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# HHS 'Investigative Memorandum' Revives Controversy Over AIDS Virus, Royalties

In an unusual move, the HHS Office of Inspector General has issued a report raising, once again, the question of whether NCI scientist Robert Gallo misappropriated the AIDS virus from French researchers.

The 35-page "investigative memorandum" suggests that HHS officials reconsider the US-French agreement splitting the royalty payments from the AIDS blood test and questions whether Gallo and former NCI colleague Mikulas Popovic are entitled to a share.

The report, dated June 10, was the result of a two-year investigation to determine whether Gallo made false statements when he applied for a US patent for the AIDS blood test. A copy of the report was obtained by **The Cancer Letter**.

The drafting of an investigative memorandum is an uncommon practice by OIG. The memos, intended for agency use, can be issued in

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*In Brief*

## Mary-Claire King Named Disney Professor By Cancer Society; Date Corrected In Article

**MARY-CLAIRE KING**, molecular geneticist and epidemiologist at Univ. of California at Berkeley, has been chosen as the first recipient of the Walt Disney Research Professorship for Breast Cancer, the American Cancer Society announced. The new professorship was endowed by a $1 million contribution from Mrs. Walt Disney in memory of her late husband. King will serve as a spokesman for the ACS Breast Cancer Research Program while she continues her research. She will receive $50,000 a year in partial salary and an additional $10,000 annually in discretionary funds. . . . **CORRECTIONS**: A date contained in a quote by John Patterson, Zeneca Pharmaceuticals Group, speaking before the hearing held by the Subcommittee on Oversight and Investigations, House Committee on Energy and Commerce, in last week's issue of **The Cancer Letter**, was incorrect. The statement should have read, "According to the subcommittee staff, the NSABP apparently has claimed that it notified Zeneca of these deaths on Feb. 1, 1993." In the June 17 issue of **The Cancer Letter**, in a story on the Div. of Cancer Etiology Board of Scientific Counselors meeting, the cohort mortality study with nested case control study of lung cancer and diesel exhaust among miners, was incorrectly listed as being approved. The concept was deferred.

# In Aftermath Of OIG Report, Pasteur Seeks More Royalties

(Continued from page 1)

cases when an investigation does not result in criminal proceedings.

Over the past nine years, repeated investigations of Gallo, chief of the NCI Laboratory of Tumor Cell Biology, and Popovic, who worked under Gallo, failed to demonstrate misappropriation of the virus. Two US Attorney's offices separately declined to prosecute the two scientists.

**Consequences Of Memorandum**

Since its completion, the memorandum, classified "for official use only" and not intended for release, appears to have had consequences on three fronts:

•NIH Director Harold Varmus appears to have changed his stance on the royalties issue. In a June 8 letter to an official of the Institute Pasteur, Varmus maintained that no change in the US-French agreement was warranted. Varmus had not read the report prior to writing the letter, sources said. In a June 23 letter to the same official, Varmus agreed to reopen discussions (see story, page 7).

•The report was issued one month prior to a scheduled meeting July 11 in Washington of the trustees of World AIDS Foundation. The foundation was formed after the 1987 US-French agreement to split the royalties from the AIDS blood test. As a result of the OIG memorandum, Institut Pasteur trustees are expected to put a motion before the board to reallocate the US share of royalties to the French, sources said. The foundation's board consists of four French representatives and four US representatives, one of whom is Gallo. Six votes are required to pass a motion.

•Institut Pasteur is considering an aggressive challenge to the 1987 agreement.

James Swire, of the New York law firm Townley & Updike, said to **The Cancer Letter** that Pasteur officials asked him to draft a complaint, which, Swire said, the firm has completed and sent to Paris for approval. Swire declined to discuss the content of the proposed complaint.

However, sources said that to attack the settlement agreement directly, the institute would have to demonstrate that the agreement was based on fraudulent information and therefore cannot be regarded as a valid contract.

**Dingell Report Expected Next Month**

In August, the Subcommittee on Oversight and Investigations of the House Committee on Energy and Commerce is expected to issue a report on the subcommittee's three-year investigation of Gallo and Popovic, sources said. The subcommittee is chaired by Rep. John Dingell (D-MI).

