

Addressing Potential Conflict of Interest with the Pharmaceutical and Biomedical Devices Industries

As formulated and reviewed by the DMU Conflict
of Interest Committee

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Purpose

- **The purpose of this presentation is to raise the awareness among all DMU health professional students about potential conflict of interest in present and future interactions with industries that market their products directly to the medical community. The committee realizes that while there is always another side to the story, this program is to clarify potential conflicts of interest and to encourage discussions regarding how to avoid participating in behaviors that may be considered unethical and potentially damaging.**

Objectives

- **At the end of this lecture, the student will be able to:**
 - **Identify the conflicts that may arise between industry representatives and health care professionals**
 - **Discuss how to develop and sustain productive and ethical relationships.**

Submitted by DMU to the AMSA (American Medical Student Association) PharmFree Campaign, 2009 as our curricular objectives regarding conflict of interest


Conflict of interest

- **“Any situation in which an individual is in a position to exploit his/her professional or official capacity in some way for personal benefit.”***

***DMU Conflict of Interest Policy; 11-11-2009 Version**

The AMSA Scorecard

- **In 2008, AMSA worked with the PEW Prescription Product to develop a Scorecard, which used a rigorous and transparent methodology to assess the content of conflict of interest policies at medical schools throughout the country.**
- **This policy and resulting Scorecard was supported by strong guidelines set by the Association of American Medical Colleges (AAMC) in the summer of 2008 and the Institute of Medicine in spring 2009.**

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- **The Scorecard examines potential conflicts of interest created by industry marketing at the level of the individual physician and trainee.**
 - **The AMSA PharmFree Scorecard evaluates conflict-of-interest policies at 149 medical colleges and colleges of osteopathic medicine in the United States, with a focus on interaction between students or faculty and the pharmaceutical industry by using letter grades to assess schools' performance in eleven potential areas of conflict**

Conflict of Interest Policies at Academic Medical Centers

SHOWING: All in IA

SEARCH: State City

Click on any school to learn more. To sort by domain score, please use arrows.

BETTER \longleftrightarrow WORSE

Compare Institutions

Select the institutions below and click "Go" to compare.

[University of Iowa Carver College of Medicine Iowa City, IA](#)

[Des Moines University College of Osteopathic Medicine Des Moines, IA](#)

	Grade	Gifts	Consulting	Speaking	Disclosure	Samples	Purchasing	Sales Reps	On Campus	Off Campus	Industry Support	Curriculum	Cor
<input type="checkbox"/> University of Iowa Carver College of Medicine Iowa City, IA													
<input type="checkbox"/> Des Moines University College of Osteopathic Medicine Des Moines, IA													


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What the results mean...

- Model policy
- Good progress toward model policy
- No policy, or policy unlikely to have a substantial effect on behavior
- Did not report
- Policy not relevant to this institution (e.g., does not make purchasing decisions)

So What?

- **Iowa Senator Grassley, the ranking member on the Senate Finance Committee, has worked to achieve uniform and universal disclosure of financial arrangements that pharmaceutical, medical device, and other related companies have with physicians, especially those receiving NIH grants for research.**
- **Researchers are required to disclose financial relationships with pharmaceutical and biomedical device companies**

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- **Senator Grassley's findings over the past year indicate that enforcement of those requirements is inconsistent.**
 - **In a June 24, 2009, letter, Senator Grassley asked 23 medical schools (not DMU) for their conflict of interest policies and requirements for disclosure of financial relationships between faculty and the pharmaceutical industry. These 23 schools had either "no response" or "declined to submit policies" when the American Medical Student Association (AMSA) requested this information.**

Disclosures

- **(?) of us have accepted several textbooks, handbooks, office supplies, and meals from pharmaceutical or biomedical device companies.**
- **(?) of us has ever accepted research support, consulting fees, speakers' honoraria from companies.**
- **(?) of us has equity interest in a pharmaceutical or biomedical device company (that we are aware of).**


What's the big deal?

