



CASE OF THE MONTH



Rx Promotion:

Does it Impact the Practice of Medicine?

CASE

Dr. Giambi is a psychiatrist in a busy office. She rarely stops working long enough to eat lunch because of the high patient volume. Several pharmaceutical company representatives visit the office in hopes of meeting with Dr. Giambi to inform her of the benefits of using their newest drugs. Each time a representative from a pharmaceutical company comes to the office, Dr. Giambi asks the representative, "What did you bring me today?" She often asks the representative to go back to his or her car to bring her more items. After receiving gifts, Dr. Giambi allows the*

representatives to speak with her for 5-10 minutes. Those representatives not bearing gifts often are told, "I am too busy to talk to you." She receives gifts such as pens, clocks, and tickets to local events. She also attends dinner talks sponsored by drug company representatives.

The medical student working with Dr. Giambi believes that the psychiatrist's prescribing habits are not based on the gifts she receives. She has a vast knowledge of the side effects, interactions, and costs of all the psychiatric medications and seems to prescribe them based on their profile and the needs of each individual patient.

ANALYSIS

Accepting gifts of all sizes from the industry is widespread throughout the medical community, and Dr. Giambi's behavior is not uncommon. In fact, *American Medical News* reported that an entrepreneurial physician started a new company this year that signs up physicians willing to spend time listening to pharmaceutical representative ("drug rep") presentations. The going rate is

\$100 per 15 minute visit, and the practicing physician splits the fee with the company.

Promotional activities of drug companies include gifts to physicians and other health care professionals, hospitality, free drug samples, providing promotional information regarding new drugs and devices, subsidizing education and journals, direct advertising to patients, and sponsoring clinical research trials.

PROS VS CONS

Some argue that these promotional activities have substantial benefits, providing important educational opportunities, supplying free drugs for medically indigent patients, supporting crucial research, and encouraging appropriate use of new drugs. Others strongly disagree, arguing that such promotional activities encourage the use of drugs that are more expensive and, at times, less safe

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Questions, suggestions, or comments? Would you like to be added to our mailing list? E-mail us at ethics@upstate.edu

Have a question about an ethical issue? We are always happy to talk in confidence about ethical concerns; you may reach us at the Center for Bioethics and Humanities at 464-5404. Ethics consultations are available by calling the hospital operator (464-5540) and asking for the ethics consultant on call, or by contacting any of the senior ethics consultants at the center (Wendy Edwards MD; Kathy Faber-Langendoen MD; and Joel Potash MD).

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The Center for Bioethics and Humanities at SUNY Upstate Medical University, established through the generous support of the Medical Alumni Association, is committed to promoting clinical health care and health policy which is patient-centered, compassionate, and just. We accomplish this through educational initiatives in bioethics and the medical humanities, clinical ethics consultation, and multidisciplinary research and scholarly writing.

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or no more effective. Opponents also charge that accepting gifts ultimately increases patients' costs for already expensive drugs.

sponsored dinners or accepting funds to attend educational meetings and requesting formulary additions of associated drugs.

INFLUENCE PEDDLING?

The issue of physicians receiving gifts from drug reps has recently come under scrutiny. To a large extent, physicians are skeptical that their prescribing habits are influenced by promotional activities, including gifts. In one study, only 25 percent of residents and 30 percent of attending physicians believed that a \$50 gift would compromise a physician's judgment. Another study found that the more gifts a medical student or resident received, the more likely the recipient was to believe that he or she was not influenced by receiving a gift.

A recent comprehensive literature review by Dr. Wanzana in the January 19, 2000 *JAMA* challenged the belief that physician interactions with drug reps do not influence prescribing behavior. She reviewed several studies finding that interactions with drug reps increased drug costs, decreased use of generic drugs, and increased preferences for newer drugs. Other studies found a positive association between attending drug-company

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ACCURACY QUESTIONED

In addition, the information provided by pharmaceutical companies is not always accurate. One study of drug rep presentations preceding a residency training program's noon conference found that drug rep statements were

overwhelmingly favorable toward the promoted drug, and, when there were inaccuracies, there were unfavorable statements about competitors' products.

Reprints from supplements to peer-reviewed journals are not always themselves peer-reviewed; these supplements are often totally funded by a single drug company, and the editorial standard for publications in the supplement may be substantially lower than that for the parent journal.