In a related development, Dingell's subcommittee recently discovered NIH documents that had never been provided to investigators, sources said. The documents were held at the NIH Freedom of Information Office.

The newly-found materials include correspondence between Gallo and HIV geneticist Gerald Myers of the Los Alamos National Laboratory concerning the characteristics of the virus discovered by Gallo and the French.

The documents indicate that in early 1989, Gallo, in an statement to have been included in a monograph, acknowledged that the French and American AIDS viruses were the same. In the statement, which was ultimately withdrawn from the monograph, Gallo attributed the identical nature of the viruses to a contamination in his laboratory of his virus, HTLV-IIIb, with the French virus, LAV.

Documents expected to be cited by Dingell's subcommittee in its report indicate that Gallo continued to tell federal investigators in 1990 that the question of whether such a contamination had occurred remained open.

**Origin of HTLV-IIIb**

The origin of Gallo's HTLV-IIIb virus, which Gallo identified as the cause of AIDS in 1984, is the central issue in the OIG report.

**THE CANCER LETTER**

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Gallo and Popovic have said they pooled AIDS viruses from 10 patient samples in an attempt to grow the virus. Later, it was discovered that HTLV-IIIb was identical to LAV, the first AIDS virus isolate discovered by Luc Montagnier and colleagues at the Institut Pasteur.

Gallo maintained that contamination, not misappropriation, was the most likely explanation.

The OIG report is "riddled with errors" and contains no new information, Joseph Onek, Gallo's attorney, said to **The Cancer Letter**. "It has been known for some time that HTLV-IIIb was really LAV-LAI." LAI are the initials for the individual from whom the LAV isolate was obtained.

The origin of the virus is not a patent issue, Onek said. "We didn't patent a virus, we patented a method for growing the virus and we patented a method for making the blood test," he said. Onek sent a six-page letter dated June 23 to Inspector General June Gibbs Brown objecting to the report.

The OIG report makes few direct accusations and contains neither recommendations nor conclusions. However, in a chronology of events and a compilation of materials based on previous investigations, the report makes the following allegations:

●In their patent application for the AIDS blood test, Gallo and Popovic failed to disclose the work of the Institut Pasteur scientists with LAV, and the LAV blood test the Pasteur scientists developed.

Pasteur scientists filed for a British patent for their AIDS blood test months before Gallo filed, the report said. Disclosure of a "prior art" is required under patent law, the report said.

According to Onek's letter, Pasteur scientists had "failed to demonstrate to the scientific community that a new retrovirus was the cause of AIDS" at the time Gallo applied for the patent. The French test at that time scored positive with fewer than 20 percent of AIDS patients, while Gallo's test scored positive with about 85 percent of AIDS patients, Onek wrote.

According to the OIG report, prior to filing the patent application, Gallo was given information from the Centers for Disease Control demonstrating that the Pasteur blood test performed as well as the Gallo blood test. The CDC data were not provided to the patent office, the report said.

At a meeting in Paris in April 1984, Gallo was shown a comparison of the blood test data, the report said. Gallo later told investigators he never saw the Pasteur data.

●Gallo and Popovic may not have performed the pool experiment. "There is reason to doubt that the 'pool' experiment, as described by Gallo/Popovic, really was done, or if done, that it ever produced anything other than LAV/LAI," the OIG report said.

According to the report, a Roche Laboratories study found that four of the 10 samples the scientists said they put in the pool, which were to have been selected for the presence of HIV, contained no virus.

Gallo and Popovic said the samples were tested and found RT positive, an indication of the presence of retrovirus. However, according to evidence presented by the Office of Research Integrity, many of the samples were contaminated with mold, and "for one sample, there was no indication a viable culture was present in the laboratory at the time it allegedly was used."

According to Onek, the Roche Laboratories study found that at least six of the samples Popovic put in the pool were independent of LAV. Any of these isolates could have started the virus growing, he said.

There was no reason for Gallo to appropriate the French virus, Onek said. Popovic preferred to use the isolate RF for the blood test, Onek said. However, Gallo pressed for the pool because RF was several weeks behind.

According to the OIG report, "there is no evidence there ever was a IIIb isolate independent of LAV. There are no laboratory data showing the independent existence of a pool isolate, and, there is no sample of the pool in the LTCB freezers, although samples of all 10 putative constituent samples were found.

