

# Measuring Compliance Effectiveness and Value: Strategic Integration of Quality Medicine and Quality Business Practices



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# Overview



- **Background – The “TAP Case”**
- **Basic Principles re: Ethics & Compliance**
- **TAP’s Experience & Approach**
  - **Creating Brand Equity/Reputational Capital**
  - **Leveraging Brand Equity for Business Edge**
  - ***“Good Compliance IS Good Business!”***
  - **Measuring Results (Some Examples)**
- **What’s Next? / Final Thoughts**

# TAP Pharmaceutical Products



- Joint venture between Abbott Labs and Takeda Pharmaceuticals
- Approximately \$4 billion in gross revenues
- About 3,200 employees
- Two principal products: Prevacid and Lupron
- Headquartered in Lake Forest, IL

# TAP's Ethics & Compliance Program:



## *“Acting on Our Values”*

- 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”*



# TAP Pharmaceutical Products

## Ethics & Compliance Training – Implementing Brand




*Acting on Our Values*

### ETHICS & COMPLIANCE TEAM MISSION STATEMENT

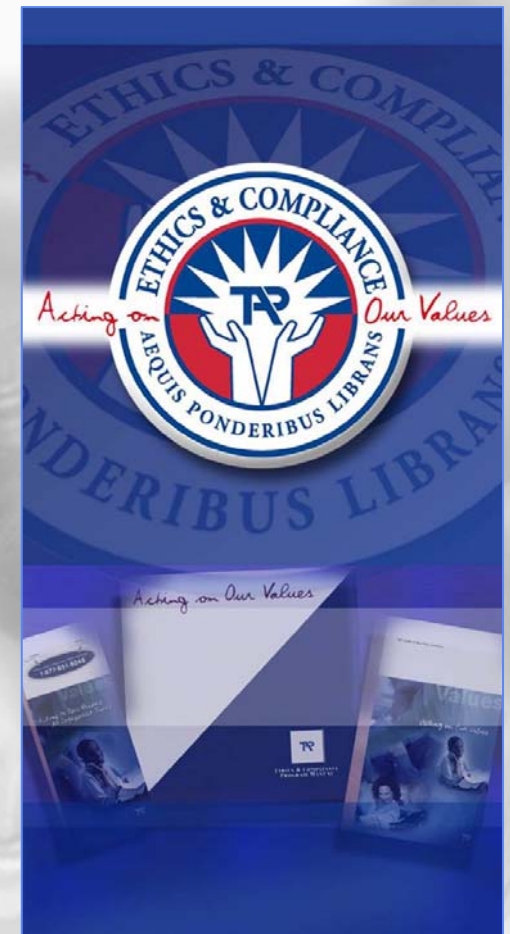
The Mission of TAP's Ethics & Compliance Team is to **foster a culture of leadership and integrity that strikes the right balance** between meeting business objectives and compliance requirements through continued:

- ◆ **Adherence to high ethical standards** and TAP's Ethics & Compliance Program elements
- ◆ **Refinement of Ethics & Compliance processes**
- ◆ **High levels of customer service** to TAP employees, managers and contractors
- ◆ **Partnership** with TAP's internal organizations to:
  - Prevent, detect and correct inappropriate conduct
  - Enhance operational performance and compliance effectiveness
  - Provide timely business solutions
  - Produce measurable results
  - Create an environment of continuous innovation, open communications and fun
- ◆ **Recognized national leadership** in the field of ethics and compliance



# TAP Pharmaceutical Products

## Ethics & Compliance Training - Environment





TR  
**SHOCKED**

connected to care

*it's people that  
make the difference*  
connected to care

*make  
the difference*



*Acting on Our Values*  
**E&C Team**




**Leading  
From  
the Front**

**Doing Things  
Right.  
Doing the  
Right Things.**



# Branding






**Dear Fellow TAP Colleagues:**

You as an individual are important at TAP. Your work helps TAP to deliver life-enhancing pharmaceutical products to patients. And it's your commitment to striking the balance between meeting your business objectives and TAP's ethical and compliance requirements that allows us to offer medicine to those patients whose lives we touch every day.

I recognize your opinion and energy, your commitment to making a difference, and your passion about our work and purpose. At TAP, we are all connected to patients, to customers, and to each other. Your daily actions reflect this commitment. That is why it is critically important that we conduct ourselves in a manner that reflects our values and the principles of our Ethics and Compliance Program - honesty, integrity and quality.

The Code of Business Conduct is not intended to govern every situation that you may encounter. It is a statement of the basic standards and principles of TAP in business in a legal and ethical manner. It is a commitment for TAP as a company. We expect our own daily business conduct and must adhere to it with integrity and abide by the Code. We expect you to do what is right, not just what is required.

