Pharmaceutical Industry Immersion Session ---
The Regulatory Enforcement Environment:
The PhRMA Code & the OIG Guidance

L. Stephan Vincze, J.D., LL.M., CHC
Ethics and Compliance Officer
TAP Pharmaceutical Products Inc.
Agenda

- **8:00 – 9:00 A.M.** Enforcement Environment, PhRMA Code & The OIG Guidance – Steve Vincze, Ethics & Compliance Officer TAP Pharmaceutical Products Inc.

- **9:00 – 10:00 A.M.** Panel Discussion: Hot Compliance Topics Between Health Systems, Physicians and Pharma – Charles Brock, Chief Ethics & Compliance Officer, Abbot Labs, Thomas H. Taylor, VP, General Counsel, Gundersen Lutheran Health System, Arthur J. Ross, III, M.D., Dir. Medical Education, Gundersen Lutheran Health System, Moderator: Steve Vincze

- **10:00 – 10:20 A.M.** Break

- **10:20 – 11:20 A.M.** Having Fun & Being Effective in Ethics & Compliance Training, Communications, HIPAA Implementation and Investigations – Mark Graves, Senior Manager, E&C Training, TAP, Christine Handel, Senior Manager, Audit & Review, TAP

- **11:20 – 12:00** Q&A with Panel – Brock, Taylor, Ross, Vincze
Overview/Learning Objectives

1. What Is PhRMA?
2. Who Is PhRMA?
3. What Has PhRMA Done?
4. Why Has PhRMA Done This?
5. What Has TAP Done to Implement the Code?
6. What Will TAP Do?
7. What Are the Benefits of the New PhRMA Code?
8. What is the OIG Guidance and how does it fit with the PhRMA Code?
9. Final Thoughts/Q&A
“Wisdom comes only through suffering.”

Aeschylus, Agamemnon, 458 B.C.
“There are only two forces that unite men – fear and interest.”

Napoleon Bonaparte
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
      - FDA
    - DOJ
    - Congress
- Media
- Public
What is PhRMA?

The Pharmaceutical Research and Manufacturers of America (PhRMA) is a non-profit association that represents the country’s leading research-based pharmaceutical and biotechnology companies.

[Go to www.phrma.org for more information.]
Who Is PhRMA?

Abbreviated Membership List

3M Pharmaceuticals
Abbott Laboratories
Allergan, Inc.
Amersham Health
Amgen Inc.
AstraZeneca LP
Aventis
Bayer Corporation Pharmaceutical Division
Boehringer Ingelheim
Bristol-Myers Squibb
Eli Lilly and Company
Fujisawa Healthcare, Inc.
GlaxoSmithKline
Hoffmann-La Roche Inc.
Johnson & Johnson
Ortho
Merck
Novartis
Pfizer Inc
Pharmacia Corporation
Procter & Gamble Company
Sanofi-Synthelabo Inc.
Schering-Plough Corporation
SCHWARZ PHARMA, INC.
Serono, Inc.
Solvay Pharmaceuticals, Inc.
Wyeth
On April 18, 2002, the PhRMA Executive Committee voted *unanimously* to adopt a new PhRMA Code on Interactions with Healthcare Professionals.

The *voluntary* code outlines guidelines for how sales rep’s and others involved in marketing should interact with healthcare professionals.

Took effect on July 1, 2002.
Main Points of PhRMA Code

- **General Interaction** – Should focus on informing healthcare professionals about scientific and educational information and supporting medical research to maximize patient benefits.

- **Entertainment** – Interaction should NOT include entertainment (no golf, sporting events, recreational events, etc.)
  - Only meals allowed at venues conducive to providing scientific and educational information -- no spouses or guests -- $100/HCP or less.

- **Continuing Education** – Can provide support for conference sponsor but not individual participation.
What Has PhRMA Done? (cont’d)

Main Points of PhRMA Code (cont’d)

- **Consultants** – Legitimate consulting OK (i.e., retention based on expertise, not as reward or inducement for prescribing, only retain what is needed not more) but token consulting is not.

- **Gifts** -- “Educational & Healthcare Practice-Related Items”
  - No personal benefit items (No golf balls, tennis balls, flowers, etc.)
  - Only items for healthcare benefit of patients worth $100 or less
    - E.g., office pens, notepads, anatomical models
Who qualify as “healthcare professionals?”