"Every IIIb sample sequenced by Roche Laboratories was found to be LAV/LAI, except for the earliest sample, one dating from February 1984. This sample was found to contain no virus at all," the report said.

"Therefore, the claim that IIIb was contaminated by LAV comes into question since there appears to be no evidence there ever was a IIIb to be contaminated," the report said.

●Gallo and Popovic used an isolate called MOV, a renaming of LAV, to perform the initial experiments on their AIDS antibody blood test.

Onek characterized this contention is "a deliberate misreading" of Popovic's laboratory notes. LAV and MOV were separately described by Popovic in a series of reports, Onek said. Popovic did not know the two were the same, the letter said.

The existence of MOV was unknown until the Office of Scientific Integrity investigation in 1991, the OIG report said. "Gallo/Popovic told OSI that MOV probably originated with patient HM," the report said. "However, the Roche analysis found no virus in a sample taken from patient HM, and the LTCB's recrods show that HM samples and culture were negative in subsequent tests for the presence of virus."

●Gallo and Popovic knew that LAV was identical to HTLV-III prior to the submission of their key paper to Science in 1984.

"In April 1984, there was no way that Dr. Gallo or any other scientist could know whether LAV and HTLV-III isolates were the same," Onek wrote. "There were many apparent differences between LAV and the HTLV-III isolates." These included the percentage of AIDS patients reacting positively to the viruses, and whether the viruses contained the gp41 protein, he wrote.

According to the OIG report, Gallo testified to OSI that "the same virus type was suspected, I would say, by the early part of 1984."

In March 1984, Gallo lectured in Europe, and repeatedly asserted that his virus was very similar to the French virus, the OIG report said.

**Years Of Investigations**

Separate panels have come to different conclusions about whether the Gallo and Popovic committed scientific misconduct in their use of the French AIDS virus.

The NIH Office of Scientific Integrity (now the HHS Office of Research Integrity) did not find Gallo guilty of misconduct in an April 1992 final report on its investigation. The OSI report said Gallo had misstated the ability of his laboratory to grow the French virus, did not place enough effort on determining the origin of a key cell line, and placed severe restrictions on groups that wanted to use his materials. The report did find Popovic had committed misconduct in falsifying results in the key 1984 Science paper.

The Richards panel, a committee named by the National Academy of Sciences to oversee the investigation, criticized the OSI report and charged Gallo with "intellectual appropriation" of the French virus.

In December 1992, the ORI reviewed the OSI report and found Gallo guilty of misconduct for editing the Popovic paper to say that LAV was not grown in a permanent cell line.

In June 1993, the HHS Departmental Appeals Board, Research Integrity Adjudications Panel exonerated Popovic of all misconduct charges, saying that ORI had not proved its case. Last November, the ORI then withdrew its charges against Gallo.

Last January, the US Attorney in Baltimore declined to prosecute Gallo and Popovic for false statements, obstruction or mail fraud, among other charges. The US Attorney for the District of Columbia had declined prosecution in October 1991.

**Gallo Searching for New Job**

**The Cancer Letter** has learned that in recent months Gallo has been looking for a university position and has held discussions with at least four institutions.

One of the four, the Medical Univ. of South Carolina, is actively courting Gallo, according to a June 14 story in the Charleston Post and Courier.

Gallo has visited MUSC for medical symposia three times in the past year, the article said. The story quoted MUSC President James Edwards saying he would "like very much" for Gallo to work there.

"He is the greatest researcher alive today," Edwards was quoted saying. "I would like him to be working in our lab when he gets the Nobel laureate."

Peter Fischinger, director of the university's Hollings Cancer Center and chairman of the Dept. of Experimental Oncology, said to **The Cancer Letter** that Gallo "has been exploring options" and has held talks with the university. However, Fischinger said there was "really nothing substantive" to the discussions at this point.

Fischinger, a former deputy director at NCI, last year hired Takis Papas, chief of the Laboratory of Molecular Oncology, in NCI's Div. of Cancer Etiology, to direct the Center for Molecular and Structural Biology at Hollings.

NCI spends about $7 million a year on Gallo's laboratory, sources said. Funding would be a major obstacle, Fischinger said.

