


# *The Future Of Compliance*



*Taking a Look at  
the Past, The  
Present &  
The Future  
of Compliance*



# *The Past, The Present & The Future*

*Michael B. Mayes, Esq.*  
*Head of Ethics & Compliance, International Operations*  
*Astellas Pharmaceuticals*

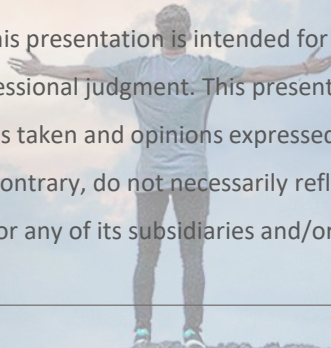
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## ***Disclaimer***

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I am a paid employee of Astellas. This presentation is intended for informational purposes only and does not replace independent professional judgment. This presentation is not intended to be legal advice. Statements of fact, positions taken and opinions expressed are those of myself individually and, unless expressly stated to the contrary, do not necessarily reflect the opinion or position of my employer, Astellas, or any of its subsidiaries and/or related entities.

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**FUTURE**

**PRESENT**

**PAST**



# HISTORY

1970s



## Vietnam War – Defense Scandals

- FCPA (1977)

1980s



## Recession & Downsizing

- 1<sup>st</sup> Business Ethics Office ('85) – (Gen. Dynamics)

1990s



## Globalization

- Birth of Modern Ethics Departments

2000s



## Market Boom & Bust

- Sarbanes-Oxley Act of 2002

2010s



## Bank Collapses & Occupy Wall Street

- Regulation expands (Privacy, Transparency, Etc.)

# LOOKING BACK: A Brief History of Compliance Program Guidance

Compliance Guidance Springing from the US  
Attempt to Deter Corporate Wrongdoing.

## US Sentencing Reform Act

Passed in 1984  
to bring  
uniformity to  
federal  
sentencing.

1984

## FSGO

Gives credit for  
effective  
compliance  
programs as a  
means of  
detering  
corporate  
wrongdoing.

1991 –  
Present

## OECD Good Practice Guidance

Follows the  
FSGO  
Guidance

2010

## FCPA Resource Guide

Follows the  
FSGO  
guidance and  
provides  
specific  
examples for  
high-risk  
areas.

2012

## OECD Handbook

Continues to  
build on the  
FSGO  
Guidance.

2013

**\*In addition, authorities in a number of key antitrust jurisdictions provide guidance - often very detailed - on how companies can drive antitrust compliance.**

# LET'S START WHERE IT ALL BEGAN...

FSGO: Designed to *deter* – provides significant leniency for companies with *effective compliance programs*.



## §8B2.1. Effective Compliance and Ethics Program

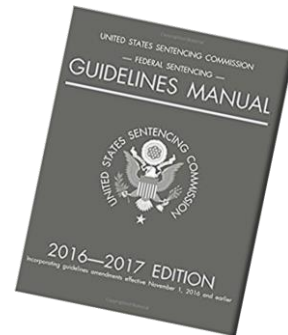
- (a) To have an effective compliance and ethics program ..., an organization shall—
- (1) exercise due diligence to **prevent and detect criminal conduct**; and
  - (2) otherwise promote an **organizational culture** that encourages ethical conduct and a commitment to compliance with the law.

Such compliance and ethics program shall be reasonably designed, implemented, and enforced so that the program is generally effective in preventing and detecting criminal conduct. The failure to prevent or detect the instant offense does not necessarily mean that the program is not generally effective in preventing and detecting criminal conduct.

