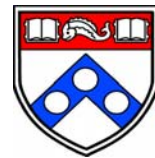


PENN Medicine

Pharmaceutical Industry Relationships Educational Materials

Adam Lessler
David A. Horowitz, M.D.



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Overview

- ◆ Pharmacoeconomics
- ◆ Attitudes, Practices & Bias
- ◆ Gifting & Conflicts of Interest
- ◆ Summary of Policies
- ◆ Case Studies
- ◆ Resources

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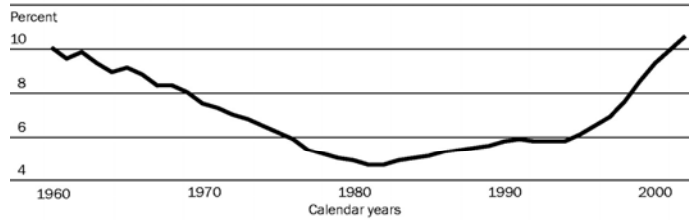
Pharmacoeconomics

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Pharmaceutical Spending

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

EXHIBIT 3
Prescription Drug Spending As A Share Of U.S. Health Spending, 1960-2002



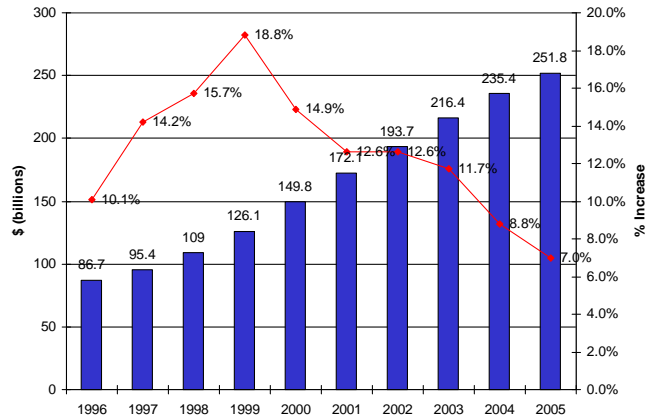
SOURCE: Centers for Medicare and Medicaid Services, Office of the Actuary, National Health Statistics Group.

Source: Centers for Medicare and Medicaid Services and the Bureau of Economic Analysis. Graph from Smith C. Retail prescription drug spending in the National Health Accounts. Health Aff (Millwood). 2004;23:160-7.

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Total U.S. Pharmaceutical Sales

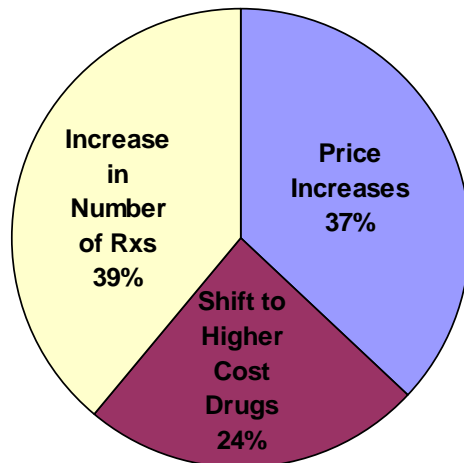
- ◆ Drug sales (Rx & OTC) have trended up steadily over the past decade although the rate of increase has diminished in recent years



Source: IMS Health, Top-Line Industry Data.

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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.

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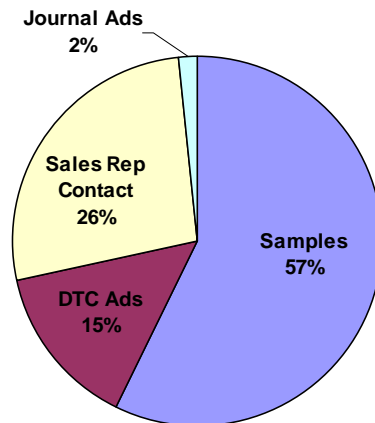
Pharmaceutical Industry Marketing

- ◆ In 2004, pharmaceutical companies spent almost \$12 billion on marketing activities
 - This amount does not include the retail value of samples (>\$15 billion)
- ◆ Despite (or perhaps because of) these high marketing expenses, pharma profit margins are among the highest of any industry
- ◆ The trend of increasing promotional spending and profit margins has substantially increased over time

Sources: IMS Health, Top-Line Industry Data; Fortune 500, 2006 (<http://money.cnn.com/magazines/fortune/fortune500/performers>)