- Those people who interact with patients and who may affect purchasing or prescribing decisions and formulary status of pharmaceutical products
- Examples include physicians, nurses, office managers and administrative staff in a physician’s office

Does the new PhRMA Code apply to Wholesalers or Managed Care Organizations?

- Yes to wholesalers
- Yes to managed care executives, such as pharmacists, who can affect purchasing and prescribing behavior or formulary status
Has the new PhRMA Code eliminated charity events, such as charitable golf events?

No, however, each case will require review and approval by the Ethics & Compliance Office. The key will be to pay contributions directly to charities for the purpose of supporting bona fide charitable causes and not for recreational entertainment for health care professionals.
Who else will be implementing the new PhRMA Code and how will the industry police itself?

- All the members of PhRMA have agreed to implement the new Code. (See slide #10.)

- Companies will report to each other through appropriate senior management channels known or suspected violations of the Code.
Why Has PhRMA Done This?

- To Voluntarily and Proactively Refocus the Pharmaceutical Industry to Scientific Medical Research and Education
- To Remove the Need for Government Regulation or Legislation
- To Improve the Industry’s Image & Reputation
- To Regain the Public’s Trust
What Has TAP Done?

- Implemented the PhRMA Code.
- Issued communications to the sales field (voice- and/or e-mail)
- Posted presentations and new PhRMA Code on TAP Ethics & Compliance Intra-net web site.
- Conducted training sessions in the field on new PhRMA Code
- Created new module on PhRMA Code for interactive computer-based Ethics and Compliance Training, “Acting on Our Values.”
- Issued talking points and Executive Summary of PhRMA Code to Sale Reps.
What Will TAP Do?

- Lead by example
  - Focus energy on implementing change and new rules, not getting around them

- Work with health care professionals to meet the spirit and letter of the new PhRMA Code by providing quality information and spending quality time to address how TAP products can meet physician and patient health care needs.

- Focus on the science of pharmaceuticals and medicine.
What Are the Benefits of the New PhRMA Code?

- New PhRMA Code will:
  - Re-focus on science of pharmaceuticals
  - Shift battleground from entertainment to scientific and medical research, education and core communication skills
  - Make life simpler
  - Shift resources ($$$) from entertainment to research and clinical studies
  - Serve the industry and the public well
The OIG Compliance Guidance

- Evolution & History
- Legal Status – “Guidance”
- Risk Areas
1. Integrity of Data for State and Federal Payments
2. Kickbacks and Other Illegal Remunerations
3. Drug Samples Laws & Regulations (PDMA)
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 …”
## Effective Ethics & Compliance Results

<table>
<thead>
<tr>
<th>Increases</th>
<th>Reduces</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Precision and Accuracy of Documentation</td>
<td>- Inaccuracies Leading to Mistakes or Poor Decisions</td>
</tr>
<tr>
<td>- Quality of Decision Making and Operational Efficiency</td>
<td>- Risk of Government Investigations</td>
</tr>
<tr>
<td>- Employee Competence, Morale, Loyalty and Productivity</td>
<td>- Risk of Whistleblower or Other Suits</td>
</tr>
<tr>
<td>- Customer/Public Trust Satisfaction &amp; Security</td>
<td>- Employee/Customer Dissatisfaction &amp; Turnover</td>
</tr>
</tbody>
</table>

### Financial Impact

- **$\$ Revenue/QUALITY $\$**
- **$\$ Costs/FINES $\$**

*Acting on Our Values*
What’s Ahead?

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

Compliance Effectiveness
What’s Ahead?

- A Theme of Partnership and Common Purpose Between Public & Private Sectors
“With regard to excellence, it is not enough to know, but we must try to have and use it.”

Final Thoughts

Good compliance is good business!
Acting on Our Values
Contact Information

Steve Vincze
Ethics & Compliance Officer
TAP Pharmaceutical Products Inc.
675 North Field Drive
Lake Forest, IL 36106
Tel. (847) 582-6301
Fax. (847) 582-5006
e-mail: steve.vincze@tap.com
Acting on Our Values

Thank You!