



Drug Money: Ethical Implications of Pharmaceutical Influence

Pharmaceutical drug promotion at medical centers and doctors' offices has grown ever more pervasive. Accordingly, doctors and hospital administrators at Upstate have considered ways to manage the relationship between medical practitioners and the drug industry. Key issues include how drug samples, meals, travel subsidies, sponsored symposia, writing fees, and other pharmaceutical gifts can influence physicians' prescription practices and impact patient care.

IMPACT OF RX PROMOTION

Physicians may be loathe to admit that something as seemingly benign as a free lunch can manipulate their prescription habits, but studies suggest that even seemingly nominal gifts can produce big results. One review study (JAMA 2000;283(3):373-380) found that outreach by drug representatives altered physicians' practices "in terms of prescribing cost, nonrational prescribing, awareness, preference and rapid prescribing of new drugs, and decreased prescribing of generic drugs." Pharmaceutical influence was evident even when gifts had negligible value (a pen or a mug), and despite physicians' beliefs that they could not be influenced.

Across the U.S., pharmaceutical companies spent \$29.9 billion dollars on marketing in 2005 — in the form of direct-to-consumer advertising, journal advertisements, physician "detailing," and free samples (NEJM 2007;357(7):673-681). Pharmaceutical activity is widespread: 94 percent of physicians surveyed in a landmark study (NEJM 2007;356(17):1742-50) reported some type of relationship with the pharmaceutical industry. Approximately 83 percent of all respondents reported receiving food, 78



Is It Ethical to Restrict Physicians' Duty Hours?

Since 2003, all U. S. residency programs have been mandated to restrict residents' duty hours to 80 per week (on average) and a single-shift to 30 continuous hours, with at least 10 hours off between shifts and a guaranteed one day in seven free. Considering that fatigue can lead to impaired learning, mistakes, automobile accidents, and dissatisfaction with quality of life, limiting a resident's work hours sounds like the right thing to do. And yet, not everyone agrees.

Clearly, some studies suggest that residents now commit fewer errors, are more available to teach medical students, do not lack important clinical experience, and enjoy a more satisfactory quality of life than before the work hours restrictions. In these cases, residents are happier and more functional, and patient care stands to benefit.

By contrast, other studies report fragmented learning experiences, lapses in continuity of care, multiple patient hand-offs and sign-outs, and no improvement in sleep. Furthermore, since attending physicians have not been mandated to reduce their work hours, residencies in some specialties no longer mirror the demands of actual clinical practice. Residents lack faculty models of a harmonious work-life balance and uncompromising dedication to patient care with reliance on trusted colleagues. In these cases,

Bioethics *in brief*

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Bioethics in Brief is a newsletter of the Center for Bioethics and Humanities, in cooperation with University Hospital's Ethics Committee.

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80 Hour Week

residents are unrealistically and inadequately prepared for their future careers, and patients stand to suffer.

One explanation for these conflicting studies may be that it is difficult to ascertain whether fatigue, errors, accidents, and personal dissatisfaction are caused by acute or chronic sleep deprivation. While work hour restrictions may likely diminish episodes of acute sleep deprivation, they may not impact chronic fatigue. European residents, who currently work 56 hours per week, are reportedly still tired and falling asleep on the job.

A more effective solution might be to base residency training programs on the actual tasks and demands of each subspecialty. In addition, medical educators must find out why residents are not resting when they are not at work. Finally, attending physicians should first ask *themselves* to fashion a patient-centered practice that relies on collegial trust and requires they reason through whether it is better for patient care if they stay in the hospital or go home. With such models to follow, residents could learn to do the right thing rather than just hand off a patient simply because their shift is up.

— Catherine V. Caldicott

Adapted from CV Caldicott, JW Holsapple. Training for Fitness: Reconsidering the 80-Hour Work Week. Perspectives in Biology and Medicine (forthcoming).



