FOIA Number: 2018-0756-F

FOIA MARKER

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Collection/Record Group: Clinton Presidential Records

Subgroup/Office of Origin: National AIDS Policy Office

Series/Staff Member: Kristine Gebbie

Subseries:

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Folder Title:
[GP-160 Aids Vaccine] [loose]

Stack:	Row:	Section:	Shelf:	Position:
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DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Assistant Secretary for Legislation

Washington, D.C 20201

September 27, 1993

NOTE TO: Dr. Lee

Through: Karen Pollitz, KP

SUBJECT: GP-160 AIDS Vaccine Clinical Trials--ACTION

On Thursday September 16, White House, HHS and DoD personnel briefed the House Energy and Commerce Committee staff (summary attached) on the status of the GP-160 AIDS vaccine clinical trials required in the fiscal year 1993 DoD appropriations act.

Subsequent to that meeting, Dr. Gebbe recommended that a letter be prepared by Dr. Fauci for signature by the Director, NIH and the Commissioner, FDA, that states clearly the Department's recommendations as to whether the single candidate, GP-160 AIDS vaccine clinical trials should proceed and, if not, the hierarchy of options that should be pursued given current scientific needs regarding AIDS vaccine research.

When Dr. Gebbe's recommendation was conveyed to Dr. Fauci he asked that a memorandum be sent by you to Drs. Kirschstein and Kessler informing them of the request. That memorandum requesting that the letter be prepared is attached for your review, and if you concur, your signature.

If you have any questions, or need additional information, please call me on 690-7450. Thank you.

Sean Donohue

Attachments

cc: Ms. Fleming
Dr. Gebbe
Mr. Klepner
Ms. Rabb

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Office of the Assistant Secretary
for Health
Washington DC 20201

TO: Director, NIH,
Commissioner, FDA

FROM: Assistant Secretary for Health

SUBJECT: GP-160 AIDS Vaccine Clinical Trials

On Thursday September 16, White House, HHS and DoD personnel briefed the House Energy and Commerce Committee staff (summary attached) on the status of the GP-160 AIDS vaccine clinical trials required in the fiscal year 1993 DoD appropriations act.

Subsequent to that meeting, ~~Dr.~~ Ms. Debbie Gebbe recommended that a letter be prepared for signature by the Director, NIH and the Commissioner, FDA, that states clearly the Department's recommendations as to whether the single candidate, GP-160, AIDS vaccine clinical trials should proceed and, if not, the hierarchy of options that should be pursued given current scientific needs regarding AIDS vaccine research.

This memorandum requests your cooperation in writing that letter. Further, because of Dr. Fauci's role in this issue, I am requesting that he be given the task of writing, in collaboration with each of you, a letter that addresses: 1) the advisability of conducting a single candidate, GP-160, AIDS vaccine clinical trial, and 2) given the existing scientific needs, what alternatives, if any, should be pursued in the area of AIDS vaccine research. Do we want to say something about language consistent w/ Kerr amendments?

Please contact me on 690-7694 if you have any questions or need additional information. Thank you for your cooperation and assistance.

Attachments

cc: Dr. Fauci
Ms. Fleming
~~Dr. Gebbe~~ Ms. Gebbie
Mr. Klepner
Ms. Rabb

September 27, 1993

NOTE TO: Karen Pollitz

SUBJECT: GP-160 Briefing for Energy and Commerce Committee Staff, Thursday, September 16.

Background

As you know, for FY 1993, DoD received $20 million to conduct a single candidate Phase III clinical trial for the AIDS vaccine, GP-160. The appropriations language stipulated the trial was to occur unless the NIH Director, the FDA Commissioner, and the DoD Secretary certified in writing to the Congress within 6 months of enactment that the trial should not proceed.

At the request of Representative Waxman's office, HHS and DoD staff provided a briefing on the current status of the GP-160 issue.

Attendees

Hill:	Tim Westmoreland (Rep. Waxman), Kay Holcomb (Rep. Dingell)
WH:	Kristine Gebbe, White House AIDS Policy Coordinator
HHS:	Harriet Rabb, GC, Patsy Fleming, IOS, Tony Fauci, NIH, Art Lawrence, NAPO, Sean Donohue, ASL
DoD:	Jamie Gorelick, GC, John Casciotti, GC, Ed Martin, ASH (Acting), Sandy Stuart, Assistant to the Secretary, Legislative Affairs.

