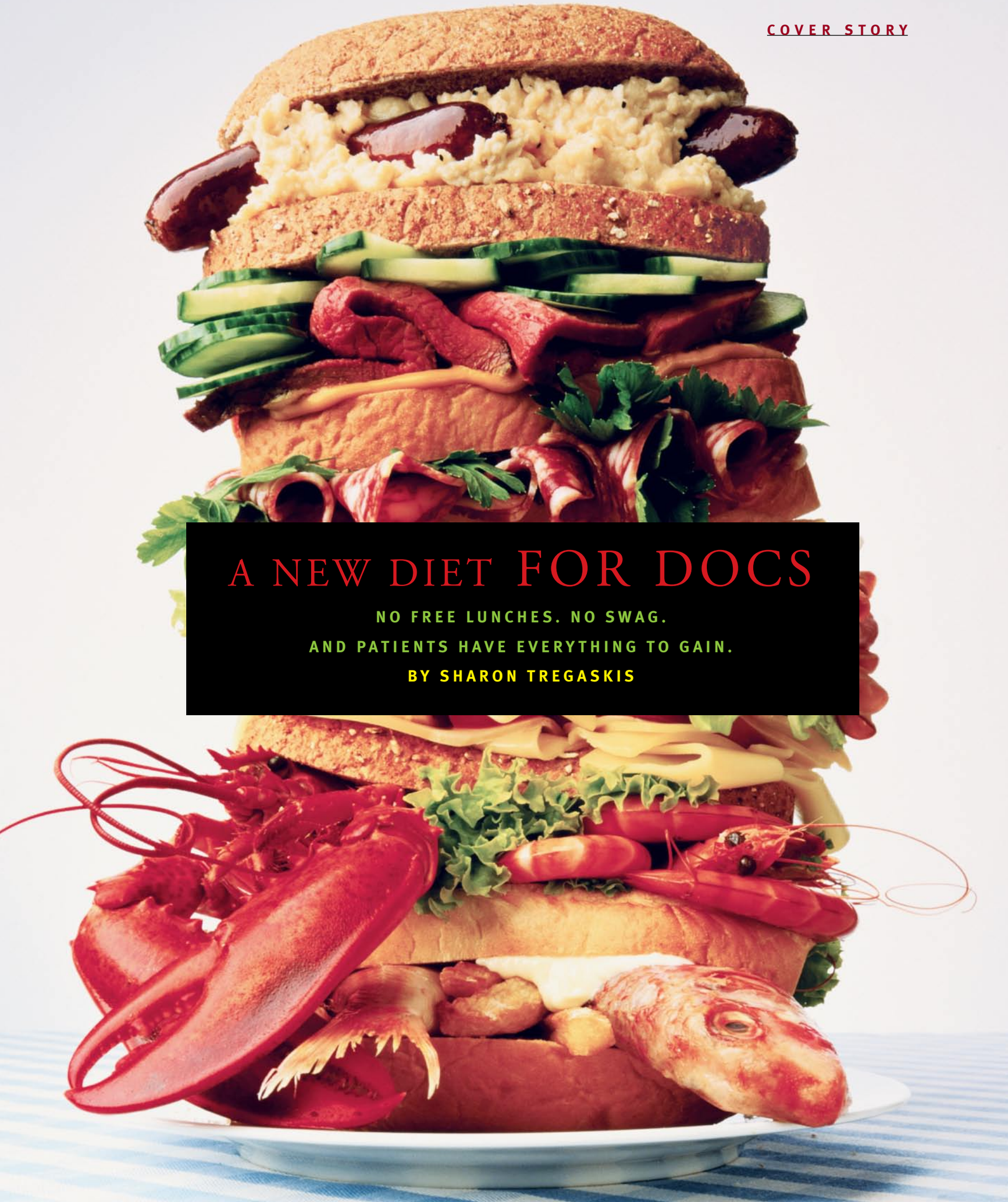


A NEW DIET FOR DOCS

NO FREE LUNCHES. NO SWAG. AND PATIENTS HAVE EVERYTHING TO GAIN.

