

How to Survive a Compliance Failure: Turn Ethics & Compliance Into a Strategic Advantage



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Overview



- **Background – How did we get to this point?**
- **Basic Principles re: Ethics & Compliance**
- **TAP's Experience & Approach**
- **Some Historical Perspective**
- **Measuring for Effective Compliance**
- **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 & TRUST **Are The Keys To Effectiveness!**



Partnership Principles Produce Positive Results



AMA Principles of Medical Ethics



Preamble

The medical profession has long subscribed to a body of ethical statements developed **primarily for the benefit of the patient.** As a member of this profession, a physician must recognize responsibility to patients first and foremost, as well as to society, to other health professionals, and to self.

[From Code of Medical Ethics, 2004-2005 Edition, American Medical Association (AMA), page xiv.]

The Relation of Law and Ethics



Section 1.02

...Ethical values and legal principles are usually closely related, but **ethical obligations typically exceed legal duties**. In some cases, the law mandates unethical conduct. In general, when physicians believe the law is unjust, they should work to change the law. In exceptional circumstances of unjust laws, the ethical responsibilities should supercede legal obligations...

[From Code of Medical Ethics, 2004-2005 Edition, American Medical Association (AMA), page 1.]

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
 - DoD
 - 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**



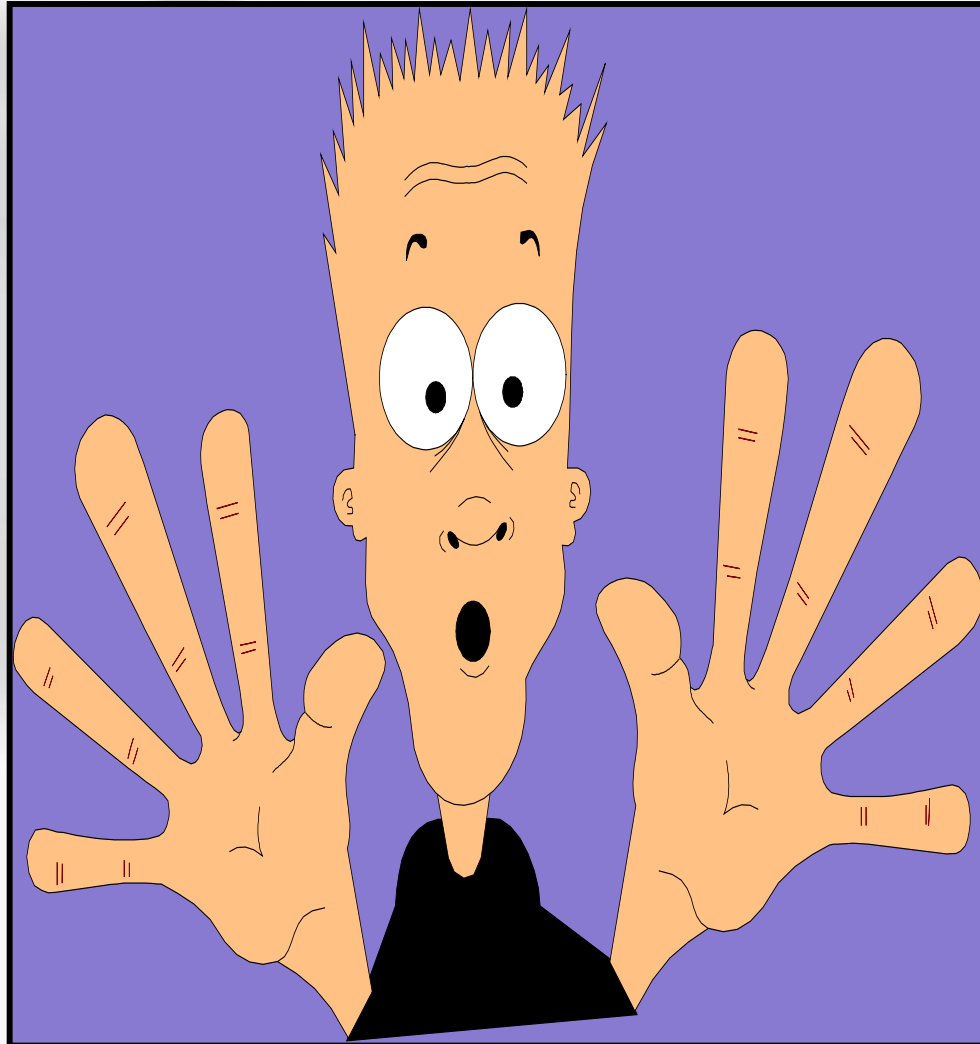
TAP's CIA



- 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



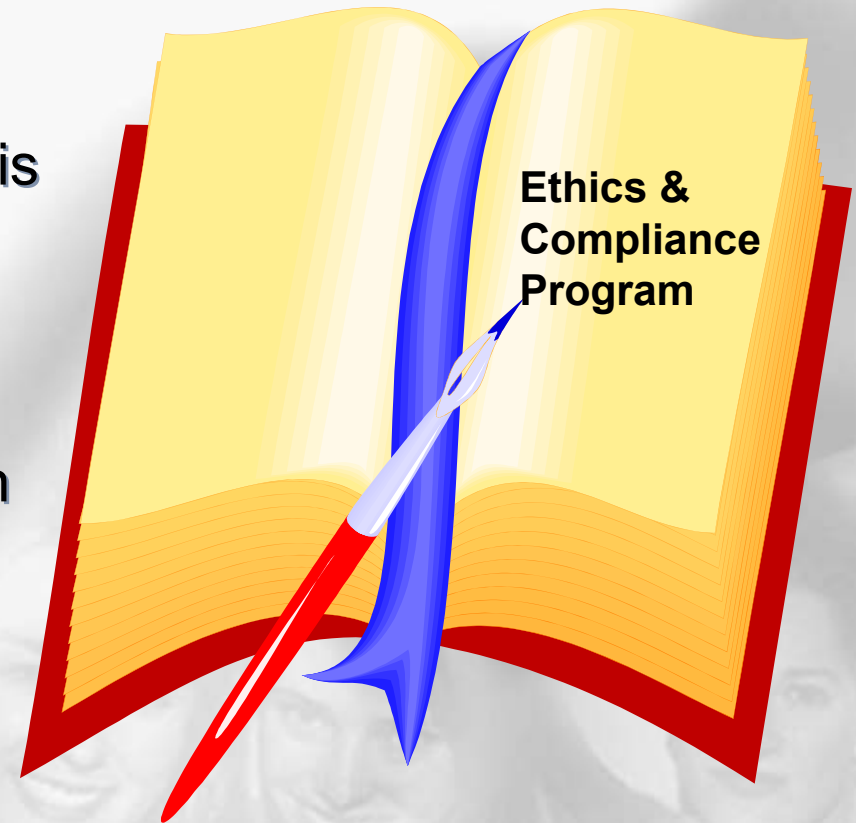
What Is an Ethics & Compliance Program?



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



TAP's Ethics & Compliance Program



- Values-based
- Action-focused
- Service-oriented
- Customized and Branded
- Cutting edge technology/Multi-media
- Positive, practical, team approach





Acting on Our Values

ETHICS & COMPLIANCE TEAM MISSION STATEMENT

The Mission of TAP's Ethics & Compliance Team is **to foster a culture of leadership and integrity that strikes the right balance** between meeting business objectives and compliance requirements through continued:

- ◆ **Adherence to high ethical standards**
- ◆ **Partnership**, customer service and continuous process improvement to:
 - Prevent, detect and correct inappropriate conduct
 - Enhance operational performance and compliance effectiveness
 - Provide timely business solutions with measurable results
 - Create an environment of open communications and fun
- ◆ **Recognized national leadership**

