French Agency Exonerates Zagury

The storm that has been swirling around AIDS vaccine researcher Daniel Zagury for more than a year may be beginning to clear. A French organization that licenses physicians and oversees medical ethics has rejected a complaint against Zagury from France's minister of health. The complaint, based on the fact that three of Zagury's patients died after receiving an experimental AIDS vaccine he formulated, questioned whether Zagury, an immunologist at the Pierre and Marie Curie University in Paris, had acted in the best interest of his patients. The French licensing body said he had.

In its 3 January decision, a regional branch of the National Medical Order, a nongovernmental body, found that Zagury and his collaborators had "shown a willingness to act openly" by voluntarily clearing their experiments with both the National Ethics Committee and the one at Saint-Antoine Hospital in Paris where Zagury has been conducting his trials of therapeutic vaccines in patients already infected with HIV. The council also concluded that the AIDS patients had been properly informed of the experiment's risks, which were not "out of proportion [to their] state of health and prognosis." Zagury, who could have been barred from practicing medicine if the complaint had been upheld, called the decision "historically important for my family, my research group, my patients, and the scientific community."

The vaccine in question, which Zagury stopped testing after the deaths, was made by isolating white blood cells from each patient and infecting those cells with vaccinia virus that had been genetically engineered to express HIV proteins. Before giving this vaccine to patients, Zagury treated the infected cells with chemicals to kill the vaccinia virus; he added antivaccinia sera to mop up any residual vaccinia particles. More than 20 patients received the vaccine by a slow-drip, intravenous infusion, and no complications occurred. But three died after also receiving either subcutaneous or intramuscular injections of the vaccine. Each developed necrotic lesions at the site of the injections, suggesting that in spite of the precautionary treatments the vaccine contained live vaccinia.

The National Medical Order refused to censure Zagury, noting that the three patients were treated on a "compassionate" basis because they were at a "bad clinical stage" of full-blown AIDS: Each had fewer than 50 T4 cells, critical white blood cells that HIV destroys, when they received the vaccine injections, compared with the normal count of 800-1200. The council stressed that the inactivation methods used by Zagury are widely agreed on in the scientific community and that the necrosis was "not normally predictable, even for confirmed researchers and clinicians."

Supportive as the French licensing body's report is to Zagury, he is not out of the woods yet in France or in the United States. The French minister of health could still appeal the regional branch's decision. And in this country, after Chicago Tribune reporter John Crewdson questioned the French researcher's collaborations with Robert Gallo and other National Institutes of Health scientists-and work done by Zagury in Zaire-the NIH Office for Protection from Research Risks (OPRR) issued a stinging interim report in July 1991 criticizing NIH for failing "to provide adequate protection for human research subjects involved in these studies." Zagury, charged OPRR, had violated the collaborative agreement by not promptly notifying OPRR of the deaths in the immunotherapeutic trials. OPRR halted all NIH collaborations with Zagury, although it allowed him to submit new protocols for evaluation. OPRR further |

recommended that before approving a Zagury collaboration, the NIH must "develop special administrative procedures" to guarantee that patients are protected.

OPRR's plan was to issue a final report based on further information that was to be developed, in part, by the French authorities. Indeed, after the interim report was issued by NIH, the French government had asked Zagury to stop his research in Zaire, where he was testing HIV vaccines in infected and uninfected patients, and formed an official mission to go to Zaire to investigate whether Zagury had breached ethics in his trials there. That mission had intended to visit Zaire in early November but called off its fact-finding trip because of political turmoil in that country. At the time of writing, the French mission had no plans to make the Zaire trip.

Even before the supportive recent verdict, however, Zagury had begun to move forward. With the health minister's approval, he has continued tests of AIDS immunotherapeutics in three patients—although he's now using a different vaccine that is vaccinia-free. Zagury says he hopes to start new vaccine therapy trials this spring with vaccinia-free preparations.

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NSF Under the Magnifying Glass

Investigators on Capitol Hill have been gunning for scandal at the National Science Foundation (NSF) since last August, and NSF director Walter Massey, who is relatively new to the job, sits right where the cross-hairs intersect. This may be why he is sounding jumpy lately: "None of the things that seem to surround other agencies, like internal misconduct or fraud...have come out of this agency," Massey told *Science* last week, yet "we have been subjected to a whole series of inquiries that seem to imply that something is wrong."

The series of investigations Massey refers to began last summer when anonymous informants sent notes to Congress charging NSF staffers were "wiring" contracts (giving them to companies in which they had a financial or personal interest), promoting friends, and shading studies in a way that tended to support NSF's appeal for a bigger budget. The probe gained momentum in August when the House science investigations subcommittee, chaired by Representative Howard Wolpe (D-MI) began asking questions of the NSF staff. He wasn't satisfied with the first batch of answers he got, and the inquiry continues, focusing on two areas: The NSF's Division of Science Resources Studies (SRS), which publishes data on the R&D workforce and the financial support of science and technology, and on what used to be called the Division of Policy Research and Analysis.

Neither Massey nor his predecessor Erich Bloch would claim there were no problems in these two offices. According to Science and Government Report, Bloch had warned Massey at the time he turned over the directorship that dangers lurked-especially in the SRS division. Under Massey, both offices were reorganized. Furthermore, Massey points out, the SRS division has undergone several close examinations in the past year. The U.S. Office of Government Ethics took a look, as did NSF's inspector general, Linda Sundro. She concluded in a report issued in December that the investigation turned up nothing criminal-no "actionable findings of bias" or unacceptable conduct-just "a pattern of mismanagement and poor contracting practices."

More esoteric than the contract inquiry but potentially just as embarrassing for NSF is the investigation into what is being called the "pipeline paper," a series of analyses by