

Surviving Under a CIA: TAP's Experience After Year One



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Overview



- Key Concepts
- Know Your Audience
- Reduce the Fear Factor
- Apply the “KISS Rule”
- Cover the Basics
- Roles & Leadership
- Make Compliance Fun & Effective
- Final Thoughts



Food For Thought



“Wisdom comes only through suffering.”

Aeschylus, Agamemnon, 458 B.C.

More Food For Thought



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

Napoleon Bonaparte

CREDIBILITY **Is The Key To Effectiveness!**



Partnership Principles Produce Positive Results



Remember Who Your Audiences Are



● Internal

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

Remember Who Your Audiences Are



● External

■ Government

– HHS

– OIG

» IRO

– FDA

– CMS

– DOJ

– Congress

■ Media

■ Public

Corporate Integrity Agreements (CIA)



- ✓ Agreement between the Office of Inspector General (OIG) of the U.S. Department of Health & Human Services (HHS) and an Organization
- ✓ Requires a Compliance Program that meets U. S. Sentencing Commission Requirements
- ✓ May require an Independent Review Organization (IRO) to review Compliance Program and to test compliance with federal standards through annual statistically valid random samplings
- ✓ Generally 5-7 years in length
- ✓ Does NOT exclude organization from Medicare or Medicaid participation