"We would have a difficult time trying to absorb an operation like Bob's, however, we certainly are interested," Fischinger said to **The Cancer Letter**. "We already absorbed Takis Papas. The upfront investment has to be large before you can hope to get grant funding."

Attorney Onek confrimed that Gallo "is talking

to people" about leaving NIH, but said the talks were not prompted by the issuance of the OIG report.

## Gallo AIDS Virus Research As Told By Inspector General

*The June 10 investigative memorandum issued by the HHS Office of Inspector General contained a chronology of events in the dispute over the AIDS virus. Following are excerpts of the chronology.*

May 20, 1983: Luc Montagnier and colleagues at Institut Pasteur publish their first paper on the virus LAV, later identified as the cause of AIDS (Science, 220, 1983).

July 1983: Gallo's laboratory receives first shipment of LAV from the Institut Pasteur.

Sept. 14, 1983: Montagnier presentation at Cold Spring Harbor reports additional isolates of LAV, and first data on use of LAV in a blood test to detect virus antibodies in AIDS and pre-AIDS patients. Gallo was present at this meeting.

Sept. 15, 1983: Pasteur scientists file a British application for a patent on their virus antibody blood test.

Sept. 22, 1983: Pasteur scientists send Gallo two additional samples of LAV, one of which is LAV/LAI. Popovic signs a transfer agreement that the virus "will not be used for any industrial purpose without the prior written consent of the Director of the Pasteur Institut."

Oct. 20, 1983: Popovic instructs a technician to use one of the LAV samples (LAV/LAI) in an attempt to grow the AIDS virus in permanent cell lines. The experiment results in two permanent virus-producing lines, HUT 78/LAV and Ti7.4/LAV.

Nov. 15, 1983: Popovic starts his virus pool experiment.

Nov. 22, 1983: Popovic's laboratory notes show the HUT 78/LAV and Ti7.4/LAV cell lines are renamed MOV.

Dec. 5, 1983: Pasteur scientists file a US patent application for a patent on the LAV antibody blood test.

Jan. 13, 1984: Gallo implies that he has the two LAV cell lines frozen.

Jan. 19, 1984: Popovic clones the HUT 78 cell line and produces the clone H9.

Jan./Feb. 1984: Popovic reportedly infects H9 with the pool virus, HTLV-IIIb. In 1991, several H9 samples were analyzed and were found to be LAV/LAI. No sample of IIIb independent of LAV has been found, the report said.

March 12, 1984: Gallo meets with James Curran of the Center for Disease Control. Current tells Gallo that CDC scientists found that the Gallo and Pasteur blood tests are compatible.

March 30, 1994: Gallo submits four papers to Science reporting his lab's discovery of the AIDS virus and development of a blood test.

According to the report, Gallo rewrote one of the papers, by Popovic, over Popovic's objections. Gallo deleted Popovic's description of LAV as "HTLV-III" along with the description of the use of LAV as a "reference virus" in Popovic's early experiments. Popovic gives drafts of the paper to his sister in Czechoslovakia because he believed he might later have to prove he tried to give fair credit to the Pasteur scientists. Gallo also added to the paper the assertion that LAV had not been grown in a permanent cell line and suggests at the conclusion of the paper that HTLV-III and LAV may be different.

April 1984: Malcolm Martin from NIH and Murray Gardner, Univ. of California at Davis, both independently receive samples of LAV directly from Pasteur scientists.

April 23, 1984: HHS press conference announcing Gallo's discovery of the AIDS virus, the method to grow the virus, and the development of a blood test. Gallo submits two US patent applications.

May 1984: The four Gallo and Popovic papers are published in Science.

May 15, 1984: HTLV-IIIb in the H9 cell line is taken to Paris for comparison studies.

June/July 1984: Gallo's lab compares Ti7.4/LAV with IIIb and finds they are identical. Gallo repeatedly asserts that he could not grow the LAV samples he received in 1983.

July 15, 1984: Montagnier sends Gallo another LAV sample, this one in the B cell line.

August 1984: Gallo telephones Montagnier to tell him he has compared B/LAV with HTLV-IIIb and found they are genetically identical. Gallo also says he compared "original LAV" with IIIb and found they were different, thus Montagnier must have contaminated his LAV cell lines with IIIb sent to him in May.