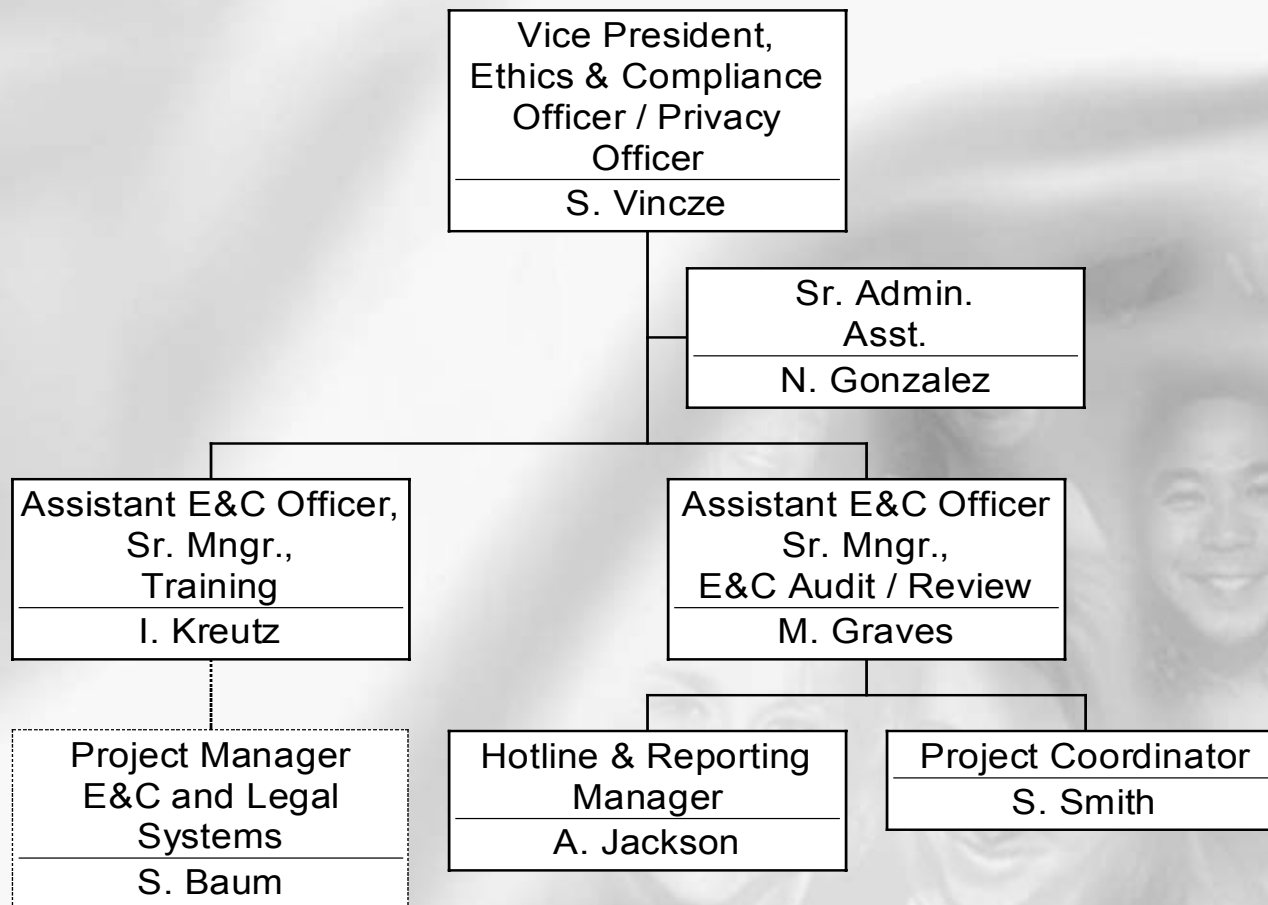


Acting on Our Values

ETHICS & COMPLIANCE



TAP PHARMACEUTICAL PRODUCTS INC.
April 2005



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***

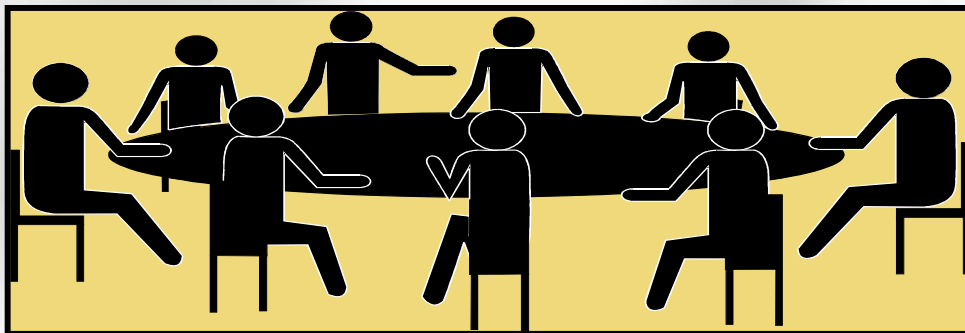


The Human Element of Effective Ethics & Compliance



Requires:

- Senior Leadership
- Open Communications
- Teamwork
- A Willingness to “think different”



Some Historical Perspective



- Theodore Vail and AT&T
 - Turn a threat into a strength, an enemy into a partner
 - Win over the public
- Theodore Roosevelt
 - “Reform is the antidote to revolution...”
 - “.. interested in the next step, not the one thousandth step...”
- The Quality Revolution as a Model
 - Shift from defense to offense – adopt a new paradigm
- Listening to What the Market/Public Demands

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

Use Multiple Media to Communicate/Train

- Redundancy of message can be good
- Do NOT rely on any ONE medium.
- Seek to compliment and enhance different forms of training.

