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Dr Robert Windom Assistant Secretary for Health Dept of Health & Human Services Washington DC 20201 USA

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Dear Dr Windom

Dr M Koch sent me a copy of the letter signed by you and by Mr R E Robertson. I trust you will show my letter to Mr Robertson. I deliberately said 'signed' but not wrote. It appears that you, like others before you, have also been used by Dr Gallo. To prove this point, I will systematically go over every point raised in the letter you signed.

Firstly, of the alleged errors in Dr Koch's book, I say, and will prove, that he understates his case. I grant that on the first point you are probably right, namely "the viclation of certain provisions of the US copyright act of 1976 and the Lanham Act of 1947" but I assume that you would not have written your letter were this your major concern. Indeed you are right to feel that "the integrity of the Department, certain of its scientists and the United States Patent and Trademark Office" is questionable to say the least. The earlier legal battle between the Pasteur Institute and the NIH was probably settled on political, rather than scientific, grounds but this is not the essence of Dr Koch's thesis. There is no question in my mind "that certain scientists at the National Cancer Institute (NCI) are responsible for the lost year in AIDS research. You must realize that this resulted in the logarithmic increase in the number of cases of AIDS virus infection both through sexual intercourse and the transfusion of thousands of units of contaminated blood. You continue saying that the author's "factual allegations are not true". Not only are they true but scientific publications from the NCI prove that they are an understatement of what really took place.

As to "misunderstanding... the United States patent laws and procedures", I am not a patent agent but I do know that the Pasteur Institute applied for a patent on the test for LAV in 1983 while Gallo applied for a patent in 1984 for a virus which the scientific community knows was the French LAV he had received earlier. The astonishing fact is that the US patent was granted to Gallo in 1985 and not to the French. So much for my misunderstanding of US patent laws. Indeed it takes some understanding.

You have no right to say "that the author fails to appreciate the differences between a scientific discovery on the one hand and a patentable invention on the other hand". There was no original development of a method for detecting antibodies to the AIDS virus. Basically the very same ELISA test system is being used which was developed years ago for other microorganisms. In fact many companies such as Abbott are using the very same machine and format for HIV testing that they have used in the past.

As to your specific points (page 2, second paragraph) which are required:

- 1) "A virus or portion thereof" was isolated in France early in 1983 and was given twice to Dr Gallo (July and September 1983), (Montagnier, Nature August 9 1986).
- 2) "Proof that the isclated virus is the etiologic agent of AIDS", was provided in Dr Montagnier's paper which he presented on September 15 1983 in Gallo's Cold Spring Harbour meeting and subsequently published in Gallo et al's proceedings of the meeting. In addition, the 1983 French patent application contains proof that LAV was the cause of AIDS;
- 3) "A method for propagating the virus" was also achieved by the French team when they were the first to show that the virus replicated in vitro in lymphocytes;
- 4) "A technique for measuring the presence of antibodies to that virus" the ELISA method used for detecting antibodies was over ten years old by the time it was used in AIDS research.

You are wrong in stating "that both teams isolated HIV in 1983 and that beginning in 1982 scientists in Dr Gallo's laboratory undertook a dual task". In fact Dr Gallo has published three misleading papers on the involvement of the adult T-cell leukaemia virus, ATLV/HTLV-I in AIDS (Science 1983; 220: 965). His third paper on HTLV alone in AIDS which was submitted to Science on December 12 1983 was published in the May 11 1984 issue of Science. We know that even the electron micrographs of the AIDS virus in the Science 1984 publication were in fact those of LAV Gallo received on September 23 1983. Initially he tried to claim that LAV never grew in his laboratory and in order to prove it he produced a photomontage of a letter in which the data on the active replication of LAV was painted over (see enclosure 1). In this original version of the letter you can see that in fact the LAV grew very well in Hut 78 cell line (see enclosure 2).

You are also wrong in claiming that Gallo's laboratory developed a cell line clone (H9) of a human T4 lymphocyte" because Gallo's H9 cells are the Hut 78 cell line which Dr A Gazdar and his associates developed in 1978 or 1979 (Blood 1980; 55: 409). By changing the name of the virus from LAV to HTLV III and the cell line from Hut 78 to H9, Gallo claimed credit for achievments of two independent groups. You are even wrong in saying that "Without the discovery of such an immortalized cell line, large-scale tests would not have been possible", because the AIDS virus also grows very well in other human T-cell lines such as the CEM line which was developed in the Children's Hospital in Boston in 1964 and my own T-cell line which I developed in Cambridge in 1975, to mention but two such T-cell lines.