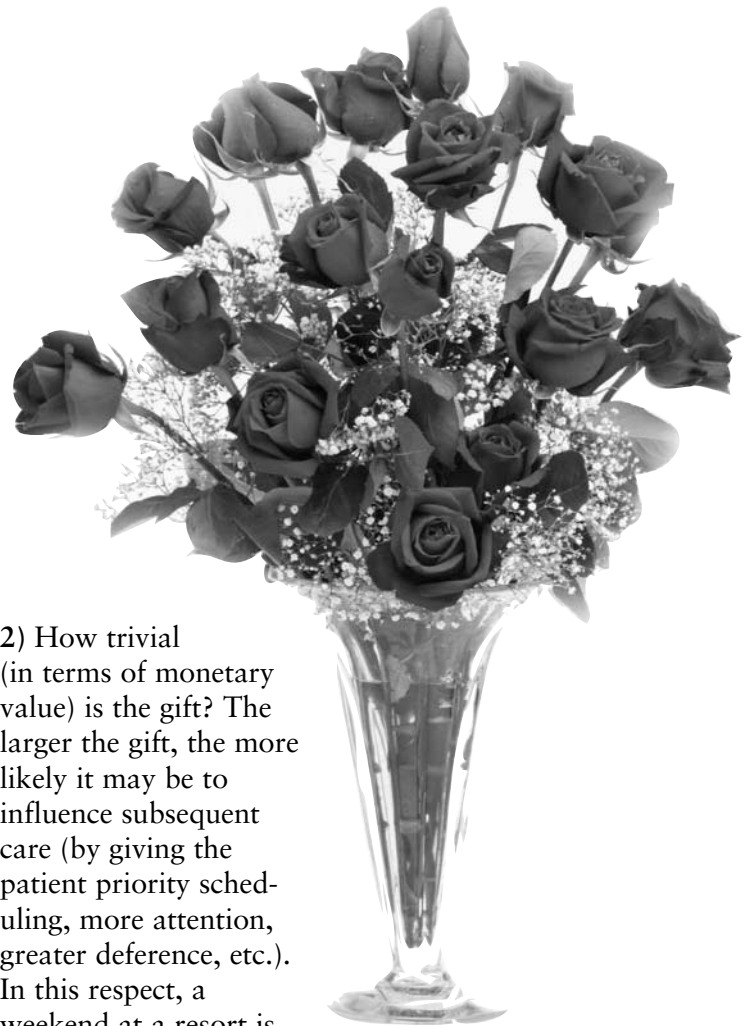
Gifts to Clinicians

Q. *In my role as a clinical nurse specialist, I helped take care of a patient with leukemia over the last ten years. The patient died a few weeks ago and her husband sent me a card and gift of money. Is it ethical for me to accept a monetary gift? This hasn't happened before to me. It is very nice but did leave me with a few questions.*

A. The appropriateness of accepting gifts is an interesting and complicated question, with both ethical and legal considerations. Depending on the circumstances of employment, you may be legally barred from accepting some gifts. As stated in the previous piece, state employees may not accept any gift of more than “nominal value” if it would constitute a substantial conflict with their professional duties or if the gift is intended to influence the employee.

Setting aside legal or policy prohibitions for the moment, the ethical issues are intriguing. One would imagine that most physicians and nurses providing direct patient care receive some personal gifts from patients. As an oncologist, I have received (or been offered and declined) gifts including a homemade “friendship” bracelet, a Minnesota Vikings lapel pin, very expensive roses, homemade Ukrainian lunches (brought warm by a patient every month prior to her appointment), a needle point pillow, and an invite to the family’s cabin for the weekend. Although one might have greater qualms about accepting money, it is not obvious, from an ethical viewpoint, why a gift of \$50 cash is more problematic than \$50 of roses. Here are some considerations:

1) What is the relationship between the gift and the services? For example, if gifts are given on an ongoing basis, as one continues to care for the patient, they might be perceived as trying to “buy” better care. So, thinking back to a patient who frequently gave me roses as I treated her for lymphoma, I was concerned that maybe she was angling for more attentive care (and maybe I would actually fall prey to this). In your case, this is not an issue because the gift is clearly merely a “thank you” and can’t influence future care.



2) How trivial (in terms of monetary value) is the gift? The larger the gift, the more likely it may be to influence subsequent care (by giving the patient priority scheduling, more attention, greater deference, etc.). In this respect, a weekend at a resort is of more concern than the Minnesota Vikings lapel pin.

“...THERAPEUTIC DISTANCE” IS IMPORTANT BOTH FOR PROVIDING THE BEST CARE TO THE PATIENT AND MAINTAINING CLINICIAN WELL-BEING.

3) Should a clinician personally benefit from the care she delivers, beyond fair compensation, satisfaction of a job well done, and sentiments of gratitude? Waitresses need tips because they are underpaid. Health care should be (and, in this country, is) structured so that clinicians receive fair wages and need not rely upon added compensation from gifts.

