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INVESTIGATIVE MEMORANDUM

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ALLEGED SCIENTIFIC FRAUD
FRAUD AGAINST THE GOVERNMENT
FALSE STATEMENTS
FILE NUMBER: W-90-00066-4

This is the closing Investigative Memorandum (IM).

This matter was initially closed on February 11, 1991 and reopened with an IM dated October 25, 1991. This reopening was based upon contact the Subcommittee on Oversight and Investigations had with a whistleblower/source who believed there still to be unresolved false statements in Dr. Gallo's November 8, 1986 Patent Declaration. The Subcommittee contacted the Office of Inspector General (OIG) and investigation was reinitiated.

On April 23, 1984, the United States Department of Health and Human Services (HHS) held a press conference for the international news media to announce a series of discoveries by Dr. Robert Gallo and his associates at the Laboratory of Tumor Cell Biology (LTCB), National Cancer Institutes (NCI), National Institutes of Health (NIH). Among the accomplishments announced on this occasion were the following:

- o the discovery of the AIDS virus, which Gallo called "HTLV-III";
- o the development of a method to mass produce the virus; and
- o the development of a virus antibody blood test.

The same day as the HHS conference, Gallo and his associates filed United States patent applications for the virus antibody blood test and the method by which they grew the virus in quantity. In the May 1984 journal Science, Gallo and his associates at the LTCB published their first papers on the AIDS virus.

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In the Gallo et al. patent applications, Gallo and his fellow-inventors were under a sworn duty of disclosure concerning work that might be considered prior art to their own. The only apparent reference they made to the work of the Institut Pasteur (IP) scientists was mention of "another retrovirus" among a number of different viruses occasionally found in AIDS patients, but not etiologically related to the diseases.

Subsequent to the HHS press conference, questions began to arise concerning the validity of Gallo's claims. The IP filed a civil suit and an interference proceeding was declared. After several months of intense negotiation, a settlement was signed by representatives of the French and U.S. Governments and all related legal proceedings were dropped. The agreement allowed for a joint patent and a sharing of royalties to be awarded to both the IP and American scientists. This agreement remains in force today.

From November 1991 to January 1994, the Washington Field Office, Office of Inspector General (OIG), conducted an investigation to determine if any statements made by Dr. Gallo in his patent application of April 1984 and his November 1986 declaration, filed in connection with the interference proceeding, were false. Both documents signed by Gallo were subject to Title 18 USC Section 1001 (False Statements). The initial patent applications were for a blood diagnostic test kit for AIDS and the method for growing the virus used in the test kit. The controversy that arose between the French scientists at the IP, and American scientists under the direction of Dr. Gallo at the National Institutes of Health (NIH), National Cancer Institute (NCI), Laboratory of Tumor Cell Biology (LTCB), was over whose HIV virus was utilized. The French IP virus is called "LAV", for lymphadenopathy-associated virus and is of the lenti-virus family. Gallo's candidate was referred to as a HTLV, for Human T-Cell Leukemia Virus, and HTLV-III is what Gallo called the AIDS virus until it was universally referred to as HIV. At issue was what Dr. Gallo knew and when he knew about the true identity of his own virus and that of the IP. Dr. Mikulas Popovic was Gallo's key associate at the LTCB. He worked directly with the virus and performed the seminal experiments. An early attempt to interview Dr. Popovic through his attorneys was declined.

The IG investigation included over 50 interviews of former and current Government employees from the Departments of Commerce, Justice, and Health and Human Services (HHS), including attorneys, research physicians/practitioners and investigators in

the private and public sector. The investigation involved detailed analysis of a substantial quantity of documentary evidence dating from 1983. Two IG subpoenas were issued, and forensic analyses of key documents were performed by the Forensic Services Division of the United States Secret Service. In addition, the IG was given access to several interviews conducted by the General Accounting Office (GAO), as part of their parallel investigation.

The following is a chronology of events as they relate to this HIV blood test patent dispute, compiled from numerous interviews, the review of documents, laboratory notebooks and correspondence, published scientific articles and from testimony before the National Institutes of Health (NIH) Office of Scientific Integrity (OSI) and Health and Human Services (HHS) Departmental Appeals Board hearings. The chronology is being provided to bring focus to those statements made or actions taken by Dr. Gallo as they relate to the allegations and investigation conducted by the OIG.

