

Conflicts of Interest at the NIH's Intramural Research Program

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David B. Resnik

NIEHS/NIH

A controversy over conflicts of interest (COIs) in the intramural research program at the National Institute of Health (NIH) erupted in December 2003, when the *Los Angeles Times* published several articles on consulting arrangements between NIH administrators and senior scientists and pharmaceutical and biotechnology companies.[1][2] The articles alleged that some officials received hundreds of thousands of dollars from consulting deals, which apparently did not violate any of the NIH's ethics rules pertaining to outside activities. Two of the NIH's directors allegedly received fees or stock options worth several hundred thousand dollars.[3] Most of the officials who had these arrangements did not make any public disclosures.[4]

In response to these allegations, NIH Director Elias Zerhouni appointed a blue-ribbon panel in January 2004 to examine the charges and make recommendations for changes in NIH policies. Two Congressional subcommittees also held hearings to examine COIs at the NIH's intramural program. Zerhouni's predecessor, Harold Varmus, loosened the NIH's ethics rules in 1995 to encourage intramural researchers to consult with industry and to recruit and retain top biomedical scientists.[5]

In May 2004, the panel issued its report, which called for tighter controls on relationships with industry. In July 2004, Zerhouni announced rules stricter than those recommended by the panel. Zerhouni's proposed changes include (1) no NIH staff may serve on corporate boards or as paid consultants for grantee institutions; (2) consulting fees may not exceed 25% of an employee's annual salary (limits on salaries for clinicians are set by local market rates); (3) employees who are required to file financial reports are not allowed to own any stock in pharmaceutical or biotechnology companies and other employees are limited to \$5000 in such stock; (4) all outside activities by NIH staff, such as consulting arrangements, will be publicly disclosed on the Internet; (5) limits on the awards that NIH employees may receive, such as cash prizes, (6) NIH scientists may serve on industry advisory boards, but only after review and approval; and (7) the NIH will initiate additional training and compliance mechanisms related to outside activities, including random audits.[6]

Shortly after Zerhouni's announcement, the Office of Government Ethics (OGE), which had previously found no major problems with the NIH's consulting policies, issued a report recommending that the NIH prohibit all consulting with pharmaceutical companies.[7] Zerhouni responded to this report by announcing a one-year moratorium on consulting with pharmaceutical or biotechnology companies for all NIH employees, to allow the NIH some time to reformulate its policies and reporting procedures. He stated that relationships with industry could continue to take place, where appropriate, only as official duty (unpaid) activities. He also declared that the NIH would seek to prohibit all NIH senior staff from receiving money to consult with pharmaceutical or biotechnology companies.[8]

There are several reasons why it is important for individuals and organizations to address COIs in research. First, COIs can compromise scientific judgment and undermine

the objectivity and integrity of research.[9] For example, an NIH scientist who has a financial relationship with a pharmaceutical company may deliberately (or subconsciously) analyze or interpret data in a way that favors the company's products. Second, COIs can erode the public's trust in research institutions and the research enterprise.[10] If people know that NIH researchers are receiving money from private industry, they may view the NIH's research or public health recommendations as biased or untrustworthy, and they may decide not to support the NIH's programs. Even financial relationships that generate merely the appearance of a bias can still have a negative affect on the public's trust in research.[11] Third, since research institutions also have financial interests, these interests may compromise their collective decision-making and undermine the public's trust.[12]

Although it is important for NIH researchers to collaborate with industry, the NIH is a branch of the U.S. government, and, as such, is charged with serving the public interest.[13] The NIH must maintain independence from private corporations, especially pharmaceutical and biotechnology companies. Unlike the Food and Drug Administration (FDA), the NIH does not directly regulate private corporations. Nevertheless, the NIH can have a significant impact on pharmaceutical and biotechnology companies because it conducts and sponsors research that may affect their financial interests. For example, an NIH institute might sponsor a study that compares a new, patented medication to a generic alternative, which could have an adverse impact on the drug's sales.

Relationships with private companies can place the NIH's reputation—and its integrity—in jeopardy. Since so much is at stake when it comes to relationships between the NIH and private industry, one might argue that the organization should prohibit its intramural scientists from receiving any money for consulting with pharmaceutical or biotechnology companies. This radical solution, proposed by the OGE, would be simple, straightforward, and easy to implement.

