

Physician Relationships with The Pharmaceutical Industry



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The University of Iowa Carver College of Medicine

Physicians & The Pharmaceutical Industry

- Background: Why is this topic important?
- Overview: Physician-Industry Interactions
- Types of Interactions with Physicians
- Research on Effects of These Interactions
- Guidelines on Proper Interactions – The UI Health Care Policy
- Practical Applications of This Policy

Physician-Industry Interactions

Why is this Important?

Very Much in the News Today!

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April 25, 2007, 5:29 pm

Docs Like Free Lunch and Drug Samples

Posted by Jacob Goldstein



More than 80% of doctors have accepted free food from drug reps, and more than 90% have some sort of relationship with the pharmaceutical industry, according to a [study](#) published in the current issue of the New England Journal of Medicine.

Researchers mailed surveys to more than 3,000 doctors in 2003 and 2004. A little more than half responded. The doctors were randomly selected from six specialties: anesthesiology, cardiology, general surgery, family practice, internal medicine and pediatrics. Those specialties were selected to give a comprehensive picture of primary care, and a slice of an inpatient specialty (anesthesiology), a medical specialty (cardiology) and a surgical specialty.

Some 83% of all respondents had accepted food in the work place; 78% accepted free drug samples; 35% had been reimbursed for costs associated with continuing education or professional meetings; and 28% had been paid for consulting, lecturing or enrolling patients in trials.

Cardiologists, whose prescribing patterns are often followed by primary care doctors, were the most likely to have accepted payments. Doctors in solo and group practices met more often with industry reps than doctors at hospitals and clinics did. The authors speculate that this disparity could result from the greater freedom doctors who work outside of institutions have in deciding what to prescribe; from hospital and clinic rules that limit doctor-industry relationships; and from greater availability of medical education for doctors who work at hospitals and clinics.

Senior Citizen Politics

Senators Kohl, Grassley Demand Drug Companies Reveal Gifts to Doctors

McCaskill, Schumer, Klobuchar and Kennedy co-sponsor new bill

Sept. 10, 2007 - U.S. Senators Herb Kohl (D-WI), chairman of the Senate's committee on aging, and Chuck Grassley (R-IA) are introducing legislation to require manufacturers of pharmaceutical drugs, devices and biologics to disclose the amount of money they give to doctors through payments, gifts, honoraria, travel and other means.



"Right now the public has no way to know whether a doctor's been given money that might affect prescribing habits," Grassley said.

Related Stories


[Larry Craig, Former Senate Aging Committee Chair, Busy Explaining Restroom Arrest](#)

Idaho Republican has

"This bill is about letting the sun shine in so that the public can know. Whether it's dinner at a restaurant or tens of thousands of dollars or more in fees and travel, patients shouldn't be in the dark about whether their doctors are getting money from drug and device makers."

"At our June hearing, the pharmaceutical

JAMA: April 16, 2008

 EDITORIAL

Editorials represent the opinions of the authors and JAMA and not those of the American Medical Association.

Impugning the Integrity of Medical Science The Adverse Effects of Industry Influence

Catherine D. DeAngelis, MD, MPH

Phil B. Fontanarosa, MD, MBA

THE PROFESSION OF MEDICINE, IN EVERY ASPECT—clinical, education, and research—has been inundated with profound influence from the pharmaceutical and medical device industries. This has occurred because physicians have allowed it to happen, and it is time to stop.

Two articles^{1,2} in this issue of *JAMA* provide a glimpse of one company's apparent misrepresentation of research data and its manipulation of clinical research articles and clinical reviews; such information and articles influence the education and clinical practice of physicians and other health professionals. The direct influence of for-profit companies on education³⁻⁶ and clinical practice^{7,8} has been well documented, so this Editorial deals primarily with clinical research.

The articles by Ross and colleagues¹ and by Psaty and Kronmal² document how one company, Merck & Co Inc, apparently

to note that for some of the referenced publications listed in the Table of the article by Ross et al,¹ some of the authors either did not actually receive financial support from the company; were not required by the journal in which the study was published to disclose their financial support or relationship with the sponsor; did report their financial support or relationship with the sponsor, but the journal chose not to publish those author disclosures; or did disclose their financial support, and those disclosures were published.

However, it is clear that at least some of the authors played little direct roles in the study or review, yet still allowed themselves to be named as authors. Individuals, particularly physicians, who allow themselves to be used in this way, especially for financial gain, manifest a behavior that is unprofessional and demeaning to the medical profession and to scientific research.