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Promotional Spending on Drugs, 2004

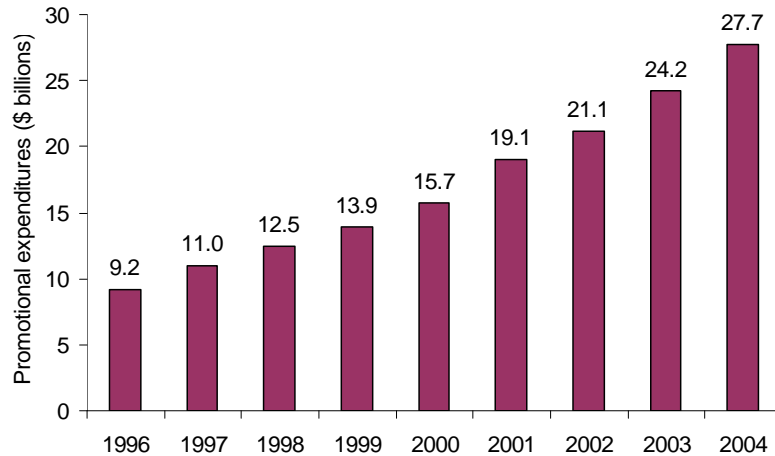


Total Spending: \$27.7 billion

Source: IMS Health, Top-Line Industry Data.

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Promotional Spending on Rx Drugs, 1996-2004



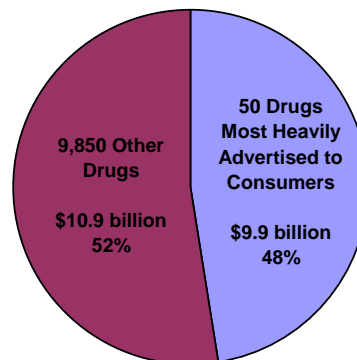
Source: IMS Health, Top-Line Industry Data.

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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.

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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

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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

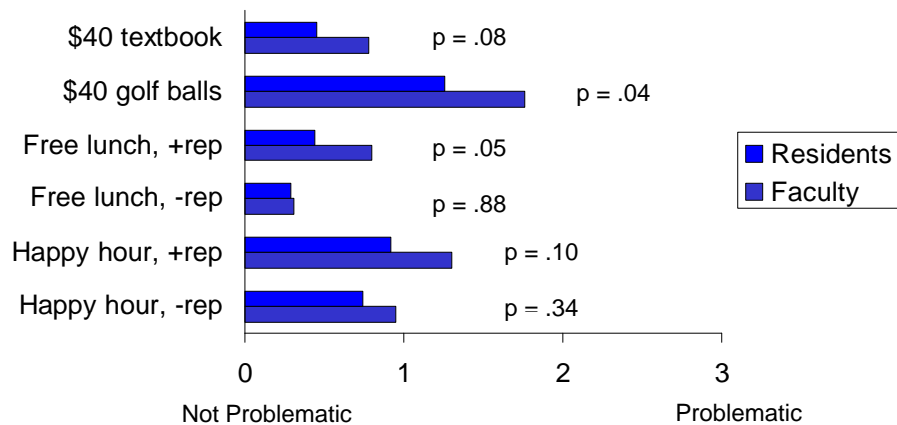
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Attitudes, Practices & Bias

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Attitudes Towards Promotional Activities

Resident and Faculty Responses

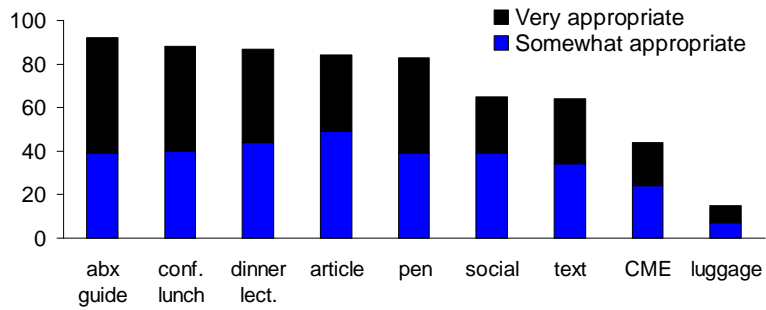


Brett AS, Burr W, Moloo J. Are gifts from pharmaceutical companies ethically problematic? A survey of physicians. Arch Intern Med. 2003. 163:2213-8.

