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NIH to launch ethics review

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The National Institutes of Health (NIH), stung by recent allegations of financial wrongdoing on the part of some present and former senior officials, plans to announce a major review of how the agency handles conflict-of-interest matters when top agency employees receive lucrative consulting contracts from private companies.

NIH Director Elias A. Zerhouni will announce the creation of a 'blue ribbon panel' of advisory committee members and outside experts "to review how NIH addresses outside consulting activity in order to identify systemic solutions for improvement," NIH spokesman John Burklow told us.

Zerhouni will also order an "immediate review" of every outside consulting relationship that NIH employees have established during the past 5 years "to confirm that all rules and regulations are being followed and that the activities are in the best interest of the public," Burklow said.

"It is clear that we will need to consider changes after a thoughtful analysis of the issues," Burklow said. "We are vigorously investigating the allegations because openness and review are our best allies."

The *Los Angeles Times* on Sunday (December 7) [reported](#) that several high-level NIH scientists and officials had received more than \$2.5 million in fees and stock options from drug companies for consulting outside of their government work over the past 10 years.

Stephen I. Katz, director of the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS), collected between \$476,369 and \$616,365 during the past decade in fees from drugmaker Schering AG and six other companies, the Times reported. During this time, NIAMS conducted clinical trials involving one of the company's drugs and pledged \$1.7 million in small business research grants to another. Five other present and former senior NIH officials reportedly received up to \$2.2 million in company fees and stock options during the time period.

Janet Austin, Katz's spokeswoman, did not respond to a request for comment yesterday. But Katz and other officials told the *Los Angeles Times* that NIH officials had approved their consulting agreements in advance and that they had recused themselves from any decision making involving the companies.

Arthur L. Caplan, director of the University of Pennsylvania's Center for Bioethics, said he was surprised that this type of outside consulting was even permitted by the federal government. "It's a big problem. If you work for the federal or a state government and are making decisions about funding for key government expenditures, you don't want to be seen as being beholden to or being able to be influenced by outside funding arrangements," he told us.

"If you are going to distribute money from grants and if you are going to be turned to for independent evidence about different drugs or research ideas, which is what NIH's role is, then they've got to be a lot more careful about generating conflicts of interest," he said.

On Monday (December 8), 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 supply by January 8, 2004, all documents relating to the payments reported by the *Times*.

"The receipt of outside payments, even though approved, raises concerns about whether the integrity of NIH clinical research has been affected and whether the honor system used by NIH to enforce recusals signed by NIH scientists and other conflict of interest rules has been violated," the congressmen wrote.

The House investigation is part of an ongoing ethics probe begun earlier this year. In June, the committee [announced](#) it was investigating Richard D. Klausner, former director of the National Cancer Institute (NCI), and other current and former senior NIH officials for accepting 'lecture awards' and other cash gifts from universities and research institutions that receive NCI and NIH research grants. Klausner and other officials have denied any wrongdoing.

In November, the committee [announced](#) it was seeking to determine whether Klausner steered a \$40 million contract to Harvard University during the time he was a candidate to become the school's president. Klausner, who is currently director of the Global Health Program at the Bill and Melinda Gates Foundation in Seattle, told us at the time that the committee's allegations were "bizarre" and "baseless."

Burklow yesterday said it is important that NIH scientists "stay involved in the science and help communities beyond NIH to share their information broadly. At the same time, we recognize that there must be stringent standards and transparent policies for managing potential conflicts of interest," he said.

"In addition, we must do everything possible to avoid even the perception of a conflict because the appearance can be as important as the legal technicalities," Burklow added.

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