4) Does the gift, if accepted, violate an important clinician-patient boundary? For example, a weekend at a patient’s cabin seems to cross the patient-professional boundary. While this is not absolute (e.g., sometimes clinicians care for personal friends or family members, a practice which, while not encouraged, is sometimes unavoidable or the best among imperfect choices), the prevailing opinion

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percent reported receiving drug samples, 35 percent reported receiving reimbursements for costs of professional meetings or continuing medical education, and 28 percent reported receiving payments for consulting, giving lectures, or enrolling patients in trials. These figures raise professional questions about the influence of pharmaceutical companies. Business logic suggests that they would not be paying out if they were not getting something in return.

PUBLIC DISCLOSURE LIMITED

As of March 2007, Vermont and Minnesota were the only two states requiring pharmaceutical companies to publicly disclose payments to physicians, including lecture honoraria and outright gifts. Despite these mandates, Vermont companies disclosed just 39 percent of payments, guarding the majority as trade secrets (JAMA 2007;297(11):1216-1223). In Minnesota, only a quarter of pharmaceutical companies complied. An analysis by the *New York Times* (5/10/07) found that Minnesota psychiatrists who received \$5,000 or more prescribed industry drugs three times as often as psychiatrists who took less or no money. A third of Minnesota's licensed psychiatrists took payments between 1997 and 2005. Such efforts to ply physicians with gifts, meals, and gadgets have turned some drugs into blockbusters.

FOCUS ON ANTIPSYCHOTICS

Such pharmaceutical influence has sparked concern, particularly regarding the widespread adoption of antipsychotics such as Risperdal, Seroquel, Zyprexa, Abilify and Geodon. Although antipsychotics reach half a million U.S. children each year, the side-effects are not fully understood. As for costs, generic versions are cheaper than their brand name competitors and sometimes considered equally effective. For example, Lexapro, a drug made by Forest Labora-

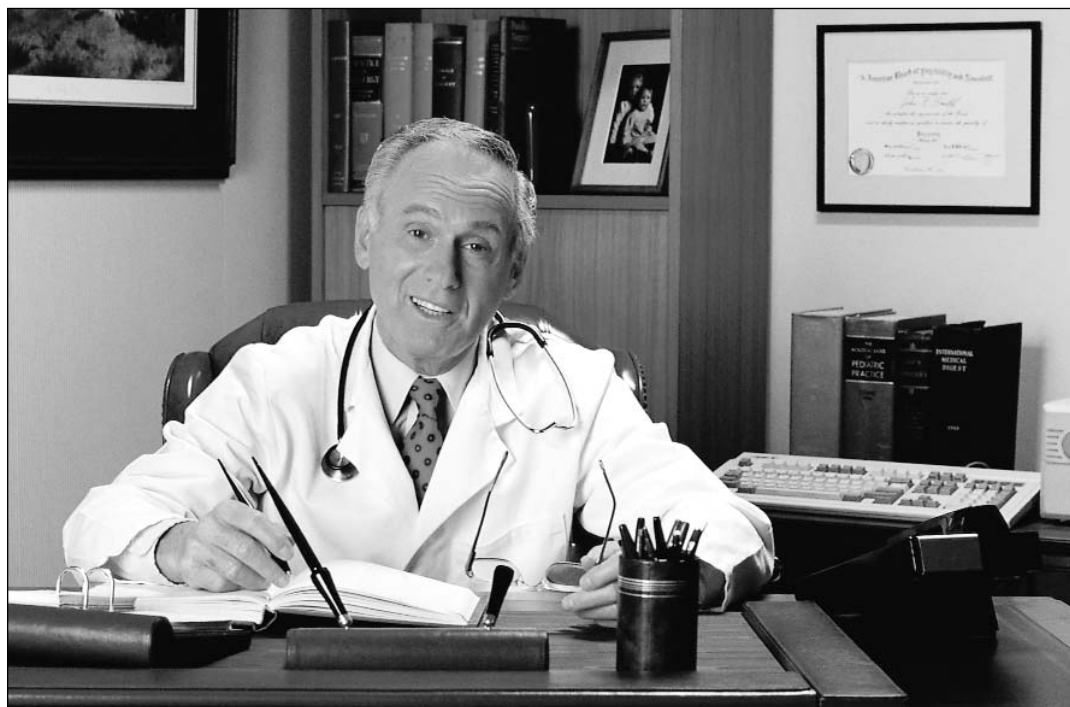
ories, is the most widely used antidepressant in the United States. But according to Dr. Steven S. Sharfstein, past president of the American Psychiatric Association, generic versions of Prozac are "just as good if not better" (*New York Times* 5/10/07). Dr. Sharfstein attributed the high sales of more expensive brand name drugs to industry marketing.