You might be wrong in saying that the H9 cells (Hut 78) were licensed to the Pasteur Institute because as far as I know they use the CEM cell line. There is no question in my mind that you are wrong in saying that "the development

of the immortalized cell provided the breakthrough necessary to undertake the testing required to establish the cause of AIDS "not only because other human T-cell lines were available but simply one can use also HIV-infected fresh human T-lymphocytes to demonstrate the causal association of LAV with the disease. Again the published record clearly shows that you have no right to claim that Gallo showed "throughout the latter part of 1983" the involvement of HIV in AIDS when in fact Dr Gallo submitted his third paper to Science on December 12 1983 claiming that only the leukaemia virus HTLV-I was involved in AIDS. In Gallo's letter to Dr Deinhardt of September 27 1983, he wrote "I have never seen the virus that Luc Montagnier has described ... and I suspect he has a mixture of two" (see enclosure 3). So much for Gallo's 1983 test results!!! In addition to the letter he submitted to Science on December 12 1983 about the leukaemia virus involvement in AIDS, he sent another one to the Lancet in December 1983 about HTLV-I in AIDS, but held it back subsequently.

The development of the collaboration between the Pasteur Institute and the CDC vis-a-vis Gallo is told in great detail in R Shilt's book, 'And the Band Played On' as well as by Dr Don Francis in the British TV programme in the series 'World in Action' which was broadcast in the UK in March 1987 (I believe that Dr Walter W Stewart of your Department (Room B2A-15, Building 8, NIH) has a copy of the TV programme). You have no reason to emphasize that Dr Gallo and his co-workers described 48 independent isolates of the AIDS virus'; he claimed that he had 48 but he did not even prove that he had even one genuine isolate. Subsequently, we learned first from the nucleic acid analysis of Drs Rabson and Martin of the NIH that Gallo's 48 isolates spoke French with a single voice. "The analysis of nucleotide sequence heterogeneity presented in Table 1 indicates that HTLV-III and LAV are virtually identical. This result is surprising in view of their independent isolation and published reports" (Cell 1985; 40: 477).

I therefore hope that by now you will also agree to withdraw your statement "that the inventions at issue were in fact jointly developed by both teams".

I also hope that when you finish reading my letter you will apologise to Dr Koch for accusing him of "basic misunderstanding of the events surrounding the development of the test kit". Your reference to the first quoted translation of Dr Koch's book as scientifically and historically incorrect" is probably right for the wrong reasons because what was supposed to be the first successful isolation from Dr Gallo's laboratory turned out to be the French LAV, namely the sequence data of Gallo's "first isolate" which was published in January 1985 turned out to be indistinguishable from LAV. Remember it was first pointed out by Dr Rabson and Martin of the NIH in their paper in the March issue of Cell. The identity of LAV and HTLV-III is based on sequence data alone and not on morphology as you were made to state (first paragraph page 2).

You are also wrong in stating that an appropriate genetic name was not even possible until the development by Dr Gallo's group of the first specific reagents to this type of virus. Indeed by the middle of 1983 while Gallo's group was still claiming that HTLV-I was the cause of AIDS the French team established that LAV was a lentivirus and that it cross-reacted with equine infectious anaemia virus which is also a lentivirus.

Your second paragraph on page 4 is ridiculous. I wonder whether you actually understand what you are made to sign. The third paragraph on page 4 further convinces me that you did not even realize what you were signing. Indeed Dr Gallo renamed LAV 'HTLV-III' in order to avoid retracting his repeated claims that HTLV-I was the cause of AIDS. By changing the meaning of

