HOW THE ORGANIZATIONAL SENTENCING GUIDELINES AFFECT COMPLIANCE AND ETHICS PROGRAMS

FIFTH ANNUAL PHARMACEUTICAL REGULATORY AND COMPLIANCE CONGRESS
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JOHN R. STEER
COMMISSIONER AND VICE CHAIR
UNITED STATES SENTENCING COMMISSION
“CARROT AND STICK”
Operation of the Criminal Penalty Structure

- Encourage partnership in crime control
- Reward self-policing, self-reporting, and voluntary disclosure
FINE RANGE §§8C2.7; 8A1.1 n.2

Seriousness of the Offense \times Culpability = Fine Range

BASE FINE

MULTIPLIERS
Minimum
Maximum

Environment, Export, Food/Drug Violations

Exception
DETERMINING CULPABILITY SCORE

§8C2.5

- **BASE OFFENSE LEVEL** 5 POINTS
- Level of Authority + 5/+4/+3
- Size of Organization + 2 or + 1
- Prior History + 2 or + 1
- Violation of an Order + 2 or + 1
- Obstruction of Justice + 3
- Effective Program to Prevent and Detect Violations of Law - 3
- Self-Reporting, Cooperation and Acceptance of Responsibility - 5/ - 2
- Acceptance of Responsibility - 1
INCENTIVE STRUCTURE:
WHAT’S IT WORTH?

$40,000,000
$10,000,000
$500,000
GENESIS OF 2004 AMENDMENTS

- Decade of compliance and business ethics practice
  - Caremark case and corporate governance
  - Expanded field of practitioners

- Legislative and regulatory responses to corporate scandals
  - Sarbanes-Oxley Act, SEC, NYSE

- Recommendations of Ad Hoc Advisory Group
OVERVIEW OF CHANGES

- Stand-alone Guideline for “Compliance and Ethics Program”
- Promote ethical conduct & organizational culture of compliance
- Seven minimum steps expanded
- Small organizations addressed
- Assessing risks of criminal conduct made explicit
- Cooperation credit not contingent on privilege waiver
§8B2.1(a) CRITERIA FOR EFFECTIVE PROGRAM

- Exercise due diligence in fulfilling seven minimum requirements at §8B2.1(b)(2)

- Promote ethical conduct and organizational culture that encourages a commitment to compliance with the law
§8B2.1(b)(1)
STANDARDS AND PROCEDURES

- “[E]stablish standards and procedures to prevent and detect criminal conduct”

- “[S]tandards and procedures” = “standards of conduct and internal controls that are reasonably capable of reducing the likelihood of criminal conduct”
  - See Application Note 1
§8B2.1(b)(2)
PROGRAM RESPONSIBILITY

- **Governing Authority**
  - Must be knowledgeable and exercise oversight

- **High-Level Personnel**
  - Overall responsibility to ensure effectiveness of program
  - Senior Management or equivalent
    - See Application Note 3(b) §8A1.2

- **Operational Responsibility**
  - Adequate resources and appropriate authority
  - Periodic reporting
  - May be delegated by high-level personnel but then direct access to governing authority required
Screen Substantial Authority Personnel
- See Application Note 3(c) of §8A1.2 for SAR Definition

Applicable Screening Standard
- “[O]rganization knew or should have known [individual] had engaged in illegal activities or other conduct inconsistent with an effective . . . program”

Application Note 4: Factors for Screening
- Relatedness of prior misconduct to specific responsibilities
- Recency of prior misconduct
- Frequency
§8B2.1(b)(4) TRAINING

- Training Now a Requirement
  - Training in standards and procedures for compliance

- Extends to All Levels of Organization
  - Directors and senior management
  - Employees
  - Agents, as appropriate
§8B2.1(b)(5)(A)(B): EVALUATION, MONITORING, AUDITING

- Ensure program is followed
  - By monitoring and auditing
  - To detect criminal conduct

- Periodically evaluate program effectiveness
§8B2.1(b)(5)(C)
REPORTING SYSTEMS

- Maintain and publicize a reporting system
  - To be used by employees and agents
  - To report potential or actual criminal conduct
  - To seek guidance on potential conduct

- Reporting systems may include
  - Mechanisms for anonymity or confidentiality or
  - Any other system organization may devise to meet goal
§8B2.1(b)(6): PROMOTE PROGRAM

- Appropriate Incentives
- Appropriate Disciplinary Measures

§8B2.1(b)(7): APPROPRIATE RESPONSE TO DETECTED VIOLATIONS
§8B2.1(c): ASSESSING RISK OF CRIMINAL CONDUCT

- **Explicit new requirement**
  - Design, implement, or modify application of seven requirements within organization to reduce risk of occurrence of criminal conduct

- **Guidance in Application Note 6**
  - Nature and seriousness of conduct
  - Prior history of organization
  - Likelihood of violations given nature of business
FOCUS ON SMALL ORGANIZATIONS

- Modified requirements for smaller organizations
  - Application Note 2(C)(iii)

- Suggests large organizations encourage small organizations to promote ethics and compliance programs, especially with potential and actual vendors
  - Application Note 2(C)(ii)

- Establishes a rebuttable presumption if high-level involvement in offense
  - See §8C2.5(f)(3)(A)
WAIVER OF PRIVILEGES

Addition to Commentary to §8C2.5(f); See Note 12

“Waiver of [privileges] is not generally required in order to qualify for credit for cooperation”

But there may be times when necessary “in order to provide timely and thorough disclosure of all information known to the organization”