



Monday, October 19
9:00 am–10:30 am

301 How to “Globalize” an Effective US Compliance Program

Roy Birnbaum

Senior Legal Director, International
Schering-Plough Corporation

Mark Ehrlich

Director, Business Conduct and Compliance
AES Corporation

Lawrence Weiss

Vice President-Chief International Counsel
Covidien

Alexandra Wage

Chief Legal Officer
Trace International, Inc.

Faculty Biographies

Roy Birnbaum

Roy B. Birnbaum is senior legal director, international law, at Schering-Plough Corporation, Kenilworth, New Jersey. He is responsible for general legal support to all company operations in the Asia Pacific region, including Japan.

Prior to joining Schering-Plough, Mr. Birnbaum held similar positions with Pfizer Inc., Pharmacia Corporation and its predecessors, located in New Jersey, Hong Kong and Michigan. He has also worked as a foreign legal consultant with the law firm of Kim & Chang in Seoul, Korea and began his career in private practice in Washington, DC.

Mr. Birnbaum does pro bono work for various non-profit organizations in New Jersey through assignments from Pro Bono Partnership.

Mr. Birnbaum received a BA from Brandeis University and is a graduate of the Harvard Law School.

Mark Ehrlich

Mark Ehrlich serves as director, business conduct and compliance for The AES Corporation, in Arlington, VA, a global power company with operations in 29 countries. AES business lines include traditional energy generation, renewable and alternative energy generation (wind, solar, hydroelectric, biomass), electricity distribution, and climate change projects. Mr. Ehrlich is responsible for implementation and operation of the AES ethics and compliance program, including training and communications, internal investigations, and transaction risk mitigation.

Prior to joining AES, Mr. Ehrlich served as director, ethics and business conduct at MCI where he designed the ethics and compliance program following the discovery of WorldCom's financial improprieties including drafting a code of conduct, establishing a confidential help line, developing internal investigation procedures, and launching company-wide ethics and compliance training. In addition to his work in the ethics and compliance field, Mr. Ehrlich also has extensive litigation and regulatory experience. He held positions with the MCI litigation and regulatory support groups, served as an attorney advisor in the Wireline Competition Bureau of the Federal Communications Commission, and was a trial attorney with the U.S. Department of Justice in the Civil Division's Commercial Litigation Branch.

Mr. Ehrlich is a graduate of Harvard Law School with an undergraduate degree from the University of Michigan. Mr. Ehrlich clerked for the Honorable Roger B. Andewelt of the United States Court of Federal Claims.

Lawrence Weiss

Lawrence Weiss is Covidien's chief international counsel, managing the company's international legal staff in Mansfield, MA. Covidien was originally Tyco Healthcare, which spun off from Tyco and was renamed. Covidien has worldwide sales of medical devices, supplies, imaging products and pharmaceuticals of approximately \$10 billion in over 130 countries and employs over 43,000 employees in 57 countries. Mr. Weiss joined Tyco Healthcare, supporting the company on a variety of corporate, transactional, and compliance matters including developing training programs addressing antitrust law, compliance with the US fraud and abuse regulations, and the implementation of an international trade compliance program. Mr. Weiss was named vice president and chief international counsel, in anticipation of Tyco Healthcare's separation from Tyco, and created the company's first dedicated international legal staff.

Prior to joining Tyco Healthcare, Mr. Weiss worked as an associate in the corporate department of Goodwin Procter, concentrating on corporate transactions, securities offerings and compliance.

Alexandra Wrage

Alexandra Wrage is the president of TRACE in Annapolis, MD, an international non-profit membership association working with companies to raise their anti-bribery compliance standards. She is also the author of *Bribery and Extortion: Undermining Business, Governments and Security* and the host of the training DVD "Toxic Transactions: Bribery, Extortion and the High Price of Bad Business."

Ms. Wrage is chair of ACC's International Legal Affairs Committee, chair of the Women in International Regulatory Law ("WIRL") steering committee, co-chair of the ABA's anti-corruption committee, and a member of the working group for the United Nation's Global Compact 10th Principle. Ms. Wrage has written three guidebooks: *The TRACE Standard for Doing Business with Intermediaries Internationally*, *The High Cost of Small Bribes*, and *First to Know: Robust Internal Reporting Programs*. She speaks frequently on topics of international law, anti-corruption initiatives and the hidden costs of corruption. Ms. Wrage was named as one of the 100 most influential people in business ethics for by *Ethisphere Magazine* and as one of Maryland's innovators of the year for *BRIBELINE*.