L from Leukaemia to Lymphotropic which he did by himself, he thought he would not need to retract his earlier papers about HTLV-I in AIDS. The ten scientists were Dr Gallo's guests (was it at the expense of US tax payers?) at his Cold Spring Harbour meeting. This gathering of Gallo's did not constitute an authoritative committee on the nomenclature of viruses and their letter dealt only with the question as to whether to call the virus, which was in fact Hinuma's (he was not invited) discovery, HTLV-I instead of ATLV. However, to justify naming the AIDS virus HTLV he fabricated the cross-hybridization data of ATLV/HTLV-I with the AIDS virus (Science 1984; 225: 927) which no one else could reproduce and we now know could never have happened because they belong to two distinct groups of viruses. By doing it Gallo kept misleading many scientists who found themselves, like our group, wasting time in Gallo's blind alleys. As to your comments on the second example from Dr Koch's book (page 4 last paragraph), you keep amazing me how you can put in print that "Gallo never suggested, let alone advocated, that HTLV-I was the cause of AIDS". If you had read, or heard of Gallo's three papers on the involvement of HTLV-I in AIDS, surely you would not have signed such letters. You say that *beginning in early 1983, the Gallo group devoted considerable effort to developing a permanent cell line which could enable them to mass-produce HTLV-III". By now you ought to know that in this sentence you are wrong on two accounts. First in 1983 he was publishing papers on HTLV-I on AIDS and secondly the only thing he did was in 1984 and it was to change the name of Gazdar Hut 78 cells to H9 and LAV to HTLV-III. The continuation of this paragraph on to page 5 does not make any sense whatsoever. What happened in 1984 between Gallo, CDC and the French you can read in R Shilt's book, and hear from Dr Don Francis in the British TV programe.

You have been made to sign a letter, even the contents of which you could not have verified.

Your third quote (page 5) was followed not by facts but rather by an attempt to rewrite history. You should realize that you will not succeed in this. There are too many filing systems and not enough shredders. Let me repeat, while Gallo was still publishing papers on the involvement of HTLV-I in AIDS and claiming in his September 27 1983 letter that he never saw the virus that Luc Montagnier described, the conclusive data on the involvement of LAV in AIDS and that the virus belonged to the lentiviridae group were presented during two meetings in 1983 which were attended by Gallo. The reasons the French paper was not published in 1983 was probably due to Gallo's man in Nature, Dr R Weiss. The French August 1983 paper was rejected and Gallo delayed publication of the proceedings of his September 1983 Cold Spring Harbour meeting which included the detailed manuscript he received on September 15 1983 from Dr Montagnier on the involvement of LAV in AIDS. Your further comment (page 5, third paragraph). How can you say that "the author's rendition is grossly inaccurate" when the record, namely Dr Gonda's letter to Dr M Popovic of December 14 1983, clearly states that there was active replication of LAV in the Hut 78 cells while Dr Gallo tried to claim that it failed to grow in his laboratory (enclosures 1 and 2). Indeed Gallo tried to redact the laboratory records. The enclosed letter (enclosure 1) with the missing data on the replication of LAV in Hut 78 cells in Gallo's laboratory was obtained from the lawyers of the Pasteur Institute who received it under the Freedom of Information Act from the NIH. Only subsequently did they receive the copy of the original letter anonymously which revealed the truth (enclosure 2). Who else but Gallo had interest in concealing the truth? Who else but Gallo stated that LAV did not grow in his laboratory? It is no good saying "the Department has no idea where the redacted copy came from ... but it appears that it came from a non-government source and further that the redaction was done by someone outside Gallo's laboratory when in fact I was

told that your Department supplied Pasteur's lawyers with Gonda's redacted letter. Do you really assume that any one is going to believe you when you say "that the redaction was done by someone outside Gallo's laboratory"? And when you continue about the "analysis of the original six isolates ... as described in the original Gallo publications" it reveals that you did not even take the trouble of reading those original Gallo publications because none of the four papers in question contain such an analysis. I hope that in the future you will not allow yourselves to be used in such a way by signing such letters.

Page 6 second paragraph, for once you scored a point. Although I am not going to check it, I trust that you are right in stating that Gallo's patent was issued on May 28 1985 and not in January 1985 as Dr Koch wrote. However, you still fail to explain now Gallo who applied for a patent in 1984 on a virus which he received from France as LAV and renamed HTLV-III, and a cell line which was developed as Hut 78 and he renamed HT and H9 without acknowledging the developer is granted a patent while the French pioneers who discovered the virus and its role in AIDS and applied for the patent in 1983 were not granted a patent by May 28 1985. So much for the fair play of the US Patent Office. How would you react if other countries treated US patent applications in the same manner?

