NIH Eases Stock Restrictions for Most Employees

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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 top ranking NIH official, 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 also consistent with the need to continue to attract and retain the best scientists and staff,” he said.

Under the final rule, which became effective on Jan. 30, 2006, about 12,000 employees won’t be asked to specifically disclose stock holdings, according to Raynard S. Kingdon, M.D., NIH deputy director. Employees may be required to disclose 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 those guidelines, about 6,000 top NIH employees would have been required to sell off all stock holdings in companies affected by NIH decisions. The deadline for divestiture is Jan. 30, 2006.

The changes aim to target the requirements for 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 pharmaceutical and or scientific organizations, serve on data safety monitoring boards, give grand rounds lectures, perform grant related peer 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.

Employees also can practice medicine with prior approval.

But NIH held firm on its prohibition on relationships with pharmaceutical, biotech, 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 used as a “cooling off period” and served as an opportunity to gather employee feedback, she said. The final regulation will serve as a benchmark for the rest of the research community, Ms. Woolley said.

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 certain types of outside activities such as giving lectures or grant reviews,” 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.