

Conflicts of Interest and Professionalism in Medicine

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Learning Objectives

- Learn the history of the growth in the pharmaceutical industry in the United States
- Learn about the increase in the role of marketing in pharmaceutical industry interactions with physicians
- Learn from high profile cases of conflict of interest
- Learn the definition of conflict of interest
- Review ethical principles underlying the concept of professionalism
- Understand the adverse impact of lapses in professionalism

Public Opinion About Physicians

Doctors' role in drug studies criticized

Some recommend drugs, vouch for studies but don't see raw numbers

By [John Fauber](#) of the Journal Sentinel

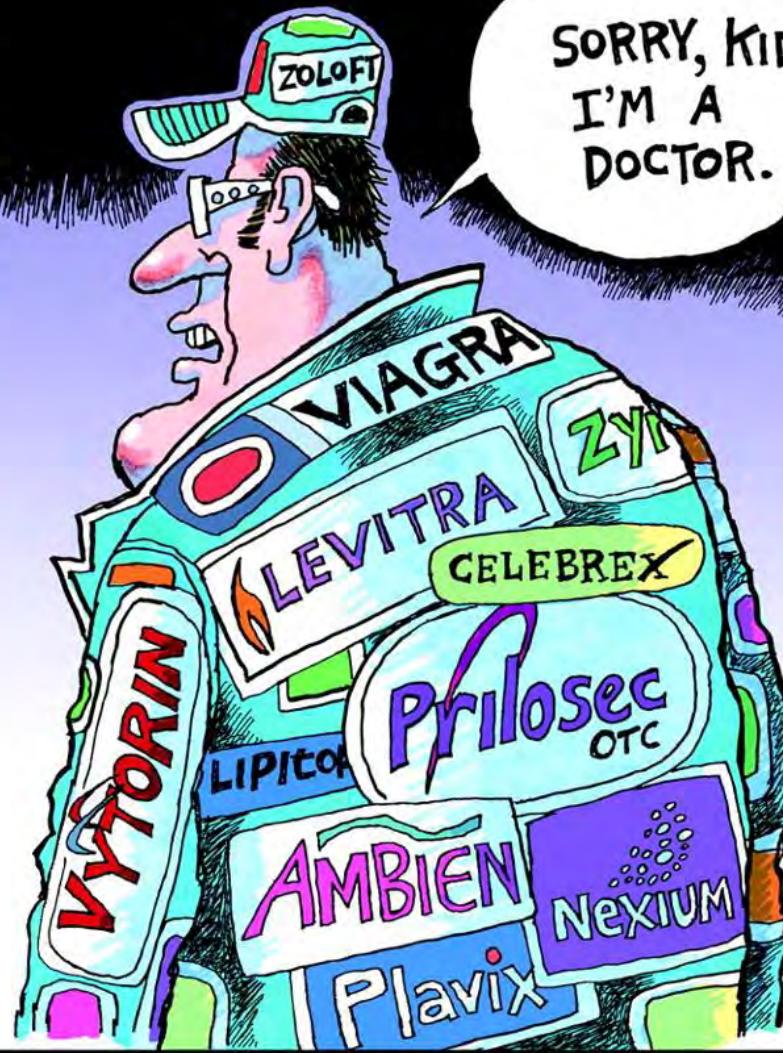
May 30, 2010 6:09 AM: "Everyone knows that the big drug companies dictate what's given to patients these days. Psychological meds are especially being abused -- half of them should be taken off the market immediately with their ridiculous and dangerous side effects. Walk into any psychiatrist's office these days and most of the time the walls are plastered with posters of every drug imaginable -- run, don't walk, away from doctors like these. They get a commission for every prescription they write, or at least a "bonus check" for having done a deal with one of the drug companies. Sickens me. (no pun intended)"

SECOND OPINION

BY ROB ROGERS

I LOVE
NASCAR!....
CAN I HAVE
YOUR AUTOGRAPH?

SORRY, KID...
I'M A
DOCTOR.

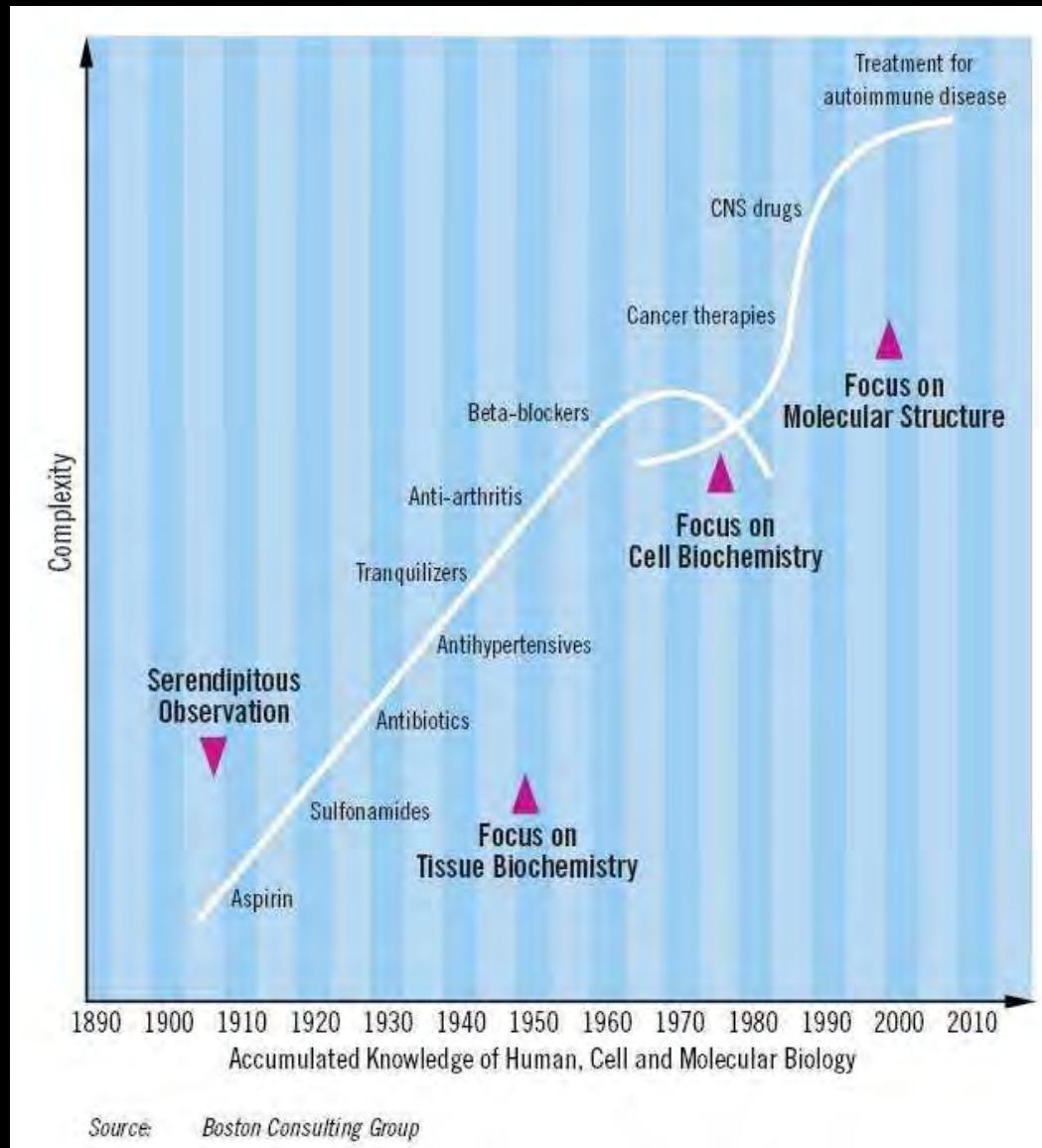




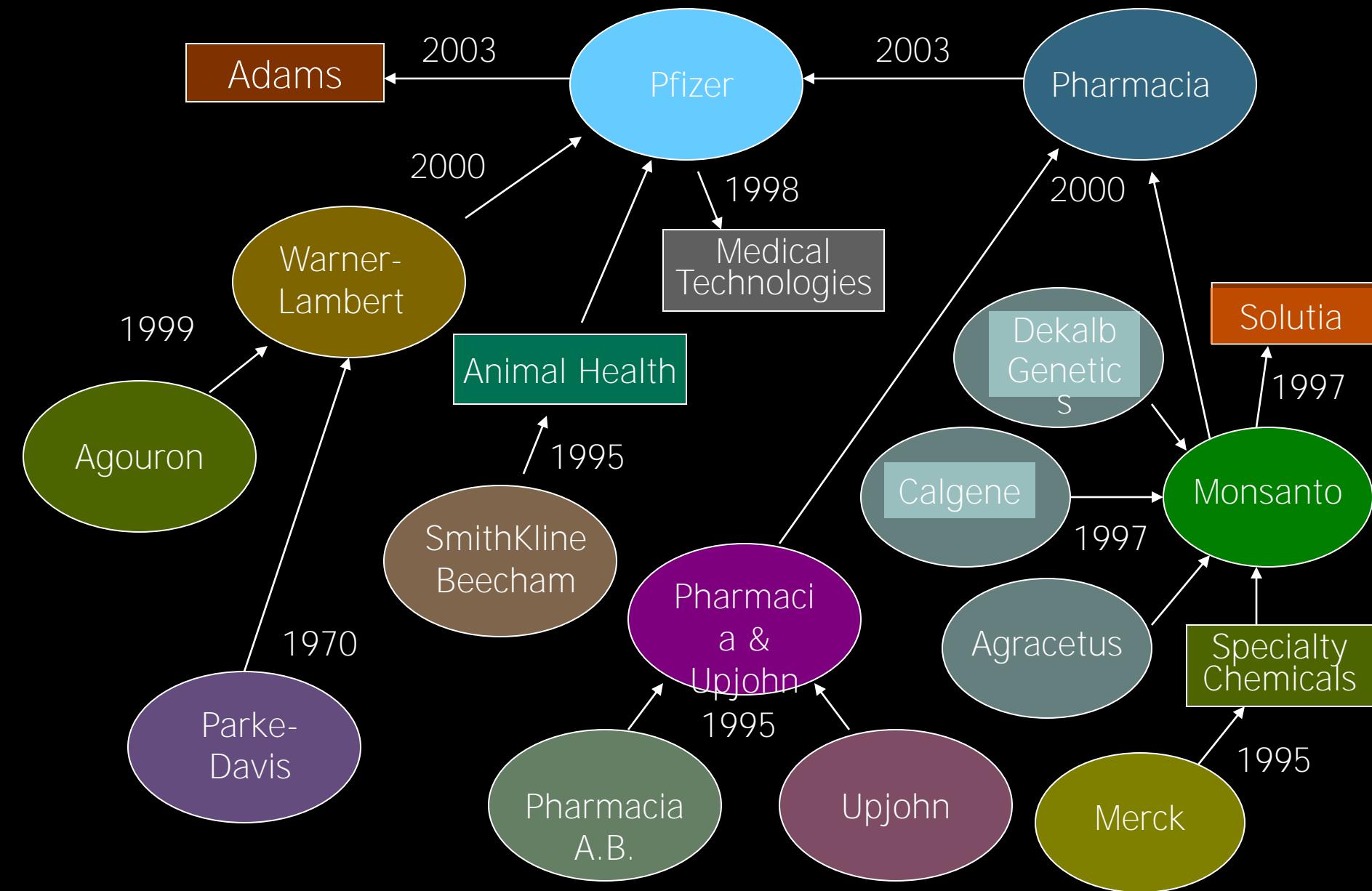
The Pharmaceutical Industry: Pharmacoconomics

