Bioethicists increasingly find their work underwritten by pharmaceutical companies. Who passes on the ethics of ethicists?

I WAS RAISED IN A HOUSE FILLED WITH DRUG-INDUSTRY trinkets. My father has been a family doctor for more than 40 years, and drug representatives bearing gifts have visited him throughout his career. My brothers and I grew up tossing Abbott Frisbees and Upjohn Nerf balls. We took down messages on Inderal notepads, wrote with Erythromycin pens, carried Progestin umbrellas. We constructed weird Halloween costumes from models of the human hand and brain supplied by Parke-Davis and Merck. My father was no great fan of "detail men," as drug reps were called then. (These days, if you're a male physician, your detail man is likely to be an attractive young woman.) Nor did he take part in the drug industry's more outrageous marketing efforts, such as frequent-flier miles in exchange for drug prescriptions. But he saw no great harm in accepting drug samples for his patients or toys for his children. Like virtually all doctors, he did not think that the gifts influenced him in any way.

Why pharmaceutical companies want the goodwill of doctors is no great mystery. The surprise is why they want the goodwill of someone like me. I am a philosophy professor, and I work at a bioethics center. While I do happen to have a degree in medicine, that degree is largely decorative: The only prescriptions I write these days are moral ones. Despite this difference (or maybe because of it), the pharmaceutical and biotechnological industries are funneling more and more cash into the pockets of academics who teach and study ethics. Some of it goes straight to individuals, in the form of consulting fees, contracts, honoraria, and salaries. Some of it--such as gifts to bioethics centers--is less direct. Many corporations are putting bioethicists on their scientific advisory boards or setting up special bioethics panels to provide in-house advice. While I have not yet been offered Frisbees or Nerf balls, I suspect that it is only a matter of time.

The issue of corporate money has become something of an embarrassment within the bioethics community. Bioethicists have written for years about conflicts of interest in
scientific research or patient care yet have paid little attention to the ones that might compromise bioethics itself. Arthur Caplan, the director of the University of Pennsylvania Center for Bioethics, counsels doctors against accepting gifts from the drug industry. "The more you yield to economics," Caplan said last January, "the more you're falling to a business model that undercuts arguments for professionalism." Yet Caplan himself consults for the drug and biotech industries, recently co-authored an article with scientists for Advanced Cell Technology, and heads a bioethics center supported by Monsanto, de Code Genetics, Millennium Pharmaceuticals, Geron Corporation, Pfizer, AstraZeneca Pharmaceuticals, E.I. du Pont de Nemours and Company, Human Genome Sciences, and the Schering-Plough Corporation.

By no means does Caplan's center stand alone in its coziness with industry. The University of Toronto houses the Sun Life Chair in Bioethics; the Stanford University Center for Biomedical Ethics has a program in genetics funded by a $1-million gift from SmithKline Beecham Corporation; the Merck Company Foundation has financed a string of international ethics centers in cities from Ankara, Turkey, to Pretoria, South Africa. Last year the Midwest Bioethics Center announced a new $587,870 initiative funded by the Aventis Pharmaceuticals Foundation. That endeavor is titled, apparently without irony, the Research Integrity Project.

Bioethics appears set to borrow a funding model popular in the realm of business ethics. This model embraces partnership and collaboration with corporate sponsors as long as outright conflicts of interest can be managed. It is the model that allows the nonprofit Ethics Resource Center in Washington, D.C., to sponsor ethics and leadership programs funded by such weapons manufacturers as General Dynamics, United Technologies Corporation, and Raytheon. It also permits the former president of Princeton University, Harold Shapiro, to draw an annual director's salary from Dow Chemical Company while serving as chair of the National Bioethics Advisory Commission. Dow, of course, has been the defendant in a highly publicized lawsuit over the Dow Corning silicone breast implants as well as in numerous legal actions involving disposal of hazardous waste.

Part of the problem is aesthetic. It is unseemly for ethicists to share in the profits of arms dealers, industrial polluters, or multinationals that exploit the developing world. But credibility also is an issue. How can bioethicists continue to be taken seriously if they are on the payroll of the very corporations whose practices they are expected to assess?