Summary Report

Hill staff asked: 1) what is the current status of the $20 million DoD appropriation for the GP-160 vaccine clinical trial? 2) what would be the best scientific use of the $20 million? 3) what would be a reasonable solution to current problems? and 4) what is the Administration's position?

1) Current Status?

Ed Martin reported that because the April deadline for DoD, NIH and FDA to certify to Congress had passed, a contract had been let in August with the vaccine manufacturer, MicroGeneSys, to develop the clinical trial protocol. He also noted that DoD could, at its discretion, terminate the contract at any point.

2) Best Scientific Use?

In discussion, Ed Martin and Tony Fauci agreed on several points: that the best use of the resources would be for basic AIDS research, that the scientific community, in and out of government, believed now was not the right time to proceed with

Phase III clinical trials, and, that although expanding to a multi-candidate trial would provide more useful data, it would be "throwing good money after bad" and misdirecting scarce scientific talent.

3) Solutions?

Tim Westmoreland mentioned in passing reprogramming and recision authority. During discussion there was general agreement that the easiest "fix" would be to change the written certification date to Congress and for DoD, NIH and FDA to then certify that the single candidate trial shouldn't proceed.

4) Administration's position?

Kristine Gebbe indicated that she was discussing the issue widely, at DoD, HHS, and the White House to determine whether, in the context of other important appropriations issues, the Administration wished to change the certification date. Given that the FY '94 DoD Appropriations would be final within several days, she assured the Hill staff that she would get back to them with an Administration decision.

Closing

Tim W. indicated the need to act quickly to avoid funding a questionable study and asked both departments to summarize their objections for the public record. Noting the absence of a firm Administration position and the desire not to offend key members of the Appropriations committees, both DoD and HHS declined his request. Despite Kristine's assurances that she would get an answer back to him, Tim indicated that both Departments would soon be hearing from Representative Waxman.

/s/

Sean Donohue
690-7450

cc: Jerry Klepner

THE WHITE HOUSE

WASHINGTON

January 21, 1994

MEMORANDUM

TO: Donald S. Burke, M.D., Colonel
Director, Division of Retrovirology

FROM: Kristine M. Gebbie, R.N., M.N.
National AIDS Policy Coordinator

SUBJECT: HIV vaccine research

As I indicted in our telephone conversation, I think it is essential that you meet with some of the parties interested in HIV vaccine research to review the ideas on how to invest the $20 million (or remaining portion thereof) now that we have informed Congress that it will not go to the gp160 study as originally mandated. Such a meeting will affirm the Administration's continuing interest in open communication about our HIV activities, and our interest in collaboration in research efforts. I do not see a problem with the meeting occurring concurrently with your efforts to place an announcement about proposals through your procurement process.

If you like, this office would be happy to work with you on an invitation list for such a meeting, though I suspect you know the possible players better than I do. One group that has a deep interest in this issue is in Philadelphia, and I would encourage you to include Jane Shull of Philadelphia Fights at (215) 557-8265.

Please let me know if I can be of further help.

gp160

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Office of the Assistant Secretary
for Health
Washington DC 20201

OCT - 4 1993

TO: Acting Director, NIH,
Commissioner, FDA

FROM: Assistant Secretary for Health

SUBJECT: GP-160 AIDS Vaccine Clinical Trials

On Thursday September 16, White House, HHS and DoD personnel briefed the House Energy and Commerce Committee staff (summary attached) on the status of the GP-160 AIDS vaccine clinical trials required in the fiscal year 1993 DoD Appropriations Act.

Subsequent to that meeting, Ms. Gebbie recommended that a letter be prepared for signature by the Director, NIH and the Commissioner, FDA, to the House and Senate Appropriations Committees stating clearly the Department's recommendations as to whether the single candidate, GP-160, AIDS vaccine clinical trials should proceed and, if not, the hierarchy of options that should be pursued given current scientific needs regarding AIDS vaccine research.

This memorandum requests your cooperation in writing that letter. Further, because of Dr. Fauci's role in this issue, I am requesting that he be given the task of drafting, in collaboration with each of you, a letter that addresses: 1) the advisability of conducting a single candidate, GP-160, AIDS vaccine clinical trial, and 2) given the existing scientific needs, what alternatives, if any, should be pursued in the area of AIDS vaccine research.

Please contact me on 690-7694 if you have any questions or need additional information. Thank you for your cooperation and assistance.

Philip R. Lee, M.D.

Attachment

cc: Dr. Fauci
Ms. Fleming
Ms. Gebbie
Mr. Klepner
Ms. Rabb

September 27, 1993

NOTE TO: Karen Pollitz

SUBJECT: GP-160 Briefing for Energy and Commerce Committee Staff, Thursday, September 16.