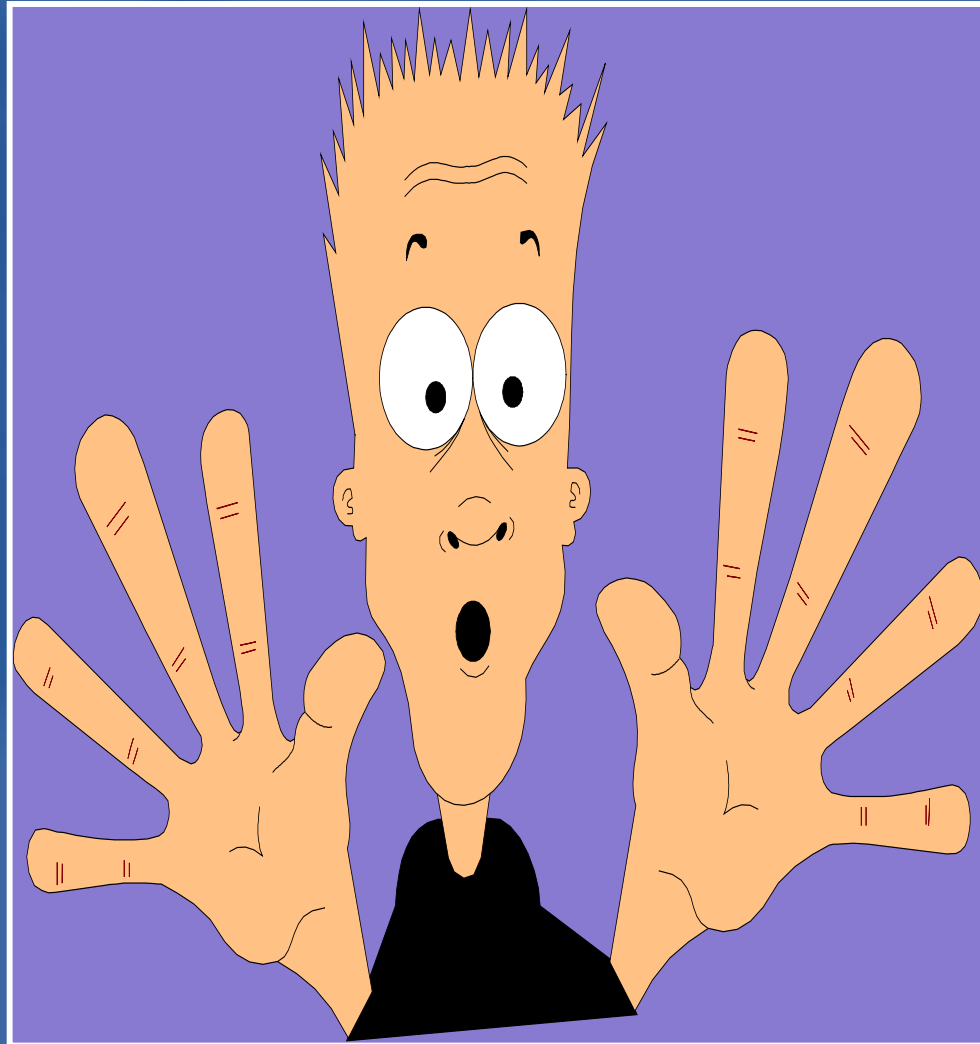
TAP's CIA



- 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)



Reduce the Fear Factor



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



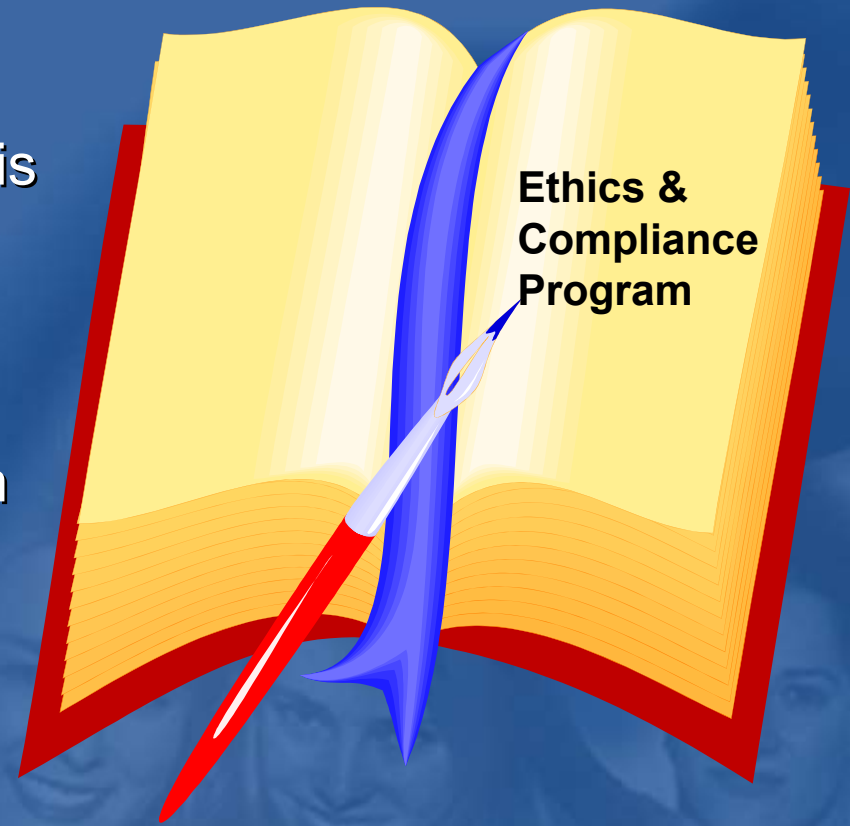
What Is an Ethics & Compliance Program?



