

NOTES

INTRODUCTION:

- I would like to make several introductory comments prior to addressing substantive issues directly related to the AIDS controversy:

. First, I did not keep a written log of events, so please don't hold me to specific dates. I have tried to reconstruct a calendar of events from memory and written articles or memos.

. Second, after I retired in Nov., 1986, I told several people that I would not make unsolicited comments about the AIDS controversy. If, however, I was contacted by someone representing a reputable organization, I would address the same issues I had addressed while I was with the Government. This is what occurred when I received a call from Mr. Crewdson sometime in 1988. He is the only media representative I have spoken to concerning the AIDS controversy. I had neither met nor heard of him prior to his call, and I was completely unaware of his activities which, as I later learned, had already been ongoing for a considerable time.

. Finally, early during the controversy, I reached two conclusions which I believe are still valid today:

a. The first was that a watergate-type syndrome was pervading the controversy, wherein relatively minor facts were being misrepresented. In was my opinion that this misrepresentation was more damaging to the U.S. patent position than would have been the admission of the actual facts.

b. Second, the controversy, including the innuendoes and rumors which were rampant throughout the period in question, need never have occurred had those responsible for determining the facts done their job properly. In other words, I believe that the controversy reached such a high crescendo because of the improper actions of one or more Government officials.

SUMMARY OF SOME MAJOR EVENTS RELATING TO MY INVOLVEMENT IN THE AIDS CONTROVERSY

- In 1981, I was appointed General Manager of the FCRF, and reported directly to PJF who at the time was NCI's Associate Director in overall charge of Frederick.

- Sometime in 1983, the NCI Director, at a meeting held in Bethesda, announced that the NCI would concentrate its AIDS efforts on retroviruses, to the exclusion of other viruses, based upon evidence generated by Gallo suggesting that HTLV-1 or a related virus was the cause of AIDS. At the meeting, the Director asked if we could grow the HTLV-1 virus at Frederick. I responded that we could, and we proceeded to construct appropriate containment facilities for handling the virus and other putative human viruses.

- Towards the latter half of 1983, additional arrangements were made by PJF for contractor laboratories at Frederick to carry out work for Gallo's laboratory, including electron microscopic studies. In carrying out this work, the contractor communicated directly with Gallo's laboratory, and I was not in the loop with respect to these communications.

- Sometime in late 1983, the contractor addressed with me a number of concerns it had relating to its AIDS work; including the labelling of samples by Gallo's lab. This prompted me to look into the matter, and I obtained from them copies of their communications with Gallo's lab. From these I learned that the first virus positive AIDS sample observed by electron microscopy at Frederick occurred in Oct., 1983 and was labelled LAV. The virus was classified by the contractor as a lentivirus. Additional findings of lentivirus in LAV infected cells were reported in Dec., 1983. I also learned that one or more non-LAV AIDS samples furnished by Gallo's laboratory were negative for virus.

- Based upon this information, I started to address with PJF at our weekly meetings questions related to EM data generated by Gallo at facilities other than Frederick. Specifically, I asked whether Gallo had positive EM results identifying a lentivirus in AIDS samples prior to the work performed at Frederick. His initial response was that other contractors were doing EM work for Gallo. I pursued my questioning over the ensuing months until PJF finally said that Electro-Nucleonics had such EM evidence. I asked him for substantiating documents, but they were not forthcoming.

- Another question raised by the contractor was their belief that the H9 cell may have been derived from the HUT 78 cell line. When I questioned PJF as to the origin of the H9 cell, he insisted it was not derived from HUT 78, but from another cell line. It wasn't until 1989 that evidence describing the true origin of the H9 cell was published.

- The contractor's identification of LAV as a lentivirus in late 1983 resulted in a series of outbursts by both P.J.F. and Gallo. In the case of P.J.F., for example, I vividly remember his coming into my office at Frederick and going into a tirade because the contractor had identified LAV as a lentivirus. At about the same time, my office received reports from the contractor that Gallo had phoned Gonda and made comments as to how Gonda was destroying his (Gallo's) reputation. As reported to my office, Gallo's calls included threats of retribution. It should be remembered that up to this time in late 1983, Gallo and P.J.F. were still promoting the argument that AIDS was caused by an HTLV-I related virus. As late as August of 1983, for example, Gallo's lab was planning to conduct a large serological survey at Frederick using HTLV-1 as the test antigen. Obviously, if LAV was a lentivirus, and the French had already provided evidence that sera from AIDS patients reacted with LAV, than Gallo's theory was wrong.