The study by Psaty and Kronmal,² which is based on analysis of published articles, information provided by the company to the US Food and Drug Administration (FDA), and the company's own internal analysis, shows how Merck may

Citing Ethics, Some Doctors Are Rejecting Industry Pay - New York Times

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April 15, 2008

Citing Ethics, Some Doctors Are Rejecting Industry Pay

By [GINA KOLATA](#)

June 8, 2008

Researchers Fail to Reveal Full Drug Pay

By [GARDINER HARRIS](#) and [BENEDICT CAREY](#)

A world-renowned [Harvard](#) child psychiatrist whose work has helped fuel an explosion in the use of powerful antipsychotic medicines in children earned at least \$1.6 million in consulting fees from drug makers from 2000 to 2007 but for years did not report much of this income to university officials, according to information given Congressional investigators.

By failing to report income, the psychiatrist, Dr. Joseph Biederman, and a colleague in the [psychiatry](#) department at Harvard Medical School, Dr. Timothy E. Wilens, may have violated federal and university research rules designed to police potential conflicts of interest, according to Senator [Charles E. Grassley](#), Republican of Iowa. Some of their research is financed by government grants.

Like Dr. Biederman, Dr. Wilens belatedly reported earning at least \$1.6 million from 2000 to 2007, and another Harvard colleague, Dr. Thomas Spencer, reported earning at least \$1 million after being pressed by Mr. Grassley's investigators. But even these amended disclosures may understate the researchers' outside income because some entries contradict payment information from drug makers, Mr. Grassley found.

In one example, Dr. Biederman reported no income from Johnson & Johnson for 2001 in a disclosure report filed with the university. When asked to check again, he said he received \$3,500. But Johnson & Johnson told Mr. Grassley that it paid him \$58,169 in 2001, Mr. Grassley found.

Voices & Commentary

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Large doses of gifts, money gain influence for drug reps

As a pre-med student, Elaina Ori arrived at the Chicago office of a doctor she was shadowing, and found her happily sharing lunch with a pharmaceutical-industry rep who was buying, and brought gifts to boot.

"I saw the lunch and all the stuff, and I thought, 'You mean this is legal?'" said an incredulous Ori, now a second-year med student at Des Moines University (DMU).

Ori had hit on one of the biggest problems in medicine today: aggressive marketing by drug companies to doctors, who then push drugs on their patients.

What Ori saw was the tip of the iceberg. To sell drugs, the pharmaceutical industry has paid its way into doctors' offices, medical groups and public airwaves, promoting cures to illnesses that don't really exist. Doctors have responded by prescribing drugs to people who don't need them.

Author Melody Petersen, an Exira native, was in Des Moines Monday discussing her new book, "Our Daily Meds." She got interested in the issue covering the pharmaceutical industry for the New York Times. She says prescription pills kill more than 240 people a day. Doctors routinely prescribe one pill to remedy the side effects of another. Nine in 10 doctors surveyed last year had taken drugs and/or cash for speeches, consulting and the like to promote drugs. And two-thirds of men, women and children in America take a long-term prescription drug — up 60 percent from 12 years ago.

One way doctors become industry shells, Petersen says, is by giving speeches pro-



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Melody Petersen, author of "Our Daily Meds"

Petersen found that 30 percent of Iowans diagnosed with Alzheimer's Disease were taking drugs that can themselves cause memory problems. "In Iowa, it had gotten to the point where if there was a conference involving health care, there was a better-than-even chance that the pharmaceutical industry would be footing at least some of the bill," she wrote in her book.

But some concerned people are fighting back. Since her Chicago experience, Ori joined the American Medical Students Association (AMSA), which has a campaign to limit the influence of drug companies at med schools. Her concerns have helped propel DMU to reconsider its poli-

education is possible "only because of the ability to have sponsorship." He says it's important for students to learn how to interact with drug reps. But Ori says no one is teaching how to scrutinize their claims.

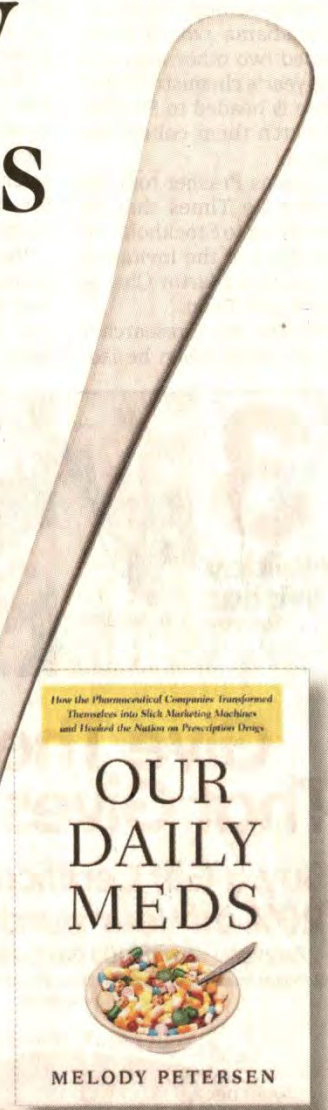
Under pressure, the pharmaceutical industry has issued guidelines, to be implemented next month, that stipulate any meals bought be "modest" and reimbursement to consultants be "fair-market value."

