nature medicine

Bad medicine

The US National Institutes of Health (NIH) instituted sweeping regulations last month aimed at managing conflict of interest. The regulations put strict restrictions on the outside activities of 17,500 NIH employees, including banning its scientists from engaging in paid or unpaid consulting for industry, health care providers or universities. The NIH should be at the forefront of new initiatives designed to further medicine. Instead the new regulations risk harming the interactions between scientists and outside entities that turn scientific findings into treatments. While reform at the NIH was long overdue, the current measures go too far.

The issue ignited when the *Los Angeles Times* reported a range of apparent ethical lapses at the NIH. Elias Zerhouni, the director of the NIH, was brought before a congressional subcommittee to get his house in order last spring. He appointed a 'blue-ribbon panel' to draw up recommendations for new rules, consisting of prominent scientists, ethicists and lawyers. The panel recommended banning institute directors and top administrators from outside consulting, and placed time and compensation limits on consulting for rank-and-file scientists. Another recommendation endorsed rules barring clinicians from accepting payments from a company with a financial interest in their research. While the recommendations were stricter than standards at most universities, the congressional committee felt that the panel did not go far enough. Meanwhile, new allegations surfaced. For instance, one researcher had failed to reveal that he had received more than $500,000 from drug companies—putting even more heat on the NIH.

Exactly what the new rules will and will not permit may not become clear for some time. But some things are plain. In addition to the ban on consulting, the rules effectively prohibit scientists from accepting small honoraria for speaking—an extra incentive for scientists to reach out to the larger scientific community. This prohibition strengthens already strict rules on small honoraria—standard for invited speakers at many institutions, including the NIH. The rules also limit NIH scientists and their spouses from owning stock in biotechnology or pharmaceutical companies.

At the root of the drive for reform are legitimate concerns that some NIH employees in influential positions—such as those who help draw up guidelines for clinicians—were also receiving compensation from drug companies. But some concerns might stem from a misunderstanding of the role of the NIH. What some critics fail to realize is that the by far most researchers at the NIH are engaged in just that—research. They do not create government policy, approve drugs, create clinical guidelines, nor administer grants. By far, most granting decisions are made by committees of outside researchers, and employees of the NIH granting office have long had extremely strict restrictions on outside activities.

Fortunately, some of the most important activities of the NIH that foster medical innovations will not be curtailed. NIH employees can still form research agreements with companies, which enable the sharing of reagents and information. Such agreements are responsible for 122 licensing agreements issued last year by the NIH.

It is harder to quantify the benefits of consulting arrangements and the effect of banning them. In January 2004, there were about 200 such arrangements, dwindling to about 100 earlier this year, as many scientists put them on hold while the new rules were created. Almost every biotechnology company has academic consultants who provide critical advice to keep science moving from bench to bedside. These two-way interactions also add to the vitality of the scientific enterprise at the NIH. Such arrangements can be abused—they should be transparent, limited and subject to serious vetting for conflict of interest. But they should not be banned. Numerous recent analyses of how drugs make it to market have shown that most innovations originate with NIH-funded research. The drug pipeline now flows from academia to biotechnology to 'big pharma'—why slow the flow?

In the meantime, new revelations are certain to appear outside of the NIH campus. Zerhouni has called for an 'ethics summit,' and rules for scientists at outside institutions receiving NIH grants could be heavily scrutinized. While many universities have lax conflict-of-interest policies, imposing the current NIH restrictions on outside grant recipients would paralyze the pipeline.

In the mid-1990s, Harold Varmus, director of the NIH at the time, relaxed the rules on outside activities for NIH scientists, widely heralded as revitalizing an agency then too cloistered in the ivory tower. Throughout the last few decades, contacts have gradually broadened between industry and academic scientists—at the NIH, universities and research centers. In an era of change, conflict-of-interest policies overall have yet to keep up.

The Bush adminstration's current budget calls for a 40 percent increase in funds for the NIH 'Roadmap' program, which promotes translational research. If the administration is truly concerned about translating findings from the bench to the bedside, they would make sure that the NIH has a set of workable rules to deal with the process. There are still about 40 days left in the comment period for the new rules. And the NIH has said they will revisit the rules after one year. When they do, they should reassess the recommendations of the blue-ribbon panel. Ethics problems won't disappear with the new rules and must be addressed head on, with greater finesse and intelligence. As an example to the many research institutions without adequate conflict policies, the NIH should not retreat into an idealized past—the agency should lead the country by dealing positively with changing times.