Medicine and the Pharmaceutical Industry - How Did We Get Here? Where Are We Going?

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Faculty Disclosures:

Dr. Way and Dr. Fenstemacher have disclosed that they have no relevant financial relationships.
Learning Objectives:

By the end of the session, participants will be able to:

• Describe the history of the relationship between prescribers and the pharmaceutical industry.
• Analyze the current status and impact of this relationship on individuals, healthcare institutions, and government.
• Compare the benefits and burdens of a system in which the pharmaceutical industry finances the prescribers.
Introduction

• Increasing Awareness
  – Changing Regulations
    • Increasing restrictions on industry-prescriber interactions
  – Decreasing funding for CME

• Controversial Areas
  – Prescribing Data
  – Direct to Consumer Advertising
Financial Reality

- Industry sponsored CME - $1.44 Billion in 2006
- U.S. drug market sales over $200 Billion in 2010, industry profits most from branded 35% of the total
- $258 Million in payments given to 17,700 healthcare professionals by 7 companies in 2009 – 2010 (Ave. $14,576)

Pharma Marketing News 2009; 8(7)
meetingsnet.com June 2009
www.propublica.org
Financial Reality

• Medical Devices
  – One of the fastest growing industries
  – US sales were $86 Billion in 2006
  – Growth rate projected to be 10% annually

AdvaMed 2006
Prescribing Influence . . .
PhRMA and the Prescriber

- Prescriber Influence
  - Prescriber Awareness
  - Financial reality
  - Research Evidence

- Prescriber Profiling

- DTC Advertising
PhRMA Influence

Product Information
- Meals
- Pens
- Perks

Physician-PhRMA Relationships
- Speakers
- Consultants
- Research – seeding trials

Samples

DTC Advertising
- Prescriber-Patient interaction
- Prescriber
PhRMA Payments to Massachusetts Prescribers in 2009

Source: DPH, available at [www.mass.gov/dph/pharmamed](http://www.mass.gov/dph/pharmamed)
Prescriber Awareness

“Overall Pharmaceutical Representative interactions were perceived as beneficial by most participants.”

“A pervasive belief that prescribing is not adversely influenced by PR detailing”

J Gen Intern Med 2009; 24(7):795–801
Physicians and the Pharmaceutical Industry
Is a Gift Ever Just a Gift?

- Objective – to identify the extent and attitudes toward the relationship and its impact on physician knowledge, attitudes and behavior
- Study design - Medline Search, 29 studies were included
- Conclusion – The present extent of physician-industry interaction appears to affect prescribing and professional behavior and should further be addressed at the level of policy and education

JAMA, 2000;283 (3):373-380
Physicians and the Pharmaceutical Industry
Is a Gift Ever Just a Gift?

– Interactions were generally endorsed, they began in medical school, there were four per month

– Detailing resulted in
  • Drugs being added to hospital formularies
  • Changes in prescribing practice

– CME Event
  • Highlight the sponsor’s drug
  • If funding for travel and lodging was accepted, sponsor's prescription rates increased

– Sponsored presentation
  • Associated with nonrational prescribing

JAMA, 2000;283 (3):373-380
Prescriber Awareness

• Background - Physicians do not believe that promotion affects their own prescribing but studies have shown that promotion increases prescribing of targeted drugs

• Goal - assess the effect of education on physician attitudes toward promotion of drugs

• Study Design – PharmedOut a Georgetown based project educated physicians on prescriber influence and then assessed their attitudes with pre and post tests

*J Cont Ed Healthcare Prof 2010; 30(3):197-204*
Prescriber Awareness

• Results:
  – Drug reps influence what I prescribe
    • 12% to 28% change in “strongly agree”
    • 53% to 81% change in “agree” (somewhat to strongly)
  – Pens, pads and sticky notes influence physicians’ prescribing behavior
    • 1% to 10% change in “strongly agree”
    • 37% to 51% in “agree” (somewhat to strongly)
  – Overall, drug samples are beneficial to patient care
    • 73% to 50% change in “agree” (somewhat to strongly)

*J Cont Ed Healthcare Prof 2010; 30(3):197-204*
Historical Perspective of Prescriber Profiling

- **Prior to early 1940’s** – pharmacies targeted
- **Late 1940’s to early 50’s**
  - AMA
    - Creates Physician Masterfile
    - Distributes 20 reports to Pharmaceutical and Device Manufacturers about Pharmaceutical influence on prescribers
    - Physician receptivity analyzed
  - National Prescription Audit (NPA)
- **1954** – Federal Law mandates prescriptions
- **1956** – National Disease and Therapeutic Index (NDTI)

[www.annals.org](http://www.annals.org)
Promotional report on survey data, circa 1953.[22].