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



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



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



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



TAP's Ethics & Compliance Program



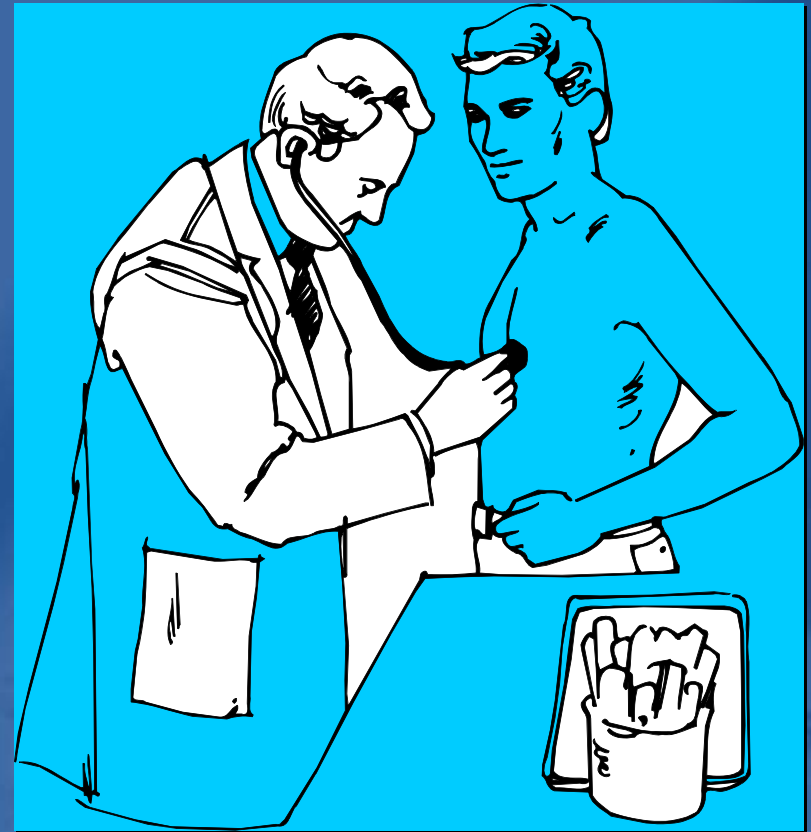
- Compliance Program in place for a number of years with improvements/enhancements added over time
- E.g., Compliance Officer, Compliance Committee, Hotline, Code Training
- Incorporates *“The Spirit of TAP”* and *“Connected to Care”*



Scope of TAP's Ethics & Compliance Program



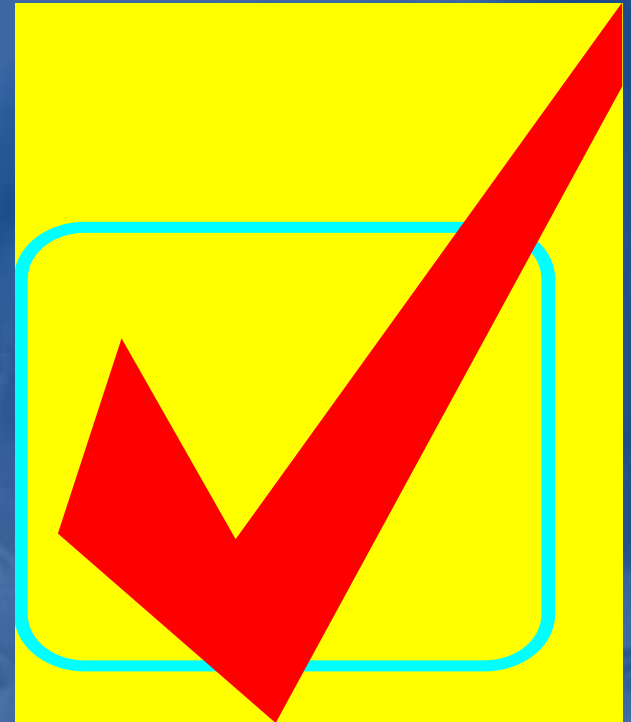
- Scope: Holistic, **NOT limited** to Sales & Marketing issues only.
 - Should implement the results of a **“head-to-toe corporate physical”**



Core Benefits



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



The Human Element of Effective Ethics & Compliance



Requires:

- Senior Leadership
- Open Communications
- Teamwork



Organizing an Ethics & Compliance Program



- Starts at the TOP:
 - Board of Directors
 - President
 - Management
 - Employees
- Leadership By Example:
 - Walk-the-walk
 - Vigorous, visible & vocal
 - **THE #1 KEY TO SUCCESS**



