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Correspondence - Sandra L. Thurman - Outgoing - 7/97

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Withdrawal/Redaction Sheet

Clinton Library

DOCUMENT NO. AND TYPE	SUBJECT/TITLE	DATE	RESTRICTION
001a. letter	Sandra Thurman to Individual living with HIV re: Past collaboration (Personal) [partial] (1 page)	07/14/1997	b(6)
001b. letter	Individual living with HIV to Sandra Thurman re: Past collaboration (Personal) [partial] (1 page)	04/10/1997	b(6)
002a. letters	Sandra Thurman to Citizen re: Views on AIDS (Personal) [partial] (2 pages)	07/08/1998	b(6)
002b. letter	Citizen to Sandra Thurman re: Views on AIDS (Personal) (1 page)	06/20/1998	b(6)
002c. letter	Citizen to Sandra Thurman re: Views on AIDS (Personal) (1 page)	01/06/1998	b(6)
002d. clippings	re: Citizen's personal views on AIDS [partial] (5 pages)	00/00/0000	b(6)

COLLECTION:

Clinton Presidential Records
National AIDS Policy Office

OA/Box Number: 19399

FOLDER TITLE:

Correspondence - Sandra L. Thurman - Outgoing - 7/97

2018-0764-F

jm2098

RESTRICTION CODES

Presidential Records Act - [44 U.S.C. 2204(a)]

- P1 National Security Classified Information [(a)(1) of the PRA]
- P2 Relating to the appointment to Federal office [(a)(2) of the PRA]
- P3 Release would violate a Federal statute [(a)(3) of the PRA]
- P4 Release would disclose trade secrets or confidential commercial or financial information [(a)(4) of the PRA]
- P5 Release would disclose confidential advice between the President and his advisors, or between such advisors [(a)(5) of the PRA]
- P6 Release would constitute a clearly unwarranted invasion of personal privacy [(a)(6) of the PRA]

C. Closed in accordance with restrictions contained in donor's deed of gift.

PRM. Personal record misfile defined in accordance with 44 U.S.C. 2201(3).

RR. Document will be reviewed upon request.

Freedom of Information Act - [5 U.S.C. 552(b)]

- b(1) National security classified information [(b)(1) of the FOIA]
- b(2) Release would disclose internal personnel rules and practices of an agency [(b)(2) of the FOIA]
- b(3) Release would violate a Federal statute [(b)(3) of the FOIA]
- b(4) Release would disclose trade secrets or confidential or financial information [(b)(4) of the FOIA]
- b(6) Release would constitute a clearly unwarranted invasion of personal privacy [(b)(6) of the FOIA]
- b(7) Release would disclose information compiled for law enforcement purposes [(b)(7) of the FOIA]
- b(8) Release would disclose information concerning the regulation of financial institutions [(b)(8) of the FOIA]
- b(9) Release would disclose geological or geophysical information concerning wells [(b)(9) of the FOIA]

THE WHITE HOUSE

WASHINGTON

July 31, 1997

Seth Berkley, Interim President
International AIDS Vaccine Initiative
420 Fifth Avenue
New York, NY 10018-2702

Dear Dr. Berkley:

Seth

I am pleased to inform you that on July 27, 1997, the Presidential Advisory Council on HIV and AIDS voted unanimously for its name to be added to the list of those endorsing the *International Call for Action on HIV Vaccine Development*.

Your efforts in working toward the eventual control of the HIV/AIDS pandemic are important and appreciated.

Sincerely,

Sandra

Sandra L. Thurman
Director

Office of National AIDS Policy

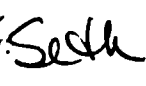
THE WHITE HOUSE

WASHINGTON

July 31, 1997

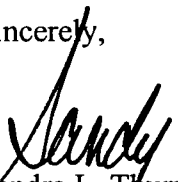
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Sincerely,


Sandra L. Thurman
Director
Office of National AIDS Policy

THE WHITE HOUSE
WASHINGTON

July 22, 1997

The Honorable Carol Moseley-Braun
United States Senate
Washington, DC 20510

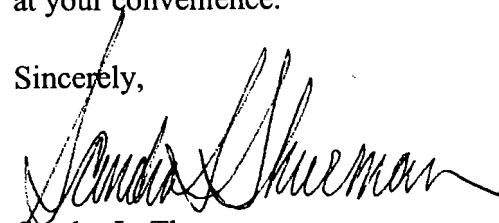
Dear Senator Moseley-Braun:

The President has asked me to respond to your letter drafted on April 30, 1997 regarding the use of placebos in AZT trials in developing countries.

