

Office of Special Investigations

**SYNOPSIS:** Dr. Donald P. Francis, former Regional AIDS Consultant, Centers for Disease Control (CDC), San Francisco, CA, was interviewed in concerning alleged false statements made by Dr. Robert Gallo concerning the US Patent for the AIDS blood test.

**DETAILS:** Dr. Francis was interviewed on March 11, 1992, at the San Francisco GAO Regional Office by Special Agents Leo D'Amico and Robert J. Gettings, at which time he advised substantially as follows:

In 1971, he entered into employment with the Public Health Service, CDC, in the capacity of an Epidemic Intelligence Service Officer in Oregon. From July 1975 through July 1978, he served as a Research Fellow at Harvard University, at which time he worked with Max Essex in the study of the feline leukemia virus (FTLV). Dr. Robert Gallo, whom he first met during this time, collaborated with Essex in search of human retroviruses and to determine the extent, if any, that feline leukemia affects humans. In July 1978, he returned to CDC where he worked as Assistant Director for Medical Science, Hepatitis and Viral Enteritis Division, Phoenix, through May 1983. From May 1983 to June 1985, he established the CDC AIDS Laboratory which performed much of the early etiological work linking the Human Immunodeficiency Virus (HIV) with AIDS.

During 1979, Dr. Francis provided HTLV specimens which he had accumulated during a six year study conducted in various cities across the country for the study of the affects of hepatitis in gay men to Dr. Gallo. In June 1981, Dr. Francis stated that he consulted with Dr. James Curran, current acting Deputy Director for HIV research at CDC and Director for HIV Programs, regarding a new deadly disease characterized by opportunistic infections such as pneumocystic pneumonia and Kaposi Sarcoma which was infecting the gay population and displayed the same characteristics as FTLV. Dr. Francis also provided Dr. Essex with specimens. According to Dr. Francis, this was the beginning of a triumvirate between CDC, Dr. Gallo and Dr. Essex in the study of the AIDS virus. In May 1983, Dr. Francis was named Coordinator of AIDS Laboratory activities for CDC in Atlanta. In this capacity, he reported directly to Dr. Walter Dowdle, Director, Center for Infectious Diseases. Concurrently, he also

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served as Assistant Director of Viral Diseases. Dr. Fred Murphy served as Director of Viral Diseases. After assuming his position in Atlanta, communication between CDC, Dr. Gallo and Essex increased while CDC continued to provide blood specimens to both labs.

According to Dr. Francis in May 1983, four (4) papers were simultaneously published in the same issue of Science, which included two (2) papers by Dr. Gallo on molecular biology and the affects of HTLV-I virus on AIDS patients; the French Institute Pasteur (IP) reported LAV findings; and CDC published findings relative to HTLV-I.

In June 1983, Dr. Francois Barre of IP telephoned Dr. Francis from Paris to request blood specimens for use in a blood test that IP scientists had developed. According to Dr. Francis, Barre stated that they had determined the cause of AIDS and had developed a test for its detection. Dr. Francis advised that, in response, he provided IP with five (5) blood specimens from gay men within the San Francisco area whom he had been tracking for over a period of five (5) years. The samples were particularly significant since they included samples that were taken before infection as a part of the Hepatitis B study he had conducted. The samples were submitted to IP in the form of a blind test.

In September 1983, Barre advised Dr. Francis of the results of their test. Dr. Francis stated that the results were particularly impressive since they were completely accurate. Dr. Francis said that it was evident to him that the French researchers had developed a reliable test to identify the antibodies to the AIDS virus. Although the same specimen were supplied to Dr. Gallo for testing, Dr. Francis indicated that to his knowledge, the Gallo lab did not provide any test results until January 1984. In September 1983, Dr. Luc Montagnier of IP presented a paper at a conference in Cold Springs Harbor, New York, which included the results of serological testing and electron micrographs (EM), as well as evidence of the makeup of the virus which they had isolated which was referred to by IP as LAV. According to Dr. Francis, although it was not conclusive that LAV caused AIDS, the evidence provided by Montagnier was overwhelming. Dr. Francis noted that Dr. Gallo did not provide any information concerning the cause of AIDS or antibody tests to detect AIDS at the conference, however, Dr. Gallo later published a book of work where presumably he conducted testing during this time which related to HTLV-III and the AIDS virus. Dr. Francis criticized Dr. Gallo's actions as unethical at best.

