

RECENT TRENDS IN CORPORATE INTEGRITY AGREEMENTS

Presented by:
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EPSTEINBECKERGREEN



II. CURRENT CIA TRENDS



1. BOARD OF DIRECTORS OVERSIGHT

BOARD OF DIRECTORS OVERSIGHT

- Example: AstraZeneca CIA (4/10)
 - Board of Directors (or Board Committee) Obligations
 - Meet at least quarterly to review and oversee the Compliance Program
 - Adopt a resolution for each CIA reporting period that summarizes its review and oversight of matters relating to AstraZeneca's compliance with Federal health care program requirements, FDA requirements and CIA obligations

BOARD OF DIRECTORS OVERSIGHT

- Example: Ortho-McNeil-Janssen CIA (4/10)
 - Board of Directors Obligations
 - Meet at least quarterly to review and oversee OMJPI's Compliance Program
 - Arrange for a review of the effectiveness of OMJPI's Compliance Program by a Compliance Expert for each reporting period that is provided to the OIG in each annual report
 - Retain a Compliance Expert to create a work plan for the Compliance Program Review, oversee the performance of the Compliance Program Review and prepare a written report about the Compliance Program Review
 - Board must adopt a resolution for each CIA reporting period that summarizes its review and oversight of OMJPI's Compliance Program

BOARD OF DIRECTORS OVERSIGHT

- Example: Pfizer CIA (8/009)
 - Board of Directors Audit Committee
 - Responsible for review and oversight of matters related to compliance with the Federal health care programs, FDA requirements and CIA obligations
 - Review and oversee the Compliance Program at least quarterly
 - Adopt a resolution for each reporting period signed by each member of the Audit Committee that summarizes its review and oversight

BOARD OF DIRECTORS OVERSIGHT

- Example: Eli Lilly CIA (Jan. 2009)
 - Board of Directors Obligations
 - “[B]e responsible for the review and oversight of matters related to compliance with Federal health care program requirements, FDA requirements, and the obligations of [the] CIA”
 - Meet at least quarterly to review and oversee Lilly’s Compliance Program
 - Arrange for a review of the effectiveness of Lilly’s Compliance Program for each reporting period that is provided to the OIG in each annual report
 - Board must adopt a resolution for each CIA reporting period that summarizes its review and oversight of Lilly’s compliance program

BOARD OF DIRECTORS OVERSIGHT

1. Defining current fiduciary obligations for a Board of Directors
2. Determining which Board of Directors committee should have responsibility for review and oversight of the compliance program
3. Implementing review and oversight responsibilities

2. SENIOR MANAGEMENT CERTIFICATIONS

SENIOR MANAGEMENT CERTIFICATIONS

- Example: AstraZeneca CIA
 - Certifications by “Certifying Employees”
 - “Specifically expected to monitor and oversee activities within their areas of authority”
 - Annual certification that the applicable component is compliant with Federal health care program requirements, FDA requirements and CIA obligations
 - AZ’s Certifying Employees must include:
 - President, US Business
 - VPs of Commercial Functions (including sales, marketing, brand)
 - Sales Directors (national, area and regional)
 - Senior Brand Leaders (commercial and development)
 - VP of Medical Affairs and direct reports with responsibilities for Medical Affairs or Field Medical Relations
 - Executive Director of Promotional Regulatory Affairs

SENIOR MANAGEMENT CERTIFICATIONS

- Example: Ortho-McNeil-Janssen CIA
 - Certifications by “Certifying Employees”
 - “Specifically expected to monitor and oversee activities within their areas of authority”
 - Annual certification that the applicable business unit is compliant with applicable Federal health care program requirements, FDA requirements and CIA obligations
 - OMJPI’s Certifying Employees must include:
 - President
 - VPs of HR, Strategic Customer Group, Commercial Analytics, Medical Affairs, Communication and Public Policy, New Business Development
 - General Managers of CNS, 1M/Pain, Virology, Immunology/Oncology
 - Chief Scientific Officer
 - Treasurer
 - Appropriate executive, VP or director of any other OMJPI business unit that performs sales, marketing, promotion, pricing, contracting, regulatory affairs, compliance, and medical affairs functions not covered by the certifications listed above

SENIOR MANAGEMENT CERTIFICATIONS

- Example: Pfizer CIA
 - Certifications by Senior Executives and “Certifying Employees”
 - Business unit presidents and finance directors must make certifications annually that, among other things, he/she has reviewed certain enumerated reports and reported potential issues identified to Compliance and/or Legal
 - Similar certifications also must be made by certain “Certifying Employees”
 - Includes sales, marketing, medical, commercial development, strategy

SENIOR MANAGEMENT CERTIFICATIONS

- Example: Lilly CIA
 - Obligations for “Certifying Employees”
 - “Specifically expected to monitor and oversee activities within their areas of authority”
 - Annual certification that the applicable Lilly component is compliant with Federal health care program requirements, FDA requirements, and obligations of the CIA
 - Lilly’s Certifying Employees include certain employees at the following levels:
 - President
 - Vice President
 - National directors, executive directors and directors
 - Brand leaders and business unit leaders

SENIOR MANAGEMENT CERTIFICATIONS

1. Key considerations for employee certifications

- Who
- What
- How
- When

2. Key considerations for implementation of the certification requirement

3. Additional “ancillary” considerations

- Policies and procedures
- Code of conduct

3. TRANSPARENCY

TRANSPARENCY

- Example: AstraZeneca CIA
 - CIA imposes several transparency obligations
 - Post information regarding payments to physicians and entities on its company website
 - Phase I – payments in connection with promotional speaking
 - Phase II – all “payments or other transfers of value” as defined by Section 6002 of PPACA
 - Post information regarding medical education grants and charitable contributions bi-annually on its website
 - Require business partners to comply with disclosure obligations from associated entities (e.g., formulary & P&T committee members)
 - Require Authors of biomedical manuscripts to comply fully with ICMJE criteria regarding authorship and disclosure requirements
 - Post clinical study information on the NIH and company website
 - Post information regarding postmarketing commitments on its company website

TRANSPARENCY

- Example: Ortho-McNeil-Janssen CIA
 - Three-Phase Reporting Structure
 - Phase I – Report the following by September 30, 2010:
 - All payments or transfers of value (whether in cash or in kind) made by OMJPI to physicians and/or to Related Entities in return for contracted services
 - Phase II – Report the following by July 1, 2011:
 - All Phase I payments and all payments or transfers of value made by OMJPI for research, education, and payment or reimbursement by OMJPI for business meals
 - Phase III – Report the following by the earlier of June 30, 2012 or 180 days from the publication by HHS of final regulations implementing the Patient Protection and Affordable Care Act:
 - Phase I and Phase II payments and all other payments or transfers of value made by OMJPI, directly or indirectly, to a physician or Related Entity

TRANSPARENCY

- Example: Pfizer CIA
 - CIA requires Pfizer to publicly post information related to certain gifts, fees and other payments

“Each listing made pursuant to this Section III.O shall include a complete list of all individual physicians, and/or Related Entities to whom or to which Pfizer directly or indirectly made Payments . . . for the preceding quarter or year . . . For each physician, the applicable listing shall include the following information: i) physician's full name; ii) name of any Related Entities (if applicable); iii) city and state that the physician or Related Entity has provided to Pfizer for contact purposes; and iv) the aggregate value of the Payment(s) in the preceding quarter(s) or year (as applicable).”

TRANSPARENCY

1. Key considerations for voluntary transparency
 - State law reporting
 - Vendor relationships
 - Other legal and regulatory obligations

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