- My questioning of P.J.F. continued until I announced my retirement in 1986. Initially, the questions were restricted to the EM data and the origin of the H9 cell, but later they were broadened, as I will elaborate below. Suffice it to say, my persistent questioning was not well received.

- In April, 1984, HTLV-III was sent to Frederick for virus production, and a press conference was held by the DHHS announcing the discovery of the AIDS causative agent.

- Subsequent to the press conference, P.J.F. told me that the French had filed a patent application prior to the U.S. filing in May of 1984. I was unaware of the U.S. application prior to its filing, and I did not participate in its preparation.

- Shortly thereafter, 5 licenses were issued to private concerns for developing a serologic AIDS test, and Frederick was asked to produce the virus in quantities sufficient for the licensees to initiate their work. Dr. Harmison, whom I had not previously met, held a meeting at Frederick with the licensees and the virus was distributed.

- On May 28, 1985, the U.S. patent was issued.

- Subsequent to the issuance of the U.S. patent, the French raised concerns with the DHHS Secretary as to why a patent had been issued to the U.S. for an application filed in 1984 when the French had filed an application covering the same subject matter in 1983 (For the record, the French had filed a European application on Sept. 15, 1983 and a U.S. application on Dec. 5, 1983; under U.S. patent law, the French's priority date was the Sept. 15 date). P.J.F. instructed me to participate with him in a group being put together to formulate the Government's response to these concerns. The group was headed by Dr. Harmison, and included Dr. Rose, Harmison's assistant, P.J.F. and myself. Mr. Leroy Randall and Mr. Thomas Ferris, NIH patent attorneys, were also involved, although they were not present at all of the

meetings. The group met a number of times, and prepared a response which said, essentially, that since the issues raised were legal rather than scientific, they should more properly be addressed to the PTO. This was my first official involvement in the AIDS controversy.

- In Aug., 1985, a meeting was held at the DHHS with a delegation from the Pasteur Institute, including its Director, American patent attorney and representatives of its U.S. licensee who had come to Washington to present their case in person. A number of U.S. representatives were present, including Harrison, PJF, myself, a number of attorneys (Grinsted, Randell, Ferris, Auber), and at least one department representative.

- During the meeting, Dr. Nowinski, representing the licensee, brought up past problems which had occurred in Gallo's lab. involving virus contamination of cultures, and he suggested that the same may have occurred with LAV. The attorney representing the French discussed a number of causes of action which could be brought if the U.S. did not acquiesce on the issue of priority, including the conversion of LAV by Gallo.

- Following the meeting, the French delegation left and the American contingent remained to discuss what had transpired. The gist of the discussion was that the French would not prevail in any litigation. I spoke up and said that we should investigate the French claims in depth, since I did not believe that a prestigious institute such as the Pasteur would bring frivolous allegations unless they had some evidence to support their position. Additionally, I said that we should gather our evidence so that we could counter the French allegations with facts rather than rhetoric. To the best of my recollection, I was the only participant who expressed any concerns.

- When the meeting adjourned, PJF and I left to return to Frederick. During the trip, I said that I understood everything that had transpired except the allegation of conversion of LAV, since this would not be easy to prove using scientific evidence. As any virologist knows, many viruses are prone to genetic alterations with prolonged passage in vitro. For example, my laboratory had done extensive studies with herpes simplex virus where we were able to document minor antigenic changes with prolonged cell passage. Consequently, I felt that it would be very difficult to prove whether or not two viruses passaged independently in two different laboratories were identical.

- Although the conversion of LAV by Gallo is the issue most often cited in the media, I did not believe in August of 1985 nor do I believe today that this is the critical issue. I relayed this to Dr. Hadley during our phone conversation in Sept., where we discussed my appearance here. For the reasons stated above, I believe that the critical issues relate to patent priority; namely, what was done and when was it done. I reiterated this to Gallo during our meeting in Feb. of this year.

- Following the meeting with the French, my questioning of PJF broadened to include the facts surrounding Gallo's identification of HTLV-III as the cause of AIDS. In other words had Gallo reduced his invention to practice prior to the French priority date of Sept. 15, 1983. PJF insisted that he (Gallo) had.

- The meetings of Harmison's group also continued for the purpose of addressing the mounting controversy surrounding the discovery of the cause of AIDS, as well as the attempt by the French to instigate an interference in the PTO. Here again, my participation was not voluntary, but was based upon instructions received from PJF. In fact, even though I asked to be relieved of any further involvement because of my concerns, I was instructed to continue my participation. At that time, I had developed a feeling that the Government was not being objective in its approach or interpretation of the facts as they were uncovered.