CHRONOLOGY

May 20, 1983: Dr. Luc Montagnier and his colleagues at France's Institut Pasteur (IP) publish their first scientific paper on the virus that will later be identified as the cause of AIDS: HIV/LAV (Barre-Sinoussi et al., Science, 220, 1983).

The published version of the Barre-Sinoussi et al paper reflected edits made by Dr. Robert C. Gallo and also included an abstract for the paper, written by Dr. Robert Gallo. These edits appear to portray the French virus as a member of the "HTLV" family of viruses (defined by Gallo as "Human T-Cell Leukemia Viruses and therefore, related to the Leukemia virus "HTLV-I).

July 18, 1983: Dr. Montagnier visits the NIH and lectures on the IP virus, now called "LAV," for "lymphadenopathy-associated virus." Montagnier reports several new isolates of the virus, along with data on its characterization and electron micrographs of its morphology.

July 1983: Gallo and his Laboratory of Tumor Cell Biology (LTCB) receive the first shipment of LAV from the IP. These reagents are used in experiments at Gallo's Laboratory by early October 1983.

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

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

September 22, 1983: The IP scientists send Gallo et al two additional samples of LAV virus, one of which is LAV/LAI, the IP's prototype HIV isolate. Dr. Mikulas Popovic, the chief scientist working on the AIDS virus at the LTCB, signs a transfer agreement upon receipt of the LAV samples; the form includes the following non-commercialization provision in restricting use of the LAV virus: "It will not be used for any industrial purpose without the prior written consent of the Director of the Pasteur Institut."

October 20, 1983: Dr. Popovic instructs his technician to use one of the September LAV samples (LAV/LAI) in an attempt to grow the AIDS virus in permanent cell lines. The experiment is carried out the next day, and results in two permanent, productively-infected virus producing lines -- HUT 78/LAV and Ti7.4/LAV.

November 15, 1983: Popovic starts his virus "pool" experiment, the experiment that allegedly resulted in the "isolation" of "HTLV-IIIb," Gallo's prototype HIV isolate (confirmed in 1991 to be LAV/LAI -- see June 3, 1993 below).

November 22, 1983: Popovic's laboratory notes show the HUT-78/LAV and Ti7.4/LAV cell lines are renamed "MOV" on this date (in 1991, samples identified as "MOV" are proven to be LAV/LAI -- see June 3, 1993 below).

December 5, 1983: The Institut Pasteur (IP) scientists submit a patent application to the U.S. Patent Trademark Office (PTO) for a patent on their LAV antibody blood test.

January 13, 1984: Gallo implies he has the two LAV cell lines (HUT-78 and Ti7.4) frozen on this date.

January 19, 1984: Popovic clones the HUT-78 cell line (now renamed "HT") and produces the clone "H9."

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Late January/Early February 1984: Popovic reportedly infects H9 with the "pool" virus, HTLV-IIIb. It should be noted that in 1991, several H9/IIIb samples were analyzed, all dating from 1984. All such samples were found to be LAV/LAI. No sample of "IIIb" independent of LAV has been found.

March 12, 1984: Gallo meets with Dr. James Curran of the HHS Centers for Disease Control (CDC). Curran advises Gallo that, based on comparative serology studies recently completed by the CDC scientists, the LTCB and IP antibody blood tests are compatible and in concordance in detecting the presence of antibodies to the suspected AIDS virus in AIDS and pre-AIDS patients.

March 30, 1984: Gallo and his associates submit four papers to Science (May 1984), reporting the LTCB's discovery of the AIDS virus and development of an antibody blood test.

Gallo extensively rewrote one of the four Science papers, i.e., the paper by Popovic et al., over Popovic's objections. In the process, 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. In striking Popovic's statements regarding the use of LAV, Gallo writes in the margins of the draft, "Mika you are crazy. I just don't believe it and you are absolutely incredible." Popovic gives the drafts of this paper that bear Gallo's notations to his (Popovic's) 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 5/6, 1984: Gallo travels in Europe, stating at a meeting in Zurich he has heard the IP blood test data are "almost as good as we have." The following day, Gallo travels to the IP, where he sees the computer print-out of the CDC data, and where he gives a talk announcing the discovery of HTLV-III, which Gallo says is "the same virus these guys (IP) discovered last year."