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Attitudes Towards Promotional Activities

Percent Who Consider Appropriate

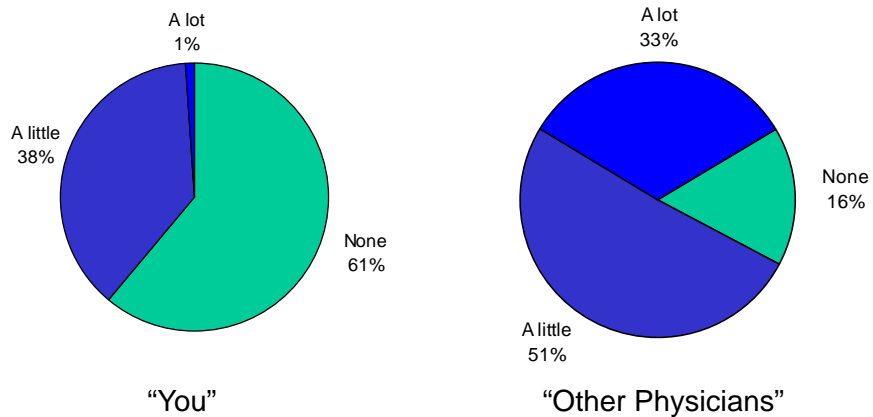


Steinman MA, Shlipak MG, McPhee SJ. Of principles and pens: attitudes and practices of medicine housestaff toward pharmaceutical industry promotions. Am J Med. 2001;110:551-7.

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Attitudes Towards Promotional Activities

Perceived Influence of Pharmaceutical Reps on Prescribing Practices



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.

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Pharmaceutical Branding of Residents

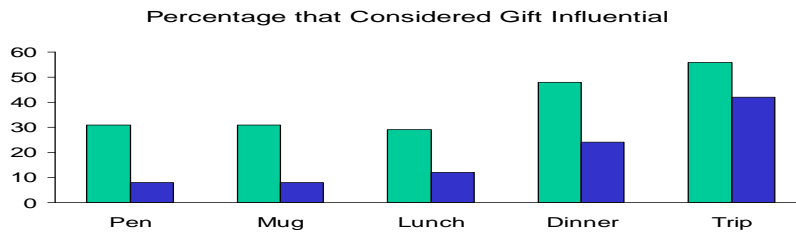
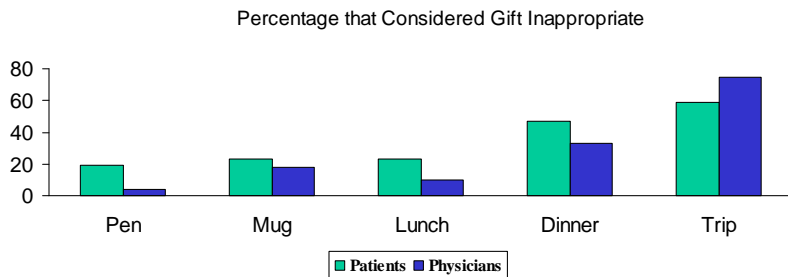
Table. Frequency of Items Found in Residents' White Coats

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)

Sigworth SK, Nettleman MD, Cohen GM. Pharmaceutical branding of resident physicians. JAMA. 2001;286:1024-5.

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Physician vs. Patient Attitudes



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

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Bias in Promotional Materials

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

Cooper RJ, Schriger DL, Wallace RC, Mikulich VJ, Wilkes MS. The quantity and quality of scientific graphs in pharmaceutical advertisements. J Gen Intern Med. 2003;18:294-7

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Are Physicians Part of the Problem?

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

- ◆ 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

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Gifts & Conflicts of Interest

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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.

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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.

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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

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Conflict of Interest

- ◆ Set of conditions in which professional judgment concerning a primary interest (such as a patient's welfare or the validity of research) tends to be unduly influenced by a secondary interest (such as financial gain)¹

¹Thompson DF. Understanding financial conflicts of interest. N Eng J Med. 1993;329:573-6.

Should Doctors Be Held to a Higher Standard?