Background

As you know, for FY 1993, DoD received $20 million to conduct a single candidate Phase III clinical trial for the AIDS vaccine, GP-160. The appropriations language stipulated the trial was to occur unless the NIH Director, the FDA Commissioner, and the DoD Secretary certified in writing to the Congress within 6 months of enactment that the trial should not proceed.

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WH:	Kristine Gebbe, White House AIDS Policy Coordinator
HHS:	Harriet Rabb, GC, Patsy Fleming, IOS, Tony Fauci, NIH, Art Lawrence, NAPO, Sean Donohue, ASL
DoD:	Jamie Gorelick, GC, John Casciotti, GC, Ed Martin, ASH (Acting), Sandy Stuart, Assistant to the Secretary, Legislative Affairs.

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3) Solutions?

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Closing

Tim W. indicated the need to act quickly to avoid funding a questionable study and asked both departments to summarize their objections for the public record. Noting the absence of a firm Administration position and the desire not to offend key members of the Appropriations committees, both DoD and HHS declined his request. Despite Kristine's assurances that she would get an answer back to him, Tim indicated that both Departments would soon be hearing from Representative Waxman.

/s/
Sean Donohue
690-7450

cc: Jerry Klepner

THE WHITE HOUSE

WASHINGTON

September 28, 1993

The Honorable Henry A. Waxman
2408 RHOB
Washington, DC 20515-0529

Dear Representative Waxman:

There have been a number of questions asked about the trial of GP160 vaccine about to be conducted by the Department of Defense. This is a study specifically mandated in the FY93 appropriations process and funded at $20 million.

In the opinion of many in the scientific and AIDS-interested community, in which I concur, this single-vaccine trial is not a useful investment at the present time. While the study could be slightly improved by comparing this product to other vaccines, that would cost more and be only a slightly better investment. It would be far wiser to allow an appropriate review process to identify more basic research questions essential to the successful development of a vaccine, whether therapeutic or preventive.

If it would be possible to identify some amendment to the existing language which would allow a reconsideration of this study, and the possible reinvestment of these funds, I would be delighted to work with you or your staff.

Sincerely,,

Kristine M. Gebbie, RN, MN
National AIDS Policy Coordinator

cc: Secretary Aspin
Secretary Shalala
Ms. Rasco

THE WHITE HOUSE

WASHINGTON

September 28, 1993

The Honorable Edward M. Kennedy
315 SROB
Washington, DC 20510-2101

Dear Senator Kennedy:

There have been a number of questions asked about the trial of GP160 vaccine about to be conducted by the Department of Defense. This is a study specifically mandated in the FY93 appropriations process and funded at $20 million.

In the opinion of many in the scientific and AIDS-interested community, in which I concur, this single-vaccine trial is not a useful investment at the present time. While the study could be slightly improved by comparing this product to other vaccines, that would cost more and be only a slightly better investment. It would be far wiser to allow an appropriate review process to identify more basic research questions essential to the successful development of a vaccine, whether therapeutic or preventive.

If it would be possible to identify some amendment to the existing language which would allow a reconsideration of this study, and the possible reinvestment of these funds, I would be delighted to work with you or your staff.

Sincerely,

Kristine M. Gebbie, RN, MN
National AIDS Policy Coordinator

cc: Secretary Aspin
Secretary Shalala
Ms. Rasco

THE WHITE HOUSE

WASHINGTON

September 28, 1993

The Honorable Daniel K. Inouye
722 SHOB
Washington, DC 20510-1102

Dear Senator Inouye:

There have been a number of questions asked about the trial of GP160 vaccine about to be conducted by the Department of Defense. This is a study specifically mandated in the FY93 appropriations process and funded at $20 million.

In the opinion of many in the scientific and AIDS-interested community, in which I concur, this single-vaccine trial is not a useful investment at the present time. While the study could be slightly improved by comparing this product to other vaccines, that would cost more and be only a slightly better investment. It would be far wiser to allow an appropriate review process to identify more basic research questions essential to the successful development of a vaccine, whether therapeutic or preventive.

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Sincerely,

Kristine M. Gebbie, RN, MN
National AIDS Policy Coordinator

cc: Secretary Aspin
Secretary Shalala
Ms. Rasco

THE WHITE HOUSE

WASHINGTON

September 28, 1993

The Honorable John D. Dingell
2328 RHOB
Washington, DC 20515-2216

Dear Representative Dingell:

There have been a number of questions asked about the trial of GP160 vaccine about to be conducted by the Department of Defense. This is a study specifically mandated in the FY93 appropriations process and funded at $20 million.

