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What I didn't tell him was that the virus grows very well in permanent T-cell lines" (6/26/90 OSI interview; p. 111).

During the Spring of 1984 and thereafter, Dr. Gallo claimed to the IP scientists and to HHS officials that he could not/did not grow LAV. Statements by Gallo to this effect were cited in the ORI Final Report, demonstrating the consistency of his claims. For example, in early March 1984, Dr. Gallo wrote to the editor of The Lancet that the IP virus (viruses),

". . . have never been characterized nor transmitted permanently to recipient target cells. Therefore, no one has been able to work with their particles, and because of the lack of permanent production and characterization, it is hard to say they are really 'isolated' in the sense that virologists use this term" (3/5/84 Gallo-to-Ian Munro letter; p. 1).

According to Dr. Montagnier's testimony to OSI, Gallo telephoned both him and Dr. Chermann at the end of March 1984, saying that,

". . . he had a virus growing to a very high titer on a continuous cell line and he believed it was the cause of AIDS. When I asked him whether this virus was similar to LAV, he refused to answer." (6/18/91 Montagnier-to-Hadley letter; p. 1).

During the French/American patent dispute, Gallo claimed to NCI officials that July LAV "did not contain detectable virus" (8/19/85 Gallo-to-Fischinger memorandum; p. 2). Concerning September LAV, Dr. Gallo, in the same memorandum, said only that his colleague, Dr. Mikulas Popovic, ". . . was able to detect R.T. [reverse transcriptase, indicative of the presence of a retrovirus] in the supernants . . ." (p. 2).

In public, Gallo made additional statements to the effect that he had not grown/could not grow LAV. A November 1985 article in Science about the French/American dispute (based in part on interviews with Gallo and Popovic) described the IP claim that "Gallo's group somehow grew the French isolate" and reported Gallo's reaction as follows:

"Gallo indignantly disputes this allegation on several counts, including the fact that the viruses are not identical and that the amount of virus Montagnier sent would not have been sufficient to infect a cell line" (230, p. 642).

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Further, according to the Science article,

"Gallo and Popovic say they infected fresh lymphocytes with the virus Montagnier sent, but when the reverse transcriptase activity declined they put the material in the freezer" (op cit., p. 643).

To the journal Nature, Gallo said about his work with LAV that he had ". . . achieved transient growth . . . but for one week only and in small quantity" (320, 1986, p. 96).

Dr. Gallo restated this transient growth explanation in his November 1986 sworn declaration before the PTO. In the declaration, Dr. Gallo said that Dr. Popovic succeeded in "temporarily transmitting" the Pasteur virus to two permanent cell lines. However, Gallo said, "both transmissions were only temporary in nature" (11/8/86 Gallo declaration; p. 12).

Regarding the July LAV sample, Gallo stated,

". . . we could find no detectable virus in the sample . . . subsequently some minute viral activity was noted in the sample but this was so small that nothing could be done with the sample . . . the sample I received did not show any meaningful viral activity" (op cit., p. 11).

Dr. Gallo apparently recognized the discrepancy between the facts and his earlier statements that LAV did not grow at the LTCB. When explaining his statements, Gallo told the OSI:

". . . 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. But what I am talking about is for commercial purpose in mass production (5/16/90 OSI interview; transcript p. 87).

In a subsequent interview, Gallo said:

"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" (5/25/90 OSI interview; transcript p. 13).

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The knowledge and experience Dr. Gallo and his colleagues gained from working with LAV, was found by the Richards Committee to be substantial:

"The Gallo lab 'went to school' with the French virus . . ." (emphasis in original; Richards-to-Healy; p. 2).

The knowledge and experience gained from LAV, contrasted with the statements in the Popovic et al. paper denying its utility, led the Richards Committee to conclude the following:

"The Gallo lab . . . failed to mention the fact that they had propagated the French virus and stated (in the Popovic et al. manuscript) that the French virus had never been transmitted to a permanent cell line. Given the quality of the information derived from propagation of the French virus, we believe that this constitutes intellectual recklessness of a high degree -- in essence, intellectual appropriation of the French viral isolate" (emphasis in original; Richards-to-Healy; p. 3).