Early-to-Mid April 1984: Drs. Malcolm Martin from NIH and Murray Gardner, at the University of California at Davis both independently receive samples of LAV directly from IP scientists. At this point, no HTLV-IIIb samples had been sent from the LTCB to Paris. The significance of these events would become apparent later, when Gallo accuses Montagnier of contaminating LAV with HTLV-IIIb. (See May 15 and August 1984 below and Dr. Gardner OI-3).

April 23, 1984: HHS holds a press conference for the international media to announce Gallo's "discovery" of the AIDS virus, the discovery of a method to grow the virus, and the development of an HIV antibody blood test. This same day, Gallo et al. submit two U.S. patent applications, one for the blood test, one for the method of growing the virus.

In the sworn application for the blood test patent, Gallo and his associates claimed to be ". . . the original, first and joint inventors of the subject matter which is claimed and for which a patent is sought . . ." The application also included an acknowledgement of the applicants ". . . duty to disclose information which is material to the examination of this application in accordance with Title 37, CFR § 1.56(a)."

May 1984: The four papers written by Gallo and his associates, including the Popovic et al. paper, are published in the May 1984 journal Science (see March 30, 1984).

May 15, 1984: Dr. M. Sarngadharan from NIH takes the first sample of HTLV-IIIb in the H9 producing cell line to Paris for comparison studies.

May 15, 1984: CDC scientists Drs. Frederick Murphy and James Curran sign restrictive transfer forms for receipt of HTLV-IIIb as a condition for receipt of the virus. The forms prohibit any comparison experiments using the HTLV-IIIb sample and require presubmission approval by Gallo of any manuscripts resulting from research using the IIIb sample.

June/July 1984: LTCB scientists compare Ti7.4/LAV (received the previous September) with IIIb and find they are identical. Gallo repeatedly asserts that he could not grow the LAV samples he received in 1983.

July 15, 1984: After numerous requests from Gallo, Montagnier sends the LTCB another sample of LAV, this one in the "B" cell line ("B/LAV").

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 HTLV-IIIb and found they were different, ergo, Montagnier must have contaminated his LAV cell lines with the IIIb sent to him in May of 1984. Montagnier adamantly rejects Gallo's charge, but Gallo repeats it in a telephone conversation to NCI Associate Director Dr. Peter Fischinger and later in a memorandum to NCI Director Dr. Vincent DeVita dated August 24, 1984. (The date of the Gallo telephone call to Montagnier is an approximation.)

Fall 1984: Gallo delays the Bryant et al. manuscript that reports LAV and HTLV-IIIb are genetically "identical," while a third HIV isolate, ARV is clearly different (Detailed in OI-3 interviews of Drs. Cardiff, Pedersen, Gardner, Bryant, Yamamoto and Gross).

May 29, 1985: Gallo et al. are awarded a U.S. patent on their HIV antibody blood test. At the time the Gallo et al. patent issues, the Montagnier et al. patent application submitted in December 1983, remains pending.

August 6, 1985: Representatives of the IP meet with HHS officials, in a meeting chaired by Dr. Lowell Harmison, Science Advisor to the Assistant Secretary for Health. The IP representatives charge that Gallo's putative "IIIb" prototype virus actually is LAV, and threaten litigation unless they are given at least equal credit and a corresponding share of the blood test royalties.

August 27, 1985: Acting at the direction of Dr. Harmison, NCI Associate Director Dr. Peter Fischinger completes a three week investigation of Gallo's claims. With input from Gallo and Popovic, a report is written, the conclusion of which is that, "There is no evidence that material from any outside laboratory, including the French, was used in generating the HTLV-IIIb virus . . . Dr. Gallo and his laboratory were the first to identify the virus and to describe the virus antibody test . . ."

September 11-18, 1985: In response to a request from Dr. Harmison, Dr. Malcolm Martin writes a memorandum recounting experiments he performed with the LAV sample he received in April 1984 that showed LAV was genetically identical with Gallo's claimed prototype isolate, HTLV-IIIb. Gallo discounts Martin's data and states he has other pairs of independent isolates more alike than LAV and IIIb. In 1990, Gallo tells OSI that Martin's data convinced him he must have contaminated his cell lines with LAV.

