

Charges and Findings in the HHS Investigation of Dr. Robert Gallo

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In April 1984, the United States government staged what the HHS Inspector General's office later described as an extraordinary moment in biomedical history: a press conference for "the international news media" to announce Dr. Robert C. Gallo's discovery of the AIDS virus, which was then designated as HTLV-III. In addition, Gallo announced his laboratory's ability to mass produce the HTLV-III virus in order to create an antibody blood test. In the words of the HHS Investigative Memorandum (which had not been released to the public), "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." Of crucial importance, these patent filings preceded the publication of Gallo's four *Science* papers in May 1984 and were accompanied by sworn declarations asserting that he and his co-inventors were "the original, first and joint inventors" of the claimed methods. Under patent law, the National Cancer Institute researchers had a duty to disclose any "information which is material to the examination" of the application. Yet, as the memorandum notes, "the only apparent reference" to the work of the Institut Pasteur (IP)—the French institution also with claims of its own virus associated with AIDS--was a casual mention of "another retrovirus... not etiologically related to the disease."

The roots of the controversy lay a year earlier. In May 1983, IP's Luc Montagnier, Françoise Barré-Sinoussi, and colleagues published the first description of a virus they would call lymphadenopathy-associated virus or LAV—in the journal *Science*. That paper had passed through the editorial hands of Robert Gallo, who, in his capacity as a reviewer, wrote the abstract and edited the text to suggest that the French virus was a member of his own "HTLV" family of human T-cell leukemia viruses. This framing, contrary to IP's own data was later found to be erroneous and intentionally repositioned LAV within a conceptual viral framework Gallo had already claimed to be his own.

By July 1983, Montagnier was lecturing at NIH about new LAV isolates uncovered by his IP lab. His presentation showed electron micrographs and early blood test data. That September, at Cold Spring Harbor in Maryland, Montagnier presented the first evidence of an LAV-based antibody test for AIDS and pre-AIDS patients. Gallo was present at both meetings. On September 22, 1983, Pasteur sent Gallo's lab two further samples, including the prototype LAV/LAI, under a signed agreement that it "will not be used for any industrial purpose" without IP's written consent. Within a month, on October 21, Dr. Mikulas Popovic, Gallo's chief virologist, used the LAV/LAI sample to infect permanent T-cell lines in order to generate HUT-78/LAV and T17.4/LAV. The following month, Gallo's team renamed these lines "MOV" thereby giving it a label that obscured their French origin.

A later forensic review conducted by Roche Molecular Systems' genetic analysis established that MOV and Gallo's vaunted HTLV-IIIb were in fact LAV/LAI. Four of the ten pooled patient samples supposedly yielding HTLV-IIIb contained no AIDS virus at all, and none contained a unique virus distinct such as anything from the HTLV virus family, from LAV. This data flatly contradicted Gallo's sworn claim that his HTLV-IIIb was independently isolated from American patients.

In November 1983, Popovic began the “pool” experiment that he and Gallo would later cite as the method to produce HTLV-IIIb. By January 1984, he had cloned the HUT-78 line into H9 cells, infecting them with the pool virus. Early in 1984, CDC’s James Curran told Gallo that comparative testing showed the IP and NIH blood tests to be “compatible and in concordance” in order to detect AIDS virus antibodies.

On March 30, 1984, Gallo and his team submitted four papers to *Science*. Popovic’s draft, according to both HHS investigators and the *Chicago Tribune*’s John Crewdson’s reporting, acknowledged the use of LAV as the reference virus and described it as “HTLV-III.” Gallo “extensively rewrote” the paper “over Popovic’s objections.” He deleted all references to LAV’s role and its growth in his lab. Penciling in the now-infamous marginal note, Gallo wrote, “Mika you are crazy. I just don’t believe it.” Crewdson adds that Gallo told Popovic by phone from Utah that if he didn’t finish the paper by week’s end “it wouldn’t be published,” which prompted Popovic to rush back to NIH only to find his work already altered by Gallo. Popovic, fearing future legal or investigative trouble, sent annotated drafts to his sister in Czechoslovakia for safekeeping.