# THE ELEMENTS OF AN EFFECTIVE PROGRAM

The Guidelines identify the following *minimal* components of an *effective* compliance program:

- **Standards and Procedures** to prevent and detect criminal conduct
- **Management Oversight**
  - BODs is adequately informed of the compliance program and exercises reasonable oversight of it
  - Senior Management responsibility for compliance (e.g., CCO)
- **Empowered Compliance Function**
  - Specific individuals with day-to-day responsibility for compliance that have direct access to the board, adequate resources and appropriate authority.
- **Communication & Training**
- **Pre-screening Management Employees**
  - Reasonable efforts to screen-out personnel that have engaged in illegal activities or other misconduct from management positions.
- **Monitoring & Auditing**
- **System to Report Compliance Concerns**
- **Prompt Response and Remediation of Issues**
- **Fair Enforcement of Compliance Standards**
  - Appropriate incentives and discipline for employees
- **Periodic Risk Assessments & Evaluation of Program Effectiveness**



**SOUND FAMILIAR?**

## **– OIG’S “7 ELEMENTS”**

### **FSGOS STANDARDS**

**Prompt Response &  
Remediation**

**Monitoring &  
Auditing**

**Fair Enforcement, incl.  
appropriate discipline**

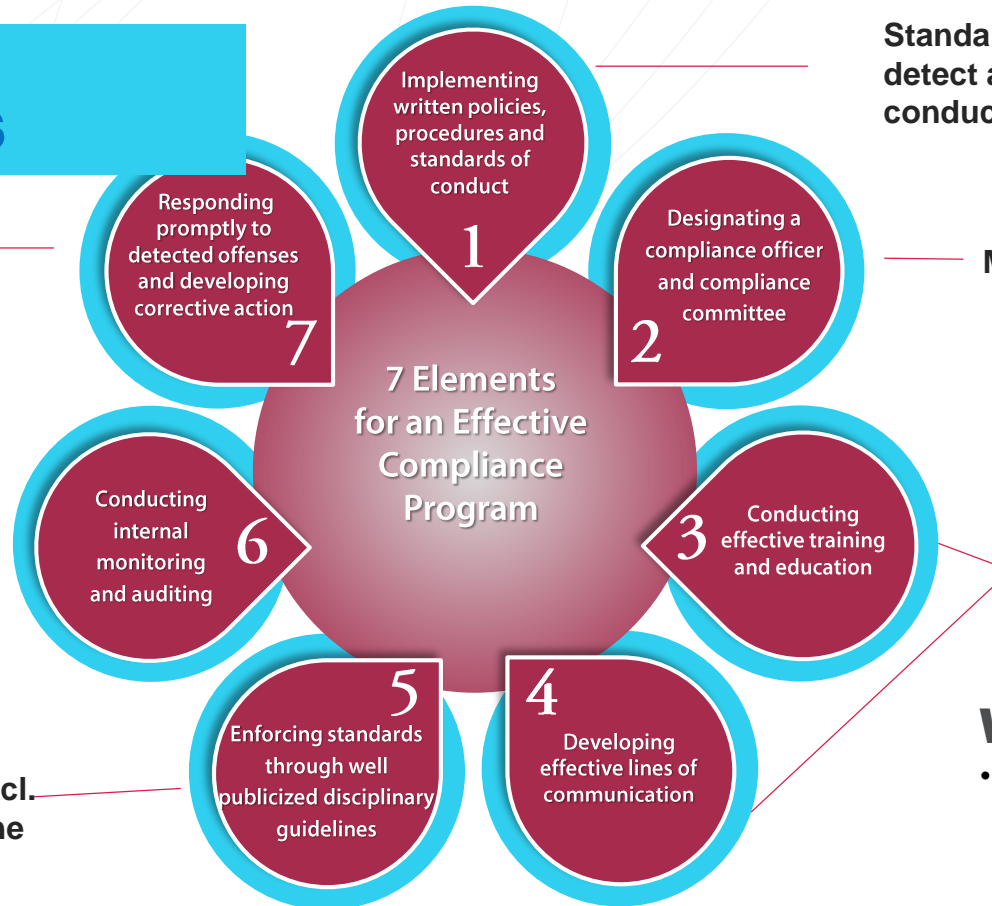
**Standards & Procedures to  
detect and prevent criminal  
conduct**