**Congressional Budget Office Report, Research and Development in the Pharmaceutical Industry,
October 2006**

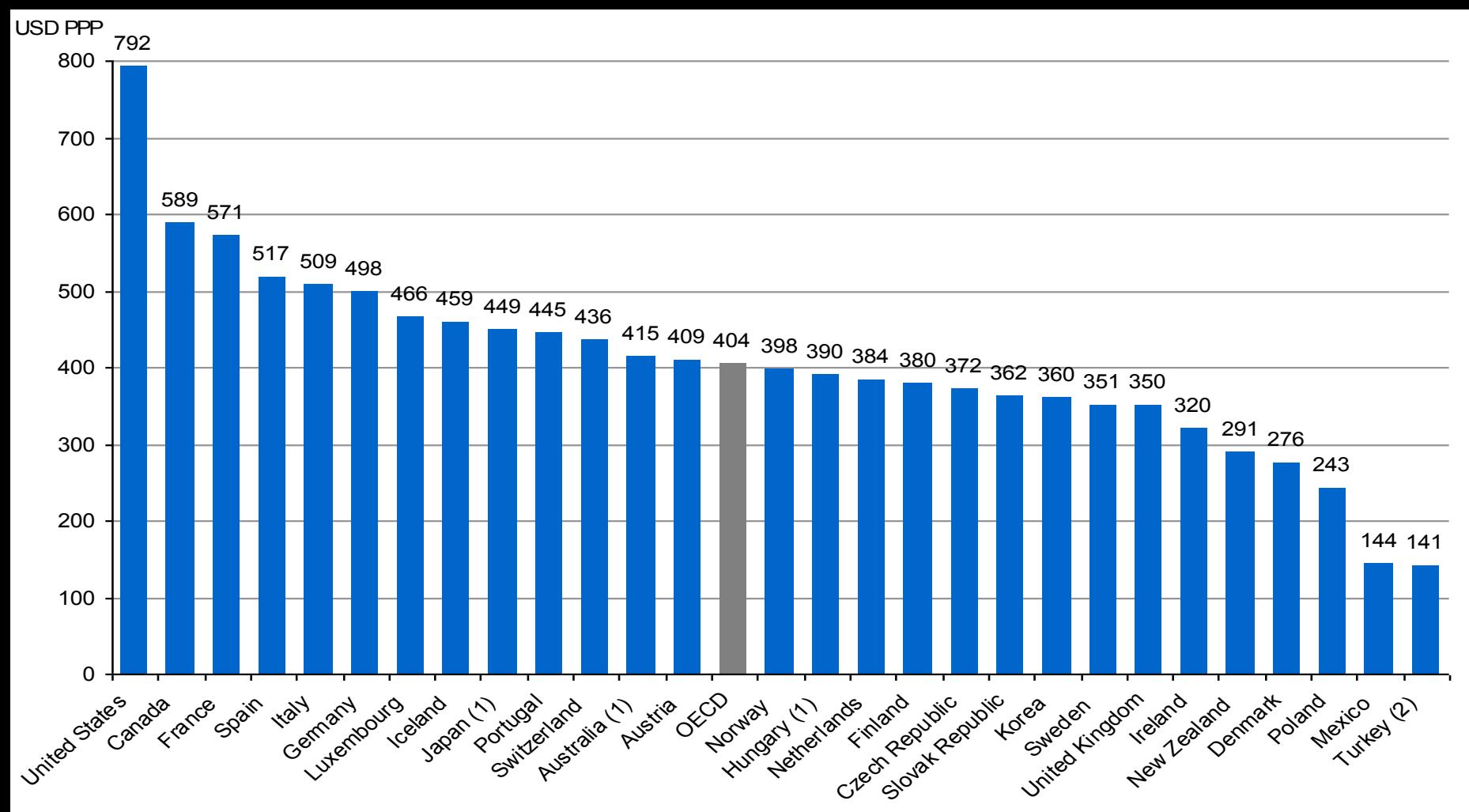
Evolution of Innovative Medicines



Mergers & Acquisitions



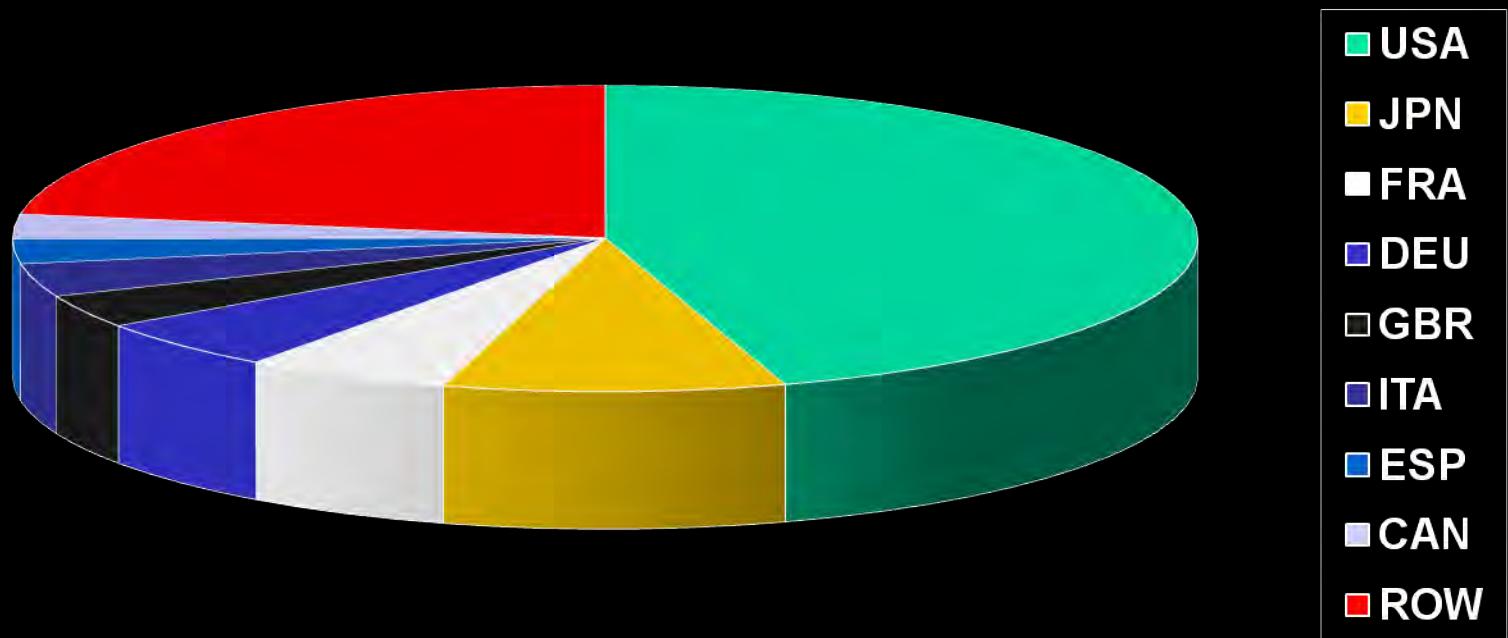
Per capita spending on pharmaceuticals in 2005



(1) 2004; (2) 2003; (3) 2005 pharmaceutical sales per capita

Source OECD HEALTH DATA 2007, July 07

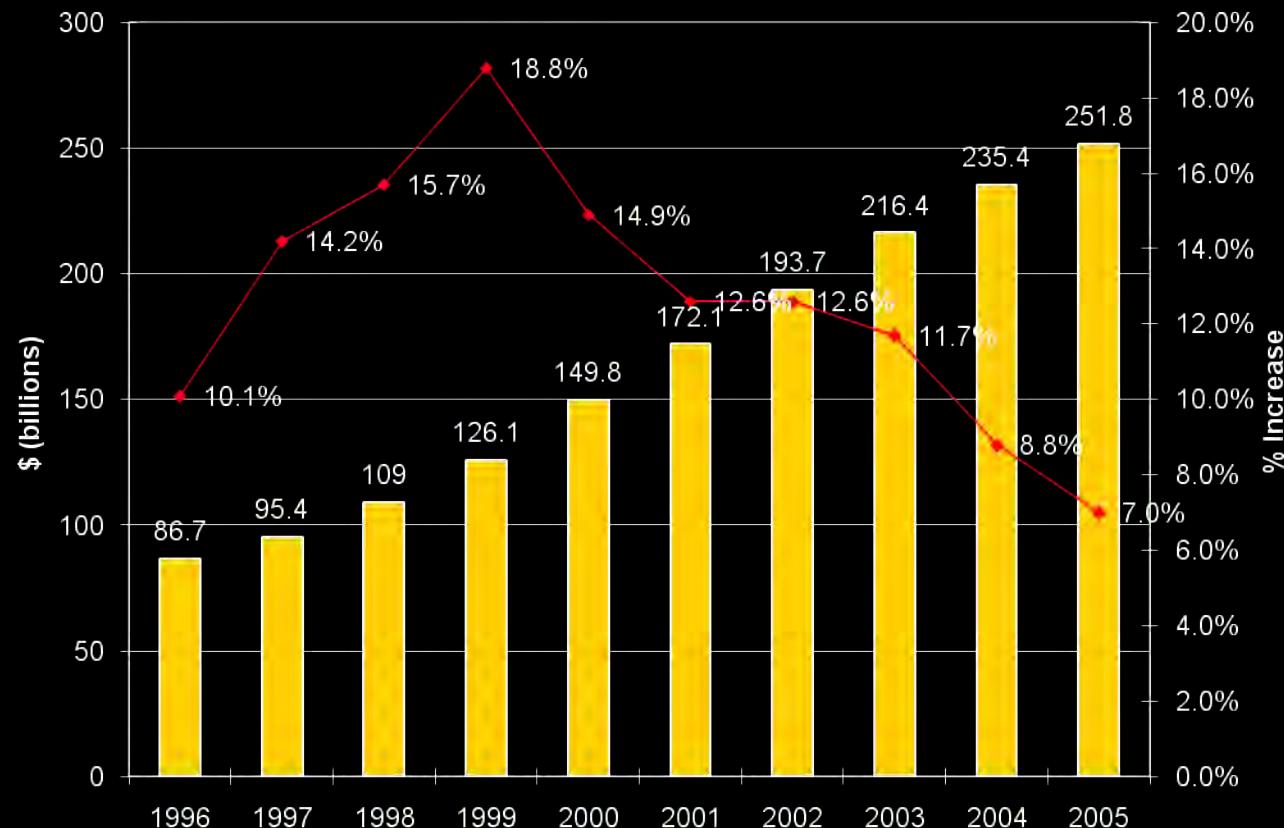
**The United States account for 45% of worldwide sales,
followed by Japan (9%), Germany and France (5%),
United Kingdom and Italy (4%)**



Source: IMS Health (2007), *Intelligence.360: Global pharmaceutical perspectives 2006*.

