PRACTICAL REFLECTIONS ON THE ROLES OF LEGAL AND COMPLIANCE

The relationship between Compliance and Legal varies across industries yet presents some common questions. Trends in healthcare may be indicative of future trends.

The program will address recent trends in the relationship between these functions, ethical and communication issues presented by the different functions and practical tips for forming effective working relationships.

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Disclaimer

• The views expressed by the presenters are their individual views and do not represent the views of their organization/company.
Summary

• Rise of the Compliance Function
• Trends in US Healthcare
• Contrary View: ABA/Model Rules of Professional Conduct
• Practical Considerations and Action Steps
Rise of the Compliance Function


• Seven factors from the Guidelines: establishment of standards and procedures; high level personnel involvement; careful delegation of discretionary authority; communication of standards and procedures to employees; monitoring, auditing and reporting systems; consistent enforcement; appropriate response to violations.

• Prior to the Sentencing Guidelines, many large companies already had ethics and compliance programs and codes of business conduct.
Rise of the Compliance Function

- Financial Services Companies were at the forefront in 1980s after regulatory action.

- Compliance Program Rules under Investment Advisers Act of 1940 and Investment Company Act of 1940.

- Impact of *Graham v. Allis-Chalmers* (Duty to Act when board becomes aware of wrongdoing), *In re Caremark* (Obligation not only to act in face of obvious signs of wrongdoing, but also to be informed and vigilant of wrongdoing), *Stone v. Ritter* (limiting *Caremark* by incorporating duty to monitor into duty of good faith and loyalty – board’s liability for failing to monitor is now conditioned upon proof of scienter, key element to finding lack of good faith).
Rise of the Compliance Function


• 2010 Amendments require direct reporting obligations to the board or board committee. §8C2.5(f)(C)(2010).
Rise of the Compliance Function

• 1994: 60% of companies had a code of ethics, 33% offered ethics training, 33% had an ethics officer.
• 2013: Nearly 100% for all three
• Ethics Officer Association – founded in 1991 shortly after the promulgation of the Organizational Sentencing Guidelines, with 19 members;
  • 2001: 720 Members
  • 2013: now called the Ethics and Compliance Officer Association, more than 3000 members
  • (For comparison, ACC had 2400 members at founding in 1982, 30,000+ members in 2013)
Rise of the Compliance Function

- High level of variation in titles, reporting structures
- Highly dependent upon size of company, level of regulatory exposure
- Most Fortune 500 have “Chief Compliance Officer” (CCO) and most report to CEO and Board of Directors
- Some report to General Counsel (GC)
- Some are the GC or an in-house lawyer
- Smaller number report to Chief Financial Officer (CFO)
Rise of the Compliance Function

- 2006 Corporate Executive Board (CEB) Survey
  - Majority (54%) of compliance functions in legal department
  - More mature compliance functions (10 years plus) predominately reside outside of the legal department (68%)

- 2010 CEB Survey
  - Across industries, percentage is identical (54%) to 2006 but regulatory environment drives location of compliance function
  - 71% of biotech/pharmaceutical companies have “independent” compliance functions

- 2012 CEB Survey
  - Increase in CEO reporting for CCO from 23% in 2008 to 36% in 2012
  - CEO reporting common in pharmaceutical industry (69% of surveyed companies (PWC/Arnold & Porter 2011 Survey)))
Trends in U.S. Healthcare

• “Freestanding compliance functions help to ensure independent and objective legal reviews and financial analyses of the institution’s compliance efforts….By separating the compliance function from the key management positions of the general counsel or chief financial officer…a system of checks and balances is established…” (OIG Compliance Program Guidance for Hospitals (1998))

• “The lawyers tell you whether you can do something, and compliance tells you whether you should . . . upper management should hear both arguments.” (former OIG Chief Counsel Lew Morris (2009))

• “[N]either Tenet nor (its General Counsel) saw any conflict in her wearing two hats as Tenet’s General Counsel and Chief Compliance Officer….It doesn’t take a pig farmer from Iowa to smell the stench of conflict in that arrangement” (Sen. Charles Grassley (2003))
Trends in U.S. Healthcare

- OIG Corporate Integrity Agreements (CIAs) typically mandate that the CCO reports to the CEO and is not subordinate to the GC or CFO

- Recent CIAs focused on management and Board accountability through annual certifications and resolutions
  - Criminal prosecution theories against executives under the Responsible Corporate Officer and Park Doctrines
  - Public statements on expended use of OIG’s exclusion authority

- Recent CIAs and criminal plea agreements (GSK) mandate Business Unit Compliance Officers are on each management team
Contrary View

• ABA Task Force on Corporate Responsibility (2003)
  • “The [G]eneral [C]ounsel should have primary responsibility for assuring the implementation of an effective legal compliance system under the oversight of the board of directors.”