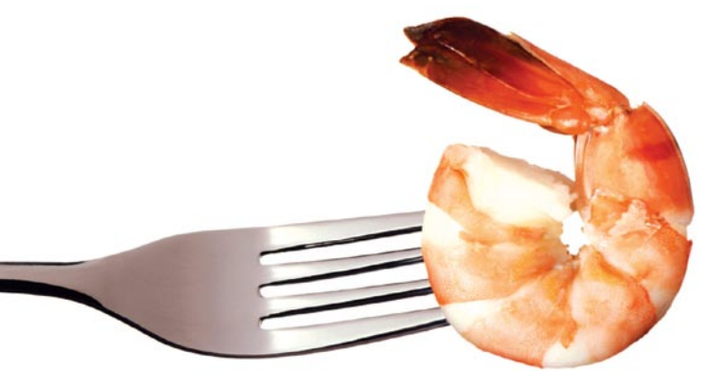
BY SHARON TREGASKIS

When Arthur S. Levine finished medical school, pharmaceutical companies gave the future Pitt dean of medicine two graduation presents: his first physician's bag and his first stethoscope. Pharmacist Randy Juhl, who would go on to serve 16 years as dean of Pitt's School of Pharmacy before his promotion to vice chancellor for research conduct and compliance for the University, has a shelf of mortar-and-pestle sets presented by industry reps to successive graduating classes. And as a pediatric resident in Denver in the '70s, Jerry Vockley recalls the downhill ski weekends in Vail hosted by infant-formula companies. (Vockley and friends organized their own low-budget, self-funded cross-country trips in response. He won't soon forget the tongue-in-check pronouncement of a fellow resident that he could never recommend breast-feeding to a new mother. "La Leche League has never given me anything," the young man declared of the nonprofit breast-feeding advocacy group, by way of explaining his shocking declaration.)

Since the mid-'40s, when pharmaceutical companies began professionalizing their sales enterprise and tracking the prescribing habits of doctors, they have been attempting to get in physicians' good graces.

Doctors are now bombarded with a range of inducements—from free lunches to complimentary samples and generously funded continuing medical education programs—offered by companies selling not only drugs, but medical devices and services to health care providers.

What's the harm now and then in accepting a free slice of pizza or a super-powerful refrigerator magnet with a company logo? Does it really influence the prescription a doctor writes? Docs are likely to say, "No." But the companies that provide these goodies must think otherwise, or they wouldn't spend truckloads of cash each year attempting to build relationships with physicians through these and other tactics.



Today, concern over such practices has reached a fever pitch, with both houses of Congress considering legislation to impose reporting requirements on industry, and physicians and medical students joining groups like No Free Lunch and PharmFree (which eschew handouts from industry and the potential conflict of interest such gifts might create). Building on the trend, academic medical centers nationwide have begun imposing policies to bring transparency and remove any hint of tarnish from what could be an enormously positive association for patients, physicians, and industry.

At Pitt and elsewhere, clinicians have signaled that they do not want to appear insensitive to the high cost of health care by accepting expensive and unnecessary blandishments.

This spring, Pitt will institute a new policy on industry relationships designed to protect the integrity of health care providers throughout the system. The code, which takes effect on February 18, covers all faculty, staff, and students of the University of Pittsburgh schools of the health sciences and the health care professionals and staff employed or contracted at all domestic locations of the University of Pittsburgh Medical Center. The comprehensive document (online at www.coi.pitt.edu, click on "Industry Relationships") prohibits gifts and free lunches, imposes narrow limits on faculty consulting arrangements, disallows participation in speakers' bureaus and ghostwriting, and bars sales reps from all patient areas. The policy, which applies equally on- and off-site, also defines acceptable use of industry funds for continuing education and scholarships. Says Arthur S. Levine, senior vice chancellor for the health sciences and dean of the School of Medicine: "It was my feeling, and that of my colleagues, that we needed to have a very precise, declarative policy."

David Rothman, coauthor of the 2006 *Journal of the American Medical Association* (*JAMA*) article, "Health Industry Practices That Create Conflicts of Interest: A Policy Proposal for Academic Medical Centers," pronounces the new regulations exemplary.