- Sometime around Sept., 1985, PJF prepared the memo referred to in Crewdson's article of March 18, 1990. I saw a draft of the memo and commented that a statement to the effect that Gallo could not grow LAV in a permanent cell line was incorrect. The statement was deleted from the final version.

- During the ensuing months PJF, in response to my questions, persisted in his position that Gallo had found the cause of AIDS prior to the French, but he never provided any substantiating evidence. His arguments, rather than being substantive, involved statements to the effect that Gallo was a better scientist than Montagnier, and that Gallo's evidence linking HTLV-III to AIDS was better than that of the French's with LAV. I persisted in my insistence on concrete evidence backing these claims, since the French were actively attempting to instigate an interference. I told PJF, in no uncertain terms, that we were dealing with patent matters, and that the quality of the science, if indeed that was a valid concern, was not the issue. I emphasized that patent priority involved legal issues, and that priority would not be determined by who did or did not do the best science. I further cautioned him that in dealing with the PTO, candor and honesty were of the utmost importance, since anything less could lead to charges of fraud.

- My expressions of concern about the lack of substantiating evidence were not limited to my discussions with PJF, since I continued to bring them up at the meetings being held with Harmison. At one of these meetings, in fact, I said point blank that the U.S. should consider settling the patent dispute with the French. The answer by Harmison was a definite no.

- On a separate occasion, I asked PJF why he persisted in advocating priority claims which to my mind even he did not believe. He answered rather sheepishly that this was what the Institute wanted.

- At some point towards the end of 1985, word was circulated that the French would be willing to settle the patent dispute. A meeting was arranged at the Parklawn building, I believe in Mr. Riseberg's office, which PJF was to attend. He was at Frederick on the day in question, but he decided, for whatever reason, not to attend the meeting and directed me to go in his place. He gave me a package to distribute to the participants. The package included the 1983 memos from Gonda to Popovic describing positive EM results with LAV, as well as several notebook pages from Gallo's lab. The meeting was chaired by Dr. Harrison with several U.S. attorneys in attendance (Riseberg, Randall, Grinsted), as well as the same DHHS representative who was present at the meeting with the French. I distributed the package prepared by PJF, and during the meeting word was received that the French had decided not to settle. The DHHS representative placed a call to Mr. Haddow at the DHHS from the meeting room and told him what had transpired. The meeting then adjourned.

- In early 1986, I received a call from Gilden, the contractor P.I., who asked if I could come to his office. When I arrived, I found Gonda and Gilden present. Gonda said that something had happened which he wanted me to know about. As he related to me, for some time someone in D.C. had been calling him for the purpose of his serving as a consultant on EM matters. Since he (Gonda) was not enthused about the idea, he kept putting the individual off. Finally, he agreed to meet with the individual at the latter's office in D.C. When he arrived, there were two individuals present, one of whom introduced himself as a lawyer for the Pasteur Inst. The lawyer showed Gonda copies of his memos from 1983 describing the EM results with LAV as well as photographs which Gonda recognized. The lawyer then asked Gonda if the composite published by Gallo in one of the May 4, 1984 Science papers was in fact LAV and not HTLV-III. Gonda told me that he left without responding.

- I immediately called Mr. Grinsted and informed him of what had transpired and I notified the NCI.

- Some time later, Gilden again asked me to come to his office. When I arrived, Gonda said that he had determined that the composite photo in the Science paper was indeed LAV. I asked how this could have occurred and how did he discover the error. He said that someone from Gallo's lab had called a few days earlier and asked him to recheck the origin of the photos used to make the composite.

- I told Gilden he should immediately call PJF and tell him what had transpired. Sometime later, Gilden said PJF's initial reaction was that it was not too important, but he had called back later to say that it was. Subsequently, a meeting, to which I was not invited, was held at the NCI. As related to me by Gilden, the Director said that if a scientific error had been made, it must be corrected, and he instructed Gallo and the

Frederick personnel to prepare a letter to Science. During the ensuing weeks a lot of haggling occurred between Gallo and the Contractor personnel as to who was responsible for the error and who should be the senior author of the letter. Finally, against my advice, Gilden acceded to PJF pleading that the contractor be the senior author.