Montagnier rejects Gallo's charge, but Gallo repeats it in a telephone call to NCI Associate Director Peter Fischinger and later in a memorandum to NCI Director Vincent De Vita dated Aug. 24, 1984.

Fall 1984: Gallo delays a manuscript by Gardner et al. that reports LAV and HTLV-IIIb are genetically identical while a third HIV isolate, ARV, is clearly different.

May 29, 1985: Gallo awarded US patent on blood test. Montagnier patent remains pending.

Aug. 6, 1985: Pasteur representatives meet with HHS officials, charging that IIIb is actually LAV and threaten litigation unless they are given equal credit and share of the blood test royalties.

Aug. 27, 1985: Fischinger completes an investigation of Gallo's claims, with input from Gallo and Popovic. His report concludes that, "There is no evidence that material from any outside laboratory, including the French, was used in generating the HTLV-IIIb virus."

Sept. 11-18, 1985: Malcolm Martin writes a memo to HHS recounting experiments he performed with LAV showing that LAV was identical to IIIb. Gallo discounts Martin's data and states he has other pairs of independent isolates more alike that LAV and IIIb. In 1990, Gallo tells the Office of Scientific Integrity that Martin's data convinced him he must have contaminated his cell lines with LAV.

Dec. 1985: Institut Pasteur files a civil suit charging breach of contract.

April 27, 1986: US Patent and Trademark Office declares an "interference" between the Gallo blood test and the Pasteur blood test.

Nov. 8, 1986: Gallo signs a sworn declaration before the PTO concerning his use of LAV. Gallo says Popovic succeeded in "temporarily transmitting" the Pasteur virus to two permanent cell lines, but that "both transmissions were only temporary in nature." Gallo states further: "at the time the Gallo patent was filed my colleagues and I did not consider LAV and HTLV-III to be the same, or even substantially the same virus."

March 30, 1987: President Ronald Reagan and French Prime Minister Jacques Chirac sign a settlement agreement, ending the patent dispute. Gallo and Pasteur scientists are awarded joint inventorship.

Nov. 19, 1989: The Chicago Tribune publishes John Crewdson's 16-page article on Gallo's research.

Feb. 1990: The NIH Office of Scientific Integrity begins inquiry into issues raised in the Tribune story.

April 8, 1990: Gallo tells OSI that the growth of the Pasteur virus was "significant and continuous."

May 16, 1990: Gallo tells OSI that "there has been confusion in the response of what we did to LAV. In my response during the passionate period ... 'oh we never grew LAV' and of course we did grow LAV." In a followup interview, Gallo tells OSI, "there is a point where I say I didn't grow LAV. And, of course, LAV was grown... Quite frankly, it wasn't so germane to me at the time and I was just anguished as to what was coming out of the newspaper. At that moment bombs were going off."

May 17, 1991: Pasteur scientists publish a paper in Science in which the authors state they prove the origin of IIIb is LAV/LAI.

May 30, 1991: In a letter to Nature, Gallo concedes that HTLV-IIIb is LAV/LAI. He claims this is due to an "accidental contamination."

June 1991: OSI issues a draft report that finds Popovic guilty of scientific misconduct and said Gallo's actions "warrant significant censure."

Oct. 1991: US Attorney for the District of Columbia declines prosecution based on reasons of insufficient evidence of credible fraud, the technical complexity of the issues and the fact the alleged falsifications in the May 1984 Science article are immaterial.

April 1992: OSI issues a final report. Popovic is still found to have committed scientific misconduct, but the number and seriousness of the charges are reduced and significant censure of Gallo has been eliminated.

June 1992: Chicago patent law firm Allegretti and Witcoff commissioned by HHS completes a review of the French patent claims. They find no evidence to support allegations of false statements in the patent application and no intent by Gallo to act inequitably.

Dec. 1992: PHS Office of Research Integrity completes review of OSI report. Findings with respect to Popovic remain; however, Gallo is now also found guilty of scientific misconduct for saying in the Popovic paper that LAV was not grown in a permanent cell line.