November/December 1985: Informal negotiations between IP and HHS attorneys are attempted, but soon break down. The IP attorneys seek LTCB records showing the growth of LAV at the LTCB. (See Swire OI-3 interview.)

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December 12, 1985: The IP files a civil suit in U.S. Court of Claims, charging breach of contract.

January 13, 1986: U.S. News & World Report prints that Gallo called the charge of possible contamination of his cultures with LAV "the height of outrage." Gallo is quoted as saying "it was physically impossible" to grow LAV at the LTCB and therefore could not have contaminated the LTCB's virus cultures.

April 12, 1986: Gallo tells the New York Times that he had grown LAV in a permanent cell line, but only briefly. The article reported ". . . Dr. Gallo said that his lab had been able to infect human cells with the virus sample received from France only transiently." Gallo further tells the journal Nature (320, 1986, p. 96) that he had ". . . achieved transient growth . . . but for one week only and in small quantity."

April 27, 1986: The U.S. Patent and Trademark Office (PTO) declares an "interference" between the Gallo et al. blood test patent and the IP blood test patent application. The IP scientists are named "Senior Party" in the interference, a formal recognition by the PTO of the IP priority in submitting an earlier application for a patent on their blood test. (See Moskowitz, Wiseman, Van Horn OI-3 interviews.)

August/September 1986: Continuation-in-part (CIP) patent applications (follow-ups to the parent Gallo et al. blood test patent) are rejected at the U.S. Patent Office, on grounds that the claimed inventions are anticipated by or obvious over the prior art of the IP scientist.

November 8, 1986: Gallo signs a sworn declaration before the PTO concerning his use of LAV and his alleged independent isolation of the AIDS virus and development of an antibody blood test. In the declaration, Gallo says that Dr. Popovic succeeded in "temporarily transmitting" the Pasteur virus to two permanent cell lines, but that "both transmissions were only temporary in nature" (p. 12). Gallo states further: "at the time the Gallo patent was filed (April 23, 1984) my colleagues and I did not consider LAV and HTLV-III to be the same, or even substantially

the same, virus . . ." and ". . . I was satisfied that HTLV-III had been proven to be the cause of AIDS, but saw no evidence of this for LAV up through the allowance of the Gallo patent" (May 29, 1985) (pp 13-14).

March 30, 1987: President Ronald Reagan and French Prime Minister Jacques Chirac sign a settlement agreement, ending the patent dispute and all related legal proceedings. Gallo et al. and IP scientists are awarded joint inventorship.

November 19, 1989: The Chicago Tribune publishes John Crewdson's lengthy article on Gallo's research, "The Great AIDS Quest."

February 1990: The NIH Office of Scientific Integrity (OSI) begins a formal inquiry into the issues raised in the Chicago Tribune story.

April 8, 1990: Gallo tells the OSI that the growth of the Pasteur virus was "significant and continuous" (OSI transcript p. 25).

May 16, 1990: In responding to further OSI questioning about the growth of LAV, Gallo says, ". . . 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" (OSI transcript p. 87). In a follow-up OSI interview on May 25, Gallo states, "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" (OSI transcript p. 13).

October 1990: OSI moves to a formal investigation of Gallo and Popovic for suspected scientific misconduct associated with the Popovic et al. Science paper.

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May 17, 1991: A group of IP scientists headed by Dr. Simon Wain-Hobson publish a paper in Science (252, pp. 961-965) 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, but claims this is due to an "accidental contamination."

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

October 28, 1991: The United States 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.

March/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 based 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.

December 1992: The PHS Office of Research Integrity (ORI) completes its review of the 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 (Chang et al., 363, pp. 466-469), two years after the results were obtained. Results show that both MOV and HTLV-IIIb are LAV/LAI; four of the ten alleged "pool" samples did not contain any AIDS virus; and none of the ten samples contained LAV/LAI.

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

November 3, 1993: The HHS/DAB exonerates Popovic of all misconduct charges stating that the ORI was unable to prove that Dr. Popovic is guilty of scientific misconduct. ORI subsequently withdraws all charges against Gallo.

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

NARRATIVE

When applying for a patent on their HIV blood test in 1984, Dr. Gallo and each of his co-inventors signed an affirmation that acknowledged their duty to disclose information which is material to the examination of the application. Such information is material where there is substantial likelihood that a reasonable examiner would consider it important when considering an application to issue as a patent.

