Conflict-of-Interest Rules Worry Some Scientists

By Renee Twombly

Results from a survey designed to clarify whether the strict new conflict-of-interest rules at the National Institutes of Health have affected the agency—perhaps by sending campus scientists packing and keeping others from joining—may have actually muddied the picture.

The survey of 8,000 employees at 10 institutes paints a portrait of a place where most say they are satisfied with their jobs, despite 2005 rules that ban all consulting within the health care industry, and plan to be at NIH in the next year. Yet most believe that the agency won’t be able to hold on to its staff because the new ethics rules prohibit the kind of collaborative interactions that are now common in the academic world.

The response was even more contradictory when you look only at scientists: 88% intend to be working at NIH in the coming year, but 72% think the new rules will affect NIH’s ability to retain existing staff. The view that the NIH workforce will suffer was even greater among tenured and tenure-track scientists, 88% of whom said the new rules—believed to be among the toughest in the federal government—will hurt staff retention, whereas a whopping 91% thought that NIH will not be able to recruit the scientists it needs.

These results don’t provide enough clear support for relaxing the conflict-of-interest rules, put in place after several years of negative national press and humiliating congressional hearings, said NIH Deputy Director Raynard Kington, M.D., Ph.D.

“The reason why we did the survey, why we stated publicly that we were going to follow this issue, is we were concerned that the restriction might affect our ability to recruit and retain the brightest,” he said. “If we felt there was a compelling case, we would approach the Department of Health and Human Services and the Office of Government Ethics and ask them to consider changing the rules.”

Kington, who was assigned by NIH Director Elias Zerhouni to oversee the new ethics rules, said the survey results don’t point in one direction. “We don’t believe it would be received as compelling evidence” to push for modifications.

So far, recruitment has not been a problem despite what respondents to the survey think, Kington said. Although it is true that some senior positions have not been filled in the past few years—especially at the National Cancer Institute, which has been unable to fill several positions, including the radiation oncology branch chief—“it’s always been difficult recruiting,” he said. To suggest that the new rules are responsible for the inability to fill these positions “is preposterous,” Kington said. “We have recruited some...
very senior, extraordinary scientists since these rules came in.”

Relaxing the Rules
The perceived problems at NIH come from a 1995 change in the rules governing the outside activities of intramural scientists. Those changes, which came in the wake of technology transfer agreements put in motion by the Bayh–Dole Act of 1980 and other similar laws, encouraged universities to commercialize publicly funded research. Doing so allowed them to patent discoveries and share in licensing fees, according to an analysis of NIH’s conflict-of-interest policy, published in 2004 in the New England Journal of Medicine.

Around the same time, then-director Harold Varmus sought to improve NIH’s internal research program by recruiting top scientists. To make NIH attractive to them, he worked to change NIH policies to less restrictive executive branch standards. This change removed limits on types or amounts of compensation or hours spent on outside work, as long as these outside activities were disclosed and approved. It also allowed NIH employees to consult with outside organizations that had business with their laboratories, accept stock or stock options as payment for outside activities, and earn more than $50,000 a year from outside sources.

In the agency newsletter NIH Record, Zerhouni noted that the 1995 ethics policy was “very simple—you do pretty much whatever you want to. I think 99.5% of all requests were approved.”

Then in December 2003, the Los Angeles Times reported that some agency employees, including several institute directors making more than $200,000 annually, had earned up to $300,000 in extra income or stock options from consulting, some of it with drug companies who stood to benefit. Most of these arrangements were not publicly disclosed, although they had been approved by NIH, the Times reported. In fact, according to reporter David Willman, only 6% (127) of 2,259 NIH employees making more than $102,168 a year filed disclosure forms that were available to the public. This veil of secrecy contributed to the perception that senior researchers could easily hide extra income. (Kington pointed out that less than 10% of the intramural and tenure-track scientists were engaged in outside consulting with pharmaceutical and drug companies.)

The Times report led to a showdown a month later between Zerhouni and the Senate Appropriations Subcommittee on Labor, Health, and Human Services. Sen. Arlen Specter, R-Pa., said that the consulting deals and the appearance of conflicts of interest were a “major problem” that the agency had to take steps to eliminate. According to the New York Times, Specter warned Zerhouni that “this subcommittee is prepared to do it if you don’t.” At the hearing, Zerhouni said he would create an independent panel of outside experts to examine consulting agreements.

The ethical problems and congressional pressure have continued since. In September 2006, Kington told a House panel that the agency had disciplined 34 NIH scientists who had violated conflict-of-interest rules. Most received admonishments, but six scientists were suspended or placed on probation, he said, and the cases of two of the scientists, Trey Sunderland III, M.D., and Thomas Walsh, M.D., are pending with the U.S. Public Health Service Commissioned Corps, which can fire the researchers. Sunderland, of the National Institute of Mental Health, allegedly didn’t report more than $700,000 in consulting fees and has been accused of sharing tissue samples with industry.