In the opinion of many in the scientific and AIDS-interested community, in which I concur, this single-vaccine trial is not a useful investment at the present time. While the study could be slightly improved by comparing this product to other vaccines, that would cost more and be only a slightly better investment. It would be far wiser to allow an appropriate review process to identify more basic research questions essential to the successful development of a vaccine, whether therapeutic or preventive.

If it would be possible to identify some amendment to the existing language which would allow a reconsideration of this study, and the possible reinvestment of these funds, I would be delighted to work with you or your staff.

Sincerely,

Kristine M. Gebbie, RN, MN
National AIDS Policy Coordinator

cc: Secretary Aspin
Secretary Shalala
Ms. Rasco

THE WHITE HOUSE

WASHINGTON

September 28, 1993

The Honorable Nancy L. Kassebaum
302 SROB
Washington, DC 20510-1602

Dear Senator Kassebaum:

There have been a number of questions asked about the trial of GP160 vaccine about to be conducted by the Department of Defense. This is a study specifically mandated in the FY93 appropriations process and funded at $20 million.

In the opinion of many in the scientific and AIDS-interested community, in which I concur, this single-vaccine trial is not a useful investment at the present time. While the study could be slightly improved by comparing this product to other vaccines, that would cost more and be only a slightly better investment. It would be far wiser to allow an appropriate review process to identify more basic research questions essential to the successful development of a vaccine, whether therapeutic or preventive.

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Sincerely,

Kristine M. Gebbie, RN, MN
National AIDS Policy Coordinator

cc: Secretary Aspin
Secretary Shalala
Ms. Rasco

THE WHITE HOUSE

WASHINGTON

September 28, 1993

The Honorable Robert C. Byrd
311 SHOB
Washington, DC 20510-4801

Dear Senator Byrd:

There have been a number of questions asked about the trial of GP160 vaccine about to be conducted by the Department of Defense. This is a study specifically mandated in the FY93 appropriations process and funded at $20 million.

In the opinion of many in the scientific and AIDS-interested community, in which I concur, this single-vaccine trial is not a useful investment at the present time. While the study could be slightly improved by comparing this product to other vaccines, that would cost more and be only a slightly better investment. It would be far wiser to allow an appropriate review process to identify more basic research questions essential to the successful development of a vaccine, whether therapeutic or preventive.

If it would be possible to identify some amendment to the existing language which would allow a reconsideration of this study, and the possible reinvestment of these funds, I would be delighted to work with you or your staff.

Sincerely,

Kristine Gebbie

Kristine M. Gebbie, RN, MN
National AIDS Policy Coordinator

cc: Secretary Aspin
Secretary Shalala
Ms. Rasco

THE WHITE HOUSE

WASHINGTON

September 28, 1993

The Honorable Mark O. Hatfield
711 SHOB
Washington, DC 20510-3701

Dear Senator Hatfield:

There have been a number of questions asked about the trial of GP160 vaccine about to be conducted by the Department of Defense. This is a study specifically mandated in the FY93 appropriations process and funded at $20 million.

In the opinion of many in the scientific and AIDS-interested community, in which I concur, this single-vaccine trial is not a useful investment at the present time. While the study could be slightly improved by comparing this product to other vaccines, that would cost more and be only a slightly better investment. It would be far wiser to allow an appropriate review process to identify more basic research questions essential to the successful development of a vaccine, whether therapeutic or preventive.

If it would be possible to identify some amendment to the existing language which would allow a reconsideration of this study, and the possible reinvestment of these funds, I would be delighted to work with you or your staff.

Sincerely,

Kristine M. Gebbie, RN, MN
National AIDS Policy Coordinator

cc: Secretary Aspin
Secretary Shalala
Ms. Rasco

THE WHITE HOUSE

WASHINGTON

September 28, 1993

The Honorable Ted Stevens
522 SHOB
Washington, DC 20510-0201

Dear Senator Stevens:

There have been a number of questions asked about the trial of GP160 vaccine about to be conducted by the Department of Defense. This is a study specifically mandated in the FY93 appropriations process and funded at $20 million.

In the opinion of many in the scientific and AIDS-interested community, in which I concur, this single-vaccine trial is not a useful investment at the present time. While the study could be slightly improved by comparing this product to other vaccines, that would cost more and be only a slightly better investment. It would be far wiser to allow an appropriate review process to identify more basic research questions essential to the successful development of a vaccine, whether therapeutic or preventive.