LISTENING TO ELI LILLY

Last year some colleagues and I helped put together "Prozac, Alienation, and the Self," a special issue of The Hastings Center Report, a bioethics journal. Some of the papers that we published, including one by me, expressed worries about the extent to which antidepressants are being prescribed, especially for patients who are not clinically depressed. One paper in particular--"Good Science or Good Business?"--was especially critical of the drug industry. Its author, David Healy, is a psychopharmacologist and a historian of psychiatry at the University of Wales.

Shortly after these Prozac essays were published, Eli Lilly and Company, which manufactures Prozac, withdrew its annual gift to the Hastings Center, citing the special issue as its reason. Lilly's yearly check for $25,000 was not especially large by industry standards, but it was the Hastings Center's largest annual corporate donation. Lilly's letter to the organization was especially critical of Healy's article. Healy had previously published research indicating that some patients, particularly those who are not clinically depressed, may be more likely to commit suicide while taking antidepressants. He has also testified as an expert witness against Lilly and other drug manufacturers in lawsuits brought by family members of patients who killed themselves or others after taking antidepressants. In "Good Science or Good Business?" Healy argued that manufacturers of antidepressants have gone into the business of selling psychiatric illnesses in order to sell psychiatric drugs. Apparently, this was not the kind of bioethics scholarship that Lilly had in mind when it donated money to the Hastings Center.

THE REACTION OF BIOETHICISTS TO ALL OF THIS IS emblematic of the difficulties raised by corporate money. Some were encouraged by the response of the Hastings Center staff--particularly by the Report's editors, who published the special issue without regard to Lilly's reaction. We are never hostage to corporate money, these scholars say. We can always turn it down, resign our posts, and do the right thing despite enticements to the contrary. For others, however, the fact that the Report's editors faced such incentives is
precisely the problem. Given enough cases where bioethicists must choose between scholarship and their corporate funders, the funders will eventually win out. In the long run, money conquers all.

But the Hastings Center episode was only the first chapter of the Healy affair. In November 2000, Healy gave a talk on the history of psychopharmacology at the University of Toronto’s Center for Addiction and Mental Health (CAMH), where he was scheduled to take up a new position as director of the Mood Disorders Program. In that lecture, Healy mentioned his worries about Prozac and suicide. Shortly thereafter, the center rescinded his appointment. He was given no reason but merely informed by e-mail that CAMH did not feel that his “approach was compatible with the goals for development of the academic and clinical resource” of the clinic. CAMH officials insist that the Eli Lilly Corporation had nothing to do with the decision; yet the center is the recipient of a $1.5-million gift from Lilly. The Mood Disorders Program, which Healy was to direct, gets 52 percent of its funding from corporate sources.

Whether Lilly or any other corporate funder had anything to do with Healy’s dismissal is impossible to know. Even so, the trouble CAMH has had in convincing the public that industry sources were not involved points to the difficulty of discerning financial influence. Would CAMH have dismissed Healy if it had no ties to Lilly whatsoever? Does fear of being unable to attract future corporate money count as influence? Does fear of angering powerful industry-tied psychiatrists?

"Doctors fear drug companies like bookies fear the mob," says Harold Elliott, a psychiatrist at Wake Forest University. Corporate money is so crucial to the way that university medical centers are funded today that no threats or offers need actually be made in order for a company to exert its influence. The mere presence of corporate money is enough.

And researchers are probably right to be afraid. The University of Toronto itself has seen two other public scandals erupt over pharmaceutical-company funding in recent years. The most visible one involved Nancy Olivieri, a researcher at the university’s Hospital for Sick Children, who was conducting clinical trials of deferiprone, a thalassemia drug, for the generic-drug manufacturer, Apotex. When Olivieri became concerned about possible side effects of deferiprone, she broke her confidentiality agreement with Apotex and went public with her concerns. In response, Apotex threatened her with legal action. Rather than backing Olivieri against Apotex, the Hospital for Sick Children attempted to dismiss her. News headlines had hardly faded when Apotex promised the University of Toronto $20 million (about $13 million in U.S. dollars) in funding for molecular biology, then threatened to withdraw it if the school’s then-president, Robert Prichard, did not lobby the federal government to change its drug-patent regulations. Apotex wanted rules that would be more favorable to generic-drug manufacturers. The president did as he was asked and was later forced to apologize publicly when the story broke.