- A copy of the final letter was faxed to Frederick along with a photo which was to be included. Since the fax was too poor to evaluate, Gallo's lab was asked to send another copy by messenger. When it arrived at about 5:00 pm, Gilden and Gonda came into my office and showed me the photo which contained two virus particles (this is the misquote in Crewdson's article to which I referred in my letter of Sept. 4, 1990). Gonda said that the particles were HTLV-I and not HTLV-III. Included was a handwritten note by PJF stating that this was the EM photo selected by him and Vince, referring to the Director. I tried to reach PJF, but he had already left for the day. I told Gilden to contact the Director. He called him at home and left a message on his answering machine. A short time later, while I was in Gilden's office, the Director called, and Gilden told him about the photo. The Director denied any involvement in selecting the photo, and told Gilden to contact Gallo. Sometime later that evening, Gilden got through to Gallo, told him about the photo and learned that the letter and photo had already been submitted to Science. The letter was subsequently recalled, a new version was submitted without a photo, and it was published on April 18, 1986.

- Following these events, I instructed the contractor to turn over to the Contracting Officer, Mr. DeFelice, all of the documents relating to the letter, including PJF's memo. This was done and was made part of the official Contract records. I discussed this material with Mr. DeFelice in early 1987. If for some reason he doesn't recall the documents in question, I would be glad to help jog his memory.

- At about this same time, the PTO declared an interference, and Justice Dept. attorneys took over the prosecution for the Government. Mr. Byrne, the Justice Dept. attorney and I believe Mr. Randall paid a visit to Frederick to check Gonda's laboratory procedures, since PJF and Gallo insisted that Gonda had given the French attorney the photos in question. While in my office, I stated to Mr. Byrne that I didn't think he would get cooperation from Gallo in trying to gather evidence for prosecuting the interference.

- Sometime later, I heard that Gallo was making critical comments concerning how the Justice Dept. attorney's were handling the interference; specifically that they were not representing him (Gallo) properly. I subsequently heard that on Gallo's insistence, a private patent law firm was engaged to assist the Gov't attorneys.

- Sometime in mid-1986, I received a call from Peter Newmark, who was then Editor of Nature. He said that he had heard of a second mixup in published HTLV-III photos, this time in a review article authored by PJF. I said that I didn't know anything about it, and that PJF was on extended leave and not available. After the call, I asked Gilden if he knew what Newmark was talking about. He said he knew the article and composite in question and that it was HTLV-III and not LAV. I asked how he knew it was not LAV. He responded that Gonda had checked all of the LAV photos and none matched the composite in question. I said that I wanted Gonda to check his photos and determine which were used to make the composite, since it was not sufficient to know where the composite didn't come from, we had to know where it did come from. I called the Director's office and notified Mr. Ficca of what had transpired. A couple of hours later the Director called and told me that he had just heard about the incident. I told him that I had checked with the contractor and was assured that the composite in question was HTLV-III and not LAV.

- Over the next couple of months I asked Gilden on at least 3 occasions if Gonda had determined the origin of the composite in question. In each instance he gave some excuse as to why it was not done. In Sept., 1986, while I was at the NIH, PJF told me that the composite in question was indeed LAV, and that the Director had been told. I asked how he knew, and he said that they had checked Gonda's LAV photos submitted to Popovic. I reminded him that I had asked Gilden at the time of Newmark's call and he had assured me that the composite represented HTLV-III. I also said that if Gilden had lied about the second photo, he may have lied about the first.

- In Feb., 1987, at a dinner meeting with Gallo, I brought up the issue of the second photo mixup. He acknowledged that he knew about it. When I asked why the director had not fired the contractor for lying, Gallo replied that he (the director) was afraid of a congressional investigation of Frederick.

- On July 27, 1986, a Sunday, I received a call from Mr. Swire, the attorney representing the Pasteur asking me to help them in the patent dispute. I was surprised to receive the call, but as I've said, my concerns about the U.S. claims were well known and not a secret. I immediately reported the call and need not go into further details since the document is available.

- Sometime in July or Aug., 1986, I had dinner with Gallo at his request. This was our first direct communication since commencement of the AIDS controversy. I told him about the call from Mr. Swire, and during our discussion Gallo offered that much of his work had been done retrospectively. I was surprised at this statement, since it was exactly what I had been telling PJF, who insisted otherwise.

- I met with Gallo on two other occasions since 1986. The first occurred in Feb. of 1987 and the last in Feb., 1990 when he

called to express concerns about the Crewdson article. During that phone conversation, I said I would meet with him at anytime and do whatever was necessary to get the truth out. At the meeting, which lasted several hours and was attended by a third person, I reiterated to Gallo that my concerns were related to patent issues. I then went into a step by step discourse of the facts as I knew them, and showed him several documents which supported my position. He interrupted several times to remind me of his scientific achievements, but I stopped him and told him that I was not questioning his science, but rather his claims as to what was done and when. I reiterated that I was only interested in the facts, and was not involved in any attempt to discredit him based upon rumors or innuendoes.