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

Multiple Dimensions of Effectiveness



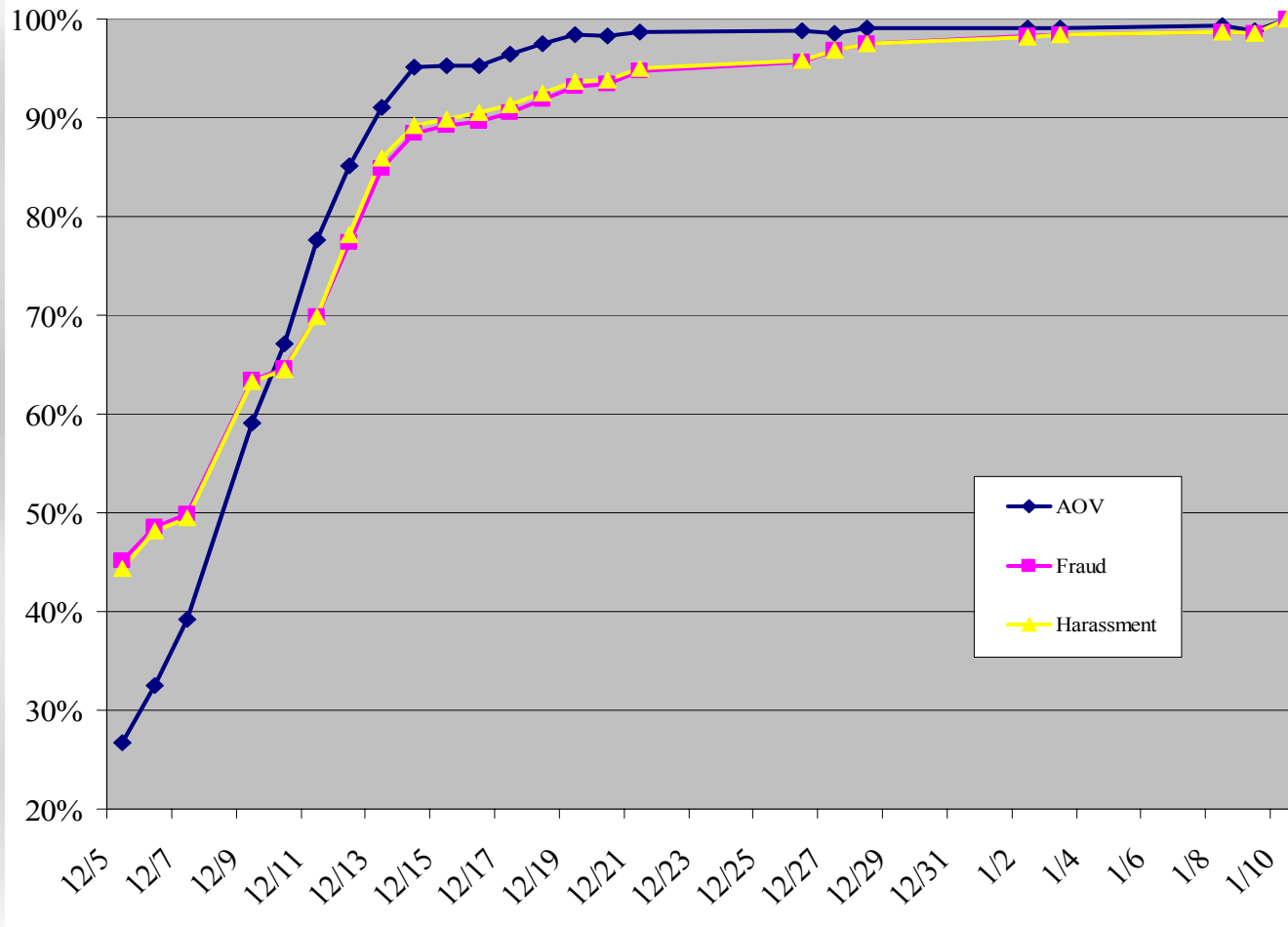
- Micro – Programmatic Impact
 - Structural
 - Substantive
 - Effort/Input
 - Outcomes/Results
- Macro – Organizational Impact
 - Legal
 - Operational

Types of Measurement



- Training Participation Rate
- Training Efficiency
- Employee Awareness, Understanding and Support
- Hotline/Helpline Call Rates
- Comparison of Hotline/Helpline Types of Calls
- Investigations
- Disciplinary Reports
- Comparison of Disciplinary Reports

TAP Ethics & Compliance Training Results



TAP Ethics & Compliance Training Results



Code of Conduct/TAP Ethics and Law Center Training Courses Completed As of 12/31/2001

