The Ninth Annual Pharmaceutical Regulatory 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

OIG Compliance Guidance (2003)

- OIG guidance highlights potential risk areas for a pharmaceutical manufacturer
  - Purchasers
  - Physicians and other health care professionals
  - Sales agents
- Separation of grant-making functions from Sales & Marketing
- Adherence to PhRMA Code substantially reduces risk

Key Elements of the BMS Compliance Program

- Written Standards of Conduct
- Chief Compliance & Ethics Officer
- Education and training programs
- Communication and complaint processes
- Auditing and monitoring Sales & Marketing
- Investigating non-compliance and misconduct
- Corrective actions (coaching and disciplinary action as necessary, up to and including termination)

Settlements and CIAs ($ in Millions)

- 2001 TAP $ 875
- 2003 Astra-Zeneca $ 355
- 2004 Pfizer $ 430

(Warner Lambert/Parke-Davis Division)

- 2004 Schering-Plough $ 345
- 2005 Serono $ 704
- 2005 Eli Lilly $ 36
- 2006 Schering-Plough $ 435
- 2006 InterMune $ 36.9
- 2007 Cell Therapeutics $ 10.5
- 2007 Medicis $ 9.8

Settlements and CIAs ($ in Millions)

2007 Pfizer (Pharmacia) (Pharmacia & Upjohn)	$ 34.7
2007 Purdue Frederick	$ 634.5
2007 Sanofi-Aventis	$ 190
2007 Jazz Pharmaceuticals	$ 20
2007 Bristol-Myers Squibb	$ 499
2007 Merck	$ 670
2008 Otsuka	$ 4
2008 Biovail	$ 25
2008 Merck	$ 58
2008 Cephalon	$ 425

BMS Settlement

- In September 2007 after a long running healthcare law investigation, BMS entered into a civil settlement with the government and paid a $499 million fine.

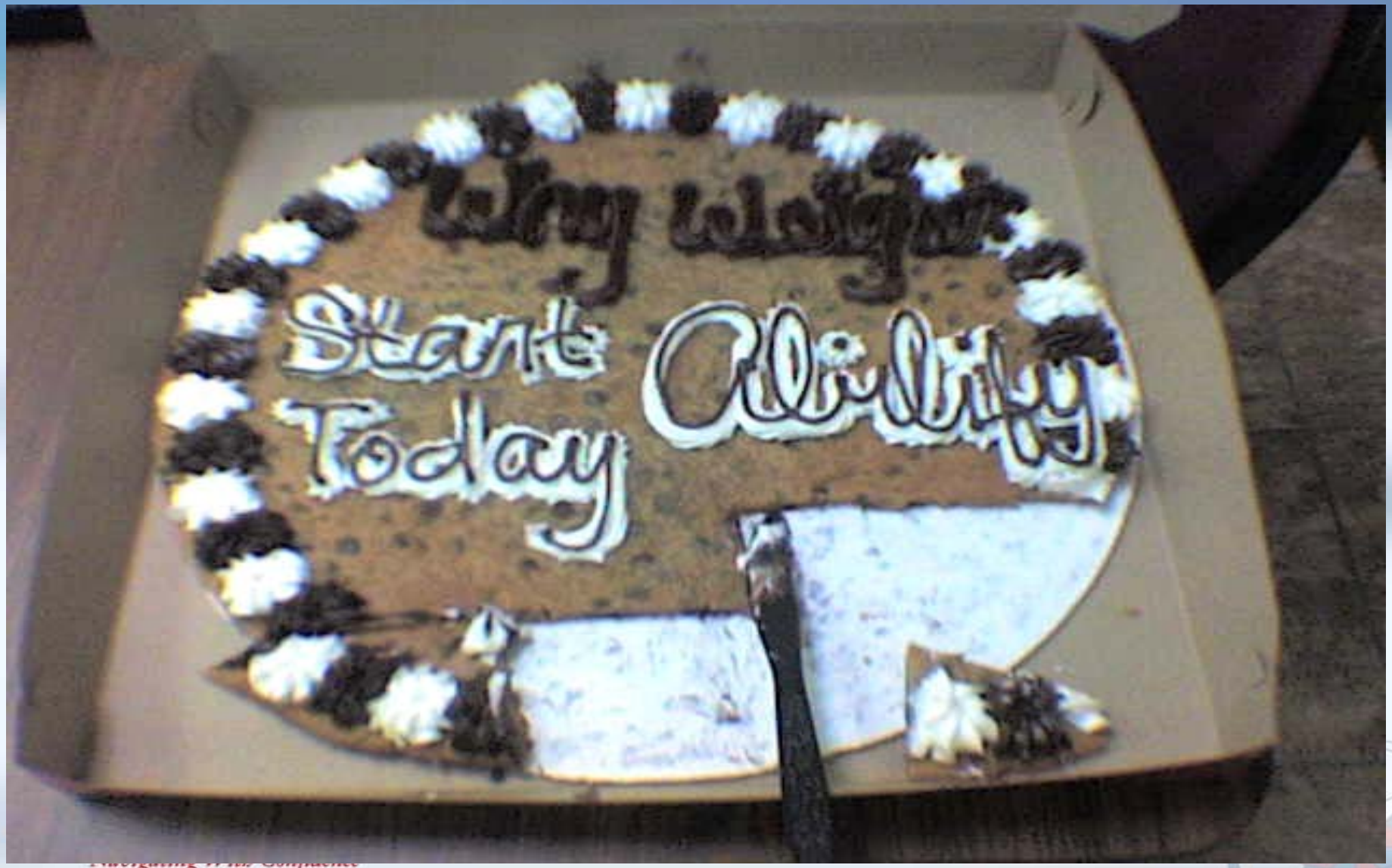
- Government allegations:
  - Payments (consulting fees) and lavish entertainment were used to influence health care professionals (HCP) prescribing habits
  - Promotion of Abilify for "off-label" uses - pediatric and dementia-related psychosis
  - Pricing-related practices