SUBSTANTIVE FACTS

- In Feb. of this year when I met with Gallo, I told him that his claim of having identified "aberrant" particles by EM prior to Sept., 1983 was questionable. He replied that the EM data were not important. I responded that they were since PJF had insisted that Gallo knew prior to Frederick's identification of LAV as a lentivirus that AIDS samples contained particles morphologically distinct from HTLV-I or -II. I also told Gallo that his lack of EM data suggested that he had not reduced his invention to practice prior to the French filing date. Finally, I said that the facts suggest that an attempt was being made to make a paper trail to cover up the fact that the identification of "aberrant" HTLV-I particles by Electro-Nucleonics was done retrospectively after LAV was shown to be a lentivirus. The facts in issue may be summarized as follows:

- On Dec. 6 and 7 of 1984, A Symposium on HTLV was held at the NIH which was published in Sept. of 1985 as a Supplement to Cancer Research. Included was an overview article by Gallo on pages 4524s-4533s entitled The Human T-Cell Leukemia/Lymphotropic Retroviruses (HTLV) Family: Past, Present, and Future. When, I received the article, I immediately called Harmison's office and spoke to Dr. Rose. I told her that the article answered many of the questions as to when things were done.

. In the article on page 4527s Gallo states "By November, 1982 transient RT activity was detected and suggestions (by electron microscopy) of a retrovirus different from HTLV-I or -II were found."

a. When I confronted Gallo with this statement during our meeting in Feb. of this year, he responded that the word "suggestions" did not refer to EM. I showed the statement to the other person present who, to say the least, also was surprised at Gallo's explanation, since the plain meaning of the words was that "suggestions" did refer to EM. In any case, we could now exclude Nov., 1982 as the time Gallo had EM evidence of "aberrant" HTLV-I particles.

. In the article, Gallo also states: "By February 1983 we had five such isolates.... "We could only conclude that the particles were retroviruses but not HTLV-I or -II, since the only reagents of human retroviruses then available were to HTLV-I or -II."

. Finally, the article clearly states that substantive work with HTLV-III was not done prior to Nov., 1983 when a method for growing the virus was developed. It is significant that nowhere in the article does Gallo claim knowledge of "aberrant" HTLV-I particles other than the Nov., 1982 reference which he now disclaims.

- I told Gallo that now that the Nov., 1982 date could be excluded as the time he recognized "aberrant" HTLV-I particles, we now could address his assertion that such particles were identified in Feb. of 1983.

a. I showed him The History of Key Events and Side Issue of the HTLV-III/LAV Discovery which was prepared in 1986 and where he makes the following statements:

. "First detection of HTLV-III in Gallo lab (not called HTLV-III until mass produced and characterized and proven to be cause of AIDS) was December, 1982."

i) "Evidence: Reverse Transcriptase + particles, cytopathic, negative for HTLV-I and -II. No electron microscopy."

. "First detection of HTLV-III in Gallo lab with above data plus electron microscopy was February 1983."

. "Many more detections, several with electron micrographs, prior to Montagnier sending us virus particles on September 23, 1983."

. "All the above can be documented and conclusively proven."

b. In a Science article on 18 April, 1986 entitled A New Twist in AIDS Patent Fight it is stated: "It can be conclusively documented," says Gallo that he had electron micrographs taken by a different laboratory, Electro-Nucleonics, well before the sample of LAV arrived at his lab.

b. A final example is an article which appeared in the 12 February, 1987 issue of the New Scientist where on page 58 it is stated: "In an interview in an American Newspaper, the New York Native, in October, 1986, Gallo said: "Let me say for the record: We could EM (electron micrograph) this virus for the first time in February, 1983, months before the virus was sent to us from France. We have proof of that; that's why we're not pushing too hard not to go to court." The article continues "Gallo says that another laboratory, run by a company called Electro-Nucleonics was able to take pictures of the AIDS virus before he received samples of LAV."

. What is of interest and what I believe is significant is that in none of these three examples does Gallo say that he was aware of "aberrant" HTLV-I particles prior to the French filing date. All he does claim in these examples is that electron micrographs were available prior to the critical date. I have no argument with this claim.