Finally, journal ads for new drugs are notoriously deceptive. One ad for Metastron (strontium), a radionuclide for palliation of bone pain, displayed side-by-side bone scans, with the second scan showing far fewer bony metastases, even though strontium does not shrink tumors.

THE COST & REWARDS

According to the web site www.nofreelunch.org (see back page), drug companies spent almost \$16 billion in 2000 on promoting their products. The median profit margin that year for drug companies was 18 percent (compared to 5 percent for other Fortune 500 companies). Astra-Zeneca hired 1,300 drug reps to promote their new antacid, Nexium. In 2000, Merck spent more on advertising for Vioxx than PepsiCo spent on Pepsi. *The New York Times* reported that the American Medical Association receives \$20 million annually by selling its “physicians’ master file” (listing all U.S. physicians, including the 60 percent who do not belong to the AMA) to the pharmaceutical industry and others interested in market research. This data file, combined with databases the drug companies buy from pharmacies, allows drug companies to figure out the prescribing habits

UNIVERSITY HOSPITAL POLICY

Drug Reps’ Access to University Hospital

- drug reps need to make an appointment with individual physicians or staff to provide drug information
- drug reps may provide information to residents and medical students only during department-sponsored presentations
- drug reps are not permitted in patient care areas, including outpatient clinics

of specific physicians, so they can target their marketing efforts.

NEW STANDARDS

A variety of physician organizations, continuing education accreditors, and institutions have articulated ethical standards for interactions with drug reps. The AMA guidelines are relatively weak. Acknowledging that many gifts “given to physicians by companies ... serve an important and socially beneficial function,” the AMA nonetheless cautions that gifts should not be of substantial value and should be related to the physician’s work.

Some providers may choose not to accept gifts from the industry because they believe their acceptance of such gifts leads to increased costs of pharmaceutical products, suboptimal medical practice, or the appearance of impropriety. Other providers may decide that it is inappropriate for them to accept gifts when their patients are the ones buying the product. Still others will remain unpersuaded that accepting gifts adversely affects practice and will continue to foster such relationships.

University Hospital has a new policy on pharmaceutical representatives’ access at our hospital and clinics (see box). In addition, Upstate faculty and staff who are state employees are prohibited from receiving gifts whose value is greater than \$75. ■

—Jackie Nichols, MSIV, and
K. Faber-Langendoen

For Your Own Good: Supreme Court and The ADA

Employment discrimination is generally prohibited, but a recent US Supreme Court decision (*Chevron USA Inc. v. Echazabal*, June 2002) says it is sometimes justified. The Court unanimously ruled that Chevron could refuse to hire Mr. Echazabal because an underlying liver condition made him more susceptible to permanent liver damage from workplace toxins.

The ruling affirms that the Americans with Disabilities Act allows some forms of justified discrimination, if “unfair” treatment in the workplace is intended to protect the individual from on-the-job risks to that person’s health or safety. The Supreme Court acknowledged that discriminatory employment decisions may also be justified if designed to protect other workers or the public from serious health or safety risks.

This ruling may open the door to discrimination based on genetic testing that reveals increased susceptibility to certain diseases. For example, can an airline refuse to hire a pilot with the gene for sudden cardiac arrest? Would it be legal for UPS to terminate or transfer an employee who is susceptible to back injury because he has the gene for ankylosing spondylitis? Look for further litigation down the road. ■

—Robert Olick

CT Scan or CT Scam?

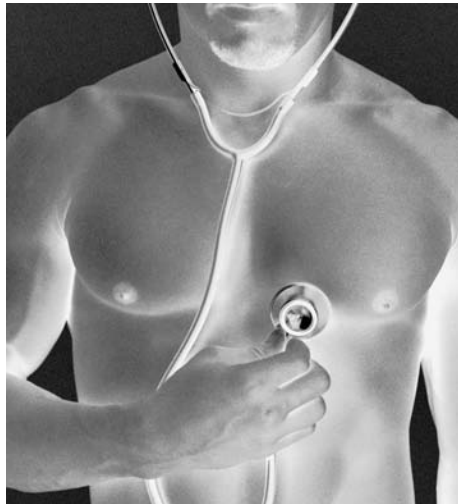
Is body CT scanning to screen “normal” people for cancer or heart disease a legitimate medical procedure or a financial scam? CT (computed tomography) scans use high-speed, sensitive X-rays to illuminate the inner torso; they can find tiny tumors, weak spots on blood vessels and calcified areas that may indicate heart disease. Originally developed as diagnostic tools for high-risk patients, CTs are commonly used to evaluate patients with a wide range of symptoms and diseases.

