When Ethicists Have Conflicts of Interest

Carl Elliott

In February, the online magazine *Slate* published an article with the title, "Go Away, Ethics Police; Leave the NIH Alone." The author of the piece was Richard Epstein, a law professor at the University of Chicago and a senior fellow at the Maclean Center for Clinical Medical Ethics. The "ethics police" to whom Epstein objected were the critics who had pushed the National Institutes of Health (NIH) into adopting a strict new set of conflict-of-interest regulations. Last year, a muckraking series of reports in the *Los Angeles Times* revealed that some NIH scientists had parlayed their elite scientific positions into lucrative consulting contracts with the pharmaceutical industry. Several NIH scientists had received more than $2.2 million in company fees and stock options. The director of one NIH institute received more than $600,000 from Schering AG and other companies at the same time that his institute conducted studies for Schering and pledged it $1.7 million in grants. Another scientist wrote national cholesterol guidelines while accepting $114,000 from the makers of cholesterol-lowering drugs.

When Congress decided to investigate, the NIH began to clean up its house. In early February, the NIH director, Elias Zerhouni, announced that the NIH would impose strict limits (which were later loosened) on the relationships that its staff could maintain with industry. It was this strict policy to which Epstein objected. "In my experience as a member of a conflict-of-interest committee at the University of Chicago," wrote Epstein, "it is par for the course for the leaders in cutting-edge technologies to take consulting jobs or stocks in outside ventures that harness the results of their academic research."

What Epstein did not say (and what *Slate* did not reveal until later) is that Epstein has one of the same kinds of financial relationship to the pharmaceutical industry that he wants the NIH to preserve. Not only is Epstein a paid consultant to Pfizer, the world's largest pharmaceutical company, he also consults for PhRMA, the pharmaceutical trade organization. Along with Merck, those two organizations have underwritten an annual medical ethics and health policy conference at the University of Chicago that Epstein helps to organize and whose 2003 proceedings he recently published in the bioethics and medical humanities journal *Perspectives in Biology and Medicine*. The 2004 proceedings were published (without disclosure) in the *Yale Journal of Health Policy, Ethics and Law*. Ironically for the sponsors of a bioethics conference, Merck and Pfizer were both among the nine companies included in the Dow Jones Industrial Index that were convicted of corporate crimes last year.

Epstein's ties to the pharmaceutical industry are no secret. Epstein himself wrote about them in a recent article in *Legal Affairs* that was advertised on the cover with the slogan "I Heart Big Pharma." But Epstein's article in *Slate* (perhaps inadvertently) raises a far more important ethical question: what is a person with such obvious conflicts of interest doing on a University of Chicago conflict-of-interest committee?

In the world of bioethics and health policy, such questions are no longer academic. The pharmaceutical and biotechnology industries have begun adding academic bioethicists and health policy analysts to their corporate payrolls. Some companies employ bioethicists as consultants or advisers; others contribute funds to academic bioethics and health law centers; many sponsor bioethics projects, task forces,

and conferences. For example, the program of the 2005 spring meeting of the American Society for Bioethics and Humanities included full-time bioethicists from Glaxo SmithKline and Millennium Pharmaceuticals; a bioethics consultant to Eli Lilly; and a presentation by Glenn McGee, editor of the *American Journal of Bioethics*, who spoke about a funding grant he and his bioethics colleagues had received from deCODE Genetics. Bioethicists are no longer disinterested commentators on the question of whether pharmaceutical industry money constitutes a conflict of interest for academic researchers. They have a financial stake in the answer.

What have bioethicists concluded? Not much. Although a handful of bioethicists have objected strongly to industry funding, the most vocal defenders of ethicists' accepting pharmaceutical money have been those with industry ties themselves. In fact, among the most outspoken opponents of the new NIH conflict-of-interest policy has been its own chief bioethicist, Ezekiel Emanuel, whose disclosure statements have included speaking fees from Merck, and who has reportedly been forced by the new NIH guidelines to sell off $140,000 in stock. Several years ago, the two major American professional bioethics associations appointed a task force, led by Baruch Brody of Baylor University, to look at the issue of for-profit bioethics consultation. When the task force published its conclusion that there was nothing ethically wrong with paid bioethics consultation to industry, it also included an addendum saying that eight of the ten members of the task force had performed paid consultations to industry themselves.