If only the solution were this simple. To see why it is not, one must consider the larger social and economic context that frames the problem. There is a rough division of labor between private and public science in biomedicine: public science focuses on basic research and private science develops practical applications from this new knowledge. Most of the basic, biomedical research is sponsored by the government and is conducted at universities, colleges, or government laboratories. In the U.S., the government spends about \$30 billion per year on biomedical research, \$27 billion of which is sponsored by the NIH. Most of the applied biomedical research, such as clinical trials or product development, is sponsored by pharmaceutical or biotechnology companies. Applied biomedical research is conducted in many different settings, such as hospitals, clinics, medical centers, universities, or private laboratories. The private sector spends about \$50 billion per year on biomedical research and development (R &D).[14]

For this division of labor to be productive, public and private sectors must work together toward the common goals of promoting human health and treating or preventing disease. Researchers working in these different sectors need to cooperate, collaborate and share ideas, expertise, and data. Scientists working for the NIH can benefit from interactions with scientists working in industry or academia and vice-versa. Indeed, legislation adopted in the 1980s, such as the Bayh-Dole Act and the Technology Transfer Act, encourages collaborations between industry and the government.[15]

Zerhouni and Varmus have both promoted collaborations with industry. Zerhouni's NIH Roadmap, for example, includes a plan to reengineer the clinical research enterprise to encourage better communication and partnerships among all stakeholders, including patient groups, communities, basic researchers, clinical researchers, universities, and private companies.[16] The completion of the human genome project (HGP), which occurred during Varmus' tenure, was a striking example of the benefits of public-private collaboration, despite some of the conflicts that occurred along the way.[17]

While government agencies, academic institutions, and private companies frequently collaborate in research, they also compete for scientists from the same talent pool.[18] To attract the top researchers, employers must offer competitive salaries, benefits, job security, and intangibles, such as job satisfaction. If an academic institution cannot afford to offer a scientist a competitive salary, then the institution may allow the scientist to enhance his or her salary through consulting arrangements and other outside activities. Many researchers working in universities, especially those in the biomedical sciences, earn thousands of dollars per year through consulting deals and other financial relationships with industry.[19]

This social and economic context serves as a basis for two arguments against strict ethics rules at the NIH's intramural program. First, the NIH should not set overly restrictive rules because this will prevent the organization from recruiting and retaining top scientists. The NIH pays basic and clinical investigators according to government pay classifications. Although the mid-range scales are competitive with academia and industry, the upper-range scales are not. For scientists hired under a Title 42 permanent appointment, who are working at the NIH's clinical center in Bethesda, MD, the top pay scale, GS 15, has a maximum salary of \$124,783 per annum. The NIH can also hire scientists under Title 5 renewable, term appointments at pay rates for clinical researchers that range from \$120,000 to \$200,000 per annum.[20] The top biomedical researchers working for academic institutions or private corporations often make more than \$120,000 per year and many have annual salaries of \$500,000 or more per year.[21] Since the NIH cannot afford to offer its top researchers competitive salaries, according to this argument, it should allow them to supplement their income with payments from outside agencies.

Although it is important to try to offer competitive salaries to NIH scientists, this first argument for loosening the ethics rules could push the organization toward corruption. Taken to its logical extreme, this argument would recommend that the NIH should place no restrictions on relationships with industry, since this would allow the organization to attract scientists who want to earn more outside income. To avoid sliding toward corruption, the NIH needs to place limits on income from outside activities. These limits will be difficult to maintain, however, if NIH leaders give credence to the first argument, since there will always be pressure in the organization to ease ethics rules in lieu of raising salaries. The promise of income from outside activities should not be used as an incentive for recruiting or retaining top scientists. The NIH offers researchers non-economic benefits, such as job satisfaction, public service, and the opportunity to conduct cutting-edge research on human health. Scientists who are interested only in money can look elsewhere for employment.

According to second argument, highly restrictive ethics rules will inhibit relationships with industry by barring scientists from consulting or serving on advisory boards. Since it is important for NIH intramural scientists to develop relationships with

industry, NIH scientists should have considerable leeway in forming these arrangements.

Most people on both sides of the COI dispute agree that NIH intramural scientists should develop relationships with scientists from pharmaceutical and biotechnology companies, but do scientists need to receive money from the private sector in order for collaborations to occur? The second argument against strict ethics rules assumes that NIH intramural scientists must receive financial remuneration for consulting or service on boards. Although scientists usually receive compensation for this type of work, there is no *a priori* reason why they must be paid for consulting work. Indeed, scientists often do *pro bono* work for outside organizations, such as scientific journals or societies, as part of their official duties for the government. The ethics rules forbid scientists from receiving compensation from an outside organization, other than reimbursement for travel related expenses, for work done as an official duty. The rules concerning official duties allow scientists to treat relationships with outside organizations as official work, provided that “any official work performed with an outside organization must also be consistent with the authority and mission of NIH. There should be compelling agency policy reasons for official duty activities with outside organizations.”[22] Consulting with a company would seem to meet these requirements, especially given the NIH’s Roadmap. Indeed, Zerhouni’s proposed changes at the NIH include encouraging researchers to consult with industry as official duty activities.