"Pitt's policies are outstanding," says Rothman, the associate director of the $6 million Prescription Project, a two-year, Pew Charitable Trusts–funded effort to overhaul the relationship between doctors and industry, with a particular emphasis on replacing marketing hype with medical evidence to inform physician prescribing habits.

"I'm not just gilding the lily here," says Rothman. "Pitt wants its place clean, and it's got it." And perhaps best of all, he says, though many schools crafting such policies have dedicated minimal thought to follow-up, Pitt has declared clear, unambiguous enforcement mechanisms.

"Development of the policy is the easy part," says Barbara Barnes, Pitt associate dean for continuing medical education in the School of Medicine. Barnes cochaired the committee that drafted the policy with Randy Juhl. "It demands tremendous commitment to implement and create culture change."

Barnes is optimistic because of the policy's strong backing from administrative leaders, including Levine, UPMC President and CEO Jeffrey Romoff, and Marshall Webster, president and CEO of the University of Pittsburgh Physicians and professor of surgery.

"We're part of a national groundswell of concern about these issues," says Webster, who coauthored with Levine the charge to the Industry Relationships Advisory Committee urging its members to take Rothman's *JAMA* article as a starting point.

"We're not operating out there in a vacuum," adds Webster. "Many of our faculty have had concerns and responded appropriately even before a policy was developed."

In 2006, the pharmaceutical industry, which employs some 90,000 sales reps, generated sales of $272 billion and spent more than $25 billion marketing to physicians—including $18 billion in free samples. Former pharmaceutical rep and Lunch and Earn founder Amy Kristjanson, whose online business coordinates take-out meals to physicians' offices paid for by drug companies, estimates the national market for docs dining with reps at close to $1 billion.

Last July, Oregon Representative Peter DeFazio introduced H.R. 3023 to require pharmaceutical and medical device concerns to disclose certain gifts made to physicians. In August, U.S. Senator from Iowa Chuck Grassley introduced the Physician Payment Sunshine Act, which proposes a national registry of payments from industry to physicians who bill Medicare or Medicaid. It covers consulting, lectures, and seminar attendance. The bill, cosponsored by U.S. senators from Massachusetts, Minnesota, Missouri, New York, and Wisconsin, was referred to the Senate Finance Committee. State-level bans on gifts already exist in Maine, Minnesota, and Vermont, and several academic medical centers—including those of Boston University, the University of Pennsylvania, Stanford University, the University of Wisconsin, and Yale University—have instituted policies of their own, which is as it should be, says the Prescription Project's Rothman.

"Medicine itself should take responsibility for getting its house in order and keeping its house in order," he says.

"There are two kinds of businesses," says Juhl. "*Caveat emptor*, let the buyer beware—you go to buy a car, you better do your homework." Health care falls into another category, he says: "*Caveat venditor*, let the seller beware. Our obligation is at all times and in all places to act on behalf of our patients. We should be doing what's best for our patients, not [prescribing something] because some nicely dressed young lady or young gentleman just bought me lunch."

It's a question of motives not lost on patients. Juhl himself sees a physician who tends to run late. "It gives me an opportunity to watch," he says. Often, shortly before lunchtime, a delivery person arrives with boxes of food, followed a few minutes later by a young rep. The receptionist promptly buzzes in each of them.

"When the salespeople who are bringing lunch get to go in before a patient, it doesn't look good," says Juhl. "It's not difficult for patients to figure out that the sales call will further delay their appointment with the physician, and to add insult to injury, they and the other patients huddled in the waiting room are further 'rewarded' by being the ultimate source for the payment of the lunch being shared by the physicians and the salesperson.

"That's an experience a lot of people have, and physicians may not think of it when they're behind the door."

The prospect of eroding trust motivates Gabriel Silverman, an MD/PhD student in Pitt's joint program with Carnegie Mellon University. As a member of the committee that drafted Pitt's industry policy, he drew both on his research—investigating the role of conflicts of interest in physician interpretation of clinical trial data—and his participation in the American Medical Student Association's (AMSA) PharmFree effort.