POLICIES TO LIMIT INFLUENCE

Drug-makers may hire data-mining companies in order to track physicians' prescription practices so they may target certain physicians through personal visits. At least a dozen states have attempted to enact laws to bar drug company access to this prescription information. On the federal level, a pending Senate bill (S.2029) requires greater transparency about pharmaceutical marketing. Other policies attempt to restrict drug representatives' access to physicians or limit the value of their gifts. In Minnesota, for instance, sales representatives are barred from giving doctors more than \$50 worth of food or other gifts per year.

Under New York law, Upstate faculty and staff who are state employees may not accept any gift of more than "nominal value" "if it would constitute a substantial conflict with the proper discharge of your State duties, or when it could be reasonably inferred that the gift was intended to influence you or could reasonably be expected to influence you in the performance of your official duties or was intended

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as a reward for any official action” (NYS Commission on Public Integrity, September 2007). It should be noted that any gift from a pharmaceutical company is intended to influence the receiver in some way and that the employee does not actually have to be influenced for the transaction to be unlawful. While not specifying a dollar amount as to what constitutes a gift of “nominal value,” New York law does provide several parameters for acceptable gifts. For example, employees may receive meals during job-related professional and education programs, unsolicited promotional material “of little intrinsic value,” and “reasonable and customary presents given on special occasions.”

At University Hospital and UHCC, all pharmaceutical visits must be announced and pre-scheduled by individual appointment. Drug representatives must register with University Hospital police and wear a UH visitor’s pass as well as a company-issued identification badge. In addition, drug representatives are not permitted in patient care areas, including outpatient clinics. They may provide information to house staff and students only in department-sponsored presentations. Not to be overlooked, UH policy specifies that drug representatives should park in the visitor’s area of the parking garage on Adams Street. In addition, Policy UHCC M03 sets forth specific rules for interactions with pharmaceutical representatives at University Health Care Center, UH’s primary outpatient center.

BANNING RX PROMOTION?

Several academic medical centers, including Stanford and the University of Pennsylvania, have banned drug representatives from their campuses and eliminated free drug samples, free lunches, and even free pens. A total ban on industry gifts, they argue, is the only way to reliably mitigate our human reflex to reciprocate. Such policies remain controversial. Some have argued that drug representatives provide educational materials to doctors, and that free samples help patients in financial need cover the cost of care. Proponents of the pharmaceutical-medical relationship

even argue that physicians ought to actively collaborate with the drug industry to research new products and to prepare papers for publication.

Numerous testimonials, however, show that pharmaceutical companies are prone to exaggerate the effectiveness of their products, downplay side-effects, and misrepresent competing products, including



cheaper generics. In Senate testimony (06/07/07), former NEJM editor-in-chief Dr. Jerome P. Kassirer described drug-industry-sponsored CME programs as “thinly disguised bribes” and “mini-circuses replete with enormous glittering displays and hovering attractive personnel.” Many have come to view these activities with suspicion, noting that drug companies are primarily interested in serving their shareholders, not in serving patients or ‘educating’ physicians. Kathleen Slattery-Moschkau, a former sales representative for Bristol-Myers

Squibb and Johnson & Johnson, put it this way: “I hate to say it out loud, but it all comes down to ways to manipulate the doctors” (*Syracuse Post-Standard*, 3/25/07).

PROTECTING CLINICAL INDEPENDENCE

Institutional policies are important in limiting improper pharmaceutical influence. They allow physicians to exercise clinical judgment, retain the trust of patients, and guard against impropriety and the appearance of impropriety. Yet policy is incomplete without a strong professional ethic prioritizing patient welfare. Unfettered pharmaceutical access to physicians tacitly teaches medical trainees to expect gifts and meals as a matter of professional due.

What is the proper relationship between medicine and the pharmaceutical industry? Physicians are often reminded not to allow the financial (and culinary) benefits of participating in industry-sponsored events to interfere with their clinical independence. Thus they are taught to monitor possible “conflicts of interest.” A more skeptical assessment, given the promotional efforts of drug companies, would frame interactions with the pharmaceutical industry not as conflicts of interest, but as conflicts between financial interests and fiduciary duties.

— Eli Braun

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Gifts

PATIENTS AND FAMILIES

“MAY FIND SOME

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BY OFFERING SOME

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is that “therapeutic distance” is important both for providing the best care to the patient and maintaining clinician well-being.