Printed: 1/16/2002

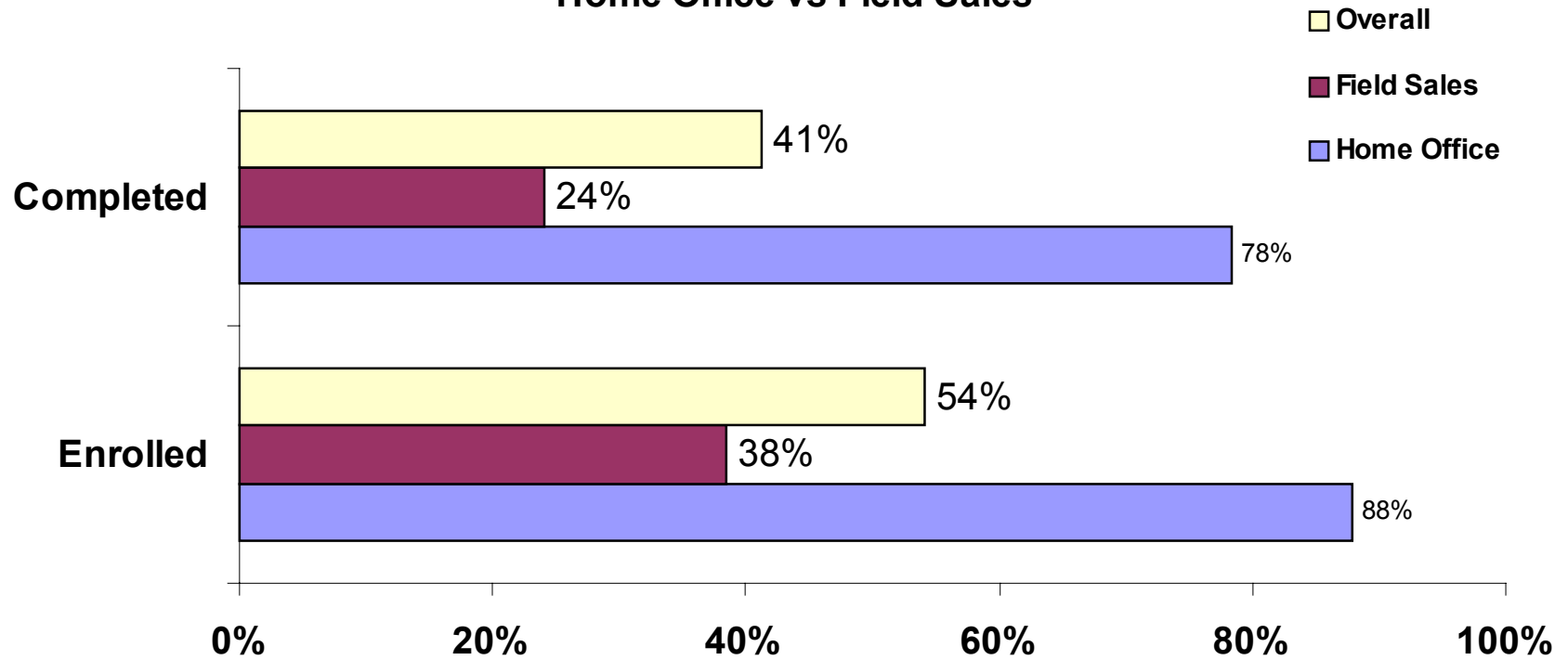
	People Required To Take	Code of Conduct		Fraud and Abuse		Work Place Harassment	
		Completed	Percent	Completed	Percent	Completed	Percent
Field Sales	1,903	1,903	100.0%	1,903	100.0%	1,903	100.0%
Home Office	1,044	1,044	100.0%	1,044	100.0%	1,044	100.0%
Total	2,947	2,947	100.0%	2,947	100.0%	2,947	100.0%
Managers	608	608	100.0%	608	100.0%	608	100.0%
Non-Managers	2,339	2,339	100.0%	2,339	100.0%	2,339	100.0%
Total	2,947	2,947	100.0%	2,947	100.0%	2,947	100.0%
Left		-		-		-	

Notes: 1) Excludes people on leave of absence. These people will be required to take all 3 classes on their return to work.

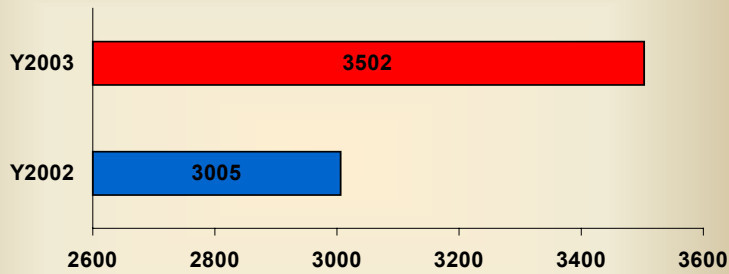
2) Includes all people working at TAP on 12/31/2001, who were required to take the class by 12/31/2001, and were not terminate or go on leave by 1/15/2002



