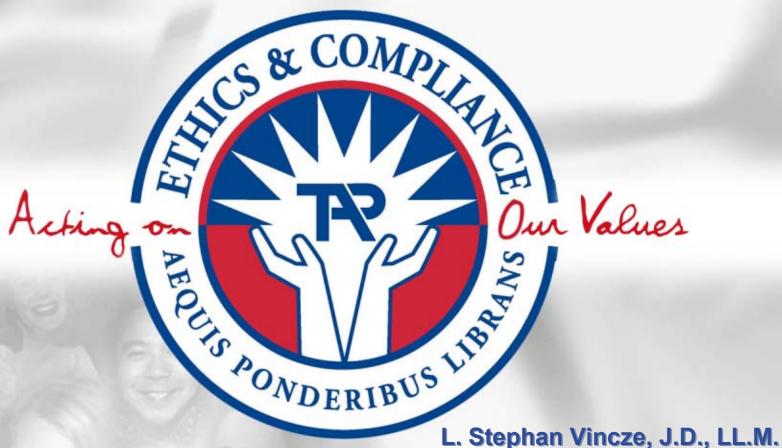
Measuring Ethics & Compliance Program Effectiveness



L. Stephan vilicze, J.D., LL.IVI.

Vice President, Ethics & Compliance Officer / Privacy Officer

TAP Pharmaceutical

October 20, 2004

Food For Thought



"Wisdom comes only through suffering."

Aeschylus, Agamemnon, 458 B.C.

Overview



- I. The Multiple Dimensions of Effectiveness
- II. Sample Metrics
- III. Conclusion
- IV. Q&A

Multiple Dimensions of Effectiveness



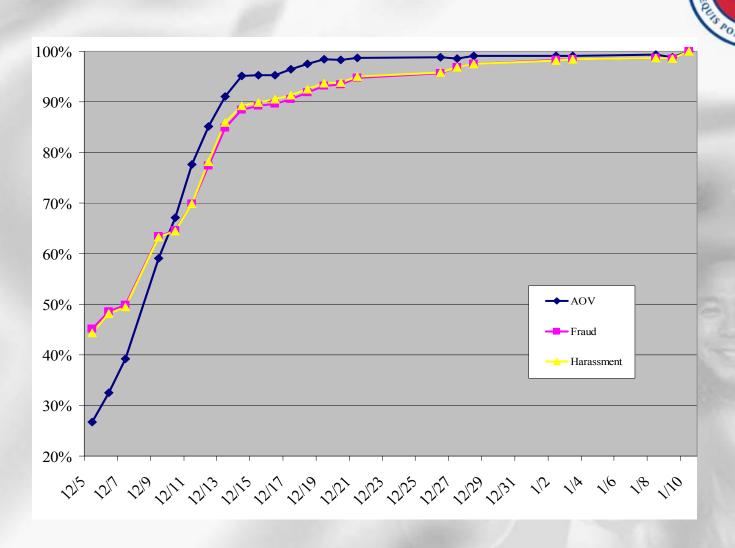
- Micro Programmatic Impact
 - Structural
 - Substantive
 - Effort/Input
 - Outcomes/Results
- Macro Organizational Impact
 - Legal
 - Operational