Sunderland has pled guilty to violating the NIH’s conflict of interest rules, and he will serve two years probation, do 400 hours community service, forfeit the $300,000, and pay a fine up to $100,000. Walsh, of the National Cancer Institute, received more than $100,000 in consulting fees for which he apparently did not receive prior permission.

New ethics rules were announced in February 2005, and they upset many in the agency. All consulting was banned, all 6,000 scientists were asked to sell all shares in biotech and pharmaceutical companies, and all 18,000 employees had to limit shares in any one company to $15,000. Outside activity of any kind that earned money would have to be approved, even if it was baking cakes for profit. The rules did not apply to scientists outside NIH who received extramural grants.

The rules were prompted by “identified problems with our system of ethics oversight,” as well as congressional and media pressure, Kington said. “We work for the American people. The one thing we could not and would not allow to happen was for our integrity to be questioned as an agency.”

But the rules did not sit well with some of the agency’s employees. “It was Draconian, indefensible,” said Ezekiel Emanuel, chair of the department of clinical bioethics at the NIH’s clinical center. “How can you tell secretaries that don’t do any research that they can’t hold stock?” Emanuel belongs to the leadership council of the NIH’s Assembly of Scientists, a group of intramural scientists who hired a law firm to fight the new rules. That lawsuit was eventually dropped because the group was given assurances that the blanket rule on stock holdings would be relaxed.

Based on public and employee feedback and program reviews, final NIH ethics rules were issued in August 2005 that relaxed the stock holdings rule for all but
the most senior NIH employees but retained the ban on consulting (see sidebar).

At the time, Zerhouni and Kington said a three-part assessment plan would determine how the new rules affected the agency. The recent survey was the first part. The two other assessments—a survey of employees who recently left NIH and a survey of potential employees—originally were to be completed by this fall, but the work has not begun, Kington said. NIH is waiting for the Office of Management and Budget to approve funding for these surveys because they involve questioning people outside government, he said.

**Not Business as Usual**
The Assembly of Scientists, which pushed the agency to do the survey, is still pressing for relaxed conflict-of-interest rules, especially regarding outside consulting.

Emanuel said the survey demonstrates that tenured and tenure-track scientists feel that they are “hermetically sealed” inside the NIH campus. The conflict-of-interest rules have not only inhibited NIH’s participation with industry but have also “cast a pall, an uncertainty, so that even when it is perfectly legitimate, industry doesn’t call to collaborate,” he said. “They view it as a hassle, paperwork, and they wonder if it will land them in front of a congressional committee.

“Why go the route to total prohibition? The [executive branch] doesn’t understand the institution and that science is about discovery and interactions,” Emanuel said.

While recruitment and retention of basic researchers and young investigators does not seem to be affected by the new conflict-of-interest rules, that is not the case for positions that require clinical responsibility, said Alan Schechter, M.D., chief of the molecular biology and genetics section of the National Institute of Diabetes and Digestive and Kidney Diseases. “We perceive it is getting very much harder to recruit good people, especially clinically related people, and a very significant number of people who have clinical responsibility have been, and are, leaving.”

Physicians who do clinical studies “have become used to being active consultants for pharmaceutical and biotechnology companies, both for the opportunity to work with industry and for the extra income, and this is happening all over the country,” said Schechter, who is also a member of the assembly’s leadership. “They are very reluctant to consider NIH jobs if such involvements are not practical under any circumstances.

“There is a tendency for these rules to wind up putting the NIH staff on ice and leaving [extramural scientists] to do business as usual,” he said.

Schechter said that the rules at the NIH did need to be tightened somewhat, but so do the rules applying to university researchers. “What occurred here was just a mirror of what happens universally in this country’s academic medicine,” he said. “I think one needs strict rules, enforcement and disclosure, but ... interactions with industry are too important, especially for clinical studies, to not allow them.”

Former NIH researcher Curt Furberg, M.D., Ph.D., agrees. “There are violators in several places, and, more than we think, people are in the pocket of industry. When I came to the NIH we couldn’t even get drugs from the drug companies free of charge,” said Furberg, who headed clinical research at the National Heart, Lung, and Blood Institute before leaving in 1985 for Wake Forest University. But the change in policy and lack of transparency led to the kind of selective abuse that is much more prevalent outside NIH and forced a public crackdown, says Furberg, a professor of public health sciences. But they may have gone too far. “I find it very unfortunate, because the NIH is a wonderful place, a beacon of science, and 98% of the people there are honest,” he said.

