Keys to Negotiating a Corporate Integrity Agreement

A Presentation to the Pharmaceutical Congress

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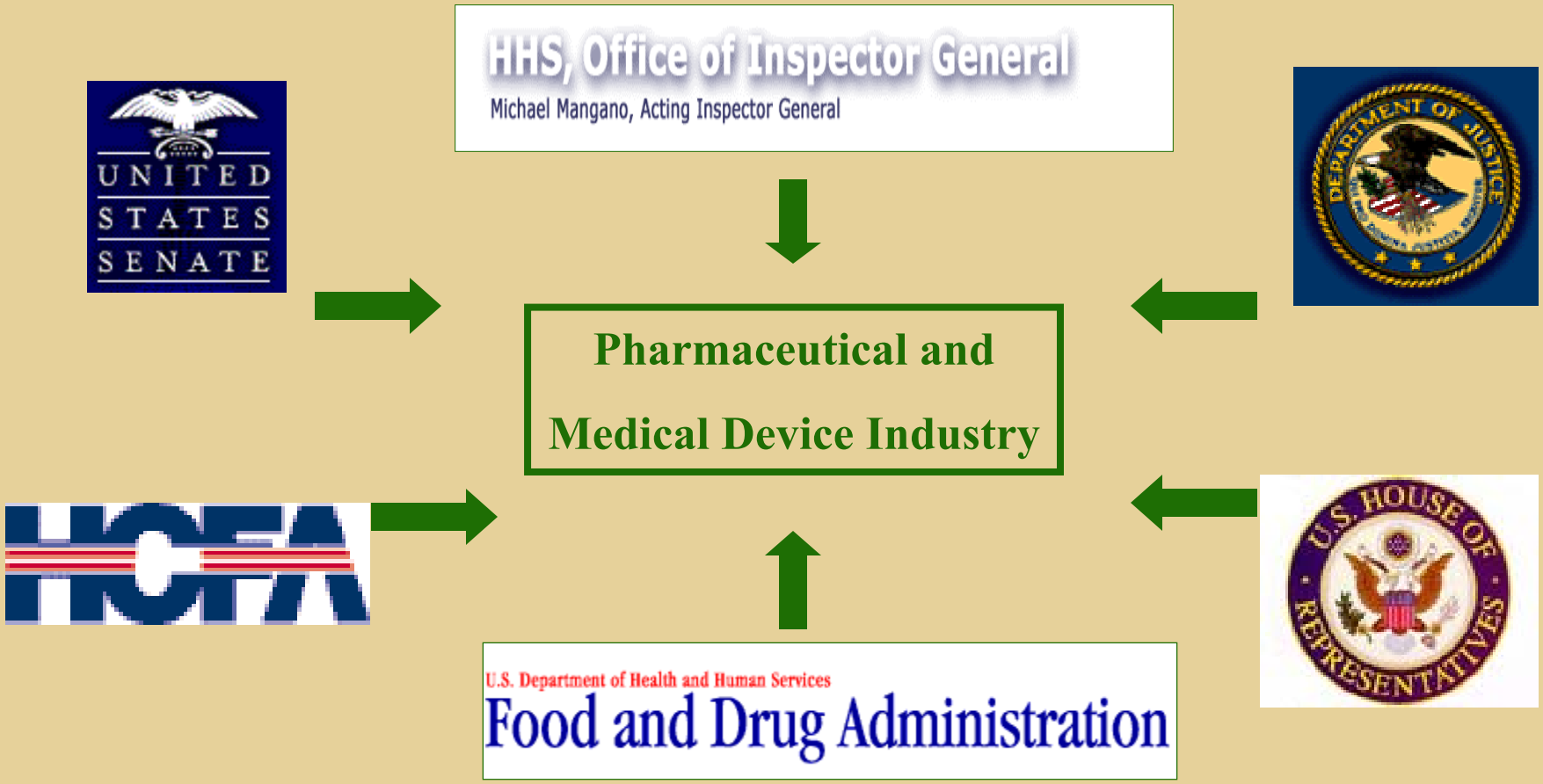
nathon L. Kellerman
nior Manager
cewaterhouseCoopers LLP
7) 330-2466
nathan.l.kellerman@us.pwc.com

Breakout Session Agenda

- The Current Regulatory Environment
- Landmark Settlements
- Issues and Implications
- Key Takeaways
- An Overview of the CIA Process
- Usual CIA Requirements
- Typical Issues to Consider for the CIA
- Begin Thinking Through the IRO Workplan
- OIG's Compliance Program Assessment
- Notional Outline for a "Compliance Story"

The Current Regulatory Environment



Landmark Settlements

- To date, there have been seven landmark settlements in the pharmaceutical and medical device industry resulting in over $2.1 billion in recovery to the federal government (all in a 3-year period!)
  - Bayer - $14M and $257
  - TAP - $875M
  - Pfizer - $49M
  - GSK - $88M
  - AZ - $355
  - Ross - $414M
  - Guidant - $92M
- These settlements have involved civil and criminal implications
- Additional pharma manufacturers and medical device companies are currently under investigation or are “on the radar”

