

## Biotech consulting, investing by NIH scientists curbed

National Institutes of Health (NIH) director Elias Zerhouni announced sweeping reforms early in February that will halt consulting arrangements by NIH scientists and severely restrict investments by them in biotechnology and other companies developing and making therapeutic and diagnostic products. The impact of these changes on the biotechnology industry is difficult to gauge, with some observers saying the new policy will constrict the flow of valuable know-how from NIH to the private sector. Others suggest that the biotech sector may soon welcome entrepreneurial-spirited NIH scientists, now more inclined than before to leave and start companies.

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The new measures will prohibit NIH employees from “outside employment” with “substantially affected” organizations such as pharmaceutical and biotech companies, research institutions—particularly those that receive NIH grant support—healthcare providers and insurers, and also “trade, professional, or similar associations.” Senior NIH employees also may no longer hold investments in biotech and pharmaceutical companies, whereas other NIH employees will

be restricted to holdings of \$15,000 in any particular company.

Zerhouni’s announcement of these new measures is provoking what he describes as a “mixed response” from NIH scientists—a euphemistic description of the criticism received. One observer points out that the uproar over conflicts of interest at NIH focused mainly on cases where high-level scientists had not disclosed their consulting arrangements, even though they were supposed to do so (**Box 1**). “How will banning consulting solve that problem? And what will the penalties be for continuing to do it secretly?” this observer asks.

Consultant Nina Siegler of Columbia, Maryland, who has worked on technology transfer issues at NIH and Johns Hopkins University in nearby Baltimore, calls the new policy “horrible.” The now-forbidden consulting by NIH scientists was “providing valuable perspective and opportunities for them to understand the needs of the biotech industry and the problems the companies are facing,” she says. Although the policy does not stop NIH scientists from patenting and NIH from establishing cooperative research and development agreements (CRADAs) with companies, those “CRADAs don’t exist in a vacuum,” she adds. They tend to work better when inventors can collaborate with company scientists because “biotechnology is a relationship-driven business.”

Zerhouni recognizes that such rules may not be entirely fair to all: “It is unfortunate that the activities of a few employees have tainted the stellar reputation of the many thousands of NIH scientists who have never compromised their integrity and have selflessly served the nation with great distinc-



NIH director Elias Zerhouni announced measures prohibiting NIH scientists from outside employment with private sector companies to prevent conflicts of interest.

tion through their discoveries.” In any case, an industry observer says, “it’s better for NIH to have technology transfers go out the front door.”

However, other observers are not so worried about the forthcoming consequences for the biotech industry. “In some ways I’m agnostic on the NIH policy,” says Phillip Singerman, executive director of the state development agency Maryland Technology Development in Columbia. “Many of the entrepreneurs that we fund to start up companies are motivated by their passion to see some new medical treatment made available, and believe the quickest way to do this is through forming a new company.” He adds: “That’s why they leave NIH or a university, so it’s not clear that this new NIH policy ... will affect [new company spin-offs] all that much.” In other words, “I don’t think that if you can’t consult, you’ll start a company instead.”

Jeffrey L. Fox, Washington

### Box 1 What triggered the new NIH rules?

The NIH reforms, which go well beyond a moratorium on consulting imposed last September, are in part a response to congressional hearings last year (*Nat. Biotechnol.* **22**, 796, 2004). Those hearings helped to expose previously undisclosed practices by several dozen senior NIH scientists and administrators, which caught Zerhouni off guard. In addition, “these new regulations are more severe than those that were in place before 1995,” Zerhouni says. He adds, “nothing is more important to me than preserving the trust of the public in NIH,” he adds. News of the reforms led Representative Joe Barton of Texas, a vocal critic of NIH during those hearings, to commend Zerhouni for “taking a step that is both difficult and necessary.” NIH, Barton says, “must be a place where the trust of the public is earned and warranted.” JLF

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