Home Office vs Field Sales

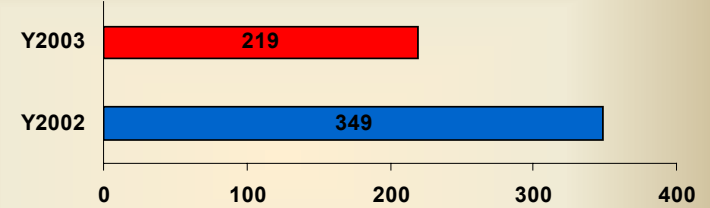


Covered Persons



	Y2002	Y2003
Covered Persons	3005	3502

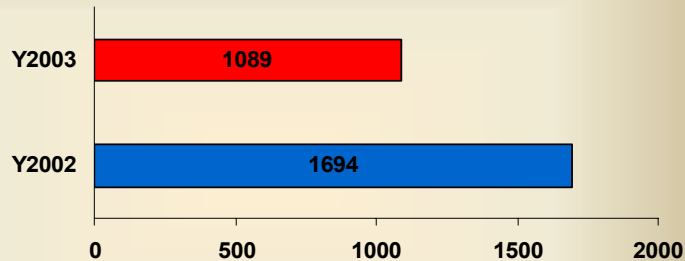
AOV Costs (\$000's)



	Y2002	Y2003
AOV Costs (\$000's)	349	219

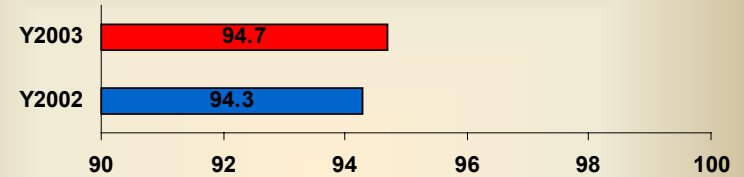
*Vendor development and MIS support costs

MIS Training Support Calls



	Y2002	Y2003
MIS Training Support Calls	1694	1089

Employee Survey Results*



	Y2002	Y2003
Employee Survey Results*	94.3	94.7

Area	Y2002	Y2003	% Change
1. Covered Persons	3005	3502	17%
2. AOV Costs	349	219	-37%
3. MIS Training Support Calls	1694	1089	-36%
4. Employee Survey Results	94.3	94.7	0.4%

Conclusions:

Data points demonstrate increased efficiency of E&C Training in terms of both financial impact and employee positive survey results regarding training/materials and understanding/awareness. Specifically, overall cost and number of support calls were reduced by 37% and 36% respectively, while the number of employees trained increased by 17%. Employee survey results increased by 0.4%.

Acting on Our Values



	Strongly agree	Agree	Neutral	Disagree	Strongly disagree
1. I have received and read the Code of Conduct booklet.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
2. I understand how to use the Code of Conduct to help meet my job responsibilities.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
3. I have read the Operational Guidelines.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
4. I understand how to use the Operational Guidelines to help meet my job responsibilities.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
5. I have taken the computer-based "Acting on Our Values" annual training course within the last 12 months.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
6. The annual "Acting on Our Values" training has improved my understanding of how to use the Code of Conduct and the Operational Guidelines.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
7. I have attended specific compliance training that addresses my technical areas of responsibility.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Next

we are what we stand for. the spirit of TR

Acting on Our Values



	Strongly agree	Agree	Neutral	Disagree	Strongly disagree
8. I am aware of the Ethics & Compliance Program (previously known as the Compliance Program).	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
9. I understand the purpose of the Ethics & Compliance Program.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
10. I am aware of and understand the purpose of the non-retaliation/non-retribution policy.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
11. I understand the purpose of the organizational chain-of-command, i.e., the different levels of managerial support that are available to me for assistance.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
12. I would personally feel comfortable using the Compliance Hotline.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
13. I believe my co-workers would feel comfortable using the Compliance Hotline.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
14. I believe that my identity would remain private if I called the Hotline and asked for anonymity.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

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	Strongly agree	Agree	Neutral	Disagree	Strongly disagree
15. I believe the Hotline is an effective tool for reporting and solving problems.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
16. I am aware of and understand the serious reporting purpose of the Compliance Hotline (as distinguished from an informal call for general assistance to the Compliance Hotline).	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
17. I feel comfortable asking or raising a compliance-related question or concern with my manager.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
18. I feel comfortable using the chain-of-command, i.e., going to my managers to address a compliance-related question or concern.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
19. I believe that no retaliation or retribution will occur if I properly raise a question about a compliance-related issue.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
20. I believe that the Ethics & Compliance Program is a top priority of TAP's President and senior management.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
21. I support the Ethics & Compliance Program.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

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	Strongly agree	Agree	Neutral	Disagree	Strongly disagree
22. I believe the Ethics & Compliance Program has been a positive development for our organization.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
23. I will use the Ethics & Compliance Program process to address a compliance concern if I become aware of one.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
24. I have personally been involved in the review and resolution of an Ethics & Compliance Program related issue.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
25. I believe that policies, procedures, and work-rules are consistently enforced.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
26. I am aware of and understand the PhRMA Code on Interactions with Healthcare Professionals ("PhRMA Code").	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