The Richards Committee never met with Gallo during their deliberations nor did they give Gallo an opportunity to respond to accusations.

Gallo's "Breakthrough" Discoveries

"MOV" (LAV/LAI): Dr. Gallo patented and claimed as his HIV prototype an isolate he identified as HTLV-IIIb. This isolate supposedly originated in a pool of virus samples (see below). However, records reveal that Gallo did not perform any of his initial, significant experiments with this isolate. Rather, these accomplishments were achieved with another isolate, the existence of which was unknown until the OSI investigation, and identified in the LTCB records as MOV.

The LTCB laboratory records and Gallo/Popovic's OSI testimony reveal the following about the isolate called "MOV":

- o The designation MOV appeared in Popovic's notes for November 22, 1983, along side two infected permanent cell lines in which LAV was growing. No HIV isolate other than LAV ever was growing simultaneously in these two cell lines at the LTCB; there is no record of an attempt to infect these cell lines with an isolate other than LAV.

- o Gallo/Popovic told OSI that MOV probably originated with patient HM. However, the Roche analysis found no virus in a sample taken from patient HM, and the LTCB's records show that HM samples and cultures were negative in subsequent tests for the presence of virus.

The "Pool Isolate," IIIb: Notwithstanding its importance to the seminal AIDS/HIV experiments of the LTCB, the isolate designated as MOV could not be used for the publications and particularly, the patents reporting the LTCB experiments, due to the uncertainty about its origins. Therefore, for purposes of their patent applications and for many publications, Gallo/Popovic claimed the existence of another HIV isolate, designated IIIb, an isolate said to be derived from a pool of ten patient samples. (The first time the designation IIIb appeared in any document from the LTCB was in the patent applications submitted April 23, 1984.)

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. Among the facts that call into question the pool experiment are the following:

- (a) As reported by Roche Laboratories, four of the ten samples allegedly used in the pool, samples Gallo/Popovic claimed were selected for the presence of HIV, contained no virus at all.
- (b) Gallo and Popovic asserted that the samples used for the pool were tested and found RT+ before they were used for the pool ("RT" stands for reverse transcriptase, an enzyme present in retroviruses that permits the virus to reproduce itself and thus an indicator of the presence of a retrovirus). Gallo himself said, in a memorandum to the NCI's Peter Fischinger during the French/American dispute, that the samples for the pool came from "several patients who showed high RT activity in primary culture" (8/19/85 Gallo-to-Fischinger memorandum; p. 3).
- (c) According to evidence presented by ORI in the Popovic Appeals Board hearing, many of the samples allegedly used for the pool were noted in the LTCB records to be contaminated with mold, one was terminated the same day it allegedly was used for the pool, and for one sample, there is no indication a viable culture was present in the laboratory at the time it allegedly was used.

(d) According to other testimony at the Popovic hearing, 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 ten 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. 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.

A major unknown concerning Popovic's pool experiment is whether, at any point, Popovic told Gallo that he had put LAV in the pool. However, it should be noted that Dr. Popovic's use of LAV in his experiments, was entirely proper. The only restrictions on the use of LAV at the LTCB were those set forth in a transfer agreement Popovic signed on September 21, 1983, signifying receipt of the September LAV samples. The full spectrum of scientific uses of LAV, even if used in the pool experiment, was permitted by this agreement. What was restricted was commercial use of the LAV.

The CDC Data: In mid-March 1984, Dr. Gallo obtained important new information about the IP blood test. This information came from Dr. James Curran at the Centers for Disease Control (CDC) in Atlanta, Georgia. Curran had previously sent Gallo a panel of over 200 sera for blind testing with the LTCB HIV antibody blood test, and on March 12, he met with Gallo and Sarngadharan to "break the code" with them. Gallo has frequently recalled this meeting, always asserting that Curran told him his results were "clear-cut" and that, in Curran's view, Gallo and his colleagues "had determined the cause of AIDS" (4/30/86 Gallo "History of Key Events . . ."; 11/8/86 Gallo sworn declaration).

