

Compliance vs. the Law Department: How to Work Together

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Working Towards What?

- **Embedding compliance into Company DNA**
- **Helping employees to base decisions on internal values, not external rules**
- **Transforming Company culture, not just creating new policies and procedures**
- **Taking these broad principles and applying them to the work of two specific departments -- Compliance and Law**

Compliance vs. Law Department

- **If the two departments are not working together, what result?**
 - Business often plays one off the other in order to divide and conquer
 - Lawyers become policemen without training or expertise in compliance functions
 - Business doesn't take ownership of their own issues, resulting in a rules-based versus a values-based organization

Compliance vs. Law?

- **Working together, what result?**
 - Law function supports compliance efforts
 - Law interpretations develop into compliance implementation
 - Compliance interfaces with business operations in ways that not only implement legal guidance, but also in ways that ultimately improve business processes
 - Values-based versus rules-based organization can evolve

Organizational Structure

- **How Compliance fits within organizational structure often drives ultimate ability to effectively collaborate with Law**
 - Compliance Organization within Law Department
 - Compliance Organization within Finance Department
 - Compliance Organization Reports Directly to CEO or Board of Directors

Compliance Program Guidance for Pharmaceutical Manufacturers

The OIG believes it is generally not advisable for the compliance function to be subordinate to the pharmaceutical manufacturer's general counsel, or comptroller or similar financial officer.

Separating the compliance function from the key management positions of general counsel or chief financial officer, establishes a system of checks and balances that more effectively achieve the goals of the compliance program.

*See Office of Inspector General
April 2003*

Report Directly to CEO

- **Presentation assumes Compliance Organization reports directly to CEO or Board of Directors**
- **Alternative Considerations:**
 - Does structure subsume compliance function to other priorities within the Company?
 - Does tension exist between business goals and compliance goals?
 - Does structure end up promoting rules-based culture rather than values-based culture?

Compliance Program Development

- **Does the Law Department have any role in developing a Compliance Program?**
- **Compliance Department drives process, but both bring needed expertise to the table**
 - Compliance guides and advises business operations to develop policies and procedures specific to business operations
 - Law reviews documents based on core legal principles
 - Balanced approach between hyper-vigilant legal analysis versus ability to stay competitive within the marketplace
- **Law and Compliance work together as agents for change within organization**

Process Improvement

- **Building compliance into a Company's DNA means building compliance upstream in all Company processes**
- **Involving business in improving Company processes allows Compliance and Law to become trusted business partners, not just enforcement officers**

Process Improvement Example

- **Law and Compliance partner to improve Grant and Charitable Contributions process**
 - PhRMA Code recommends removal of grants from sales and marketing
 - Law department evaluated current processes and recommended change
 - Compliance implemented process change to remove sales force from equation
 - Process improved by requiring qualified medical and scientific review of grants
 - Charitable contribution process centralized to create holistic approach to company giving

Process Improvement Result

- **Sales reps able to concentrate on product education and promotion, not administrative details of grants and charitable contributions**
- **Allows physician interaction for specialty products like oncology to be spent on issues of ultimate value to patient health**
- **Prevents inappropriate linking of clinical decisions to financial decisions**

Guidance and Advice

- **Partner with business by early involvement of Compliance and Law in analysis of upcoming events and programs**
- **Provide parameters and underlying principles business can use to ultimately make business decision regarding events and programs**
- **Early involvement may also stop fatally flawed concepts from ever getting off the ground**
- **Cross-functional collaboration with business, Law and Compliance is more likely to result in initiatives that are both competitive within the marketplace and consistent with compliance objectives**

Investigations

- **Privilege Investigations**

- Different process altogether, not addressed here

- **Non-privilege Investigations**

- Compliance receives information from hot-line, monitoring activity or from another investigation
- Compliance seeks Law involvement to determine whether violation involves legal issues and/or policy and procedure issues
- Law seeks Compliance involvement to resolve issues discovered through interaction with business

Investigation Completion

- **Completion of investigation may result in corrective action**
 - May involve Law department
 - process improvement (changes to contract templates)
 - labor law issues regarding employee disciplinary actions
- **Before deciding on corrective action, always ask: did the individual break the policy, or was policy broken to begin with?**
- **Learning from investigations is an example of continuous improvement**

Risk Assessment

- **Law assesses legal risk**
 - Advises business and Compliance
- **Compliance assesses CIA, public relations and regulatory risk perceptions**
 - Even if not a violation of law, what is possible perception created by this activity?
- **Issues are rarely black and white; require team approach to risk assessment**
- **Compliance becomes a part of company DNA**

Conclusion