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Acting on Our Values 2003 Survey Results Summary

	<u>1**</u>	<u>2</u>	<u>3</u>	<u>4</u>	<u>5</u>	<u>6</u>	<u>7</u>	<u>8</u>	<u>9</u>	<u>10</u>	<u>11</u>	<u>12</u>
Strongly Agree/Agree 2001	91.1	93.8	92.7	87.6	86.3	90.0	79.0	60.1	94.1	75.6	61.7	61.5
Neutral 2001	5.7	3.2	5.8	6.9	9.1	4.7	15.1	20.3	4.7	19.5	34.3	26.8
Disagree/Strongly Disagree 2001	3.3	2.9	1.5	5.5	4.6	5.3	5.9	19.7	1.3	4.9	4.0	11.6
Strongly Agree/Agree 2002	97.8	95.9	98.3	95.2	97.2	98.2	92.9	74.6	98.4	89.8	83.8	80.2
Neutral 2002	1.8	2.8	1.3	3.7	2.3	0.9	5.8	18.6	1.4	7.8	13.7	13.7
Disagree/Strongly Disagree 2002	0.5	1.3	0.4	1.1	0.5	0.9	1.4	6.9	0.3	2.4	2.5	6.1
Strongly Agree/Agree 2003	98.2	96.1	98.5	95.5	97.4	97.3	92.2	76.4	98.6	89.8	84.1	81.8
Neutral 2003	1.4	2.4	1.2	3.4	2.1	1.3	6.1	17.1	1.1	8.0	13.6	13.3
Disagree/Strongly Disagree 2003	0.3	1.4	0.3	1.1	0.5	1.4	1.6	6.5	0.3	2.2	2.3	4.9
2003 vs. 2002 SA/A	0.4	0.2	0.2	0.3	0.2	-0.9	-0.7	1.8	0.2	0.0	0.3	1.6
2003 vs. 2002 Neutral	-0.4	-0.4	-0.1	-0.3	-0.2	0.4	0.3	-1.5	-0.3	0.2	-0.1	-0.4
2003 vs. 2002 SD/D	-0.2	0.1	-0.1	0.0	0.0	0.5	0.2	-0.4	0.0	-0.2	-0.2	-1.2
	<u>14</u>	<u>15</u>	<u>16</u>	<u>17</u>	<u>18</u>	<u>19</u>	<u>20</u>	<u>21</u>	<u>22</u>	<u>23</u>	<u>24*</u>	<u>25</u>
Strongly Agree/Agree 2001	67.9	52.2	89.9	88.3	89.2	70.6	92.2	96.5	88.2	91.9	22.2	71.8
Neutral 2001	20.2	20.5	5.6	7.7	7.1	18.5	6.2	3.4	10.5	7.5	23.2	18.3
Disagree/Strongly Disagree 2001	12.0	27.3	4.6	4.0	3.8	11.0	1.6	0.1	1.4	0.6	54.7	9.9
Strongly Agree/Agree 2002	95.1	88.5	93	97.2	93.2	83.7	97.5	98	95.6	97.3	42.7	85.7
Neutral 2002	4.1	8.2	4.9	2.3	4.5	12.1	2.2	1.7	3.9	2.4	23.2	10.6
Disagree/Strongly Disagree 2002	0.8	3.3	2.2	0.6	2.3	4.3	0.4	0.3	0.6	0.3	34.1	3.8
Strongly Agree/Agree 2003	95.7	91.1	94.0	97.2	93.5	85.2	97.6	98.1	96.2	97.6	44.3	87.1
Neutral 2003	3.6	6.9	4.2	2.3	4.5	11.0	2.0	1.6	3.4	2.2	22.1	10.1
Disagree/Strongly Disagree 2003	0.7	2.0	1.8	0.5	2.0	3.9	0.4	0.3	0.4	0.2	33.7	2.9
2003 vs. 2002 SA/A	0.6	2.6	1.0	0.0	0.3	1.5	0.1	0.1	0.6	0.3	1.6	1.4
2003 vs. 2002 Neutral	-0.5	-1.3	-0.7	0.0	0.0	-1.1	-0.2	-0.1	-0.5	-0.2	-1.1	-0.5
2003 vs. 2002 SD/D	-0.1	-1.3	-0.4	-0.1	-0.3	-0.4	0.0	0.0	-0.2	-0.1	-0.4	-0.9
	Overall	Materials & Training			Understanding & Awareness			Hotline/Helpline		Support & Usage		
2001 Average Positive Response	80.7	84.2			81.4			66.3		86.3		
2002 Average Positive Response	92.4	93.7			95.5			86.8		93.0		
2003 Average Positive Response	93.0	93.9			96.3			87.7		93.7		
* Omitted from Overall and Support & Usage Averages												
**Numbering follows the 2001 and 2002 Presentations - NOT either the schema in the database or order asked in AOV												

