

# NIH need clear definition of fraud

Behind the pyrotechnics surrounding the way the National Institutes of Health investigate fraud are substantive issues of fairness.

THE 1 August hearing in the US Congress at which Representative John Dingell locked horns with Bernadine Healy, the new director of the National Institutes of Health (NIH), became a battle of titans as Healy boldly stood her ground in the face of Dingell's accusations that she was dismantling the NIH's fraud office for personal and vindictive reasons (see *Nature* 352, 461; 8 August 1991).

At issue was Dingell's assertion that Healy had no business getting into the middle of the Office of Scientific Integrity's interminable investigation of two cases involving, separately, virologist Robert C. Gallo and Nobel laureate David Baltimore and Thereza Imanishi-Kari. Dingell was enraged that Healy had taken steps to 'rein in' OSI's former acting director, Suzanne Hadley, who she said was editorializing inappropriately in the OSI's official reports and who was suspected of becoming too close to the whistleblower in the Baltimore case. Dingell said that because Hadley had reviewed and found wanting Healy's own handling of a case at the Cleveland Clinic, Healy's previous employer, Healy could be accused of a conflict of interest — a charge Healy called "preposterous".

Behind the colourful pyrotechnics of the hearing lie several substantive issues crying out for resolution in a serious and sober environment. The first is the government's very definition of misconduct, which is vague and open-ended to the point that OSI has been at liberty to label as wrongdoing any behaviour that it decides does not fit the 'norm'.

The second is the question of whether Dingell's continuous pursuit of alleged fraud has become so dominant and distracting that potentially life-saving science is going undone. Martin Delaney, head of Project Inform, one of the largest US AIDS activist groups, has taken that tack and threatens to launch a vigorous effort to stop what he sees as Dingell's harassment of scientists.

Finally, a status report by the government's Office of Scientific Integrity Review, which has authority over NIH's fraud office, suggests that the incidence of serious wrongdoing is, indeed, rather minor. For instance, of 21 cases reviewed by OSIR as of December 1990, findings of misconduct are broken down as follows: data fabrication or falsification, six; plagiarism, five; "other deviant practices", such as multiple manuscript submission, seven. With respect to the five cases of plagiarism, the report says each involved the use of review material that was acknowledged in a bibliography but not sufficiently credited. "There were no cases where research results or research data were found to be plagiarized."

It is this kind of information that makes one wonder whether the NIH are spending too much time investigating trivia, and it is the ill-defined matter of "other deviant practices" that has Healy demanding a new look at the institutes' approach to policing science. It is here that Healy's quarrel with Hadley lies.

In 1986, official guidelines defined misconduct as fabrication, falsification and plagiarism. Three years later the definition was amended to include "other practices that seriously deviate from those that are commonly accepted within the scientific community for proposing, conducting, or reporting research". Healy wisely would like to see the latter go, leaving the government's fraud investigators to concentrate on real fraud, committed with intent. "Intent and purposefulness", in Healy's view, are necessary components of fraudulent behaviour — the element that distinguishes fraud from sloppiness or error. Hadley, on the other hand, has explicitly told scientific groups that she finds intent irrelevant in identifying misconduct.

Healy is also taking issue with OSI's definition of due process which expressly denies the accused the right to see at first hand all of the evidence against him or her. Hadley's organizing principle for OSI has been that if someone sees all of the evidence, he or she is in a better position to explain it away. Better to keep the allegedly damaging data secret, available to the accused only in summary form.

When it comes to procedure, due process is not the only issue. Healy reports her "astonishment" at witnessing a debate amongst high-level NIH staff about just which set of procedures the fraud office is supposed to be following. She finds the OSI's definition of conflict of interest at odds with that used by the rest of NIH. Healy is distressed that Hadley apparently failed to follow existing guidelines for logging phone calls and blocked the early release of the Gallo report to an advisory committee that was not duly constituted. Healy recalls early

advice from Dingell: to do a good job, follow the rules. Healy wants OSI to have good, clear rules.

Then there is the matter of confidentiality. Healy is furious that the OSI's draft report in the Imanishi-Kari case was widely leaked to the press where its preliminary findings were often reported as final. Add to that what is suspected to be OSI's recent leak of a draft report in the Gallo case (see page 555) and Healy has every reason to think that the office has "run amok".

A fundamental point needs to be resolved in this debate. Is it the government's job to ferret out and punish scientists who commit fraud in the course of conducting federally funded research, or, should the government's official fraud office extend its reach to matters that are properly defined as error and carelessness? A logical response is that the government should stick to the former, leaving judgements about the adequacy of footnotes, perfection of data presentation in published tables or handling of students to editors, tenure committees and the bodies that award prizes to people whose behaviour is so exemplary that it sets them above the average.

Concern that the government is getting into the business of bringing its full weight to bear on ordinary human imperfections, whether through NIH or the office of Representative Dingell, is beginning to have a psychologically crippling effect on the research community. It is that angst that AIDS activist Delaney hopes to tap. In a letter to Dingell, Delaney accuses the congressman of acting as judge and jury at the Healy hearing before even hearing her testimony and finds "a pattern of bias in your office stretching back for more than three years".

In a new twist to the story, Delaney is calling for an independent investigator of the sort brought into the Watergate and Iran-Contra scandals to examine not only the Office of Scientific Integrity but also Dingell's office itself.

"Bureaucratic zeal", Delaney charges, "is itself a major enemy in the fight against AIDS." A petition signed by AIDS activists, community figures and, he hopes, scientists will mark Delaney's first move in this new battle to get research instead of fraud at the top of the country's scientific agenda.

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