- ◆ The physician-patient relationship is a *fiduciary relationship*
- ◆ A fiduciary is one who:
 - Has specialized knowledge or expertise
 - Holds the trust of others
 - Held to high standards of conduct
 - Avoids conflicts of interest
 - Is accountable or obligated (ethically and legally)

UPHS View

- ◆ Relationship with industry is important but challenging
- ◆ Purchasing decisions should be free of conflict
- ◆ Decision-making should be evidence-based
 - Burden of evidence is on Pharma
- ◆ Staff should be shielded from marketing interference
- ◆ UPHS should be a leader in drug use education

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Summary of Policies

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PENN Medicine – Pharma Standards

- ◆ Guidelines for Interactions between Health Care Professionals and Pharma

- ◆ Pharmaceutical Company Representative Activity

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Health Care Professionals & Pharma

- ◆ Purpose of Guidelines:
 - Define appropriate interactions
 - Minimize undue influence

- ◆ Scope: All professionals who deliver care

- ◆ Implementation: Professionals, Chairs, Chiefs, and program directors

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Health Care Professionals & Pharma

◆ Meals and Gifts:

- No meals; No gifts

◆ Unrestricted support for education permitted

- Support to Department or Division
 - Used at Discretion of Chair/Chief

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Health Care Professionals and Pharma

◆ Sample Medications

- No samples in HUP/CPUP
- Longstanding policy

◆ Formulary

- No conflicts permitted among decision-makers
- Consulting participants must actively disclose conflicts

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Health Care Professionals and Pharma

◆ Industry Contact with HUP/CPUP MD/Staff

- No industry use of HUP/CPUP resources
 - No use of HUP/CPUP e-mail
- HUP/CPUP may not provide staff contact information
- No compensation to staff for listening to detailing
 - Includes on-line detailing
- Contacts may only be made in designated areas
- No industry attendance at conferences

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Health Care Professionals and Pharma

◆ Consulting/travel

- Expenses for research presentations may be accepted
 - No honoraria for research presentations
- Enrollment of patients in trials should cover direct and indirect costs and should be budgeted
- No reimbursement for providing lists of patients
- No payment for passive consulting

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Staff Should Not Participate in Industry Marketing Activities

- ◆ Professional staff should not participate in industry marketing activities
 - Staff should not attend marketing activities
 - This includes but is not restricted to dinners, socials, entertainment events
 - Staff should not give lectures at marketing activities
 - CME-approved activities supported by industry are appropriate as long as UPHS staff controls the content

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Formulary Practices: Center for Evidence-Based Practice

- ◆ UPHS system-wide function
- ◆ Established under the Office of the CMO
- ◆ Focused on the application of evidence to practice
- ◆ Virtual center with small staff
- ◆ Draws on and integrates existing resources across UPHS

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Center for Evidence-Based Practice

How will the Center function in the context of UPHS-Pharma relationship?

- ◆ Single point of contact for industry
- ◆ Invites industry to participate and inform
- ◆ Utilizes existing UPHS resources
- ◆ Seeks external consultant opinions
- ◆ Recommends formulary addition and utilization
- ◆ Establishes guidance for pharma rep practice

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Pharma Representative Activity

- ◆ UPHS authorizes and coordinates activity
- ◆ Applies to all staff and all pharma reps
- ◆ Protects staff efficiency and integrity
- ◆ Supports patient safety and privacy
- ◆ **ACCESS TO PENN IS CONTINGENT ON PARTICIPATION IN UPHS EVIDENCE-BASED SINGLE POINT OF CONTACT PROCESS**

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Expressed Concerns About Pharma Policies

- ◆ Food
- ◆ Samples
- ◆ Paid Lectures
- ◆ Education

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Response to Concerns: Food

- ◆ Physicians receiving industry-sponsored meals request formulary additions more frequently^{1,2}

¹Chren MM, Landefeld CS. Physicians' behavior and their interactions with drug companies. A controlled study of physicians who requested additions to a hospital drug formulary. JAMA. 1994;271:684-689.

²Lurie N, Rich EC, Simpson DE, et al. Pharmaceutical representatives in academic medical centers: interaction with faculty and housestaff. J Gen Intern Med. 1990;5:240-243.

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Response to Concerns: Food - *continued*

- ◆ Pharma meals are not an employee benefit

- ◆ Philanthropy is encouraged and can be used at discretion of chair/chief

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Response to Concerns: Samples

- ◆ Sampling is not an indigent drug program
 - Samples are promotional in nature
 - Samples are often not used for indigent patients^{1,2}

- ◆ Voucher program has been effective

¹Westfall JM, McCabe J, Nicholas RA. Personal use of drug samples by physicians and office staff. JAMA. 1997;278:141-143.

²Tong KL, Lien CY. Do pharmaceutical representatives misuse their drug samples? Can Fam Physician. 1995;41:1363-1366.

