Disclosures
The following faculty speakers, moderators and planning committee members have disclosed NO financial interest/arrangement or affiliation with any commercial companies who have provided products or services relating to their presentation(s) or commercial support for this continuing medical education activity:

• Lisa A. Bero, PhD
• Elizabeth Boyd, PhD
• Yeuen Kim, MD
• Kirby Lee, PharmD
• Thomas B. Newman, MD, MPH
• Kristin Rising
• Sei Lee
• Nicholas Rosenlicht

Overview of Pharmaceutical Industry Marketing Practices
Lisa A. Bero, Ph.D.
University of California, San Francisco
Marketing of Medicines
November 3, 2007

Acknowledgement
This program was made possible by a grant from the state Attorney General Consumer and Prescriber Education Grant Program which is funded by the multi–state settlement of consumer fraud claims regarding the marketing of the prescription drug Neurontin®.

Why do we care? Research
• Marketing = skepticism
• Research = trust
• Industry funding for research is substantial
• A growing number of researchers also have personal financial ties to their sponsors
• Financial ties = potential conflicts of interest
Why do we care? Drug costs

- 75% higher in 2002 than 1997
- $188.5 billion spent on Rx drugs in 2004
- Drug costs are about 11% of all healthcare expenditures (GAO)

Why do we care? Marketing

- Pharmaceutical industry spent about $25 billion on marketing in 2004
  - About $5 billion on detailing
  - About $3 billion on direct to consumer
- 2007 NIH budget is $29 billion

Marketing is ....

- Disease mongering
- Research and information
- Education
- Detailing
- Gifts, samples
- Advertising (to health professionals and consumers)

Disease Mongering

- Turning the ordinary processes of life into medical illnesses
- Exaggerating the extent and severity of disease
- Are the boundaries of disease and illness being widened in part to expand the markets for doctors and new drugs?

»Raymond Moynihan, Selling Sickness, 2005
“Statin mongering”

- National Cholesterol Education Program updated the Adult Treatment Panel III (ATP III) guidelines in 2004.
  - Recommend a LDL cholesterol level below 100 mg/dL in patients at risk for coronary heart disease.
- 40 million Americans should be on statins in higher doses and for a longer period (up from 13 million)
- New ATP III guidelines were based on evidence from 5 published randomized controlled trials (RCTs)
  - ALL received funding from industry
- 8 of the 9 members of the panel had financial ties with pharmaceutical companies manufacturing statin drugs

Drug Industry: A lawsuit

- Lawsuit against Parke-Davis by a former employee
- Company promoted gabapentin (Neurontin®) off-label
- Gabapentin officially approved only for adjunctive treatment of partial seizures in persons over age 12 at doses up to 1800 mg/day.
- Pain, psychiatric conditions, migraine, and other unapproved uses

The settlement

- Drug Industry Document Archive (DIDA)
  - http://dida.library.ucsf.edu
  - 8000 vs 50,000,000 pages

Michael A. Steinman, MD
Lisa A. Bero, PhD
Mary–Margaret Chren, MD
C. Seth Landefeld, MD

Pharma documents ...

Motives

- Marketing
  - To increase number of prescriptions sold / profit
  - Public relations / credibility
Pharma documents... Strategies

• "Territory managers"
• Advertising
  • To health professionals
  • DTC
• Patient education / support
• Medical liaisons
• Directly-sponsored CME
• Advisory board / consultant meetings
• Research
• Publication
• Educational grants
• Independent CME

Target audience

• Physicians who frequently prescribed anticonvulsants
• "Thought leaders," "key influencers," and "movers and shakers"
• Residents
  • "in order to influence physicians from the bottom up" and "to solidify Parke-Davis' role in the resident's mind as he/she evolves into a practicing physician."

