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**LOOKING AT FLOWERS FROM A GALLOPING HORSE:
 DESIGNING A DYNAMIC ETHICS AND COMPLIANCE PROGRAM
 An Annotated Outline**

[NOTE: Boldface numbers in brackets refer to references listed at the end of this outline.]

I. INTRODUCTION

A. Objectives

- (1) Discuss program design from the points of view of both large companies and small companies
- (2) Discuss integration of the ethics and compliance components of the program, through the concept of “organizational integrity”
- (3) Highlight certain recent legislative/regulatory developments relevant to design of the program

B. Outline

- (1) Program design – Internal controls
- (2) Program design – External relationships
- (3) Other initiatives that intersect/overlap the ethics and compliance program

II. PROGRAM DESIGN – INTERNAL CONTROLS

A. Design – General Framework – Historical Development

- (1) Defense Industry Initiative on Business Ethics and Conduct – Six principles [21]
- (2) Organizational Sentencing Guidelines
 - (a) Seven elements [24]
 - (b) Review by USSC Advisory Group [23]
- (3) OIG Draft Guidance – Seven elements summarized [2]

B. Design – Key Drivers

- (1) Organization
 - (a) Leadership
 - (i) The Business Roundtable, Statement on Restoring Investor Trust: “Those of us who have the privilege to be leaders of corporate America have a special responsibility to our investors, employees

- and the public. We are responsible for setting the ethical standards under which our companies operate, and for creating and maintaining a corporate culture driven by always doing what is right, not just what is legally allowable.” [19]
- (ii) OIG Draft Guidance, I: “In order for a compliance program to be effective, it must have the support and commitment of senior management and the company’s governing body.” [2]
- (b) Size and resources (see Part II.C below)
- (c) Structure
- (2) Ethical framework
- (a) Judge Diana E. Murphy [22]
- (i) “Is ethics part of effectiveness?”
- (ii) “It is questionable whether a compliance program can be truly effective if it does not have an ethics component.”
- (b) Preliminary Report of the American Bar Association Task Force on Corporate Responsibility: “At the very least, ‘corporate responsibility’ should be understood to include behavior by the executive officers and directors of the corporation that conforms to law and results from the proper exercise of the fiduciary duties of care and loyalty to the corporation and its shareholders. In the Task Force’s view, moreover, the term ‘corporate responsibility’ also embraces ethical behavior beyond that demanded by minimum legal requirements” (pp. 4-5). [11]
- (c) USSC Advisory Group: In its August 21, 2002 request for additional public comment, the Advisory Group raised the following questions: Should the Organizational Sentencing Guidelines “encourage organizations to foster ethical cultures to ensure compliance with the intent of regulatory schemes as opposed to technical compliance that can potentially circumvent the purpose of the law or regulation? If so, how would an organization’s performance in this regard be measured or evaluated? How would that be incorporated into the structure of Chapter Eight?” [23]
- (d) Professor Lynn Paine: Is there an “emerging set of ‘generally accepted ethical principles’ for business”?
- (3) Operations
- (a) Location(s) – How widely dispersed are your employees?
- (b) Key operating systems
- (c) Use of contract workers and agents
- (4) Risk assessment
- (a) Nature of the business (see Organizational Sentencing Guidelines, §8A1.2, comment 3(k)(7)(ii)) [24]

- (b) Prior history of the organization (see Organizational Sentencing Guidelines, §8A1.2, comment 3(k)(7)(iii)) [24]
- (5) Industry practice
- (a) Organizational Sentencing Guidelines, §8A1.2, comment 3(k)(7)(iii): “An organization’s failure to incorporate and follow applicable industry practice...weighs against a finding of an effective program to prevent and detect violations of law.” [24]
- (b) What can we learn from the practices of other industries (for example, the Defense Industry Initiative on Business Ethics and Conduct [“DII”])? [21]
- (i) Six principles of self-governance
- (ii) Principle 5: “Each company has a responsibility to each of the other companies in the industry to live by standards of conduct that preserve the integrity of the defense industry.”
- Annual “best practices” forums
 - Information clearinghouse
- (iii) Principle 6: “Each company must have public accountability for its commitment to these principles.”
- Annual questionnaire
- (6) “Audit-ability” – Elements of the design must be auditable
- (7) The desire for metrics – Ways to measure and demonstrate the success of the ethics and compliance program
- DII: “Finding a broadly accepted metrics solution remains elusive, principally because of the challenge of proving a negative (avoidance of sanctions and penalties because of a good ethics program).” [21]
- C. Design – Small Company versus Large Company
- (1) Organizational Sentencing Guidelines – Degree of “formality” of the program (§8A1.2, comment 3(k)(7)(i)) [24]
- (a) “[T]he larger the organization, the more formal the program typically should be”.
- (b) “A larger organization generally should have established written policies defining the standards and procedures to be followed by its employees and other agents.”
- (2) USSC Advisory Group – In its August 21, 2002 request for additional public comment, the Advisory Group specifically raised the question whether the Organizational Sentencing Guidelines can “better address any unique concerns and obstacles faced by small and medium-sized organizations? What size organization requires unique/special treatment (e.g., 50 employees, 200, 1000, 5000)?” [23]