However, in a recent example of how the entrepreneurial spirit follows medical progress, radiologists, medical centers, and entrepreneurs have joined forces to create traveling CT scan units or CT centers that offer a body CT scan for only a few hundred dollars.

WHO REALLY BENEFITS?

The FDA’s Dr. Larry Kessler cautions that although these tests are safe and can find abnormalities, this does not necessarily mean that a person will benefit from the tests. “We have a technology that’s gotten caught in the gaps between the scientific agencies, the regulatory agencies, and the payers; the fair evaluation of these procedures is no one’s province. That’s the gap.”

Those who provide the scans argue that they provide consumers with a valuable service. The Cooper



Clinic in Dallas was one of the first to offer whole body scans in the mid-1990s. Dr. Kenneth Cooper, CEO, says his staff is currently conducting a federally financed study of heart scans to determine their medical efficacy. Dr. Cooper believes the scans save lives, pointing to 70 people whose scans turned up small kidney tumors. “We know that if it breaks through the kidney capsule, only 6 percent survive the next five years. Do you want to take that chance?”

The American College of Radiology has responded by pointing out that much of what these random CT scans will find “will not ultimately affect patients’ health but will result in increased anxiety, unnecessary follow-up examinations and treatments and wasted expense.”

While debate and research continue, companies like CAT Scan 2000 (based in Florida) are happy to drive their mobile units onto

church parking lots or malls. A receptionist collects the money (cash only, since this is not covered by insurance), and a technologist runs the scanner. Radiologists back at company headquarters read the scans and send results to the clients in a few weeks. Clients are then encouraged to take the results to their own physicians and request whatever further tests or procedures seem warranted.

RAISING MONEY AND ANXIETY

Some physicians warn that the tests do little more than raise anxiety levels for the majority of clients. They point to cases where people have taken the results and demanded their physicians perform surgeries and biopsies based on those results, only to discover that the lesions were from old scars or infections that have little consequence for these individuals. The costs of these unnecessary tests strain an already over-taxed health care system.

The scans are so profitable, however, that companies will not be moving away from doing them any time soon, as long as governmental regulation is absent and enough radiologists and radiology technicians believe such practices are compatible with their ethical norms. ■

—Deirdre Neilen,
compiled from *New York Times* and
Newsweek reports

Artificial Nutrition: Always in the Patient's Best Interest?

A basic nursing component of providing patient care is attending to the patient's need for food and fluids. While nutrition is necessary to sustain life, many patients cannot eat or drink well enough to meet their nutritional needs. In these cases, if adequate nutrition and hydration are to be maintained, medical means (for example, NG or gastrostomy tubes, intravenous fluids) must be used.

Why is it that giving artificial nutrition can sometimes be viewed by nurses as a "good" thing or the "right" thing to do—and yet at other times the same intervention is judged by the same nurses as not to be in the patient's best interest? Is such intervention always a good thing, or are there situations in which withdrawing food and fluids might also be considered the right thing to do?

WHAT'S THE GOAL?

When making decisions like this, one of the most important questions is whether the provision of nutrition and hydration through medical means accomplishes the established goals of care for that patient. If the problem that the

patient is being treated for is reversible, temporary methods of providing nutrition and hydration until the patient can resume normal intake of food and fluids makes perfect sense. In other cases, the feeding problems might be irreversible, but the patient chooses to live as long as possible with the support of nutrition intervention. When there is little hope for recovery, the decision



"THE HOSPICE LITERATURE SUGGESTS THAT HYDRATION AT THE END OF LIFE SOMETIMES WORSENS RESPIRATORY DISTRESS..."

to provide hydration and nutrition becomes more difficult. Decision makers may not be fully aware of the burdens and the benefits of such intervention. While it may prolong the patient's life, it can also cause suffering in the form of discomfort, infection, diarrhea, and other complications. The use of restraints to prevent a patient from removing a line may also make the patient uncomfortable.

PROLONGING LIFE OR PROVIDING COMFORT?

Curing disease as the goal of care requires different interventions than when patient comfort is the primary goal. For those patients who are imminently dying, a time often comes when prolonging life is not as great a priority as the provision of comfort measures. Artificial methods of nutrition and hydration can actually prolong the dying process and add to the suffering of the patient. The hospice literature suggests that hydration at the end of life sometimes worsens respiratory distress as excessive fluids leak into the lungs.

