

Acting on Our Values

Building an Ethics & Compliance Program



Presented by ■ Steve Vincze
TAP Ethics & Compliance Officer

Food For Thought

“Wisdom comes only through suffering.”

Aeschylus,, Agamemnon, 458 B.C.

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More Food For Thought

“There are only two forces that unite men – fear and interest.”

Napoleon Bonaparte

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Partnership Principles Produce Positive Results

E&C Team



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Remember Who Your Audiences Are

- Internal
 - Board
 - Executive Management
 - Functional Areas
 - Senior Management
 - Mid-Level Management
 - Employees
 - Stakeholders

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Remember Who Your Audiences Are

- External
 - Government
 - HHS
 - **OIG**
 - **FDA**
 - DOJ
 - Congress
 - Media
 - Public

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CREDIBILITY
Is The Key To Effectiveness!



TAP's CIA

- Signed on Sept. 28, 2001
- 7-year Duration
- Requires:
 - ✓ Compliance Program Review by IRO
 - ✓ Average Sale Price (ASP) Reports (Attachment A)
 - ✓ Review of ASP and Best Price by IRO (Attachment B)
 - ✓ Sales & Marketing Systems & Documentation Review by IRO (Attachment C)



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Apply the “KISS” Rule & Stay Focused

Review the Basics

- ✓ **What** Is an Ethics & Compliance Program?
- ✓ **Why** We Need an Ethics & Compliance Program
- ✓ **How** an Ethics & Compliance Program Can Improve Our Organization



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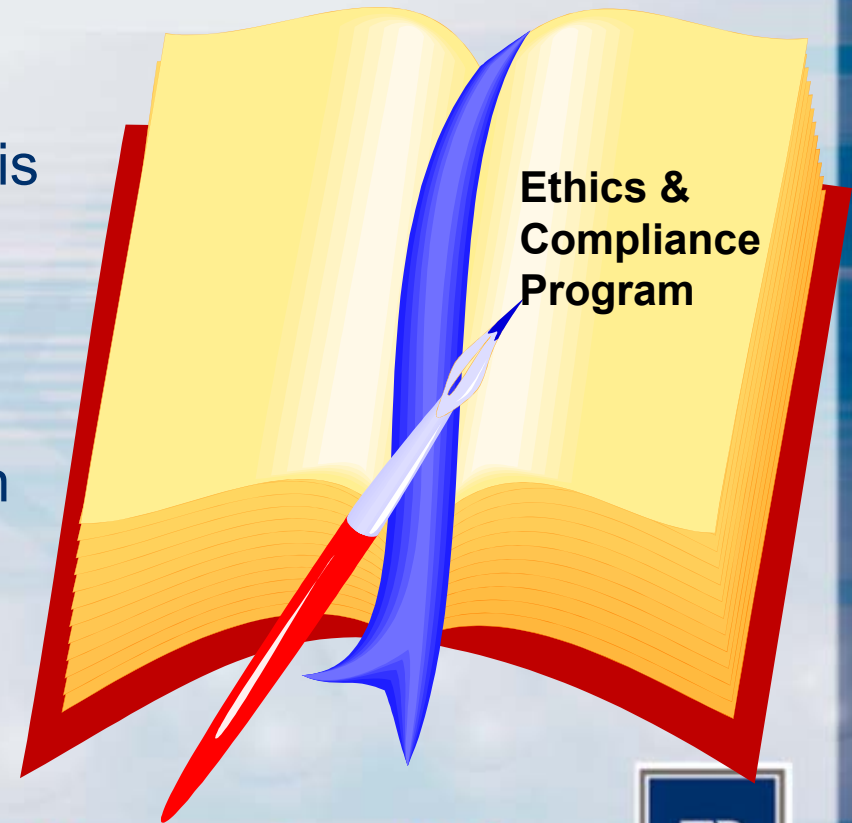


What Is an Ethics & Compliance Program?

The Process of Ethics & Compliance

An ethics & compliance program is a centralized **process** to detect, correct and prevent illegal or improper conduct* **AND** to promote honest, ethical behavior in the day-to-day operations of an organization.