Dr. Francis advised that he had invited Dr. Essex, Dr. Gallo and Dr. Mullins of Gallo's lab to Atlanta prior to the Cold Springs September 1983 conference with the intent of promoting more involvement in AIDS research and also to provide them with the opportunity to meet the CDC staff, consisting of Drs. Dowdle, Cabradillo, Murphy and Curran. During his visit to CDC, Dr. Gallo became enraged when he learned that CDC had been sharing research results with Dr. Essex's lab without his knowledge. Dr.

Gallo stressed that since he had provided the reagents for testing, he wanted to be briefed on the work CDC was performing and the subsequent results of that work before anyone else.

During 1983, Dr. Francis received a referral from Dr. Davarre of Abbott Laboratories to hire V.S. Kalyanaraman (Kaly), whom he (Francis) described as a noted human virologist and discoverer of HTLV-II. Kaly was an employee of Dr. Stuart Aronson at NIH, and had worked in Gallo's Laboratory of Tumor Cell Biology at NIH as a Bionetics contract employee. Dr. Francis stated that he had informed Dr. Gallo that Kaly was seeking employment with CDC and that Dr. Gallo responded that he did not wish to lose him. Approximately one or two months after having hired Kaly, Dr. Gallo telephoned Dr. Francis to express in a caustic manner his displeasure that he had hired Kaly away from him. During the conversation, Dr. Gallo made direct references to Dr. Francis that he would prevent him from publishing in the future or perform any work in the area of retrovirology.

According to Dr. Francis, while working at Gallo's lab, Dr. Gallo called upon Kaly to charge the cost of dinners that Dr. Gallo hosted against Bionetics account. Both Kaly and former Bionetics employee Robert Ting would be required by Dr. Gallo to use the firm's credit card to pay for dinner functions. On occasion, neither Ting nor Kaly would be included in the dinner, however, they would be summoned by Dr. Gallo to the location of the function for the specific purpose of paying for dinner. Kaly told Francis that Bionetics accumulated entertainment expenses on behalf of Dr. Gallo in the amount of \$30,000.

Dr. Francis stated that in February 1984, Dr. Chermann of IP came to speak at a meeting in Park City, Utah, at which time he took the opportunity to announce that IP had determined the cause of AIDS. Dr. Chermann brought with him a sample of the LAV virus which Dr. Francis indicated CDC successfully isolated with the assistance of Dr. Chermann. Over the period of February/March of that same year, Dr. Francis advised that CDC had several controls in place and had performed numerous studies, resulting in the production of data in support of the claim by IP that LAV was the cause of AIDS.

Dr. Francis stated that by March 1984, he was convinced that LAV and HTLV-III were the same virus. Without stating a reason for his actions, Dr. Gallo had provided written instructions prohibiting CDC from comparing the isolate which he identified as HTLV-III with any other isolate. Dr. Gallo refused to provide CDC with a sample of the HTLV-III virus for comparative purposes. Despite the fact that no comparative tests were performed, Dr. Francis stated that comparisons were not necessary at this point since enzyme sequencing tests had been performed by Mal Martin which evidenced that the viruses were the same. Dr. Gallo specifically forbade Dr. Francis from collaborating with IP or any other lab other than his own. Dr. Francis noted, however, that Gallo was at a disadvantage since CDC and IP had specimens

of the isolate and were more familiar with the AIDS disease than he.