All those involved in the care (patients, their loved ones, physicians and nurses) need to be clear about the goals of care as the condition of the patient changes. There is no moral requirement that a patient accept medical treatment. This right extends to a patient's refusal of artificial nutrition or hydration. ■

—Barbara Fero

Is Poor Pain Control a Problem of Ethics?

Mr. Hingis, a 76 year old man, has a stroke while undergoing cardiac catheterization and is left blind, unable to speak and swallow. He doesn't respond to his son's voice. Further recovery is not expected. Mr. Hingis is restless and groans with movement. His son, who is also his health care agent, believes Mr. Hingis is in considerable pain. Mr. Hingis has a living will that calls for relief of pain under all

circumstances and prohibits artificial nutrition if permanently unable to eat. A covering physician orders a morphine drip at 1 mg/hr, which relieves the restlessness and groaning. The next morning the primary attending discontinues the morphine and calls for an ethics consultation, because the patient "doesn't have a terminal illness, and morphine may speed the patient's death."

Most patients fear pain and desire pain relief, although some patients, families, and doctors are concerned about the possibility of addiction and undesired side effects when opioids are required for pain control.

WIDESPREAD DISREGARD

Reports in medical journals reveal that pain is often poorly controlled in hospitals and nursing homes, even when patients are terminally ill and dying. The SUPPORT study revealed that 50 percent of families believed their hospitalized loved ones had inadequate pain control in the last three days of life. Up to one-quarter of hospice patients may describe their pain as severe or intolerable. Why is there such widespread disregard for the plight of patients with intractable pain?

One might suppose that this is merely a knowledge gap in health care professionals. If so, this is no longer acceptable. The American Medical Association's Code of Ethics includes this clear statement: "Physicians have an obligation to

relieve pain and suffering and to promote the dignity and autonomy of dying patients in their care even though it may foreseeably hasten death." The US Agency for Healthcare Policy and Research states: "The ethical obligation to manage pain and relieve suffering is at the core of a health care professional's commitment."

MINIMIZING HARM

Pain is a harm, and physicians ought to minimize or remove harms. But there are also harms from using opioids: side effects include nausea, confusion, sedation and respiratory depression. It is unlikely, though, that an appropriate dose of morphine, even if increased daily by 25-75 percent, will cause a patient to stop breathing or die. The incidence of addiction in patients treated with opioids for medical conditions is less than one percent.

Additionally, patients build a tolerance to most side effects of opioids, except constipation. On the positive side, control of pain promotes quality of life, is respectful of the wishes of most people, and may actually lengthen life, rather than shorten it.



Even in the uncommon event that appropriately prescribed opioids hasten a patient's death, such use may still be ethically justified. Because of the strength of our duty to treat pain, particularly in those who are imminently dying or irreversibly

ill, many legal, ethical, and medical experts agree that, if a physician's primary intent is to relieve the pain of a dying patient, the physician should use whatever doses of opioids are clinically necessary, even at the risk of hastening death. This secondary, unintended (but foreseen) consequence of respiratory depression is ethically

It's Legal, but is it Ethical? Informed Consent

Prior to surgery to correct a duodenal ulcer, Dr. Rivera meets with Mr. Palmer to obtain his consent. He tells him what he plans to do during the surgery, explains that Mr. Palmer might experience post-operative pain, and presents him with a general "Consent to Operate" form. The form, which Mr. Palmer signs, states that the "purposes and benefits of the procedure have been explained to me." Other paragraphs of the form state that the patient has read the form, understands its contents, and has had the opportunity to ask questions. Several days later Mr. Palmer experiences intense abdominal pain. Internal bleeding is discovered (caused by premature absorption of a suture), and a subsequent surgery is required to repair a severed artery and to remove the spleen.

justified in such cases by the strength of our primary duty to relieve pain.

Health care professionals should be conscientious in their responsiveness to the needs of patients in pain. Any tendency to undertreat pain or disregard patient reports of pain is ethically problematic. We ought not minimize patients' pain. Denying pain relief appropriate to an expressed need is itself an unjustified harm. The relief of pain and suffering remains a major goal of medicine.