The patent application, and a November 1986 sworn declaration in support, contained the following statements:

that they were ". . . the original, first and joint inventors of the subject matter which is claimed and for which a patent is sought . . ." (4/23/84 PTO patent application).

"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. Quite clearly the data available to us indicated that the two viruses functioned differently and reacted differently." (Gallo declaration, 11/8/86, pg. 13).

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"I was satisfied that HTLV-III had been proven to be the cause of AIDS, but I saw no evidence of this for LAV up through the allowance of the Gallo patent" (op. cit. pg. 14).

"I received another sample of LAV from Pasteur in September 1983 that sample was found to be viral by checking for reverse transcriptase activity. An attempt was made to co-cultivate the LAV with human cord blood T-cells in the same way as we had done with HTLV-I and HTLV-II. However, only transient transmission was obtained, and the cells soon died . . . Dr. Popovic did succeed in temporarily transmitting LAV to a cell line called HUT-78 and one other T-cell line. However, both transmissions were only temporary in nature." (op. cit., pg. 12).

The OIG investigation sought to ascertain whether these statements were false and whether Dr. Gallo knew of the falsity of these statements at the time they were made. To this end, there was an attempt to interview Dr. Popovic (who declined), and then analyze the many statements made by Dr. Gallo over a period of years bearing on his knowledge. This following narrative sets forth the major items of information obtained in the investigation relative to these issues.

Isolation and Initial Characterization of the AIDS Virus: In 1983, scientists at both the Institut Pasteur (IP) (Montagnier et al.) and the Laboratory of Tumor Cell Biology (LTCB), National Cancer Institutes (NCI) (Gallo et al.), searching for the cause of AIDS, attempted to isolate a retrovirus (a virus that reproduces itself using RNA as well as DNA) from AIDS and pre-AIDS patients. The IP scientists discovered and were first to publish the preliminary characterization of the retrovirus ultimately identified as the human immunodeficiency virus or "HIV." The IP scientists isolated and began to grow this virus in January/February 1983. They published a paper reporting its discovery in May 1983 (Barre-Sinoussi et al., Science, 220, pp. 868-871). The Barre-Sinoussi et al. paper was edited by Dr. Gallo in his role as a "reviewer" of the paper. Gallo wrote an abstract and edited the paper to include certain indicators, contrary to the views and data of the IP scientists, that LAV was a member of the "HTLV" (human T-cell leukemia virus) family of viruses. These indicators were later determined to be erroneous.

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After publication of their seminal paper, the IP scientists developed an ELISA (enzyme-linked immunosorbent assay) to test human blood samples for antibodies to their newly-discovered virus, which they called "LAV" for lymphadenopathy-associated virus. The IP scientists also made important discoveries about the characteristics of their virus, including the size of its proteins, its morphology, and its selective tropism for human T-cells. Additional isolates of the virus and results of its further characterization were reported by

Dr. Montagnier at the July 1983 meeting of the NCI AIDS Task Force; initial results of the IP ELISA and more aspects of the characterization of the virus were presented by Dr. Montagnier at a September 1983 meeting at Cold Spring Harbor, New York. Simultaneously, in Great Britain (September 1983), the IP scientists filed a patent application on their LAV blood test.

Documentary evidence, witness testimony, and Dr. Gallo's statements to OSI show that he was present at both the July 1983 and September 1983 meetings where he heard Dr. Montagnier's presentations. It should be noted that all those interviewed during the OSI investigation including Gallo and Popovic, were admonished to tell the truth but were not put under oath.

Dr. Gallo received prepublication copies of a number of the IP scientists' papers, including both the Barre-Sinoussi et al. May 1983 paper and a chapter by Montagnier, published in a volume of the Cold Spring Harbor meeting proceedings (Dr. Gallo was editor of this book). These publications were later significant in the evaluation by the examiner at the United States Patent and Trademark Office (PTO) who handled both the Gallo et al. and Montagnier et al. HIV antibody blood test patent applications. During 1986, the examiner rejected the pending claim in several Gallo et al. follow-on applications (continuations-in-part" [CIPs]) to the Gallo et al. blood test patent, on grounds that the work of the IP scientists was "prior art" to Gallo et al.

