

The Third International Pharmaceutical Regulatory and Compliance Congress and Best Practices Forum

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This presentation represents my own personal
opinion and is not the official position of
Bristol-Myers Squibb

PhRMA Code 2009

- Updated in response to concerns of healthcare stakeholders
- Reaffirms that interactions between pharmaceutical company representatives and healthcare professionals (HCPs) should:
 - Inform HCPs about the benefits and risks of our products
 - Provide scientific and educational information
 - Obtain feedback and advice about our products through consultation with medical experts
- The PhRMA Code is the new industry standard

PhRMA Code Signatory Companies

- Abbott
- Amgen, Inc.
- Amylin Pharmaceuticals, Inc.
- Astellas US LLC
- AstraZeneca LP
- Bayer HealthCare Pharmaceuticals
- Boehringer Ingelheim Pharmaceuticals, Inc.
- Bristol-Myers Squibb Company
- Cephalon, Inc.
- *Covidien Ltd.*
- Daiichi Sankyo, Inc.
- Eisai, Inc.
- EMD Serono
- *Endo Pharmaceuticals, Inc.*
- Genzyme Corporation
- GlaxoSmithKline
- Hoffmann-La Roche, Inc.
- Johnson and Johnson
- Eli Lilly and Company
- Merck & Company, Inc.
- Millennium Pharmaceuticals, Inc.
- Novartis Pharmaceuticals Corporation
- Novo Nordisk Inc.
- Otsuka America, Inc.
- Ovation Pharmaceuticals, Inc.
- Pfizer, Inc.
- Purdue Pharma LP
- sanofi-aventis US
- Schering-Plough Corporation
- Sepracor, Inc.
- Signa-Tau Pharmaceuticals, Inc.
- *Solstice Neurosciences, Inc.*
- Solvay Pharmaceuticals, Inc.
- Takeda Pharmaceuticals North America, Inc.
- Wyeth

Spirit of the Revised Code

- Ethical relationships with healthcare professionals are critical to our mission of helping patients by developing and marketing new medicines
- We are committed to following the highest ethical standards as well as legal requirements
- Discussions with healthcare professionals are designed to benefit patients and enhance the practice of medicine
- Interactions should be focused on informing healthcare professionals about products, providing scientific information and supporting medical education

PhRMA Code Revision Highlights

- Gifts/Educational Items
- Meals
- Speaker and Consultants
 - Compensation
 - Conflicts of Interest
 - Utilization
 - Entertainment
- CME Sponsorship and Support
 - Providing Advice
 - Funding Decisions
 - Meals

PhRMA Code Revision Highlights (continued)

- Responsible Use of Prescribing Data
- Promotional Material
- Training of Employees
- Compliance Mechanisms and Certification to the the PhRMA Code
 - Annual Certification
 - External Verification

Gifts: Prohibition of Non-Educational and Practice Related Devices

Items for healthcare professionals must advance disease or treatment education —

- a) even if they are practice-related items of minimal value (such as pens, note pads, mugs and items with company or product logos) — may foster misperceptions about company interactions with healthcare professionals
- b) non-educational items should not be offered to healthcare professionals or members of their staff

Educational Items

It is appropriate for companies, where permitted by law, to offer items designed primarily for the education of patients or healthcare professionals provided they meet the following criteria:

- Clearly educational
- Do not have substantial value (\$100 or less)
- No value to HCPs outside his or her professional responsibilities
- Occasional

And for educational items designed for patient use:

- Assist in the administration of their treatment or management of their condition
- Are essential to proper treatment or patient compliance

Informational Presentations by Pharmaceutical Company Representatives and Accompanying Meals