- (3) OIG Draft Guidance – Examples of differences between program for small company and program for large company [2]
- (a) Recognition of difference – “Some pharmaceutical manufacturers are small and may have limited resources to devote to compliance measures. Conversely, other companies are well-established, large multi-national corporations with a widely dispersed work force.” [I.B]
 - (b) Importance of leadership for all companies – “The OIG recognizes that full implementation of all elements may not be immediately feasible for all pharmaceutical manufacturers. However, as a first step, a good faith and meaningful commitment on the part of the company’s management will substantially contribute to the program’s successful implementation.” [II.A]
 - (c) Compliance officer’s responsibilities – Compliance responsibility as sole duty versus added to other management responsibilities, “depending upon the size and resources of the company and the complexity of the task” [II.C.1]
 - (d) Compliance committee – “[S]mall companies or those with limited budgets...may not have the resources or the need to establish a compliance committee” [II.C.2]
 - (e) Education and training – “[T]he format of the training program will vary depending upon the size and resources of the pharmaceutical manufacturer. For example, a company with limited resources or whose sales force is widely dispersed may want to create a videotape or computer-based program for each type of training session....” [II.D]
 - (f) Lines of communication – “[P]rotecting anonymity may be infeasible for small companies”. [II.E.2]

D. Design – Organizational Integrity – Integration of Ethics and Compliance
[6] [7] [8]

- (1) Organizational integrity
 - (a) The importance of personal integrity
 - (b) Integrity of the organization as a whole, based on an ethical framework that defines purpose, values and responsibility
- (2) Ethical decision-making – Responsibility to purpose, principles and people
 - (a) Does the proposed decision contribute to the purpose for which the organization exists?
 - (b) Is the proposed decision consistent with the organization’s values and ethical standards, and with applicable legal requirements?
 - (c) What is the impact of the proposed decision on people (stakeholders)? Who benefits? Who is harmed?

- (3) Integrating the ethical framework into the key operating systems of the organization (for example, the performance evaluation and reward system)
 - (4) Translating the framework into a pragmatic checklist for responsible decision making – The four dimensions of “organizational integrity”
 - (a) Individual – Conscience; newspaper test
 - (b) Company – Organizational purpose, values and ethical standards
 - (c) Law – Applicable laws and regulations
 - (d) Stakeholders – All of the organization’s constituencies
 - (5) Making “organizational integrity” visible
- E. Design – Components
- (1) Structure
 - (2) Documentation
 - (3) Processes
- F. Design – Structure
- (1) Periodic reporting to board of directors (or board committee)
 - (2) Compliance committee
 - (3) Compliance officer
 - (4) Compliance officer’s funding, resources and staff
 - (5) Divisional compliance liaisons (see OIG Draft Guidance, II.C.1, footnote 8) [2]
 - (6) Compliance risk auditing manager
 - (7) Employee background checking manager
 - (8) Others
 - (9) Ethics and compliance – One department or separate departments?
- G. Design – Documentation
- (1) Written standards of conduct
 - (a) Ethical framework
 - (b) Code(s) of conduct
 - (i) OIG Draft Guidance, II.B.1 – “[A] general corporate statement of ethical and compliance principles...the fundamental principles, values, and framework for action...brief, easily readable....” [2]
 - (ii) NYSE Corporate Governance Rule Proposals, Subsections 9 and 10 – Listed companies must adopt and disclose a code of business conduct and ethics for directors, officers and employees [16]
 - Objectives of code: “[F]ocus the board and management on areas of ethical risk, provide guidance to personnel to help them recognize and deal with ethical issues, provide mechanisms to report unethical conduct, and help to foster a culture of