But doctors still should be restricted by law from profiting from such promotions.

Medicine saves lives. The problem is when it's dispensed unnecessarily. Petersen wants TV drug ads banned. She praises Iowa Sen. Charles Grassley for his efforts to require drug companies to disclose their payments to doctors.

The problem requires a fundamental shift in our approach to medicine, from profit making to public health. We're the only developed country, says Petersen, that doesn't control drug prices.

Hopefully, with greater awareness, the public will demand change. Meanwhile, on Dec. 8, 2004, AMSA held its first national PharmFree Day, dumping thousands of pharmaceutical giveaway pens outside Pfizer headquarters. A token way of saying those future physicians aren't for sale.



The Des Moines Register

Iowa couple finalist for eHarmony's most inspirational IOWALIFE

FRIDAY, JANUARY 23, 2009 | DESMOINESREGISTER.COM | THE NEWSPAPER IOWA DEPENDS UPON | 75¢ | METRO EDITION

U of I to bar free drug samples, gifts

Health officials make changes to block conflicts of interest by medical employees.

By ERIN JORDAN
ejordan@dmreg.com

Iowa City, Ia. — A new University of Iowa policy would prohibit physicians from giving free drug samples to patients, a long-standing practice that hospital leaders and consumer advocates say contributes to the ballooning cost of health care.

Other changes include barring U of I Health Care employees from accepting gifts and meals from private companies and requiring all doctors who do industry consulting to report who they work for and how much they are paid.

The restrictions, to be implemented by June, come after a U of I-requested audit showed U of I Health

Care needed more specific conflict-of-interest policies and better ways of monitoring potential conflicts.

The audit was released in May and revealed some U of I doctors were paid for private consulting while they were on the clock for the university and others purchased equipment directly from companies with which they had financial ties. Nine doctors out of more than 800 did not file required reports in 2006 disclosing their potential conflicts of interest, according to the audit done by the Iowa Board of Regents audit committee.

Vice President for Medical Affairs Jean Robillard sent faculty and staff an

CONFLICTS, PAGE 8A

Time for the Medical Profession to Act

New Policies Needed Now on Interactions Between Pharmaceutical Companies and Physicians

Philip Greenland, MD

Arch Intern Med. 2009;169(9):829-831.

On January 1, 2009, the Pharmaceutical Research and Manufacturers of America¹ enacted a new code governing the interactions between pharmaceutical company representatives and health care professionals. The new code, while voluntary for the pharmaceutical manufacturers and physicians, has been endorsed by more than 30 major companies, and it will eliminate small gifts to physicians such as the familiar logo-embossed pens and coffee mugs. The new code, however, does not prohibit sponsorship of office-based or hospital-based meals, continuing medical education (CME) events, or other forms of marketing contacts that are also exceedingly common. Blumenthal² noted in 2004 that over 90% of physicians in the United States reported at least 1 yearly interaction with a pharmaceutical company, typically in the course of an office "detailing" visit or a CME event. Wazana³ reported in 2000 that, on average, practicing physicians met with drug company representatives 4 times a month. Thus, elimination of small gifts alone will not reduce the contact of physicians with pharmaceutical representatives, and the question remains as to whether the new code of interactions is enough to assure that physicians act in the best interest of their patients at all times, uninfluenced by biased information from drug company marketers.

The powerful influence by drug companies on physicians and medicine has drawn increasing public attention. In 2008 alone, multiple damaging stories concerning lucrative and presumably biasing relationships between academic physicians and pharmaceutical companies were revealed.⁴⁻⁵ Physicians in the research community were accused of being "shills" in an editorial in the *New York Times*,⁶ the general media documented serious ethical concerns about academic physicians' significant financial relationships with drug companies, and several articles highlighted examples where payments were in excess of hundreds of thousands of dollars per year.⁷⁻¹⁰

Extent of Physician-Industry Interactions

- Prescription Drugs ~9% of total health care costs in USA
- Estimates:
 - \$11 billion/yr on promotion & marketing
 - ~20% of industry revenues
 - ~\$5 billion spent by PSRs
 - \$8–13 K/yr spent on each physician

Types of Interactions: Physicians & The Pharmaceutical Industry

- High Point: ~1 PSR per 15-30 physicians in US
- Interactions with Industry have started early:
 - Average ~4 interactions/yr for Med Studs
 - Average ~6 interactions/yr for Residents
- Why start early: Industry research confirms value of early positive interactions

Traditional Types of Industry Interactions with Physicians

- Gifts
- Pharmaceutical Samples
- Educational Support
- Research Support

Effect of Industry Gifts to Physicians

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

Katz, D. Am J Bioethics 3:39-46, 2003.