- **There has been an erosion of the trust between the American public and the pharmaceutical and biomedical devices industries based on well publicized litigations involving fraudulent practices**
- **Is big PhARMA distorting the facts?**

AMSA's PharmFree Campaign

November 16, 2009

- **“According to AMSA’s recommendations, industry has influenced the practice of medicine through traditional advertising, manipulation of the evidence base for pharmaceuticals and devices, and by more subtle means of promotion such as showering gifts, money, and lucrative contracts on physicians, who have frequently come to accept these benefits as a well-deserved right. These practices have influenced patient care, from the drugs that physicians prescribe to the clinical research that provides the evidence base for prescription decisions.”**

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- **“Today’s recommendations seek to provide medical students (and all DMU students) with the knowledge and analytical skills necessary to:**
 - 1) Understand the nature of potential conflicts-of-interest and how they pertain to the practice of medicine**
 - 2) Recognize how industry interaction can impact clinical care and develop strategies to mitigate the negative influences**
 - 3) Properly manage industry relations to maximize benefit to patients and public health”**

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- **At DMU we need to model behavior and educate students on conflict of interest**
 - **Health education accrediting bodies expect it, and our various codes of professional ethics demand it**

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- **AAMC: (American Association of Medical Colleges)**

“Students will “describe the limitations of the claims of therapeutic efficacy and safety as they might be reported by a pharmaceutical manufacturer” and ... “understand how receipt of gifts, payments, or other relationships can influence the judgment of physicians and can distort prescribing practices.”



- American College of Healthcare Executives:

“Executives should take care that interactions with suppliers not result in perceptions of undue influence or other perceived impropriety.”



- **American Physical Therapy Association, Code of Ethics:**

“Physical therapists shall not accept gifts or other considerations that influence or give an appearance of influencing their professional judgment.”

Myth #1 (?)

- “Drug companies spend more on R&D than on marketing”
- \$29.6 billion on R&D in 2004 in the US as compared to US\$27.7 billion for all promotional activities*

*Based on the data provided by IMS, and reported by the Pharmaceutical Research and Manufacturers of America (PhRMA), an American industrial lobby group for research-based pharmaceutical companies

NOT SO FAST, MY FRIEND!


Study by two York University (Toronto, Canada) researchers estimates the U.S. pharmaceutical industry spends almost twice as much on promotion as it does on research and development, contrary to the industry's claim

Type of Promotion	IMS (US\$ Billions)	CAM (US\$ Billions)	New Estimate (US\$ Billions)	Percent of Total of New Estimate
Samples	15.9	6.3	15.9 (IMS)	27.7
Detailing	7.3	20.4	20.4 (CAM)	35.5
DTCA (Data provided by CMR)	4	4	4 (CMR)	7
Meetings	nd	2	2 (CAM)	3.5
E-promotion, mailing, clinical trials	nd	0.3	0.3 (CAM)	0.5
Journal advertising	0.5	0.5	0.5 (CAM/IMS)	0.9
Unmonitored promotion (estimate ^a)	nd	14.4	14.4 (CAM)	25
Total	27.7	47.9	57.5	100

^aIncludes incomplete disclosure and omissions by surveyed physicians, promotion to unaudited physician categories, promotion in unmonitored journals, and could possibly include unethical forms of promotion funded out of the firms' marketing budget. See text for details about this category.

DTCA, direct-to-consumer advertising; nd, no data

doi:10.1371/journal.pmed.0050001.t001


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- **Data from the annual reports is misleading**
 - **No info on how much is spent on drug marketing, only non-drug marketing**
 - **Merges marketing with administrative costs**
 - **Marketing is more than promotion and should include the costs of packaging and distribution**

Myth #2 (?)

- “Drug costs are high in the US because so much is invested in R&D to bring new drugs to market”

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- **2002: of 78 drugs approved by the FDA, 17 contained new ingredients, and 7 were classified as improvements over older drugs***

***The Truth About the Drug Companies: How They Deceive Us and What to Do About It, 2004. Marcia Angell, MD**


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- **Dr. Sharon Levine, associate executive director of Kaiser Permanente Medical Group**
“If I’m a manufacturer and I can change one molecule and get another twenty years of patent rights, and convince physicians to prescribe and consumers to demand the next form of Prilosec...just as my patent expires, then why would I be spending money on a lot less certain endeavor, which is looking for brand-new drugs?”

Myth #3 (?)

- **“As a health professional, I rely on drug reps to provide me with the latest information on drug actions/interactions.”**

Problems with drug rep information

- Discuss a single, favorable clinical trial vs systematic review
- Measure disease endpoints and not patient oriented outcomes
- The review articles and monographs they quote are funded and may lack peer review
- They never, never, NEVER give unfavorable info (exception is “black-box warning”)

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- **A black box warning is the sternest warning by the U.S. Food and Drug Administration (FDA) that a medication can carry and still remain on the market in the United States.**
 - **A black box warning appears on the label of a prescription medication to alert you and your healthcare provider about any important safety concerns, such as serious side effects or life-threatening risks.**

The following excerpt from the prescription label of Zoloft is an example of a black box warning.