Serving patients as members of the pharmaceutical industry is a privilege. The work is both challenging and rewarding. We need to stay focused on the issue at hand, to be honest, together, we can learn, grow, improve, and create a future we can be proud of by "Acting on Our Values" and "Striking the Balance" each and every day. Thank you for your commitment to TAP and for improving the lives of the patients we serve. Good ethics and good compliance is good business. Let's do it right at TAP.


Sincerely,  
  
 Alan MacKenzie  
 President

**Acknowledgement**

The Company requires that all employees, contractors and agents working at TAP sign an acknowledgement confirming that he or she has received and read the Code, understands it, and is complying with it. Accordingly, please sign and date the Acknowledgement Form below and return it to:

TAP Pharmaceutical Products Inc.  
 Attention: Ethics & Compliance Department  
 675 North Field Drive  
 Lake Forest, IL 60045

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**Acknowledgement Form**

and read the Code, understand it and am complying with it.

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**TAP Code of Business Conduct**





Acting on Our Values

  
 TAP PHARMACEUTICAL PRODUCTS INC.

Branding with the E&C logo on key TAP documents.

# TAP Pharmaceutical Products

## Ethics & Compliance Training - Objectives



Objectives in building support for ethics and compliance training:


- Create buy-in
- Overcome barriers
- Build a relationship with the department
- Drive participation
- Reduce “Fear Factor” and increase “Fun Factor”
- Demonstrate that:


***“Good Compliance IS Good Business!”***

# TAP Pharmaceutical Products

## Ethics & Compliance Training - Interaction



 The E&C National Team Challenge



**:42**


Which venue would be the most appropriate for a clinical discussion with a group of three physicians?

- a** The Waldorf Astoria dining room
- b** A table in the back of an Outback Steakhouse
- c** A taping of a Jerry Springer episode
- d** An inexpensive local restaurant that features singers serenading guests.


# TAP Pharmaceutical Products

## Ethics & Compliance Training - Interaction





The E&C National Team Challenge



**:15**

TAP may control the content presented at a CME program under the following circumstances:

- a** When TAP funds the entire program
- b** When TAP funds any portion of the program
- c** Both a and b
- d** None of the above.

# TAP Pharmaceutical Products

## Ethics & Compliance Training - Promotion



Get Ready To Be...

### ROCKED OR SHOCKED

Acting on Our Values

PLAY THE GAME! WIN PRIZES!

COMPETE FOR YOUR TEAM!

## THE E&C NATIONAL TEAM CHALLENGE

IF YOU THOUGHT LAST YEARS QUESTIONS WERE TOUGH?

### ARE YOU READY TO GET ROCKED OR SHOCKED? AGAIN?

WIN PRIZES!  
DEFEND YOUR TEAM'S HONOR!  
INCREASE YOUR OPERATIONAL EFFECTIVENESS!  
RECEIVE VALUABLE NEW BUSINESS PROCESS INFORMATION!

PATHOLOGIC (PREVACIO CENTRAL)  
JAMMIE JEFF & Managed Markets Group (SPECIALTY GROUPS)  
TEAM LUPRON  
MORGANST (PREVACIO WEST)  
CHITWOOD (PREVACIO EAST)

ARE YOU READY TO GET

### ROCKED OR SHOCKED?

The E&C Home Office Challenge

PLAY THE GAME! WIN PRIZES!

to Thank the Home Office, You're Invited...

### E&C ROCK & SHOCK SHOWCASE

Join us for Ice Cream & a Shockingly Good Time

### COMPETE FOR YOUR TEAM!

DATE: JULY 17th, TIME: 11 am to 3pm, PLACE: PDNA

MIS WARRIORS  
President's Office Human Resources  
TEAM FINANCE  
R&D-QA-MT NAVIGATORS  
SALES & MARKETING ALLSTARS

# Rocked & Shocked

**“Good Compliance Is Good Business!”**



- Increasing TAP's Reputational Capital
  - Internally
  - Externally
- Generating Revenue
- Licensed by:
  - Wal-Mart
  - Abbott
  - Pfizer
  - U.S. Food Service
  - Etc...

# Earning External Brand Equity that Translates into a Business Advantage



## eLearning program, AOV, wins several national awards

- The AOV e-learning program has won wide acclaim both internally and externally. Awards earned include:
- **2004 - Brandon-Hall.com Excellence in Learning Award – Silver Medal**
- **2005 – The Communicator Awards - Award of Distinction**
- **2005 – Telly Awards – Bronze Telly Award**

# TAP Pharmaceutical Products

## Ethics & Compliance Training – Next Generation



### The evolution of the program:

- Flexible
- Translatable
- Versatile
- Cost effective
- Engaging
- Provides results
  
- The next level

**What it is**  
**How to use it**  
**Demo it live!**  
**Testimonials**  
**For more information**  
**How to order**

**Give Your Training a Jolt!**  
Are you ready to...  
- Make training fun instead of frustrating?  
- Communicate your goals in an entertaining way?  
- Break down barriers between groups on hard-to-teach topics?  
- Create buy-in for your initiatives?