The CDC had sent many of the same sera tested by Gallo to the IP scientists, for testing with their LAV antibody blood test. The IP blood test scored as well as the LTCB blood test, and according to Curran's interview by GAO investigators, he told Gallo about the concordance of his results with those of the IP, during the March 1984 meeting.

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Less than three weeks after the meeting with Curran, on April 6 at the Institut Pasteur in Paris, Gallo personally was shown the computer print-out containing a side-by-side tabulation of the LTCB and IP blood test data. Five other scientists were present in the room, including two scientists from the United States. They substantiate that Gallo saw the data on both blood tests.

Gallo supposedly revealed nothing about the CDC data to the PTO, nor to the attorney who prepared the patent applications, who instructed him concerning his duty of disclosure to PTO. Neither did Gallo cite any information about the CDC data or its implications in the Science papers, submitted just six days before he saw the data, and which, by Gallo's own account to OSI, would be "updated" to the time the galley proofs were reviewed.

Gallo later asserted he had no knowledge of the CDC data. In OSI interviews, Gallo made statements about what he saw during the April 1984 meeting at the Institut Pasteur:

"I saw nothing. I saw where I am and they were working on a corner of a circled table, but I didn't know why Don Francis was there. He said, 'oh you know, the results were quite comparable in the blind comparative test.' I was saying, 'I am going to get right sucked into this. They are going -- to I said, ' look I am not publishing CDC data sera. We have our own publications planned and gone off already. I was getting worried that they were going -- this is what was happening.

I was thinking to myself, what the heck is Don doing here? But I never had a chance to review this data . . .

I repeat again, I saw that data from six feet away for two milliseconds. I saw no real numbers" (7/27/90 OSI interview; transcript pp. 95-97).

". . . in that meeting, I never saw the data" (8/30/90 OSI interview; transcript p. 225).

". . . I knew there was no data from Pasteur or CDC. I mean, I knew it well because I had just been there. I mean, what data was new? There was no new data. It was very little and it wasn't going to be published for another six or seven months" (12/2/90 OSI interview; transcript pp. 79-80).

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On December 17, 1991 Gallo wrote a memorandum "To the Record," titled "Blood Test Patent and Related Information." The memorandum was meant for top-level management at the NIH; copies were noted to Drs. Samuel Broder and Bernadine Healy, Directors of the NCI and NIH, respectively, as well as to the NIH Legal Advisor, Robert Lanman, and Thomas Mays, Director of the NCI Office of Technology Development.

In this December 1991 memorandum, Gallo said he had,

" . . . learned of rumors . . . [of] still another 'new' argument being made against me, NIH, the patent and and the Agreement . . . that I 'knew' and reviewed data 'from Pasteur scientists' in early April 1984 (about two weeks before submitting our patent application), which showed that 'their' blood test was about as good as ours."

Gallo stated, "This is a big misrepresentation of the facts."

Three months later, in a recorded telephone message left on the answering machine of Dr. Donald Francis, the CDC scientist who showed Gallo the computer print-out on April 6, 1984 in Paris, Gallo stated:

"I'm well aware of the serology data that you gave for me to look over on one occasion during the visit to Pasteur. I am aware of that happening."

The significance of the CDC data, and the official HHS position on the matter, was stated by Dr. Robert Windom, the then Assistant Secretary for Health and Mr. Ronald Robertson, then the HHS General Counsel, in an April 6, 1988 letter to a German publisher of a book critical of Gallo:

" . . . in early 1984, under the auspices of the Centers for Disease Control in Atlanta, Georgia, a series of blind tests was undertaken to ascertain whether the sera from patients with AIDS contained antibodies to HIV. Of significance is the fact that both NCI and Pasteur participated in these tests. Each laboratory was provided with sera and asked to judge whether each specimen contained antibodies to the virus. The results of those tests unequivocally established that HTLV-III/LAV was the presumptive causative agent of AIDS."