June 3, 1993: Results of the Roche Laboratory studies commissioned by OSI are published in Nature. Results show that MOV and HTLV-IIIb are LAV/LAI; four of the 10 alleged pool samples did not contain any AIDS virus; and none of the 10 samples contained LAV/LAI.

June 1993: HHS Departmental Appeals Board, Research Integrity Adjudications Panel hears 12 days of testimony in Popovic's appeal to the ORI findings of scientific misconduct.

Nov. 3, 1993: The board exonerates Popovic of all misconduct charges, stating that ORI was unable

to prove that Popovic is guilty of scientific misconduct. ORI subsequently withdraws all charges against Gallo.

Jan. 1994: US Attorney for the District of Maryland in Baltimore declines to prosecute Gallo and Popovic for, among other things, false statements, obstruction and mail fraud.

## Varmus, In Letter To Pasteur, Reopens Discussion Of Claim

HHS officials last week agreed to reopen discussion of a claim by the Institut Pasteur that it is entitled to a greater share of royalties from the AIDS blood test.

In a letter dated June 23 and addressed to Maxime Schwartz, director general of the Institut Pasteur, NIH Director Harold Varmus wrote that HHS General Counsel Harriet Rabb would be willing to meet with lawyers for the Paris-based institute.

In addition, Varmus said HHS would be willing to consider making a statement acknowledging the use of the AIDS virus discovered by Pasteur scientists in developing the American blood test kit.

The letter appears to represent a dramatic turnaround for Varmus and HHS. On June 8, in another letter to Schwartz, Varmus maintained that "no alteration in our shared royalty arrangement is warranted."

During the two weeks that elapsed between the two letters, the HHS Office of Inspector General issued a memorandum summarizing its investigation of the use of the French virus by NCI scientist Robert Gallo. Several observers at NIH and on Capitol Hill said the report appeared to have caused Varmus to modify his stance on royalties.

Under a 1987 agreement that settled a suit brought by the Institut Pasteur against HHS, France and the US agreed to a split of the royalties from the blood test. The distribution is set by the World AIDS Foundation.

The foundation is governed by a board of directors made up of four representatives from each country.

That arrangement notwithstanding, for the past eight years, Institut Pasteur officials persisted in their claims that Gallo, chief of the Laboratory of Tumor Cell Biology, used the AIDS virus discovered by Luc Montagnier, a Pasteur scientist, to develop the AIDS blood test.

Sources said the June 8 letter was written before Varmus had read the "investigative memorandum" by the HHS Office of Inspector General.

In that letter, Varmus wrote that he and Assistant Secretary for Health Philip Lee had reviewed the French claims and concluded that "the current arrangement should be maintained."

"The key facts are that a French virus was used by the American scientists who developed the test kit, and that the American scientists developed and patented that test kit invention," Varmus continued.

"Each contribution was necessary to the final result. I share your sense that the acknowledgment of the role of the Institut Pasteur in isolating the AIDS-causing virus was very slow to occur, causing much frustrating litigation and other unproductive activity. I am deeply sorry that those events occurred. I also recognize the contribution of the scientists at the National Institutes of Health, without which the test kit would not have been developed when and how it was. Both hands, as it were, were necessary to grip the problem. Talent and hard work on both sides were indispensable to the solution.

"The distribution of our shared royalties under the 1987 agreement reflects both the French and American contributions. Cumulatively through 1993, the US side generated $36.8 million in royalty payments and the French side, $5.7 million."

After the 1987 settlement, the US received $20.1 million, the Institut Pasteur $13.9 million, and the World AIDS Foundation, $8.5 million.

"Stated otherwise, the United States generated 87 percent of the total royalties; France, 13 percent. After distribution, the United States received 47 percent while the Institut Pasteur received 33 percent of the final disbursements."

"Your letters to me suggest the need to bring closure to this matter so that we put the conflict behind our institutions and continue the productive collaboration that we have otherwise enjoyed. I quite agree.

"It now appears to me that no resolution is possible unless you and I and our colleagues resolve to put the matter behind us and commit to our future work," Varmus wrote.

**Damage to Cooperation**

In a response dated June 13, Schwartz wrote that evidence that has emerged in recent years necessitates a renegotiation of the royalty split.