LEGAL CONCERNS

There may be professional and legal implications to not providing adequate pain control. In 1999, an Oregon physician was disciplined for unprofessional conduct for refusing to use or discontinuing opioids in patients with terminal illnesses, on ventilators, and in congestive heart failure. In 2001, a California jury found a physician liable for prescribing too little pain medication for a patient with lung cancer who experienced excruciating pain as he died.

CONCLUSION

Mr. Hingis specifically requested pain control in his living will. Had he not, treatment of his apparent pain is still warranted by the mandate to assuage patients' pain and suffering. In this case, the benefit of pain relief outweighs any transient harms such as sedation or even unintended hastening of his death. ■

—Joel Potash

This case, drawn from several sources, illustrates a common everyday reliance on a legalistic model of informed consent. How often do we hear the phrase, "go consent the patient." Is getting the patient's signature sufficient to establish informed consent? Mr. Palmer's case also opens a window on the question, "it may be legal, but is it ethical?"

The legal model of informed consent has developed largely through court cases in which patients who suffered bad outcomes have claimed that had they known about the risk of injury, they would not have consented to the procedure. The legal argument is that failure to disclose the risk deprives the patient of the opportunity to make an informed decision. This posture has strongly focused the law's approach to informed consent on the physician's duty of disclosure, especially disclosure of risk information. Over the years physicians and hospitals have responded to the law's expectations by making documentation of consent, including acknowledgement of risks, standard practice for invasive procedures, such as Mr. Palmer's surgery.

By contrast, the prevailing ethical model takes autonomous informed consent more seriously: stressing

that patients should understand and appreciate the nature of the recommended procedure, its benefits and risks, and the benefits and risks of reasonable alternatives, including the option of no treatment. If Dr. Rivera's exchange with his patient seems formulaic and focused on getting the signature, the ethical norm presses for a more interactive, ongoing exchange that fosters patient understanding – a model of partnership and shared decision making grounded in trust between physician and patient.

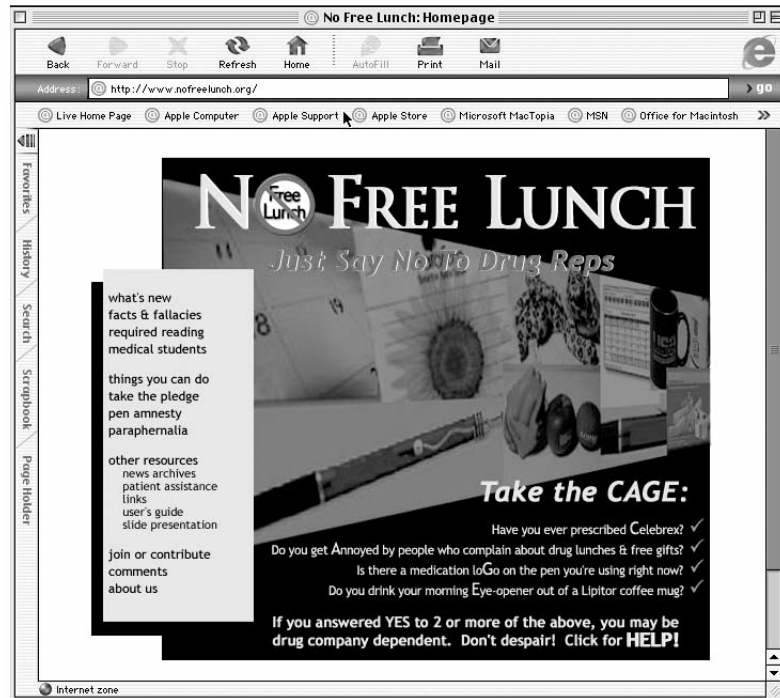
To assess whether Mr. Palmer gave legally valid informed consent, we would need a more detailed account of the physician-patient interaction. Did Dr. Rivera recite or explain the risks of the complications that in fact materialized? It is customary to disclose these risks? Would a reasonable patient in Mr. Palmer's situation find these risks relevant to his decision? Even if Dr. Rivera met his legal obligations, we would need a still more detailed account to determine whether Mr. Palmer understood the risks he was undertaking, in order to satisfy the ethical norm of informed consent. On either model, Mr. Palmer's case teaches that a consent form is worth a little, but *informed* consent is more than the paper it is written on. ■

—Robert Olick

Web Site of the Month

www.nofreelunch.org

This web site explores the physician-pharmaceutical relationship and the potential for altering behavior, beliefs and attitudes (see feature article, page 1).



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