Issues and Implications

- The *primary business practices* that have been and are under scrutiny include:
  - Sales and marketing activities to purchasers and prescribers
  - Contracts with managed care companies
  - Reporting BP for Medicaid
  - Other government pricing matters
  - Offering of kick-backs
  - Sales of defective products
  - Others on the horizon – off label promotion, quality
- The *impact* to these companies has been significant:
  - Reputational harm in the eyes of consumers, business partners and investors
  - Big dollar payouts
  - Significant “one-time” investments in information systems and other support systems
  - Investment in an IRO for 5-7 years
  - “Real-time” Impact to the day-to-day business (e.g., fixing processes/systems, working with the IRO for a period of time, etc.)
  - Reduced “say” in the direction and tone of your compliance program activities

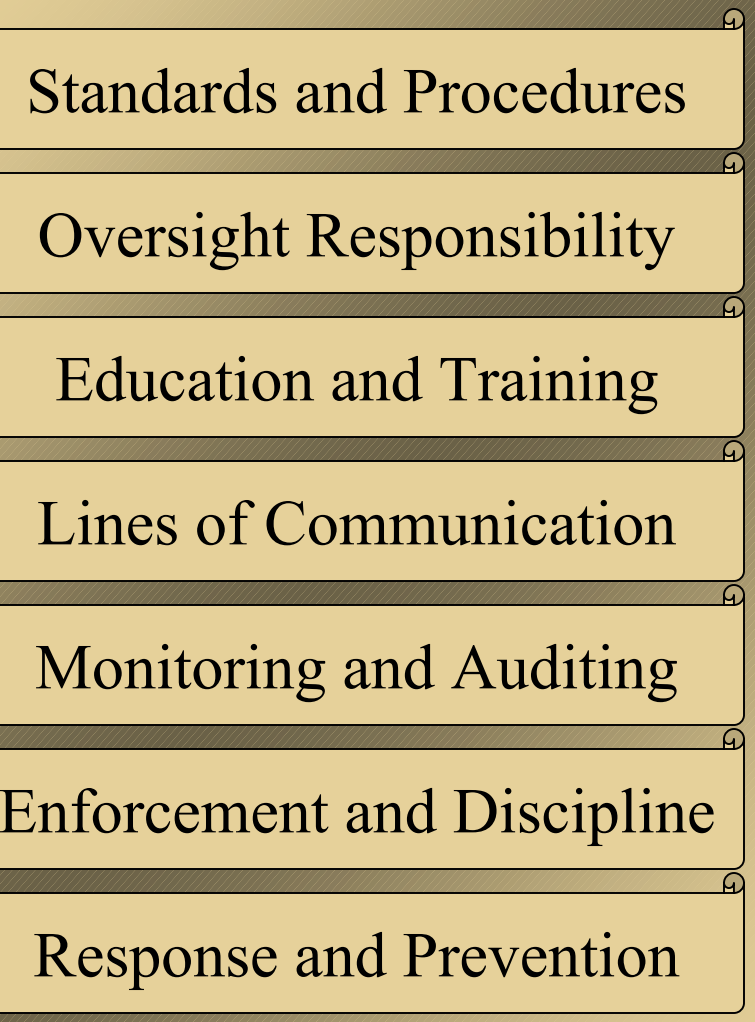
Key Takeaways

- Engaging proven and experienced advisors may save you hundreds of thousands of dollars and mitigate the impact to your day-to-day business
- Keep the focus sharp on the issues
- Leverage the strength of your existing compliance program activities – write your “compliance story” early
- Build goodwill and credibility with the OIG during your negotiations and the duration of your CIA
  - Keep an open line of communications about what you are doing
  - Always be transparent
- Be proactive – compliance should not be reactionary!

An Overview of the CIA Process

- Company to finalize settlement with the DOJ
- Company to call the OIG to identify their assigned contact and begin dialogue – establish the “open book” working relationship
- Company to meet with the OIG to present their compliance program with a focus on the areas to be covered under the CIA
- OIG to present a draft CIA to Company for consideration and review (including IRO Workplan)
- Company to negotiate and agree to the terms and conditions of the CIA (including timing of the Annual Report, key definitions, etc.)
- Company to submit an Implementation Plan (generally within 120 days of the effective date)
- Company to work with the IRO to plan for the audits

Usual CIA Requirements



- A Corporate Integrity Agreement will be based on:
  - The Company's specific issues investigated
  - Federal Sentencing Guidelines
  - OIG Compliance Program Guidance
  - Experience from other industry sectors
  - Prior CIAs

Anticipated Components of an IRO Audit

- Transactions testing for ASP (i.e., identification of “like kind transactions” for testing, such as sales, credits, chargebacks, paid rebates, estimated rebates, manual adjustments, etc.)
- Transactions testing for BP (see above)
- Systems Review for ASP and BP (i.e., a comprehensive analysis of the controls, systems, processes, policies and practices in place during the testing period)
- Testing of sales and marketing activities (e.g., grants, charitable contributions, CME, display fees, speaker agreements, consulting arrangement, etc.)
- Systems Review for sales and marketing activities (i.e., a comprehensive analysis of the controls, systems, processes, policies and practices in place during the testing period)
- Other “new” areas (e.g., FMV)?