Ms. Wrage studied law at Kings College, Cambridge University.

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Elements of an Effective Compliance Program

- Clear Policy, communicated effectively
- Strong controls
- Management accountability
- Effective training
- Monitoring and enforcement
- Ombudsman/concern-line for employees to report concerns
- Discipline / remediation

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Challenges Presented by Globalization

- Transmit corporate culture across diverse countries and local cultures
- Make "tone at the top" local
- Communicate policies and standards in a simple way that global employees can understand
- Reconcile corporate values with local values, norms and customs;
- Conflicting or contradictory local laws and regulations

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Example: FCPA for Medical Device/Life Science Companies

- Employees ex US may think of "foreign government officials" only as obvious public officials
- In many countries with extensive govt involvement in health care, every sales call with a health care professional may be a contact with a foreign government official
- Therefore, the number of employees who require training is higher than other industries with more discrete interactions with government employees
- Use of terms like "bribery" can create a disconnect with the employees targeted for policy communication and training
- Local customs may conflict with corporate values and US expectations
- M&A targets may have outgrown international infrastructure
- Use of distributors and other 3rd party agents
- Globalization of our industry and different cultures

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Example: FCPA for Medical Device/Life Science Companies

- Incorporating unique pharmaceutical/life sciences elements into an effective FCPA compliance program
 - The purpose of compliance policies and training
 - Dealing with government employees – state owned hospitals
 - How (or whether) to define who a "government employee" is
 - Training sales and marketing and other employees to recognize "government officials"
 - Setting standards for common business activities
 - Sponsoring attendance at medical conferences
 - Engaging health care professionals for speaking, consulting service

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Globalization of Compliance

- Begin with uniform high level conduct-based standards that apply across all divisions and geographies
- Identify key "customers" of a policy and get their input up front
- Develop more detailed local standards based upon local laws, regulations, industry codes of conduct and legitimate social customs (e.g., socially customary gifts)
- Eliminate risks where possible (i.e., prohibit payment of "facilitating payments" (even though these are allowed by the FCPA)).
- Remove decision-making in "gray areas" by employees who are not experts in legal requirements, either by forbidding conduct that is close to the line of what is permissible or by requiring higher-level approval.

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Law and Policy Interaction

Clear Legal Requirements

Buffer Zone

Policy Requirements

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Challenges Presented by Globalization: Implementation, Communication and Training

- The importance of examples and not just reciting rules
- Employees learn best when they can apply what they have learned:
 - case studies
 - scenarios
 - examples
 - role-playing
- Use real-world situations - incorporate lessons learned from internal investigations and hotline calls and external publicity on other companies into training
- Feedback – incorporate feedback from the audience and loop that back into future training (or amendments to the policy if appropriate) – voice of the customer

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Challenges Presented by Globalization: Implementation, Communication and Training

- Ensure employees see a positive example from their managers
- Covidien "Ethics Circles", Schering-Plough compliance "board game" (quizzes, scenarios, role playing, 2 way communication, internal competition)
- Incorporate compliance/ethics into performance reviews
- Incorporate compliance/ethics into periodic operating reviews (make it part of the operating review template)
- Incorporate training, contract language requirements, etc., into SOx controls
- Emphasize increase in global enforcement activity and individual liability

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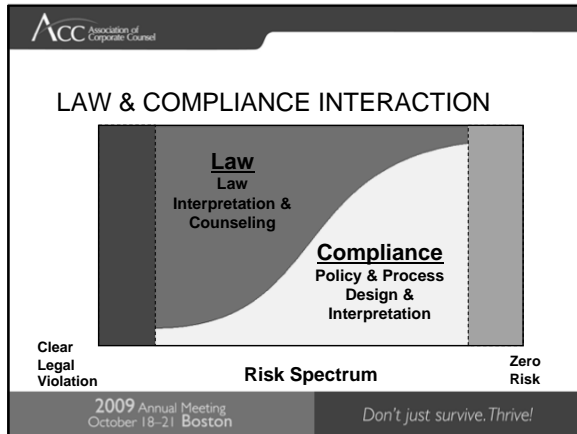
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Mechanics and Logistics of Global Training