- If we now turn to Gallo's letter to Nature published on May 8, 1986 and entitled First Isolation of HTLV-III, he states

"Before receipt of LAV we had detected reverse transcriptase activity in a number of cultures from AIDS and ARC patients which showed no cross-reactivity with HTLV-I or -II reagents, thus indicating the presence of a new retrovirus. In a number of cases, electron microscopic examination showed the presence of virus particles with a cylindrical core characteristic of HTLV-III (Table 1, Fig. 1)." Here Gallo does state that lentivirus type particles were present in photos taken prior to his receipt of LAV on Sept. 22, 1983, but he does not claim that he was aware of the particles.

. Table 1 shows that the first EM positive results were obtained with a sample labeled C.C. which was received 2/15/83, and which showed +/- reactivity with HTLV-I antisera. In the footnote to the Table it states "C.C. was infected with both HTLV-III and HTLV-I". The next EM positive sample in Table 1 was isolate R.F. which was received on 10/18/83, a date after the critical date of Sept. 15, 1983. Parenthetically, from the sequence published in Crewdson's article, Gonda reported sample RF negative for virus by EM on Jan. 18, 1984 and Mar. 26, 1984 and positive for virus on Oct. 17, 1984.

- Getting back to my meeting with Gallo in Feb. of this year, I then showed him two versions of letters written by Electro-Nucleonics on Dec. 11, 1985. It is my understanding that more than these two versions of the same letter may have been written on the same date. In any case, both versions state that sample 3731 was not received by Electro-Nucleonics until May 9 of 1983. Further, in an attachment to the letters, sample 3731 is identified as isolate C.C. Consequently, any claim by Gallo that he had EM data in Feb. of 1983 which showed virus particles different from HTLV-I, regardless of when these particles were identified, could not be correct. In addition, two photos were attached to the letters of Dec. 11, 1985 purporting to show lentivirus particles. One of these photos contains 2 particles and is the photo originally submitted to Science with the letter published on April 18, 1986, and which Gonda identified as HTLV-I rather than HTLV-III.

- Once Gallo saw the copies of the letters, he decided that Electro-Nucleonics must have identified "aberrant" HTLV-I particles in May of 1983. I said baloney or something to that effect, and cited several reasons why he could not even claim May as the critical date.

. First, the fact that multiple versions of a letter covering the same subject matter were prepared by Electro-Nucleonics on the same date raises the possibility that this was an attempt to develop a paper trail after the fact. Further, from the plain meaning of the language used in both versions, it is clear that Electro-Nucleonics was not claiming in Dec., 1985 that it had identified "aberrant" HTLV-I particles, no less lentivirus particles, in May of 1983. All the letters say is that EM photos were taken in May of 1983. For example, one

version of the letter written on Dec.11,1985 states "Dr. Kramarsky has found two thin, cell pellet sections (attached) which have aberrant morphology, neither HTLV-I nor HTLV-II." The second version dated the same day says "Dr. Kramarsky has found two thin, cell pellet sections (attached) which appear to have morphologically distinct HTLV-III virus." Neither version implies either explicitly or implicitly that the aberrant particles were identified as such at the time the photos were made on May 26,1983. The possibility now becomes a probability. When I confronted Gallo with these facts, he replied that discussions of aberrant particles were done orally at lab meetings. I said if that was so, he should get something in writing from Electro-Nucleonics verifying that it had identified the aberrant particles at the time the photos were made. He replied he would not even ask them. I conclude from this exchange that the probability is a fact; namely, that the preparation of multiple versions of the letters written in Dec., 1985 was an attempt to develop a paper trail retrospectively..

. My second reason for refuting Gallo's claim that he had identified "aberrant" HTLV-I particles in May of 1983 was that had he done so, neither he nor PJF would have had any reason to fly off the handle as they did when Gonda reported in late 1983 that LAV was a lentivirus.

. My final reason was that in late 1983, both Gallo and PJF were still pushing an HTLV-I related virus as the cause of AIDS. As I previously mentioned, as late as Aug. of 1983, a large serological survey was being planned for Frederick using HTLV-I as the antigen.

. Parenthetically, I understand that in his statement to this committee, Gallo may have implied that "aberrant" HTLV-I particles were identified in electron micrographs of sample C.C. in May of 1983.

- From the facts reviewed above, we can answer several questions:

. First, did Electro-Nucleonics have EM photos of AIDS samples from Gallo's lab. prior to Sept. 15,1983? The answer is YES, such photos were available in May of 1983.