While the idea of having NIH intramural scientists collaborate with industry as an official duty activity has considerable merit, this solution to the COI dispute introduces new problems. An intramural scientist who spends a great deal of time working for an outside organization on behalf of the NIH has less time to devote to his or her other duties, which drains the NIH’s resources. One might argue that it is unfair for the government to bear this cost; if companies require valuable services, they should pay for them. The government should not subsidize pharmaceutical and biotechnologies companies by providing them with free expertise. Treating consulting as an outside activity avoids this problem because NIH employees who are paid consultants (or paid board members) work on their own time, not on the NIH’s time. NIH employees who perform outside activities are required to take annual leave or unpaid leave, if their activities occur during the NIH’s normal working hours.[23]

There are no easy solutions to the NIH’s problems with COIs at its intramural research program. The simplest solution—banning all income from relationships with industry—is not optimal or productive. Innovative solutions, such as treating collaborations with industry as official duty activities, create other problems. The best resolution to this debate is to tighten up and clarify existing rules on outside activities. Zerhouni has proposed some useful changes in the NIH’s ethics rules, but these probably do not go far enough. First, while it is important to limit the amount of income that researchers can receive from external sources, it would also be useful to limit the amount of time that researchers may spend on outside activities, since time spent on outside activities can interfere with obligations to the NIH. Second, while encouraging researchers to consult with industry as an official duty is a good idea, the NIH should require researchers to report how much of their official duties they spend collaborating with industry, and the NIH should set individual and organizational targets for time devoted to these activities, so that the organization will not drain its own resources or unfairly subsidize industry. The

controversy over COIs at the NIH has damaged the public's trust in the organization, but that trust can be restored if leaders at the NIH take decisive and practical measures to deal with legitimate concerns raised by the press, politicians, and the public.

Disclaimer: The article does not represent the views of the NIEHS, the NIH, or the U.S. government.

Notes

- [1] Willman D. Stealth merger: drug companies and government medical research. *Los Angeles Times*, 7 December 2003, sec. 1, p. 1.
- [2] The NIH's intramural program consists of scientists, postdoctoral students, fellows, and research staff hired by the NIH to conduct basic and applied research. The NIH's extramural program consists of grants and contracts awarded to other institutions, such as universities or medical centers, to conduct research. Most of the NIH's budget supports extramural research, which is not the focus of this current dispute. Steinbrook R. Financial conflicts of interest and the NIH. *N Engl J Med* 350: 327-30.
- [3] Willman D. Curbs on outside deals urged. *Los Angeles Times*, 9 April 2004, sec. 1, p. 1.
- [4] Willman, op cit., note 1.
- [5] Kaiser J. Senators probe alleged financial conflicts at NIH. *Science* 2004; 303: 603-604.
- [6] Kaiser J. Feeling the heat, NIH tightens conflict-of-interest rules. *Science* 2004; 305: 25-26.
- [7] Kaiser J. Conflict of interest: report suggests NIH weigh consulting ban. *Science* 2004; 305: 1090.
- [8] Zerhouni, E. Memorandum: Policy Proposal for Management of Conflict of Interest, September 24, 2004. Available at: www.nih.gov/about/092404coi_policymemo.htm. Accessed: November 3, 2004.
- [9] Thompson D. Understanding financial conflicts of interest. *N Engl J Med* 1993; 329: 573-76.
- [10] DeAngelis C. Conflict of interest and the public trust. *JAMA* 2000; 284: 2237-38.
- [11] Resnik D and Shamoo A. Conflict of interest and the university. *Acc. in Res.* 2002; 9: 45-64.
- [12] Resnik and Shamoo, op cit, note 11.
- [13] Krimsky S. *Science in the Private Interest*. Lanham, MD: Rowman and Littlefield, 2003.
- [14] Resnik D. The distribution of biomedical research resources and international justice. *Devel World Bioeth.* 2004; 4: 42-57.
- [15] Krimsky, op. cit., note 13.
- [16] National Institutes of Health. NIH Roadmap, October, 2003. Available at: nihroadmap.nih.gov/. Accessed: September 2, 2004.
- [17] Resnik, D. *Owning the Genome*. Albany, NY: S.U.N.Y. Press, 2003.
- [18] Bok D. *Universities in the Marketplace*. Princeton, NJ: Princeton University Press, 2003.
- [19] Blumenthal D. Academic-industrial relationships in the life science. *N Engl J Med.* 2003; 349:2452-59.

[20] National Institutes of Health, Clinical Center. Senior Investigator Appointment Mechanisms. Available at: ohrm.cc.nih.gov/employ/title42/srinves.htm. Accessed: September 2, 2004.

[21] Bok, op cit, note 18.

[22] National Institutes of Health. Official Duty Activities with Outside Organizations, June 25, 2003. Available at: ethics.od.nih.gov/Topics/official.htm. Accessed: September 2, 2004.

[23] National Institutes of Health. Outside Activities, June 25, 2003. Available at ethics.od.nih.gov/Topics/oa520.htm. Accessed: September 6, 2004.