Part of the difficulty is that questions of conflict of interest are increasingly decided by institutional conflict-of-interest committees, such as the one on which Epstein serves at the University of Chicago. Most institutions prefer to police their own behavior rather than submit to external regulators, and they also prefer to write their own ethical guidelines rather than have them imposed from the outside. But when institutional insiders are writing the guidelines, they are often tempted to write them in a way that serves the institution. The presence of impartial outsiders on institutional committees is supposed to lend the committees a measure of credibility; yet an institution can easily choose outsiders whose judgments mirror those of the insiders. This problem is not limited to conflict-of-interest committees; any pharmaceutical company conducting ethically controversial research can cherry-pick bioethicists who are most likely to give them the opinions they want. Michael West, the biotech entrepreneur who set up ethics advisory boards at Geron and Advanced Cell Technologies, recognized this when, as Stephen Hall reports in *Merchants of Immortality*, he told Hall, "You're not getting whether something is right or wrong, because it all depends on who you pick."

Such problems can be seen in the ongoing conflict-of-interest saga at the NIH. A year or so before the current, rigorous guidelines were announced in February, the NIH had responded to the scandal in a rather more modest way: it announced that it would appoint a special Blue Ribbon Panel on Conflict of Interest Policies to devise some recommendations. But the Blue Ribbon Panel itself included many members who either worked for private industry or who had industry ties. One of the co-chairs was the chairman and former CEO of Lockheed Martin; another panel member was the vice president of a for-profit health care company. Two members were connected to ethics organizations: the Hastings Center, a bioethics think tank that accepts funding from the pharmaceutical industry, and the Ethics Resource Center, an organizational ethics center funded by a variety of private industries, including Merck.

Perhaps unsurprisingly, the Blue Ribbon Panel did not exactly bring down the hammer on the NIH. Under its recommendations, more than four thousand NIH employees would have been exempt from public disclosure of their conflicts. NIH scientists would have been allowed to work up to four hundred hours a year for the pharmaceutical industry and to earn amounts as much as half their base salaries.

When Zerhouni presented the report of the Blue Ribbon Panel to Congress, its recommendations were met with disdain from both political parties. According to the *Wall Street Jour-*

nal, some committee members "openly scoffed at the recommendations." The *Los Angeles Times* reported that a Florida Democrat called the report "an apology for the status quo" and characterized the guidelines as "a system of careful twisting of the rules and overlooking of the consequences." It was apparently this disdainful response that led Zerhouni to conclude that the credibility of the NIH would not be restored unless more restrictive guidelines were instituted.

THE PROBLEM for bioethicists, like that of the members of the Blue Ribbon Panel, is that that they are often seen as apologists for the status quo. Sometimes that perception is unfair, but not always. As the field of bioethics has evolved, bioethicists have become embedded in the very enterprises that they study. They have moved out of divinity schools, law schools, and philosophy departments and into medical schools, hospitals, and pharmaceutical companies. Being a biomedical insider brings some advantages, of course—namely, insider knowledge and bureaucratic power. But it also carries some costs. One cost may well be public credibility as a fair-minded critic of the biomedical enterprise, or even as an impartial arbiter on questions of ethical concern.

At a time when the pharmaceutical industry is coming under heavy public criticism for unethical practices—illegal marketing, Medicare fraud, research abuse, ghostwritten journal articles, unexplained deaths in research studies—it is striking how little of the criticism has come from bioethicists. Most has come from watchdog groups; disaffected journal editors; and muckraking journalists such as David Willman, whose articles in the *Los Angeles Times* led to the congressional investigation of the NIH. Journalists such as Jennifer Washburn, the author of *University Inc.*, have investigated the legal and regulatory climate that has forced American universities to behave like corporations; yet bioethicists, who work in those very universities, have been largely silent. (When universities behave like corporations, perhaps it should not be surprising if its faculty members behave like corporate employees.)

Bioethicists who accept money from the pharmaceutical and biotechnology industry are not impartial arbiters on the question of whether industry funding constitutes a conflict of interest for academic researchers. After all, industry-funded bioethicists have a financial interest in promoting and legitimizing their own financial ties to industry. The more widely accepted it becomes for university scientists and physicians to accept funding from the pharmaceutical industry, the more widely accepted it will become for bioethicists working in the same institutions to accept such funding. At a bare minimum, bioethicists writing on conflict of interest need to disclose their industry ties in their scholarly publications on the topic.

More important, however, industry-funded bioethicists should not be writing the guidelines under which their own financial activities will be regulated or serving on the conflict-of-interest committees that enforce those guidelines. Richard Epstein can accept money from PhRMA and Pfizer or he can serve on his university's conflict-of-interest committee, but he should not do both. Bioethicists who write ethics rules that permit them to profit from their industry ties sound suspiciously like the Republicans on the ethics committee in the House of Representatives who rewrote House ethics rules to suit their own political agenda and protect themselves from scrutiny. If a member of an ethics committee has a significant financial stake in what the ethics guidelines say, then that person should resign from the committee. Otherwise he or she is not just a member of the ethics police, but a police officer on the take. ●

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