The NIH "swivel chair"

The Health and Human Services agency's conflict-of-interest policies are under heavy scrutiny.

BY DAVID FILMORE

For NIH scientists, official government business involves performing intramural research, assessing grant applications, or participating in formal joint research programs with industry or academia; and then for some there are "outside activities." The latter category has attracted considerable criticism over the past eight months, most notably in the U.S. House of Representatives.

At a May 12 House Energy and Commerce Oversight and Investigations subcommittee hearing, Chairman James Greenwood (R-PA) referred to the arrangement as the "swivel chair," a step up in potential conflict of interest from the more common "revolving door" policy. Instead of needing to retire and then get an industry job, he said, NIH employees can work in both worlds at once by consulting for drug companies while on the government payroll. Speaking engagements and receiving certain awards are other activities that concern Greenwood and members of the subcommittee, which has held two public hearings on the matter and has an ongoing investigation.

NATIONAL INSTITUTES OF HEALTH

NIH head Zerhouni says it would be a mistake to ban all outside compensated activities.

"It is clear from the cases we have reviewed that some NIH scientists are either very close to the line or have crossed the line," Greenwood said at the May 12 inquiry. "NIH scientists should not even be close to the line."

The NIH leadership, despite a willingness to make changes, is holding firm about the importance of these arrangements. "It would be a mistake to ban all compensated activities with outside organizations," NIH Director Elias Zerhouni warned at the May 12 hearing. "Such an action would be bad for science, unfair to employees, and ultimately hinder our efforts to improve the nation's health."

Two sides of a coin

The issue goes back to the mid-1990s during the tenure of NIH Director Harold Varmus. Now the president and CEO of Memorial Sloan-Kettering Cancer Center, Varmus told the subcommittee at its second hearing on May 18 that when he came on board in 1993, the NIH's Intramural Research Program (IRP) was suffering from low morale and was held in "relatively low esteem."

U.S. HOUSE OF REPRESENTATIVES

Greenwood (R-PA) has led two recent hearings on NIH conflict-of-interest issues.

Varmus attributed this phenomenon, which he said led to problems with recruiting and retaining a high-quality staff, in part to heavy restrictions on interactions with industry and other activities such as receiving honoraria for speaking, editing, and writing. He also noted the government's less generous salaries.

In response, Varmus expanded the use of alternative pay scales, such as Title 42, a provision that allows for hiring specialists at a salary higher than the standard federal pay grade. And, on the advice of the Office of Government Ethics (OGE), he implemented a case-by-case ethics review and lifted the blanket limitations on compensation amounts, hours, and other issues related to outside activities.

"In my estimation—and, I believe, in the estimation of most of the scientific community—the IRP has largely regained its stature and productivity," Varmus testified to Congress. He presented anecdotal evidence that the new freedoms to pursue consulting and other practices played an important role in this transition.

On December 7, 2003, however, the *Los Angeles Times* presented a different view of the results of Varmus's changes. Reporter David Willman detailed multiple cases of top-level NIH scientists being paid hundreds of thousands to millions of dollars in consulting fees and stock options from drug and biotechnology companies that received NIH funding, collaborated with one of the NIH institutes, or presented some other conflict-of-interest potential.

Although it didn't bring up charges of illegal activity, the article related that "the NIH is one of the most secretive agencies in the federal government when it comes to financial disclosure," reporting that 94% of the agency's top-paid employees are allowed to keep their consulting information confidential.

The following day, Greenwood and then House Energy and Commerce Committee chairman W. J. (Billy) Tauzin (R-LA) opened an investigation. Zerhouni, for his part, began an internal review and formed a blue-ribbon panel, chaired by Lockheed Martin Chairman and CEO Norman Augustine and National Academy of Sciences President Bruce Alberts, to assess the NIH's conflict-of-interest and disclosure policies. The Department of Health and Human Services (HHS), the OGE, and the General Accounting Office each launched investigations as well.

Destructive partnerships?

The stated issue at hand in each of these investigations is preserving public trust and confidence in the NIH. As Rep. Henry Waxman (D-Los Angeles) put it during the May 18 hearing, "Americans need to know that when the NIH reaches a conclusion, that conclusion is based on hard evidence and the scientific method."

In addition to assuring patient trust in the NIH's performance, House members concentrated on the issue of companies' confidence in working with the NIH to accelerate commercialization of government-based scientific discoveries.