"Gabe brought a unique perspective," says Barnes. "It's a wonderful demonstration of the richness of an academic environment. We increasingly have a role reversal between physicians and students where we experience them stretching and challenging our thinking."

For AMSA, Silverman helped design a toolkit with materials to make it easier for an interested student to approach his or her dean to request the formation of a committee to craft an industry policy. In December, he was appointed the AMSA PharmFree coordinator for Pitt's region, an extension of his work to craft a scorecard that grades the policies in place at each of the nation's academic medical centers.

"This is our profession," says Silverman. "If we want to advocate for improved quality of care, patient welfare, this is an issue we should be concerned about. Second, this has an impact on the way our profession is perceived. I certainly wouldn't want my patients to doubt my objectivity, or have it interfere with my relationship with my patients."

Pitt just learned that it has won AMSA's 2008 Paul R. Wright Excellence in Medical Education Award in recognition of the school's commitment to professionalism in education, especially its initiatives to reduce pharmaceutical marketing influence.

A few details remain to be resolved about the new policy, including the question of how to handle free samples. A subcommittee is considering the possibility of having the samples

received by a central UPMC location, then delivered to appropriate physicians' offices through an existing internal delivery system.

"We received a lot of feedback from our physicians about the importance of samples, and we recognized they're used in a variety of ways," says Barnes, who notes that Pitt's policy covers close to 400 outpatient sites in both rural and urban settings.

Pitt physicians pointed out that samples help them supply patients with just-in-time medication, allow them to test whether a patient experiences side effects before paying for a full supply, and provide patients with affordable access to pharmaceuticals—a boost, physicians believe, for elderly patients trapped in the Medicare Part-D doughnut hole. Says Barnes: "We wanted to be absolutely sure that whatever we designed for the sample policy was not going to compromise patient care."

In the end, says Juhl, a desire to bolster patient care and confidence in physicians undergirded every decision the committee made. Perhaps, he says, Pitt's policy could engender a new way for industry and health care providers to work together to develop the best treatments—and the best information about those options—for all patients.

"If I were to wave a magic wand," Juhl says, "[I'd make it so the] pharmaceutical industry finds a new way to communicate with practitioners, institutions, and health plans that's much more data driven than relationship driven. We'd like that information to be published in the literature and have it at our fingertips when we need it. The pharmaceutical industry should be rewarded for good drugs and good data on the drugs—not on the basis of who delivers the freshest bagels." ■

THINKING OUT LOUD

THE DEAN CONTEMPLATES TCHOTCHKES AND THE ROLE OF INDUSTRY AT PITT

INTERVIEW | SHARON TREGASKIS

Pitt Med talked in depth with Arthur S. Levine, dean of the University of Pittsburgh School of Medicine and senior vice chancellor for the health sciences, about the issues behind a new industry relationship policy at Pitt. (Related story begins on p. 17.) Here are excerpts from that discussion.

PM: How do you think of the relationship between Pitt and the biomedical industries?
Levine: The challenge for us is equipoise—maintaining a vibrant relationship with industry, but at the same time one that isn't in any way harmful to the public trust, to the public health, or, for that matter, to industry itself.

PM: What made this issue resonate with you?
Levine: I don't think there was a single experience. It's something I've always been aware of. When I was a medical student, I received a medical bag from one company and a stethoscope from another. There isn't anything new about this. What's changed is the magnitude—the money involved, the scale and the scope of this kind of marketing to physicians, and to patients, for that matter.

PM: What brought the issue to the fore at Pitt?
Levine: The 2006 Brennan/Rothman paper in *JAMA* was extremely important—it was our wake-up call. There are a lot of institutions buying into this. It's not only Pitt and Penn, but also Michigan, Hopkins, Yale, and Stanford. We've captured an emerging societal, cultural, political, and financial context of which this is one element.

