

NIH Eases Stock Restrictions on Employees

BY MARY ELLEN SCHNEIDER
Senior Writer

The Department of Health and Human Services has loosened restrictions on ownership of pharmaceutical and biotech company stocks by National Institutes of Health employees.

A final rule on conflict of interest, announced at a teleconference, continues to bar NIH employees from engaging in outside consulting relationships with industry.

NIH Director Elias A. Zerhouni, M.D., called the final regulation "stringent" despite the changes to stock ownership. "We have worked hard with the Department of Health and Human Services and the Office of Government Ethics to try to come up with rules that first and foremost protect the integrity of NIH science and are balanced in terms of our ability to continue to attract and retain the best scientists and staff," he said.

Under the final rule, which became ef-

fective in August, about 200 NIH employees with senior decision-making authority and their families must divest of all stock holdings in excess of \$15,000 per company for organizations substantially affected by NIH decisions. The deadline for divestiture is Jan. 30, 2006.

About 6,000 individuals will be required to disclose more details about their financial holdings. The other approximately 12,000 employees won't be asked to specifically disclose stock holdings, according to

Raynard S. Kington, M.D., NIH deputy director. Employees may be required to divest of stocks on a case by case basis if a potential conflict of interest is found.

This is a shift in the policy spelled out by NIH in February 2005 in the wake of a series of congressional hearings that exposed potential conflicts of interest among NIH scientists. Under the earlier plan, about 6,000 top NIH employees would have been required to sell off all stock holdings in companies affected by NIH decisions. The remainder of NIH employees would have faced the \$15,000 limit.

The changes aim to target the requirements at employees making decisions on grants and studies, Dr. Zerhouni said.

The final rule will give NIH employees more leeway to engage in outside activities with professional or scientific organiza-

A final rule on conflict of interest continues to bar NIH employees from engaging in outside consulting relationships with industry.

tions, serve on data and safety monitoring boards, give grand rounds lectures, and perform scientific grant reviews, subject to prior approval and review by ethics officials.

The regulation continues to allow NIH scientists with prior approval to participate in compensated academic work such as teaching, writing textbooks, performing journal reviews or editing, and giving general lectures as part of continuing education programs. NIH employees also can practice medicine with prior approval.

But NIH held firm on its prohibition on relationships with pharmaceutical, biotechnology, or medical device manufacturers, health care providers or insurers, and NIH grantee institutions. Keeping in place the ban on these activities is the best way to maintain the integrity of the agency at this point in time, Dr. Zerhouni said.

The changes were praised as being "right on target" by Mary Woolley, president of Research!America. The stronger interim guidelines released in February were useful as a "cooling off period" and served as an opportunity to gather more information, she said. The final regulation will serve as a benchmark for the rest of the research community, Ms. Woolley said.

But Sidney M. Wolfe, M.D., director of Public Citizen's Health Research Group said the changes weakened the agency's earlier attempts to address conflicts of interest. Allowing NIH employees to participate in paid outside academic work, which often includes money from industry, is riddled with loopholes, he said.

The final rule does not impose restrictions on extramural scientists, but Dr. Zerhouni advocated a broad dialogue about conflict of interest with the entire scientific community. "This is a debate that is way beyond that of NIH," he said. ■

For more information on NIH ethics rules visit www.nih.gov/about/ethics_COI.htm.

**WANTING TO HELP IS ONLY HUMAN
DOING SOMETHING ABOUT IT IS ONLY RIGHT**

We're Doctors of the World-USA: an American nonprofit, humanitarian organization dedicated to providing essential medical care to those most in need. No matter who they are, or where they live. Our volunteers are American healthcare professionals who believe that health is a human right for all people.

1.888.817.HELP
www.doctorsoftheworld.org

To make a donation or volunteer, call our toll-free number today.



MAKING HEALTH A HUMAN RIGHT

Doctors of the World • 375 West Broadway, 4th Floor • New York, NY 10012, USA • info@dowusa.org