Panel Addresses NIH Policies on Income From Outside Consulting

Perhaps no other part of America’s federal government has enjoyed a better reputation for dedication to public service than the National Institutes of Health. That reputation was frayed when the Los Angeles Times reported at length in December that some of the agency’s leading scientists and research officials had been substantially supplementing their salaries by serving as paid consultants to drug and biomedical firms, raising questions of possible bias about how they had conducted their work at NIH.

These civil servants, the newspaper found, had nevertheless complied with government rules requiring them to get the agency’s approval for any paid outside employment. However, the world at large had known nothing of these particular financial arrangements because NIH had allowed the information to be filed on forms that were not publicly disclosed. The upshot was that more than 94% of NIH’s top earners—many of them with six-figure salaries—had been able to keep their consulting incomes to themselves.

The Times, besides, reported that it had “documented hundreds of consulting payments to ranking NIH officials,” some of whom had received a total of more than $2.5 million in fees, stocks, and stock options in the last 10 years as the result of their financial ties to industry. And many of these deals required that the consultants sign confidentiality agreements with their corporate employers, further shrouding such agreements from public view.

Blue Ribbon Panel

All of this has attracted Congressional attention and had repercussions at the NIH itself. As of February 6, for example, the agency’s 66 most senior staff must annually report any private consulting they do on forms that are subject to public disclosure. The change was ordered by the U.S. Government Office of Ethics at the request of Elias Zerhouni, M.D., the current NIH director, and may later also apply to additional agency personnel.

In addition, Zerhouni announced in January the creation of a “blue ribbon” panel that will “review how NIH addresses outside consulting activities, in order to identify systemic solutions for improvement.” Co-chaired by molecular biologist Bruce Alberts, Ph.D., president of the National Academy of Sciences, and Norman Augustine, a former Pentagon official who is now a Lockheed Martin executive, the 10-member group is to complete its report no later than early May.

Current Policies

The current policies on outside activities were put in place by Zerhouni’s immediate predecessor as NIH director, Harold Varmus, M.D., who has been president and chief executive officer of the Memorial Sloan-Kettering Cancer Center in New York since January 2000. Prior to Varmus’s arrival, the NIH had long tightly controlled the paid outside activities of its employees. At the panel’s first meeting on March 1, an NIH ethics officer gave the example of an intramural scientist who, decades ago, was writing a wine column for the Washington Post—and was forced to give it up. Although the situation had eased by 1993 when Varmus arrived, staffers could still earn no more than $25,000 a year from any one outside client and no more than $50,000 a year extra in the aggregate. Moreover, there could be no compensation with stocks or stock options, and senior NIH officials could not accept outside payments of any type.

In 1995, after learning that conflict of interest rules at some federal agencies were less stringent, Varmus lifted these restrictions entirely. He told the panel at its second meeting on March 12 that he did so to help the intramural program attract and retain the best scientific talent—a task he described as having been “particularly onerous” at the time.

Reversing Course?

His current advice, nonetheless, is to reverse course. “Institute directors should probably not be consulting for any companies” and “certainly not for companies that might be candidates for grants from the NIH,” he said at the meeting, where he also recommended that institute deputy directors, scientific directors, and clinical directors should toe these lines, too. Noting that he has taken a “vow of chastity” on consulting and so does not do it, he, besides, urged “full public disclosure by all who have major leadership positions” at NIH (the change that took effect there February 6).

Still, Varmus said he would cut those in lower positions some slack by having NIH set limits on how much they could earn from outside consulting and how much time they could spend doing it. And—because staff researchers may wish to take part in the industry’s development of their discoveries into products, and not just for monetary reasons—he would not set those limits in stone. His suggestion, instead, is that any outside consulting that could be expected
to exceed the limits should go to an NIH ethics committee for prior review.

Welcome as these ideas are to some in the scientific community, they could be controversial. Among the reasons is one that NIH’s deputy director, Raynard Kington, M.D., Ph.D., mentioned at the panel’s second meeting: Companies able to hire government scientific expertise could be perceived as getting an unfair competitive advantage. Another potential problem is that pharmaceutical industry mergers and acquisitions—of which there now are many—can create conflict of interest issues for consulting arrangements that initially were free of them.

**Role of Bayh–Dole**

Then, too, some see the NIH’s present policies that allow its scientists to be paid consultants to industry as not really surprising, given a law—the Bayh–Dole Act—that has permitted federally funded extramural scientists and institutions to patent the fruits of their taxpayer-supported labors and otherwise profit from them financially since the early 1980s.

Marcia Angell, M.D., a former editor of the *New England Journal of Medicine* and a critic of Bayh–Dole, is in that camp. Asked to comment on the revelations in the *Times* articles, she called them “a matter of grave concern” because “they show the extent to which the pharmaceutical industry has insinuated itself into government and academic institutions that are supposed to be impartial.”

Diana Zuckerman, Ph.D., spoke to the panel in a similar vein at its March 1 meeting. A former Congressional staffer who now heads the nonprofit National Center for Policy Research for Women and Families, Zuckerman warned that “conflicts of interests are undermining the integrity of medical research … as studies are (increasingly) being reported at professional meetings and in medical journals by individuals with a product or point of view to sell.”

The panel met a third time on April 5–6, and they are expected to issue a report in early May.

—Judith Randal