- **Suicidality in Children and Adolescents**

Antidepressants increased the risk of suicidal thinking and behavior (suicidality) in short-term studies in children and adolescents with Major Depressive Disorder (MDD) and other psychiatric disorders. Anyone considering the use of Zoloft or any other antidepressant in a child or adolescent must balance this risk with the clinical need. Patients who are started on therapy should be observed closely for clinical worsening, suicidality, or unusual changes in behavior. Families and caregivers should be advised of the need for close observation and communication with the prescriber. Zoloft is not approved for use in pediatric patients except for patients with obsessive compulsive disorder (OCD).

Summary

Background The value of azithromycin for treatment of acute bronchitis is unknown, even though this drug is commonly prescribed. We have investigated this question in a randomised, double-blind, controlled trial.

Methods Adults diagnosed with acute bronchitis, without evidence of underlying lung disease, were randomly assigned azithromycin (n=112) or vitamin C (n=108) for 5 days (total dose for each 1.5 g). All individuals were also given liquid dextromethorphan and albuterol inhaler with a spacer. The primary outcome was improvement in health-related quality of life at 7 days; an important difference was defined as 0.5 or greater. Analysis was by intention to treat.

Findings The study was stopped by the data-monitoring and safety committee when 220 patients had been recruited. On day 7, the adjusted difference in health-related quality of life was small and not significant (difference 0.03 [95% CI -0.20 to 0.26], p=0.8). 86 (89%) of 97 patients in the azithromycin group and 82 (89%) of 92 in the vitamin C group had returned to their usual activities by day 7 (difference 0.5% [-10% to 9%], p>0.9). There were no differences in the frequency of adverse effects; three patients in the vitamin C group discontinued the study medicine because of perceived adverse effects, compared with none in the azithromycin group. Most patients (81%) reported benefit from the albuterol inhaler.

Interpretation Azithromycin is no better than low-dose vitamin C for acute bronchitis. Further studies are needed to identify the best treatment for this disorder.

Lancet 2002; 359: 1648


Myth #4 (?)

- “Drug company drug trials and information are reliable because they must be approved by the FDA.”



From bad....


- News Update - **Pfizer pleads guilty and agrees to pay \$430 Million.** On May 13, 2004, Reuters reported that Pfizer Inc agreed to pay \$430 million and plead guilty to criminal wrongdoing for **falsely marketing top-selling epilepsy drug Neurontin.** The case involved the marketing of Neurontin for various illnesses that it was not approved to treat, including migraines and back pain. The allegations were first made in 1996 in a lawsuit filed by David Franklin, a whistle-blower, who had worked for the drug's maker.

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- “...the manufacturer of the seizure medication gabapentin (Neurontin) **illegally promoted** the drug to prescribing physicians for at least 11 **‘off-label’ or unapproved medical conditions.**”
 - “The company is alleged to have **paid physicians to appear as authors** of medical journal articles on unapproved uses for gabapentin when the articles had actually been **written by others working under the company’s marketing company.** The safety and effectiveness of gabapentin for these uses is suspect.”

- “The allegedly, illegal, promoted uses for gabapentin (Neurontin) made the drug a ‘blockbuster’ drug. Estimated sales of gabapentin in 2001 totaled **\$1.7 billion**. The majority of these sales were for unapproved uses with **no evidence that the drug was safe or effective.**”
- Settlement: **\$430 million**

...to worse

- July 31, 2009, 4:12pm
- ABUJA, Nigeria, July 30, 2009 (AFP) - US drugmaker Pfizer reached a \$75-million (53-million-euro) final settlement with a Nigerian state Thursday over 1996 drug trials that led to the deaths of 11 children, a joint statement said.
- ...an **illegal test** of the meningitis drug Trovan on 200 children”
- For which the company **did not follow Nigeria's laws on advised consent.**

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- Eleven children died after taking Trovan, which is also alleged to have caused deformities including blindness, deafness, brain damage and paralysis in 189 others.
 - The joint statement by Kano State and Pfizer on Thursday said that one of the terms of the settlement was that there would be **"no admission of liability by Pfizer** in connection with the 1996 Troval study."