- honesty and accountability”
 - Code “must require that any waiver of the code for executive officers or directors may be made only by the board or a board committee and must be promptly disclosed to shareholders”
 - Code “must also contain compliance standards and procedures that will facilitate the effective operation of the code”
 - Code “should address the most important topics”, including certain specified topics: conflicts of interest; corporate opportunities; confidentiality; fair dealing; protection and proper use of company assets; compliance with laws, rules and regulations (including insider trading laws); and encouraging the reporting of any illegal or unethical behavior
 - Code must be set forth on the company’s website
 - Code will be required within six months from SEC approval of the proposed governance rules
- (iii) NASDAQ Corporate Governance Proposals [16]
- Code of conduct addressing, at a minimum, conflicts of interests and compliance with with applicable laws, rules and regulations
 - Appropriate compliance mechanism
 - Disclosure of any waivers to executive officers and directors; waivers can only be granted by the independent directors
 - Code must be publicly available
- (iv) AMEX Proposed Enhanced Corporate Governance Rules [16]
- Each Amex-listed company must adopt and disclose a code of ethics and compliance program
- (v) Sarbanes-Oxley Act, Section 406 – Code of ethics for senior financial officers [13]
- SEC Release No. 33-8138 (October 22, 2002) – Proposed rules implementing Section 406, extending the scope of the code of ethics to include the principal executive officer as well as senior financial officers, and broadening the definition of “code of ethics” in terms of the standards to be codified: honest and ethical conduct;

- conflicts of interest; disclosure; compliance with laws, rules and regulations; internal reporting of violations of the code; and accountability for adherence to the code
- Immediate disclosure required of any change in or waiver of the code; under the proposed regulations, this would include “an implicit waiver due to inaction on the part of the company with respect to a reported or known violation of a code provision”
 - The proposed regulations require a company to file a copy of its ethics code as an exhibit to its annual report
 - See Financial Executives International – Proposed “Code of Ethical Conduct for Financial Managers” [5]
- (vi) Certification (in writing or electronic)
- (2) Written policies, procedures and protocols
- (a) Addressing structure
- (i) Charter of compliance committee
 - (ii) Position description of compliance officer (see OIG Draft Guidance, II.C.1) [2]
 - (iii) Workplan of compliance officer’s staff
 - (iv) Others
- (b) Addressing documentation – A policy on policies
- (c) Addressing processes
- (d) Addressing specific potential risk areas
- (i) Organizational Sentencing Guidelines, §8A1.2, comment 3(k)(7)(iii): “An organization’s failure to incorporate and follow...the standards called for by any applicable governmental regulation weighs against a finding of an effective program to prevent and detect violations of law.” [24]
 - (ii) Federal health care program requirements, including requirements relating to the calculation and reporting of pricing and rebate information, and requirements relating to sales and marketing practices [2]
 - (iii) Use and tracking of drug samples [2]
 - (iv) PhRMA Code on Interaction with Healthcare Professionals [9] [2]
 - (v) PhRMA Principles on Conduct of Clinical Trials and Communication of Clinical Trial Results [10]
 - (vi) Data privacy

- (vii) Sarbanes-Oxley Act, Section 402 – Prohibition of personal loans to directors and executive officers [13]
 - (viii) Others
 - (3) Periodic review and updating of documentation
 - (4) Records retention policy and procedures
- H. Design – Processes
- (1) Evaluating the performance of employees on the basis of adherence to the ethics and compliance program
 - (2) Education and training
 - (a) Curriculum design
 - (i) General training versus specific training
 - (ii) Initial training versus subsequent re-training
 - (iii) Identification of target audiences
 - (iv) Messages, media and metrics
 - (b) In-person training versus eLearning
 - (c) Certification (in writing or electronic) and tracking
 - (d) Publications
 - (3) Lines of communication
 - (a) Hotline/helpline/ethics line
 - (b) Sarbanes-Oxley Act, Section 301 – Public company audit committees – Complaints
 - “Each audit committee shall establish procedures for –
 - (A) the receipt, retention, and treatment of complaints received by the issuer regarding accounting, internal accounting controls, or auditing matters; and
 - (B) the confidential, anonymous submission by employees of the issuer of concerns regarding questionable accounting or auditing matters.” [13]
 - (c) Non-retaliation policy
 - (d) Publicity
 - (e) Database
 - (f) Other lines of communication (for example, exit interviews)
 - (4) Internal monitoring and auditing
 - (a) OIG Draft Guidance: Prospective systemic review of processes, protocols and practices, or retrospective review of actual practices in a particular area [II.F] [2]
 - (b) Baseline compliance assessment
 - (c) Auditing the ethics and compliance program
 - (5) Background checking of employees and contract workers; exclusion/debarment [2]
 - (6) Consistent enforcement through well-publicized disciplinary mechanisms