CONSIDER THE SPIRIT

The ethical principle underlying all of this is that we want our nurses and doctors to treat all of us equally and with skill and compassion, regardless of our ability to gift

them. At the same time, kindness suggests that clinicians should consider the spirit in which the gift is offered. Patients and families are sometimes acutely aware when they are disproportionately on the receiving end, and they may find some satisfaction in being able to “level the field” by offering some kindness in return. Many health care institutions encourage philanthropic gifts from “grateful

patients” to fund special projects. These gifts benefit the institution and, at times, the clinicians who work there. The boundaries between personal benefit and professional benefit are not so clear to maintain that gifts to an individual are always wrong, while gifts to an institution are always right.

A monetary gift is easy enough to pass along to a charity that would support something of importance to the patient or family; this could be a way to graciously accept a monetary gift while minimizing some of the ethical concerns of accepting gifts. It is harder to figure out what to do with the hand-crocheted stuffed pumpkin with the ghoulish face embroidered on it. Reasonable, thoughtful people may disagree on the ethics of accepting gifts from patients, particularly if the monetary value is not large. The overriding consideration is that all patients should receive expert and compassionate care, regardless of their ability or inclination to give us gifts.

— K. Faber-Langendoen

Website of Interest <http://www.nofreelunch.org>

NoFreeLunch.org is a comprehensive website that addresses the ethical issues of the pharmaceutical company–physician relationship. It also exposes the negative impact drug companies can have on medical students and residents, and educates the public about drug company practices and how they may impact their care.

Gov. Spitzer Signs Surrogate's Court Procedure Act

On June 22, 2007, Governor Spitzer signed into law The Surrogate's Court Procedure Act, after it passed both the State Assembly and Senate. The Act applies to decision making for a mentally retarded or a severely developmentally disabled patient. It provides that if a guardian has not already been legally appointed for the patient, a family member may make any and all health care decisions, including to withhold or withdraw life-sustaining treatment, that the patient would be legally authorized to make if s/he had decisional capacity.



In 2002, The NYS Health Care Decisions Act for Persons with Mental Retardation required that formal guardianship be obtained in order to allow a family member to withhold or withdraw life-sustaining treatments for persons with mental retardation who lacked capacity to make their own decisions. The new law recognizes that appointment as a guardian is time-consuming and costly and as such was an obstacle to some family members that sought this role. Under the new Act, the family member must have “a significant and ongoing involvement in the person’s life,” know the person’s needs, and consider the person’s wishes and moral and religious beliefs if ascertainable. For family members to make decisions to forgo life-support, the patient must be certified by a physician as (1) terminally ill; (2) permanently unconscious; or

(3) having an irreversible condition requiring life-sustaining treatment which will continue indefinitely. Proposed life-sustaining treatment must be certified as extraordinarily burdensome by a physician. These conditions are the same as in the 2002 law. However, prior to 2002, unless appointed as guardian for the mentally retarded patient, family members could only consent to a Do Not Resuscitate (DNR) order, and could not authorize forgoing of other forms of life-sustaining treatment. The Commissioner of the Office for the Mentally Retarded and Developmentally Disabled (OMRDD) is directed to develop a prioritized list of qualified family members. Similar lists already exist, as in the Do Not Resuscitate law. The Act takes effect in December 2007.

—Joel Potash

This feature offers excerpts from Upstate's 2007 issue of *The Healing Muse* published by the Center for Bioethics and Humanities. These pieces speak to the often complex relationship between medicine and ethics.



Star Break

— Anne Jacobson Ryan

Nurse on the graveyard shift
does the stats
hands out an occasional Ambien
avoids the polarity trap:
the argument on the floor
between Born Again and Liberal Muslim
smiles, says
“let’s just do our jobs
come to my garden this summer
have tea
enjoy the roses
that we love as roses
and the lilies
that we love as lilies”

goes out with the smokers on break
to see the constellations
to take a star break.

Anne Jacobson Ryan is a retired art teacher who writes poems and paints. She lives in the Endless Mountains of Pennsylvania; her work has also appeared in *Bloodroot and Plum Series*.

You can order copies of the 2007 edition of *The Healing Muse* for \$10 each by calling 315-464-5404 or by going to the website: www.thehealingmuse.org. Or you can purchase a copy at the HealthLink/OASIS site in ShoppingTown Mall (lower level). Earlier editions can also be purchased.



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