Role of Ethics & Compliance Officer



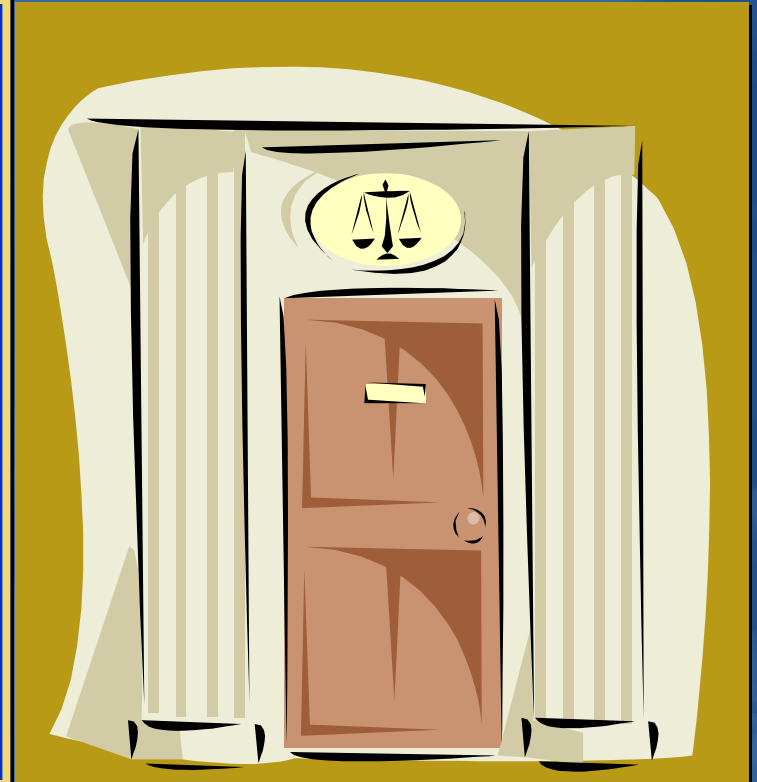
- Focal point for Ethics & Compliance Program
- Establishes accountability, credibility and structure
- Independent, well-respected senior manager who reports to the President and has direct access to the Board of Directors
- Oversees design, implementation of compliance standards, training, auditing/monitoring, 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..



Role of Legal Counsel



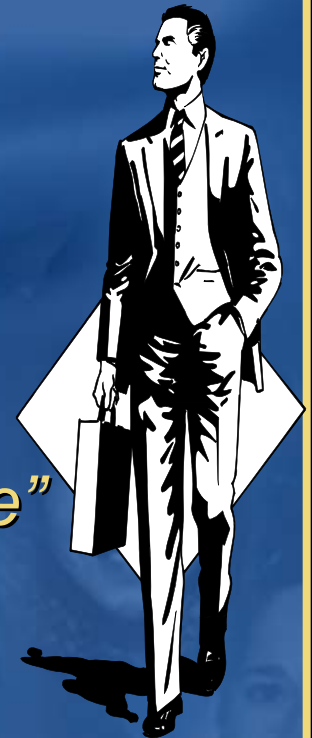
- Advise on pharmaceutical legal and corporate governance issues
- Review compliance risk areas
- Review compliance implementation
- Retain credible consulting advice, as needed
- Participate on Compliance Committee



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



Multiple Dimensions of Compliance Effectiveness



- Macro – Organizational Impact
 - Legal
 - Operational
- Micro – Programmatic Impact
 - Structural
 - Substantive
 - Effort/Input
 - Outcomes/Results

Making Compliance Fun & Effective



Have the Right Resources/Team

- Resources
 - Senior Management Support
 - Time
 - Money
 - Technology/Systems
 - People
- People –
 - Compliment your skill sets
 - Emphasize communication skills
 - Emphasize credibility
 - Seek diversity



Making Compliance Fun & Effective



Use Effective Marketing Techniques to Brand YOUR Product

- Create a theme, recognizable brand, logo
- Use visual and vocal branding through color, sound
- Pay attention to details
 - Font type, size and color
 - Use of punctuation
- Apply your brand to all of your materials
 - Code of Conduct
 - Training Materials
 - PowerPoint Presentations
 - Displays and Posters

Making Compliance Fun & Effective



Use Relevant Case Studies

- Tailor training to real-world issues that your audience experiences
- Makes it real, more memorable and more effective
- Use role plays or some form of interactive participation
 - Video vignettes
 - Case study teams in live training
 - Interactive computer questions
- Inject humor when possible but strike careful balance not to go “over the top”



Making Compliance Fun & Effective



Use Multiple Media to Communicate/Train

- Redundancy of message can be good
- Resources allowing, use
 - Live training
 - Computer-based training
 - Voice-mail
 - E-mail
 - Written materials
 - Web-based materials
 - Audio & video tapes
- Do NOT rely on any ONE medium.
- Seek to compliment and enhance different forms of training.