- (7) Internal investigations and corrective actions; procedures instituted to prevent recurrence; reporting; government-negotiated integrity agreements [12]
- (8) Benchmarking
- (9) Sharing of best practices across the organization

III. **PROGRAM DESIGN – EXTERNAL RELATIONSHIPS**

A. Organizations

- (1) Pharmaceutical Compliance Forum
- (2) Ethics Officer Association [4]
- (3) Health Care Compliance Association
- (4) Conference Board
 - (a) Annual Business Ethics Conference
 - (b) Global Council on Business Conduct
 - (c) Commission on Public Trust and Private Enterprise [20]
- (5) Better Business Bureau
- (6) Others

B. Universities/Colleges

- (1) Bentley College Center for Business Ethics
- (2) DePaul University Institute for Business and Professional Ethics
- (3) Others

C. Publications

- (1) Business Ethics Magazine
- (2) Others

IV. **OTHER INITIATIVES THAT INTERSECT/OVERLAP THE ETHICS AND COMPLIANCE PROGRAM**

A. Corporate Governance

- (1) NYSE Corporate Governance Rule Proposals [16]
 - (a) Requirement for code of business conduct and ethics (see Part II.G(1)(b)(ii) above)
 - (b) Audit committee’s written charter must address, among other things, assisting board oversight of the company’s compliance with legal and regulatory requirements; the audit committee should review with the full board any issues that arise with respect to the company’s compliance with legal or regulatory requirements, among other things (subsection 7(b))
- (2) The Business Roundtable, Principles of Corporate Governance: “Effective corporate governance requires a proactive, focused state of mind on the part of directors, the CEO and senior management, all of whom must be committed to business success through maintenance of the highest standards of responsibility and ethics. Good corporate governance is far more than a ‘check-the-box’ list of minimum board and management policies and duties. Even the most thoughtful and well-drafted policies and procedures are destined to fail if directors and management are not committed to enforcing them in practice. A good corporate governance

structure is a working system for principled goal-setting, effective decision-making, and appropriate monitoring of compliance and performance” (pp. 1-2). [18]

- (3) Standard & Poor’s Governance Services – Corporate Governance Scores; Transparency and Disclosure Rankings [17]
- B. Sustainability, Corporate Social Responsibility, Global Corporate Citizenship
- C. Ethics Officer Association – Proposal to Develop ISO Business Conduct Management System Guidelines Standard [4]

References

- [1] A special thanks to Bill Giffin of the Ethical Leadership Group (Wilmette, Illinois).
- [2] Department of Health and Human Services – Office of Inspector General (“OIG”) – Draft Compliance Program Guidance for Pharmaceutical Manufacturers, 67 Fed. Reg. 62057 (October 3, 2002) (*available at* <http://www.oig.hhs.gov/fraud/docs/complianceguidance/draftcpgpharm09272002.pdf>). (“OIG Draft Guidance”)
- [3] Department of Justice, “Federal Prosecution of Corporations” (June 16, 1999) (*available at* <http://www.usdoj.gov/criminal/fraud/policy/Chargingcorps.html>).
- [4] Ethics Officer Association, “Business Conduct Management System Standard Project” (*available at* <http://www.eoa.org/BCMS/bcms.html>).
- [5] Financial Executives International, “Code of Ethical Conduct for Financial Managers” (*available at* <http://www.fei.org/download/CoEmodel.doc>).
- [6] Lynn Sharp Paine, “Managing for Organizational Integrity”, *Harv. Bus. Rev.* 106 (Mar-Apr 1994).
- [7] Lynn Sharp Paine, Cases in Leadership, Ethics, and Organizational Integrity: A Strategic Perspective (1997).
- [8] Lynn Sharp Paine, Value Shift: Why Companies Must Merge Social and Financial Imperatives to Achieve Superior Performance (2003).
- [9] Pharmaceutical Research and Manufacturers of America, PhRMA Code on Interactions with Healthcare Professionals (effective July 1, 2002) (*available at* <http://www.phrma.org>).
- [10] Pharmaceutical Research and Manufacturers of America, PhRMA Principles on Conduct of Clinical Trials and Communication of Clinical Trial Results (effective for clinical trials begun after October 1, 2002) (*available at* <http://www.phrma.org>).
- [11] Preliminary Report of the American Bar Association Task Force on Corporate Responsibility (July 16, 2002) (*available at* <http://www.abanet.org/buslaw/corporateresponsibility>).
- [12] Robert J. Gareis, “The Implementation and Strategies of Internal Corporate Investigations and Effective Compliance Programs”, published in Legal Audits & Investigations (Business Laws, Inc., September 2002). Mr. Gareis is Senior Counsel with Baker & McKenzie, Chicago, Illinois.