* U.S. Sentencing Commission



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U. S. Sentencing Commission Guidelines for “Effective” Compliance

- (1) Establish Compliance Standards & Policies
- (2) Assign Senior Management Oversight
- (3) Use “Due Care” When Assigning Responsibility To An Employee (i.e., screen employees for past offenses)
- (4) Conduct Effective Training & Communications
- (5) Establish Reporting & Monitoring Mechanisms
- (6) Enforce Standards & Discipline Violators
- (7) Respond to Violations to Prevent Future Offenses



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Basic Steps to Implement an Ethics & Compliance Program -- “ADIM”

- (1) Assess Compliance Risks
- (2) Develop Basic Elements
- (3) Implement Program
- (4) Measure Effectiveness



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TAP's Ethics & Compliance Program:

E&C Team

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- Compliance Program in place for a number of years with improvements/enhancements added over time
- E.g., Compliance Officer, Compliance Committee, Hotline, Code Training
- Incorporates *“The Spirit of TAP”* and *“Connected to Care”*



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Scope of Our Ethics & Compliance Program

- Scope: Holistic, *NOT limited* to Sales & Marketing issues only.
 - Should implement the results of a “head-to-toe corporate physical”



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Core Benefits

- ***Liability Protection***
- ***Quality Enhancement***
- ***Public/Patient Trust***
- ***Competitive Advantage***



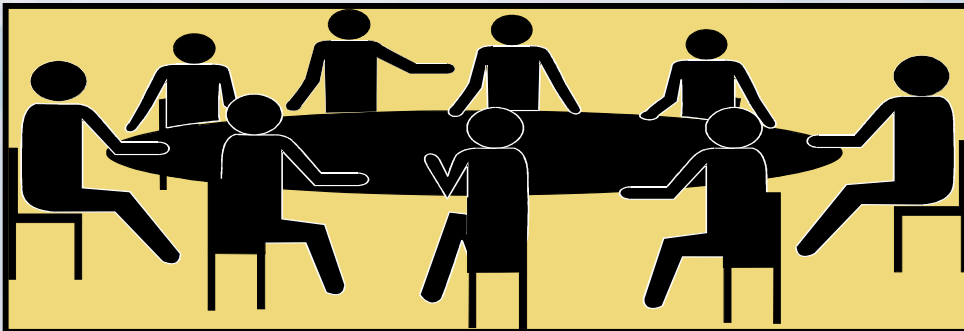
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The Human Element of Effective Ethics & Compliance

Requires:

- Senior Leadership
- Open Communications
- Teamwork



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Organizing an Ethics & Compliance Program

E&C Team

■ Starts at the TOP:

- Board of Directors
- President
- Management
- Employees

■ Leadership By Example:

- Walk-the-walk
- Vigorous, visible & vocal
- **THE #1 KEY TO SUCCESS**

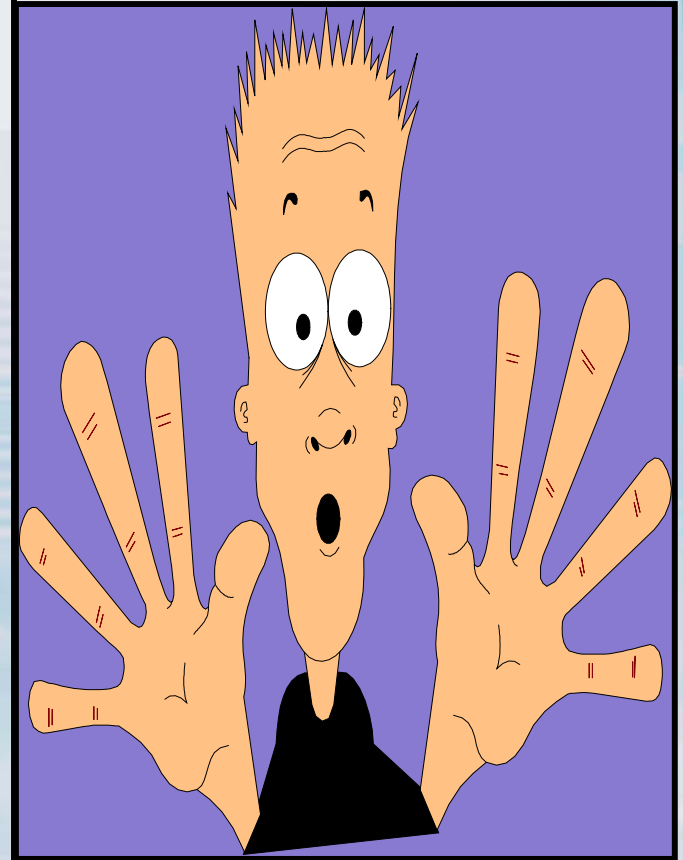


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Role of Ethics & Compliance Officer