The published *Science* article contained the unqualified statement that LAV “has not yet been transmitted to a permanently growing cell line for true isolation.” The HHS-appointed Richards Committee later wrote to NIH Director Bernadine Healy that this claim “is simply false, and was known to be false at the time the paper was written... part of the pattern of misrepresentation... There is no way in which Dr. Gallo can be excused from sharing the blame.”

The HHS Inspector General’s timeline shows that only days before publication, in early April 1984, Gallo traveled to Europe to tell an audience in Zurich that IP’s blood test was “almost as good as we have.” The following day, Gallo told colleagues at Pasteur that HTLV-III was “the same virus these guys discovered last year.” But by August 1984, after receiving another LAV sample (“B/LAV”) from Montagnier, Gallo phoned him to assert that B/LAV and IIIb were genetically identical but that the “original LAV” was different. Gallo thus accused Montagnier of contaminating his own stock with IIIb. Montagnier “adamantly rejects” the charge, but Gallo repeated the charge internally to the NCI leadership.

Throughout 1985, the dispute escalated. Malcolm Martin at the NIH had already shown LAV and HTLV-IIIb were genetically identical, but Gallo dismissed his data. In April 1986, under considerable media pressure, Gallo began conceding that he had grown LAV “transiently,” which directly contradicted his earlier claim that it was “physically impossible.” This was followed by the U.S. Patent Office declaring an interference between the Gallo and Montagnier blood test patents, and named Pasteur as the senior party. By August–September 1986, Gallo’s continuation-in-part patent applications were rejected for being anticipated or obvious in light of Pasteur’s work.

In a November 8, 1986 sworn declaration to the patent office, Gallo reiterated that he and his colleagues “did not consider LAV and HTLV-III to be the same” and that any transmissions of LAV to cell lines had been “only temporary in nature.” The HHS investigation therefore sought to determine whether these were false statements and whether Gallo made them with knowledge of their falsity. By 1991, molecular evidence and Roche’s studies made clear they were indeed false.

In February 1990, the NIH's Office of Scientific Integrity opened a formal inquiry. The investigation was in part spurred by John Crewdson's *Chicago Tribune* exposé "The Great AIDS Quest". During testimony, Gallo began to backpedal. He stated, "Of course, LAV was grown... There has been confusion... oh we never grew LAV and of course we did grow LAV." However, by May 1991, after Wain-Hobson's genetic sequencing proved HTLV-IIIb was LAV/LAI, Gallo conceded the identity but now invoked "accidental contamination" having taken place at NIH. This was the very scenario Gallo had earlier called "the height of outrage."

The Office of Research Integrity's December 1992 report found Gallo guilty of scientific misconduct for falsifying his permanent-growth statements in *Science*. The report also confirmed that "by Gallo and Popovic's own admissions" they had withheld from Institut Pasteur their successful growth of LAV in continuous cultures. The 1993 Roche data further discredited the HTLV-IIIb origin story. Although an HHS Appeals Board later exonerated Popovic and withdrew all charges against Gallo, the documentary record--which includes the patent filings omitting known prior art, deliberate manuscript alterations to erase acknowledgment of LAV, false sworn statements, shifting and contradictory explanations, and resistance to publishing data proving HTLV-IIIb was LAV--remains a meticulously documented account of intentional scientific misrepresentation and fraud.

The saga of Dr. Robert C. Gallo's claimed discovery of the AIDS virus is, as laid bare in the Department of Health and Human Services' (HHS) Investigative Memorandum and subsequent journalistic inquiry, a case study in how the politics of science, personal ambition, and governmental prestige can converge to produce a pattern of conduct that investigators later described as a "pattern of misrepresentation." It is a story not simply of disputed credit but of deliberate editing, inconsistent testimony, misleading patent filings, and the suppression of facts that, if disclosed, would have undercut the American claim to priority in identifying the cause of AIDS and creating the first diagnostic test. It is now up to the current HHS to re-open an investigation as to the rationale for the HHS Appeals Board to exonerate Dr. Gallo despite the Inspector General's evidence of misconduct.