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THE WHITE HOUSE
WASHINGTON

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DATE: 5-20-97

Instructional Art Studies

NOTE FOR: Sandra Thurman

The President has reviewed the attached, and it is forwarded to you for your:

Information ☒

Action ☐

Thank you.

Staff Secretary
(x6-2702)

cc:

Copied
*Reed
Thurman
COS

5-20-97

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THE WHITE HOUSE
WASHINGTON

MEMORANDUM FOR THE PRESIDENT

FROM: Bruce Reed, Assistant to the President for Domestic Policy
Sandra Thurman, Coordinator for National AIDS Policy

SUBJECT: International Studies on Reducing Maternal-Infant HIV Tranmission

This memorandum will provide background on the controversy over an ongoing group of U.S.-supported international clinical trials studying options to reduce maternal transmission of HIV in developing countries. A brief overview of current knowledge, the rationale for further research, the World Health Organization position, concerns of domestic public interest groups, and the Department of Health and Human Services' position will be covered. Attached separately are talking points and Q&A's prepared by HHS on the issue.

Perinatal Transmission The World Health Organization (WHO) estimates over 1,000 HIV+ infants are born each day. Women with HIV disease have a 15%-40% risk of transmitting HIV to their baby with each pregnancy. The National Institutes of Health demonstrated that this transmission risk can be lowered to 8.3% by the administration of the drug AZT to women orally during pregnancy and intravenously during labor, and to their newborn infants orally for 6 weeks. This NIH study, known as ACTG 076 - comparing AZT with a placebo - was halted and published in 1994 when these dramatic results were evident. It has become the standard of care to offer all HIV+ pregnant women AZT therapy in the U.S.

An important unanswered research question is at what point during pregnancy or birth do women transmit HIV to their babies -- and if it is necessary to administer AZT over many months to prevent HIV infection in infants. Because many developing countries cannot afford expensive drug therapies for their citizens, pinpointing the critical period in which to administer AZT to prevent perinatal transmission is important so that the greatest number of women could be offered treatment.

Research Study Design Issues The public health leadership of several WHO member countries collaborated with the NIH and Centers for Disease Control and Prevention (CDC) to design and develop research studies to prevent perinatal HIV transmission in countries with limited health care infrastructure and resources. Each research study included an informed consent document outlining the research question, the randomization to an AZT or placebo group, and a detailed description of potential risks study participants may incur. All study protocols were reviewed and approved by the NIH and CDC Institutional Review Boards (IRBs) and the host countries. The political leadership of each host country were also fully informed of the study methodologies and concurred with their implementation. The first studies proposed by this international collaborative group began in 1993 with funding support from the U.S. (NIH, CDC) and France.

World Health Organization Activity In June 1994, the WHO hosted a meeting of researchers and public health practitioners from the U.S., Europe, and countries in Africa, Asia and the Carribean which have a high incidence of HIV disease. The purpose of the meeting was to examine the results of the NIH ACTG 076 trial in terms of their applicability internationally. The following recommendations were issued from this meeting:

1) Encourage the use of AZT as outlined by the NIH ACTG 076 study in industrialized countries; and

2) Immediate exploration of alternative regimens that could be used to achieve prevention of perinatal HIV prevention in the developing world.

WHO participants established parameters for the conduct of research studies in developing countries. The studies supported by the U.S. and France were consistent with these parameters.

Concerns of Some U.S. Public Interest Groups Dr. Sidney Wolfe of the Public Citizen Health Research Group wrote a long critique of U.S. involvement and support for these international perinatal HIV prevention studies in a letter to Secretary Shalala. The letter was broadly distributed to the media. Key concerns raised were:

- Some research designs include a placebo arm when AZT has proven benefit. Such a research design would never be allowed in the U.S.

- The studies violate major international ethical guidelines, specifically: the World Medical Association's 1975 Declaration of Helsinki; four of the Nuremberg codes for human experimentation; and the International Ethical Guidelines for Biomedical Research Involving Human Subjects designed to address ethical issues in developing countries

- There is no guarantee that women and infants in host countries will benefit from the research knowledge gained

- The lack of appropriate care in host countries does not justify study designs with placebo arms that have no benefit. The standard of care in many countries does not include access to prenatal care, medications, hospital births or intravenous infusions

- Comparison of these studies to the Tuskeegee syphilis study; criticism that IRBs should ensure that risks to subjects are minimized and subjects are not unnecessarily exposed to risk; this is colonialism at its worst

Senator Carol Moseley-Braun (D-IL) has also voiced her concern regarding study designs with a placebo arm when there is a known effective treatment for HIV prevention. She is alarmed that such studies are supported with U.S. funds, and thinks it is inappropriate to continue such funding in face of the apology being offered to the Tuskeegee survivors this Friday.