• Ben Heineman (Don’t Divorce the GC and Compliance Officer, HLS Program on Corporate Governance, December 2010)
  • “It is ludicrous to suggest, as some do, that the GC only worries about what is “legal” and the chief compliance officer worries about what is “right.” The “what-is-right” set of issues is at the center of the role of the modern, broad gauged general counsel as wise counselor and leader.”
  • Favors CCO reporting to GC and CFO to deal with the process of compliance
Model Rules of Professional Conduct

• PREAMBLE: A LAWYER'S RESPONSIBILITIES
  • [2] As a representative of clients, a lawyer performs various functions. As advisor, a lawyer provides a client with an informed understanding of the client's legal rights and obligations and explains their practical implications. As advocate, a lawyer zealously asserts the client's position under the rules of the adversary system. As negotiator, a lawyer seeks a result advantageous to the client but consistent with requirements of honest dealings with others. As an evaluator, a lawyer acts by examining a client's legal affairs and reporting about them to the client or to others.

• Counselor
  Rule 2.1 Advisor
  • In representing a client, a lawyer shall exercise independent professional judgment and render candid advice. In rendering advice, a lawyer may refer not only to law but to other considerations such as moral, economic, social and political factors, that may be relevant to the client's situation.
Practical Considerations – Views From the Inside

• Relationship between GC and CCO
• Privileged Communications
• Communicating Roles to the Business
• Special considerations when an in-house lawyer also has a formal compliance role
• Internal Investigations – roles, responsibilities
• When other functions (Finance, Audit, H.R.) have a compliance role
Considerations and Action Steps

• Where the GC/CCO positions are held by the same position:
  • Review this practice in view of recent developments and regulatory pronouncements relevant to applicable industry

• Where the positions are separated:
  • Clarify the job descriptions for the two positions
  • Establish appropriate executive and board reporting relationships
  • Establish a peer based relationship founded on mutual respect/trust
  • Create an effective communication to the business on the roles
  • Clear communication protocols on certain issues (such as privilege/investigations)
Presenters

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In his role, Mr. Smollen reports to Endo’s Chief Executive Officer and is responsible for the strategic direction and operations of Endo’s corporate compliance program. Mr. Smollen previously was Vice President and Chief Compliance Officer for Siemens Healthcare USA. Prior to Siemens, Mr. Smollen held a number of legal and business leadership positions at Wyeth including Vice President, Commercial Excellence, Chief Privacy Officer and Senior Division Counsel.

Prior to Wyeth, Mr. Smollen was an Attorney Advisor to Federal Trade Commissioner Thomas B. Leary and was an associate with Squire, Sanders & Dempsey in Washington, D.C. He also served as a federal judicial clerk. He holds a B.A. from Georgetown University, an M.A. in International Relations from Columbia University and a J.D. from the University of Virginia School of Law.
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John C. Ryan is a partner in Duane Morris' Trial Practice Group. Mr. Ryan represents organizations and individuals in government investigations and related litigation, conducts internal corporate investigations, defends *qui tam* actions and commercial disputes and advises organizations on regulatory matters. Mr. Ryan has conducted complex internal investigations and defended companies in government investigations around the globe and he has particular experience defending government investigations involving the U.S. Foreign Corrupt Practices Act and allegations of government contracting fraud. Mr. Ryan has also successfully defended companies in high-stakes commercial litigation, including contractual disputes, consumer class actions and antitrust cases. Mr. Ryan also has experience designing and implementing compliance programs for multinational companies and evaluating and reducing compliance risks in multinational transactions, with particular experience in FCPA due diligence.

Mr. Ryan began his association with Duane Morris in 1999, joining the firm after serving as an Assistant District Attorney in the Investigations Division of the Manhattan District Attorney's Office. From 2005-2013, he served first as Senior Vice President and Associate General Counsel, and ultimately as Deputy General Counsel, of ARAMARK Corporation, where he established the company's Litigation and Government Investigations Function, and served as chief counsel for ARAMARK's Healthcare, Education, Sports & Entertainment and Business & Industry business lines. Mr. Ryan also served as counsel for ARAMARK's Chief Compliance Officer and led ARAMARK's government relations efforts. Mr. Ryan returned to Duane Morris in 2013 with deep experience in helping business leaders to deliver cost-effective results and to achieve business objectives.