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

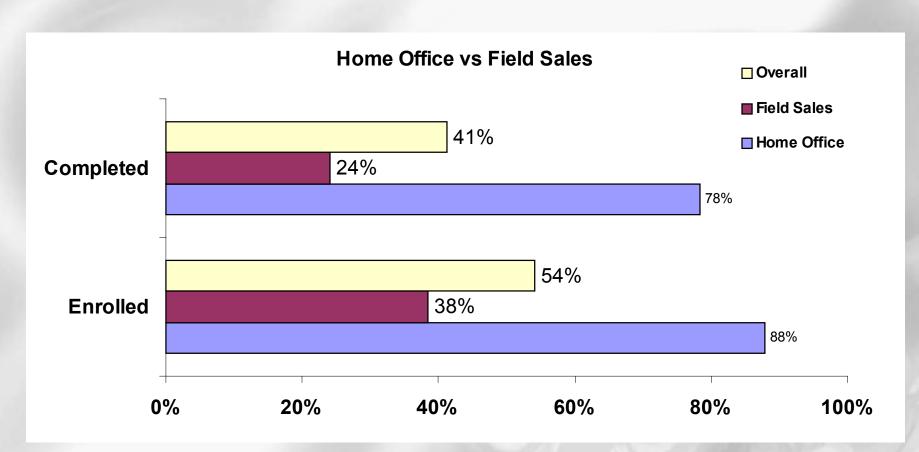
Printed: 1/16/2002

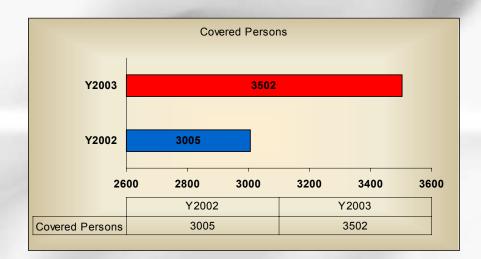
	People Required	Code of C	onduct	Fraud and	Abuse	Work Place Harassment		
	To Take	Completed	Percent	Completed	Percent	Completed	Percent	
Field Sales	1,903	1,903	100.0%	1,903	100.0%	1,903	100.0%	
Home Office	1,044	1,044	100.0%	1,044	100.0%	1,044	100.0%	
Total	2,947	2,947	100.0%	2,947	100.0%	2,947	100.0%	
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		-		-		-		

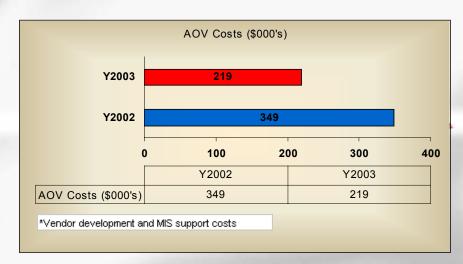
Notes: 1) Excludes people on leave of absence. These people will be required to take all 3 classes on their return to work.

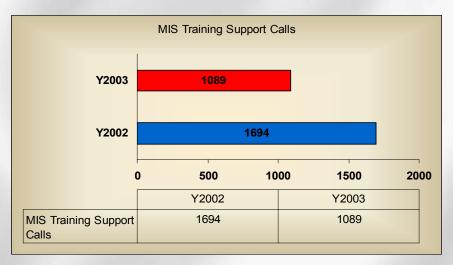
2) Includes all people working at TAP on 12/31/2001, who were required to take the class by 12/31/2001, and were not terminate or go on leave by 1/15/2002

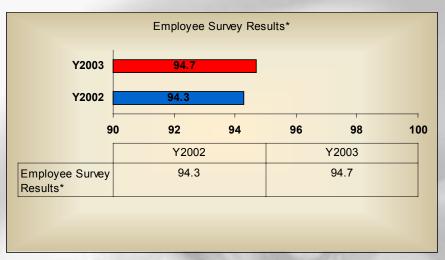












Area	<u>Y2002</u>	Y2003	% Change
1. Covered Persons	3005	3502	17%
2. AOV Costs	349	219	-37%
3. MIS Training Support Calls	1694	1089	-36%
4. Employee Survey Results	94.3	94.7	0.4%

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

74

		Strongly agree	Agree	Neutral	Disagree	Strongly disagree	4
1.	I have received and read the Code of Conduct booklet.						-
2.	I understand how to use the Code of Conduct to help meet my job responsibilities.						١
3.	I have read the Operational Guidelines.						4
4.	I understand how to use the Operational Guidelines to help meet my job responsibilities.						
5.	I have taken the computer-based "Acting on Our Values" annual training course within the last 12 months.		0				١
6.	The annual "Acting on Our Values" training has improved my understanding of how to use the Code of Conduct and the Operational Guidelines.						-
7.	I have attended specific compliance training that addresses my technical areas of responsibility.						4