- Training should be delivered by local legal or compliance team or local management, and local law should be incorporated (U.S. lawyer lecturing on U.S. law may not be particularly effective)
- Go to the business - try to attend business/sales meetings rather than inviting business employees to attend training in isolation
- Most effective if person delivering the message has a relationship with the business
- Translating live and on-line materials can be expensive, but is necessary

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Policy Number: C-112

CORPORATE POLICY

CONFLICT OF INTEREST, GIFTS AND ENTERTAINMENT

Giving of Gifts and Entertainment

Except as otherwise specifically provided in this or another Schering-Plough policy, **employees may not give money or its equivalent (i.e., gift certificate) to any present or potential customers, vendors, suppliers, contractors or partners of Schering-Plough, unless it is a donation and meets the requirements set forth in C-107, Charitable Contributions.**

Employees may not provide money or its equivalent, gifts, meals or entertainment of any value to any government employee, unless specifically allowed by law. Prior to the transaction, employees should consult with a company attorney or a compliance officer to confirm the legality of anything to be provided to a government employee.

Any gift provided by a Schering-Plough employee to a present or potential customer, vendor, supplier, contractor or partner of Schering-Plough must be modest in value, designed to create goodwill and establish trust in a business relationship and not reasonably be expected to affect the recipient's independent judgment in the performance of his/her job. All such gifts should, wherever practical, bear the Company or business unit logo. Even gifts of modest value may not be permitted if they become frequent or are conditional. In all cases, the giving of gifts, meals or entertainment must comply with applicable industry codes and local law.

In certain countries and under certain circumstances the exchange of gifts may be traditional and customary; failure to participate in this custom may be offensive or disturbing and thereby damage Schering-Plough's reputation. **In such countries the business must have an appropriate and approved policy to address local custom that is consistent with and no less restrictive than this policy.**

Except where prohibited by law or other company policy (i.e., U.S. Sales and Marketing Policy), modest and appropriate meals and entertainment may be provided to persons who have or potentially may have business with Schering-Plough. Such meals and entertainment must be in connection with business discussions and where the primary purpose of the meeting is business related. A Schering-Plough employee must be present at the entertainment or meal; otherwise it is considered a gift and is subject to the separate standards above.

Cultural Customary Gifts**风俗礼品**

1. An inexpensive gift not related to the practice of medicine may be given on an infrequent basis to doctors in acknowledgment of the official holidays of China.

销售/市场人员可偶尔在节日场合向医生赠送少量与医疗职业不相关的风俗礼品。

The cultural courtesy gifts should not be more than RMB 200 in value per person per holiday.

每人每个节日不超过200元人民币的礼品。

The aforementioned holidays include: Mid-Autumn Festival, Dragon Boat Festival, Spring Festival and National Day.

可赠送风俗礼品的节假日包括：中秋节、端午节、春节、国庆节。在这四个法定假日的当月，销售/市场人员可以向医生赠送风俗礼品。

Acceptable cultural courtesy gifts only include: flowers, fruits, moon cakes, rice dumpling (i.e. Zongzi) and rice cake (i.e. Niangao).

可赠送的风俗礼品包括：鲜花、水果、月饼、粽子、年糕。

2. Purchase of cultural courtesy gifts should be centralized to Marketing and Purchasing Department, except flowers and fruits. If sales people need to purchase the courtesy gifts by themselves due to some special difficulties in managing central purchase, prior approval from Purchasing Manager should be obtained. And the unit price should not exceed the central purchasing price.

除鲜花、水果外的风俗礼品的采购应集中于市场部和采购部。由于特殊原因无法统一采购而需要自行采购的，事先取得采购部经理审批，并且单价不应超过采购部统一采购的价格。

3. Sales people can purchase flowers and fruits in the field. The gifts shall be correctly reflected in the expense reports and get approval from District Manager. The gift receiver should be noted clearly with name, position, hospital etc.

销售人员可自行采购鲜花、水果，并在费用报告中如实予以反映，必须清楚地写明受礼人姓名、职位、所在医院/科室等，并交地区经理批准。

The value limits of purchase of flowers and fruits

<u>Position</u>	<u>Upper Limitation</u>	<u>Others</u>
PSR	RMB 150/person	Maximum 5 customers/doctors per event
SV	RMB 150/person	Maximum 10 customers/doctors per event
DM/PM	RMB 200/person	Maximum 10 customers/doctors per event

礼品的限额规定如下：

<u>职 位</u>	<u>最高限额</u>	<u>其 他</u>
PSR	人民币150元/每人	每次最多5个客户/医生
主管	人民币150元/每人	每次最多10个客户/医生
地区/产品经理	人民币200元/每人	每次最多10个客户/医生