If it would be possible to identify some amendment to the existing language which would allow a reconsideration of this study, and the possible reinvestment of these funds, I would be delighted to work with you or your staff.

Sincerely,

Kristine Gebbie

Kristine M. Gebbie, RN, MN
National AIDS Policy Coordinator

cc: Secretary Aspin
Secretary Shalala
Ms. Rasco

THE WHITE HOUSE

WASHINGTON

September 28, 1993

The Honorable Joseph M. McDade
2370 RHOB
Washington, DC 20515-3810

Dear Representative McDade:

There have been a number of questions asked about the trial of GP160 vaccine about to be conducted by the Department of Defense. This is a study specifically mandated in the FY93 appropriations process and funded at $20 million.

In the opinion of many in the scientific and AIDS-interested community, in which I concur, this single-vaccine trial is not a useful investment at the present time. While the study could be slightly improved by comparing this product to other vaccines, that would cost more and be only a slightly better investment. It would be far wiser to allow an appropriate review process to identify more basic research questions essential to the successful development of a vaccine, whether therapeutic or preventive.

If it would be possible to identify some amendment to the existing language which would allow a reconsideration of this study, and the possible reinvestment of these funds, I would be delighted to work with you or your staff.

Sincerely,

Kristine M. Gebbie, RN, MN
National AIDS Policy Coordinator

cc: Secretary Aspin
Secretary Shalala
Ms. Rasco

THE WHITE HOUSE

WASHINGTON

September 28, 1993

The Honorable John P. Murtha
2423 RHOB
Washington, DC 20515-3812

Dear Representative Murtha:

There have been a number of questions asked about the trial of GP160 vaccine about to be conducted by the Department of Defense. This is a study specifically mandated in the FY93 appropriations process and funded at $20 million.

In the opinion of many in the scientific and AIDS-interested community, in which I concur, this single-vaccine trial is not a useful investment at the present time. While the study could be slightly improved by comparing this product to other vaccines, that would cost more and be only a slightly better investment. It would be far wiser to allow an appropriate review process to identify more basic research questions essential to the successful development of a vaccine, whether therapeutic or preventive.

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Sincerely,

Kristine M. Gebbie, RN, MN
National AIDS Policy Coordinator

cc: Secretary Aspin
Secretary Shalala
Ms. Rasco

THE WHITE HOUSE

WASHINGTON

September 28, 1993

The Honorable William H. Natcher
2333 RHOB
Washington, DC 20515-1702

Dear Representative Natcher:

There have been a number of questions asked about the trial of GP160 vaccine about to be conducted by the Department of Defense. This is a study specifically mandated in the FY93 appropriations process and funded at $20 million.

In the opinion of many in the scientific and AIDS-interested community, in which I concur, this single-vaccine trial is not a useful investment at the present time. While the study could be slightly improved by comparing this product to other vaccines, that would cost more and be only a slightly better investment. It would be far wiser to allow an appropriate review process to identify more basic research questions essential to the successful development of a vaccine, whether therapeutic or preventive.

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Sincerely,

Kristine M. Gebbie, RN, MN
National AIDS Policy Coordinator

cc: Secretary Aspin
Secretary Shalala
Ms. Rasco

THE WHITE HOUSE

WASHINGTON

September 28, 1993

The Honorable Thomas J. Bliley, Jr.
2241 RHOB
Washington, DC 20515-4607

Dear Representative Bliley:

There have been a number of questions asked about the trial of GP160 vaccine about to be conducted by the Department of Defense. This is a study specifically mandated in the FY93 appropriations process and funded at $20 million.

In the opinion of many in the scientific and AIDS-interested community, in which I concur, this single-vaccine trial is not a useful investment at the present time. While the study could be slightly improved by comparing this product to other vaccines, that would cost more and be only a slightly better investment. It would be far wiser to allow an appropriate review process to identify more basic research questions essential to the successful development of a vaccine, whether therapeutic or preventive.

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Sincerely,

Kristine Gebbie

Kristine M. Gebbie, RN, MN
National AIDS Policy Coordinator

cc: Secretary Aspin
Secretary Shalala
Ms. Rasco

THE WHITE HOUSE

WASHINGTON

September 28, 1993

The Honorable Carlos J. Moorhead
2346 RHOB
Washington, DC 20515-0527

Dear Representative Moorhead:

There have been a number of questions asked about the trial of GP160 vaccine about to be conducted by the Department of Defense. This is a study specifically mandated in the FY93 appropriations process and funded at $20 million.