Since you use the dating of the patent as an example of "the author's repeated failures to accurately report on the scientific history of AIDS" I will volunteer my help to Dr Koch to see to it that in the English edition of the book the entire string of Dr Gallo's "scientific accomplishments" over the past eighteen years will be meticulously recorded and accurately interpreted with the aid of Dr Gallo's own publications. I hope that in the meantime you will provide me with the figures which will show how many hundreds of millions of dollars of US tax payers money Gallo received directly and indirectly and managed to direct to his lieutenants such as Dr Essex in the USA and Dr Weiss in the UK as well as others.

Since you also mention that the book contains micrographs which are the property of the US, I will advise Dr Koch to take out all the micrographs from Dr Gallo's articles, most of which are misleading anyhow. Take for example Fig 10.43 with Gallo's mar of the World where he tries to say that the few blacks that the Portuguese brought to Japan in the sixteenth century are responsible for over one million infections with adult T-cell leukaemia virus in Japan when in Portugal the disease has not been detected as yet. Furthermore, infection with the virus is uncommon in the Americas where millions of African blacks live. And what about Fig 10.44 - its also from Gallo but the virus he labelled HTLV-III we now know that even he had to admit that it was the French LAV. So the photo is IS property but the virus is French. I wonder what a judge would say. And what about the copies of Gonda's letter with and without the evidence that LAV felt very happy with Popovic and grew very well in the Hut 78 cells even before the cell's name was changed to H9 and the virus to HTLV-III. Are you going to ask the FBI or the CIA to investigate who redacted Gonda's letter?

And what are you going to do about Gallo's letter of September 23 1985 on your Department stationery in which he said "I have never seen the virus that Luc Montagnier has described" when according to the letter you signed Gallo discovered its involvement with AIDS even earlier...

As you can see from the enclosed copy of the letter to Dr J B Wyngaarden -Head of the NIH- I tried to draw his attention to the misleading scientific data which has been generated by Dr Gallo. He did not reply but had Dr Fishinger

wrote a letter which at best can be described as a whitewash. What I found amazing is that the Gallo machine manages to get even individuals of your calibre to sign letters.

In conclusion the AIDs virus could and should have been isolated in the USA for the following reasons:

- 1. It was in the US that AIDS was first recognized as a new disease of man in 1981 by Gottlieb and others
- 2. The US had the largest number of diagnosed AIDS patients
- 3. The US scientific and medical might, in particular having excellent retrovirologists in Tenim, Bishop, Baltimore etc.

The latter reason could have been sufficient for the US to be the first to isolate the causative virus. However, because of Dr Gallo, the French were first. Progress in ALDS research has been delayed by a full year while Drs Gallo and Essex published eight articles on HTLV, the rare human leukaemia virus, as the cause of AIDS. In the process they prevented directly and indirectly the publication of medical and scientific data that HTLV was not involved in AIDS and that another virus was the cause of this new disease. As a result many thousands of individuals became infected with contaminated blood and the virus kept spreading at an accelerated pace. Only after Dr Gallo received the AIDS virus from France and managed to grow it did he change its name from LAV to HTLV-III and claim himself as the discoverer. In order to justify calling it HTLV-III, Gallo with Wong-Staal presented scientific "data" on the similarity of the HTLV-I and HTLV-III which they published in Science and Nature, thereby causing further delay in AIDS research by sending newcomers to this field into blind alleys.

There is no question in my mind that Dr Gallo is responsible for the large number of infections especially through blood transfusions during the lost year. However, he objects to anyone who tries to keep the record straight while trying to recreate the history of the discovery of HIV and dictate the originality of his cwn findings. A further example of the way he operates is the letter he wrote asking Dr D Francis to sign the letter (a copy of which is enclosed). I was told that it was followed by a life-threatening telephone call from Gallo to Francis.

I find it amazing that this situation is being tolerated in the USA. Consider that a democratically elected President had to resign because of the Watergate episode in which not even a single life was lost while Gallo is allowed to continue to dominate USA AIDS research with untold millions from USA tax payers, many of whom became infected by the virus due to his scientific incompetence and ruthlessness.

Yours sincerely

A Karpas ScD

Assistant Director of Research

cc Dr M Koch, Mr K-G Firshow, Dr Walter W Stewart