AIDS Case Dismissed on Legal Technicality

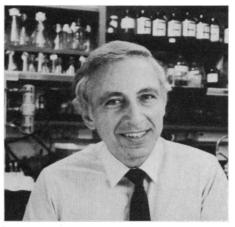
Two legal cases between the Pasteur Institute and the U.S. government stem from their dispute over a commercial blood test that detects antibodies to the AIDS virus. One case, a suit by the French alleging a breach of contract by National Cancer Institute (NCI) scientists, was dismissed on 7 July by the United States Claims Court in Washington, D.C., because Judge James Merow decided that the Court lacked jurisdiction in the matter. Attorneys for the Pasteur Institute plan to appeal the dismissal.

A key issue in the recent decision is whether or not a signed agreement between Robert Gallo's laboratory at NCI and Luc Montagnier's laboratory at the Pasteur is in fact a government procurement contract. Attorneys for the U.S. government argue that it is, and attorneys for the Pasteur say that it is not, an argument they will pursue in their appeal. The decision to dismiss the case assumes that the Pasteur had "a valid and binding contract with the United States as it pleaded" and goes on to dismiss the suit because the Pasteur failed to follow the proper procedures for filing a certified complaint with the Department of Health and Human Services as mandated under the Contract Disputes Act.

"It is important to recognize that the Court did not rule on the merits of the case," says U.S. government attorney Robert Charrow. James Swire, an attorney for the Pasteur, also emphasizes this point and further indicates that the recent decision, if it stands, may set an unusual precedent. It could mean that American scientists do not have the authority to sign the usual agreement that research materials received from a foreign country will be used only for scientific, and not commercial, purposes.

The original suit claims that Robert Gallo and other NCI researchers breached their contract with Luc Montagnier and his Pasteur colleagues. The disputed "contract," a 1983 letter of agreement signed by Mikulas Popovic, of Gallo's lab, indicates that the NCI researchers will not use samples of lymphadenopathy-associated virus (LAV) sent to them by Montagnier for commercial or industrial purposes without permission of the Pasteur Institute.

Subsequent to receiving the virus, Gallo and his associates filed, and later were awarded (May 1984), a patent for developing a test to detect antibodies in blood samples of people contaminated with the AIDS virus. The Pasteur scientists claim that



Robert Gallo: Latest court decision favors the National Cancer Institute.

Gallo and his colleagues used the French LAV virus sample to develop the antibody test. Gallo and the NCI scientists say they did not, stating that their antibody test is based on isolates of a different (although very similar) virus, human T-cell leukemia virus III (HTLV-III).

In a related but separate action is the battle for the antibody test patent. The French are contesting the American patent in a case that is currently before the U.S. Patent and Trademark Office Board of Patent Appeals and Interferences. The Pasteur Institute made its own patent application in December 1983, 5 months prior to Gallo's application. Because of this earlier filing, the French have been identified as the "senior party" in the interference case.

Thus, the outcomes of the legal decisions are split in terms of which party benefits—an earlier decision favoring the French and the more recent Claims Court dismissal favoring the Americans. Interestingly, neither decision was made on the merits of the case. **Deborah M. Barnes**

New Funds for AIDS Drug Centers

The National Institute of Allergy and Infectious Diseases (NIAID) has awarded contracts totaling \$100 million to establish AIDS treatment evaluation units. Fourteen U.S. institutions* will receive the \$100 million over the next 5 years.

*Harvard University, Johns Hopkins University, Memorial Sloan-Kettering Cancer Center, New York State University at Buffalo and Syracuse, University of California at Los Angeles, San Diego, and San Francisco (including San Francisco General Hospital), University of Miami, University of Pittsburgh, University of Rochester, University of Southern California, University of Texas M. D. Anderson Hospital and Tumor Institute, and the University of Washington in Seattle.

NIAID and the National Cancer Institute (NCI) will soon award an additional contract and grants for the development and screening of drugs against AIDS. In August, contract money to do a mass screening of drugs will be awarded. And in September, NIAID and NCI will award grant money to "cooperative drug discovery groups" that will work at the earliest stages of drug development.

Samuel Broder of NCI, who chairs a joint NCI/NIAID committee on drug selection, says that "the mandate for the newly funded treatment evaluation centers will be to develop and implement protocols to test drugs and biological agents for use against the AIDS virus." The centers will start with drugs that exist now, such as AZT (3'-azido-3'-deoxythymidine), ribavirin, HPA23, and foscarnate, and will test new drugs as they become available.

Some of the centers will also design protocols and test drugs for the opportunistic infections and cancers that occur in many AIDS patients. In addition, some of these centers will evaluate compounds that do not attack the AIDS virus itself, but that may enhance immune responses in AIDS patients.

Maureen Myers and John La Montagne of NIAID are coordinating the newly funded multicenter effort. Myers says that the process for testing drugs against AIDS will have to be worked out carefully because there are different populations of AIDS patients and many different stages of the disease.

The money for all three stages of AIDS drug testing—development, screening, and treatment evaluation—comes from NIAID and NCI, who are joint sponsors of the program. Congress appropriated the funds as part of the 1986 budget and they will all be awarded before the end of this fiscal year. **Deborah M. Barnes**

NIH Restores Animal Funds to Columbia

The National Institutes of Health, as anticipated, has lifted its suspension of funds for animal research at Columbia University. The suspension, covering work with nonrodent vertebrates, was announced on 27 January after the university submitted an animal welfare assurance statement documenting various deficiencies in facilities.

NIH approved a revised assurance statement following another site visit conducted in May.

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