Acting on Our Values

2003 Survey Results Summary



Percent Positive Responses

Surveyed Area

Year	Materials & Training	Understanding & Awareness	Hotline / Helpline	Support & Usage	Overall
2001	84.2%	81.4%	66.3%	86.3%	80.7%
2002	93.7%	95.5%	86.8%	93.0%	92.4%
2003	93.9%	96.3%	87.7%	93.7%	93.0%

Positive Communications



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

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

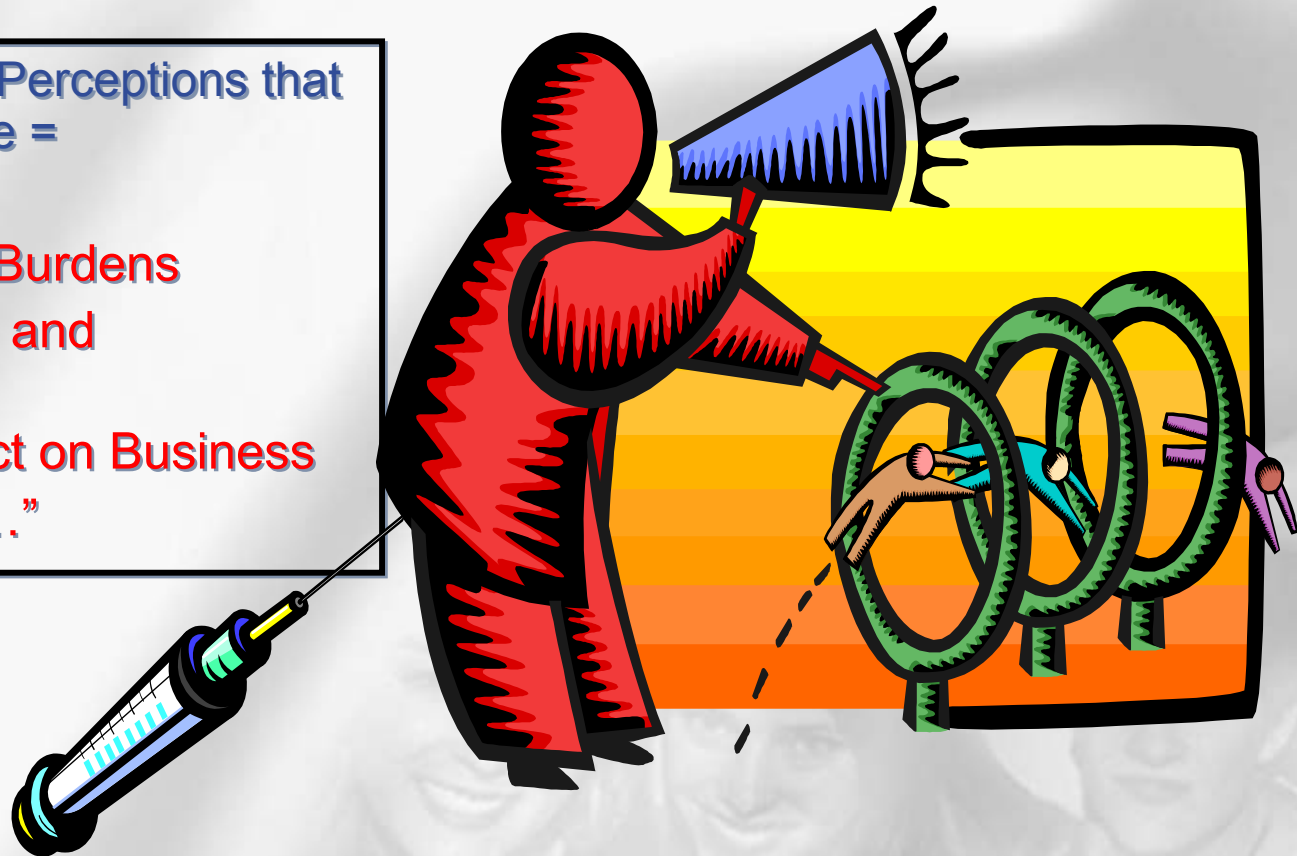
- Better Information/Documentation
- Better Decision-Making
- Higher Quality/More Efficient Operations
- More Competitive Position
- Lower Risk of Violations



Positive Communications



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



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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Thank You!