[13] Sarbanes-Oxley Act of 2002, Pub. L. 107-204, 116 Stat. 745 (*available at* <http://www.access.gpo.gov/nara/publaw/107publ.html>). Only certain provisions of the Act are cited in this outline. The Act contains numerous other provisions relevant to the implementation and enforcement of the ethics and compliance program.

[14] Securities and Exchange Commission, Release No. 33-8138, “Disclosure Required by Sections 404, 406 and 407 of the Sarbanes-Oxley Act of 2002” (October 22, 2002) (*available at* <http://www.sec.gov/rules/proposed/33-8138.htm>).

[15] Securities and Exchange Commission, Securities Exchange Act of 1934 Release No. 44969, “Report of Investigation Pursuant to Section 21(a) of the Securities Exchange Act of 1934 and Commission Statement on the Relationship of Cooperation to Agency Enforcement Decisions” (October 23, 2001) (*available at* <http://www.sec.gov/litigation/investreport/34-44969.htm>).

[16] Securities Exchanges – Corporate Governance Proposals

- New York Stock Exchange: Corporate Governance Rule Proposals submitted by the NYSE to the Securities and Exchange Commission for review and approval on August 16, 2002 (*available at* <http://www.nyse.com>).
- NASDAQ: NASDAQ Corporate Governance Proposals (October 1, 2002) (*available at* <http://www.nasdaq.com>).
- American Stock Exchange: Exchange Release – “American Stock Exchange Board Approves Enhanced Corporate Governance Rules & Remits to SEC for Review and Approval” (September 13, 2002) (*available at* <http://www.amex.com>).

[17] Standard & Poor’s Governance Services (*see* <http://www.governance.standardandpoors.com>). S&P “has developed both a scoring process to aid companies and boards examine internal corporate governance controls; and a ranking process that uses publicly available information to assess company transparency and disclosure practices”.

[18] The Business Roundtable, Principles of Corporate Governance (May 2002) (*available at* <http://www.brtable.org/pdf/704.pdf>).

[19] The Business Roundtable, Statement on Restoring Investor Trust (July 8, 2002) (*available at* <http://www.brt.org/press.cfm/728>).

[20] The Conference Board Commission on Public Trust and Private Enterprise (*see* <http://www.conference-board.org>). This high-profile Commission is examining compensation, auditing and governance issues as they relate to publicly held corporations. It will issue a series of best-practices guidelines.

[21] The Defense Industry Initiative on Business Ethics and Conduct, 2001 Annual Report to the Public and the Defense Industry (*available at* http://www.dii.org/annual/2001/annual_report2001.DOC).

[22] The Honorable Diana E. Murphy, “The Federal Sentencing Guidelines for Organizations: A Decade of Promoting Compliance and Ethics”, 87 Iowa L. Rev. 697 (2002).

[23] United States Sentencing Commission – Ad Hoc Advisory Group on Organizational Sentencing Guidelines (*see* <http://www.ussc.gov/corp/advgrp.htm>). This Advisory Group was formed in February 2002, and will serve for eighteen months. It was established to review the general effectiveness of the Organizational Sentencing Guidelines, with primary focus on the application of the criteria for an effective compliance program, as listed in comment 3(k) to §8A1.2. The Advisory Group has solicited public comments, which are available on its website. In its August 21, 2002 request for additional public comment, it set forth a list of key questions, several of which are referred to in this outline. The Advisory Group has scheduled a public hearing on November 14, 2002. (“USSC Advisory Group”).

[24] United States Sentencing Commission, 2001 Federal Sentencing Guideline Manual – Sentencing of Organizations (*available at* <http://www.ussc.gov/2001guid/tabconchapt8.htm>). (“Organizational Sentencing Guidelines”).