"Unless we can find a way to change the present situation in such a way that there would be no penalty

for having shared information and strains, I am afraid that the cooperation which has existed between our two institutions, and more generally between scientists, will be greatly damaged," Schwartz wrote.

"We settled in 1987 for one simple reason: senior officials of the Reagan Administration repeatedly told us that there were two viruses; they told us that there was not a single document in their files which could remotely be construed as supporting the position that they used our virus," Schwartz wrote. "Therefore, the settlement and the sharing of royalties were based on the assumption that there were two viruses, but that the Institut Pasteur isolated its virus first.

"Documents later released, as well as Dr. Gallo's own subsequent statements, indicated that a cover-up of the true facts was deliberately undertaken so that we would settle, and new experiments have shown that the virus 'isolated' by Dr. Gallo was in fact the virus sent by the Institut Pasteur. You cannot now tell us that we must abide by a sharing of royalties based on what would appear as a previous Administration's deliberate fabrication, and on an assumption that later proved incorrect."

A "solution" can be found that does not involve renegotiation of the 1987 agreement, Schwartz wrote. "A simple motion" of the AIDS Foundation board "is all that is required to reallocate royalties," Schwartz wrote.

"Institut Pasteur cannot accept to just forget the issue," Schwartz wrote. "This matter will not die.... It is still our hope that it can be done amicably, and in a reasonable and quiet way."

**NIH Open To Acknowledgment**

In his June 23 response to Schwartz, Varmus said the HHS General Counsel would meet with Pasteur lawyers.

"Were I to be persuaded that a change in our current arrangement for distribution of royalties is warranted, I would surely take steps to see that a change is made," Varmus wrote.

Varmus invited the Pasteur lawyers to send HHS a proposal for a formal recognition of the role of the French virus.

"When we last spoke, you reiterated your wish for an acknowledgment from me appropriate to the current state of knowledge: that the French virus was used by National Institutes of Health scientists in developing the American test kit," Varmus wrote. "I am entirely open to taking steps that appropriately accomplish that goal."

Varmus took issue with Schwartz's statement that the US made a deliberate attempt to cover up Gallo's use of the French virus. "Neither the US Attorney nor the Inspector General has established the deliberateness that you assume," Varmus wrote. "None of the forums in which your cases were pending ever made a finding of deliberate misconduct by the government."

The World AIDS Foundation is scheduled to meet July 11.

## RFA Available: Breast SPORE

**RFA CA-94-027**

Title: **Specialized Programs Of Research Excellence In Breast Cancer**

Letter of Intent Receipt Date: July 29

Application Receipt Date: October 25

The Organ Systems Coordinating Branch of the NCI Div. of Cancer Biology, Diagnosis and Centers invites grant applications for Specialized Programs of Research Excellence in Breast Cancer. The intent of this initiative is to expand the Breast Cancer SPOREs from the current four to a minimum of five SPOREs through open competition by making awards to those institutions that can conduct the highest quality balanced translational research approaches on the prevention, etiology, screening, diagnosis, and treatment of breast cancer. SPOREs are at institutions that have made or will make a strong institutional commitment to the organization and conduct of these programs.

Applications may be submitted by domestic for-profit and non-profit organizations. To be eligible, applicant organizations must have (1) a minimum of three independent investigators who are successful in obtaining peer-reviewed research support directly related to breast cancer, and who together represent experience in both laboratory and clinical research, or in the alternate, a minimum of three independent investigators, each having published articles that significantly address breast cancer in peer-reviewed research journals, and who, as a group, represent experience in both laboratory and clinical research; (2) access to a patient care and service facility that serves breast cancer patients and, if the facility is not part of the parent institution, a statement that assures access to breast cancer patients for clinical research; (3) although applications must be submitted from a single institution, they may include subcontracted collaborative scientific arrangements with scientists from other institutions.

The total project period for renewal SPORE applications may not exceed five years; new applicants or applicants that have received P20 SPORE feasibility awards may request up to three years of support. All new and competing renewal P50 SPORE applications may request a maximum annual direct cost of $1.5 million and maximum annual total cost of $2.5 million per individual SPORE. NCI anticipates making at least five awards and anticipates setting aside $2.5 million per award or $12.5 million total for the initial year's funding.

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