In the opinion of many in the scientific and AIDS-interested community, in which I concur, this single-vaccine trial is not a useful investment at the present time. While the study could be slightly improved by comparing this product to other vaccines, that would cost more and be only a slightly better investment. It would be far wiser to allow an appropriate review process to identify more basic research questions essential to the successful development of a vaccine, whether therapeutic or preventive.

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National AIDS Policy Coordinator

cc: Secretary Aspin
Secretary Shalala
Ms. Rasco

United States Senate
COMMITTEE ON LABOR AND HUMAN RESOURCES
WASHINGTON, DC 20510-6300

TELECOPIER COVER MEMORANDUM

TO: Kristine

FAX NUMBER: 632-1096

FROM: Michael Kantz

DATE AND TIME: _____

NUMBER OF PAGES: Cover + 1

RETURN FAX NUMBER: (202) 224-3533

If there is trouble receiving this fax, please call (202)224-5880

At long last — VICTORY — at least this phase!

Thanks!

CONGRESSIONAL RECORD — HOUSE

November 9, 1993

CONFERENCE REPORT ON H.R. 3116, DEPARTMENT OF DEFENSE APPROPRIATIONS ACT, 1994

Mr. MURTHA submitted the following conference report and statement on the bill (H.R. 3116) making appropriations for the Department of Defense for the fiscal year ending September 30, 1994, and for other purposes.

TITLE VIII—GENERAL PROVISIONS

Amendment No. 135: Restores House language which extends an Administration disapproval notification period from six to eighteen months for a GP-160 AIDS vaccine trial.

RG

CONFERENCE ON ADVANCES IN AIDS VACCINE DEVELOPMENT - 1993

Put a my GP160 file

Background Information on

The Guidelines for Selection of HIV Vaccines for Efficacy Trials

---

Provided in association with the presentation:

Vaccine Selection Guidelines

Lewellys Barker

at the

COLLOQUIUM: EFFICACY TRIALS PREPARATIONS

V. Vaccine Development to Meet U.S. and International Needs

9:00 am, Thursday, November 4, 1993

GUIDELINES OF CLINICAL AND RESEARCH DATA WHICH WILL FACILITATE THE DECISION-MAKING PROCESS FOR ENTRY OF CANDIDATE VACCINES INTO PIVOTAL PHASE III EFFICACY TRIALS

September 1993

The development of a safe and effective vaccine to prevent HIV-infection and/or modulate disease is of high public health importance. Significant progress has been made in the development and clinical testing of potential candidate vaccines and novel adjuvants. In the absence of validated correlates of immunity in humans, it is impossible to develop rigid criteria for moving potential vaccine candidates into pivotal Phase III efficacy trials. However, we do need data to judge whether a vaccine candidate has a reasonable expectation of being effective prior to entry into a pivotal efficacy trial.

At the present time, it is anticipated that a graded priority would be afforded to candidate vaccines, based on an analysis of supportive scientific and clinical data.

These guidelines apply to adult Phase III trials. Phase III perinatal/pediatric vaccine trials are also a high priority but may require data not specifically addressed in these guidelines prior to the initiation of trials.

CORE STUDIES

A "core" set of laboratory and clinical studies are identified. The data from these studies will be utilized in making a recommendation regarding moving a candidate vaccine from Phase I/II trials into a pivotal Phase III efficacy trial.

1. From Primate Protection Studies:

   Data from a primate model utilizing a vaccine product close or identical in design and formulation to the candidate vaccine proposed for Phase III trial.

2. From Virologic And Immunologic Analysis Of Viral Strains:

   Information on immunologic and genetic similarity of the candidate vaccine strain to the predominant HIV isolates circulating in the proposed efficacy trial population.

3. From Phase I/II Clinical Trials:

   a. Frequency and severity of local and systemic toxicity.

   b. Development of HIV-specific humoral immune response, including timing of response relative to the administration schedule, magnitude, duration, data on functional antibody (e.g., viral neutralization) and breadth of response (ability to cross-neutralize non-homologous strains).

c. Development of HIV-specific cell-mediated immune response (measurement of MHC class I-restricted cytotoxic T cells and other measures of cytolytic, proliferative, or secretory T cell activities), including timing of response relative to the administration schedule, magnitude, duration, and breadth.

