



909 Assessing Your Risk for Compliance

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Faculty Biographies

Valli F. Baldassano

Valli F. Baldassano is the vice president of global compliance for Schering-Plough's global prescription business and global specialty operations, in Kenilworth, New Jersey. Ms. Baldassano is responsible for implementing Schering-Plough's global compliance program in all its commercial operations.

Ms. Baldassano has extensive experience in the design and implementation of compliance programs for multinational corporations. Ms. Baldassano joined Schering-Plough from Tyco International where she was brought in by new management as the chief compliance counsel, responsible for creating Tyco's compliance program. Previously, she served as senior director, global compliance for Pharmacia Corporation and senior counsel for compliance and fraud for Independence Blue Cross in Philadelphia. She spent eight years as an Assistant United States Attorney for the Criminal Division of the United States Attorney's Office for the Eastern District of Pennsylvania, where she prosecuted federal crimes relating to healthcare fraud, public corruption, insurance fraud, and serious narcotics trafficking.

Ms. Baldassano holds a B.A. from Georgetown University, Washington, DC and a J.D., magna cum laude, from Syracuse University College of Law.

Kathleen Chagnon

Kathleen Chagnon previously served as senior vice president, general counsel, corporate secretary and chief compliance officer of Constellation Energy Group, Inc., a Fortune 200 energy company, located in Baltimore. At Constellation, she was responsible for managing an 80 person legal department and overseeing all legal matters for the organization, including general corporate matters, commercial finance, securities compliance, acquisition and new venture activities, environmental and regulatory matters, litigation, and supervision of outside counsel. She also served as chief compliance officer and developed and implemented a compliance program to analyze, communicate, and manage compliance risk throughout the organization.

Prior to joining Constellation, Ms. Chagnon served as vice president, corporate general counsel of The St. Paul Companies, Inc. where she was responsible for the management of the corporate legal division, and as assistant vice president and associate general counsel at USF&G Corporation where she did general corporate and merger and acquisition work. Ms. Chagnon practiced law at Hogan & Hartson and O'Melveny & Myers prior to going in-house.

She currently serves on the board of trustees for the Baltimore Symphony Orchestra and is a member of the executive committee of the women's initiative of the Baltimore chapter of the United Way.

She graduated from Stanford University, with honors and earned her J.D. from Columbia University, with a concentration in international law.

Angeline G. Chen

Angeline G. Chen currently serves as associate general counsel at International Launch Services in McLean, Virginia. Ms. Chen is also an adjunct professor with George Mason University Law School, where she has taught a course in technology, terrorism, and national security law, and an executive-in-residence at the University of Maryland.

Prior to joining Lockheed Martin, Ms. Chen served as deputy associate general counsel for information security with the National Security Agency, and as assistant general counsel for INTELSAT. Her responsibilities at these entities included the provision of legal advice in a variety of substantive legal areas, including international, commercial, regulatory, compliance, policy, and risk management. Prior to going in-house, she spent several years in private practice specializing in complex litigation with a concentration in antitrust and securities, focusing on the technology sector.

Ms. Chen is an active member of a number of professional organizations, including the ABA, currently serving as chair of the aerospace and defense industries committee and as an editor on the air and space law forum's Air & Space Lawyer. She previously served a three-year appointment on the ABA standing committee on law and national security.

Ms. Chen holds a J.D. from Villanova University Law School, an LL.M in international and comparative law, with distinction, from Georgetown University Law Center, and an M.B.A., with highest honors, from the University of Maryland.

Managing Risk in Practice

Valli Baldassano
VP, Global Compliance

Identify

Assess

Brainstorm

Implement

Identify

- Increased focus on payments to healthcare professionals
 - U.S. Department of Justice
 - Office of Inspector General, HHS
 - PhRMA

Assess

- Policy Review
- Processes Review
- Interviews
- Data Analysis

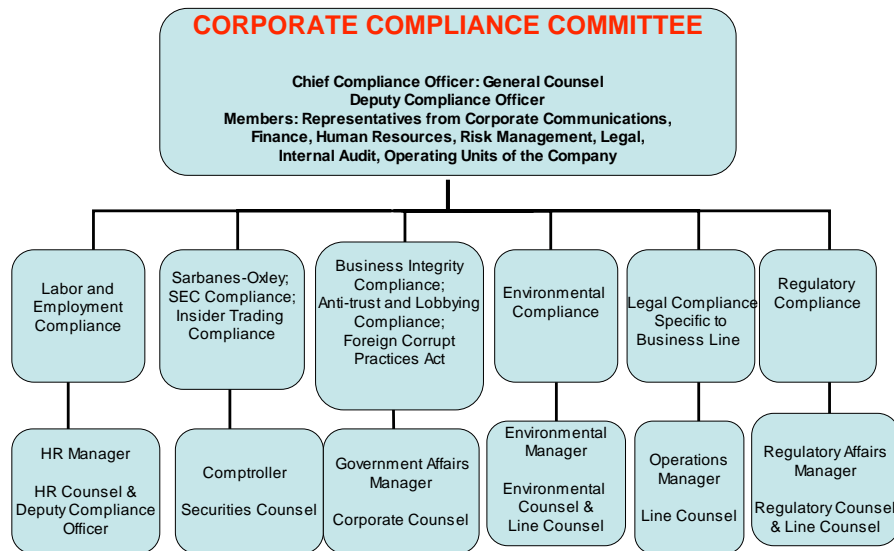
Brainstorm

- What is the Mercedes Benz solution?
 - what would the government expect?
- What can we realistically do?
 - cost
 - time to complete
 - resources
 - impact on productivity
 - culture

