GALLO PROBE

Dingell Rips Healy for 'Obstructionism'

Just as the main investigation of AIDS researcher Robert Gallo appears to be quietly pulling into the station—only a few years behind schedule—Representative John Dingell (D–MI) is clanging bells and blowing whistles. In a 24 November letter to National Institutes of Health (NIH) Director Bernadine Healy, Dingell—whose subcommittee is staging its own investigation of Gallo and a dispute over the HIV blood test patent—vents a full head of steam at NIH for "a clear pattern of delay, obstructionism, and abuse." The eight-page missive concludes that NIH's actions "strongly suggest an attempted cover-up is under way."

In 1990, the now-defunct NIH Office of Scientific Integrity (OSI) launched an investigation of Gallo to determine whether the National Cancer Institute retrovirologist or members of his lab had committed scientific misconduct while running the critical experiments that led to the HIV blood test. At the controversy's center was the allegation that Gallo had misappropriated a sample of the AIDS virus supplied by Luc Montagnier of France's Pasteur Institute. A year later, when the OSI inquiry became an investigation, however, theft was barely an issue, and most of the charges concerned errors in a seminal 1984 paper published in *Science* that detailed how to grow HIV.

Last spring, the OSI's final report was leaked to the press (*Science*, 8 May, p. 735). Though it did not find Gallo guilty of misconduct, it concluded that he had behaved in a "less than collegial" manner during the period when HIV was isolated and the blood test was developed, and charged the first author of the *Science* paper, virologist Mikulas Popovic, with three instances of misconduct. The OSI report is now receiving its final review by the newly formed Office of Research Integrity (ORI), the branch of the Department of Health and Human Services (HHS) that took over OSI's duties.

Dingell's angry letter, which was reported in the 1 December issue of *Science and Government Report*, grows out of his own investigation of the feud between the Pasteur Institute and HHS over roylaties from the AIDS blood test. Dingell is looking into whether NIH itself is guilty of misconduct and obstruction of justice. He writes that if NIH had promptly provided documents he requested on 15 January 1992, the subcommittee investigation may have been completed "long ago."

Dingell is particularly outraged about what he calls the "shredding incident," which involved the destruction of notes taken by Jules Hallum, then the director of OSI, during investigation interviews. According to Dingell, NIH sent him a report about the shredding, insisting that Hallum's notes "were intended to be kept only until the transcipts [from the interviews] were prepared." At best, Dingell writes Healy, the shredding is "a very serious mistake," and at worst, "a potential obstruction of the subcommittee's investigation."

In a closing blast, Dingell says his "patience is nearing an end," seeks Healy's "urgent, personal attention," and warns that the matter reflects on her "stewardship as NIH director." Dingell asks for a response by 4 December. In a statement to *Science*, Healy's spokeswoman says the director has requested a 1-week extension so she can gather more facts. "Dr. Healy takes the request from the chairman very seriously," the statement says.

As for the NIH investigation of Gallo, it, too, is passing a final switching point on the way to the rail yards. All that's left is the ORI report. But that's not just a formality, since ORI could add new charges or discount old ones. J. Michael McGinnis, head of that office, has told HHS assistant secretary for health James Mason that the report should be released before the year's end. If misconduct charges remain, the principals can appeal to an HHS adjudication board, which holds public hearings.

Popovic's attorney, Barbara Mishkin, says "if anything comes out that's like the last version [of the OSI report] our intention is to seek an appeal." Should that occur, for the first time, all documents from the OSI investigation may well end up in the public domain. And since documents have been the driving wheel of the Gallo saga all along—both for the media and the investigators—you can expect this locomotive to keep rumbling down the track.

–Jon Cohen

AIDS VACCINES

Trials Set in High-Risk Populations

Experimental AIDS vaccines designed to prevent infection with HIV have moved one step closer to real-life human tests. The National Institute of Allergy and Infectious Diseases (NIAID) announced last week that it is launching a trial of two candidate vaccines that will be given to people considered to have a high risk of infection with HIV as well as those at low risk. Previous small-scale tests of preventive vaccines, conducted over the past 6 years, have included only volunteers from low-risk groups. The new trial will evaluate safety and immune responses, not efficacy, but the high-risk cohort might give hints of whether experimental preparations will work. "This is a rational, important step in the process of moving toward an efficacy trial," says NIAID's Patricia Fast, a trial coordinator.

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–Patricia Fast

The placebo-controlled, Phase II trial will recruit 330 uninfected volunteers at five different university medical centers.* The volunteers will include drug users, people with sexually transmitted diseases, and minorities. All participants will be counseled and encouraged to avoid risky behaviors.

The focus of the tests is to assess whether people at high risk and minorities have different responses from the healthy whites who dominated the earlier trials. For example, says Fast, some high-risk, uninfected people may already have been exposed to HIV, an exposure that might have altered their immune systems. Since the new trial will enroll hundreds rather than dozens of people, safety problems with the vaccines are also more likely to surface.

The pair of vaccines selected for the trial are genetically engineered versions of the HIV surface protein called gp120; both rely on viral strains common in the United States. One vaccine, made by Genentech of South San Francisco, is based on an HIV strain designated MN; the other, developed by Biocine of Emeryville, California (a Chiron and CIBA-GEIGY joint venture), relies on the SF-2 strain. (A vaccine made by Connecticut's MicroGeneSys has been tested by NIAID the longest, but was not included in the trial because, says Fast, it is based on the relatively rare 3B strain.)

No one knows when a Phase III trial in thousands of people at high-risk—the real test of AIDS vaccine efficacy—will take place. But in life it's usual to crawl before you walk, and in vaccine development you usually can't do a Phase III trial until you've surmounted Phase II. So, crawling or walking, AIDS vaccine development is slowly gaining momentum.

–Jon Cohen

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