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Response to Concerns: Samples - *continued*

- ◆ Monitoring and accounting for samples is a challenge
 - No documentation of safe practices
 - Logs and labeling are not complete
 - Issues of drug recalls and instructions for patients
- ◆ UPHS considering generic sampling system - Medvantix

¹Westfall JM, McCabe J, Nicholas RA. Personal use of drug samples by physicians and office staff. JAMA. 1997;278:141-143.

²Tong KL, Lien CY. Do pharmaceutical representatives misuse their drug samples? Can Fam Physician. 1995;41:1363-1366.

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Response to Concerns: Samples - *continued*

- ◆ Samples lead to inappropriate prescribing
 - Peay and Peay found that accepting samples was associated with awareness, preference and rapid prescription of a new drug¹

¹Peay MY, Peay ER. The role of commercial sources in the adoption of a new drug. Soc Sci Med. 1988;26:1183-1189.

²Adair RF, Holmgren LR. Do drug samples influence resident prescribing behavior? A randomized trial. Am J Med. 2005;118:881-4.

³Chew LD, et al. A physician survey of the effect of drug sample availability on physicians' behavior. J Gen Int Med. 2000;15:478-483.

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Response to Concerns: Samples - *continued*

- ◆ Samples lead to inappropriate prescribing –
 - Adair, et al. found that residents who were randomized to use samples were less likely to prescribe over-the-counter medications and more likely to prescribe advertised drugs than residents randomized to agree not to use samples²

¹Peay MY, Peay ER. The role of commercial sources in the adoption of a new drug. Soc Sci Med. 1988;26:1183-1189.

²Adair RF, Holmgren LR. Do drug samples influence resident prescribing behavior? A randomized trial. Am J Med. 2005;118:881-4.

³Chew LD, et al. A physician survey of the effect of drug sample availability on physicians' behavior. J Gen Int Med. 2000;15:478-483.

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Response to Concerns: Samples - *continued*

- ◆ Samples lead to inappropriate prescribing - *continued*
 - In a survey of physicians at an academic medical center, Chew, et al. found that in the treatment of an uninsured male hypertension patient, over 90% of physicians who use samples would dispense a sample that differed from their preferred drug choice³

¹Peay MY, Peay ER. The role of commercial sources in the adoption of a new drug. Soc Sci Med. 1988;26:1183-1189.

²Adair RF, Holmgren LR. Do drug samples influence resident prescribing behavior? A randomized trial. Am J Med. 2005;118:881-4.

³Chew LD, et al. A physician survey of the effect of drug sample availability on physicians' behavior. J Gen Int Med. 2000;15:478-483.

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Alternatives to Samples

- ◆ Vouchers
 - Take samples out of practices
 - Improve patient safety
 - Improve prescribing habits
 - Permit better screening for ADEs
 - Allow for better patient instructions
- ◆ Generic Sampling

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Response to Concerns: Paid Lectures

- ◆ Physicians who accept drug company honoraria are more likely to request formulary additions^{1,2}
- ◆ Policy does not interfere with “One Day in Seven”
 - Policy states staff should not participate in marketing
 - No police function in these documents
- ◆ Philanthropy is encouraged and can be used at discretion of chair
- ◆ Setting a standard

¹Chren MM, Landefeld CS. Physicians' behavior and their interactions with drug companies. JAMA. 1994;271:684-689.

²Lurie N, Rich EC, Simpson DE, et al. Pharmaceutical representatives in academic medical centers. J Gen Intern Med. 1990;5:240-243.

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Response to Concerns: Education

- ◆ Medical Board policies do **not** supersede Medical School CME policies

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Case Studies

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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?

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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—as long as it is on the hospital formulary—with the rep, but you must do so under neutral conditions

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Case 2: Dr. Robin Hood

- ◆ You just graduated from med school and finally had to cut your long hair and dispose of the Birkenstocks. Your white coat is adorned with “No Free Lunch” paraphernalia. 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?

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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, Medvantix)

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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 Dr. Brennan won't find out you're giving these talks

- ◆ What should you do?

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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

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Case 4: The Newbie

- ◆ It's your first week as a new intern. You're eager to learn and have read all the HUP 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?

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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

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Resources

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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_inde.htm)
 - PhRMA – Code on Interactions with Healthcare Professionals (http://www.phrma.org/code_on_interactions_with_healthcare_professionals)
- ◆ Bibliography of relevant literature

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