

NIH Eases Stock Restrictions for Most Employees

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Officials at the Department of Health and Human Services have loosened restrictions on ownership of pharmaceutical and biotech company stocks for employees of the National Institutes of Health under a final rule on conflict of interest.

But the final regulation announced at a teleconference on NIH conflict of interest regulations 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," Dr. Zerhouni said.

Under the final rule, which became effective in August, about 200 NIH employees with senior decision-making authority and their families will be required to 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 a number of potential conflicts of interest by NIH scientists. Under the policy outlined earlier, about 6,000 top NIH employees would have been required to sell off all of their stock holdings in companies impacted by NIH decisions. And the remainder of NIH employees would have been subject to the \$15,000 limit.

The changes are designed to target the requirements at employees who are making decisions on grants and studies, Dr. Zerhouni said. The final regulation will also allow NIH employees more leeway to engage in outside activities with professional or scientific organizations, serve on data and safety monitoring boards, give grand rounds lectures, and perform scientific grant reviews. Under the earlier policy, these activities were prohibited, but they will now be allowed to go forward with prior approval and review by ethics officials.

The final rule 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 can also practice medicine with prior approval.

But NIH held firm on its prohibition on relationships with pharmaceutical, bio-

technology 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. While some outside consulting activities hold value for NIH and the public, he said the agency currently has no way to distinguish between those positive interactions and others such as product marketing.

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. But the changes reflect the correct balance.

But Sidney M. Wolfe, M.D., director of Public Citizen's Health Research Group said the changes weakened the agency's earlier attempts to get control of the problem of conflict 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 said it's important to have a broad dialogue about conflict of interest with the entire scientific community. ■

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

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