DESIRABLE STUDIES*

1. From Animal Protection Studies:

   a. Challenge of actively immunized primates by heterologous "field" isolates similar to those circulating in the proposed efficacy trial population.

   b. Challenge of actively immunized primates by cell-associated virus.

   c. Challenge of actively immunized primates to assess duration of protection (i.e., not at peak humoral immune activity).

   d. Challenge of actively immunized primates by a mucosal route.

   e. Assessment of passive immunity (i.e., immunity conferred by transfer of sera or immunoglobulin preparations from actively immunized human volunteers) in susceptible primates or alternatively, in reconstituted SCID/hu mice.

2. From Phase I/II Clinical Trials:

   a. Test of mucosal immune response (e.g., detection of secretory IgA capable of neutralizing HIV infectivity).

   b. Assessment of safety and immunogenicity in volunteers similar to the populations being proposed for efficacy trials.

As consensus measures of immune responses such as viral neutralization and cytotoxic T-cell activity have not been established, data should also be presented on the validity of specific tests used to measure immune responses.

* May or may not be feasible to have done before evaluation of vaccine candidates.

High School HIV/AIDS
Resource Center
351 West 18th Street
Room 133
New York, N.Y. 10011
(212) 206-0570
Hotline (212) 255-2900

NEW YORK CITY PUBLIC SCHOOLS

FACSIMILE TRANSMITTAL

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ORGANIZATION NATIONAL AIDS COORDINATOR

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P

A RANDOMIZED, CONTROLLED STUDY OF IMMUNOGENICITY OF rgp160 VACCINE IN HIV-INFECTED SUBJECTS.

Valentine Fred, Katzenstein D*, Haslett P, Beckett L**, Borucki M, Vasquez M, Smriti K*, Smith G***, Korvick J****, Kagan J****, Merigan T*. New York Univ. Med. Cntr., *Stanford AIDS Cntr., **Harvard Sch. Pub. Health, ***MicroGeneSys, ****NIAID

Objectives: To determine the safety and immunogenicity of escalating doses of rgp160 in infected subjects with greater than 400 CD4 lymphocytes per mm^3.
Methods: 52 healthy subjects seropositive for both HIV and hepatitis B surface antigen were randomized to receive immunizations with recombinant hepatitis vaccine, or one of 4 dosages of recombinant gp160 LAV vaccine (MicroGeneSys), 20, 80, 320, 1280 mcg in alum at 0, 1, 3, 6, 9, 12 months. They were monitored monthly for toxicity, and the development of new or enhanced cellular and humoral immune responses to HIV antigens.
Results: Trivial local reactions at the injection sites were the only toxicity seen. On entry most subjects had negligible lymphocyte proliferative responses (LPR) to HIV antigens eventhough they had normal LPR to recall, microbial antigens. After immunization with rgp160 but not after hepatitis vaccine, subjects developed large LPR to rgp160. All 4 doses of vaccine induced LPR to the same degree. Some subjects also developed LPR to SF-2 env 2-3 (Chiron), an envelope protein from a different isolate made in a different expression system. After immunization, lyphocytes also made IL-2 when stimulated by rgp160 in vitro, and manifested increased cytotoxic activity against gp160-expressing autologous targets. New antibody responses to additional gp160 determinants also developed, as did delayed cutaneous hypersensitivity to the immunogen without alum.
Conclusions: Immunization of seropositive subjects with greater than 400 CD4 cells with rgp160 is safe, and induces a variety of new or enhanced specific immune responses to antigenic determinants on envelope proteins. Because many of these immune responses were not detectable prior to immunization, and had not been induced by the infection itself, it is possible that the induction of new immune responses to HIV with a vaccine might be of benefit to HIV-infected subjects.

Fred Valentine, M.D., Dept. of Medicine, N.Y.U. Medical Center, 550 First Ave., New York, NY 10016, U.S.A.
212-263-6565, FAX 212-263-8264

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Bethesda, Maryland 20892

DRAFT

The Honorable William H. Natcher
Chairman, Committee on Appropriations
House of Representatives
Washington, DC 20515

Dear Mr. Chairman:

This letter is intended to serve as a certification by the undersigned that the large-scale Phase III clinical investigation of the gp160 vaccine should not proceed. Our reasons for that determination follow.