- Focal point for Ethics & Compliance Program
- Establishes accountability, credibility and structure
- Independent, well-respected senior manager who reports to the President and has direct access to the Board of Directors
- Oversees design, implementation of compliance standards, training, auditing/monitoring, reporting and corrective action
- Coordinates closely with other functional areas in the organization, e.g., Legal, HR, Quality Assurance, Sales & Marketing, R&D, Finance, etc..



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Role of Legal Counsel

- Advise on pharmaceutical legal and corporate governance issues
- Review compliance risk areas
- Review compliance implementation
- Retain credible consulting advice, as needed
- Participate on Compliance Committee



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Role of Senior Management

- Vigorous, Visible & Vocal Support
“Leadership by Example”
- Define ethics & compliance as --
“How we do business!”
- Create a *“Culture of Ethics & Compliance”*
without fear of retaliation



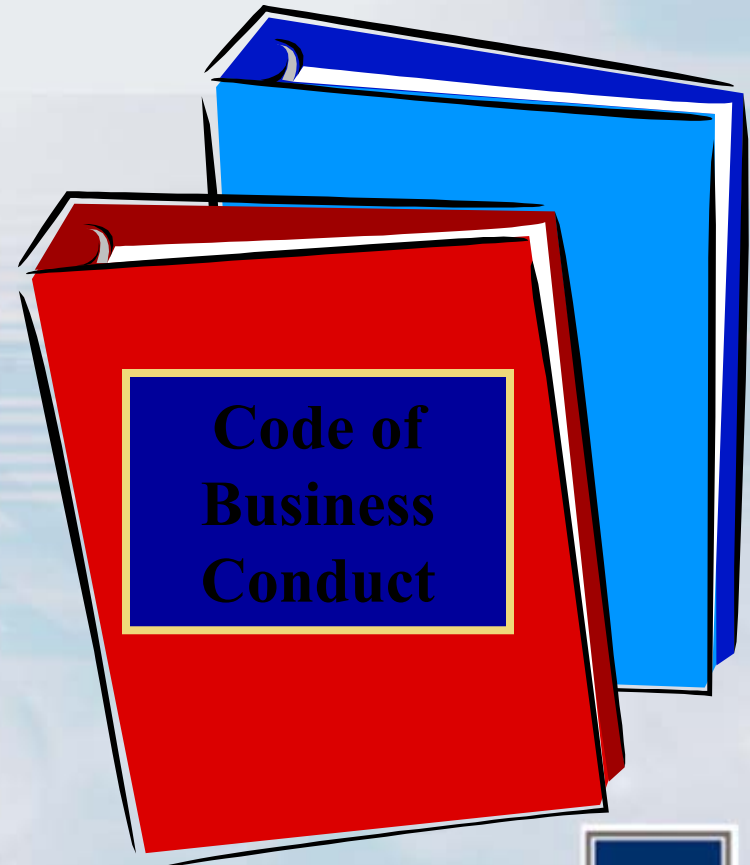
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Code of Conduct, Policies & Procedures

- Establish Standards, Policies & Procedures:

- “Central Component”
- “...focus first on risk areas most likely to arise...”
 - e.g., Sales, Marketing, FDA, etc...
- Review and amend Code of Business Conduct and Operational Guidelines as needed
- Code functions “Like a constitution...”



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Ethics & Compliance Training:



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Ethics & Compliance Training

■ Conduct Training & Education:

“...important part of any compliance program...”