. Second, did the photos show virus particles different from HTLV-I. The answer is MAYBE, since Gonda had identified the particles in one photo as HTLV-I.

. Third, and most critical, did Electro-Nucleonics or anyone else identify the particles in the photos as "aberrant" HTLV-I particles or lentivirus particles in May of 1983 or even prior to Sept. 15,1983? The answer is NO.

- The lack of EM data also suggests that Gallo had not reduced his invention to practice prior to the Sept. 15,1983 priority date of the French patent application.

. Consider first isolate C.C., which is the critical isolate in Gallo's claim of priority. If we look at the facts surrounding this isolate in a light most favorable to Gallo, we can draw the following conclusions:

a. First, from the Nature Letter of 8 May, 1986, the sample was received on 15 Feb., 1983 and it tested positive for RT suggesting the presence of a retrovirus.

b. Second, from the Nature Letter, the sample tested +/- with HTLV-I anti-p19 and anti-p24, suggesting the presence of HTLV-I or a related virus.

c. Third, from the Nature Letter, patient C.C. was infected with both HTLV-III and HTLV-I, but Gallo could not have known about the HTLV-III infection prior to Sept. 15, 1983 since he did not have reagents for this virus until later, as indicated in his Cancer Res. Article.

d. Fourth, Gallo was not aware of "aberrant" HTLV-I or lentivirus particles prior to Sept. 15, 1983 for the reasons previously stated. In addition, Gonda had classified the particles in the C.C. sample photo as HTLV-I, which made sense, since according to Gallo's Nature letter of 8 May, 1986, patient C.C. was infected with HTLV-I. Further, the photo in question was the same one originally submitted to Science and later recalled, with no objection being raised by Gallo to Gonda's conclusion.

e. Finally, from the Nature Letter it is clear that sample C.C. was not tested for reactivity with AIDS sera, thus there is no evidence that the cells contained any virus associated with the disease.

. If we now look at isolates other than C.C. obtained prior to Sept. 15, 1983, we can draw the following conclusions:

a. First, from the Nature Letter, the isolates showed positive RT activity suggesting the presence of a retrovirus.

b. Second, from the Nature Letter, the isolates did not react with HTLV-I anti-p19 or p-24. This, Gallo suggests, is evidence for "the presence of a new retrovirus." If we interpret the findings in a light most favorable to Gallo, we can accept his premise. What the evidence does not show, however, is that the new virus is unrelated to HTLV-I, either genetically, since the reagents used may have been able to differentiate between intratypic variants, or structurally, since the new virus may have been an HTLV-I like retrovirus. In other words, Gallo's long standing claim prior to the identification of HTLV-III that the cause of AIDS was a virus related to HTLV-I was not excluded by his findings prior to Sept. 15, 1983. Thus, despite Gallo's contention to the contrary, the EM data is important. In the absence of evidence showing that he had knowledge by EM of "aberrant" HTLV-I or lentivirus particles prior to the Sept. 15,

1983 date, his data showing RT activity and negative reactivity with HTLV-I antisera only support his contention that a virus distinct from HTLV-I or -II was present in his AIDS samples, but the data do not prove that the samples contained a virus unrelated to HTLV-I or -II.

c. Finally, from the Nature Letter, none of the samples in question were tested for reactivity with AIDS sera; thus there was no evidence that they contained any virus associated with the disease.

. To summarize, therefore, prior to Sept. 15, 1983, Gallo had a number of samples from AIDS patients which showed positive RT activity, suggesting a retrovirus, and +/- or negative reactivity with HTLV-I antisera, suggesting a distinct, but not necessarily HTLV-I unrelated virus. There is no convincing evidence that he was aware that the cells contained virus particles distinct from HTLV-I and there is no serologic data to relate whatever was in the cells to the disease.

- If we now look at the facts supporting the French's patent priority claim, we can draw the following conclusions:

. First, by merely filing a patent application, the French obtained a date of constructive reduction to practice of Sept. 15, 1983 under U.S. Patent Laws. As a consequence, the French were declared the senior party in the interference, and the U.S., as the junior party, had the burden of showing a prior date of invention.

. Second, in The Chronology of AIDS Research agreed to by Gallo and published in Nature on April 2, 1987, the French, in their Science paper of May, 1983: i) isolated and identified a non-transforming retrovirus (LAV) different from HTLV-I or -II, ii) were able to passage the virus, iii) identified a p25 protein and showed it was not cross-reactive with HTLV-I p24, and iv) detected antibodies against the protein in two patients.