Just to name a few (more)

- **vs. GlaxoSmithKline concerning Paxil**
- **vs. Wyeth in litigation concerning Fen-Phen**
- **vs. Pfizer in litigation concerning Zoloft**
- **vs. Merck in litigation over Vioxx**

Are we kidding ourselves???

- “My acceptance of a pen with a company’s logo on it never influences my prescription writing habits!”
- “I need drug samples to give to my patients to save them money!”

The pen is mightier than the...

- Behavior studies have shown that:
 - When one receives a gift, one feels a need to repay in kind
 - Our need to repay for kindness is NOT related to the size of the gift
 - Food and flattery makes one more likeable than others, even if the flattery is recognized as transparent

DILBERT

BY SCOTT ADAMS



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Nexium[®] vs. omeprazole

- **Nexium 40 mg: copay \$30, actual cost \$140/month**
- **Omeprazole 40 mg: copay \$10, actual cost \$30/month**
- **One month of Nexium[®] samples given to the patient**

- **Patient Cost:**


Nexium[®]: \$0 + \$30 x 11 months = \$330

Omeprazole: \$10 + \$10 x 11 months = \$120

- **Taxpayers:**

Nexium[®]: \$140 x 12 months = \$1680

Omeprazole: \$30 x 12 months = \$360

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- **Not to mention that “accepting samples was associated with awareness, preference, and rapid prescription of a new drug, and a positive attitude towards the pharmaceutical representative.”**

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

Report of the AAMC Funding of Medical Education to the AAMC Executive Council, June 18-19, 2009

- **Gifts should not be accepted**
- **Drug samples should be distributed centrally**
- **Sales reps only by appointment and outside patient care areas**
- **No food except at CME events**
- **Speakers' bureaus should not include faculty**
- **Ghost-writing not permitted**
- **Travel payment should not be accepted**

PhRMA Code on Interactions with Healthcare Professionals (updated January 2009)

- **Items primarily for the benefit of patients may be offered to healthcare professionals if they are not of substantial value (\$100 or less).**
- **Items of minimal value may be offered if they are primarily associated with a healthcare professional's practice.**
- **Items intended for the personal benefit of healthcare professionals (CDs, tickets to a sporting event) should not be offered.**

DMU Policy

- **This policy applies to all DMU students, applicable staff, part and full-time faculty members employed by DMU.**
- **All DMU faculty, deans, and chairs shall disclose relationships with Industry by completing and forwarding the Disclosure of Industry Relationships and Secondary Employment Form**

Academic Center

- Educational and/or club events sponsored by pharmaceutical or biomedical device companies must be approved by the Dean, VP of Student Services, and club advisor and monitored by faculty
- No meals or food allowed

Clinic

- **No gifts of any monetary value**
- **No food (unless associated with an approved CME event)**
- **No promotional items**
- **All reps must have an appointment, confine their activities to a designated area, and abide by the PhARMA code for interactions with health professionals**
- **Lectures permitted if speaker discloses financial interests, uses EBM, and is supervised by faculty**

Employee Consultation

- **All DMU employees involved in consulting arrangements must sign a formal written contract and compensation must be considered fair for the services performed**

Speakers' bureaus

- **DMU strongly discourages participation by its faculty and staff in industry-sponsored speakers' bureaus.**
- **If faculty and staff choose to participate in industry-sponsored, FDA-regulated programs, they must be transparent, unedited by the company, and compensated at fair-market value**

Drug samples

- **The DMU Pharmaceutical Review Committee determines if there is evidence to support the use of the drug in the DMU Clinic based on evidence-based medicine and there is no generic alternative to the drug.**
- **Patients must qualify under DMU Clinic's Financial Assistance Program.**
- **DMU will track the dispensing of approved pharmaceutical samples**
- **Faculty, staff and students may not accept free drug samples**

Industry sponsored CME


- **The Office of the Provost will serve as the university's central CME office through which all requests for industry support and receipt of funds for CME activity are coordinated and overseen.**

Other

- **Compensation for travel or attendance at off-site lectures and meetings may not be directly accepted from Industry other than for legitimate contractual services**
- **There shall be no involvement by the donor industry if student scholarships are offered. There must be no quid pro quo for the acceptance of funds.**

Additional References

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