Industry-sponsored bioethics programs face problems that parallel those encountered by industry-sponsored medical researchers. What do you do when your scholarly work conflicts with the goals of your industry sponsor? No one is forcing industry money on bioethics programs, but many of them are located in academic health centers, where faculty members are expected to generate money to fund their research either by seeing patients or by obtaining grants. If bioethics is seen as an activity that can attract industry sponsorship, university administrators strapped for cash will inevitably look to industry as a financial solution. All that remains is for bioethicists themselves to dispense with the ethical roadblocks.

REVIEW FOR HIRE

One of the duties routinely carried out by bioethicists is service on institutional review boards (IRBs), the local committees mandated to oversee any research undertaken in universities or hospitals in order to protect human research subjects. So central has the IRS become to the protection of research subjects that it has given its name to a leading journal, IRB: Ethics and Human Research. Several years ago, I served on the IRB of a psychiatric hospital, and I now see that experience as a case study in the convoluted role that corporate money has come to play in research ethics.

Soon after I joined the IRB, I found myself in sharp conflict with many other members over one recurring issue: the use of placebos in psychiatric clinical trials. When a new psychiatric drug looks sufficiently promising to be tested in human subjects, it is ordinarily
tested against a control drug. If there is no effective treatment for the illness in question, that control is a placebo. Some subjects get the new drug, others get a placebo, and the researchers measure how the two compare. But if an effective treatment exists for a research subject's illness, the new drug must be tested against it, not against a placebo. The purpose of this rule is to protect subjects from harm. A patient should not get substandard treatment, such as a placebo, simply because he or she has volunteered for a research protocol. Just as a placebo cannot ethically be given to research subjects with asthma or cancer or heart disease, one ought not be given to patients with schizophrenia or severe depression, even if they consent to the possibility. These conditions can be treated effectively with existing drugs. If an ordinary psychiatrist were to treat schizophrenia or severe depression with a placebo rather than standard therapy, he could be successfully sued for malpractice. The drugs used to treat these illnesses are not perfect, to be sure, but they have been proven more effective than placebos.

Or so I argued to the IRB. The board was reviewing industry-sponsored protocols in which patients who were severely depressed or even acutely psychotic--delusional, hallucinating, confused, tortured by their own thoughts--were being given placebos rather than effective treatments, sometimes for periods of up to eight weeks. I cited national and international ethics guidelines, even the university's own guidelines, all of which prohibited the trials. Tables were pounded. Faces turned scarlet. Blood pressures soared. Yet the IRB continued to approve many of the trials, over my objections and those of other members of the committee. The hospital administration eventually dissolved the IRB and reconstituted it with new membership.

WHY WAS THE ISSUE SO DIVISIVE? EVERYONE'S interests were involved. First of all, the pharmaceutical industry, which sponsored the trials, has a financial interest in conducting placebo-controlled trials because they usually require fewer subjects than tests with active controls and are thus less expensive. Second, the trials generated much-needed income for the hospital--and possibly for the researchers themselves. And third, many IRB members were hospital psychiatrists who conducted placebo-controlled trials for industry. Other IRB members worked under the administrative authority of senior psychiatrists who were doing this type of research. While IRB members were not privy to the financial arrangements behind these trials, clinical researchers have reportedly received $1,000 to $6,000 for each patient they've enrolled in a clinical trial, with some earning between $500,000 and $1 million a year. According to a recent article in the Baltimore Sun, the chair of the psychiatry department at Brown University earned more than $500,000 in fees from drug companies in 1998.

The role of corporate funding in research review does not stop with local IRBs. Researchers testing new psychiatric drugs against placebos often point out that the Food and Drug Administration requires evidence from placebo-controlled trials before it will approve a new psychiatric drug. And they are right. The FDA argues that such research is justified by its scientific merit unless it results in death or permanent disability to subjects. Yet the FDA is itself deeply compromised by industry money. The industry pays "user fees" to the FDA in order to speed up review of their products--an amount estimated to be more than $300,000 per drug. And while the FDA employs scientific experts to evaluate new drugs, a recent survey found that over half of those experts have a financial conflict of interest because of industry ties. Dr. Richard Horton, editor of Britain's prestigious medical journal The Lancet, has called the FDA "the servant of [the drug] industry."