Department of Health and Human Services The Department of Health and Human Services has conducted a review of the U.S.-funded studies in question and continues to support both the study designs and public health importance of completing them. They are ongoing as of this date. HHS testified to this effect before the House Government Reform and Oversight Committee last week. There was very little discussion of the issue among Representatives present.

In brief, the HHS position maintains:

o The studies address a pressing need in the global control of the spread of HIV, defining interventions that will result in reductions in maternal-infant transmission which can be safely and routinely implemented in the developing world;

o The studies are based on the assumption that the NIH ACTG 076 regimen is not a feasible therapeutic intervention in developing countries due to lack of medical infrastructure and cost constraints; the research design examines options for treatment which are viable and affordable within the medical care delivery systems of the study countries

o All ongoing studies are in full compliance with U.S. and in-country regulations and laws, have gone through extensive in-country and U.S. ethical review processes and an international ethical review, and all studies have strong in-country support; an independent Data and Safety Monitoring Board continues to provide oversight of research findings at regular intervals

o Broadly accepted ethical principles for international research recognize a role for the local standard of care when testing the effectiveness of a new intervention. In the case of developing host countries, the local standard is minimal to no health care access. Studying new research options of AZT administration at specific times during pregnancy offers a new benefit to individuals who would not otherwise have had it, while defining research knowledge that may allow many individuals to benefit if shorter courses of AZT prove effective for HIV prevention. The placebo arm is equivalent to the local standard of care.

Attached are Q&As and talking points which support the HHS position on this issues.

THE WHITE HOUSE

WASHINGTON

QUESTIONS AND ANSWERS

Q. Did you know about the NIH supported clinical trials using AZT and placebos in HIV infected pregnant women in developing countries?

A. I am aware that NIH is funding some research into how to improve prevention of mother to infant transmission of HIV in some developing countries. I understand that AZT is the drug that is being used in these studies.

I have asked the Secretary of Health and Human Services to provide me with a report on these NIH studies. I also asked for an evaluation of how these studies will help the women and infants involved and how the studies are helping to curb maternal transmission of HIV in these countries.

Q. Some of the women in these studies are not receiving AZT, they are getting a placebo. How does this compare with the U.S. position that all HIV infected pregnant women and their infants should be offered AZT?

A. That question will be addressed in Secretary Shalala's report. Just let me say that in many developing countries no HIV treatment at all is available for pregnant women or their infants. It is totally different situation than what we have in this country where AZT is readily available.

Q. Some critics are saying that the NIH funded AZT studies in developing countries are not different from what happened in the Tuskegee study where treatment was withheld from some of the participants. How do you answer that?

A. Well, I will need to see the report from HHS before I can fully address that. But I must emphasize that in the Tuskegee study, treatment that was widely available in this country was deliberately withheld from some of the participants. In the AZT studies oversees, the only AZT treatment available is the treatment provided to participants in the study.

Q. Some critics are saying that there is an issue of violation of international ethical codes in the AZT studies. Is this true?

A. I will know more about the studies and the specific concerns surrounding it when I review Secretary Shalala's's report. Until then, I can't say anything further on this. I can assure you that we will not support any studies where such violations occur.

TALKING POINTS

* OUR GOAL IN SUPPORTING THESE STUDIES IS TO FIND EFFECTIVE WAYS TO PREVENT MOTHER-TO-CHILD TRANSMISSION OF HIV THAT CAN BE USED IN DEVELOPING COUNTRIES. THAT MEANS FINDING A REGIMEN THAT IS EFFECTIVE FOR THE SPECIFIC POPULATION AND AFFORDABLE IN THAT COUNTRY.

* THE FULL AZT-076 REGIMEN, WHICH IS THE STANDARD OF CARE IN THE UNITED STATES, IS NOT FEASIBLE FOR THESE COUNTRIES. IT IS EXPENSIVE AND REQUIRES SOPHISTICATED MEDICAL MONITORING.

* WE HAVE WORKED WITH THE WORLD HEALTH ORGANIZATION, UNAIDS AND THE HOST GOVERNMENTS TO DESIGN THESE TRIALS. THEY ARE FULLY SUPPORTED BY THE INTERNATIONAL BODIES AND BY THE HOST GOVERNMENTS

* THESE TRIALS HAVE BEEN REVIEWED FROM AN ETHICAL STANDPOINT BY THE CDC AND NIH INSTITUTIONAL REVIEW BOARDS, AND BY REVIEW BOARDS IN THE HOST COUNTRIES. WE AGREE THAT THESE ARE DIFFICULT AND COMPLEX ISSUES, BUT THAT IS EXACTLY WHY WE WENT TO SOME LENGTHS TO ACHIEVE MEDICAL AND ETHICAL CONSENSUS ON THE RESEARCH NOT ONLY WITHIN HHS, BUT WITH INTERNATIONAL ORGANIZATIONS AND THE HOST COUNTRIES THEMSELVES.