Early Attempts to Grow the AIDS Virus: The AIDS virus, unlike the other human retroviruses known in 1983, is strongly "cytopathic," meaning that it kills the cells in which it grows. The IP scientists, who recognized early on the cytopathic nature of the virus, kept their virus cultures alive by adding fresh cells to the cultures or by "passaging" the virus to fresh cell cultures.

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On the other hand, the LTCB scientists, because they were looking for a variant of HTLV-I (the human T-cell leukemia virus), which immortalizes the cells in which it grows, did not recognize that the virus they detected in AIDS patients' samples was actually killing the cells. Consequently, the LTCB scientists, for a prolonged period of time, were unable to keep their AIDS patients' virus cultures alive. However, Dr. Gallo later claimed it was he who developed the methodology for detecting and propagating the AIDS virus, and that he taught these methods to the IP scientists (e.g., Gallo's 4/30/86 "History of Key Event and Side Issue of the HTLV-III/LAV Discovery"; Gallo's 4/17/90 "Preamble" to the NIH Office of Scientific Integrity (OSI)).

Dr. Montagnier and Dr. Barre-Sinoussi have denied that they were taught by Gallo how to grow the AIDS virus. Additionally, Gallo's assertions that he taught anyone how to grow HIV are inconsistent with his own admission that he failed to use the very methods he claimed to have developed. As early as November 1985, Gallo was quoted in Science magazine as saying, concerning the LTCB inability to grow the AIDS virus;

"We just didn't believe that is what this kind of virus could do --- It is certainly true that in that period of time in Summer and certainly by early Fall [1983], Chermann had recognized the cytopathic effect of that virus and I had not . . . As I look back now, I could bang my head against a wall that we were so stubborn in trying to grow those cells long term in IL-2 . . . We went through loss of months with that problem" (230, p. 520).

When questioned by OSI investigators about his attempts to grow the AIDS virus, Gallo stated:

"I could kick myself not concentrating earlier and trying alternatives to grow the HTLV-I negative specimens. But they were always in bad shape.

They were in bad shape because they often came far and because the cells were being killed. But we didn't understand yet they were being killed. So you say, 'why didn't we just keep --' Yes, now I wish we would have tried other experiments to do anything to keep those samples going" (7/27/90 OSI interview; transcript p. 104).

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In another OSI interview, when Gallo was asked if he had fed his cultures with fresh cells, as the IP scientists had done, Gallo stated this:

"Not as fast as I would like to have done. No we weren't. We were trying to grow with IL-2. It is ironic that I am telling Chermann to add more cord blood cells . . . We didn't do it with ours. We thought we could grow it with IL-2. I don't know when more primary cells were added back" (9/23/90 OSI interview; transcript pp. 83-84).

Gallo's Use of the IP Virus, LAV: One major focus of the 1985-87 French/American dispute was the assertion of IP representatives that Dr. Gallo's putative "prototype" virus, and which he called "HTLV-IIIb," was actually the LAV virus, which Gallo received from the IP before he claimed to have "isolated" IIIb. Gallo has always denied that he had willfully misappropriated LAV. He also argued that (1) the viruses were not really identical and (2) even if there were identical, there could not have been a "contamination" of his cultures with LAV, because, he stated he could not grow the IP virus.

Over the years 1984 to 1991, Gallo appeared to modify his position, as additional facts were developed that raised questions about his initial claims. Along the way, Gallo finally acknowledged that he grew LAV, but he still claimed the growth was only "transient." Finally, during the OSI investigation, new information emerged showing that the LTCB scientists grew LAV for an extended period and used it for many of their experiments.

Throughout all of 1983 and nearly the first half of 1984, the transfers of AIDS-related reagents between the IP and LTCB (with the single exception of the LTCB blood samples sent to the IP for assay in the IP LAV blood test) were all one-way, i.e., from the IP to the LTCB. Dr. Gallo provided HTLV-I related reagents to the IP scientists in 1983; these reagents were important to the IP scientists' early work with LAV (the reagents enabled the IP scientists to confirm that LAV was not HTLV-I), but Gallo sent no AIDS virus samples to the IP scientists until mid-May of 1984. And, as has now been confirmed by the OSI-commissioned studies by Roche Molecular Systems, the virus Gallo finally did send to the IP (the LTCB's putative prototype "IIIb,"), is in fact the IP virus, LAV/LAI.