Some review boards are themselves becoming corporate entities. In fact, noninstitutional review boards (NIRBs) are usually set up as profit-making ventures. They oversee industry research that is not conducted in academic medical centers. Sixty percent of industry-sponsored clinical trials are contracted out to for-profit research firms, which may in turn contract with for-profit NIRBs for ethical review. A typical NIRB will charge about $1,200 to examine a research protocol. Unlike IRBs, which are usually staffed by volunteers, most NIRBs pay their members, including their ethicists.

Defenders of for-profit review boards claim that they can operate much more quickly and thoroughly than IRBs, which depend solely on volunteers. Yet the for-profit committees are financially dependent on the companies whose research protocols they are reviewing. If a corporation does not like the results that one for-profit NIRB provides, it contracts with another. "Nothing prevents companies from searching for the most lenient NIRB," says Trudo Lemmens, an attorney and bioethicist at the University of Toronto who has published two recent studies of NIRBs. Lemmens also points out that since NIRB members are typically not guaranteed a fixed term on the board, they may be dismissed for...
objecting to problematic protocols.

To be fair, there is no evidence to suggest that NIRBs are performing any less competently than IRBs. In a system of research review so thoroughly compromised by industry funding, however, it is ironic that many people see the solution to inefficient review as more industry funding. For no matter how efficient NIRBs may be, they are structured so that both the body and its individual members may feel compelled to make things as easy as possible for the people who pay them.

ASK THE EXPERTS

Earlier this year, I got an e-mail message from the CEO of a company called Foreview inviting me to become part of its "global network of experts." Foreview is a sort of corporate-academic dating service. It matches up academic "experts" with businesses seeking expertise. According to its Web site, Foreview provides its clients with "information about tomorrow's state of the economy and politics." It does this partly through its "Ask the Experts" service, which hires people like me to respond to questions posed by clients. My payment for taking part in "Ask the Experts" would be $175 per question. I was also told that this work would probably lead to more detailed consulting projects, for which I could set my own rates--but Foreview would receive a 10 percent finder's fee, capped at a maximum of $5,000.

I did not take Foreview up on its offer, which sounded a little too much like a "Dear Abby" column; but I did start to ask colleagues in bioethics about the kinds of corporate consultations they had been asked to do. The type of work available varied: testifying as an expert witness in court cases, preparing reports, giving talks at industry-sponsored meetings (often held at ski resorts or foreign vacation spots). Many biotechnology companies have set up their own bioethics advisory boards. A list of bioethicists reported to serve on such advisory boards reads like a who's who of bioethics: Nancy Dubler of Montefiore Medical, for DNA Sciences; Ronald Green of Dartmouth, for Advanced Cell Technology; Arthur Caplan of the University of Pennsylvania, for Celera Genomics and DuPont; Karen Lebacqz of the Pacific School of Religion, for Geron Corporation. Some bioethicists work pro bono while others accept fees. Evan DeRenzo, a staff member at the Center for Ethics at Washington Hospital Center, charges Janssen Pharmaceuticals by the hour to sit in on meetings, review research protocols, and help the company develop policy and educational sessions. Bruce Weinstein, formerly a faculty member in bioethics at the West Virginia University Health Sciences Center, now delivers lectures and seminars to businesses through a for-profit service called Ethics at Work. Weinstein calls himself "The Ethics Guy" and has published a self-help ethics book--What Should I Do?--that offers moral advice on everything from dating to personal hygiene.

Defenders of corporate consultation often bristle at the suggestion that accepting money from industry compromises their impartiality or makes them any less objective a moral critic. "Objectivity is a myth," DeRenzo told me, marshaling arguments from feminist philosophy to bolster her cause. "I don't think there is a person alive who is engaged in an activity who has absolutely no interest in how it will turn out." Thomas Donaldson, director of the ethics program at the Wharton School, has compared ethics consultants to the external accounting firms often employed by corporations to audit their financial records. Like accountants, ethicists may be paid by the very industries they are assessing, but they are kept honest by their need to maintain a reputation for integrity.

