

HOW THE ORGANIZATIONAL SENTENCING GUIDELINES AFFECT COMPLIANCE AND ETHICS PROGRAMS

FIFTH ANNUAL PHARMACEUTICAL

REGULATORY AND COMPLIANCE CONGRESS

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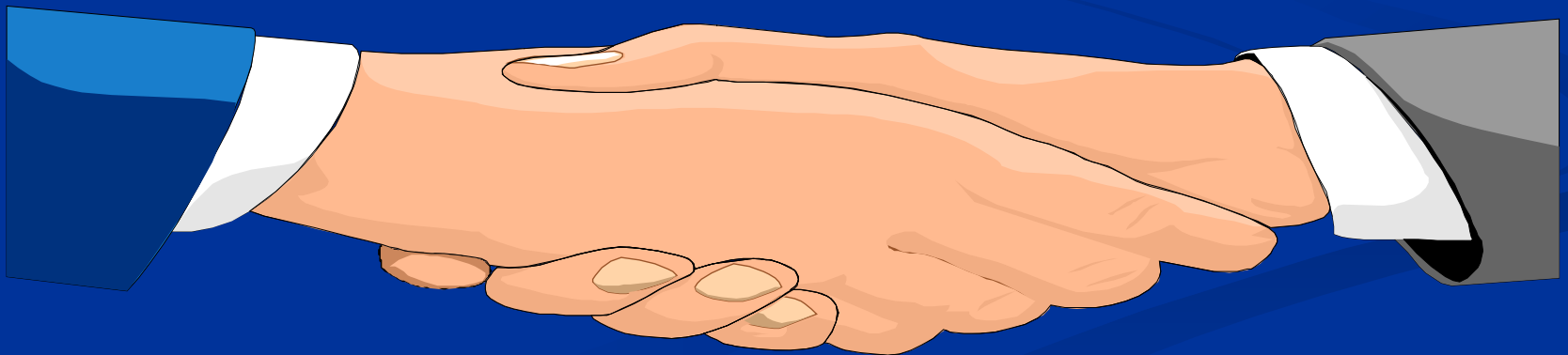
COMMISSIONER AND VICE CHAIR

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

X

Culpability

=

Fine
Range

BASE
FINE

MULTIPLIERS

Minimum

Maximum

Exception

Environmental, Export,
Food/Drug Violations

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 <u>and</u> Acceptance of Responsibility | - 5/ - 2
- 1 |

INCENTIVE STRUCTURE: WHAT'S IT WORTH?



0

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
 - See October 7, 2003, Report at <http://www.ussc.gov/corp/advgrprpt/advgrprpt.htm>

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

§8B2.1(b)(3) PERSONNEL SCREENING

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”**

UNITED STATES SENTENCING COMMISSION