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During the OSI investigation and Popovic Department Appeals Board hearing, it was established that Dr. Gallo deleted both of these statements concerning Dr. Popovic's use of LAV, writing in the margins of the paper, "I just don't believe it. You are absolutely incredible" and "Mika you are crazy." Gallo added to the conclusion of the paper, his rendition of a few selected pieces of data. He listed these items on the cover of the manuscript under the heading,

"Way to deal with this LAV originally."

Gallo wrote, in the conclusion of the paper the following:

"These findings suggest that HTLV-III and LAV may be different. However, it is possible that this is due to insufficient characterization of LAV because the virus has not yet been transmitted to a permanently growing cell line for true isolation and therefore has been difficult to obtain in quantity" (Popovic et al., Science, 224, p. 500).

Stricken from the published version of the paper was the statement that LAV grew in a permanent cell line at the LTCB. Gallo rewrote the Popovic et al. paper so that it would indicate the initial experiments were performed with the LTCB prototype isolate, rather than with LAV. There was no mention of any pool in any early drafts of the Popovic et al. paper.

Dr. Popovic secured the drafts of the paper that bore Dr. Gallo's notations with his (Popovic's) sister in Czechoslovakia, because, Dr. Popovic said, he believed that,

" . . . sometime in the future, I might need them as evidence to prove that I gave fair credit . . ." to the Pasteur scientists (5/15/91 Popovic-to-Healy memorandum; p. 7).

Dr. Popovic told OSI about the disagreement he had with Dr. Gallo concerning Gallo's deletion from the paper of Popovic's description of his LAV experiments. Dr. Popovic said, ". . . I would consider (it) a major disagreement" (4/10/91 OSI interview; transcript p. 6). In later testimony before OSI, Dr. Popovic remained consistent when he said:

"Regarding my opinion, I told him if in those time and I am telling it now that it would be better to refer to the French work and present the LAV data what we had, that has been my opinion all along . . . and I expressed this" (12/1/90 OSI interview; transcript p. 156).

LAV as the Cause of AIDS: Gallo told OSI that prior to the publication of the May 1984 Science papers, the LTCB's own data had revealed that HTLV-III and LAV "were of the same virus type . . ." (4/17/90 written submission to OSI). Dr. Gallo also said that,

" . . . the same virus type was suspected, I would say, by . . . the early part of 1984, certainly before the press conference" (4/11/90 OSI interview; transcript p. 62).

Audiotapes obtained by the OIG and GAO as evidence reveal that in March 1984, Gallo lectured in Europe and asserted that his HTLV-III virus was "very similar" to the Pasteur virus (3/17/84 address at the Association pour la Recherche sur le Cancer; Marseilles, France). On April 5, the day before he saw the CDC computer print-out at the IP, Gallo lectured in Zurich, Switzerland, where he said that the IP blood test data " . . . has gotten very good, almost as good as I know we have with these" (Beecham Symposium on Infective Agents and Their Effects).

Gallo made assertions to the OSI about what he supposedly told the Pasteur scientists, during his trip to the IP in the first week of April 1984. His comments concerned the likelihood that LAV and HTLV-III were the same virus type. Gallo advised OSI:

" . . . I said that, 'this is the cause of AIDS and I believe these guys found it last year and it's the same virus that they found.' There was no bones about it. I mean it wasn't a pulled punch" (4/11/90 OSI interview; transcript p. 63).

The Popovic et al. Science Paper: The initial drafts of Popovic's Science paper (Nos. 1-3), reflecting exclusively Dr. Popovic's writing, show that Popovic performed his seminal experiments with LAV. In the succeeding drafts, particularly Nos. 4 and 5, Dr. Gallo made extensive edits. In the process he altered the methods of the paper to indicate that Popovic's experiments were not performed with LAV, but with an unidentified LTCB isolate. Dr. Gallo also added a selective set of LAV/HTLV-III data to the paper to support his claims that these were different kinds of viruses.