**Then get ready to be Rocked or Shocked!!**  
...because "Rocked or Shocked?"™ has proven capable of achieving all these training goals.

**The "Rocked or Shocked?"™ Interactive Experience is...**

- The only game that invites your target audience to help "train" their on-screen counterparts
- Completely designed and developed, ready to be branded for your company
- Multiple choice questions that can be customized for your organization
- Great for training or competition between sales or corporate groups
- A remarkable communication tool that works effectively through humor

"Rocked or Shocked?"™ is produced and provided by the Hildebrand Creative Group, Inc. (HCG) through a licensing agreement with TAP Pharmaceuticals Products, Inc. TAP owns the rights to this game, originally proposing the game and idea that HCG custom-developed for TAP.  
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[www.rockedorshocked.com](http://www.rockedorshocked.com)

# Earning External Brand Equity that Translates into a Business Advantage



- Implementation of preventative controls
- Development of control action plan for vendors
- Ability for tracking compliance performance and vendor comparisons

**Risk Control Matrix Approach**

<b>Accredited Program Controls</b>					
<b>Non-Accredited Program Controls</b>					
Controls					
ACCME					
Total Acc					
Non-Accr					
ACCME					
Total Acc					
OIG					
ACCME					
<b>Total Accredited Program Controls</b>					
<b>Non-Accredited Program Controls</b>					
<b>ACCME</b>					
<b>Total ACCME</b>					
<b>OIG</b>					
<b>Total OIG</b>					
<b>Total</b>					

## Feedback on RCM approach from audited vendor

“I found it to be a great tool for medical education companies to use in order to review pertinent industry guidelines that impact us daily. I also view this as a potential tool for pharmaceutical companies to provide their marketing partners with clear and specific direction on their interpretation of the guidelines as well as their expectations at the onset of a contractual relationship.”

# "Good Compliance IS Good Business!"



## Earning External Brand Equity that Translates into a Business Advantage

The department's unique application of sales and marketing techniques, in conjunction with strong substantive materials, has resulted in earning brand equity with external entities that has translated into a business advantage. (Please see Attachment #4 for more details on the achievements listed below)

**Co-developed auditing tool earns praise of medical education vendor**

**eLearning program, AOV, wins several national awards**

**"Rocked or Shocked?" interactive experience licensed to other companies**

**TAP sales representatives have leveraged E&C Team and Program to win business**

These are only highlights of TAP's overall Ethics & Compliance Program. Please see the referenced Attachments and TAP's submissions in the other three categories of Monitoring and Auditing, Training, and Communication Best Practices for more detail.

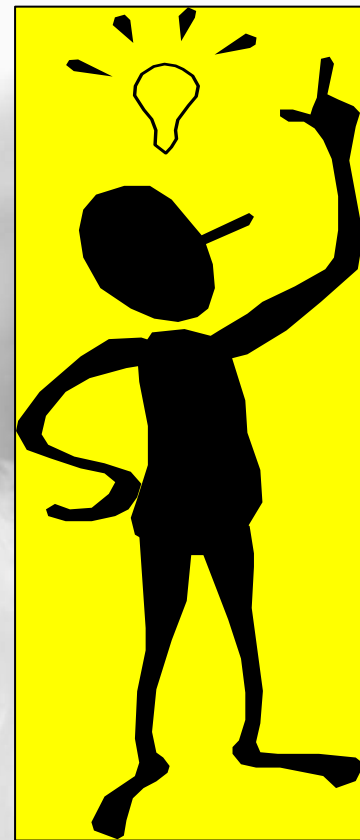
# "Good Compliance IS Good Business!"



## Additional Training Tools

- **TAPLINE "Question of the Week"** - In an effort to provide open communication for all TAP employees, we have communicated to employees through our company newsletter articles on the Hotline/Helpline and Helpline questions of the week (Fig. 9, 10).
- **Hotline/Helpline** resource - TAP has an internal Hotline/Helpline in place 24 hours a day, 7 days a week, for employees to report inappropriate activities and to request guidance on conducting their business affairs in an appropriate manner. (Fig. 11).
- **"Rocked or Shocked?"** – Computer-based, portable training tool that informs and educates in a fun delivery of ethics and compliance issues. (Fig. 12).
- **"Strike the Balance" Branding Elements** – Selected use of our internal brand on key documents that are "pulsed" regularly to TAP employees (Fig. 13).

# Q and A



# Contact Information



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