During the first week in April 1984 (April 4-6), Dr. Gallo, who had been in Switzerland at the time, and Dr. Francis met with Dr. Chermann and Dr. Barre at IP in Paris. Dr. Gardner, who was with Dr. Gallo in Switzerland, also attended the meeting. Dr. Francis described this point in time as a particularly critical period. At that time, Dr. Francis observed that photographs of the Gallo HTLV-III virus appeared identical to the LAV virus. Additionally, the serum that Dr. Gallo, Drs. Montagnier and Chermann and Dr. Francis had produced displayed identical morphological characteristics as to growth patterns, protein makeup, and the manner of response to antibody tests. Additionally, the similarity in reaction to human sera was sufficient evidence, in Dr. Francis' opinion, that they were of the same virus type. Dr. Francis showed those present the EMS consisting of CDC and IP data in addition to Dr. Gallo's serological results. The subsequent printout of results exhibited total agreement of the specimens tested. Similarly, all three blood tests performed equally well. It was evident that the cause of AIDS was attributed to only one virus, which Dr. Francis identified as being the French LAV virus. Dr. Francis recollected that Dr. Gallo did not react either positively or negatively upon being presented with the results that IP and CDC had offered in support of the LAV virus. He did note, however, that Dr. Gallo asked him to leave the room prior to revealing his data. Dr. Francis advised that it was his intention that the three labs would issue a joint statement to the public that would attempt to diminish the public's fears as much as possible and to minimize confusion that more than one virus may cause AIDS.

Prior to their departure from IP, Dr. Gallo remarked that they all should keep each other informed of their work and that they should collaborate in the preparation of three (3) scientific papers, whereby IP would be responsible for documenting the aspects of the comparative proteins; CDC for the serological work; and he (Dr. Gallo) for the nucleic acid study. In contrast, Dr. Francis stated that on the evening following their meeting, Dr. Gallo had confided privately with Dr. Chermann that IP and the Gallo lab could collaborate without involving CDC; later, Dr. Francis advised that Dr. Gallo made similar overtures to him with the exclusion of any involvement from IP.

Later in the month, Dr. Francis stated that Don Barrth, Information Officer at CDC, provided him with a courtesy copy of a draft press release issued by HHS in anticipation of a press conference scheduled for April 23 at which Dr. Gallo would announce that he had discovered the cause of AIDS in the form of the HTLV-III virus. Dr. Francis noted that the press release not only failed to extend credit to the French for their contributions in the discovery of the AIDS virus, it did not recognize the involvement of IP in any stage of the collaborative effort between the three labs. Dr. Francis stated that he

expressed his dismay to Dr. Curran relative to Dr. Gallo's intentions and told Dr. Curran that he (Dr. Gallo) couldn't go through with the announcement. Dr. Francis advised that Dr. Curran as well as Drs. Dowdle and Gardner were in agreement that the French were the rightful discoverer of the cause of AIDS. Dr. Francis stated that he was particularly incensed by Dr. Gallo's failure to acknowledge the contributions made by IP. (Dr. Francis mentioned that despite later denials by Dr. Gallo that he did not exercise any control over the press conference and had been forced to participate by the administration, he had inadvertently disclosed that the press conference had been pre-arranged during the course of a heated discussion he had with Swiss official Michelle (?) in April 1991). Dr. Francis indicated that he, with the support of Drs. Curran, Dowdle and Gardner, telephoned Assistant Secretary of HHS Brandt and informed him that credit for the discovery of the AIDS virus should be attributed to the IP and that in light of that fact, the press conference should be canceled. Additionally, a news article that had been written by New York Times reporter Larry Altman, based upon an interview of Dr. Mason, appeared in the Sunday edition just prior to the April 24 news conference which credited the work by the IP in the discovery of the virus. According to Dr. Francis, Dr. Curran had briefed Dr. Mason for the interview. Altman purportedly chose to release the article for publication at that particular time upon hearing that an HHS news conference was imminent. Dr. Francis indicated that both he and Dr. Curran briefed Dr. Mason weekly on the status of their work. Dr. Mason based his conclusions that IP had determined the cause of AIDS upon the data provided by both CDC and IP. At the request of the reporting agent, Dr. Francis was asked to review a photocopy of a letter addressed to him from Dr. Gallo, dated December 27, 1984. The contents of the letter references the corroborative effort by the three parties (CDC, IP and LTCB) in the composition of three comparative papers (nucleic, protein and serological studies) pertaining to the viruses LAV and HTLV-III. Dr. Gallo indicated in the letter that the nucleic paper for which his lab was responsible for drafting was ready and that he was waiting for IP to complete their paper on the protein makeup. In this regard, Dr. Gallo wrote, "In any case I hardly think this is very important since we have said from the first that the viruses are likely to be the same, and since the data was obtained all of us have publicly reported it." Dr. Francis stated that Dr. Gallo's remark supported his conclusion that the viruses were the same and that Dr. Gallo was cognizant of this fact. (A photocopy of the referenced document is appended to this report as Exhibit 1).

