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Hidden Payments to University Researchers Draw New Fire

Congressional investigators say medical schools and federal agencies have not policed conflicts of interest

BY RICHARD MONASTERSKI

WALL STREET bankers currently serve as the national poster children for greed, but they face a strong challenge from some university researchers who have apparently been taking millions of dollars in secret from the medical industry. Recent revelations about those undisclosed payments have universities and the National Institutes of Health scrambling to rein in biomedical researchers, even though leaders in the field have known about such problems for years.

NEWS ANALYSIS

This month, Emory University acknowledged that the NIH had halted a \$9.3-million grant to the university because of concerns raised about the financial ties of Charles B. Nemeroff, the project's former chief scientist and a professor of psychiatry. The agency's actions are causing administrators around the country to lose sleep, especially because they expect that more dirty laundry will soon be aired by Congressional investigators who have been tracking payments to academic scientists.

"The fact that some of these things get splashed into the headlines and that various members of Congress take it upon themselves to deal with these issues puts us on notice that we really need to address this as a larger issue and not on a case-by-case basis," says Keith R. Yamamoto, executive vice dean for research at the School of Medicine of the University of California at San Francisco.

"We know we have challenges, and we are working on addressing these challenges," says Susan Ehringhaus, associate general counsel for regulatory affairs at the Association of American Medical Colleges, who led a study that found significant holes in the conflict-of-interest policies at the majority of medical schools.

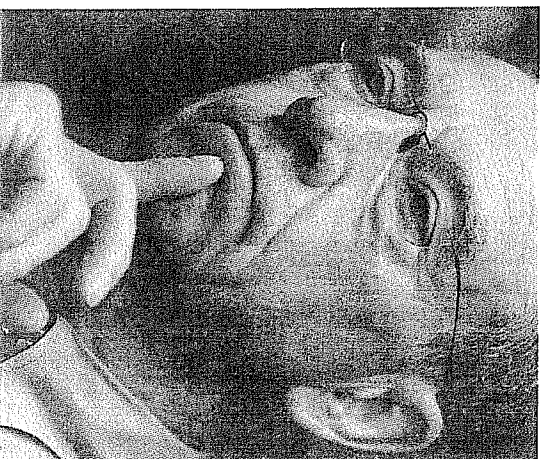
The recent budget problems in science have made conflicts more common. Accounting for inflation, the amount of money that NIH provides in grants has dropped in the past several years, and academics have turned to industry for financial support.

The force stirring up so much of the recent bad publicity for universities is Sen. Charles E. Grassley of Iowa, the top Republican on the Committee on Finance. His staff has sent letters to more than 20 universities, requesting information about industry payments to dozens of researchers in psychiatry, cardiology, and orthopedic surgery. The investigators have also solicited information from companies about how much they are paying the same scientists. By comparing the two sets of data, the committee staff has identified researchers who have received large sums that they did not disclose to their universities, in violation of institutional and federal policies.

In the Emory case, the finance committee released data this month indicating that Dr. Nemeroff collected approximately \$2.5 million from pharmaceutical companies between 2000 and 2007 but only disclosed about \$1.2 million on forms that he was required to submit to the university. Other documents indicate that Emory had repeatedly sought to reduce or stop Dr. Nemeroff's work for companies, especially those whose products he was studying. At each step, Dr. Nemeroff

thanked the university for sorting through his complex financial arrangements and promised to limit his consulting and other relationships with medical companies.

Federal regulations stipulate that researchers receiving NIH grants must remain free of conflicting financial interests, which are



ALEX WONG/GERTY IMAGES
Sen. Charles E. Grassley has cosponsored legislation that would make public any industry payments to physicians over \$500.

defined in practice as receiving more than \$10,000 a year or owning more than 5 percent of an entity that might bias their work. Investigators supported by a grant must provide financial information to their university, and the university must then ensure that any conflicts of interest are managed or eliminated. The agency does not require that the university provide information about the nature of the conflicts or how they have been resolved.

Dr. Nemeroff appears to have flouted those procedures. Between December 2000 and November 2002, for example, the NIH supported a study by Dr. Nemeroff of the drug paroxetine, which is marketed by Glaxo-SmithKline under the name Paxil. He did not report any income from the company for the years 2000 and 2001, but GlaxoSmithKline told Mr. Grassley that it paid Dr. Nemeroff \$190,918 and \$135,460 in those years. In 2002, he reported earning \$15,000 from the company but actually received \$232,248, according to a letter that Mr. Grassley sent to James W. Wagner, president of Emory.

The senator has no authority to punish Dr. Nemeroff or Emory, but he has been waging a tactical war, hoping to generate enough outrage that the NIH would act. In August, the agency quietly did. Following years of news-media reports about payments to Dr. Nemeroff and questions raised by Senate investigators, the NIH stopped funds to Emory on a large set of grants dealing with depression, which Dr. Nemeroff had been leading.

He has since been replaced as the chief scientist on the grant, and he has voluntarily stepped down as chair of the psychiatry department.