Next

we are what we stantishe spirit of

Acting on Our Values

		Strongly agree	Agree	Neutral	Disagree	Strongly disagree	4
8.	I am aware of the Ethics & Compliance Program (previously known as the Compliance Program).						H
9.	I understand the purpose of the Ethics & Compliance Program.						
10.	I am aware of and understand the purpose of the non-retaliation/non-retribution policy.						1
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.						
12.	I would personally feel comfortable using the Compliance Hotline.						
13.	I believe my co-workers would feel comfortable using the Compliance Hotline.						1
14.	I believe that my identity would remain private if I called the Hotline and asked for anonymity.						4

Next

we are what we stantishe spirit of

Acting on Our Values Strongly Strongly Neutral Disagree disagree agree I believe the Hotline is an effective tool for reporting and solving problems. 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). 17. I feel comfortable asking or raising a compliance-related question or concern with my manager. 18. I feel comfortable using the chain-of-command, i.e., going to my managers to address a compliancerelated question or concern. I believe that no retaliation or retribution will occur if I properly raise a question about a compliance-related issue. 20. I believe that the Ethics & Compliance Program is a top priority of TAP's President and senior management. 21. I support the Ethics & Compliance Program. Next

we are what we stantihe spirit of

Acting on Our Values Strongly Strongly Neutral Disagree disagree agree I believe the Ethics & Compliance Program has been a positive development for our organization. 23. I will use the Ethics & Compliance Program process to address a compliance concern if I become aware of one. 24. I have personally been involved in the review and resolution of an Ethics & Compliance Program related issue. I believe that policies, procedures, and work-rules are consistently enforced. I am aware of and understand the PhRMA Code on 26. Interactions with Healthcare Professionals ("PhRMA Code"). Next we are what we stant the spirit of

	A	cting	on Ou	r Val	ues 20	003 Sı	urvey	Resu	lts Sui	nmary	,	
	1**	2	3	4	5	6	7			10	11	12
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		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
	14	<u>15</u>	<u>16</u>	<u>17</u>	<u>18</u>	<u>19</u>	<u>20</u>	<u>21</u>	22	23	24*	<u>2</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		95.6	97.3	42.7	85.7
Neutral 2002	4.1	8.2	4.9	2.3	4.5	12.1	2.2		3.9	2.4	23.2	10.6
Disagree/Strongly Disagree 2002	8.0	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		96.2	97.6	44.3	87.
Neutral 2003	3.6	6.9	4.2	2.3	4.5	11.0	2.0			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	Mate	rials & Train	ina	Understar	ndina & Av	vareness	Но	tline/Helpli	ne Suni	port & Usag	ne
2001 Average Positive Response	80.7	.,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	84.2	<u>s</u>	3.14310441	81.4		- 10	66.3	<u></u>	86.3	<u> </u>
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	t & Usage Ave	ages										

