



Compliance Effectiveness and Board Certification

October 22, 2010

Saul B. Helman, MD
Managing Director
Navigant Consulting, Inc.
Chicago, IL

Thomas D. Forrester
VP & US Corporate Compliance Officer
sanofi-aventis US



sanofi aventis

Because health matters

CIA Developments: Board Accountability

Organization	CIA Date	Independent Compliance Advisor	Annual Compliance Program Effectiveness Review	Annual Compliance Program Effectiveness Resolution
Tenet	September 2006	X	X	X
Cephalon	September 2008	X	X	X
Bayer	November 2008	X	X	X
Quest	April 2009	X	X	X
Ortho McNeil	April 2010	X	X	X
Forest Labs	September 2010	X	X	X

Board Implications

- Expanded remit for oversight
- More than just public policy, or ethics, or audit committee
- Personal implications – accountability, responsibility
- Need for independent review – in addition to IRO system and transaction review

What is Compliance Effectiveness?

- Federal Sentencing Guidelines
 - » “....a program that has been reasonably designed, implemented and enforced so that it generally will be effective in preventing and detecting criminal conduct...The hallmark of an effective program to prevent and detect violations of law is that the organization exercised due diligence in seeking to prevent and detect criminal conduct.”
- U.S. Department of Health and Human Services:
 - » Defines effective as a program that prevents improper payments
 - » Easily understandable code of conduct provided to all employees
 - » Policies addressing specific risk areas
 - » Retooled and tested for effectiveness

Recent Developments

- Sentencing Commission's April 29, 2010 amendments to the Federal Sentencing Guidelines:
 - » Defines an appropriate organizational response once criminal conduct has been detected:
 - take steps to remedy the harm, including restitution, self-reporting and cooperation with authorities
 - conducting an assessment of the organization's existing compliance program, including modifications to the program as may be appropriate to prevent the occurrence of similar conduct. The amendment specifically refers to the use of outside professional advisors to ensure the adequacy of the assessment efforts
 - » Direct and personal reporting relationship between the compliance officer and the governing board



Company Structure

■ USA

- **Operates through sanofi-aventis US**

- A US legal entity
- Subject to US and state laws

■ Outside the US

- **Operates through non-US legal entities**

- Subject local laws

- **Some US laws may reach conduct outside the US**

- Foreign Corrupt Practices Act

- **Overall Parent**

- French legal entity



Corporate Integrity Agreement & Addendum

Key Provisions

- **5 year term ends August 2012**
- **Scope: US Pharmaceutical Operations**
- **Independent Review Organization (“IRO”) conducts audits each year and issues report.**
 - **Audit covers government price reporting for:**
 - Medicaid
 - Average Manufacturer Price
 - Best Price
 - Medicare Part B
 - Average Sales Price (in office injectable products)
- **Company files Annual Report with OIG each year including the IRO audit report.**



Corporate Integrity Agreement & Addendum

U.S. Board of Director Provisions

Board of Directors of sanofi-aventis US Inc. and sanofi-aventis US LLC

- **Must meet quarterly**
- **Oversight**
 - CCO
 - US Compliance Department
 - US Compliance Committee
- **Adopt resolution each year summarizing review and oversight of company compliance with**
 - Federal Health Care Program Requirements and CIA
 - Resolution filed with OIG each year



Corporate Integrity Agreement & Addendum

Key Provisions

Certifying Employees

- Specifically expected to monitor and oversee activities within their areas of authority
- Certify to OIG annually that their areas are compliant with applicable Federal health care program requirements and CIA obligations
 - VP Managed Markets
 - VP Contract & Pricing

CCO certifies annually to OIG:

- Company in compliance with CIA
- Annual Report is complete and truthful
- Competent legal counsel has reviewed:
 - Policies and Procedures
 - Standardized contract templates
 - Training materials
 - Promotional materials used with Government Reimbursed Products



Compliance Effectiveness and Board Certification

■ Participation of Board in Compliance Committee meetings

■ Benefits

- Debates
- Ownership
- Judgments
- Focus
- Tone at the Top

■ Issues

- Too much detail?
- Time
- Operational?
- Tactics



Compliance Effectiveness and Board Certification

Information for the Board

- Pending issues
- Types of issues/trends
- Training statistics
- Top line assessment summary
- Enforcement updates
- Legislative/legal developments with enforcement/compliance implications
- Risk Assessment process and results
- Assessment Plan
- Annual Plan
- Policy Developments
- Resources devoted to Compliance



Compliance Effectiveness and Board Certification

Information for the Board

- Significant investigations
- Significant interactions with government agencies, e.g.
 - FDA
 - OIG
 - DOJ
 - Foreign countries



Compliance Effectiveness and Board Certification

■ Independent Assessment of the Compliance Program

■ Who does the work?

- Law Firm
- Auditor/Consulting firm
- Internal Audit
- Other

■ Overseen by Law Department and under the Attorney-Client Privilege?