For researchers on the depression project, the freeze in funds has caused significant hardship. "Frankly, that's been pretty catastrophic," says Joseph F. Cubells, an associ-

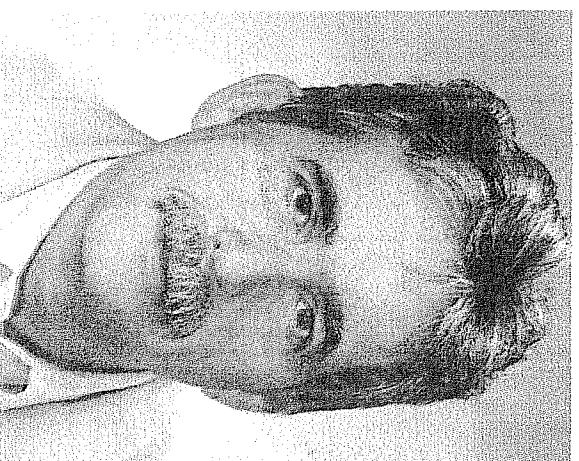
ate professor of human genetics and psychiatry, who was looking for genetic markers that might tell which people will respond quickly to antidepressant medication.

"This is not just about Charlie Nemeroff," says Dr. Cubells. "There's an entire community of researchers [on the project] that are having trouble paying salaries. Ultimately, people are going to have to lose their jobs if this continues long enough."

Elias A. Zerhouni, director of the NIH, acknowledged the troubles that a frozen grant can cause when he was asked about the possibility of pulling support from universities that had not managed to control faculty members' conflicts of interest. Last month, in a conference call with reporters, Dr. Zerhouni said that patients at the Johns Hopkins University suffered in 2001 when the NIH temporarily halted all research there following the death of a healthy subject in a study. Dr. Zerhouni was executive vice dean of the Hopkins medical school at the time.

Emory said that it had enrolled 11 people for the depression study and was continuing to provide treatment for them, but that it would not enlist any new subjects. The five-year project, which had completed its second year in June, is supposed to enroll 400 people to study different factors—such as genetic screening and brain scans—that could tell doctors how to identify the best treatments for individual patients.

Emory officials say that Dr. Nemeroff is cooperating with a university investigation. Dr. Nemeroff did not respond to an interview request from *The Chronicle*, but released a statement through Emory saying, "To the best of my knowledge, I have followed the



EMORY U.
Concern about Charles B. Nemeroff's financial ties caused a \$9.3-million grant to be pulled from a project he led at Emory U.

appropriate university regulations concerning financial disclosures."

David Wynnes, vice president for research administration at Emory, says that there had been no allegations that the payments to Dr. Nemeroff had biased the depression study. "Our hope would be that as soon as the NIH is confident that we've answered any concerns about the grant, they will start the funding for the program again."

In the wake of the Senate investigation into Dr. Nemeroff, the NIH is requiring much more specific financial disclosures from Emory. For all current and future grants, the university will have to provide information about the money that each researcher covered by a grant receives from industry and how the university is dealing with conflicts of interest.

Dr. Nemeroff was only the latest in a string of researchers whose financial conflicts were illuminated by Senate investigators. This year, they have raised concerns about scientists at Harvard and Stanford Universities, and the Universities of Cincinnati and Texas. Last month, Mr. Grassley sent a letter to Lee C. Bollinger, president of Columbia University, requesting financial information about 22 cardiologists affiliated with the university.

The attention spurred by Mr. Grassley's investigations is causing academic leaders to rethink how they do business. Over time, research universities will probably move toward fully disclosing what faculty members earn from companies, says Steven J. Fluharty, vice provost for research at the University of Pennsylvania.

University officials know that Mr. Grassley's staff has more cards to play and that the headlines about academic misdeeds will not disappear. The senator is hoping to build support for the Physician Payments Sunshine Act, which Mr. Grassley has introduced along with Sen. Herb Kohl, Democrat of Wisconsin. The bill would require medical companies to disclose in a public registry those payments to physicians that exceed \$500 per year. Many pharmaceutical and medical-device manufacturers have supported the bill, as have the American Medical Association and the Association of American Medical Colleges.

The bill would allow universities to check whether researchers had fully disclosed all their income from medical companies. But that ability would, in effect, force universities to play more of a policing role, rather than taking on faith the statements made by their faculty members.

Even that bill would not fix all the problems in the system, say officials within and outside academe.

A recent survey led by the Association of American Medical Colleges found that less than 40 percent of medical schools have policies governing institutional conflicts of interest, such as might arise when a company provides money directly to a university or to its senior officials. Over two-thirds of the medical colleges had more-limited policies governing payments to senior officials, but more than 20 percent of the institutions did not have even those narrow policies.

Ezekiel J. Emanuel, chairman of the department of bioethics at the NIH, says there are systematic problems with the way this country governs conflicts of interest in biomedical research. "The safeguards aren't working," he says. "They're onerous to those who adhere, and they don't work for those who don't adhere."

The solution, however, is not to simply prohibit payments from companies to researchers, he says, because academic scientists must interact with industry in order to translate basic science into treatments. "It's just that the usual ways of greasing that—money, food, and travel—are corrupting the system," he says.