Total U.S. Pharmaceutical Sales

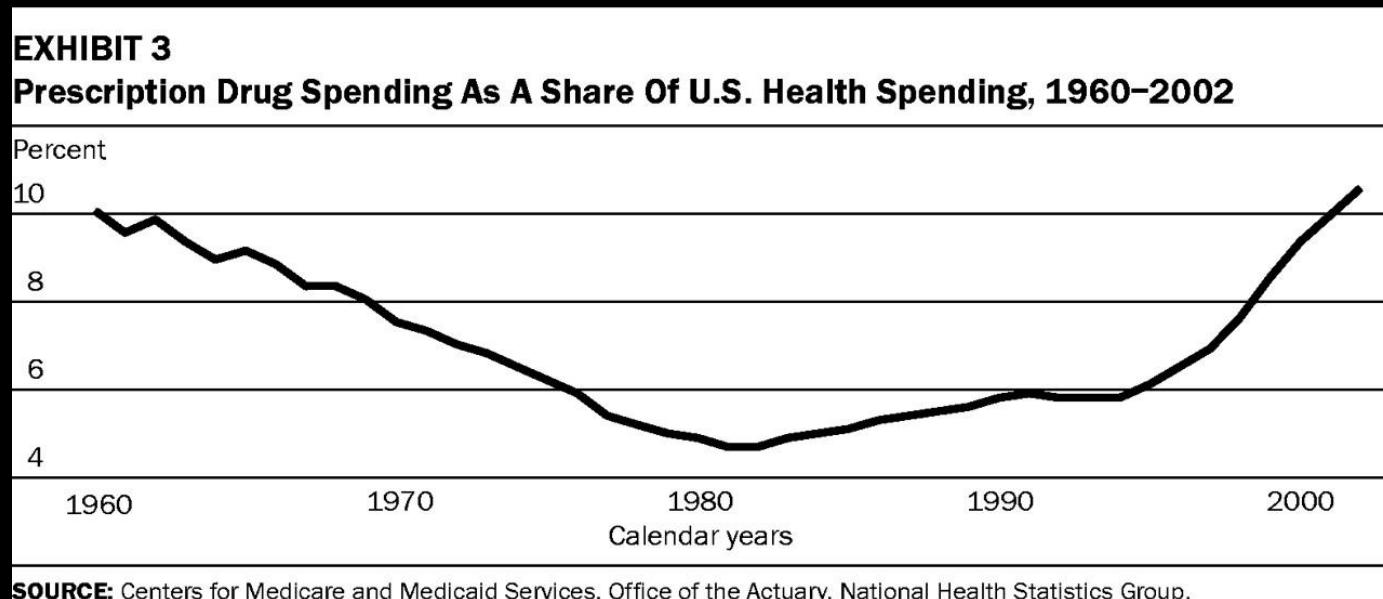
- Drug sales (Rx & OTC) have trended up steadily over the past decade although the rate of increase has diminished in recent years



Source: IMS Health, Top-Line Industry Data.

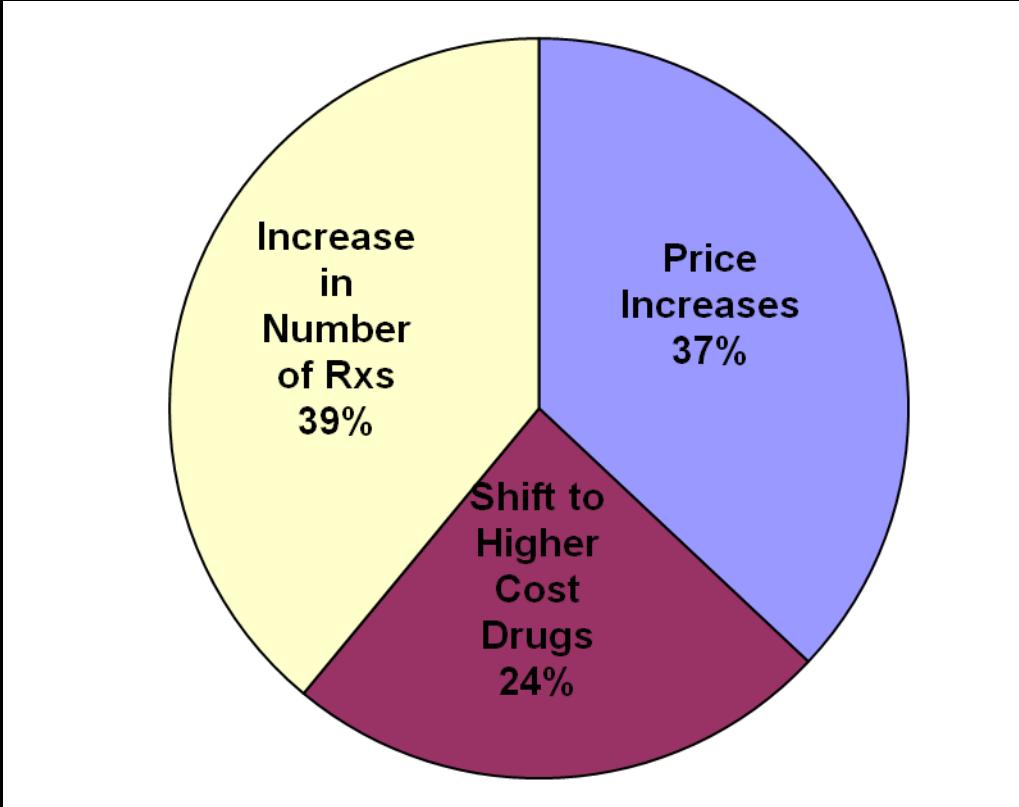
Pharmaceutical Spending

- In 2004, Americans spent over \$188 billion on prescription drugs
 - 10% of total healthcare expenditures – and trending up



Source: Centers for Medicare and Medicaid Services and the Bureau of Economic Analysis. Graph from

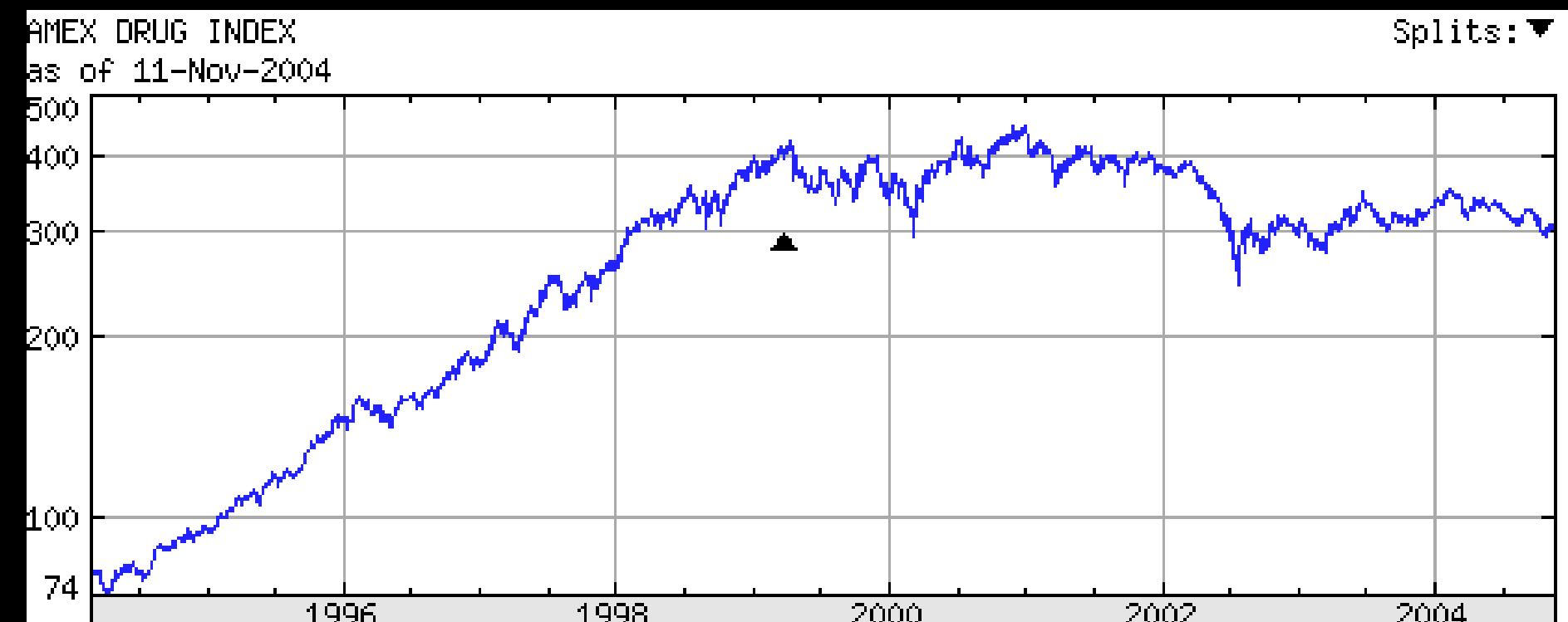
Sources of Increased Drug Expenditures, 2000-2001