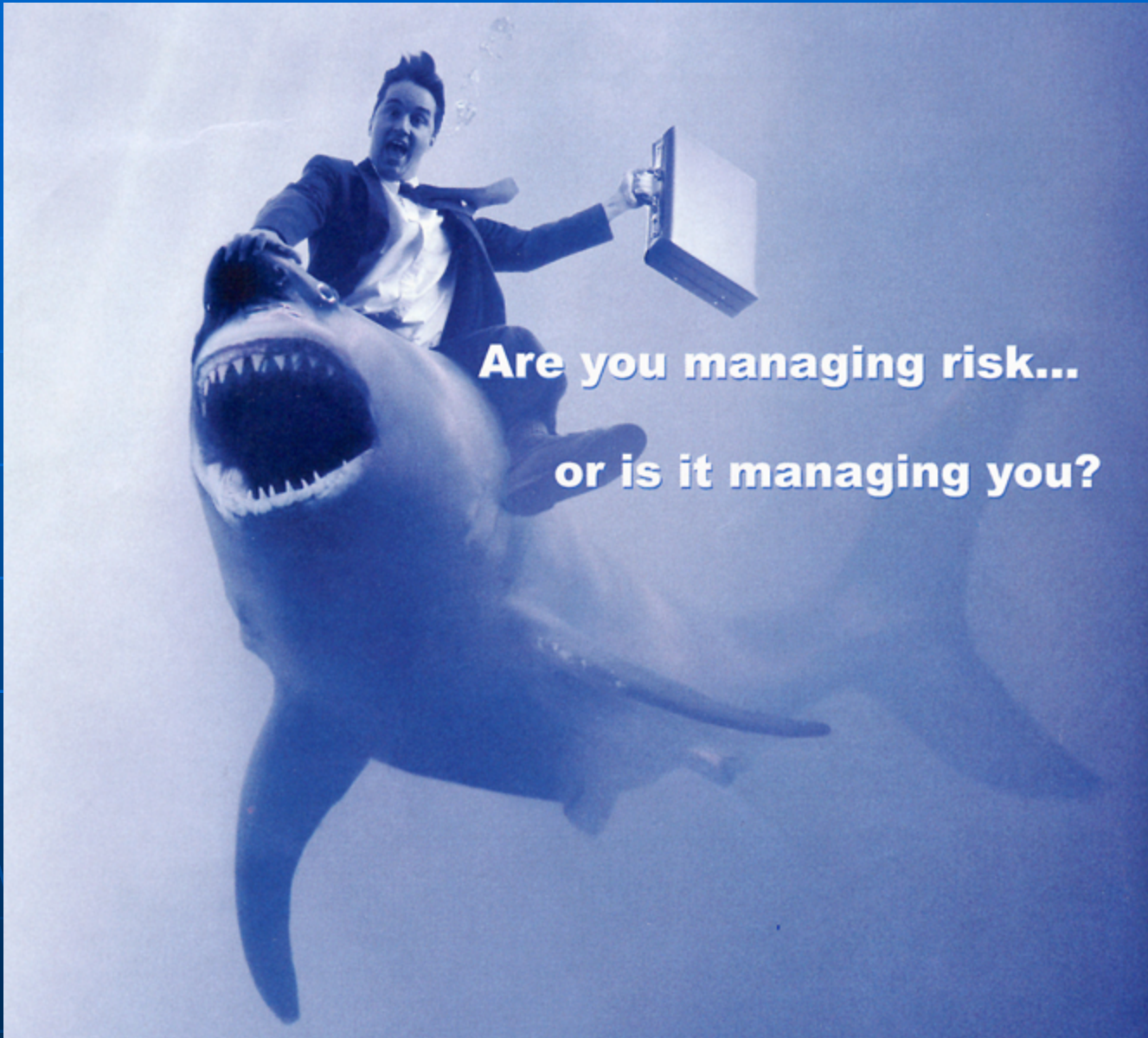
- In connection with informational presentations, occasional meals may be offered to healthcare professionals as a business courtesy
- Any such meals offered by field sales representatives or their immediate managers must be limited to in-office or in-hospital settings
- Field sales representatives or their immediate managers may not accompany other BMS employees who are permitted to have out of office meal interactions with HCPs

Additional updates to the PhRMA Code

- Prohibition on Entertainment and Recreation
 - Includes interactions with speakers and consultants
- Consultants
 - Contracts documenting legitimate need
 - Selection criteria
 - No recreation, entertainment or resorts
- Speaker Programs and Speaker Training Meetings
 - Fair Market Value
 - Utilization
 - Speaker caps
 - Continuing Medical Education
- Healthcare professionals who are members of committees that set formularies or develop clinical practice guidelines
 - Must disclose their pharmaceutical company relationships to the committee

Additional updates to the PhRMA Code

- Pharmaceutical Company Support for CME
 - No advice or guidance on content or faculty even if requested by provider
- Prescriber Data
 - Responsible use
 - Policies in place
- Adherence to Code
 - Annual certification by CEO and Chief Compliance Officer
 - Recommends obtaining a periodic, external verification of the compliance policies and procedures at least every three years



**Are you managing risk...
or is it managing you?**