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%		

Expense Reports Compliance Metrics

January 1 - July 31, 2004

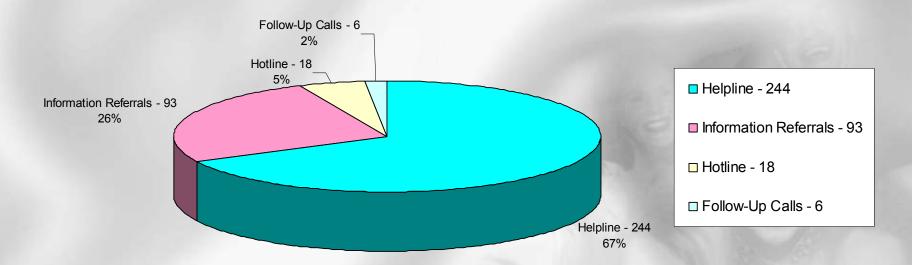


		JAN		FEB		//AR		PRIL		MAY		JUNE	JULY	
	Total #	% of Total												
TOTAL SALES														
FORCE EXPENSE														
REPORTS														
SUBMITTED	11,527		9,750		12,137		10,502		10,395		10,764		10,784	
TOTAL EXPENSE														
REPORTS														
REVIEWED BY E&C	13	0.11%	19	0.19%	31	0.26%	42	0.40%	16	0.15%	30	0.28%	27	0.25%
TOTAL EXPENSE														
REPORTS DENIED	2	0.02%	1	0.01%	3	0.02%	4	0.04%	2	0.02%	7	0.07%	8	0.07%
EXPENSE REPORTS														
IN COMPLIANCE	11,525	99.98%	9,749	99.99%	12,134	99.98%	10,498	99.96%	10,393	99.98%	10,757	99.93%	10,776	99.93%
REVIEWED REPORTS		% of												
BY REASON	#	Reviewed												
COST OVERAGE	0	0.00%		5.26%	-			0.0270		6.25%		3.33%	2	
RATIO VIOLATION	10	76.92%	14	73.68%	18	58.06%	-		10	62.50%	26	86.67%	19	70.37%
OTHER	3	23.08%	4	21.05%	10	32.26%	6	14.29%	5	31.25%	3	10.00%	6	22.22%

Hotline/Helpline Call Reports

January 1 – July 31, 2004



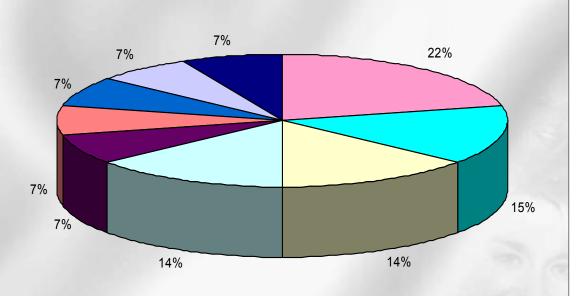


TOTAL CALLS - 361 (92 Internal Reports)

Hotline Call Reports

January 1 - July 31, 2004



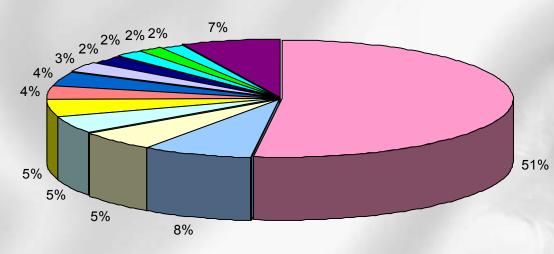


TOTAL CALLS - 18

- Confidential Information 3 (16%)
- Electronic Media Use 2 (11%)
- □ Compliance w/Law & High Ethical Business Standards 2 (11%)
- □ Accuracy & Integrity of Books & Records 2 (11%)
- EEO Workplace Harassment 1 (6%)
- Conflicts of Interest 1 (6%)
- Privacy/HIPAA Internal 1 (6%)
- TAP Speaker Programs 1 (6%)
- Other 1 (6%)

Helpline Call Reports

January 1 - July 31, 2004



Total Helpline Reports - 244 (91 Internal Reports)

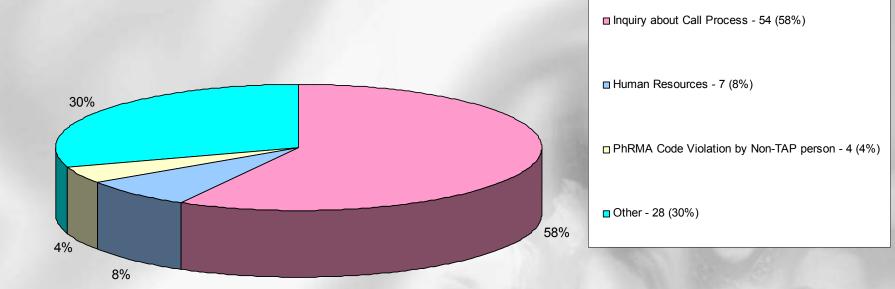


- RFG Meals, Entertainment & Gifts/Local Event Program 127 (51%)
- RFG Educational Grants 19 (8%)
- ☐ RFG Preceptorships 13 (5%)
- ☐ RFG Compliance w /Law & High Ethical Bus Standards 12 (5%)
- ☐ RFG Consulting, Speaking & other Fee-For-Service Advisory Arrangements - 11 (5%)
- RFG TAP Speaker Programs 10 (4%)
- RFG Conflicts of Interest 9 (4%)
- RFG Dealing with Vendors 7 (3%)
- RFG Charitable Contributions 6 (2%)
- RFG Advise on Reimbursement of Products 5 (2%)
- RFG Privacy/HIPAA External 4 (2%)
- RFG Informational Presentations 4 (2%)
- Other 17 (7%)