The drafts of the Popovic paper show that Dr. Popovic was certain of the functional identity of LAV and HTLV-III. In the first draft of the paper on which he was first author, he wrote, concerning his own experiments, that "LAV as a reference virus . . . had been used in the first series of experiments," and "LAV is described here as HTLV-III."

Popovic called this a "major disagreement" between he and Gallo. However, Gallo described this encounter with Popovic as "a very brief discussion" and prior to Popovic's revelation of the draft manuscripts stated:

" . . . there wasn't much emphasis. I think, Mika thought maybe we should make a statement to the effect that LAV was in culture . . . don't think that Mika argued forcefully or strongly that we have to have some data on LAV growing in the culture. That is not the case. He did mention it in an almost casual way, maybe we should put a statement in that at least for the time being with partial characterization" (12/2/90 OSI interview; transcript pp. 184-186).

Assertions in the Patent Application: In submitting the LTCB HIV antibody blood test patent application, Gallo et al. affirmed, that they were,

" . . . the original, first and joint inventors of the subject matter which is claimed and for which a patent is sought . . ."

The signed statement also included an acknowledgment 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)."

Gallo did not disclose to the United States Patent Office the Pasteur scientists' "prior art," i.e., their extensive work with the virus, LAV, and the existence and use of the LAV antibody blood test. Further, Gallo did not disclose to the patent office any of the LTCB's own experimental work with LAV.

The relevance of the IP work to that of Gallo et al. was affirmed by the PTO examiner, when she became aware of it. The examiner advised the OIG that, had she been aware of the IP prior art at the time she examined the blood test application of Gallo, she would have suspended prosecution of the Gallo application and declared an interference between the two applicants. An interference was eventually declared, but not until two years after the initial Gallo submission. The IP scientists were eventually named Senior Party in the interference, confirming their priority in submitting a patent application on the HIV antibody blood test. By the time the interference was declared, the Gallo patent had long since been issued.

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During the patent dispute, the Institut Pasteur charged that Gallo failed in his duty of disclosure to the United States patent office. Dr. Gallo attempted to defend himself against the charge by denying that he knew the Pasteur virus was the same kind of virus as HTLV-III and that LAV was the cause of AIDS. In the November 1986 declaration before the U.S. patent office, under penalty for making false statements, Dr. Gallo swore that:

"At the time the Gallo patent was filed (the patent application for the Gallo HIV blood test, 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 . . ."

". . . 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" (May 1985) (11/8/86 declaration of Dr. Robert C. Gallo before the U.S. Patent and Trademark Office; pp. 13-14)."

Comparisons of the Isolates in the Summer of 1984: During the Spring and Summer of 1984, Gallo and Montagnier carried out a collaborative comparison of the IP and LTCB prototype HIV isolates, LAV and HTLV-IIIb/LAV. Immunologic studies showed early on that the major core proteins were immunologically cross-reactive. Describing these results, Gallo wrote to Montagnier, in early July 1984, that "there is substantial cross-reaction as anticipated" (7/3/84 Gallo-to-Montagnier letter).

On June 27, 1984, Gallo wrote, called and telegraphed Montagnier all on the same day, requesting Montagnier's LAV cell line "for comparative purposes." On July 3, Gallo wrote to Montagnier repeating his request for Montagnier's cell line. Gallo told Montagnier that the LAV he (Gallo) previously received was ". . . not permanent and small in amount." On July 13, Montagnier sent LAV in a B-cell line (B/LAV) to the LTCB. Gallo then compared B/LAV to IIIb in late August or early September and found they were identical.

Then on or about August 24, 1984 (Montagnier dates the call to July; on one occasion, Gallo did as well), Gallo called Montagnier to tell him he had compared IIIb to B/LAV and found they were identical. Gallo accused Montagnier of having contaminated his B/LAV with IIIb, an accusation which Montagnier says he adamantly rejected.

