DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Centers for Disease Control

Memorandum

Date July 5, 1985

From Director
Division of Viral Diseases

Subject **Telephone Conference Call, 3 July 1985, Organizational Meeting for a Workshop on Clinical Evaluation of Candidate AIDS Vaccines.**

To THE RECORD

Organizer James C. Hill, NIAID.

Attending: Gerald Quinnan, FDA; John Petricciani, WHO; Samuel Broder, NCI; Harry Haverkos, NIAID; John LaMontagne, NIAID; Clifford Lane, NIAID [Peter Fischinger, NCI, unable to attend]; F.A. Murphy by telephone connection.

The idea of this meeting stems from a wish in NIAID to prepare for phase I, II, and efficacy trials for candidate AIDS vaccines.

There will be no suggestion that NIH favors one vaccine candidate over another; rather candidate vaccines will advance through testing processes as merit dictates. Vaccines being developed by the National Cancer Institute are likely to receive most emphasis; vaccines being developed commercially **may not be described as openly at this point. One motivation for this meeting concerns a wish to review animal models and the "successes" in retrovirus vaccine development [i.e., the success of feline leukemia virus** vaccine]--less information is likely to be forthcoming concerning proven "failures" in retrovirus vaccine development [i.e., CAE virus, EIA virus, BLV virus].

After some discussion, four background themes were developed:

1. What are the lessons from animal retrovirus vaccines? What do we know about protective immunity in these models? Are there any analogies to the questions of HTLV-III/LAV virus variability in animal retrovirus models? What do we know about the immunology of HTLV-III/LAV, per se?

2. How shall we assess vaccine efficacy in human test recipients? What shall be the definition of "efficacy" -- shall we require the prevention of AIDS disease, shall we require prevention of infection?

3. How will tests in humans of candidate vaccines be conducted? What populations are available for initial trials? What populations are at a risk that is so predictable that vaccine efficacy might be measured? Can modeling be done (with estimates of important variables) so as to predict numbers of individuals required to test efficacy characteristics at particular levels?

4. What is expected of an AIDS vaccine? This large question centers on two points: one, the general description of an ideal vaccine; two, the public sense that "anything is better than nothing." June Osborne was suggested as the ideal person to cover these background points.

The timing of this meeting is to be set, principally on the basis of Peter Fischinger's sense of the right time relative to vaccine development progress. That is, there is a wish not to have this meeting too early, before candidate vaccines are about to emerge or too late so as to evoke the criticism of delay in application. It is expected that late November or December will be most appropriate.

There was discussion concerning the appropriate audience and size of audience; there is need to include everyone directly concerned with AIDS vaccine development and representatives of the vaccine evaluation centers of NIH. There was also discussion of the need to invite representatives of risk groups and of other professional groups -- there is a wish to have representation and some expression of opinion from such groups, but this meeting is not for the purpose of consensus development. All further discussion emphasized the point that the recent Antivirals Meeting held at NIH should serve as the model for this meeting -- the Antivirals Meeting was of the right size, the right emphasis upon science, the right audience of scientists and representatives of interested groups, and it had a clear limit of agenda to the scientific matters at hand. It was anticipated that the meeting would attract approximately 100-200 people.

Jim Hill will carry these ideas forward; he will develop a rough agenda, set a target date for the meeting, and start to consider the invitation list.

Only a few participant names were mentioned in the course of this meeting, most clearly was the wish that Jim Curran be cajoled into providing the opening paper on an epidemiologic description of populations at risk, and other epidemiologic indications of vaccine needs. [It seems to me that this opening paper should be closely tied to the issue of needed modeling for the design of vaccine trials. Perhaps in anticipation of this, some further dialogue should be initiated at CDC now to attempt to answer such questions as numbers of subjects required to answer specific efficacy questions.]

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cc:
Dr. Walter R. Dowdle
Dr. John V. Bennett
Dr. James Curran
Dr. Harold Jaffe