Total increase: \$22.5 billion

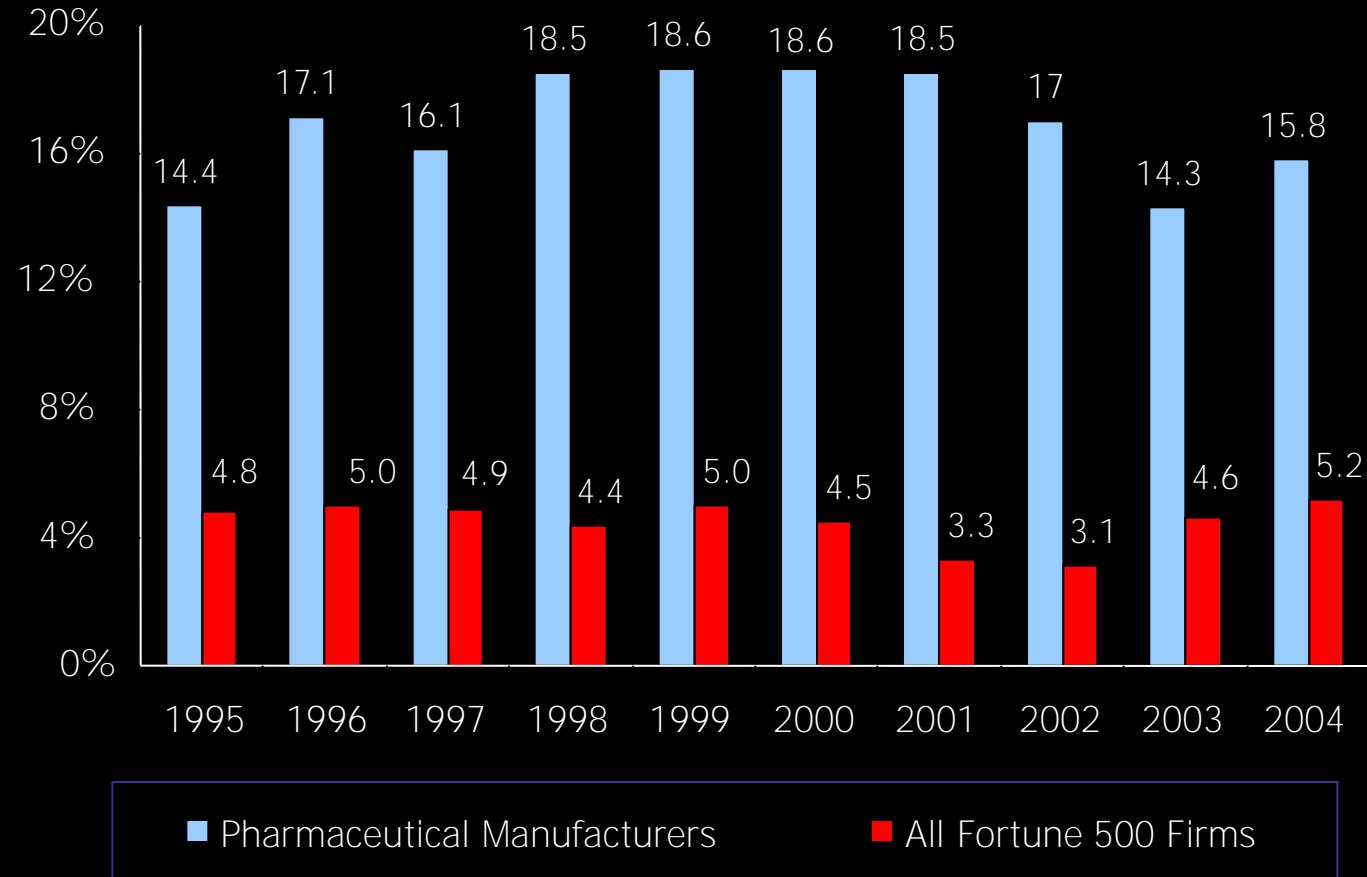
Source: American Institutes for Research (AIR) analysis of Scott-Levin and Bureau of Labor Statistics data in Prescription Drug Expenditures in 2001: Another Year of Escalating Costs, NIHCM Foundation, March 29, 2002.

Industry Performance (cont.)



AMEX pharmaceutical index is a market-capitalization weighted index

Profitability Among Pharmaceutical Manufacturers Compared to Other Industries, 1995 - 2004

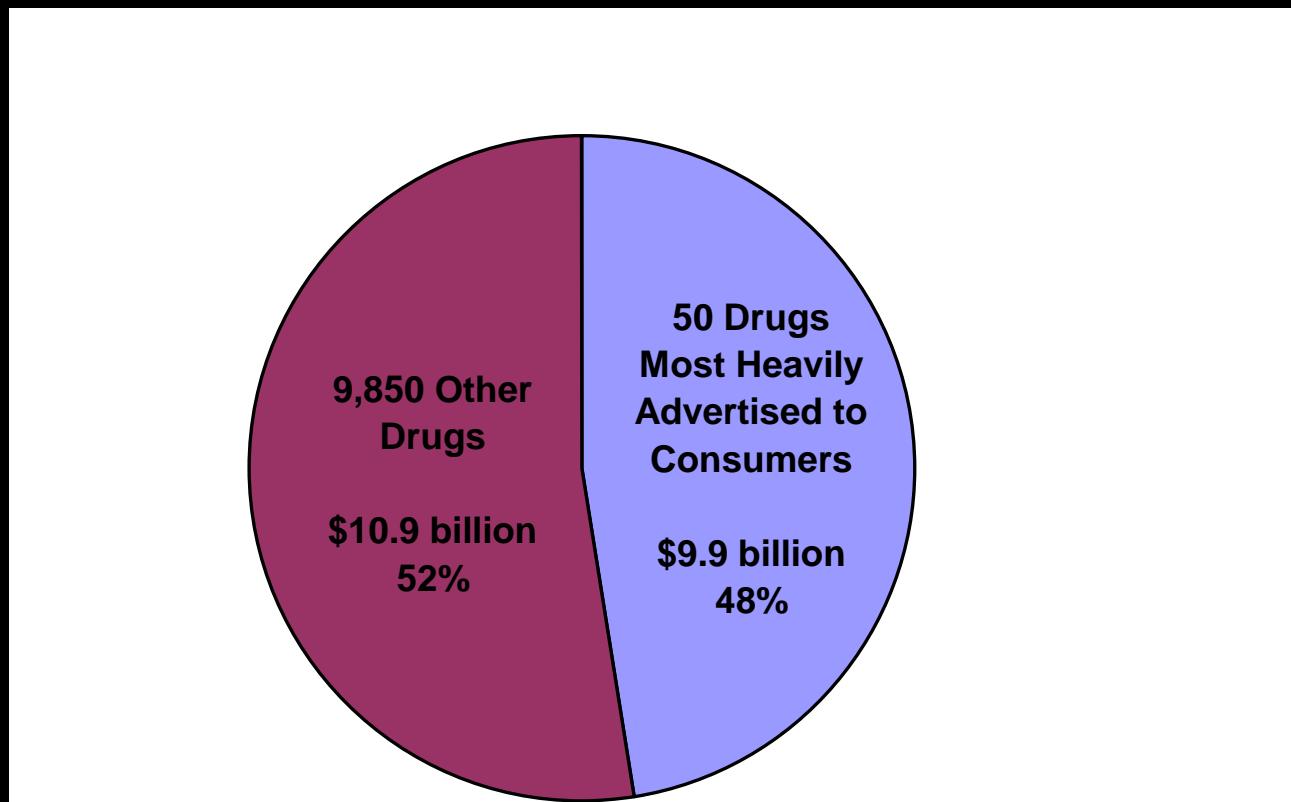


Source: Kaiser Family Foundation and Sonderberger Research Center, *Prescription Drug Trends: A Chartbook Update*, November 2001, Exhibit 4.11

Effect of Advertising on Drug Sales

- Drugs that are heavily advertised contribute disproportionately to the increase in pharma spending

Increase in Retail Prescription Drug Sales, 1999-2000



Source: Prescription Drugs and Mass Media Advertising, 2000, NIHCM Foundation, November 21, 2001.

Percent of Revenue from Blockbuster Drugs

■ Pfizer:	77%
■ Merck:	63%
■ Astra Zeneca:	61%
■ Lilly:	60%
■ GSK:	56%
■ BMS:	37%
■ Novartis:	24%
■ Roche:	23%
■ Aventis:	18%

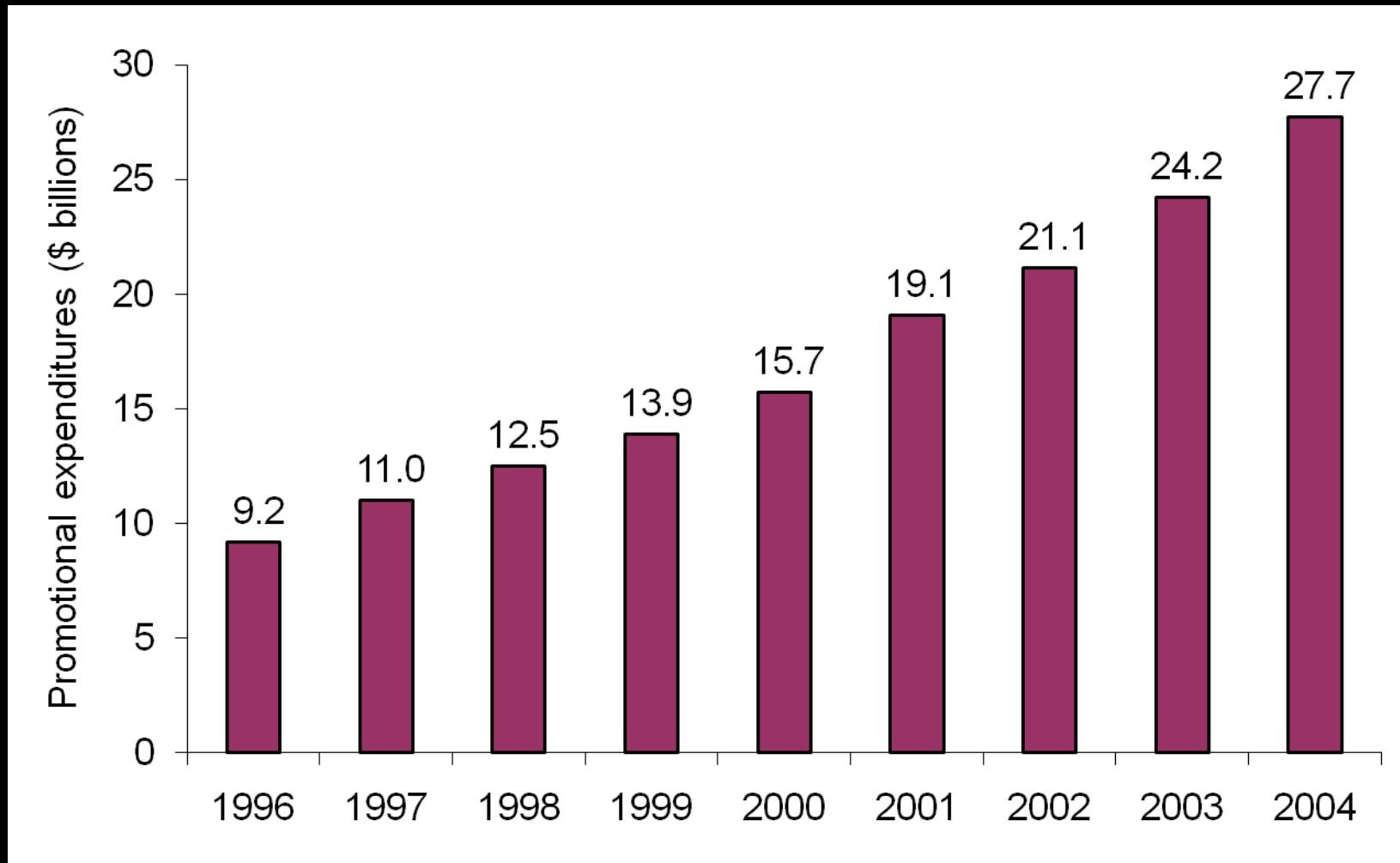
McKinsey Analysis

Pfizer Major: Revenue Drivers (2003 figures)