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The Gallo/Montagnier Telephone Call: Gallo's accounts of the phone conversation to OSI are inconsistent with Montagnier's account, and with Gallo's own statements made in the Summer and Fall of 1984.

Gallo's accounts to OSI downplayed the strength of Gallo's conviction, in the Summer of 1984, that LAV and IIIb were genetically identical. According to Montagnier, Gallo told Montagnier he (Montagnier) must have contaminated his LAV cell lines with IIIb, whereupon Montagnier told Gallo this was impossible, because Gallo had LAV long before Montagnier received IIIb, and the contamination could only have occurred at the LTCB. Gallo did not include this exchange in his statement to OSI.

One of the statements Gallo made to OSI concerning this call to Montagnier was:

"I called Montagnier to say, 'possibly LAV -- IIIb are cross contaminated.' I originally assumed if so, it happened in his lab. I said, 'Our IIIb is like your LAV but we have these other ones which differ.' And he said to me, 'So what, there should be groupings.' So you know, one goes on and continues to work. It was not a big deal" (4/8/90 OSI interview; transcript p. 44).

In his book Virus Hunting, Gallo referenced the account of a witness to events at the LTCB in the Summer of 1984, on the occasion the LAV/IIIb identity was discovered. This witness was Dr. Stanley Weiss, a scientist working at the NCI, who happened to be near Gallo's office on the day in question. What Gallo said about Weiss' account was:

"Stanley Weiss, an epidemiologist now working in New Jersey, was at NCI at that time and happened to have been near my office when I made this call. My concern, he recalls, was more for the likelihood of a contamination in Montagnier's lab, and he confirms the relaxed attitude I have described" (p. 199).

Dr. Weiss wrote to OSI in November 1990, volunteering his account of the incident. Weiss said Gallo was told the news about the LAV/IIIb data by Dr. George Shaw, one of the scientists involved in the experiment. Weiss then said the following occurred:

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"At the end of Dr. Shaw's meeting with Dr. Gallo, they both came into the hallway and involved a few of us who were around in a brief discussion. Dr. Gallo clearly did not want to create new troubles, but he felt he needed to let the French know that somehow the French group must have contaminated the LAV-I stock in France with some of the HTLV-III that Dr. Gallo's group had sent them. The French had sent IIIb back to Dr. Gallo in error! . . . No one suggested that the direction of contamination might have been the reverse. It was absolutely clear that the news from Dr. Shaw had been a total surprise to Dr. Gallo. I had had the opportunity to get to know Dr. Gallo well enough that I feel confident that this must have been absolutely new. It was one of those instances where, in the presence of close colleagues, he rattled off his evolving thoughts. This included some harsh words regarding the French -- Dr. Gallo was chagrined at the wasted effort, at all the work that his lab had just done to compare the virus, only to find that they'd been given back IIIb, when there was so much else to do!" (11/5/90 Weiss-to Hadley letter, p. 1).

Montagnier described Gallo's telephone call to OSI as follows:

"I believe he called me on the telephone in July 1984 saying that he had analyzed LAV (not the early sample of September 83 'he could not grow,' but the virus produced in B cells (B/LAV) that I sent to him on his request . . . and found it having the same restriction map as IIIb. He was surprised since he had analyzed other isolates and found different restriction maps and wondered whether I could have contaminated our B/LAV by the IIIb we received on May 15, 1984.

I told him . . . that if there were to be contamination, it could only be the other way around, IIIb contaminated by LAV, since we had LAV long before and had sent this virus to other laboratories . . .

I deny to have said to Gallo, 'So what? Different AIDS viruses may group together.' This may be rather his reply.

On the contrary, I was shocked by Dr. Gallo's accusation and decided soon afterwards to break off our collaboration, including the publication of joined papers for the comparison of LAV and IIIb" (6/18/91 Montagnier-to-Hadley letter).