I would like to share a letter written by Secretary Shalala to Dr. Sidney Wolfe at Public Citizen's Health Research Group that addresses your concerns to the President. I have also included a report entitled "The Conduct of Clinical Trials of Maternal-Infant Transmission of HIV Supported by the United States Department of Health and Human Services in Developing Countries, A Summary of the Needs of Developing Countries, The Scientific Applications, and the Ethical Considerations Assessed by the National Institutes of Health and the Centers for Disease Control and Prevention 1994-1997," July 1997.

Please feel free to call me at 632-1215 if you have any questions. I am available to visit with you at your convenience.

Sincerely,



Sandra L. Thurman
Director
Office of National AIDS Policy

Enclosure



THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

JUL 15 1997

Sidney M. Wolfe, M.D.
Director
Public Citizen's Health Research Group
1600 20th Street, NW
Washington, DC 20009-1001

Dear Dr. Wolfe:

On April 22 you wrote to me regarding clinical trials of medical interventions designed to discover methods to reduce maternal-infant transmission of human immunodeficiency virus (HIV) in developing countries. During the process of the development of my response, you wrote to President Clinton on this same matter and provided him with some additional information. I note in both letters your conclusion that the experimental designs for some of these studies are unethical because they do not meet the standard of health care that would be required were they to be conducted in the United States. This letter and its enclosure are in response to both your letter to me and your letter to the President.

Your letters raise issues about how best to seek safe and effective methods to prevent HIV infection in newborns in developing countries whose health care systems lack the substantial level of services and resources available to citizens of industrialized countries. All parties are in agreement that, before initiating any intervention seeking to identify such methods, it is essential to ensure that the intervention being studied is ethically and scientifically acceptable to the developing countries, offers sufficient promise to justify the involvement of human subjects, and is realistically adoptable if the intervention is shown to be sufficiently safe and effective. I have reviewed your letters with Dr. Harold Varmus, Director, National Institutes of Health (NIH), and Dr. David Satcher, Director, Centers for Disease Control and Prevention (CDC). In addition, Dr. Harold Shapiro, Chair of the National Bioethics Advisory Commission, has received copies of your letters.

At my request, Drs. Varmus and Satcher conducted a rigorous assessment of the previous reviews of the needs, resources, and health care capabilities of the developing countries involved. They also reviewed the process of scientific development and ethical assessment leading up to and guiding the current conduct

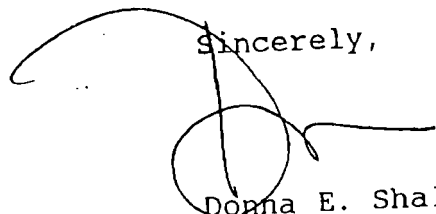
07/17/97 THU 11:25 FAX 202 359 3333
Page 2 - Sidney M. Wolfe, M.D.

of these clinical trials. These two distinguished scientists and public health leaders have concluded that researchers in the host countries and the United States are carrying out scientifically meritorious and ethically sound experimental designs, providing effective protection of human research subjects, and faithfully adhering to approved research protocols that are consistent with the recommendations of the World Health Organization and approved by all of the countries involved. I enclose a copy of their report. Please note that the two CDC-supported protocols referenced in the report had significant procedural shortcomings that have been addressed.

I endorse the assessment of Drs. Varmus and Satcher and therefore have concluded that the pertinent NIH- and CDC-sponsored clinical trials should continue. Three facts weighed heavily in my judgment. First, there is the demonstrated, urgent need for feasible interventions for preventing maternal-infant transmission of HIV in developing countries. Second, in industrialized as well as in developing countries, historical controls and national or local health statistics do not provide an adequate baseline against which to compare the outcomes of new HIV interventions. Third, the ACTG 076 zidovudine (AZT) regimen is presently not feasible as the standard of care in many developing countries because it is too logistically complex and resource-intensive and, therefore, inappropriate for use as a comparison arm of an HIV trial at this time.

Clinical trials in developing countries present a variety of extraordinarily difficult choices. I recognize that not every one of us would make the same decisions in every instance; yet, lack of unanimity on issues as complex as these is neither infrequent nor necessarily reflective of errors in decision-making. With respect to the clinical trials designed to reduce HIV infections in newborns in developing countries, I am satisfied that the choices are being addressed through a sound synthesis of knowledge, compassion, and prudence. As this Department proceeds to sponsor these and other clinical trials in developing countries, I assure you that we and our collaborators in those countries will remain committed to the simultaneous achievement of improved medical care, meritorious science, and assiduous protection of human research subjects.