■ Lipitor (Cardiovascular)	\$9.23 billion
■ Norvasc (Cardiovascular)	4.34 billion
■ Zoloft (Antidepressant)	3.12 billion
■ Neurontin (Epilepsy)	2.70 billion
■ Zithromax (Infectious diseases)	2.01 billion
■ Celebrex (Arthritis)	1.88 billion
■ Viagra (Erectile dysfunction)	<u>1.88 billion</u>
	\$25.14 billion
	(≈55.6% of total revenues)



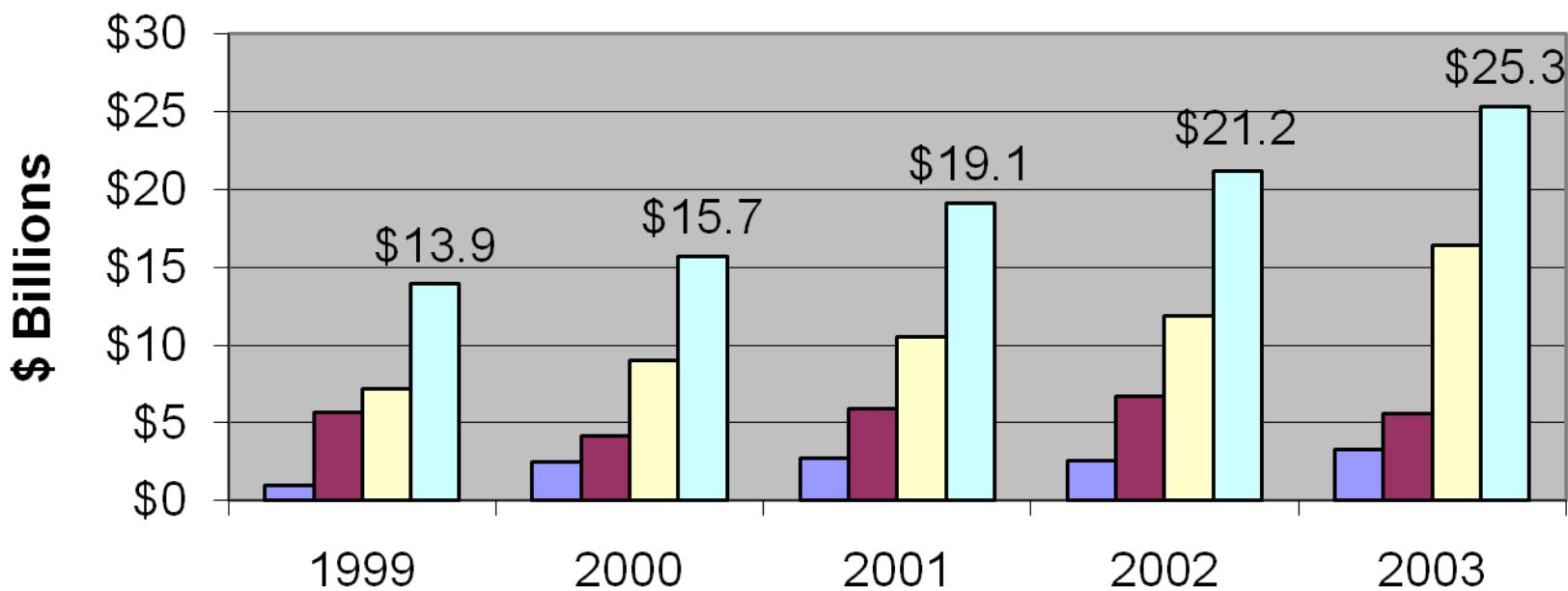
Promotional Spending on Rx Drugs



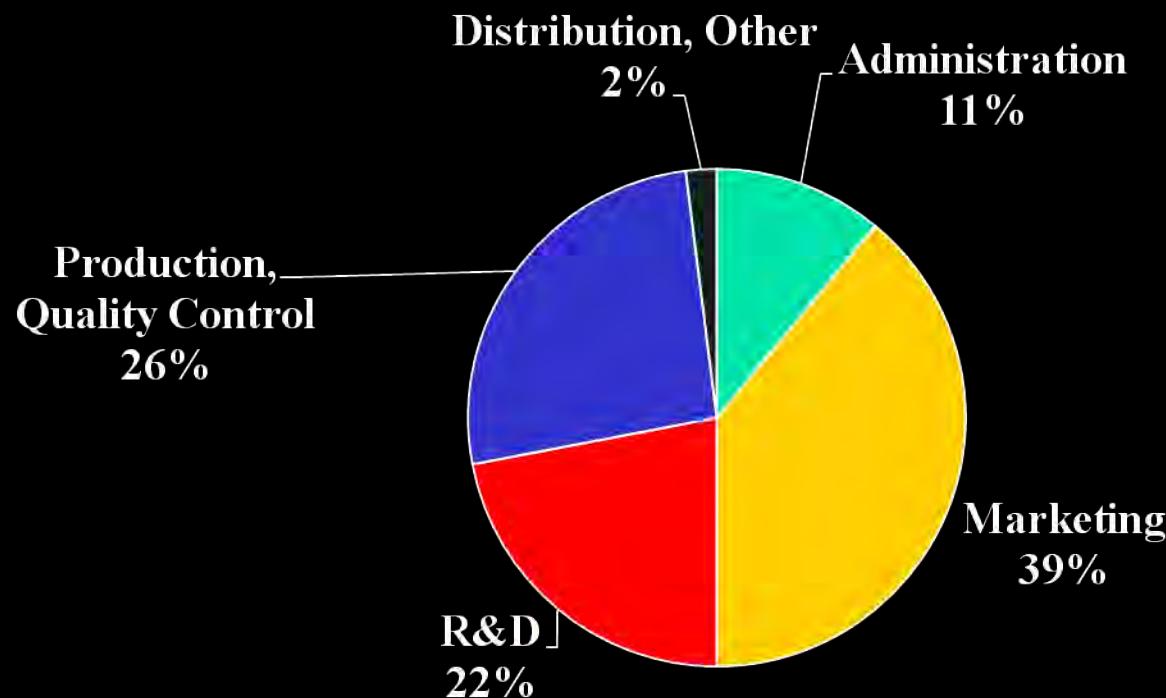
Source: IMS Health, Top-Line Industry Data.

U.S. Marketing Expenses

- Direct-to-consumer advertising
- Office, hospital, & journal promotions
- Retail value of samples
- Total