■ Ethics & Compliance Training

■ Two Goals:

- ✓ all employees receive training on how to perform job in compliance with stds & reg's.
- ✓ each employee will understand that compliance is a condition of employment

■ “...at least annual(ly)”



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Ethics & Compliance Training

■ Two Types of Training:

■ **General** (“Basic”):

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- Introduction to Ethics & Compliance Program Framework
 - Code of Business Conduct
 - Operational Guidelines
 - Control Documents
 - Reporting Mechanisms

- All employees annually

■ **Targeted Technical**, e.g.,

- Sales & Marketing
- R&D, Q/A, etc.
- Select employees regularly

■ Need Both



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- Disciplinary Action should be:
 - ***Taken*** when violations substantiated
 - ***Proportional*** to offense
 - ***Consistent*** with policies
 - ***Documented***
- Lack of appropriate disciplinary action can destroy the credibility and effectiveness of an ethics & compliance program.

INVESTIGATE



ENFORCE

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Measuring Ethics & Compliance Effectiveness



- “An on-going evaluation process is critical to a successful compliance program.”
 - OIG Compliance
Guidances

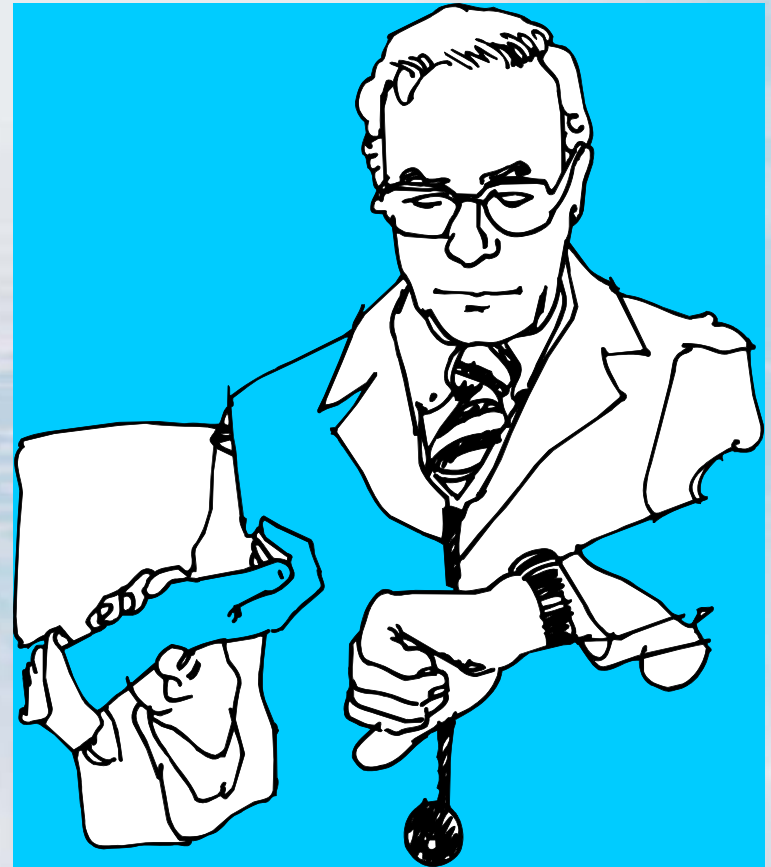
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Measuring Ethics & Compliance Effectiveness

■ “An effective compliance program should also incorporate ***periodic (at a minimum, annual) reviews*** of whether the program’s compliance elements have been satisfied...” -- **OIG**
Guidances

- Dissemination of Program’s Standards
- Training
- Ongoing education
- Disciplinary actions
- Others (Employee survey, etc.)