Sincerely,



Donna E. Shalala

Enclosure

THE CONDUCT OF CLINICAL TRIALS
OF MATERNAL-INFANT TRANSMISSION OF HIV
SUPPORTED BY THE UNITED STATES DEPARTMENT OF
HEALTH AND HUMAN SERVICES
IN DEVELOPING COUNTRIES

A SUMMARY OF THE NEEDS OF DEVELOPING COUNTRIES,
THE SCIENTIFIC APPLICATIONS, AND THE ETHICAL CONSIDERATIONS
ASSESSED BY THE NATIONAL INSTITUTES OF HEALTH AND
THE CENTERS FOR DISEASE CONTROL AND PREVENTION
1994-1997



JULY 1997

THE CONDUCT OF CLINICAL TRIALS OF
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For the past three years the United States Department of Health and Human Services (HHS), through its National Institutes of Health (NIH) and Centers for Disease Control and Prevention (CDC), has been engaged in the development and conduct of clinical trials designed to identify feasible interventions for preventing maternal-infant transmission of HIV in developing countries. The Director, NIH, the Director, CDC, and other senior scientists and administrators within the NIH and CDC, at the request of the Secretary, HHS, conducted a thorough assessment of the previous reviews of the needs, resources, and health care capacities of these developing countries and the process of scientific development and ethical evaluation leading up to and guiding the current conduct of these clinical trials. As an added measure, comments of a number of experts in biomedical ethics and the biosciences outside of NIH and CDC were also sought and considered. Based on this assessment, NIH and CDC have determined that, although these are complex matters, the studies have the potential to be of enormous value to the developing countries and are scientifically well-founded and ethically acceptable.

The NIH/CDC assessment addressed three major questions related to these clinical trials. What is the need for these studies? Are the studies adequately designed to examine options for treatment that will meet that need? Is the involvement of human subjects in these studies consistent with the internationally accepted principles of autonomy, justice, and beneficence as implemented by the United States Federal Policy for the Protection of Human Subjects, including the equitable selection of subjects, obtaining of voluntary informed consent, and employing the input, review, and authorization of the appropriate ethical and other bodies in the U.S. and in the developing countries where the research is being conducted?

THE NEED

One regimen of antiretroviral therapy has been shown to reduce substantially the likelihood of maternal-infant transmission of HIV. The identification of this successful regimen was the result of the National Institutes of Health's AIDS Clinical Trials Group protocol 076 (ACTG 076 or 076) in 1994. In spite of this knowledge, approximately 1,000 HIV-infected infants are born each day, the vast majority of them in developing countries. This occurs, in part, because the regimen proven to be effective is simply not feasible as a standard of prevention in much of the developing world.

There are two reasons for this lack of feasibility. First, to follow the regimen that has proven efficacy requires that the women be reached early in prenatal care; be tested for and counseled concerning their HIV status; comply with a lengthy oral treatment regimen; receive intravenous administration of the antiretroviral zidovudine (ZDV or AZT) during labor and delivery; and refrain from breast-feeding. Additionally, the newborns must receive 6 weeks of oral AZT therapy. During and after the time the mother and infant are treated with AZT, both must be carefully monitored for adverse effects of exposure to this drug. In the developing world countries that are the sites of these studies, these requirements could seldom be achieved, even under the infrequent circumstance when women present early enough for the screening and care requirements of the 076 therapeutic regimen to be implemented. Second, the wholesale drug costs for the AZT in the 076 regimen are estimated to be in excess of \$800, an amount far greater than these developing countries could afford as standard care. For example, in the developing country of Malawi, the cost of AZT alone for the 076 regimen for one HIV-infected pregnant woman and her child is more than 600 times the annual health care budget allocation for one person. Less complex and expensive alternatives are urgently needed to address the staggering impact of maternal-infant transmission of HIV in developing countries.

In June 1994, after the results of ACTG 076 were released, the World Health Organization (WHO) convened a group of researchers and public health practitioners from around the world in Geneva. This international panel called for the use of the 076 regimen in the industrialized world, where it is feasible, but immediately called for the exploration of alternative regimens that could be used in the developing world, stating that logistical issues and cost would preclude the widespread application of the 076 regimen. The WHO panel called for international coordination of research efforts to develop simpler, less costly drug regimens. This coordination continues in the form of meetings two to three times per year of the UNAIDS Informal Working Group on Prevention of Mother to Child Transmission of HIV. As a result, there is a global research agenda addressing the need to devise efficacious regimens that can be safely and widely implemented in the developing world.

