DHHS Office of Inspector General (OIG)
  - Industry Standards
  - Other
    - Corporate Integrity Agreements
III. Understand the legal landscape

• Laws
  – Federal
  – State
  – Local

• Enforcement
  – Who
  – How
  – When
  – Duration
  – Business consequences
III. Understand the legal landscape

• Example: USA key laws
  – Federal Anti-Kickback Law
    • Federal Health care programs
  – State Law Anti-Kickback Counterparts
  – Federal False Claims Laws
  – State False Claims Laws
III. Understand the legal landscape

- Example USA key laws
  - Medicaid Drug Rebate Law (drugs)
    - Medicaid coverage of drugs involves rebates and participation in other related government programs
    - Penalties - $100,000 civil monetary penalty for each item of false information provided
  - State Supplemental Rebate Laws (drugs)
III. Understand the legal landscape

- Example USA enforcement:

  U.S. Federal Enforcement
  - Department of Justice
  - Department of Health & Human Services
    - Office of the Inspector General
    - Food & Drug Administration (FDA) Enforcement
  - Department of Veterans Affairs
    - DOD Enforcement

  Settlement Terms
  - Financial
  - Integrity Obligations
    - Corporate Integrity Agreements
    - Warning letters
  - Punishment
    - Pleas
    - Exclusions
    - Debarment
  - Other

State Enforcement
- Medicaid Fraud Control Units
- Attorney General
  - Consumer Protection
  - False Claims
- Other
III. Understand the legal landscape

EBG Selected U.S. Health Care Fraud Settlements in the Medical Device Industry

<table>
<thead>
<tr>
<th>Name of Company (w/ U.S. Attorney’s Office)</th>
<th>Date</th>
<th>Alleged Violation</th>
<th>Civil Settlement</th>
<th>Criminal Settlement</th>
<th>Term</th>
</tr>
</thead>
<tbody>
<tr>
<td>DePuy Orthopaedics, Inc.* (D. NJ)</td>
<td>September 2007</td>
<td>Anti-Kickback Statute (42 U.S.C. § 1320a – 7b)</td>
<td>$84.7 million</td>
<td>DPA</td>
<td>18 months</td>
</tr>
<tr>
<td>Stryker Orthopedics, Inc.* (D. NJ)</td>
<td>September 2007</td>
<td>Anti-Kickback Statute (42 U.S.C. § 1320a – 7b)</td>
<td>None</td>
<td>NPA</td>
<td>18 months</td>
</tr>
</tbody>
</table>

* These companies are considered the five leading manufacturers of artificial joints. It has been reported that in December 2007, two smaller competitors – Wright Medical Group and Exactech – received subpoenas, indicating that the government is intent on attempting to have all joint manufacturers comply with similar integrity obligations. The joint business is the $6 billion core of the orthopedics industry.

Both the U.S. Attorney’s Office for the District of New Jersey and the Assistant Inspector General for Legal Affairs at the U.S. Department of Health and Human Services recently announced publicly that each intends to investigate physicians for soliciting illegal kickbacks.
IV. Examples of Key Issues that Arise Managing Health Care Fraud Investigations and Compliance Programs in Connection with Acquisitions and Divestitures

A. Access to Compliance Program Activities During Due Diligence – Nothing Pending
   1) Access Issues
   2) Best Practices
   3) Benchmarking the Compliance Program

B. Access to When there is a Government Pending Matter
   1) Access Issues
   2) Best Practices
   3) Implications and Handicapping Potential Outcomes

C. Finding Non-Compliance During Due Diligence
   1) What Next?
   2) Affect on Price?
   3) Corrective Actions?
   4) Disclosures Pre or Post-Closing?
V. Best Practices Going Forward

1. Documentation/Recordkeeping Implications
   Demonstrating Effective Compliance

2. Attorney – Client Privilege Implications

3. Potential Strategic Terms for Letter of Intent

4. Consider Who is Responsible for:
   – any financial settlements?
   – future government contractual integrity obligations?
   – any fundamental changes in the historical business models?

5. Consider Future Asset Divestitures Limitations from
   Government Contractual integrity Obligations

6. Implications of Government Contractual Integrity
   Obligations for Transactions Outside USA
V. Best Practices Going Forward

7. Remember Underlying Objectives of the Parties
   - As the purchaser you are looking for any ammunition to drive the price down
   - As the seller you are looking for any ammunition to drive the price up

8. Don’t do the Compliance Due Diligence in a Vacuum
   - Your compliance program due diligence should always be part of the overall due diligence so that answers/responses correlate

9. Don’t Just Rely on Verbal Responses - You Want to See “Substance over Form”
   - Examples of activities

10. Understand the Depth and Breadth of the Compliance Program
    - Activity only in Corporate in Office?
    - Has compliance cascaded down through the organization?

11. If there is a Monitor in Place
    - Can you get feedback from the monitor?

12. See Best Practices Handout