Implement

- Create a Buzz
 - business improvement first -- compliance tool a side benefit
- Senior Management buy-in
- Pilot
 - open to improvement
- Train
- Deliver
- Report on Successes

COMPLIANCE FUNCTION



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COMPLIANCE FUNCTION—MATRIXED MODEL

- Legal expertise is paired with operational experience to avoid staffing a large separate organization.
- This model has the benefit of leveraging existing resources and engaging the relevant lines or staff organizations in actively monitoring and managing compliance issues.
- It encourages greater accountability at the front line where decisions are frequently made.
- Each subcommittee is charged with identifying and prioritizing the compliance issues within its area of expertise.
- The subcommittee then develops a mitigation plan which is presented to the governing compliance committee, comprised of senior management within the organization.
- This structure responds to the Federal Sentencing Guidelines requirement that senior management assume accountability for compliance matters.
- Quarterly reports are provided to the Audit Committee.

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Compliance is Not an End in Itself

- Avoid exclusive focus on sentencing guidelines
- Translate into broader corporate objectives
 - E.g., Compliance reduces litigation risk and cost
- Processes should coordinate with organization processes and goals

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Compliance is Not an End in Itself

- Engaging broader buy-in enhances sustainability and reduces opposition
- Compliance may be one of the most cost effective means of reducing costs
- Compliance is anchored in proactive risk reduction in support of business goals

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KEYS TO SUCCESSFUL PROGRAM:

- Leverage organizational expertise
- Engage the line decision-makers
- Make them accountable
- Give them a stake in its success
- Track to business goals
- Be facilitator instead of cop



Session 909: Managing Your Risk for Compliance

Angeline G. Chen

Kathleen Chagnon

Valli Baldissano

ACC's 2005 Annual Meeting: Legal Underdog to Corporate Superhero—Using Compliance for a Competitive Advantage

October 17-19, Marriott
Wardman Park Hotel



**Legal Risk Assessment
and Management:
Methods and Considerations**
Angeline G. Chen

ACC's 2005 Annual Meeting: Legal Underdog to Corporate
Superhero—Using Compliance for a Competitive Advantage

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Wardman Park Hotel



What is risk?

- Uncertainty that surrounds actual and potential events and outcomes
- Likelihood that an event or omission will endanger or otherwise adversely impact an asset (*e.g.*, an individual, an entity, a structure or a function)
- Can be both known and unknown
- May or may not be in your company's or your control to influence or determine

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Underlying Elements

- What is the risk (and/or the threat)
- What interest are you trying to protect
- What is the criticality
- What/who are the potential events and/or actors
- What is or might be the trigger/what are their intentions
- What are the potential capabilities/consequences
- Where and what is the possible exposure
- Where and what is the relevant exposure
- What are your options to eliminate or mitigate that exposure



What is risk management?

- A systematic, analytical process to identifying and implementing the optimal course of action to address uncertainty, by identifying, assessing, understanding, acting on, communicating and responding to risks.
- What it is NOT: risk avoidance
- Using your legal skills as a risk management tool in advising on decision paths designed to eliminate/mitigate uncertainty in organizational and transactional interactions



A Risk Management Framework

- Risk Identification
- Risk Analysis
 - Qualitative
 - Quantitative
- Risk Response Planning
- Risk Monitoring and Control

Risk Identification

- Identifying the actual legal risks that might affect your organization and their characteristics
- Within the context of:
 - Your organization
 - Structure
 - Business
 - Strategy
 - Your industry
 - Applicable governmental jurisdictions
 - Applicable governmental authorities



Risk Analysis

- Qualitative
 - Prioritize impacts in terms of existing controls, likelihood of occurrence, severity of impact, precision with which risk is understood, intervention difficulty and risk level
- Quantitative
 - Estimating the probability of occurrence and severity of impact of risks in quantitative terms and estimating their implications for project objectives. Risks are evaluated and minor ones screened out.



Risk Response

- Development of procedures, methods, techniques and tools to respond to those risks that are identified as requiring elimination or mitigation
- Major risks:
 - Identify risk response options
 - Develop and implement detailed compliance program
 - Develop action and recovery plans for escapements
- Minor risks:
 - Identified and accepted
 - Monitored or not



Risk Monitoring and Control

- Monitoring of residual risks (after implementation of compliance program)
- Identification/analysis of new risks
- Execution of compliance program
- Evaluation of comprehensiveness and effectiveness of compliance program on an ongoing basis



Risk Monitoring and Control

- Recognition of criticality of implementation elements of any compliance program:
 - People
 - Procedures
 - Processes



Legal compliance risk arises from . . .

- An organization's failure to enact appropriate policies, procedures or controls to ensure that it conforms to laws, regulations, contractual arrangements, and other legally binding agreements, requirements and obligations.
- Choosing a no-conflict or "head in the sand" approach in aligning with business objectives

Consequences can be severe!

Commonly identified areas of legal risk

- Employee relations
- Securities
- Government Contracts
- Antitrust
- Lobbying
- Insider trading
- Regulatory/administrative
- Intellectual Property
- International business