■ Activities should include:

- Document review for compliance structure
- Interviews with key personnel including executives
- Electronic surveys of employee sample—compliance program awareness
- Review of completion of corrective actions from prior reviews
- Assess information against criteria
- Observations, recommendations, etc.



Compliance Effectiveness and Board Certification

■ Independent Assessment of the Compliance Program

■ Typical criteria

- Federal Sentencing Guidelines
- OIG Guidance for Pharmaceutical Manufacturers
- PhRMA Code
- Industry standards

■ Assess the 7 elements of compliance programs

- Governance/Structure
- Standards
- Training
- Communication
- Auditing & Monitoring
- Enforcement
- Response & Prevention



Compliance Effectiveness and Board Certification

■ Independent Assessment of the Compliance Program

■ Report for the Board

- Practical, direct assessment of the 7 elements of the compliance program
 - Governance/Structure
 - CCO access to CEO and Board
 - Compliance Committee (“CC”) meets regularly, charter, minutes
 - CC oversees Compliance Program
 - Compliance personnel are experts
 - systems and resources in place
 - Standards
 - Code of Conduct
 - Policies & procedures
 - Regular reviews and updates and evidence of same
 - Clear
 - Development of new standards



Compliance Effectiveness and Board Certification

■ Independent Assessment of the Compliance Program

■ Report for the Board

- Overall assessment description
 - Use an accepted company rating?
 - Some other executive summary verbal description of the effectiveness of the program?
 - Comparison to compliance programs of other companies?

■ Next steps

- Board review of Report
 - Added indicia of objectivity
- Board discussions with management at Board Meeting
 - Executives, CCO, Compliance Committee, etc.
 - If program not deemed effective, identify corrective action needed
 - Adoption of resolution



Compliance Effectiveness and Board Certification

■ Independent Assessment of the Compliance Program

■ Report for the Board

- Practical, direct assessment of the 7 elements of the compliance program

- Training

- CIA required
- Non-CIA required
- Who is responsible?
- types of training
- evidence that training occurs
- interviewees assessment of training

- Communications

- Helpline/email address/open door in place?
- non-retaliation policy?
- communications to leadership teams?
- company wide communications?



Compliance Effectiveness and Board Certification

■ Independent Assessment of the Compliance Program

■ Report for the Board

- Practical, direct assessment of the 7 elements of the compliance program
 - Assessments, Audits, Monitoring
 - risked based audit plan
 - Compliance Committee approval
 - Findings/corrective actions compiled in database and tracked for completion
 - Enforcement
 - Investigative groups
 - Discipline consistent—how does company achieve that?
 - performance evaluations
 - Response and Prevention
 - are logs kept of issues and responses?

Thirteen Questions That Support Compliance Effectiveness Assessments

OIG Element	Question	Answer	Tested?
Oversight	Does the compliance officer have direct access to the governing body, the president or CEO, all senior management, and legal counsel?	Y / N	Y / N
	Does the compliance officer make regular reports to the BoD and other management concerning different aspects of the organization's compliance program?	Y / N	Y / N
Written Standards	Have the standards of conduct been distributed to all directors, officers, managers, employees, contractors and vendors?	Y / N	Y / N
	Has the organization developed a risk assessment tool, which is re-evaluated on a regular basis, to assess and identify weaknesses and risks in operations?	Y / N	Y / N
Training and Education	Has the organization evaluated the appropriateness of its training format by reviewing the length of the training sessions; whether training is delivered via live instructors or computer-based training programs; and the need for general and specific training sessions?	Y / N	Y / N
Open lines of Communication	Has the organization established a well publicized, anonymous hotline or similar mechanism so that employees, contractors, and other individuals can report potential compliance issues?	Y / N	Y / N
	Are the results of internal investigations shared with the governing body and relevant departments on a regular basis?	Y / N	Y / N
	Do you evaluate the 'Tone From The Top' on a regular basis (e.g. annually)?	Y / N	Y / N
Auditing and Monitoring	Is the compliance audit and monitoring plan re-evaluated annually, and does it address the proper areas of concern, considering, for example, findings from previous year's audits, risk areas identified as part of the annual risk assessment, and high risk areas?	Y / N	Y / N
	Have you built into the formal compliance audits a degree of independence?	Y / N	Y / N
Responding to Detected Deficiencies	Has the organization created a response team, consisting of representatives from compliance, audit and any other relevant functional areas, which may be able to evaluate any detected deficiencies quickly?	Y / N	Y / N
Enforcement of Standards	Are employees, contractors and vendors checked routinely (e.g., at least annually) against government sanctions lists, including the OIG's list of excluded individuals/Entities (LEIE) and the General Services Administration's Excluded Parties Listing System?	Y / N	Y / N
	Are disciplinary standards established which describe disciplinary action (up to and including termination) for compliance-related violations?	Y / N	Y / N