. Third, in Sept., 1983, the Chronology shows that the French had identified antibodies to the main LAV antigens in 63% of patients with lymphadenopathy-associated syndrome and 20% of AIDS patients.

. Finally, in Sept., 1983, the Chronology shows that the French had shown that LAV was morphologically similar to equine infectious anemia virus (EIAV), a lentivirus, and different from HTLV's.

. To summarize, therefore, by Sept., 1983 the French had obtained sufficient information to suggest that LAV was a lentivirus and was the cause of AIDS, and although the percentage of patients positive for antibodies to the virus was not optimal, it was sufficient for them to file a patent application and claim a priority date earlier than Gallo's.

CONCLUSIONS

- I would like to end my presentation by referring again to the two conclusions I reached early during the controversy.

. The first was my feeling that a Watergate-type syndrome was pervading the controversy, wherein relatively minor facts were being misrepresented to bolster Gallo's claim of priority. Consider the following:

a. First, there was no reason to insist, as PJF did, that the H9 cell was not derived from the HUT-78 line when in fact it was, as shown in 1989. Although the origin of the H9 cell may not have been known in late 1983 or early 1984, the proper answer to any question would have been simply that the cell's origin was not known. This example, though referring to a relatively minor fact, is typical of one type of misrepresentation which was pervasive throughout the period; namely, deny it until someone comes up with evidence to refute it, then admit it but downplay its significance.

b. A second, and more serious example, was the attempt to claim that "aberrant" HTLV-I or lentivirus particles in Gallo's samples were known prior to Gonda's identification of LAV as a lentivirus, as I have described in detail. This represents another type of misrepresentation pervasive throughout the period; namely, make a claim as to when something was done, and if someone comes up with facts to refute it, change the date until a point in time is reached where the claim cannot be refuted. The irony here is that admitting the facts would not have been fatal to Gallo's patent position. I told him during our meeting in early 1987 that I had recommended settling with the French early on, since this could have precluded the ensuing controversy. I also told him that I would not have settled when he did, since I believe he could have prevailed in an interference proceeding. Although the facts would have shown that Gallo had not reduced his invention to practice prior to Sept. 15, 1983, he could have shown that he conceived the invention in 1982 and diligently pursued it up to the French filing date. In the U.S., a patent is issued to the first to invent, not to the first to file. It is my understanding, from discussions with various people during the time in question, that the attorneys representing the U.S. realized that the evidence would not support a claim of prior reduction to practice, and did plan to pursue a strategy of conception plus diligence in prosecuting the interference.

c. A third, and equally serious example, is related to Bob's personality. When someone questions him about a fact, his defense is to attack the individual, especially his or her scientific competency. The written media is replete with examples where he made such attacks. Further, and this is an opinion on my part, Bob is unwilling to admit that someone else may have done something significant in the AIDS area before he

did. Instead of letting the scientific community judge the facts and make its own conclusion as to who should get credit for what, he insists on stacking the cards in his favor.

d. A fourth example of what was pervasive during this period was the assigning of blame with no basis in fact. I could relate to this committee a number of examples where an individual or individuals was blamed for something, such as collaborating with the French or purposely mixing-up photos, with absolutely no evidence to substantiate the allegation. Not only was blame ascribed to the individual, but the word was passed throughout the scientific community using what was, at the time, a very powerful AIDS network. The purpose was clearly to deflect the blame for any problem to someone else. I remember remarking to some people during the period in question that if this was the way the NCI's AIDS program was being operated; namely, reaching conclusions without substantiating facts, than heaven help us.

. The second conclusion I reached early on was that the controversy need never have occurred had those responsible for determining the facts done their job properly. I dealt directly on a weekly basis with the NCI's Deputy Director, who was in charge of the Institute's AIDS work. I did not deal with or discuss the issues with Gallo during the entire period up to Aug., 1986. The questions I raised with PJF were related to factual issues, not discretionary issues. It is important for the committee to understand that if the positions being advocated by PJF were discretionary, I would have either supported them as an employee of the Institute or resigned if I felt that I could not support them.

It is my opinion that PJF, as the official in charge, should have insisted on seeing substantiating evidence before promoting Gallo's claims. If he merely addressed questions to Gallo and accepted the response without seeing the evidence then, in my opinion, he did not act properly. I addressed the relevant questions to PJF, so he cannot claim that he was unaware of the issues in question.

Finally, I limit my comments to the actions taken by PJF, since he was the senior official with whom I had direct contact. Whether he was acting under the direction of someone else I do not know and do not imply. That is for this committee to determine.