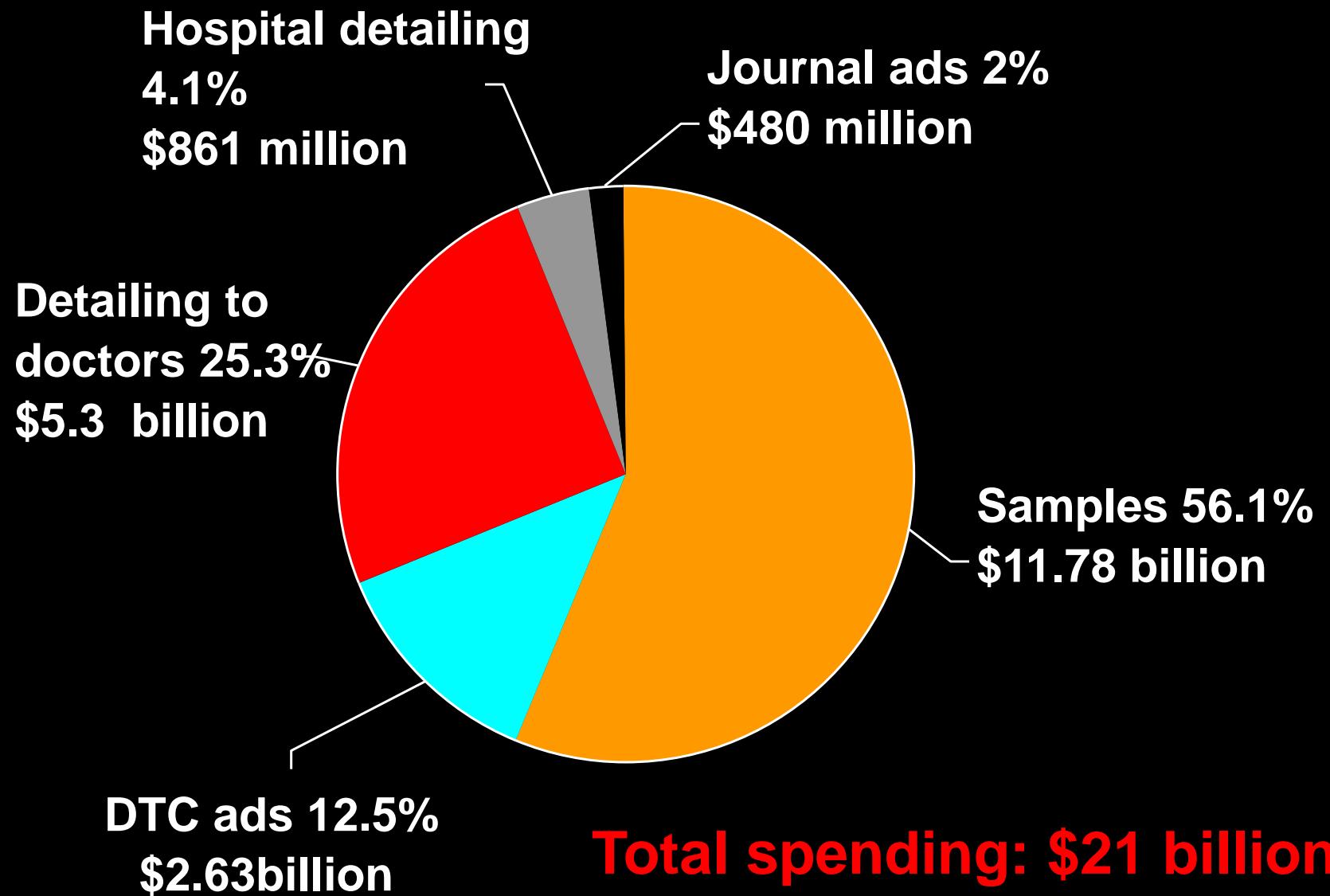


Main task of drug company employees, 2000



Source: PhRMA Industry Profile 2000; percentages calculated by Sager and Socolar

Promotional spending on prescription drugs, 2002



Recent Changes in Pharma

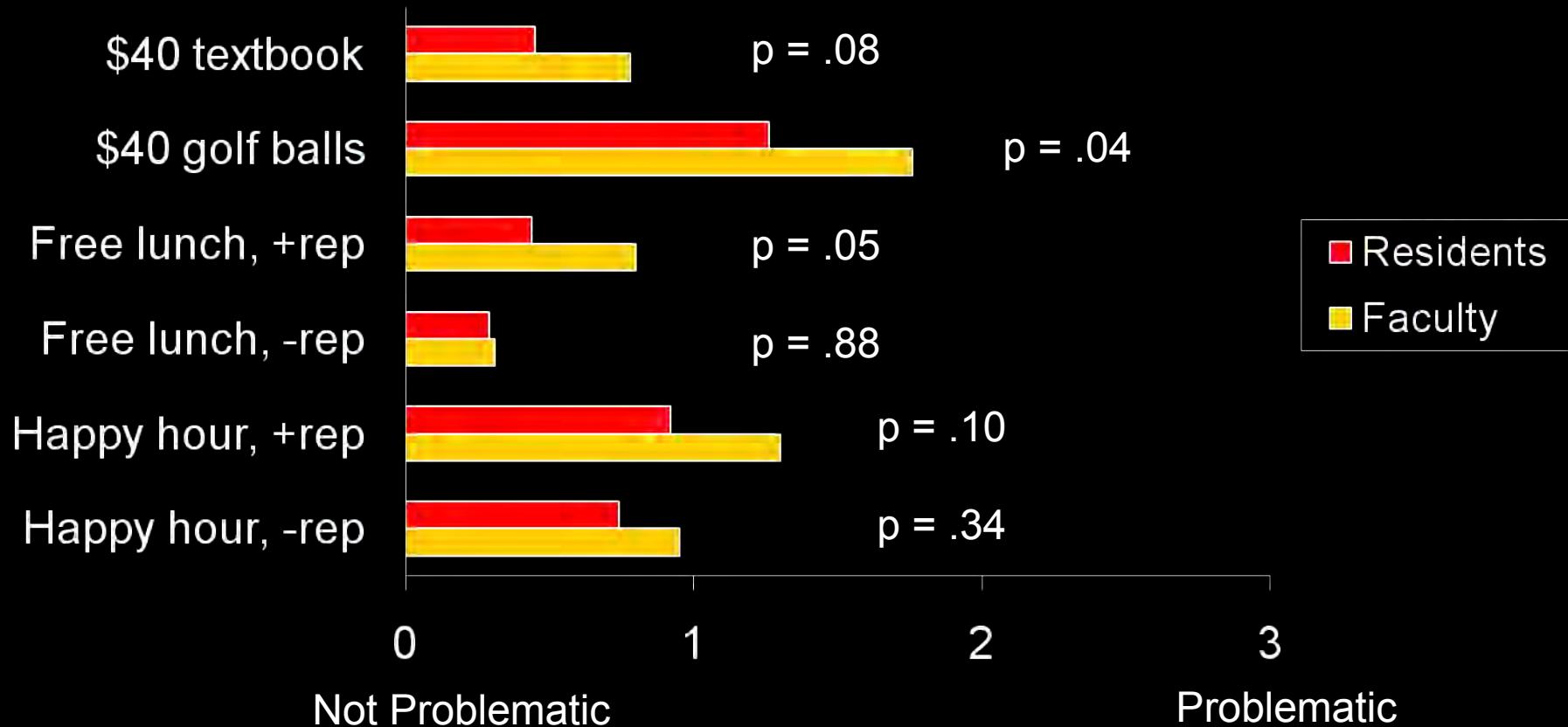
- Recently, some large companies have announced plans to cut their sales forces:
 - Late 2006 and early 2007, Pfizer announced it would cut:
 - 20% of its 11,000-person US sales force
 - 20% of its European sales force
 - In 2005, Wyeth cut:
 - 15% of its sales force
- Other companies (e.g., Novartis) have announced plans to increase sales forces

The Future of Marketing?

- Unclear whether the other big drug companies will follow Pfizer's lead and cut their sales rep forces.
- The marketplace has changed
 - Doctors have less time to see large numbers of reps
 - Academic medical centers have begun placing tighter restrictions on rep access
 - As more drugs go off patent, it will become costlier for drug companies to maintain large sales forces
- Reps in offices vs alternate marketing vs both
 - Print and electronic advertising
 - Seminar series
 - Direct-to-consumer expansion

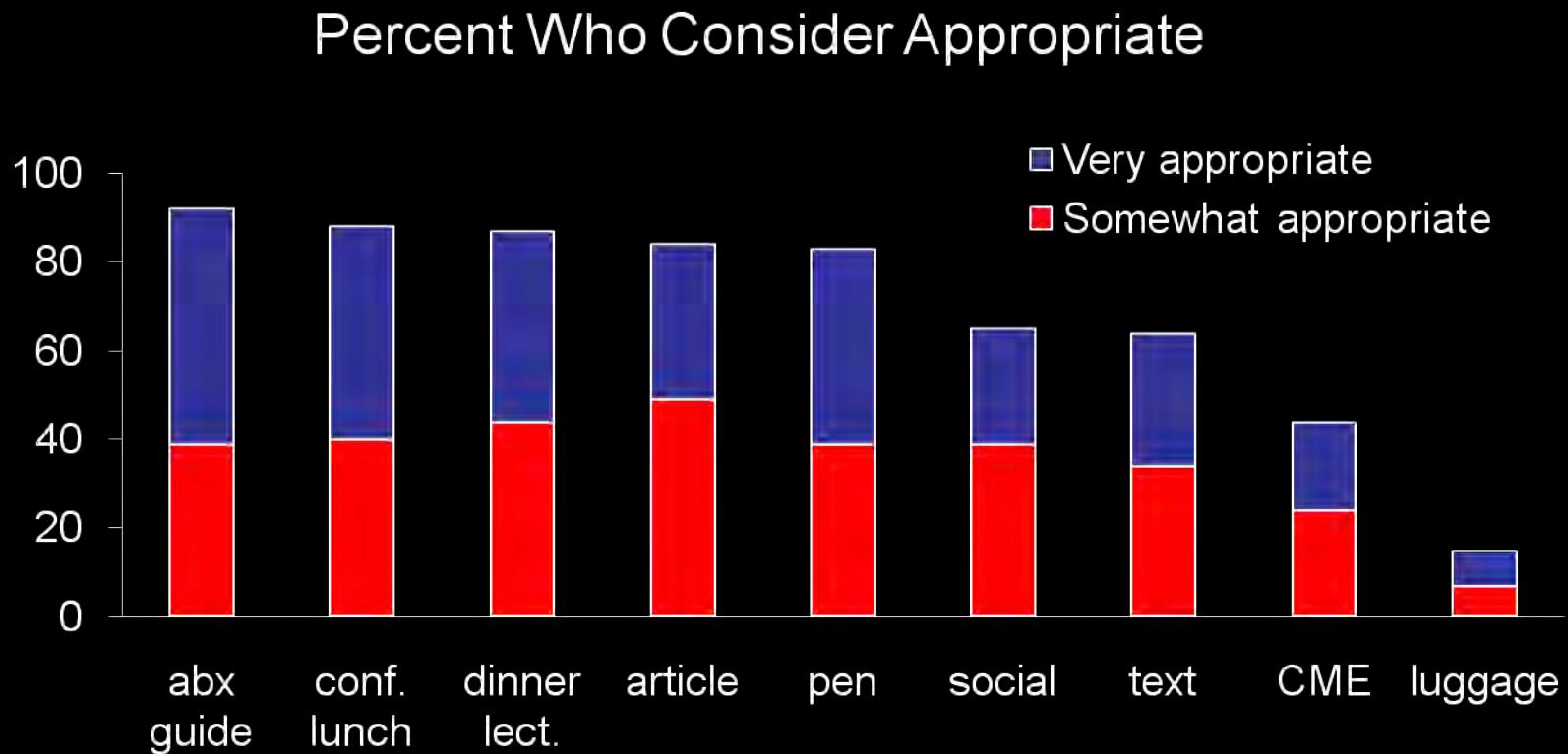
Attitudes Towards Promotional Activities

Resident and Faculty Responses



Brett AS, Burr W, Moloo J. Are gifts from pharmaceutical companies ethically problematic? A survey of physicians. Arch Intern Med. 2003. 163:2213-8.