But the comparison of ethicists to accountants is deeply misleading. Ethical analysis does not look anything like a financial audit. If a company is cooking its books and the accountant doses his eyes to this fact in his audit, the accountant's transgression can be reliably detected and verified by outside monitors. But how do you detect the transgressions of an ethics consultant? Ethicists have widely divergent views: They come from different religious standpoints, use different theoretical frameworks, profess different political philosophies. They are also free to change their minds at any point. How do you tell the difference between an ethics consultant who has changed her mind for legitimate reasons and one who has changed her mind for money? How do you distinguish between a consultant who has been hired for his integrity and one who has been hired because he supports what the company plans to do? A savvy CEO will have no problem finding an ethicist to say virtually anything.

Yet influence is not exactly what's at issue. If a policeman takes money to overlook a speeding violation and then writes the ticket anyway, he has still accepted a bribe, even if
he has not been influenced by it. The point is that certain people in whom public trust is placed must not have a financial interest in violating the duties carried by their institutional role. In this respect, at least, they must be financially disinterested. What is more, they must be seen as disinterested; otherwise, the institution they represent risks falling apart.

Judges and jurors, for instance, depend on the appearance of disinterestedness for their fragile hold on public trust. Judges get paid, of course, as do bioethicists and other academics. But the source of that payment is crucial. If we allowed judges to be paid by corporate litigators, they would soon lose their credibility—and rightly so. If bioethicists have gained any credibility in the public eye, it rests on the perception that they have no financial interest in the objects of their scrutiny.

Bioethicists who consult for industry are usually engaged in a range of other activities in which they are presumed to have a measure of distance—financially, if not ideologically—from the actions or policies in question. Students generally do not suspect that their ethics professor may be getting a paycheck from the very corporations whose actions and policies they are discussing in class. Readers of bioethics journals do not generally suspect that the author of a paper on the ethics of stem cell research may be the part-time employee of a company conducting the research. The university that appoints an ethicist to an IRB generally does not imagine that the ethicist himself is being paid by the industries whose protocols he is expected to evaluate. Such relationships can be disclosed, of course. But even bioethicists who defend taking industry money often find disclosure a little embarrassing, and so they rarely disclose their conflicts except when it's mandatory—not in the philosophy class, not when they appear on Nightline, not when they are quoted in the pages of The Washington Post defending corporate policy. Most bioethics journals do not even require conflict-of-interest disclosures. And even when a financial relationship is disclosed, the amount of money that has changed hands is not. A reader of a scholarly article cannot tell the difference between an author who has received a hundred dollars from industry and one who has received hundreds of thousands.

THE PROBLEM WITH ETHICS CONSULTANTS IS THAT they look like watchdogs but can be used like show dogs. What better way for a corporation to polish its image than to parade an ethics consultant before its critics? What better way to head off litigation than to run its plans by an in-house ethics board? No matter how outrageous a corporate policy, no matter how troubling a headline in the morning paper, it will be softened by the knowledge that the corporation in question has consulted with a team of ethics experts. Better to buy a bioethicist now than to be attacked by one later. The only challenge is how to disguise the job so that bioethicists do not realize that they have been bought.

Ken DeVille, an attorney and historian of medicine at East Carolina University, wonders whether bioethics will continue to be an enterprise worth pursuing once it is thoroughly infused with corporate money. "If ethicists are transformed into a bunch of corporate shills who exist only to serve the machine," he asks, "where is the honor in taking part?" Of course, DeVille's comment presumes that there is a distinction between honor and serving the machine. Once the very discipline of bioethics is itself a part of the machine, service is an honor. Laurie Zoloth, the current president of the American Society for Bioethics and Humanities, has written that the real temptations of industry associations are not financial but the honor and status of corporate consultancies. If she is right and advising a corporation is an honor, then bioethics is already making the shift from outsider to insider, from critic of the machine to loyal servant.

Still, we can all take heart: Help may be on the way. The American Medical Association's Council on Ethical and Judicial Affairs is planning a $590,000 initiative to educate doctors about the ethical problems involved in accepting gifts from the drug industry. That initiative is funded by gifts from Eli Lilly and Company, GlaxoSmithKline, Inc., Pfizer, U.S. Pharmaceutical Group, AstraZeneca Pharmaceuticals, Bayer Corporation, Procter and Gamble Company, and WyethAyerst Pharmaceutical.

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