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Montagnier added:

". . . It is clear now, since Dr. Gallo has admitted the contamination of IIIb by LAV/LAI, that the latter virus was grown in his laboratory, presumably in continuous lines, for some time in 1983-84. Therefore, Dr. Gallo has not said the truth in 1984, or he was not informed by his collaborators of what was going on in his lab" (op cit.).

In a memorandum dated October 25, 1984, from Gallo to the NCI Director and Associate Director and headed, "Record of Telephone Conversation with Dr. Luc Montagnier on August 23, 1984;" Gallo stated:

". . . the virus looks like H9/HTLV-IIIb virus. We went back to the original LAV that they had sent to use and when analyzed it was found to be different from the virus growing in the culture they recently sent. All isolates we have found are microheterogenous (sic.). We presume, therefore, that the cell line we received from them probably contains our virus. They had our producer cell line for months before we received theirs."

The Bryant et al. Paper: Dr. Gallo allegedly had a strong negative reaction to a manuscript which was received at the LTCB in the Fall of 1984. Coauthored by Dr. Murray Gardner, an expert in simian AIDS at the University of California at Davis, and a postdoctoral fellow, Dr. Murray Bryant, the paper reported of a series of studies, including molecular studies, that compared LAV, IIIb, and ARV. "ARV" stood for AIDS related virus and was a virus discovered by Dr. Jay Levy, a virologist at the University of California's San Francisco Medical Center.

The Bryant et al. draft concluded, concerning the molecular comparisons of these three AIDS viruses, that "ARV can be readily distinguished from the LAV and HTLV-III," but "LAV and HTLV are identical." Moreover, the paper reported that LAV was found to contain "two nearly identical viruses," i.e., "strain polymorphism." This Hind III polymorphism was the same as Gallo and his associates found in IIIb, around the same time (reported in Hahn et al., Nature, 1984 and Shaw et al. Science, 1984).

Gardner and Malcolm Martin obtained their LAV samples from Dr. Montagnier in April 1984, several weeks before Gallo sent IIIb to Paris. Therefore, the identity of the Martin and Gardner LAV samples with IIIb could only mean that IIIb was derived from LAV and not the other way around.

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When Gallo saw the draft of the Bryant et al. paper that Dr. Gardner sent to him for comment, Gallo's reaction was reported as strongly negative. According to Dr. Bryant, at first there was no response from Gallo. Weeks went by following the transmittal of the manuscript to Gallo. Then in the Fall of 1984, Gallo finally contacted Gardner and alternately harangued and pleaded with him to delay or cease any attempt at publication of the Bryant et al. paper. Dr. Gardner advised the OIG that Gallo told him that he and Montagnier were "sorting out" the virus comparisons, that the LTCB scientists were more expert at such studies, and that he and his colleagues were going to inform the scientific community about the virus comparisons in their own terms, on their own timetable.

Gallo also appealed to Gardner's patriotism, implying it was somehow unamerican to publish the Bryant data. And, whether on his own volition or because Gallo solicited it, Peter Fischinger also became involved, telling Gardner that he would be well-advised not to get in the middle of this situation. Gardner was so upset by the pressures exerted upon him that according to OIG interviews of Drs. Robert Cardiff and Jay Levy, Gardner called to confide with these colleagues. Levy in turn called Dr. Malcolm Martin, who memorialized the conversation in a November 28, 1984 memorandum to the record stating:

"At 4:30 today I received a telephone call from Dr. Jay Levy. He was quite upset because of pressure being put on Dr. Murray Gardner by the NCI staff not to publish data presented at the Montana workshop [the molecular data in Bryant et al.]. He likened the situation to a 'Watergate coverup' and stated that all data pointed to apparent theft of the French AIDS virus."

Not until the following August was the Bryant's et al. paper published, not in the PNAS, for which it was originally intended, but in the journal, "Hematological Oncology." The published version of the paper had been substantially revised from the original version. The statement that LAV and IIIb were "identical" was changed to "nearly identical." Other changes of the same nature were made throughout the paper.