Gallo's records show the following reagents were sent from the IP to the LTCB in 1983:

1. Two shipments (April and July 1983) of DNA from patient "BRU" (the individual who was the source of the original LAV isolate);
2. At least three shipments of BRU serum (July, August, December 1983), which became the principal reagent Gallo et al. used, prior to the development of the HIV-specific hyperimmune rabbit antiserum, to test cultures for the presence of the suspected AIDS virus;

No results from any of the LTCB's experiments with BRU serum were ever reported, neither was any acknowledgement of the serum's use ever made. During the blood test patent interference proceeding at the PTO, attorneys for the Department of Justice submitted a motion in which they asserted that "The receipt of sera by Gallo from Montagnier taken from the patient [BRU] . . . is . . . of no significance" and ". . . there is no evidence to indicate that the sera contained any antibodies to the AIDS virus" [Opposition of Gallo et al. to the Motion for Judgment of Montagnier et al., USPTO interference; p. 13]. The DOJ attorney who handled the Gallo patent case stated that he relied almost exclusively on Dr. Gallo and his colleagues, for the scientific information he used in arguing the U.S. Government's case.

3. Two shipments of LAV virus -- in July 1983 and September 1983.

The September 1983 shipment of LAV contained two samples with different identifiers; however, both samples were believed to contain the same virus, from patient BRU. In reality, as demonstrated in 1991 by Wain-Hobson et al. [Science; 252, pp. 961-965] and confirmed by the Roche analyses, in 1993 [Nature, 363, pp. 466-469] one of the September LAV/BRU samples had been accidentally contaminated at the Institut Pasteur and overgrown with LAV/LAI; consequently, in September 1983, Gallo et al. received one sample each of LAV/BRU and LAV/LAI.

Gallo's HTLV-IIIb isolate is LAV/LAI (Wain-Hobson et al.; Chang et al.). When faced with proof of this fact, Dr. Gallo, in May 1991, acknowledged it was so. Gallo then sought to explain the identity of LAV and IIIb by invoking the explanation he previously said was impossible -- i.e., innocent contamination. In a letter to Nature, Gallo said that,

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"It . . . appears that cultures of virus from people with AIDS became contaminated with HIV-LAI at NIH . . . (1991, 351, p. 358).

Regarding his use of LAV, Dr. Gallo claimed publically as well as privately, that the July LAV sample contained no useable virus, and that LAV had not been and could not be grown at the LTCB. Some of these statements were made in an effort to refute that HTLV-IIIb was derived from LAV, on grounds that LAV could not be grown and therefore, could not have contaminated the LTCB cultures.

Dr. Gallo specifically denied the permanent growth of LAV in the May 1984 Popovic et al. Science paper, in which Gallo wrote that LAV ". . . has not yet been transmitted to a permanently growing cell line for true isolation . . ." This is the statement for which ORI found Gallo guilty of scientific misconduct, and which the consultants nominated by the National Academy of Sciences to oversee the OSI investigation (the "Richards Committee"), stated:

"The statement that LAV had not been transmitted in a permanent cell line is simply false, and was known to be false at the time the paper was written. This is one of the most glaring faults in the paper and is part of the pattern of misrepresentation in the discussion of the problem of continuous culture. There is no way in which Dr. Gallo can be excused from sharing the blame for this misstatement" (Dr. Frederic Richards to Dr. Bernadine Healy; 2/19/92; p. 5).

By Gallo and Popovic's own admissions, prior to publication of the May 1984 Science papers, they withheld from the IP scientists information concerning their growth of LAV in permanent cell lines (special cell lines whose features permit the AIDS virus to grow without significant cell-killing) (Gallo 8/4/90 OSI interview). Gallo acknowledged that he himself did not tell the IP scientists about growing LAV, when he visited the Institut Pasteur in early April 1984 (Gallo 12/2/90 OSI interview; p. 191).

Dr. Popovic acknowledged that on at least two occasions, he withheld from the IP scientists information about his growth of LAV in permanent cell lines:

". . . when I got the data with the permanent cell lines, including his LAV [Montagnier], in the end of November '83, I again called him up at his home, and I told we got it, learned how to handle the virus . . .