“Effect of Exposure to Small Pharmaceutical Promotional Items on Treatment Preferences”

Archives Internal Medicine May 11, 2009

- Randomized, controlled experiment involving 352 M3 & M4 students at 2 U.S. medical schools
- UPenn (restricted) vs. UMiami (less restricted) differing policies re pharmaceutical marketing
- Students at UMiami evidenced more positive attitudes toward industry marketing & more influence from promotional items

Pharmaceutical Industry Freebies Collected by One Hospital in One Week



Types of Interactions: Pharmaceutical Samples

Possible Benefits:

- May allow patients to try new drug free until clear it is effective & well tolerated
- May allow indigent patients access to expensive, newer medications

Effect of Interactions: Pharmaceutical Samples

BUT:

- Samples often used by Physicians & Office Staff
- Only the newest & most expensive drugs are sampled
- May influence choice of more expensive drugs for long-term treatment

Effect of Interactions: Pharmaceutical Samples

For low income patients, there are better ways to provide needed meds:

1. Generic medication samples program
2. \$4.00/month generic med programs
3. Industry programs to provide expensive meds free to low income individuals

(Indexed at www.phrma.org/pap or www.needymeds.com)

Types of Interactions: Educational Support

1. Information detailing of medications
2. Industry-sponsored conferences
3. Industry support for CME conferences

Effects of Interactions: Educational Support

1. Information Detailing Meds

- * Concerns about information accuracy
- * Information not balanced
- * Better sources of information on new meds & comparative drug data exist

The Medical Letter

The Prescriber's Letter

Therapeutics Initiatives

Drug & Therapeutics Bulletin (UK)

Effects of Interactions: Educational Support

2. Industry-Sponsored Conferences

Great Potential for Bias

- *Promotional vs. educational intent
- *Appropriate faculty?
- *Reasonable faculty honoraria?
- *Paying travel, lodging, meals expenses
- *Funding student/resident participation

Effects of Interactions: Educational Support

3. Sponsorship of CME Conferences:

Still Some Potential for Bias

- *Unrestricted vs. restricted grants
- *Selection of Speakers: Speakers Bureaus
- *Financial disclosure by speakers
- *Balanced presentation, approved uses
- *Audiovisual support
- *Separate promotional displays

Must adhere to strict ACCME standards

Types of Interactions: Support for Research

- Basic Research & Development
- Phase I, II, III Clinical Trials
- Phase IV Clinical Trials
vs. Marketing / Promotional Studies

Effects of Interactions: Support for Research

- Need to assure only rigorously reviewed, IRB-approved research
- Drug/device developers should not conduct studies of their own products
- Concerns about physician payment for participation & enrollment of patients
- Final published works must disclose:
 1. extent of pharmaceutical company involvement
 - 2. authors' industry affiliations**

New Guidelines on Proper Physician-Industry Interactions

Why New Guidelines Developed:

- * Increasing physician awareness of professional & ethical obligations to patients
- * Increasing public concern about potential abuses
- * Increasing government examination of physician-industry interactions

New Guidelines on Proper Physician-Industry Interactions

- AMA & other Physician Professional Societies
- ACGME (Residency Programs)
- AMSA Pharm Free Campaign
- Pharma (Pharmaceutical Industry)
- AAMC (Medical Schools): Comprehensive recommendations released June 2008
- New comprehensive UI policy: Released January 2009
- Patient Protection & Affordable Care Act: Signed March 30, 2010



Report of the AAMC Task Force on Industry Funding of Medical Education to the AAMC Executive Council

For consideration, June 18-19, 2008

Task Force Guidelines Approved by AAMC Executive Council



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AAMC Calls for Strict Limits on Industry Support of Medical Education

News Release

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Association Leadership Approves New Guidelines

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For Immediate Release

[AAMC Reporter](#)

Washington, D.C., June 19, 2008—The AAMC (Association of American Medical Colleges) today urged all medical schools and teaching hospitals to adopt policies that prohibit drug industry gifts and services to physicians, faculty, residents, and students, and to limit industry support of continuing medical education activities. The recommendations were part of a new AAMC report, "Industry Funding of Medical Education," unanimously approved by the association's Executive Council. In adopting the report, the AAMC's leadership urged all association members to implement policies and procedures, consistent with the report's guidelines, by July 1, 2009.