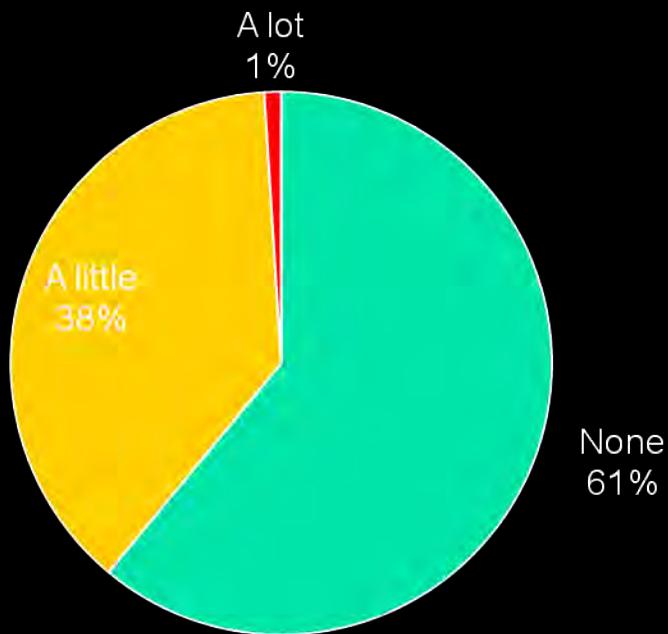
Attitudes Towards Promotional Activities



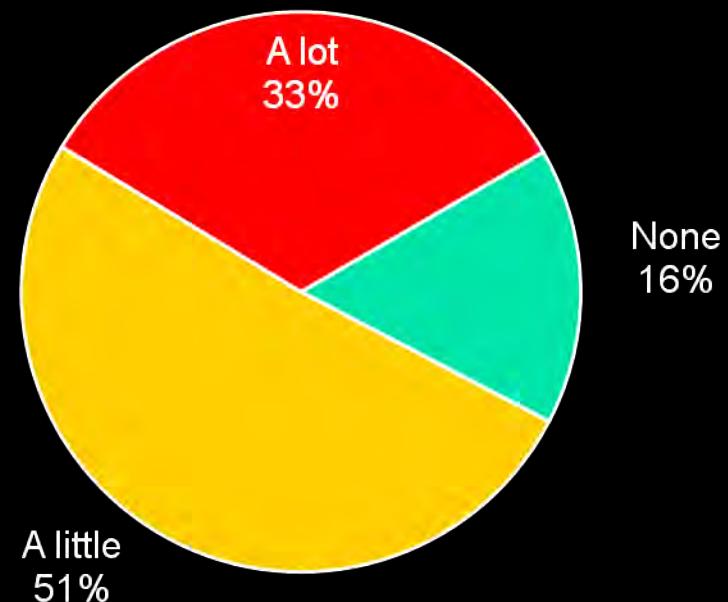
Steinman MA, Shlipak MG, McPhee SJ. Of principles and pens: attitudes and practices of medicine housestaff toward pharmaceutical industry promotions. Am J Med. 2001;110:551-7.

Attitudes Towards Promotional Activities

Perceived Influence of Pharmaceutical Reps on Prescribing Practices



“You”



“Other Physicians”

P<.0001

Steinman MA, Shlipak MG, McPhee SJ. Of principles and pens: attitudes and practices of medicine housestaff toward pharmaceutical industry promotions. Am J Med. 2001;110:551-7.

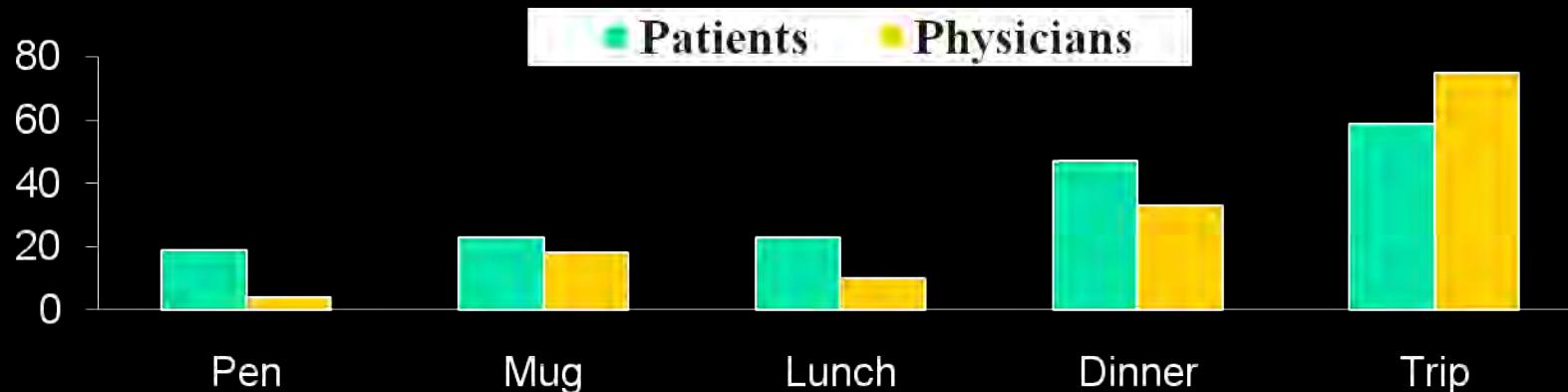
Pharmaceutical Branding of Residents

Table. Frequency of Items Found in Residents' White Coats

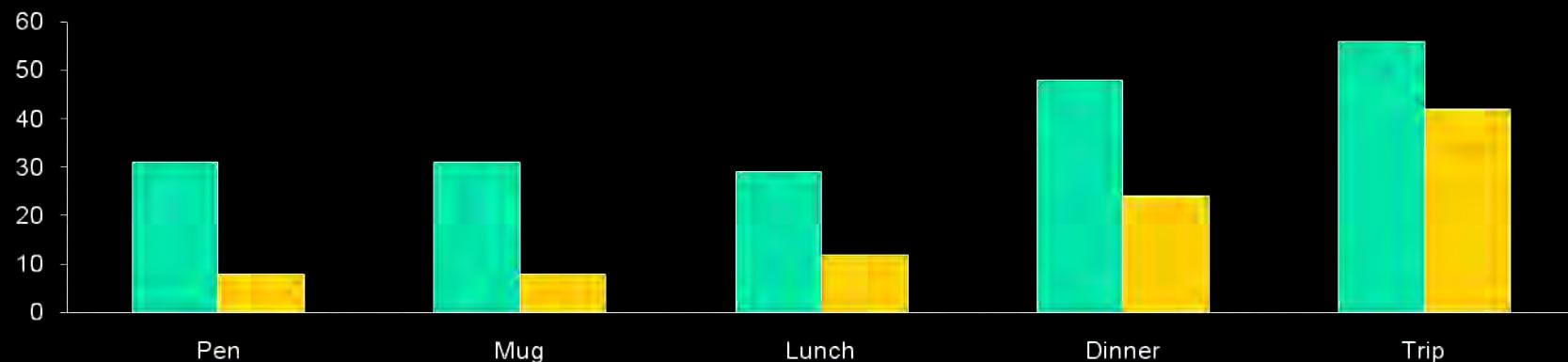
Item	No. (%) of Residents	
	Carrying the Item	Carrying the Item With a Pharmaceutical Brand
Reflex hammer	67 (41)	21 (31)
Calculator	95 (58)	13 (14)
Datebook	71 (43)	19 (27)
Calipers	46 (28)	39 (85)
Stethoscope tag	155 (95)	86 (55)
Penlight	84 (51)	38 (45)
Pens	161 (98)	127 (79)
Information cards	105 (64)	73 (70)
Reference books	152 (93)	137 (90)

Physician vs. Patient Attitudes

Percentage that Considered Gift Inappropriate



Percentage that Considered Gift Influential



Gibbons RV, Landry FJ, Blouch DL, Jones DL, Williams FK, Lucey CR, Kroenke K. A comparison of physicians' and patients' attitudes toward pharmaceutical industry gifts. J Gen Intern Med. 1998;13:151-4

Bias in Promotional Materials

- One study looking at graphs contained in pharmaceutical ads in medical journals found that:
 - 36% of graphs contained “numerical distortion”
 - Specifically prohibited by FDA
 - 66% of graphs contained “chart junk”
 - 54% reported intermediate outcomes

Are Physicians Part of the Problem?

Review of Faculty Disclosures (2006 Data from the Office of Corporate Alliances, University of Pennsylvania)

- Number of Physicians with Consults:
 - # in Range \$1-9999 = 165
 - # in Range \$10-24999 = 40
 - # in Range \$25000+ = 25
- Number of Physicians with Consults worth Undisclosed Amounts: 25
- Total Number of Consultations Reviewed: 255
- Total Number of Disclosures Reviewed: 1386

Financial Conflicts of Interest in Medicine

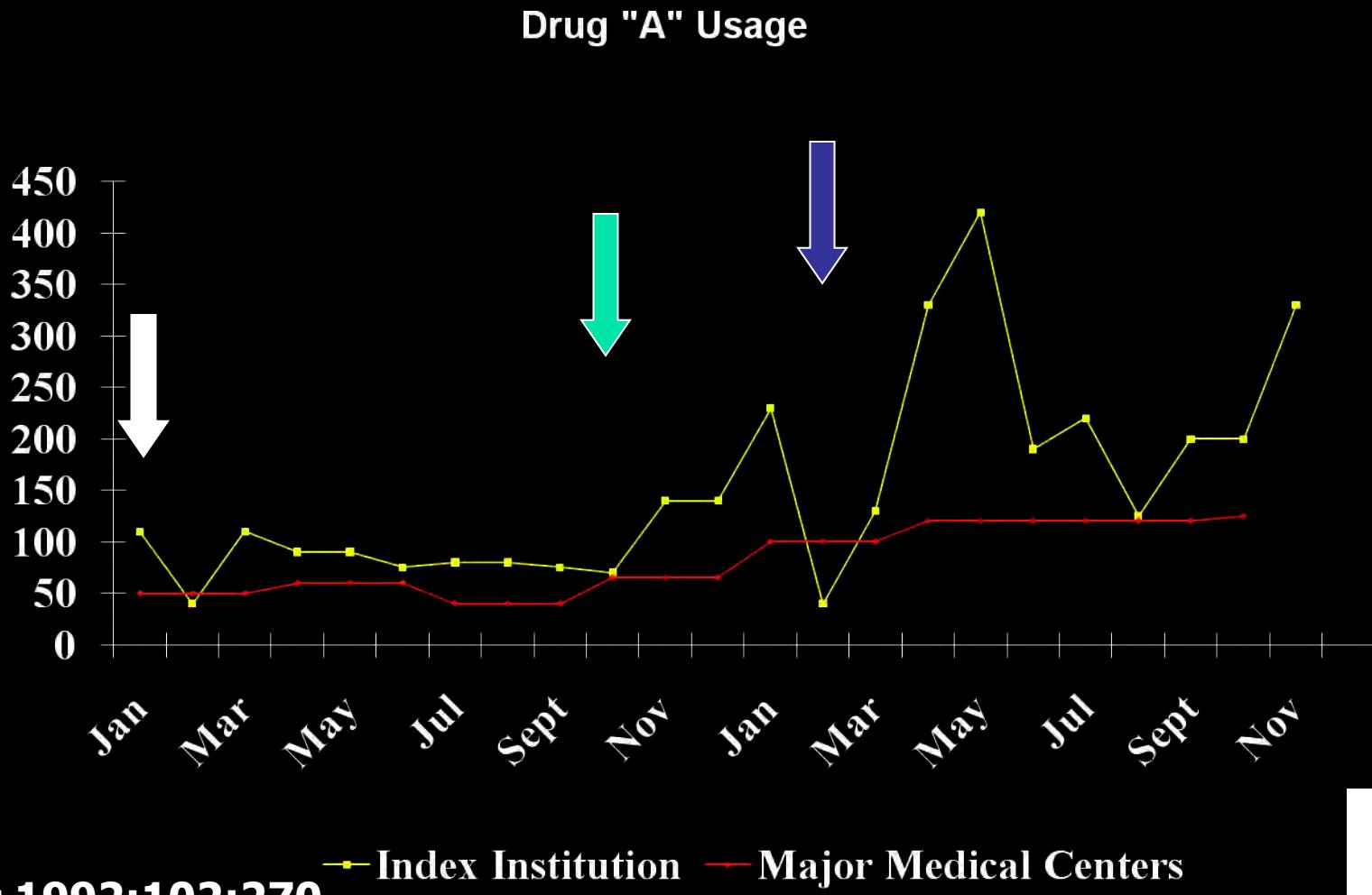


Impact of Pharma Marketing on Clinical Care

- Substantial literature has shown that pharma marketing influence detracts from optimal clinical care
 - Wazana's systematic review of the medical literature on gifting found that an overwhelming majority of industry-physician interactions had detrimental effects on clinical care¹

¹Wazana A. Physicians and the pharmaceutical industry: is a gift ever just a gift? JAMA. 2000;283:373-380.