For instance, at the May 18 hearing, the case of Lance Liotta, the National Cancer Institute's chief of the Laboratory of Pathology, and Emanuel Petricoin, an FDA Center for Biologics Evaluation and Research microbiologist, was discussed.

The scientists were approved by their respective agencies to consult for the San Francisco-based company Biospect (now Predicant Biosciences), which is developing proteomic assays for cancer diagnostics. At the same time, the NCI and FDA had a cooperative research and development agreement (CRADA), in which Liotta and Petricoin were the lead investigators, with another company, Correlogic Systems, that is developing proteomic cancer diagnostic systems.

When Correlogic charged that the scientists' relationship with Biospect represented a conflict of interest, the NCI and FDA insisted there was no overlap. However, Liotta and Petricoin both severed their relationship with Biospect a week before the May 18 hearing on the basis of what they said was new information about Biospect's activities.

At the hearing, Greenwood posed this case as a real-world example of how current NIH ethics policy was compromising the agency's mission, in this instance, by being destructive to public–private partnerships. "What company will want to enter a CRADA with NIH if this is the way conflict-of-interest issues are managed?" he asked.

Following the hearing, Acting FDA Commissioner Lester Crawford announced a comprehensive review of his agency's outside activities that, he says, "did not identify any additional approved outside activities of concern."

No NIH (or FDA) scientists have been formally accused of breaking ethics rules, but the fact that many consulting situations were not disclosed to the public looks like "a dubious pattern of trying to cover up conflicts of interest rather than trying to avoid them," Waxman commented during the May 18 hearing.

Before May, only a select few highly paid senior employees, such as Senate-confirmed presidential appointees, had to complete public disclosure forms detailing external compensations. Most others were only obliged to fill out less in-depth, confidential paperwork. Notably, public financial disclosure is not required for employees hired under Title 42, which, according to House subcommittee findings, include NIH institute directors and other senior officials with annual salary rates approaching and above $200,000.

The need to put greater limits on the outside activities of NIH scientists is acknowledged by both sides.

The NIH blue-ribbon panel, which met several times in March and issued a draft report of its recommendations prior to the House hearings in May, attempted to find an easy fix for this issue to remove future suspicions.

"We discussed the possibility of requiring, as part of the permission process, the public posting of the nature of each paid outside activity, as well as the exact amount of the compensation received each year," Augustine and Alberts wrote in their prepared May 12 testimony. However, they said, legal staff advised that the Federal Privacy Act presented "a serious barrier to virtually any agency-mandated public disclosure of the sort we were considering."

But momentum created by media and congressional queries seemed to open windows. In February, with OGE authorization, Zerhouni compelled 93 additional NIH leaders to publicly disclose outside compensation. In early May, he requested permission to require 500 more high-level employees to do the same. By May 18, Congressman Waxman was "applauding" Zerhouni for his pledge to seek "new rules to require public disclosure of potential conflict of interest for all NIH employees."

Whether government ethics officials will sanction such rules remains to be seen.

Limiting activities

Even with comprehensive public disclosure rules, the need to put greater limits on the outside activities of NIH scientists is acknowledged by both sides. The blue-ribbon panel, which generally supported the idea that outside consulting and other activities were vital for recruitment and retention, recommended that NIH senior management and all staff involved with managing or reviewing grants and contracts should be barred from consulting.

Its report (*www.nih.gov/about/ethics_COI_panelreport.pdf*) also advised reinstituting specific restrictions on compensation received and hours spent in these activities, banning stock option compensation, and changing the process of applying for and keeping track of outside compensation.

Zerhouni indicated at the May 12 hearing that he would "move ahead as appropriate" with panel recommendations. However, many subcommittee members were not satisfied, and several recommended a complete ban on NIH employees receiving any industry compensation.

Peter Deutsch (D-FL) called the blue-ribbon panel report "an apology for the status quo." He advised Zerhouni "in the strongest possible terms to end the practice today of NIH researchers taking anything of value from a drug or biotech company."

Diana DeGette (D-CO) agrees that a blanket prohibition should be on the table. She cited the blue-ribbon panel's finding of a demoralizing effect from the confusion that NIH employees are experiencing with current ethics rules. "One thing that won't help the situation is if we keep layering onto the system and revamp it in a way that causes even more confusion, especially for the scientists," DeGette said.

"We need to challenge all of our assumptions," she added, "including the assumption that we simply cannot get good people [to work at the NIH] without these large amounts of outside compensation." ■