

SENATE PROBE OF RESEARCH PSYCHIATRISTS

Senator Charles Grassley (R-IA) has cast a wide net in search of physicians who failed to fully disclose payments they received from drug and device companies. One of his concerns, he said, is that biased research could be influencing treatment decisions. Starting with psychiatrists in 2007, Grassley's investigators moved on to orthopedic surgeons this year; he has also looked into fees paid to academic cardiologists, professional associations, and a radio show host.

About 30 universities have now received queries from Grassley. This table includes cases made public by Grassley involving NIH-funded researchers—all psychiatrists, many of whom allegedly received consulting income from companies whose drugs they were studying. (Some researchers have said they didn't realize that certain types of payments had to be disclosed.) Dollar amounts are based on letters and statements from Grassley. **—J.K.K.**

Researcher	Industry Income Disclosed	Total Received	Status
Melissa DelBello, University of Cincinnati	about \$100,000 over 2 years	more than \$238,000 from AstraZeneca	UC has increased monitoring of DelBello's industry activities.
Joseph Biederman, Harvard/Mass General Hospital	about \$200,000 over 7 years	about \$1.6 million	MGH and Harvard are still reviewing, but Biederman agreed to suspend his industry-related activities in December 2008. Harvard is reviewing its conflicts policy.
Thomas Spencer, Harvard/Mass General Hospital	about \$200,000 over 7 years	about \$1 million	MGH and Harvard are reviewing.
Timothy Wilens, Harvard/Mass General Hospital	about \$200,000 over 7 years	about \$1.6 million	MGH and Harvard are reviewing.
Alan Schatzberg, Stanford	more than \$100,000	\$6 million in stock	Stanford says it knew the stock's value. Stanford's medical school soon plans to publicly disclose faculty members' industry ties but not dollar amounts.
Charles Nemeroff, Emory	\$1.2 million over 7 years	more than \$2.4 million	NIH suspended a \$9 million grant to Emory. The HHS Inspector General is investigating the case. Last December, Nemeroff stepped down from research and as department chair.
Zachary Stowe, Emory	not available	\$253,700 over 2 years from GSK for about 95 lectures	Emory told Stowe to eliminate his conflicts in April. The school recently banned promotional speaking.
Karen Wagner, University of Texas, Austin	about \$100,000 over 7 years	more than \$236,000	UT is reviewing.
Augustus John Rush, University of Texas, Southwestern	about \$600,000 over 7 years	more than \$600,000	Rush left UT for Singapore last August and is no longer being investigated, according to Grassley's staff.

AAMC and AAU also agree that NIH should collect more details from institutions on the conflicts they're managing. Under the current rules, institutions only have to tell NIH whether a conflict was managed, reduced, or eliminated. That's partly where the current problems stem from, suggests Julie Gottlieb, assistant dean for policy coordination at Johns Hopkins University School of Medicine in Baltimore, Maryland. If NIH officials are serious, says Gottlieb, "they need to do more than they've been doing."

However, a prohibition on financial conflicts above a specific level remains unpopular, even for studies involving human subjects. Although AAMC and AAU have recommended to their members that significant conflicts should be prohibited in clinical research, they say institutions need flexibility, and in comments to NIH they oppose an "a priori prohibition." One reason to avoid broad caps, notes Gottlieb, is that a great deal of human subjects research is low-risk—on human tissue samples, for example. AAU and AAMC also argue that it's premature to require policies for institutional-level conflicts. They warn that "imposing overzealous regulations could disrupt productive partnerships to the detriment of science and the public."

Grassley has applauded the AAMC and AAU statements, saying NIH "should consider everything" in the comment letter. At least one expert on academic-industry ties, however, thinks the regulation should prohibit any conflicts in clinical research. "I think there should be a zero threshold, or very small," says Sheldon Krinsky of Tufts University in Medford, Massachusetts, because even a \$100 payment could influence a researcher's objectivity.

No rule is universally obeyed, of course, and scientists could still hide their income. Many of those Grassley has probed allegedly were not following existing rules. The remedy for that, many observers say, is a public database of payments reported by companies—such as one that would be created by the bill introduced by Grassley and Senator Herbert Kohl (D-WI), potentially by October 2011. University officials could use the database to audit their faculty members, say AAMC and AAU, which support the bill.

The disclosure system would work much better, the IOM report says, if the research community developed a standard reporting format. Some major medical centers have begun discussing this with companies so that items they consider irrelevant—such as a research grant or reimbursement for travel

expenses—don't get counted as income. AAMC's Ehringhaus says standardization is "a terrific idea," but "I don't know yet" if her organization will move it forward. FASEB has suggested that PHS develop a "universal" form.

Harvard's Campbell thinks institutions are making progress. "It's gone from the Wild West 15 years ago to a system that seems to be much more regulated. Over time, people will pay greater and greater attention," says Campbell, who was also on the IOM panel.

Even with stricter rules and full public disclosure, none of these steps will change the fundamental contradiction spurred by Bayh-Dole, says C. K. Gunsalus, special counsel at the University of Illinois, Urbana-Champaign, a longtime follower of integrity in science: "We tell people with one side of the mouth to be pure as the driven snow and with the other side say, 'Take this money,'" says Gunsalus. Stanford's Schatzberg, for example, was following both commands when he came under fire for receiving compensation related to his NIH-funded research. But with the new reforms at least one thing will be clear: Right from the start, everyone will know about that private money.

—JOCELYN KAISER