

Biotech quandary

by **Jeremy Bond**

Staff Writer

Feb. 25, 2005

NIH entrepreneurs recall move to private sector as new rules come under increased scrutiny

After 26 years at the National Institutes of Health in Bethesda, Bruce D. Weintraub realized it was time to go.

He first moved to the University of Maryland at Baltimore for a few more years and then in 2001 he and a partner launched a biotechnology firm in Rockville, Trophogen, to do drug development full time.

For Frank Robey the urge came more quickly. After 13 years he left NIH in 2002 to found Ariavax, a vaccine development company in Gaithersburg.

These two men -- and the many, many others before and after them -- form the building blocks of the world-famous I-270 biotech corridor.

These NIH alumni are a large part of the reason for the prosperity of the national capital region. And the continuing ability of the federal research lab to attract brilliant scientists and launch them into private industry is vital for the future economic vitality of the region.

The current controversy over new rules strictly limiting outside employment or financial interests for NIH scientists raises a troubling question. Will the new rules dissuade science entrepreneurs of the future from coming to NIH in the first place?

"Anything that reduces the luster of NIH directly or indirectly affects the Maryland biotech sector," Weintraub said.

The rules would probably keep only the most entrepreneurial scientists away from NIH, he said. But this could potentially deprive Maryland of additional new companies down the road.

"You don't want [scientists] to leave NIH because it's not a good place," he said.

But Weintraub is so convinced the rules will change to a more balanced approach that he does not foresee a major impact.



Dan Gross/The Gazette

Frank Robey, founder of Ariavax, left the National Institutes of Health for the private sector after 13 years. Many former NIH employees work within the Interstate 270 biotech corridor.

Indeed, NIH Director Elias A. Zerhouni met Thursday with a steering committee of NIH scientists that is proposing changes to the ethics rules. Zerhouni requested the meeting with the Assembly of Scientists.

"NIH will always have a great allure for great scientists," Weintraub said.

Most scientists are not attracted to NIH because they want to start a business down the road, but because of the chance to do world-class research, said Phillip A. Singerman, executive director of the Maryland Technology Development Corp. They are unlikely to base their decision to come to NIH on rules surrounding consulting and stock options.

"Coming in and leaving are two events separated by a long period of time," Singerman said. "We're collapsing in our minds two very distinct actions that are separated by years if not decades."

However, Linda Powers of Toucan Capital Corp., who has backed several NIH alumni in their private businesses including Weintraub, cautioned that the long-term effect of the new rules could be subtle. Some NIH scientist candidates would look for the potential to collaborate with the private sector since it is a fundamental component of research, she said.

"They can do more effective work as researchers if they have at least some contact with industries," she said. "It gives a context to what the researchers are doing."

The scientists who leave NIH often say they felt constricted by NIH, and that joining the private sector had become a natural progression for them, with or without the limits on outside consulting. They recall an environment at NIH that was stifling to the business-minded.

A study conducted in 2002 by the Johns Hopkins Institute for Policy Studies, the most recent to look at all Maryland biotechnology companies, counted 41 biotechs founded by former NIH employees.

Some NIH alums are known internationally, such as J. Craig Venter and Robert C. Gallo. Others are running small shops with big dreams.

Most of the entrepreneurs who leave NIH are motivated not by financial gain but by bringing medical technology to the benefit of people, Singerman said. Starting a company is a very high-risk choice, with no guarantee of making a lot of money, he said.

Singerman said the new rules place a greater premium on the types of collaborative work that companies regularly and appropriately do with NIH. The legitimate partnerships, under cooperative research and development agreements, or CRADAs, will likely be emphasized more, he said. CRADAs allow NIH scientists to receive a fraction of royalties from inventions commercialized by outside companies.

Inspired to leave

Weintraub's inspiration to go out on his own came in part from his work through a CRADA.

At NIH, Weintraub worked with Genzyme Corp. of Cambridge, Mass., to help develop a drug to diagnose thyroid cancer. This led to Thyrogen, a drug that would "revolutionize" diagnosis, Weintraub said.