The Effects of Pharmaceutical Firm Enticements on Physician Prescribing Patterns



Chest 1992;102:270



The Issue with Gifts

■ Gifts of any size influence behavior

- According to Katz et al., — “When a gift or gesture of any size is bestowed, it imposes on the recipient a sense of indebtedness. The obligation to directly reciprocate, whether or not the recipient is conscious of it, tends to influence behavior. . . . Feelings of obligation are not related to the size of the initial gift or favor”¹

■ Nevertheless, most physicians falsely believe that gifts could not influence their behavior²

¹Katz D, Caplan AL, Merz JF. All gifts large and small: toward an understanding of the ethics of pharmaceutical industry gift-giving. Am J Bioeth. 2003;3:39-46

²Wazana A. Physicians and the pharmaceutical industry: is a gift ever just a gift? JAMA. 2000;283:373-380.

Gifts vs. Other Advertising

	Gifts	Other Advertising
Cost money	✓	✓
Influence behavior	✓	✓
Create obligation to reciprocate	✓	✗
Create sense of entitlement	✓	✗
Erode professional values	✓	✗

Unlike with other advertising, the need to reciprocate created by gifts leads to a conflict of interest

Defining Conflict of Interest

- “**conflicts of interest** occur when physicians have motives or are in situations for which reasonable observers could conclude that the moral requirements of the physician’s roles are or will be compromised”
- “**financial conflicts of interest** occur when physicians are tempted to deviate or do deviate from their professional obligations for economic or other personal gain”

Fiduciary Characteristics

- A fiduciary is one who:
 - holds a specialized knowledge or expertise
 - holds the trust of others
 - is held to high standards of conduct
 - avoids conflicts of interest
 - does not seek personal gain
 - is objective
 - is accountable or obligated (ethically and legally)

How many of these characteristics apply to physicians?

All of the characteristics should apply to a physician. Therefore, a physician is, in effect, a fiduciary, and should avoid conflicts that could undermine patient care.

Basic Ethical Principles

Fiduciary Relationships

“Fiduciary” is often used to describe the patient-physician relationship because:

- patients place their trust and well-being in the hands of physicians
- physicians are responsible for the welfare of patients
- physicians respond to patients’ actual (vs. perceived) needs
- physicians are responsible for controlling patient/third-party payer expenses for medications and other medical services

Basic Ethical Principles

Physicians and Conflicts of Interest

- A conflict of interest may exist if a professional judgment concerning a primary interest stands to be unduly influenced by a secondary interest.
- Because of the fiduciary nature of the patient/physician relationship, it is generally expected that physicians should avoid conflicts of interest that may undermine patient care.
- For actual or perceived conflicts that cannot be avoided, disclosure may function as the primary mechanism to reduce the effect of the conflict.

Notion of Professionalism

Three key features help separate professions from other occupations:

- The learning and teaching of expert knowledge
- The use of this knowledge to serve a purpose that is highly valued by society, or is of necessity to its members
- The self-regulation of professionals according to a code of conduct

Professionalism

- Professionalism is the conduct, aims or qualities that characterize a profession or a professional person
- A moral code is often the basis of professionalism
- It is more than *doing* a particular type of job but more about *being* a particular type of person
- It involves —professing” openly that you are that type of person, usually by taking an oath

Professionalism

- Professionalism is the basis of medicine's contract with society
- It demands placing the interests of the patients above those of the physician
- Setting and maintaining standards of competence and integrity
- Providing expert advice to society on matters of health

“All true universities, whether public or private, are public trusts designed to advance knowledge by safeguarding the free inquiry of impartial teachers and scholars. Their independence is essential because the university provides knowledge not only to its students, but also to the public agency in need of expert guidance and the general society in need of greater knowledge;... these latter clients have a stake in disinterested professional opinion, stated without fear or favor, which the institution is morally required to respect.”

American Association of University Professors, 1954

Take-Away Points

- Physicians are professionals and retain unique responsibilities.
- The “fiduciary” nature of the patient-physician relationship requires physicians to act according to high standards of conduct.
- Physicians should ensure that interactions with industry are free of any conflicts of interest that could compromise or appear to compromise their judgment.
- Most financial arrangements with industry should be reviewed with qualified legal counsel to verify that they conform to ethical guidelines and the law.
- The consequences of unprofessional behavior are destruction of public trust and worse outcomes for people with illness

UTHSCSA Policy – Highlights

(<http://www.uthscsa.edu/hop2000/> - Chapter 10)

- Covers all faculty, staff, students and anyone else involved in the design, conduct of reporting of research
- Code of Ethics and Standards of Conduct
- Clinicians and researchers may not accept gifts of any kind of any amount from industry representatives – includes pens, food, pads, office supplies, text books, etc.
- Clinicians and researchers may not give promotional talks, be paid for listening to a sales pitch or write prescriptions, participate in or accept compensation for speeches or papers that were —ghost written”, or accept paid travel to or payment for attending meetings at which they are not presenting their work
- Industry representatives are banned from clinical care areas unless given specific permission

UTHSCSA Policy – Highlights

(<http://www.uthscsa.edu/hop2000/> - Chapter 10)

- Pharmaceutical samples may be kept but not for personal use or given to family members
- Free device samples intended for student skills practice sessions (e.g., suturing kits) should not be provided directly to trainees.
- Industry consulting is allowed as long as it and any compensation is declared annually, based on a contract, uses fair market value, and in total does not surpass 30% of base salary
- Travel to outside compensated or uncompensated activity may not exceed the equivalent of 4 days per month.
- Compensation from outside activities in the School of Medicine must be turned over to home department
- Faculty with conflicts of interest may not participate in UTHSCSA decisions involving to the entity with which they are in conflict

Case Studies

Case 1: The Long Night

- You've been on-call all night, responding to one emergency after another. It's finally time to head home, and you're starving. As you leave Ravdin for the bus stop, you run into a pharmaceutical rep outside. He invites you to join him for breakfast at DiBruno's to discuss new research that has just been published about a new anti-hypertensive drug recently added to the formulary
- What should you do?

Case 1 - *continued*

- Discussion points:
 - Marketing vs. research
 - Inside vs. outside hospital
 - Formulary vs. non-formulary drugs
- Bottom line: The fact that a meal will be provided makes this a marketing event. You are free to discuss the new drug with the rep, but you must do so under neutral conditions

Case 2: Dr. Robin Hood

- You just graduated from med school and although you have a deep distrust of big pharma, you just examined a woman who needs an expensive new RA drug. She has 8 children and no money to spend on meds. One of your old college roommates works as a pharma rep. You hate to ask, but you know that you can get some free samples for this patient to make her life easier
- What should you do?

Case 2 - *continued*

- Discussion points:
 - Sampling as an indigent drug program
 - Better alternatives to samples
- Bottom line: Samples are ultimately promotional in nature, and the policy forbids acceptance of samples under any conditions. However, programs do exist to get your patients the drugs they need (e.g., vouchers)

Case 3: Jet-setter

- You've finally finished 8 years of post-graduate training and have been promoted to the faculty. Having spent your fellowship working with some of the world's foremost cardiologists, you have become somewhat of an expert on a new type of anti-fibrinolytic. The company wants you to join the lecture circuit and is willing to pay you for your time. The pay is not much—about \$500 per lecture—but the money could really help you pay off those student loans. All the conferences are out of state, and you're confident your Department Chair won't find out you're giving these talks
- What should you do?

Case 3 - *continued*

- Discussion points:
 - Research vs. marketing events
 - Reimbursement vs. honorarium
 - Source of the payment: drug company vs. hospital
- Bottom line: While there will be no active policing of your extramural activities, you should not be participating in marketing activities—as a lecturer or guest. When you do present research, only reimbursement of travel expenses is permitted

Case 4: The Newbie

- It's your first week as a new intern. You're eager to learn and have read all the UTHSCSA policies. You want to get the latest information on a new statin and have accepted an appointment to meet with a rep about it. Unfortunately, the only room available is the resident lounge, which is in a patient care area
- What should you do?

Case 4 - *continued*

- Discussion points:
 - Appropriate industry contact
 - Designated non-patient care vs. patient care areas
- Bottom line: Although you've had every intention to follow the rules, you may only interact with pharma rep in certain designated, non-patient care areas.
Physician lounges are off-limits

Where to Get More Information

- HUP Policy Manual (<http://uphsxnet.uphs.upenn.edu/policy/hup/index.shtml>)
 - Guidelines for Interactions between Healthcare Professionals and Industry (No. 1-07-10)
 - Pharmaceutical Company Representative Activity (No. 1-12-41)
- Penn Pharma Policies: FAQs
- Center for Evidence-based Practice website (<http://www.uphs.upenn.edu/cep/>)
- Professional guidelines
 - AMA – Ethical Guidelines for Gifts to Physicians from Industry
 - (<http://www.ama-assn.org/ama/pub/category/5689.html>)
 - ACP – Physician-Industry Relations (http://www.acponline.org/ethics/phys_inds.htm)
 - PhRMA – Code on Interactions with Healthcare Professionals (http://www.phrma.org/code_on_interactions_with_healthcare_professionals)
- Bibliography of relevant literature