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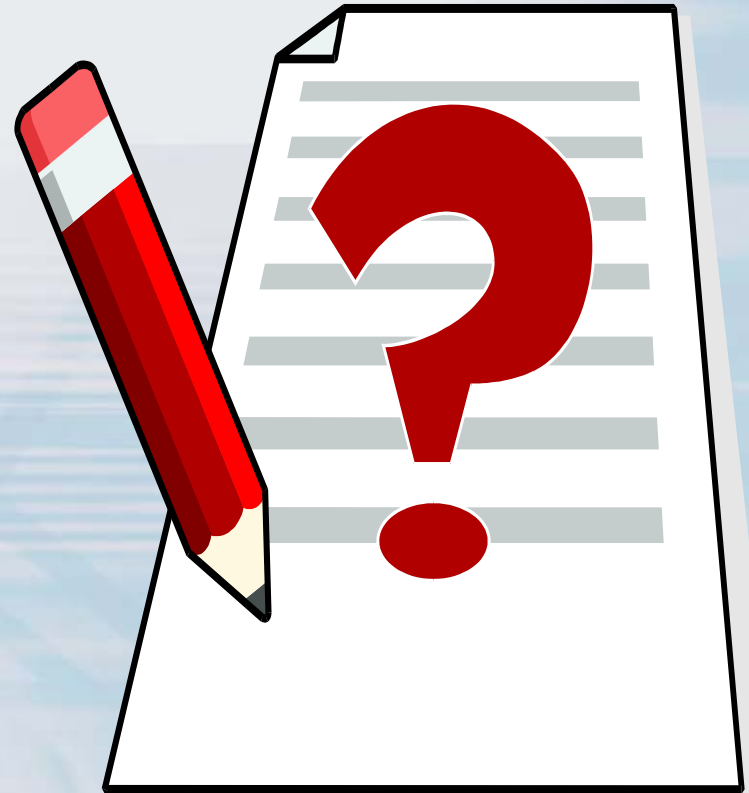


Measuring Ethics & Compliance Program Effectiveness

E&C Team

■ Employee Survey:

- Focus on Understanding and Awareness of Compliance Program elements.
- Take benchmark early in process
- Take follow-up 12-18 months later.
- Should show a difference -- evidence of impact and measurable change -- i.e., effectiveness



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**How Ethics & Compliance
Can Improve Our Organization**



Good Compliance Is Good Business!

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CREDIBILITY
Is The Key To Effectiveness!



Knowledge = Credibility

- ✓ Know Your Organization
- ✓ Know the Meaning of "Effective" Compliance
 - Legal Standard --
 "due diligent steps"
 - Technical Issues
 - Government Expectations
 - Operational Benefits



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Positive Communications

- Define Ethics & Compliance *Positively* as “a way of doing business that *adds value.*”

✓ **Ethics & Compliance =
*Precision + Accuracy =***

- Better Information/Documentation
- Better Decision-Making
- Higher Quality/More Efficient Operations
- More Competitive Position
- Lower Risk of Violations



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Positive Communications

- Counters **Negative** Perceptions that Ethics & Compliance =
 - Added Costs
 - Administrative Burdens
 - Imposed Rules and Regulations
 - Negative Impact on Business
 - “A pain in the ...”



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Effective Ethics & Compliance Results

Increases:

- Precision and Accuracy of Documentation
- Quality of Decision Making and Operational Efficiency
- Employee Competence, Morale, Loyalty and Productivity
- Customer/Public Trust Satisfaction & Security

Reduces:

- Inaccuracies Leading to Mistakes or Poor Decisions
- Risk of Government Investigations
- Risk of Whistleblower or Other Suits
- Employee/Customer Dissatisfaction & Turnover

\$\$ Revenue/QUALITY \$\$

\$\$ Costs/FINES \$\$

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What's Ahead?

- Empirical Measurement Using Technology
- Accountability
- More, more, more....



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What's Ahead?

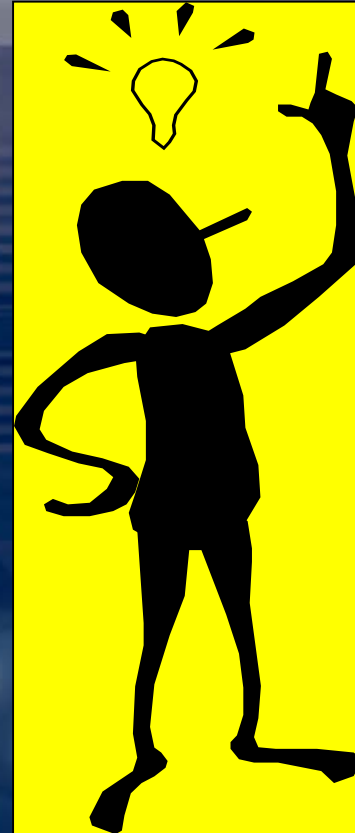
- A Theme of Partnership and Common Purpose Between Public & Private Sectors



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Food For Thought

“With regard to excellence, it is not enough to know, but we must try to have and use it.”

Aristotle, *Nichomachean Ethics*, circa 340 B.C.

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Have Fun!



Thank You!

Contact Information

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