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**Survey Shows Some Fear Rules Will Hurt Research**

A new Web survey of 8,000 National Institutes of Health employees conducted during the summer of 2006 showed contradictory findings. The survey was designed to assess the impact of the new NIH ethics rules on recruitment and retention. Although it showed high job satisfaction overall, most scientists say the rules are too restrictive and will hurt NIH’s mission.

Other findings among scientists:

- 59% said the old ethics rules could have been enforced better (72% among tenured/tenure-track scientists).
- 22% said the old rules should have been strengthened (tenured/tenure track, 16%).
- 33% said the new rules would affect NIH’s ability to complete its mission (tenured/tenure track, 12%).
- 75% think that the new rules will have a negative impact on NIH’s ability to recruit the best scientists (tenured/tenure track, 91%).
- 72% say the new rules will have a negative impact on NIH’s ability to retain existing staff (tenured/tenure track, 88%).
- 61% of tenured/tenure-track faculty said they were not looking for, or considering looking for, a job outside NIH as a consequence of the new rules.
His advice is that both NIH and academic scientists should be allowed a maximum annual income of $10,000 from such benign activities as delivering scientific presentations. He wants NIH to be more flexible and academia to tighten up its conflict-of-interest rules and enforce them. Consulting should be narrowly defined, Furberg said. “When researchers give expertise to a specific drug company, then I think they have crossed the line because they are serving the company’s interest and not the public good, directly.”

The degree of discomfort with the new conflict-of-interest rules depends on how much clinically based research is conducted within an institute and whether researchers think that they want to leave the security of an NIH position, said James Battey Jr., M.D., Ph.D., director of the National Institute on Deafness and Other Communication Disorders. In newspaper stories published after the first set of rules were announced, Battey said he would resign because the family trust he helped to administer would be affected. But he stayed when he found out it would not be. Battey says his institute does only a modest amount of intramural work, so there has been no staff turnover because of the rule changes, but that may not be the situation in institutes with larger research programs.

Still, Battey said, “one has to view one’s role as intramural scientists in totality. We have relatively stable funding for our labs, but if you go into academia, you will have to compete for research grants, and the success rate is not high,” he said. “I love my job. I have worked at the NIH since 1983, and I feel a tremendous debt to the organization that has done so much for my career.”

Scientists who are excited about translational research, “who want to see how bench wisdom can be used to make something that will help people,” will probably not be satisfied working at NIH these days, said Michael Brownstein, M.D., Ph.D., director of functional genomics at the Venter Institute in Rockville, Md. After 33 years at the NIH, Brownstein left when the ethics rules were changed because he found so much satisfaction in working with outside companies, activities that NIH approved and for which Brownstein received stock.

These companies “don’t care what you are doing in your own labs. They want you around to give critical advice about this particular target or that specific project,” he said. “And it was fun and useful, because these companies were taking steps that I couldn’t.

“NIH never saw my consulting as part of their mission. It was just something I was allowed to do,” said Brownstein, whose lab cloned dopamine and serotonin transporters. “I, on the other hand, saw consulting as something very useful to [NIH]. It let me use what I had learned over the years to do what they should have been happy about.”

With passage of the new rules, which Brownstein calls “way too severe, an overreaction,” he left. “I was incredibly happy at NIH. It is a dynamite place to work; NIH should have tidied up their house and weeded out the folks who were the violators, but not change the climate as significantly as it has.”

**Ethics Rules May Be Most Strict in Government**

In 2005, NIH Director Elias Zerhouni announced the final regulations regarding financial interests, stock divestiture, outside activities, and awards. The new rules include the following:

- A prohibition on outside consulting by NIH staff with “substantially affected organizations,” such as pharmaceutical, biotechnology, or medical device manufacturing companies, health care providers, or insurers.
- A limit on holdings in organizations affected by NIH actions in excess of $15,000 per company by senior employees, spouses, and minor children. Other employees may be required to divest their stock if a review finds a potential conflict.
- A limit on monetary awards from outside sources, including prior approval. These awards are limited to those that have been determined through a screening process to be legitimate.
- A report is required of senior employees and those involved in clinical trials who have a financial interest in organizations affected by NIH.
- Outside activities with professional and scientific organizations, service on data and safety monitoring boards, grand rounds lectures, and service scientific grant review committees are allowed, subject to prior approval and review by ethics officials.
- Academic outside activities, such as teaching courses, writing general textbooks, performing scientific journal reviews or editing, and providing general lectures to physicians and scientists as part of continuing professional education programs are allowed. NIH scientists can also practice medicine and other health professions with prior approval.