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Varmus wants tighter NIH rules

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BETHESDA, MD - In the wake of heightened concern over possible conflicts of interest at the National Institutes of Health (NIH), former NIH Director Harold E. Varmus now believes that institute and center directors should be prohibited from consulting for companies that might be candidates for research grants. Other NIH officials responsible for major programs should also be barred from participating in certain kinds of financial activities with outside companies, he said.

Varmus urged NIH's 'blue ribbon' panel on conflict of interest policies to recommend limits on the amount of money that NIH employees could receive from outside companies as well as the amount of time they could devote to such activities before triggering an internal ethics review. "These should not be rules or regulations, but guidance so that when such limits are proposed to be exceeded, those cases are referred to a conflict of interest committee to review them," Varmus told the panel.

Speaking with reporters following his hour-long presentation, Varmus said he believed "institute directors should not be consulting for companies - possibly any companies - but certainly companies that might be candidates for grants from the NIH." There are other NIH officials "in charge of major program development and developing grant programs who should be, in my view, prevented from certain kinds of activities," he added, declining to elaborate.

Varmus told the panel he supported "full public disclosure by all who have major leadership positions" at NIH, a policy that went into effect February 6. That change, which was requested by NIH Director Elias A. Zerhouniin January, affects 66 senior officials including all NIH directors, deputy directors, scientific directors, and clinical directors. These officials now are required to file public disclosure forms, known as SF 278s, rather than the confidential OGE 450s.

Varmus' views stand in contrast to positions he advocated while NIH director from 1993 to 1999. During that time, Varmus spearheaded efforts to ease restrictions on staff scientists and directors, allowing them greater freedom to interact with pharmaceutical companies and to engage in outside consulting activities. Those actions were needed, he said Friday, to attract and retain qualified scientists to NIH's intramural research program.

"The perception was that the [intramural] program was not doing very well. The external world didn't want to come here," Varmus said. "Particularly onerous" to the intramural program were the low pay scales combined with prohibitions on a wide range of outside activities, including many that had little to do with conflicts of interest, he said. "There's no point in having an intramural program if it's not excellent, and it won't be excellent if you can't attract the personnel."

Prior to 1995, NIH scientists could earn no more than $25,000 annually from any single outside source and not more than $50,000 per year in total. Stock or stock option payments were prohibited and senior NIH officials could not accept any payments from outside sources. That changed in 1995 after an audit by the federal Office of Government Ethics (OGE) determined that NIH's rules were more stringent than those of other federal agencies. The change, Varmus said Friday, had a "very salubrious effect on the retention of our scientists in this program."

The Los Angeles Times reported in December 2003 that several high-level NIH scientists and officials have received a total of more than $2.5 million in consulting fees and stock options from drug companies over the past 10 years. Zerhouni has since suspended approval of all new consulting arrangements, restructured the agency's system for implementing ethics regulations, and appointed a task force to examine these consulting deals, which have also become the topic of a Senate hearing. The blue ribbon panel is to report its recommendations by early May.

Varmus, a co-recipient of a Nobel Prize for studies of the genetic basis of cancer, has been president and chief executive of the Memorial Sloan-Kettering Cancer Center in New York City since January 2000. He urged the panel Friday to "be wary of overreaction to single events or single reports of events." Rather than establishing strict rules and regulations for outside consulting, he suggested the panel instead come up with guidelines under which individual cases could be brought to a trans-NIH ethics committee for review.

Noting that he personally has "taken a vow of chastity" at Sloan-Kettering to not engage in outside consulting, Varmus said many Sloan-Kettering scientists do spend a few days a year in scientific advisory board meetings for outside companies. "We have a 'sniff test,'" Varmus said of the outside work."If it seems high, we say, 'Let's take a look at it.'"

In addition to conflicts of interest, Varmus said, problems might arise involving conflicts of commitment on the part of the scientists. "What does someone think about when they're taking a shower?" he asked the panel. The employer, be it NIH or Sloan-Kettering, should be their primary focus, he said, not the outside company.

But Varmus noted that scientists want to interact with industry not just for the money but also to be part of translating discoveries into therapies. Investigators "want to feel they are part of the real world of medical research that is providing benefits, applying knowledge to practical applications," he said. "The flavor of the intramural research experience is changed by having a greater interaction with industry."

When asked by us if he felt unfairly scrutinized because of the changes he made to conflict of interest rules, Varmus replied: "I was director of NIH and I take responsibility for what happened when I was here."

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