August 9, 1984

Associate Director, NCI

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NIH AIDS Executive Committee Meeting

Assistant Secretary for Health, DHHS AUG 20 1984
Through: Director, NIH_____
Director, NCI_____

At the July 30 NIH AIDS Executive Committee Meeting, a number of points that were discussed at the antecedent PHS-AIDS Executive Committee were transmitted to NCI for response. Several of these points were critiques of form and substance allegedly reflective of Dr. R. Gallo's actions. These critiques, transmitted via Dr. R. Gordon in written form (Attachment I) prompted this reply to clarify these issues.

Point # 1: "Dr. Brandt asked that Dr. Gallo be reminded that he is supposed to get clearance before giving media interviews. A recent one was reproduced in the "Green Sheet", in which Gallo rekindles fears of transmission of AIDS to women. Dr. Brandt also noted that Dr. Gallo is not an epidemiologist, and should not step forward to interpret epidemiologic data."

Comment: Dr. Gallo did present recent collaborative, virological data at several lectures. Because of his visibility, reporters do follow Dr. Gallo. He may not recognize reporters as such in a lecture audience. These data do implicate heterosexual transmission of virus to women from at-risk groups. In fact, such data are only an extension on the level of virus of past well known data in the US (Attachment 2), and recently published data from Africa, which tend to confirm heterosexual transmission of the syndrome, not only to women, but also describe several clusters of AIDS where transmission presumably occurred also in a female-to-male direction (Attachment 3). Dr. Gallo is not interpreting his collaborative data, but citing facts in an open forum. He is not the principal investigator in the about-to-be published manuscript, nor is he the only member of a Federal agency. CDC investigators are collaborators in this project as well. Dr. Gallo has been alerted that he continue the standard clearance procedure for each contact with the press. As in the past, Dr. Gallo stated that when you pose specific questions over and above the normal information flow, he will be more than happy to keep you informed.

Point # 2: "Dr. Brandt also criticized Dr. Gallo for being so slow to produce a definitive statement on the identity (or otherwise) of LAV and HTLV-III. In April, he had promised this publicly within 30 days. Dr. Brandt says he wants a 2 or 3 page statement detailing the present status of these investigations (with scientific content, not only reasons for delay."

Comment: NCI discussed this very issue at our previous NIH Executive Committee meeting. The problem of comparison is a bilateral venture and NCI has unilaterally gone as far as is reasonable. NCI wanted to compare HTLV III and LAV both antigenically and molecularly. NCI has strong non-human antibodies to p24 core protein of HTLV III. We have sent Dr. Sarngadharan to France to do a reciprocal comparison of radioimmunoassays of the core protein. The French do not have a non-human antibody to p25 of LAV. The test has been performed with the US non-human serum directed against HTLV III, and the core protein p24 of HTLV III and p25 of LAV. The two viruses compete fully and are therefore related as far as the major antigenic site(s) on the core protein. The reciprocal test cannot be done because the French did not supply the corresponding antibody. Dr. Montagnier apparently does not wish to make these data public at this time.

The real degree of identity will depend on a nucleic acid sequence comparison of proviral DNA. Dr. Gallo has cloned several HTLV III isolates. The French apparently have not. The French sent a purported reverse transcriptase-derived complementary DNA of LAV to Dr. Gallo. The DNA was not viral, but consisted of cellular sequences. Dr. Gallo's laboratory wasted time and effort to verify this. As soon as the French deign to make the comparison with their reagents, NCI scientists will immediately go to France to compare LAV with our HTLV III DNA clones. Alternatively, NCI wrote to the French that we are willing to pay for a French scientist to come here with their clone to do the experiment. Recently, the French have sent NCI a B cell line producing low titers of LAV. At this time, Dr. Montagnier does not want Dr. Gallo to clone the LAV. However, they will get together at the September meeting in Urbino, Italy, to discuss the format of the pending communication which will describe the comparative analysis of the two viruses. Incidentally, a detailed analysis of several HTLV-III isolates does show some variations within the HTLV-III subgroup itself.

We personally communicated these very data at the NIH Executive Committee meeting, in Dr. Gordon's presence, and Dr. Wyngaarden has seen Dr. Gallo's letter to Dr. Montagnier to support these contentions (Attachment 4).

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NCI is continuing to move the AIDS program forward. DNA cloning, as well as antigen testing and new drug applications for AIDS therapy are being patented. We have made a number of monoclonal antibodies to the virus, and are initiating vaccine research studies. We are making tangible progress and NCI's publications are in the forefront of research on AIDS.

Peter J. Fischinger, M.D., Ph.D.

Attachments:

1. Notes from PHS Executive Committee Meeting, 7-30-84
2. New Eng. J. Med. 308: 1181, (May) 1983.
3. Lancet II(8394): 65, (July) 1984.
4. Letter of 7-3-84, Dr. Gallo to Dr. Montagnier

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