

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

Thomas E. Costa

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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

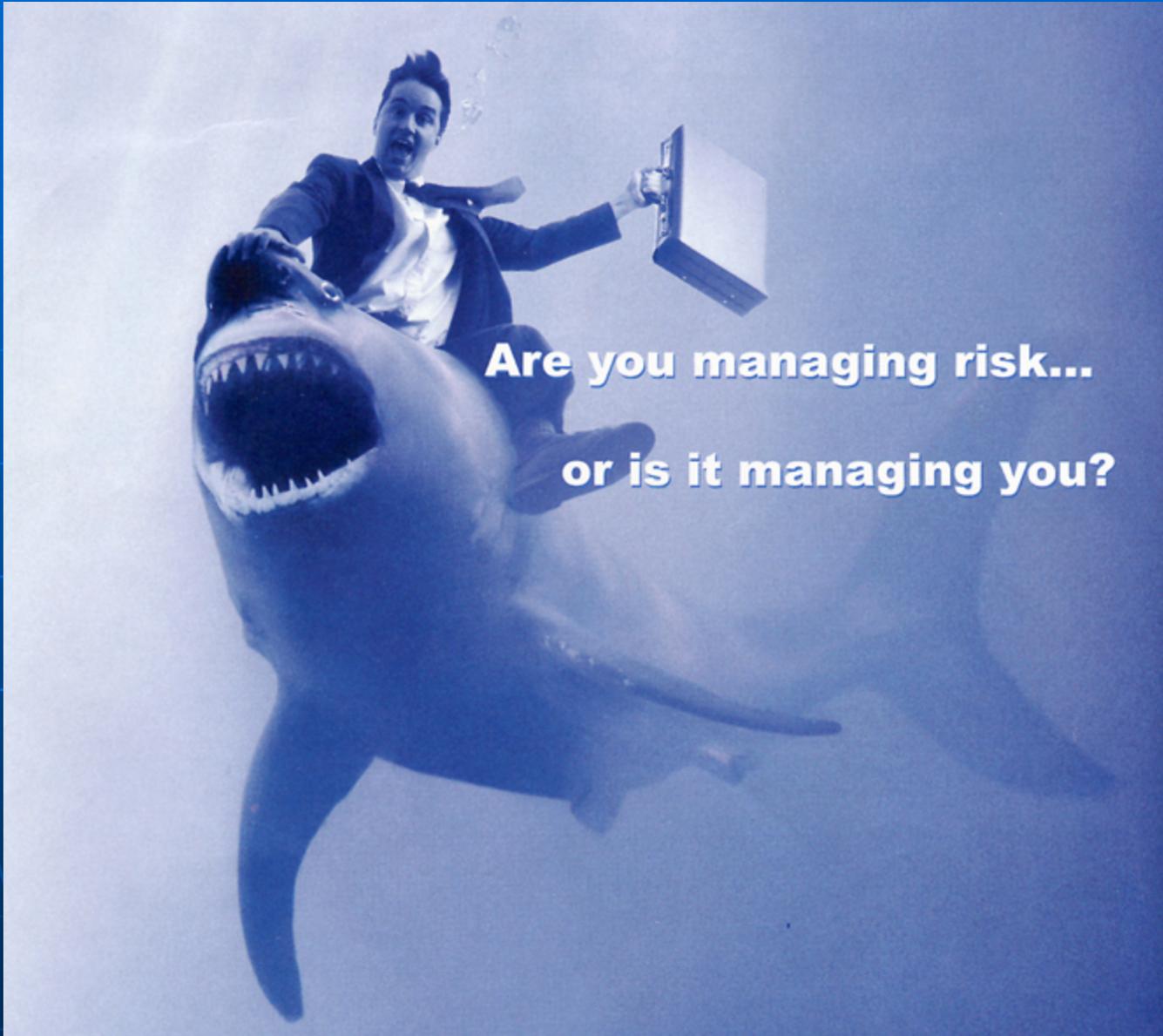
- In connection with informational presentations, occasional meals may be offered to healthcare professionals as a business courtesy
- Any such meals offered by field sales representatives or their immediate managers must be limited to in-office or in-hospital settings
- Field sales representatives or 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?**