The National Institutes of Health (NIH) convened a Panel in November of last year to consider whether or not the "large-scale Phase III clinical investigation [of gp160] should proceed," as directed by the Department of Defense Appropriations (DOD) Act, 1993. There were important considerations that were included in those deliberations. First, there was an assumption that the appropriated funds were inevitably going to be spent on a large-scale efficacy trial of the gp160 vaccine candidate. Second, the Panel assumed that if such a trial was to be implemented, it was important to express, in their best scientific judgement, how such a trial should be conducted. In this context, the recommendations of the Panel, which were widely reported, were as follows: 1) based on traditional scientific criteria, currently available scientific information on gp160 by itself cannot be considered adequate for deciding to go forward with a large-scale clinical efficacy trial; and 2) assuming that the appropriated funds were going to be expended on a clinical trial including gp160, the funds should be used for a large-scale clinical efficacy trial to study several products. Because ongoing discussions during the past year may have caused some confusion concerning our opinion in this matter, the following clarification may be useful.

If one begins with the assumption that the question of the conduct of a large-scale efficacy trial of a gp160 candidate is indeed an open question, then our intent must be restated. Based on the current state-of-the-art in therapeutic vaccine research, the NIH and Food and Drug Administration (FDA) cannot recommend, on a scientific basis, that a large-scale efficacy trial of a single therapeutic vaccine be conducted with public funds at this time. We feel that the funds in question could more appropriately be used to answer basic questions about the immune response and host defense mechanisms related to vaccines prior to initiating large-scale human trials of a therapeutic vaccine. This research could include the conduct of smaller Phase I and Phase II trials of multiple vaccine candidates. The DOD could expand these studies, if scientifically indicated, and initiate additional studies on promising products. A decision to carry out a large-scale efficacy trial at a later date should be based on the knowledge accrued from the basic research mentioned above as well as from the results of the ongoing clinical trials. As you know, the DOD has a long history of conducting vaccine trials that have led to the licensure of a number of vaccines for infectious diseases of interest to their mission. In addition, they have established infrastructure

Page Two--The Honorable William H. Natcher DRAFT

for vaccine trials around the world; in particular, the DOD has established infrastructure in Thailand, a location well-suited to the trials of promising HIV vaccine candidates. Therefore, The DOD is in an excellent position to address those issues which capitalize on their strengths in vaccine research. The NIH and FDA stand ready to share their expertise and knowledge to complement the DOD research efforts.

A similar letter is being sent to Senator Robert Byrd.

Sincerely yours,

Ruth L. Kirschstein, M.D.
Acting Director
National Institutes of Health

David Kessler, M.D.
Commissioner
Food and Drug Administration

NATIONAL AIDS PROGRAM OFFICE

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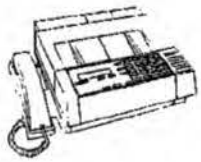

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Sent From:

Sara Henson
Director, Management & Operations _____

Sandra Bart
Deputy Assistant, Management & Operations _____

Sally Jones
Administrative Service Specialist X

Karen Williamson
Student Assistant (Co-op) _____

Number of Pages: 5 +Cover *Fax Number* 632-1096
Date: 12/6 /93

Message:

Per conversation.

PHS CORRESPONDENCE

14927

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9/30/93 Concur with comments

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OFFICE OF NATIONAL AIDS POLICY COORDINATION

GP160
NOV 15 1993

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request sent 11/18

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Date: 11-15-93

Number of Pages: 2 + cover

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MESSAGE..... Here is a copy of the letter from Kirschtein and Kessler on gp160. An identical letter has been prepared for William Natcher.

go/AH —
I need info on where this is in process —
K.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Bethesda, Maryland 20892

The Honorable Robert C. Byrd
Chairman, Committee on Appropriations
United State Senate
Washington, DC 20510

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Sincerely yours,

Ruth L. Kirschstein, M.D.
Acting Director
National Institutes of Health

David Kessler, M.D.
Commissioner
Food and Drug Administration

FYI
GP160

THE WHITE HOUSE

WASHINGTON

November 18, 1993

Donald S. Burke, M.D., Colonel
Medical Corps, U.S. Army
Director, Division of Retrovirology
Walter Reed Army Institute of Research
13 Taft Court, Suite 201
Rockville, MD 20850

Dear Dr. Burke:

This letter confirms your meeting with Kristine M. Gebbie, National AIDS Policy Coordinator, on Monday, November 29, 1993. As I mentioned, I am trying have Steve Joseph join you both (in person or by phone) in the 45 minute meeting that begins at 8:00 and will be held in her office at 750 17th Street N.W., Suite 1060 in Washington, DC. The purpose of the meeting is to discuss the process for approaching vaccine studies, such as GP160.

Please call me at (202) 632-1090 with any questions or for further clarification.

Sincerely,

W. Steve Lee

W. Steve Lee, Executive Assistant to
National AIDS Policy Coordinator