* WE ARE DEDICATED TO FINDING AN EFFECTIVE THERAPEUTIC INTERVENTION THAT CAN REALISTICALLY BE ADMINISTERED IN THE HOST COUNTRIES AND IS AFFORDABLE.

May 27, 1997

AIDS NATIONAL INTERFAITH NETWORK

Sandy - calendar items

Ms. Sandy Thurman
White House Office on AIDS Policy
808 17th Street, N.W. 8th Floor
Washington, DC 20503

Dear Sandy:

Thank you for the lovely lunch today and the chance to experience the White House Mess. It was a pleasure to be able to spend some focused time with you discussing the following items. As we agreed, I have included these agenda items to help you frame your responses.

United States Conference on AIDS: This event takes place in Miami on September 18-21,1997. We would like you to be present at the Plenary Breakfast on Thursday the 18th and to introduce a video greeting by the President.

World AIDS Day: Monday, December 1,1997. We discussed your suggestion of an interfaith service at the National Cathedral on the eve of WAD, November 30th which would reflect the theme of WAD97 *"Children Living in a World with AIDS"*. I spoke of the Ford Foundation project documenting AIDS ministries in America and featuring, in part, the work of Rabbi Joseph Edelheit and Trudy James founder of RAIN, Arkansas. We would like to see a White House Prayer Breakfast on Monday, December 1st in which the President could hold up the unique work of AIDS ministries by honoring the six or eight people featured in the report.

AIDS & American Religion Convocation: I reported on our funding by the Ford Foundation for this event to take place at the Carter Center on WAD of 1998.

Centers for Disease Control: I spoke of the need for raising the Religious Initiatives Program so that it does not "get lost in the shuffle" as CDC looks to additional changes. You mentioned that you would contact Dr. Gayle and Dr. Satcher to add your support to the importance of continuing the CDC's relationship with the religious community.

Red Cross: I shared with you the situation concerning "gay invisibility" in the Red Cross training manual and my response to date. You mentioned you may remind them of your concern for ongoing issues of homophobia and racism in light of their plans for the future.

Again a hearty thanks, and know that I keep you in my prayers for *strength and wisdom*!

Pax,

Ken South
Executive Director

1400 I Street, N.W. Suite 1220 Washington, D.C. 20005
PHONE; 202-842-0010 FAX: 202-842-3323

National Association of County & City Health Officials

Contact Information

We welcome all inquiries and comments on our Web site and any issue relating to the work of NACCHO. Contact information for NACCHO is as follows:

National Association of County and City Health Officials
440 First Street, NW, Suite 450
Washington, DC 20001
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Questions and thoughts may be sent electronically to NACCHO at info@NACCHO.org.

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National Association of County & City Health Officials

NACCHO Policy Statements and Resolutions

These are the most recent NACCHO policy statements and resolutions adopted by the NACCHO Board of Directors. For a copy of any of these statements, please contact: info@naccho.org .

NACCHO Policy Statements

Policy Statement on Tobacco Use Prevention and Control (November 1996)

NACCHO Resolutions

Topic Areas

HIV/AIDS
Tobacco
Environmental Health
Medicaid
Health Care Reform/Access
Immunization/Screening
Injury/Violence Protection
Public Health Information and Information Systems
Public Health Professionals
Federal Funding (General Issues)
Other Topics

HIV/AIDS

96-2 Resolution Concerning HIV/AIDS Ryan White and HIV Prevention Funding (February 2, 1996)

95-4 Resolution Concerning Prevention of Perinatal Transmission of Human Immunodeficiency Virus (October 29, 1995)

95-3 Resolution to Curb Transmission of HIV and Other Bloodborne Disease Infection Related to Injection Drug Use (October 29, 1995)

92-4 Resolution Concerning HIV-Infected Health Care Workers (March 21, 1992)

92-17 Resolution Concerning HIV/AIDS Funding (March 21, 1992)

91-6 Resolution Concerning the Removal of HIV from the List of Diseases Barring Immigrant Entry into the United States (July 12, 1991)

91-7 Resolution Concerning the Universal Testing of Health Care Workers for Human Immunodeficiency Virus (July 12, 1991)

Please ask support staff to call + get these 783-5550