NIH Misconduct Procedures Derailed

A ruling that NIH failed to meet legal requirements in developing its investigatory procedures could leave some misconduct investigations hanging

A FEDERAL JUDGE IN WISCONSIN HAS PLACED a major roadblock in the path of investigations conducted by the National Institutes of Health's Office of Scientific Integrity (OSI). Late last month Judge Barbara Crabbe essentially tossed out the procedures used by the office to investigate cases of scientific misconduct, ruling that NIH had technically violated a federal law when it adopted the procedures in 1986. The ruling, which came in a suit brought against NIH by University of Wisconsin neurologist James Abbs (*Science*, 3 August 1990, p. 471), could force NIH to go through a lengthy bureaucratic process to make its investigatory rules legal. In the meantime, OSI might have to suspend as many as 75 investigations currently in progress.

NIH officials, who give every indication of having been thrown into complete disarray by the ruling, declined to discuss its implications. (One official said it could take as long as a month for the agency to figure out its reaction.) But according to outside legal experts, NIH is in a bind. Judge Crabbe's opinion states that OSI's internally established procedures are actually federal "rules"—legal requirements that must be published in *The Federal Register* and opened for public comment at least 30 days before they are finally enacted. NIH failed to do this. "Normally, an agency will fall back on pre-existing procedures when new ones are invalidated on [such procedural] grounds," says Robert Charrow, a former principal deputy counsel for the Department of Health and Human Services. "In this case, however, there were no [pre-existing] procedures." As a result, the legal framework guiding OSI investigations seems to have crumbled.

Strictly speaking, Crabbe's ruling applies only in the western district of Wisconsin, so OSI could proceed with investigations under its existing procedures outside that district. But this strategy would leave the office vulnerable to legal challenges in other districts, particularly since targets of investigations could use Crabbe's opinion to demonstrate the likelihood of "prevailing on the merits"—a good way to obtain a preliminary

More Woes for Gallo

The tribulations faced by AIDS researcher Robert C. Gallo have intensified in recent weeks. Although NIH's Office of Scientific Integrity announced 3 months ago that it had cleared Gallo of charges that he misappropriated a virus he had received from a group at the Pasteur Institute, it is pressing on with an investigation into the data supporting a key 1984 paper written by Gallo and his former colleague, cell biologist Mikulas Popovic. Early last month, OSI announced it had formed a scientific panel to assist its investigation. Two weeks later, in an unrelated matter, officials at the National Cancer Institute suspended Prem Sarin, the deputy director of Gallo's laboratory, from active duty pending the completion of investigations into allegations of criminal conflicts of interest.

Sarin's case is the second potential conflict of interest problem to surface in the lab. Last September, Gallo's laboratory assistant Syed Zaki Salahuddin pleaded guilty to two felony charges, one for directing laboratory contracts to a biotechnology company where his wife worked and the other for accepting an illegal gratuity from the same company.

NCI officials refused to comment on the suspension of chemist Sarin, claiming that the action is a confidential personnel matter. But in a 28 December letter to the office of Representative John Dingell (D–MI), acting deputy NCI director Richard Adamson wrote that an internal review of Sarin's "relationships" with two pharmaceutical companies led the institute to remove him from his position as deputy chief of Gallo's Laboratory of Tumor Cell Biology and reassign him to a "non-supervisory, non-managerial position." That was apparently just a first step: According to the letter, NCI is seeking to suspend Sarin from all duties without pay while NIH's Division of Management Survey and Review and the inspector general of the Department of Health and Human Services look into the allegations. In addition, a Dingell aide confirmed that Sarin is one target of a congressional investigation into conflict of interest problems at NIH, but declined to provide details. Reached at his office, Sarin declined to comment.

As for the investigation of Gallo's scientific paper, if it hasn't been derailed by a recent court ruling in Wisconsin (see accompanying article), the newly appointed scientific panel should begin its work within the next few weeks. Its charge: to determine whether some statements in the paper—the key publication announcing the retroviral cause of AIDS—were fully supported by the data. The panel will participate in interviews of the principals and extensive reviews of documents and original primary data, says Suzanne Hadley, deputy director of NIH's Office of Scientific Integrity. Once done, the panel will tell OSI whether the evidence warrants a charge of misconduct, Hadley says, although OSI gets to make "the final call."

A separate outside panel, chaired by Yale biochemist Frederic Richards and consisting of 11 scientists nominated by the National Academy of Sciences and the Institute of Medicine, is overseeing the NIH "inquiry" into Gallo's early AIDS research. It will advise acting NIH director William Raub on whether to accept OSI's final report.

The scientific panel's members are: Kenneth Berns, chairman of the microbiology department at Cornell University Medical College; AIDS researcher Michael McGrath of the University of California at San Francisco; and Priscilla Schaffer, chief of the Laboratory of Tumor Virus Genetics at Harvard Medical School. Berns and Schaffer are virologists, while McGrath has recently been studying the experimental AIDS drug Compound Q. ■ **D.P.H.**

injunction, according to Barbara Mishkin, a Washington attorney who represents several scientists accused of misconduct. NIH might ask the solicitor general—who authorizes all federal appeals—to contest the ruling, but Charrow believes the agency is more likely to just give in and begin a formal rulemaking process. If so, its current investigations will probably grind to a halt until new rules are properly in place.