[STAT](#)

[AAMC & Member Contacts](#)

The report was the result of a 14-month effort by an AAMC task force, established in 2006, to examine the benefits and pitfalls associated with industry funding of medical education, and to develop principles, recommendations, and guidelines to help medical schools and teaching hospitals better manage their relationships with industry. The panel was chaired by retired Merck Chairman and CEO Roy Vagelos, M.D., and the vice chair was William Danforth, M.D., former chancellor of Washington University. The task force membership included institutional leaders, faculty, residents, students, CEOs from the pharmaceutical, biotechnology, and medical device industries, ethicists, and public representatives.

"Interactions between industry and academic medicine are vital to public health," said AAMC President and CEO Darrell G. Kirch, M.D. "But they must be principled partnerships effectively managed to sustain public trust in both partners' commitment to patient welfare and the improvement of health care. The recommendations outlined in this report provide essential guidance for how medical schools and teaching hospitals can achieve this important goal."

Mounting scientific evidence indicates that gifts, favors, and other marketing activities, both explicit and implicit, prejudice independent judgment in unconscious ways. In order to minimize the likelihood of biased decisions by academic physicians, establish an influence-free culture for medical students, residents and other trainees, and optimize the benefits inherent in the principled relationships between medical education and industry, the report proposes that academic medical centers:

AAMC Task Force Recommended Guidelines

- Academic Medical Centers (AMCs) should adopt policies on appropriate industry interactions across all sites
- Take leadership role
- AMCs should educate students, residents, faculty & staff on these policies

AAMC Task Force Recommended Guidelines

Policies should address:

Gifts

Pharmaceutical Samples

Site access by Pharmaceutical Reps

CME

Participation in Industry-Sponsored Programs

AAMC Task Force Recommended Guidelines (continued)

Policies should address (continued):

Educational Funds/Scholarships from Industry

Food

Professional Travel

Manuscript Writing (ghostwriting)

Purchasing Decisions

University of Iowa Health Care Conflict
of Interest & Conflict of Commitment:
Policy Regarding Interactions with Industry

January 20, 2009

Specifics of UI Policy

- No gifts of any size may be accepted
- No food (within Iowa or at national meetings)
- Travel stipends, educational scholarships, visiting professorships, GME stipends, etc.
- Medical or educational equipment, supplies, resources, or programming
- Drug samples
- Training assistance

Specifics of UI Policy (cont.)

- Consulting expertise: must be formal contract & approved by DEO and VPMA
- **Honoraria & Speakers' Bureaus**
- Industry displays
- Continuing Medical Education
- Separate *Conflict of Interest in Research* policy
- Publishing

P.L. 111 - Patient Protection and Affordable Care Act (signed March 30, 2010)

- Public reporting 1st advocated by Senators Grassley and Kohl
- By 2013, Industry must report to Secretary HHS all payments to Physicians & Hospitals
- Includes reporting of any physician ownership & research activities
- Penalties if not full disclosure
- Secretary must report this information yearly to the public, to Congress, and to the states

So, What's a M3 Student to Do?

- Don't accept any gifts, food, med samples: May need to make preceptors aware of CCOM policies
- Any Industry offers of assistance to attend conferences, other educational support must be approved by UICCOM
- Review independent resources to learn more about medications (**Medical Letter, Prescriber's Letter, etc.**)
- Know rules & watch for signs of bias in CME and in published medical literature

Scenario 1:

What should you do?

You are completing your family medicine preceptorship with a practicing physician in rural Iowa. The clinic staff invites you to join them for lunch and announces that food is provided each day by one of the pharmaceutical reps who visits their office and also provides medication samples for their patients.

Scenario 2:

What should you do?

You are completing your surgery clerkship and the residents on service invite you to join them in attending a dinner meeting that night being held at a really nice local restaurant. A nationally-recognized surgeon is going to speak on treatment of intra-abdominal infections. Food and drinks are being provided by a pharmaceutical company that manufactures an antibiotic marketed to treat these types of infections.

Scenario 3:

What should you do?

While on your internal medicine clerkship, your attending physician offers you a free Washington Manual of Medical Therapeutics. He explains that he has been provided a supply of these books to distribute to residents & students free by Accura Pharmaceuticals.

THE END



QUESTIONS?