Leading with Integrity 

Standards of Global Business Practices



*Standards of Global Business Practices intranet site:
<http://standards.us.schp.com/>*

*Global Compliance and
Business Practices department*

*Schering-Plough Corporation
2000 Galloping Hill Road
Kenilworth, N.J. 07033-0530*

*Integrity Action Line U.S.: 1-866-SPCORP-1
Integrity Action Line International:
AT&T U.S.A. Direct Service > 678-250-7535 >
8441569585 > 2309*



August 2007

Dear Colleagues:

Together, we have accomplished enormous positive change in our Company since we first issued our Standards of Global Business Practices in September of 2004. This transformation has been driven by our people, aligned around a new, high-performance way of working. At the center of our culture is operating with business integrity.

Business integrity means doing the right thing. It starts with following the letter and spirit of the law, as well as the letter and spirit of our own policies and procedures. But it also means following our own moral compass to do what is right, even when the rules are not clear. It means seeking advice when there is any doubt about what is right to do.


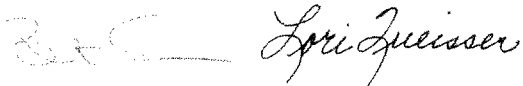
This booklet and the other elements of Schering-Plough's Global Compliance and Business Practices program are designed to give colleagues the knowledge they need to do their jobs in full compliance with the law and Company policies. All colleagues can be confident that whenever they do the right thing, they will receive the Company's full support.



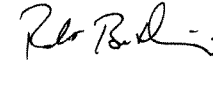
However, this booklet and our Global Compliance and Business Practices program are only guides. Ultimately, it is the responsibility of Schering-Plough colleagues, individually and collectively, to do the right thing.

Please read the booklet carefully. In addition to describing a number of important compliance laws and policies, it offers examples of some business integrity questions that you may face. However, it is not designed to answer every possible question that might arise. If you have questions about how the Standards apply to your responsibilities or a specific situation, seek advice from your manager or a member of the Global Compliance and Business Practices, Global Law or Global Human Resources departments. You can also contact any Executive Management Team member. Our signatures represent our commitment to the Standards of Global Business Practices and all the elements of "Leading with Integrity."

Sincerely,

Executive Management Team




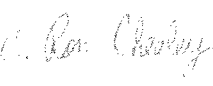





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The *Standards* do not alter the terms and conditions of your employment. Rather, they help each of us to know what is expected of us to make sure we always act with integrity.

Gifts and Entertainment

Exchanging social amenities or business gifts of a modest value such as small gifts, meals and entertainment is permitted as a common practice meant to create goodwill and establish trust in business relationships. Schering-Plough expects the use of good judgment and moderation when giving or receiving entertainment or gifts. Avoid situations that could compromise or appear to compromise your impartiality.

This means:

- * Business gifts or meals should never be conditioned upon, or be a reward for, purchasing, prescribing or promoting Schering-Plough's products and services.