If NIH does go through a formal rulemaking process, outsiders would have a chance to influence the way the OSI performs its investigations, a prospect that energizes Abbs' attorney, Carl Gulbrandsen. "I hope that universities and organizations which represent scientists get involved in urging OSI to adopt new rules," he says. In particular, Gulbrandsen would like to see OSI give those being investigated the right to question witnesses and review evidence. Mishkin also wants to see more protections built into the investigative process, pointing out that under existing rules, it can take years for a scientist to receive a full hearing.

OSI may resist such changes, however, since Crabbe ruled that although the procedures were improperly promulgated, their content does not raise constitutional problems. Abbs, who is under investigation for allegedly forging three graphs in a 1987 *Neurology* paper, had claimed that the threat to his reputation and future federal funding required OSI to provide him with "due process" protections allowing him to cross-examine witnesses and review the evidence marshaled against him. But Crabbe ruled that damage to reputation alone is not a sufficient reason to invoke due process protection, and pointed out that since the current guidelines entitle Abbs to a full hearing if NIH barred him from receiving federal funds, OSI had already afforded him sufficient due process.

Although NIH may use this element of the decision as justification for avoiding a full-scale reformulation of its procedures, Crabbe also made clear that the agency has plenty of room for improvement. In a court hearing last August, the judge said she was "appalled" by the "discretionary" and "unspecified" nature of the OSI procedures. "I must say I was shocked that an agency of the United States...would permit procedures such as the ones that I saw promulgated. I thought they were the work of amateurs. They didn't seem to have any consideration whatsoever for the very serious subject matter that they were investigating." The lengthy process of taking such considerations into account not only leaves NIH with a major predicament, it also leaves those it has been investigating—some for well over a year—still twisting in the wind.

■ DAVID P. HAMILTON

Leon Lederman's Quest: Double Science Funding

A report sent to all AAAS members urges special treatment for science, but Lederman's calculations and tactics draw fire

LEON M. LEDERMAN, THE NOBEL PRIZE-winning physicist and president-elect of the American Association for the Advancement of Science, has a mission. He aims to convince anybody who will listen—from his fellow scientists, to science policy makers, to members of the public—that "academic science is in very serious trouble." He bases this conclusion on an informal survey of some 250 scientists at 30 research universities and on his personal calculations of how the ratio of research dollars to researchers has declined since 1968—a year he picks as science's Golden Age. To bring a return to those happier days, he believes the federal government will have to double its spending on academic research.

Digital Enterprise Corp.

Man with a mission. *Will Lederman's charisma help sell science?*

Lederman has made this theme a campaign, kicked off by a personally written report, *Science: The End of the Frontier* (sent with this issue of *Science*), and a meeting, held on 7 January at the National Academy of Sciences, to convey the contents of the report to policy makers in Washington, D.C. That meeting revealed that Lederman will have some convincing to do. Critics were quick to question both the way Lederman reached his conclusions and the methods he intends to use to seek more federal spending on research. In a statement commenting on the report, Presidential Science Adviser D. Allan Bromley called Lederman's evidence "anecdotal." While admitting that many individual scientists have experienced difficulty obtaining research funds, Bromley argues that between 1968 and 1988 federal support for academic research rose from $5 billion to $8 billion, an increase of 60% in constant dollars. But Lederman says Bromley isn't using the appropriate inflation corrector—inflation in science has risen faster than the rest of the economy—and the true increase is closer to 20%. Regardless of who is right on the specific budget numbers, science is clearly better off than many other segments of the budget, prompting Frederick M. Bernthal, acting director of the National Science Foundation, to say, "My heart tells me that I'm sympathetic with [Lederman's goals], but my head tells me we've got a lot of convincing to do."

Lederman is not deterred by his critics. At the meeting he acknowledged some of the shortcomings of his informal survey, but insisted the conclusions about the malaise among researchers are an accurate reflection of the true state of affairs. "I would be amazed if a more thorough survey wouldn't have come up with the same results," he said. Lederman did not have to look far to find people who share his conclusions. "I feel more and more uneasy about advising students to enter science," said Daniel Kleppner, professor of physics at the Massachusetts Institute of Technology, who presented a researcher's perspective at the meeting. "My chief contribution to my research is to raise money for it," he told the audience. Alan P. Koretsky, assistant professor of biological sciences at Carnegie Mellon University in Pittsburgh, also described how funding shortages were having a negative effect on his research lab. "I cannot give my students the same freedom I was given," he said. "The most exciting and risky projects have been put in limbo."

Lederman argued that scientists basically have two choices about how to seek remedies to their financial woes. They can either acknowledge that fiscal times are tight and tighten their belts like everyone else or, alternatively, they can argue that support for