**Management Oversight**

**Training & Communication;  
Compliance Hotlines**

### **WHAT’S MISSING?**

- **Pre-screening Management**







now

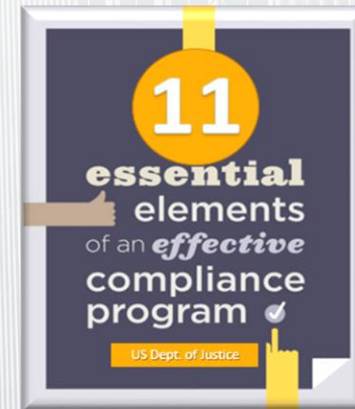
tomorrow

yesterday

## | OVERVIEW | DOJ GUIDANCE

1. Root Cause Analysis & Remediation
2. Senior and Middle Management
3. Autonomy and Resources
4. Policies and Procedures
5. Risk Assessment
6. Training and Communications


The Guidance's **11 Sections** contain a series of **119 Questions** the DOJ may ask Corporations attempting to negotiate a settlement.



7. Confidential Reporting and Investigation
8. Incentives and Disciplinary Measures
9. Continuous Improvement, Periodic Testing and Review
10. Third Party Management
11. Mergers & Acquisitions



# *The Future Of Compliance*



*Predictions for:*

- ✓ *Emerging Risks*
- ✓ *Compliance Officers*
- ✓ *Compliance Programs*
- ✓ *Our Profession*




# The Future of Risk

## One Compliance Officer's View of Emerging Risks We Face:

- 1. Global Revolt Against Corruption**  
*(e.g. Brazil, Mexico, Colombia, China, Russia, India, Ukraine, Malaysia)*
- 2. Changing Landscape of Healthcare Access Decision-Makers**
- 3. The Movement for Value-Based Pricing**
- 4. Desire for Increased Interactions with Patients**
- 5. The Effects of Global Transparency**  
*(Social Pressure to Decrease Dollars to Doctors)*
- 6. The Impact of Increased Social Activism (#metoo)**  
*(Increased Whistleblowing)*
- 7. The Impact of Digitization**  
*(e.g., Social Media, Digital Health, Big Data, RWI, Data Privacy)*





A person stands on the peak of a dark, craggy rock formation. Their arms are outstretched horizontally, and they are looking out over a vast landscape under a dramatic sky. The sky is filled with large, billowing clouds in shades of blue, grey, and white, with a hint of orange and red near the horizon, suggesting a sunrise or sunset. The overall mood is one of achievement, freedom, and looking towards the future.

# *The Future for Compliance Officers*

1. Valued Member of “Top” Management
2. Viewed as Strategic Advisors
3. Easily Demonstrates Strategic Value of Compliance
4. Separated from, but Close Partners with, Legal
5. Transforming the Effectiveness of Compliance Programs
6. Known for Attracting & Developing Skilled Teams



# *The Future for Compliance Programs*

1. Globalized & Streamlined Compliance Programs
2. Forward-Looking (Predictive & Preventive)
3. Generally Accepted Compliance Standards
4. Focus on Building Ethical Cultures
5. Shift to Business Ownership
6. Greater Focus on High Risk Areas:
  - ✓ Pricing / Discounting
  - ✓ Supply Chain Management
  - ✓ Third Parties
7. Better Incentives & Rewards for Compliance
8. Technology & Analytics
9. Personalized Compliance Training
10. KPIs for Effectiveness



# *The Future of Our Profession*

*E&C*

1. Better Education & Training Programs for Compliance Professionals
2. Better Compliance Resource Materials
3. International Exposure & Expertise
4. Required Business Rotations Through Compliance
5. Career Paths for Compliance Professionals
6. Compliance as a Leading Profession





*Thank  
You!*