Making Compliance Fun & Effective



Dare to Laugh and Poke Fun at Yourself



- Be yourself
- Self-deprecating humor works
- Use seriousness and perceived negativity of subject to lighten tension.
 - Recognize up front that this stuff can be dry and boring
 - Openly express intent NOT to demonize or play “Gotcha!”
 - Focus on service-oriented approach, partnership
 - Openly seek to have fun and laugh at yourselves
- Don't overdo it; strike a balance

Making Compliance Fun & Effective



Create Positive Incentives



- Add ethics & compliance performance criteria to performance evaluations where achieving goals lead to financial rewards
- Create team contests involving functional areas, divisions etc. where “winners” will be rewarded



HCCA Resource Document



- *“Evaluating and Improving a Compliance Program: A Resource For Health Care Board Members, Health Care Executives and Compliance Officers”*
- Available on home page of HCCA website:

www.hcca-info.org

Positive Communications



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

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

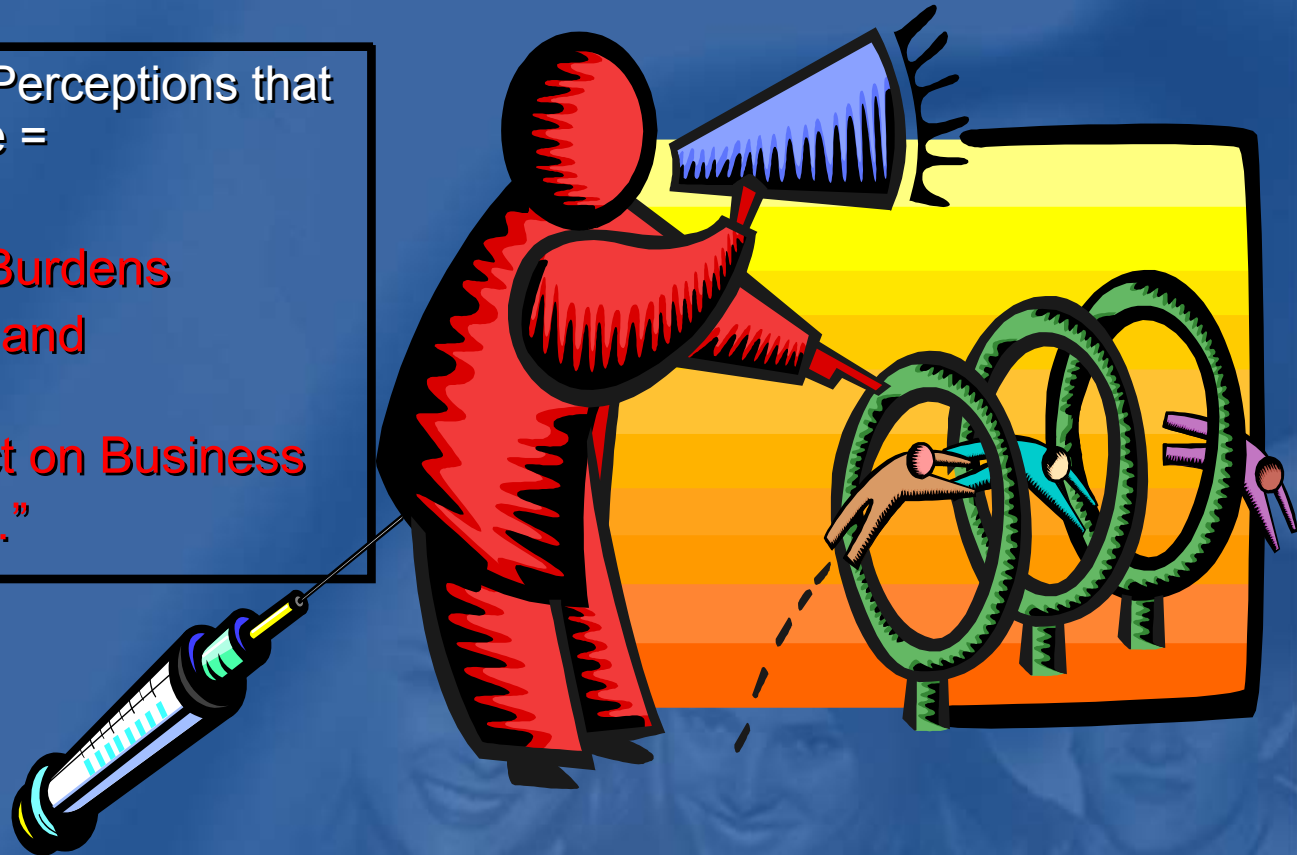
- **Better Information/Documentation**
- **Better Decision-Making**
- **Higher Quality/More Efficient Operations**
- **More Competitive Position**
- **Lower Risk of Violations**



