

# NIH Unveils Strong Ethics Policy for Employees

BY MARY ELLEN SCHNEIDER  
Senior Writer

Officials at the National Institutes of Health are tightening restrictions on outside consulting arrangements with industry after more than a year of investigations turned up potential conflicts of interest.

"Nothing is more important to me than preserving the trust of the public in NIH," Elias A. Zerhouni, M.D., NIH director, said in a statement announcing the new ethics rules. "It is unfortunate that the activities of a few employees have tainted the stellar reputation of the many thousands of NIH scientists who have never compromised their integrity and have selflessly served the nation with great distinction through their discoveries."

The new policy bars all NIH employees from engaging in compensated or uncompensated employment or consulting relationships with those organizations that are substantially affected by NIH decisions. Such organizations include pharmaceutical manufacturers, biotechnology companies, support research institutions, health care providers and insurers, and related trade and professional associations.

The policy also prohibits NIH employees from participating in compensated teaching, speaking, writing, or editing with these affected organizations.

Further, NIH employees are prohibited from self-employment activities that involve the sale or promotion of services or products from these organizations.

However, employees are allowed to teach courses that require multiple presentations and are part of an established curriculum at a university or college. They can also teach, speak, or write as part of a continuing education program. However, if the funding for the program comes from a substantially affected organization, like a drug company, it must be funded by an unrestricted grant.

NIH employees can also author articles, chapters, and textbooks that are subject to peer review provided that funding from affected organizations is in the form of unrestricted contributions.

Under the new policy, NIH employees are also allowed to continue clinical care to individual patients.

The new regulation also takes aim at stock ownership. NIH employees who are required to file financial disclosure statements are prohibited from acquiring or holding financial interests in affected organizations including biotechnology, pharmaceutical, and medical device companies. All other NIH employees are subject to a \$15,000 cap on such holdings.

"This new policy is an extension of a profession-wide examination of physicians' relationships to industry," said William E. Golden, M.D., professor of medicine and public health at the University of Arkansas in Little Rock.

Medical schools are likely to be the next major institutions to seek out greater transparency in the relationships between their faculty members and industry, Dr. Golden predicted.

The interim final regulation was devel-

oped by the Department of Health and Human Services with the Office of Government Ethics and went into effect immediately. Officials at HHS will continue to review the impact of the regulation and work on developing a comprehensive policy regarding outside consulting activities.

The new policy comes after about a year of internal NIH investigations as well as congressional inquiries into consulting arrangements between NIH employees and outside companies. NIH officials had

previously proposed a 1-year moratorium on all outside consulting arrangements.

"Though I believe that some outside activities are in the best interest of the public when designed to accelerate the development of new discoveries, we must first have better oversight systems to ensure transparency and sound ethical practices and procedures," Dr. Zerhouni said.

The new policy was praised by the Association of American Medical Colleges. "The rules are clear and unambiguous

and will enhance the public's confidence in the integrity and dedication of NIH employees and scientists," AAMC President Jordan J. Cohen, M.D., said in statement.

"We also firmly support NIH's plan to assess the impact of these new rules within 1 year. Given the sweeping changes being made and the possibility of unintended consequences, it is prudent for the agency to undertake a thorough review after full implementation so that appropriate modifications can be made, if necessary." ■

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