Information Referral Reports

January 1 - July 31, 2004

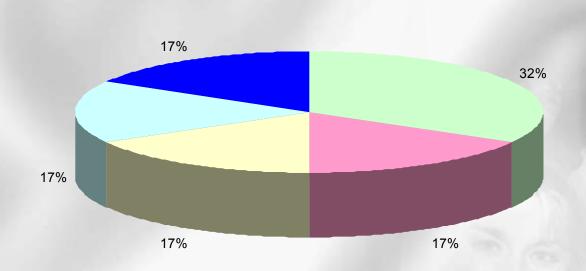




TOTAL CALLS - 93

Follow-Up Call Reports January 1 - July 31, 2004





Educational Grants - 1 (17%)Consulting, Speaking, Fee-for-service advisory arrgmts - 1 (17%)

Accuracy & Integrity of Books & Records - 1

Meals, Entertainment & Gifts - 2 (32%)

■ Confidential Information - 1 (17%)

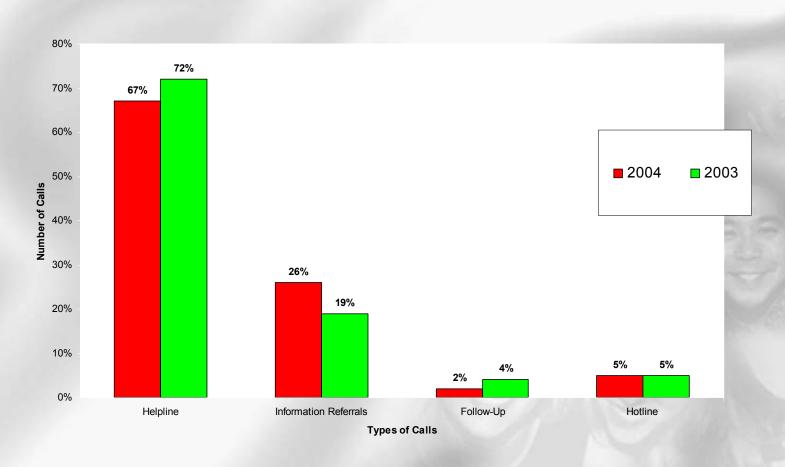
(17%)

TOTAL CALLS - 6

Hotline/Helpline Call Reports

Comparison 2004 – 2003 January 1st – July 31st Time Frame

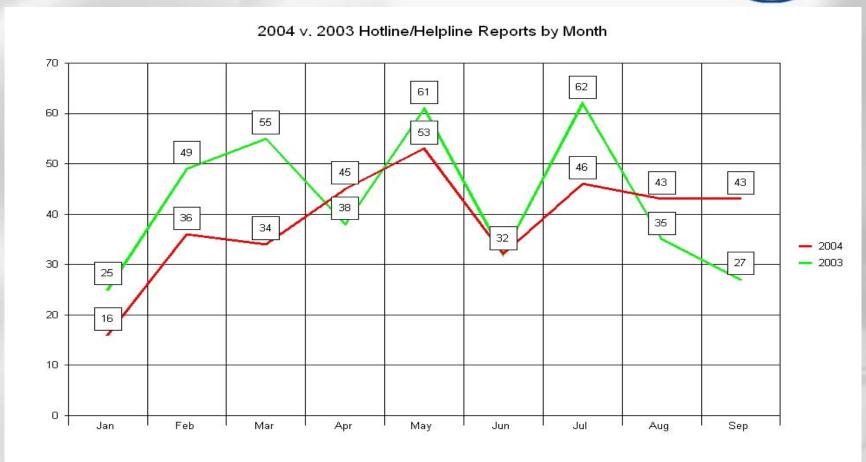




Hotline/Helpline Call Reports

Comparison 2004 – 2003 by Month





This chart does not include Information Referrals or Follow-Up Reports

Next Steps/What's Ahead?



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



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

More 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.