- Negotiation of a Corporate Integrity Agreement (CIA)

CIA Basics

- Key Issues:
  - Address off-label promotion and activities that could drive off-label use, e.g. call planning and incentive compensation
  - Kickback issues
  - Data calculation and price reporting
- Scope:
  - US Pharmaceuticals and individuals who provide support for promotional and product services and government pricing and contracting functions (Covered persons)
- Term: Five years (9/26/07-9/25/12)

Digital Age



Track 1 New Hire Training

- 12 hours of training
- Must be completed within 30 days of employment
- On-line modules:
  - Meals and Entertainment
  - Standards of Business Conduct & Ethics
  - PDMA Sample Certification
  - Adverse Events

- U.S. Pharmaceuticals Compliance Field Handbook
  - 2009 PhRMA Code
  - Standards of Business Conduct & Ethics
  - Code of Conduct

Track 2 New Hire Training

- Two-hour Compliance workshop
  - Policies and procedures

- Opportunity to focus on Compliance issues
  - Reprints
  - Call Plans
  - Medical Information Request Forms

Home Office and Field Monitoring

- Verbatim reviews
- Medical Information Request Form (MIRF)
- Compliance staff ride-alongs with sales representatives
- Call plan development (*i.e.*, target lists)

Key Ongoing Activity

- IRO review of Promotional & Product Service Systems
- Continued screening, certification and training for new "covered person" employees
  - Training required to be completed within 30 days.
- Vendor Management for Code of Conduct certification and screening
  - Assuring contract language is being incorporated into new and existing contracts.
- Audit & Monitoring Programs
  - Medical Information Requests Form (MIRF) process
  - Verbatims
  - Field Force Monitoring (30 rep rides per reporting period)
  - IME Grants review

Keep the OIG Fully Informed

- Periodic compliance reports and updates to OIG
- Certifications from the Chief Compliance and Ethics Officer and Senior Management
- An Independent Review Organization will report its findings to the OIG.

Compliance Message

- When in doubt, consult the U.S. Pharmaceuticals Compliance Field Handbook
- Teams to help you:
  - Sales and Marketing
  - Law
  - Compliance

- Use the US Healthcare Law Resource Center:
  - http://onebms.bms.com/ushclcompliance
- BMS Helpline: 1-800-348-5526