Malcolm Martin's LAV Data: Another related matter concerning early IIIb/LAV comparisons has to do with Malcolm Martin's LAV data, obtained in November/December 1984, but never published. In early September 1985, shortly after the initiation of the French/American dispute, responding to a request from senior HHS

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officials, Martin wrote two memoranda describing the LAV polymorph, identical to the polymorph reported for IIIb by Gallo et al. One of Martin's memoranda concluded with this line, ". . . informed scientists will certainly draw certain obvious conclusions."

What Gallo told OSI in 1990 concerning Malcolm Martin's data and its impact on his (Gallo's) thinking about the genetic identity of LAV and IIIb and which virus was derived from which was the following:

In time, because of one individual's data and because of realizing that we had crowded conditions, I in my mind, accepted the notion, if it was contamination, if it could be proven to be contamination, it probably happened in our laboratory, one because of the crowded conditions and the move that Popovic made, and secondly because Dr. Martin at NIH had stated that he got LAV just before we brought IIIb to France" (4/26/90 OSI interview; transcript p. 50).

Gallo made similar comments during the OSI interviews. However, in September 1985, when Gallo was given a copy of Malcolm Martin's memoranda and laboratory data, Gallo's response (in a memorandum to Peter Fischinger) characterized Martin's underlying theme -- that IIIb was derived from LAV -- as an "unfortunate innuendo." Gallo claimed he had other LAV pairs of isolates as close as or closer to each other than were LAV and IIIb, and he intimated that LAV and IIIb were so much alike because "they were derived at the same period of time from New York at a time only shortly after the virus entered the U.S."

In January 1994, the United States Attorney for the District of Maryland declined to prosecute Drs. Gallo or Popovic for matters relating to their conduct in the discovery and reporting of their AIDS research and other related matters including statements they made to the U.S. Patent Office and other Government officials.

The U.S. Attorney based this decision upon several obstacles, jurisdictional concerns and procedural rules governing criminal prosecution. Among those cited were the lack of proper venue and the statute of limitations. The U.S. Attorney also noted that the U.S. Attorney's office for the District of Columbia had

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previously considered and declined prosecution in the matter. The United States Attorney in Maryland noted that neither Dr. Gallo nor Popovic were eligible for any royalties when they applied for the patent in 1984,

"nor could they have known at the time that the Technology Transfer Act of 1986 would authorize such payments."

The United States Attorney felt that consideration also had to be given to the investigation and report of the patent firm of Allegretti and Witcoff who independently concluded that,

Dr. Gallo's statements in connection with the patent dispute were not 'prima facie' false, but rather subject to varying interruptions."

Further, the U.S. Attorney considered the recent ruling by the DHHS Departmental Appeals Board that the Office of Research Integrity was unable to prove any instances of scientific misconduct by Dr. Popovic, and that ORI decided

". . . to forego even the presentation of evidence regarding the alleged misconduct of Dr. Gallo, some of which was independent of the actions of his subordinate Dr. Popovic.

However, the U.S. Attorney did state the decision not to seek prosecution

". . . does not mean that we believe they (Gallo and Popovic) should continue to receive their annual royalty payments."

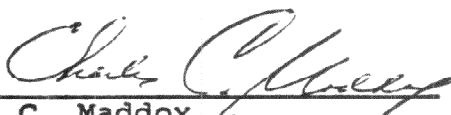
The U.S. Attorney expressed no opinion on this issue other than to draw attention to Gallo's May 30, 1991 acknowledgment that it was the French virus sent to the LTCB which formed the basis for their AIDS test. The U.S. Attorney referred consideration of the royalties question to HHS, saying HHS should examine both the question of future royalties as well as the question of,

". . . whether the Government should make any effort to recoup any payments made to them" (Gallo and Popovic).

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In view of the above declination by the U.S. Attorney, no further investigation is being conducted by the OIG and this matter is considered closed.

Approved:


Charles C. Maddox
Regional Inspector General
for Investigations
Washington Field Office

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