Significance: early exposure

• Interaction with pharmaceutical industry begins early in training
  - 1143 students at 8 med schools surveyed, 72.3% response rate
  - Exposure, skepticism, policies
  - 97% third-year med students reported some exposure to PR (e.g. lunch, pen, mug)
  - 83% felt their school had not taught well about how to interact with PR

Sierles et al, JAMA, 2005

Branding of residents

• Survey of 181 primary care residents, 91% responded
• First asked to complete survey, then asked to empty pockets of white coats
• 97% were carrying at least one item with pharmaceutical insignia
  • E.g., reference book, calipers, pen

Sigworth et al, JAMA 2001
"Medical education drives this market!!"

Teleconferences

- Physicians paid $250 to $500 per call
- 20 or 30 participants
- Focused topic for discussion – “new” information
“Unrestricted educational grants”

- To medical education and communications companies
  - “Assist in the organization of a [major university hospital’s] pain symposium…. We will probably write them an unrestricted educational grant to help fund the project. In return, they will discuss the role of Neurontin in neuropathic pain, among other topics. They do have a very favorable outlook toward Neurontin.”

Who runs the program?

- The company reserved the right in non-accredited programs “to probe the faculty further to definitively establish presentation content and make the appropriate changes and/or recruit an alternate speaker”.
"Publication strategy"

- Goal: to use research not as a means to gain FDA approval for new indications but “to disseminate the information as widely as possible through the world’s medical literature”

Ghost authors, etc.

- MECC offered substantial assistance in the development of manuscripts, reporting in a status report that “at [the author’s] request, we did an extensive literature search and submitted selected articles to him for reference. We have offered him help in identifying and collecting his appropriate cases, analyzing data, writing a manuscript, or whatever he needs.”
- 7 published articles: 4 favorable, 3 neutral
- Only 1 article disclosed author tie with Parke-Davis
Efficacy of gabapentin as adjunctive therapy in a large, multicenter study


*Columbia University, The Neurological Institute, New York, NY, USA; 2Vanderbilt University Medical Center, Nashville, TN, USA; 3University of Texas Health Science Center Medical School, Houston, TX, USA; 4University of Cincinnati Medical Center, Cincinnati, OH, USA; 5University of Alabama School of Medicine, Birmingham, AL, USA; 6Harvard Medical School, Boston, MA, USA; 7Pfizer Pharmaceuticals, Morris Plains, NJ, USA

- Uncontrolled open-label study; gabapentin titrated up to 3600 mg/day (twice the maximum FDA-approved limit)
- 700 physicians enrolled 2100 patients
- Published report: "examined the effectiveness of gabapentin" in this dose range

Selective publication

- Marketing assessment: "The results of the recommended exploratory trials in neuropathic pain, if positive, will be publicized in medical congresses and published." [italics added]
- "The results of [the negative trial] will not be published."
- The positive trial was published, negative trial not found through PubMed search.

STEPS

- Goal: Teach Physicians to Titrate Neurontin to Clinical Effect
- Study Highlights:
  - Expand Physician Experience with Neurontin
  - Establish Broad Patient Types Appropriate for Neurontin Therapy
  - Pre-empt Launch of Lamictal

IV. Overview of 1996 Strategies

- STRATEGY #1: REINFORCE THE "ADD NEURONTIN FIRST" POSITIONING AND FOCUS PROMOTIONAL MESSAGE ON TITRATION TO HIGHER Doses

No key activities for the implementation of this strategy are the 1996 promotional campaign and the STEPS trial. The Neurontin 1996 promotional campaign centered on the strengthening of the positive trial's results in neuropathic pain, which was then published in medical congresses and journals. The negative trial was not found through PubMed search.
Overview of program

- Research and marketing
- Education and marketing
- Direct-to-consumer marketing
- Does it work?
- What do we do about it?
- Small group discussions
  - Research and education
  - Direct to consumer

Reminders

- Filming for UCTV
- Evaluation
  - Complete pre-evaluation
  - Complete post-evaluation by end of Small Group session #2 – i-pod shuffle
- Enjoy your pen!