A second document, consisting of an article which was printed in the March 1985 edition of Cell magazine, entitled "Molecular Organization of the AIDS Retrovirus," referenced two unrelated reports which appeared in Science and Nature magazines in 1984, which observed that, "although the restriction maps of HTLV-III, ARV and LAV proviral DNAs have not been formally compared, superficial inspection of published cleavage maps and Southern blots suggests that HTLV-III and LAV are closely related to one

another, whereas ARV and many other isolates are substantially different." The articles went on to state that "A comparison of HTLV-III and LAV proviruses generated virtually identical results, indicating that HTLV-III was no more different from LAV than molecular clones of HTLV-III were from one another." In summary, the articles observed that "The analysis of nucleotide sequence heterogeneity presented...indicates that HTLV-III and LAV are virtually identical." Dr. Francis advised that he supported the conclusions of the aforementioned statements. (A photocopy of the referenced document is appended to this report as Exhibit 2.)

Similarly, upon reviewing portions of a paper (photocopy appended to this report as Exhibit 3) which he (Dr. Francis) was first author entitled, "Human Retrovirus in Acquired Immunodeficiency Syndrome (AIDS)," in which he stated concerning LAV and HTLV-III that "...preliminary experiments indicate that they are closely related, if not identical" (page 234), and that "From multiple aspects" LAV and HTLV-III "appear to be the same virus" (page 238), Dr. Francis remarked that since Dr. Gallo had forbade comparisons of isolates, it was not possible to state with 100% accuracy that the viruses were the same. Despite this, however, he argued that a comparison test was not required in view of the fact that researchers at IP and CDC knew that they were the same virus. Although a request for the HTLV-III virus had been made several months in advance of the HHS news conference, CDC did not receive an infected H-9 cell line from Dr. Gallo until approximately one month after the news conference. Dr. Francis indicated that support for the statement that the viruses were the same was presented at the Cold Springs, Utah conference and was exhibited through preliminary experiments conducted independently by CDC and IP. Dr. Francis stated that he knew IP had developed a working blood test in April 1984 and that Dr. Gallo had been informed that CDC had been running close to 100% accuracy for both groups. By January 1985, Dr. Francis advised that he was certain that HTLV-III and LAV were the same nucleic isolate.

In July 1984, CDC published an update in Morbidity and Mortality Weekly Report (MMWR) stating that "HTLV-III and LAV are likely to be the same virus...", citing a number of pieces of evidence supporting this assertion. (Photocopy of the referenced document is appended to this report as Exhibit 4.) Dr. Francis stated that the comparative assay tests were performed at CDC. As of July 1984, Dr. Francis indicated that the information in the article was contemporaneous, at best, and was not subjected to peer review. The main purpose for the article was to expose the general health community to this information pertaining to the similarities between HTLV-III and LAV and its transmission characteristics.

In the manner of the CDC/IP/LTCB collaborative study of AIDS patient/control subject sera, Dr. Francis indicated that the method used consisted of a blind test. Dr. Francis retained the code himself. No agreements were made in advance relative either

to the study methods to be used or for the publishing of the test results.

In summary, Dr. Francis reiterated that there is no question in his mind that LAV and HTLV-III are the same virus as exhibited by the fact that they both function in an identical manner. He stated that in his experience as a scientist, he has never encountered a situation in which two viruses which exhibited identical characteristics were later determined to be distinct from each other. In regard to statements made by Dr. Gallo as a part of his Declaration in which he stated that he saw no evidence that LAV was the cause of AIDS, he referenced the May 1983 article in Scientific Journal, statements made by representatives of IP during the September 1983 Cold Springs Harbor and the February 1984 Park City, Utah, conferences and subsequent articles in the publication Lancet as evidence that sufficient evidence had been presented in support of LAV as the causative agent of AIDS and had assumed precedence over HTLV-III.