Greene J A Ann Intern Med 2007;146:742-748
Historical Perspective of Prescriber Profiling

- **1961** – Chairman of AMA publically confronted by congress about “marketing collusion”

- **2000** - Health Information Organizations (HIOs) earn over $1 Billion/year

- **2005** - AMA makes $44.5 Million selling physician information (16% of revenue)

- **2006** - AMA Prescribing Data Restriction Program (PDRP) begins, available at the AMA website

*Ann Intern Med. 2007;146:742-748*
Handheld Physician Profiling

AvantGo

Prescriber History Data

Subject
Dr. James Adams
Contact info

Product
Naprezine
View Dr. Adams' prescription history with other products:

Summary
Dr. Adams prescribes Naprezine in 45% of applicable cases. He prescribes Competitor Intralex 50% of the time.

View Tools
Direct to Consumer Advertising

- DEA first allowed DTC in broadcasting in 1997
- $579 Million spent on DTC in 1996
- $4 Billion spent on DTC in 2008
- “Adequate” risk information must be disclosed

DTC Controversy

• DTC creates demand?
• DTC generates better medical care for more patients?
• 2005 – Lifestyle drugs in the top 20
  – Erectile dysfunction
  – Toenail fungus
  – Sleep aids

KevinMD.com
Influence of Patients’ Requests for Direct-to-Consumer Advertised Antidepressants

• Study:
  – Randomized trial using standardized patients (SP)
  – Wanted to see if requests for an advertised DRUG by SP would affect antidepressant prescribing

• Results: In major depression group
  – Asked for DRUG by name
    • 27% received DRUG
    • 25% received another antidepressant
    • 47% received nothing
  – Asked for antidepressant
    • 1% received DRUG
    • 74% received another drug

Influence of Patients’ Requests for Direct-to-Consumer Advertised Antidepressants

• Study conclusion:

“Patients’ requests have a profound effect on physician prescribing in major depression and adjustment disorder. DTC advertising may have competing effects on quality, potentially both averting underuse and promoting overuse.”

Medical Education and Industry

• Funding:
  – 2005 - CME industry obtained a little over $1 billion in commercial support when PhRMA had $200 billion in revenues
  – CME industry funding quadrupled from 1998 to 2006

• Concerns that CME is biased towards drugs and medical devices

BMJ 2004;328:485-485
Evolution of the Regulatory Environment

• Agencies Involved
  – FDA
  – OIG
  – DOJ

• Laws and Regulations
  – Anti-kickback Act - 1986
  – False Claims Act – 1986
Evolution of the Regulatory Environment

- PhRMA Code – 2002, 2009
- CMSS Code of Conduct - 2010
- Physician Payments Sunshine Act - 2009
“The Heat is On”

- **FDA**
  - Monitors marketing activities of industry for compliance with its regulations with the Office of Criminal Investigations (OCI)
  - OCI: “Limited resources” – March 2010
- **Office of Inspector General (OIG)**
  - Identifies, audits and investigates fraud waste, abuse and mismanagement of state or federally funded programs
  - Model compliance guidelines
- **Department of Justice (DOJ)**
Commonly Invoked Federal Laws and Regulations

• Anti-kickback Act
  – Government contracting – Civil War
  – Improperly obtaining or rewarding favorable treatment
  – Any form of compensation

• Stark Law (CMS) – 3 phases
  – Physician self-referral prohibitions – Medicare/Medicaid
  – Permits nonmonetary gifts up to $355

• False Claims Act
Department of Justice Prosecutions

• Rewarding Physicians for Prescribing - 2001
  – TAP Pharm. Prod. Inc. - Lupron, $875M

• Physician Consultant Agreements – 2007
  – 5 Orthopedic device companies - $300M

• Promoted off-labeled use - 2009
  – Pfizer, 4 drugs involved - $1.3 B
  – Extensive Corporate Integrity Agreement (CIA)

www.justice.gov
A National Survey of Physician–Industry Relationships

• **Methods:** Survey of 3167 physicians in 6 specialties in 2004

• **Results:**
  - 94% had a relationship with industry
    - Receiving food (84%)
    - Receiving drug samples (78%)
  - 35% Meeting/CME reimbursement
  - 28% Consulting/Speaker/Seeded trials
  - FP and private practitioners met more often than others
  - Cardiologist $ = 2 \times$ FP