Weintraub and Mariusz W. Szkudlinski launched Trophogen in 2001 with funding from Toucan Capital. The company, which currently has 10 people, seeks to develop superactive hormones and growth factors that could treat everything from infertility to cancer.

"The private sector is to me a refreshing change," Weintraub said.

"I still love the rewards of seeing disease conquered and patients' lives helped, but actually the creation of jobs and the creation of value and the creation of economic opportunities I found equally rewarding," he said. "And you can do both in the private sector."

The business world also affords the opportunity to actually see a drug being developed and used, while at NIH it is not clear when that will ever happen, Weintraub said. So the private sector has the added emphasis on meeting certain goals.

"I have found actually that it's a good thing," he said. "I like the pressure of achieving milestones and showing my investors how we're doing."

But the transition into the private sector is not always smooth.

"There is nothing in the government that really prepares you for private life, professionally speaking," said Robey, the founder of Ariavax.

"I've never written a grant before. I've never really had a boss tell me what to do."

Tedco provided him with \$50,000 and training on starting and running a business, Robey said. Like other companies launched by NIH veterans, he received a grant from NIH, for \$170,000.

Toucan Capital provided Weintraub with \$6 million. Initially he made business decisions only after close consultations with Linda Powers and her staff, Weintraub said.

"I was carefully groomed," he said. Even without ever going to business school, "you can acquire a lot of business knowledge."

Weintraub benefited also from having overseen a large budget at the endocrinology lab, providing experience similar to the budgetary responsibilities he has with his company, he said.

An imperfect fit

Frank Robey's wife, Pamela Robey, still heads the craniofacial skeletal diseases branch at NIH's National Institute of Dental and Craniofacial Research. But Frank Robey and NIH were never a perfect fit.

Robey began his career with the Food and Drug Administration at an office on the NIH campus. By its nature, FDA was more closely connected to companies seeking to get a product to market.

"You came in and worked with the company to make a safe and effective product," Robey said. "It was fun. And it was legal."

After eight years, Robey crossed over to NIH and joined the dental institute.

"I was a little bit naïve, that's for sure," Robey said. "I didn't know their emphasis is just based on basic research."

When Robey was at NIH, scientists were warned that they had to give 12 weeks advanced notice before being allowed to consult. That had its limits, since many companies needed someone the next day, Robey said.

"I thought to myself, if you follow the rules, there can't be many people at NIH in my position [who can] help a drug company," he said.

With experience writing FDA guidelines, Robey was able to consult on the side for companies seeking FDA approval. This was allowed because it was unrelated to his NIH job, but he had to take annual leave to do it. Robey recalled consulting for Genentech, the biotech giant in South San Francisco, Calif., traveling back home on Tuesday and returning to NIH on Wednesday, already exhausted.

Robey acknowledged that it probably made him less effective at his day job.

"A real scientist wakes up in the morning excited about the day, and can't wait to get to the lab, and is there 12 to 14 hours a day," Robey said. "You just can't do that effectively if you're consulting."

Robey began research at NIH on developing a technology that could be applied to vaccines, but he couldn't go far in this area as long as he was at the dental institute. Under Harold E. Varmus, the NIH director at the time, it was hard to transfer from one institute to another, Robey said. So he left.

"I wasn't getting the kind of support that I needed staying at NIH," he said.

'Golden handcuffs'

Collins Jones, biotechnology coordinator at Montgomery College, recalls that his NIH tenure of nearly 10 years began with more freedom for scientists to take longer on research. But then the institutes began requiring scientists to get their research published three to five times a year.

"That gets stressful after a while," he said.

The pressure came in part from the typical scrutiny afforded a government agency funded by taxpayers. But the trouble with the "publish, publish, publish" mentality was the temptation to conduct science that was certain to work, Jones said. Sometimes scientists would avoid taking risks that could potentially lead to new discoveries.

When Jones was at NIH, the agency actually encouraged scientists to leave after seven years to bring in new blood, Jones said. Some became staff scientists at NIH to guarantee tenure, but others considered tenure a mixed blessing.

"We used to jokingly refer to it as 'golden handcuffs,'" Robey said. "It was really hard to get, but once you get [it] you're stuck."