PM: How does this effort fit with your overall concerns about the crisis in American health care?
Levine: The cost of health care is our greatest domestic crisis. If it hadn't been for the war in Iraq, it would have been the driving domestic issue in the previous presidential election. And it certainly is becoming a driving issue in the current presidential campaign. But if all we address is health insurance, we'll just make the bill for health care even more outrageous than it already is without solving any of the underlying problems.

PM: What underlying problems?
Levine: For one, in the pharmaceutical industry, it's hard to come up with a paradigm-shifting drug. You have to spend a fortune on research, hope that you'll get lucky enough to discover and develop a truly unique drug—the first new antibiotic, the first really important antihypertensive, the first drug that is helpful in schizophrenia. Pharmaceutical companies know that happens rarely. To make themselves fiscally viable and satisfy their shareholders, they have to make knockoffs of somebody else's drug. That's how the industry works. Their knockoff might be a tiny bit better—maybe you can take it two times a day instead of three times, or maybe with food as opposed to without food. But basically, the fundamental drug is the parent drug. To elbow their way into the marketplace, if the me-too drug is only a little bit different, it means you have to spend a fortune on advertising. That's what this marketing stuff—being at the doctor's office and giving them the free pizza and trips to Bermuda—is all about.

PM: What's the alternative?
Levine: If you're a company that makes a unique drug, you don't have to do any advertising or marketing. The drug sells itself. Now that's a little bit of hyperbole, but things that are unique sell themselves—you don't have to do a lot of advertising, whether it's drugs, automobiles, or dresses. When penicillin first came along, no pharmaceutical company had to run full-page ads in the newspaper. It was saving countless lives and everyone knew it, and there wasn't a competitor.

PM: This is a strong, comprehensive policy. Why take such a detailed approach?
Levine: You have to decide between evolution and revolution. If you're changing the culture in a very major way, you have to take a major position. We already had policies that had not been effective in addressing the issue. They touched on the issue.

PM: What philosophy informed your attitude toward instituting this policy?
Levine: I'm a researcher and an experimentalist. I felt that this was a worthwhile experiment to undertake. I can't know the effect of this policy on research funding or access to free sample medications for impoverished patients. My hope and my intuition are that no bad things will happen. But they could. We'll have to see.

PM: What are the implications of policies like Pitt's for industry?
Levine: I think [our policy] will be helpful to the pharmaceutical industry. They have been tainted by this notion that they can buy their way into the marketplace with gifts. .... That's not healthy for them.

And perhaps if they aren't spending so much on marketing, and put that money into research instead, they'll be more likely to hit the jackpot with paradigm-shifting drugs.

PM: Why was it necessary to form a subcommittee to address pharmaceutical samples?
Levine: That's a logistical issue. It's technical, fiscal. We've done a lot of work on how we're actually going to get drug samples to the offices of doctors who use them and who need them. There's no problem with free drug samples provided that they're centrally managed and triaged in such a way that one particular drug isn't aggressively marketed by a detail man visiting the doc's office to the exclusion of other drugs that might be better, safer, or cheaper.

ROB KELLY

PM: In 2005, when the University of Michigan instituted a policy banning free lunches, they estimated the value of such meals at $2.5 million annually.
Levine: That's a lot of Domino's Pizza.

PM: Did anyone calculate comparable numbers at Pitt?
Levine: No. This is a huge institution. We have almost 50,000 people working for UPMC. I've got 2,000 medical school faculty, thousands of students. We'd have to ask every one of them whether they had a free tuna-fish sandwich today.

PM: Why did ghostwriting warrant a dedicated section in the policy?
Levine: I don't think that any physician should sign his or her name to an article in the medical literature that he or she cannot fully back, up to and including real authorship. Unless you struggle over the paper yourself, examine the raw data, vouchsafe for the data and its interpretation, there is no way to ensure accountability or credibility of the data or its interpretation.

PM: Do you fear that this policy could provoke retaliation in the form of lower research funding from industry?
Levine: Academia and industry rely on each other. Pharmaceutical companies will continue to turn to universities to help answer their research questions. As I noted earlier, if companies can free up money they are spending on marketing and put it toward research, that will present more opportunities to make really important discoveries that lead to life-saving and life-enhancing drugs. ■