Physician Professionalism and Changes in Physician-Industry Relationships
From 2004 to 2009

Arch Intern Med. 2010;170(20):1820-1826
ACCME Standards for Commercial Support

• Standards
  – Independence
  – Resolution of Conflict of Interest
  – Appropriate Use of Commercial Support
  – Appropriate Management of Associated Commercial Promotion
  – Content and Format without Commercial Bias
  – Disclosures Relevant to Potential Commercial Bias

• Oversight – information posted on website
  – Limited
  – Years before accreditation is lost

• MECCs – for-profit education companies
PhRMA Code 2009

• PhRMA-prescriber Interaction
  – Guidelines for the use of prescriber data
  – Sales Representative-Prescriber
    • Prohibit non-educational gifts and “reminder” items (Textbooks allowed)
    • Only modest meals in offices or hospitals during educational presentations
    • No entertainment, recreation or use of resorts
  – Promotional speakers and consultants
    • Based on expertise, not potential business
    • Compensation cap - “fair market value”
    • Disclosure

www.phrma.org
PhRMA Code 2009

• Compliance
  – Public commitment by CEO
  – Compliance program
    • Training
    • Oversight

• Education
  – Monitor programs
  – Enhance transparency
  – Promotional speakers and consultants
  – Independent CME
AdvaMed Code 2009

• Major differences from PhRMA Code
  – Broader definition of health care professional
  – Anatomical Models and Textbooks > $100
  – Consultant royalties
  – Evaluation and demonstration products
  – Professional Hands-on Training
    • Details where and how
    • Travel and lodging
      – “reasonable costs of trainees only”
      – Plant tours for non-portable equipment

www.advamed.org
Council of Medical Specialty Societies Code for Interaction with Companies

• CMSS, 32 members – ACP, AAFP, AGS

• Principles for interaction
  – Independence from Industry
  – Transparency
    • Key Society Leaders
    • Accepting - Charitable contributions or Corporate sponsorships
    • Society meetings - Educational grants and CME
    • Awarding Research Grants
    • Publications – Journals, Clinical Practice Guidelines
    • Advertising Standards

www.cmss.org
Physician Payments Sunshine Act

- Part of the new healthcare regulations
  - Payment
    - “Any payment over $100 in a given calendar year must be reported to the Department of Health and Human Services beginning in 2012”
      - In detail
      - By the payer
  - Applies to:
    - PhRMA or medical device manufacturers
    - Physicians and Teaching Hospitals
Physician Payments Sunshine Act

— Ownership or Investment Interests

• Applies to:
  — Physician
  — Family member

• That own or invest in:
  — Manufacturer covered by Medicare
  — Applicable group purchasing organization covered by Medicare

• Exception
  — Publically traded security
  — Mutual funds

• Annual report to be posted on website for public viewing (September 30, 2013) Library of Congress S.301.IS
2011 Issues

• Funds for CME and Research are more difficult to obtain
  – New codes and legislation
  – Shift to DTC advertising
  – Medical societies and Universities competing with MECCs for funding

• Limited Funding = Limited Oversight

• Guideline dilemma
Help for the “CME Dilemma”

• Meeting Planners
  – Choose locations that aren’t luxury but ARE attractive
    • Warm locations in winter
    • Major city with great shopping, entertaining, or dining
    • Locations near attractions that attendees may choose to visit on their own
      – Near ski locations
      – Near golf courses
Help for the “CME Dilemma”

• Approach non-traditional sources for funding
  – Companies with tie in to health care
    • Medical software providers
    • Textbook and journal publishers
    • Medical transcription firms
    • Long term care facilities
  – Other companies interested in getting products and services in front of health care professionals
    • Financial institutions
    • Real estate companies
The CSAC

• Commercial support/advocacy consortium model
  – Commercial supporters interested in a particular disease state or condition form a consortium
  – Each supporter contributes the same amount of money (non refundable for any reason)
  – Structure of grant review committee
    – CME group
    – Medical affairs group
    – Legal/compliance group
    – Advisory group
    – Advocacy group

Meetingsnet.com
Operation of the CSAC

- Grants reviewed and ranked by metrics
- All approvals must be unanimous
- All proposals funded based on metrics

Meetingsnet.com
Benefits of CSAC

• Multiple support sources
• Objective, thorough, effective initiatives
• Comprehensive PI activities
• Meaningful outcomes data
• Significant reduction in perception of bias
Questions?