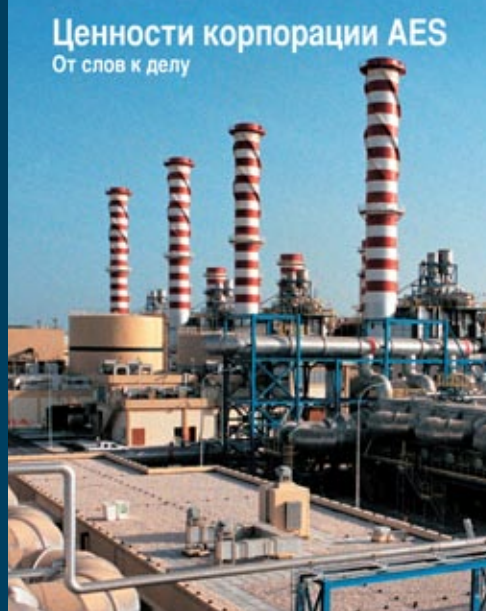
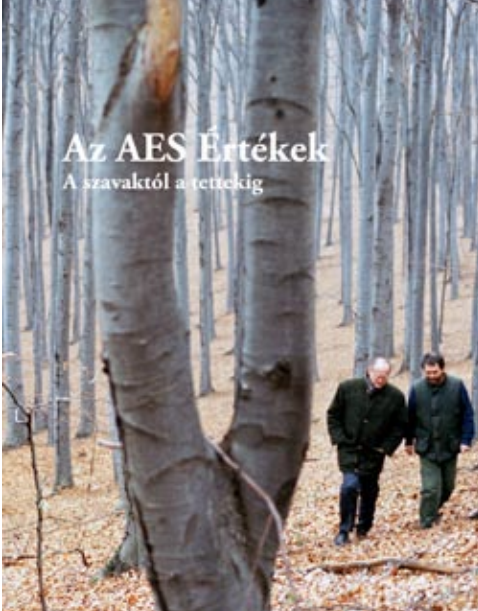
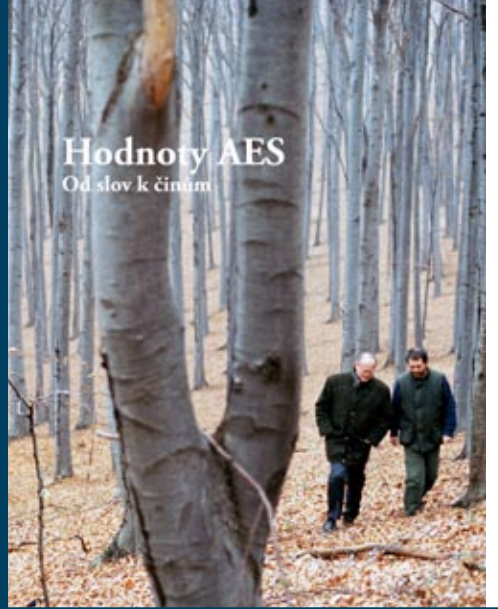
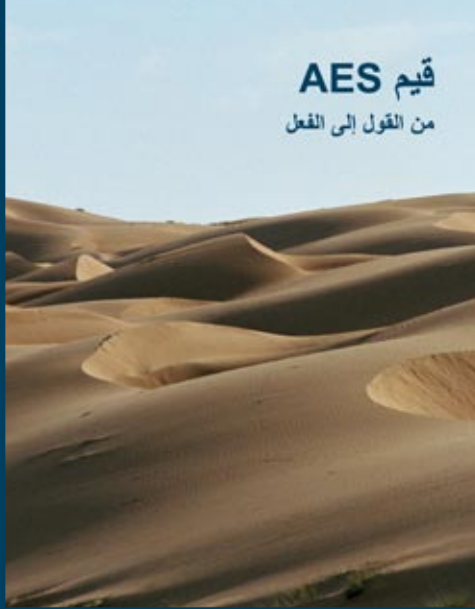
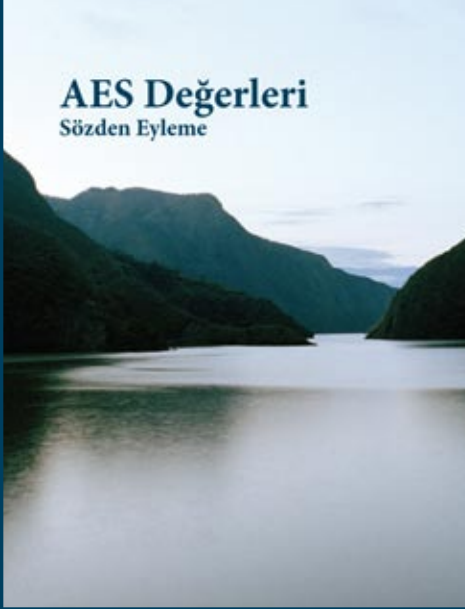
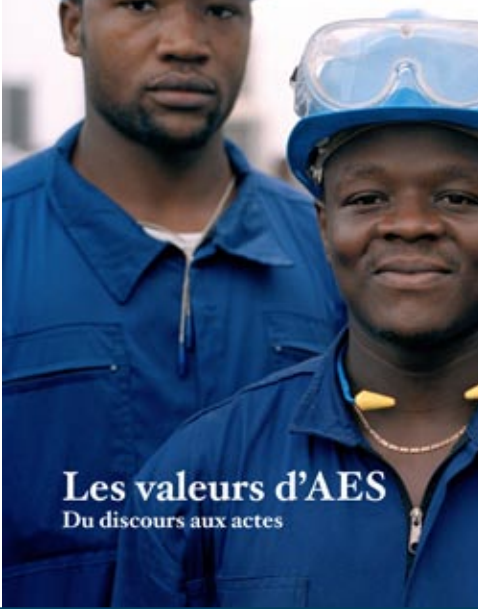
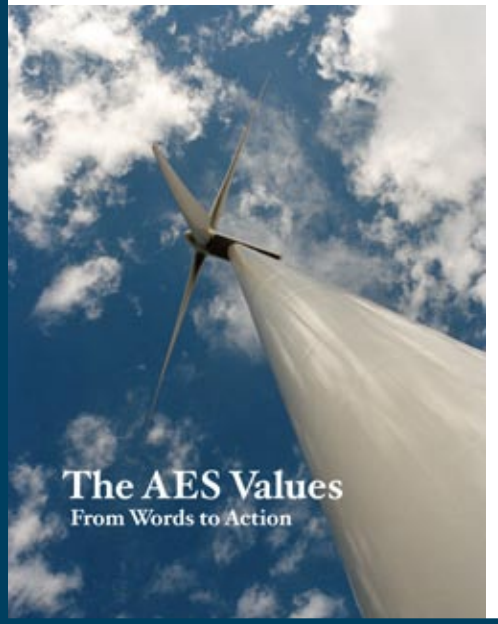
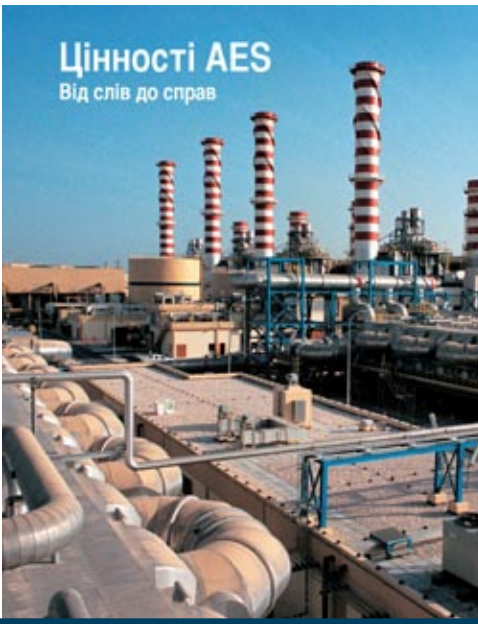
- * Business gifts or meals should be infrequent.
- * Gifts, meals and entertainment may be provided or accepted in the normal course of business as long as they:
 - Involve persons with whom Schering-Plough has or may have business;
 - Are reasonable and consistent with applicable laws and with accepted ethical standards and local business practices;
 - Are of modest value and properly recorded in Company records so they could not be construed as a bribe, payoff or kickback; and
 - Are not in violation of the rules of the recipient's organization.
- * Honorariums or fees for speaking or presenting on behalf of the Company should not be accepted.

