

PublisherInfo		
PublisherName	:	BioMed Central
PublisherLocation	:	London
PublisherImprintName	:	BioMed Central

NIH revises conflict rules

ArticleInfo		
ArticleID	:	4902
ArticleDOI	:	10.1186/gb-spotlight-20040113-01
ArticleCitationID	:	spotlight-20040113-01
ArticleSequenceNumber	:	254
ArticleCategory	:	Research news
ArticleFirstPage	:	1
ArticleLastPage	:	3
ArticleHistory	:	RegistrationDate : 2004-1-13 OnlineDate : 2004-1-13
ArticleCopyright	:	BioMed Central Ltd2004
ArticleGrants	:	
ArticleContext	:	130594411

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The National Institutes of Health (NIH) last week (January 5) finalized changes to financial conflict of interest regulations for outside experts participating in peer review of research grants and research and development contracts. The revisions raise the financial threshold for such conflicts from \$5000 to \$10,000 per year and attempt to clarify distinctions between 'real' and 'apparent' conflicts.

House and Senate subcommittees, meanwhile, are planning hearings to review allegations, first [reported in the Los Angeles Times](#) on December 7, 2003, that senior NIH officials secretly received millions of dollars in consulting contracts from pharmaceutical and biomedical companies that had dealings with the agency.

Zerhouni has been generally contrite in discussing allegations that a handful of senior NIH officials secretly pocketed lucrative consulting fees and stock options from drug manufacturers over the past decade. On December 10, Zerhouni [announced the creation of a 'blue ribbon panel'](#) to review how NIH addresses outside consulting activity "in order to identify systemic solutions for improvement."

"I believe that the public's interest is best served by complete transparency, full disclosure, independent review, and proactive management and monitoring of all outside relationships," Zerhouni wrote in a December 23 letter to Tauzin.

But in a 'Town Hall' meeting with NIH staff a week earlier, Zerhouni ardently defended the agency. "I do believe that many of the reports have been exaggerated, and that NIH has been harmed by innuendo and the juxtaposition of facts," Zerhouni said, according to an [official version of the speech](#). "Don't believe everything you read in the newspapers is all I can say, but there is always room for improvement, and we'll carefully look into that and implement any necessary change as soon as possible."

The new conflict of interest [rules published in the Federal Register](#) on January 5, 2004, apply to outside experts participating in scientific review groups, a generic term that includes regular study sections and special emphasis panels. The revisions were needed because nongovernment peer reviewers are not normally considered federal employees and not subject to federal conflict of interest rules. The final regulations, more than 3 years in the making, are not related to the NIH consulting controversy. They go into effect on February 4, 2004.

The new regulations set the financial threshold for conflicts at \$10,000 during a 12-month period, the same level as in other federal regulations. The term 'finances' includes all sources of income, including fees, honoraria, and stock holdings. "These provisions are intended to allow for routine sharing and exchange of scientific information as a result of invitations to speak at seminars, scientific consultations, and similar events that would not automatically be considered a conflict of interest for the reviewer," according to the Federal Register.

The new rules state that a 'real' conflict exists when the financial threshold is met, when the reviewer acknowledges the presence of an interest that would likely bias his or her review, or when the official managing the review determines the reviewer has such an interest. An 'apparent' conflict occurs when the financial threshold for a 'real' conflict has not been met but other personal interests exist that would

"cause a reasonable person to question the reviewer's impartiality." Under certain conditions, the NIH director can make a determination allowing a 'real' or 'apparently' conflicted peer reviewer to participate.

Following publication of the Los Angeles Times article in December, Rep. Billy Tauzin (R-La.), chairman of the House Energy and Commerce Committee, and Rep. James Greenwood (R-Pa.), chairman of the Subcommittee on Oversight and Investigations, asked Zerhouni to produce all documents relating to the payments by January 8. NIH spokesman Don Ralbovsky last week told us that the agency is "continuing to cooperate with the committee and we are providing material as it is gathered."

Both Tauzin's committee and the Senate Appropriations Subcommittee on Labor, Health and Human Services, Education and Related Agencies plan to hold hearings on NIH's consulting practices. Hearings could begin as early as January 22, Ralbovsky said.

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