Positive Communications



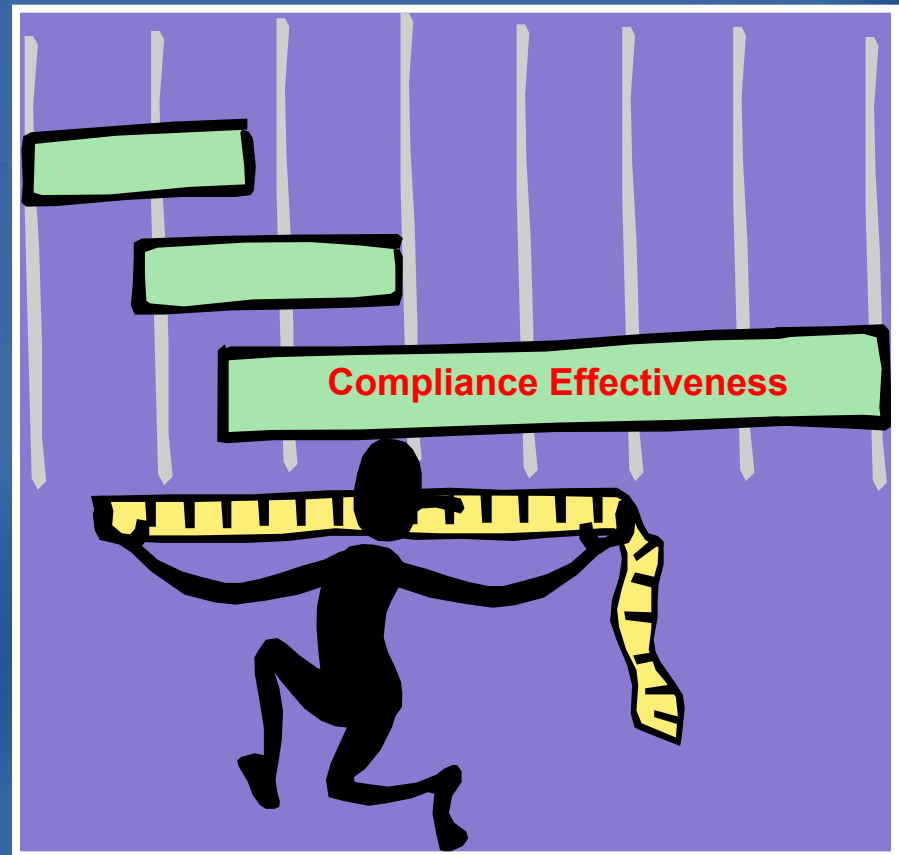
- Counters **Negative** Perceptions that Ethics & Compliance =
 - Added Costs
 - Administrative Burdens
 - Imposed Rules and Regulations
 - Negative Impact on Business
 - “A pain in the ...”



What's Ahead?



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



What's Ahead?



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



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.

Final Thoughts



Good compliance is good business!

Questions/Answers



Contact Information



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Have Fun!



Thank You!