Typical Issues to Consider for the CIA

- Duration of the CIA
- Duration and frequency of the IRO audits (e.g., 1st and 4th years for a systems review)
- Timing of the first and subsequent Annual Reports (i.e., as impacted by the real business limitations, such as the availability of four quarters of testable data)
- Engage the IRO in CIA workplan negotiations
- Opportunity to shift some audit responsibilities “in house” in later years
- Definition of “covered persons” and “relevant covered persons” (i.e., corporate roll out of training on Code of Business Conduct vs. business unit training on policies)
- Definition of “materiality” and/or “reportable event”
- Consideration for “error rate triggers” and “additional IRO reviews”
- Compliance Officer certification (i.e., documentation and “off-years”)
- Type, frequency and medium for training (e.g., web-based)
- Consider opportunities for potential re-negotiations

Begin Thinking Through the IRO Workplan

- Refine the scope of the testing to focus only on the issues raised in the settlement agreement (e.g., if managed care contracting is a driver, try to focus testing requirement on managed care customers)
- Identify and engage the key business process owners to assist with addressing critical questions around processes, information systems, timing of reviews, availability of staff to support the audit effort, etc.
- Define and agree to the “like kind transactions” to test (ensure the accessibility and aggregation of the data and make sure that the support documentation is auditable)
- Clearly define key terms (e.g., “customers,” “control documentation,” “discount arrangement,” “promotional activities,” etc.) and what is included and excluded from testing (e.g., are gifts considered a promotional activity)
- Agree to processes to validate the completeness of universes of data

OIG's Compliance Program Assessment

The following information has typically been requested by the OIG when assessing a pharmaceutical company's compliance program:

- A description of the organization and management structure (including organization charts and any documents that would be helpful in understanding the structure of the organization).
- Names, job descriptions (including non-compliance related functions) and reporting lines of Compliance Officers and any other employees whose primary job function is to assist the Compliance Officers with implementation and oversight of the compliance program.
- Budgets (including sources of funding) and time investments of the Compliance Officers and their support teams (i.e., in the areas of oversight and implementation).

OIG's Compliance Program Assessment

- Names and positions of the members of the Compliance Committee(s), if any, along with the charter of the Compliance Committee(s).
- Identification of the person, persons, or committees to whom the Compliance Officer is directly responsible or to whom any compliance issues or reports are addressed.
- Code of Conduct/Standards of Conduct.
- Compliance policies and procedures relating to the Federal health care program fraud and abuse issues.
- Disciplinary policy regarding violations of the compliance policies and procedures, and applicable Federal and state laws.

OIG's Compliance Program Assessment

- The process, if one exists, used to screen current and potential employees, independent contractors, etc. who have been debarred, excluded, or otherwise are ineligible to participate in the Federal health care programs.
- Disciplinary policy regarding violations of the compliance policies and procedures, and applicable Federal and state laws.
- Internal mechanism (e.g., help line, hotline, etc.) for the reporting of suspected compliance issues and the procedures used to track and respond to reports (i.e., depth of management reports).
- Training or educational programs that address compliance with Federal health care program requirements (including, but not limited to, presentations on fraud and abuse and/or the federal anti-kickback statute).
- Internal monitoring and auditing activities

Notional Outline of a “Compliance Story”

- Background and Overview
  - Organizational structure of Company’s businesses
  - Executive management team members
  - Company’s philosophy on R&D
  - Identify therapeutic areas and Company’s key products
- Corporate Compliance at Company
  - Overview of Company’s philosophy on business integrity
  - A statement from the CEO on the Company’s commitment to compliance
  - Company’s “compliance mission statement”

Notional Outline of a "Compliance Story"

- Corporate Compliance at Company (continued)
  - The elements of Company's compliance program
    - ✓ Oversight responsibility, reporting structure, role of the CCO and Compliance Committee(s)
    - ✓ Company's Code of Business Conduct and policy on Compliance (including distribution channels and communication plans)
    - ✓ Company's education and training efforts on compliance – corporate and business unit (including frequency, levels of participation and mediums)
    - ✓ Company's education and training efforts on key policies from the investigation – business unit (including frequency, levels of participation and mediums)
    - ✓ Company's hotline and other related lines of communication
    - ✓ Company's protocols for investigations and corrective action
    - ✓ Company's protocols for enforcement and discipline (define the policies)

Notional Outline of a “Compliance Story”

- Corporate Compliance at Company (continued)
  - Building a case study or example
    - Identify a strong policy and/or business practice and illustrate the above compliance elements through a “case study”
    - Examples to consider include grants, field force incident management, spending policy, etc.