provide money or its equivalent, gifts, meals or entertainment of any value to any government employee, unless specifically allowed by law. Laws concerning this matter are often complex and vary from country to country. Before offering or accepting any gifts, meals or entertainment to or from a government official, consult with the Global Law department or your local Compliance Officer.

 *Conflict of Interest, Gifts and Entertainment Policy C-112.*

What is considered "modest" may vary, depending on the country in which we are doing business. Certain exceptions to the *Standards* may be made in countries where differing practices are customary with approval of your management in consultation with your local Compliance Officer. Any questions regarding the appropriateness of a gift should be addressed with local management and your local Compliance Officer.

Special gift and entertainment rules apply to government employees. Schering-Plough colleagues may not



FIVE VALUES

ONE COMMUNITY

- Put Safety First
- Act With Integrity
- Honor Commitments
- Strive For Excellence
- Have Fun Through Work



ACC Extras

Supplemental resources available on www.acc.com

Corporate Compliance

InfoPak. August 2009

<http://www.acc.com/legalresources/resource.cfm?show=19684>

The Global Compliance Landscape: A Resource File

Dec 2005

<http://www.acc.com/legalresources/resource.cfm?show=20817>

In-House Counsel Perspective: Managing a Compliance and Ethics Program
in a Global Environment

Program Material. July 2008

<http://www.acc.com/legalresources/resource.cfm?show=19803>

401 Global Harmonization of Codes of Conduct.

Program Material. May 2006

<http://www.acc.com/legalresources/resource.cfm?show=20242>

Please note, these additional resources are provided by the Association of Corporate
Counsel and not by the faculty of this session.