THE STUDY DESIGNS

The NIH- and CDC-supported studies of maternal-infant transmission of HIV in developing countries are designed to meet the critical need just described. The panel convened by WHO in Geneva stated in Recommendation 6 of its *Recommendations from the Meeting on Prevention of Mother-to-Infant Transmission of HIV by Use of Antiretrovirals, Geneva 23-25 June 1994* (attached as an appendix to this report):

Since the ZDV regimen studied in ACTG 076 is not applicable in those parts of the world where most MTI [mother-to-infant] transmission of HIV occurs, placebo-controlled trials offer the best option for obtaining rapid and scientifically valid results.

The WHO panel went on to explain in its commentary on the recommendation:

Most of MTI transmission of HIV occurs in the developing world, where the ZDV regimen used in ACTG 076 is not applicable because of its cost and operational requirements. In those parts of the world, the choice of a placebo for the control group of a randomized trial would be appropriate as there is currently no effective alternative for HIV-infected pregnant women.

For each individual study there has been careful consideration of the specific needs of and treatment feasibility within the country in which it would be implemented. NIH, CDC, collaborating U.S. institutions, and the host countries will continue to monitor each study and any changes in the countries that may have an impact on study design. It is an unfortunate fact that the current standard of perinatal care for the HIV-infected pregnant women in the sites of the studies does not include any HIV prophylactic intervention at all. Nor does the standard of care for these HIV-infected women include the combination therapies recommended and used for some HIV-infected women in the U.S. However, the inclusion of this regrettable, but real, performance-site standard in the form of placebo controls provides the direct comparison of standard and new intervention that is needed to form the basis for rational policy decisions and will result in the most rapid, accurate, and reliable answer to the question of the value of the intervention being studied compared to the local standard of care.

The NIH- and CDC-supported studies are designed in a manner consistent with the still-pertinent recommendations of the WHO panel and have been developed in on-site collaboration with the health ministries, physicians, and researchers of the host countries. There is strong support for the design of the NIH- and CDC-supported studies, including the placebo arms, within the countries where the clinical trials are being carried out, in part because the studies are assessing regimens that might realistically be employed to decrease mother-to-infant transmission, taking into account the health care resources and operational capabilities of these countries.

HUMAN RESEARCH SUBJECT PROTECTIONS

The acceptability of the involvement of human subjects in the studies under discussion has been scrupulously reviewed beginning with the first proposal for ACTG 076 which was a placebo-controlled study conducted in the U.S. and France. After the complex 076 treatment regimen was proven successful, the WHO conference in Geneva quickly issued clear guidelines for research taking into account the extremely wide range of health care capabilities that characterize the broad spectrum of countries described by the term developing countries. As mentioned earlier, these matters have been debated in formal discussions, forums, and required reviews in the U.S., in international settings, and in the countries where the clinical trials are or will be

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carried out.¹ Even so, CDC determined that Assurances for performance site countries required by HHS regulations at Title 45, Part 46, Section 103 had not been obtained prior to enrolling subjects. CDC acted immediately to notify OPRR and to address these administrative procedures. The Assurances for the CDC-Thailand and CDC-Cote d'Ivoire studies were conditionally approved by OPRR on July 7, 1997 and July 14, 1997 respectively. CDC amended its human subjects protection administrative procedures to be in full compliance with 45 CFR 46.103.

Arguments against the NIH- and CDC-supported studies appear to rest on the proposition that it is unethical to conduct a clinical trial unless it offers all participants a chance to receive an effective intervention if such is available anywhere in the world, even if it is not available at the site of the clinical trial. Ideally, this would be so for all clinical trials for all therapies. But the reality is that often it is not possible. ~~The very purpose of the NIH- and CDC-supported studies of maternal-infant transmission of HIV in developing countries is to identify interventions other than those of 076 and we agree with the WHO Geneva panel's Recommendation 2 that:~~

It should be emphasized that the results of ACTG 076 are only directly applicable to a specific population. Moreover, the ZDV regimen employed in the ACTG 076 study has a number of features (cost, logistical issues, among others) which limit its general applicability. Therefore, no global recommendations regarding use of ZDV to prevent MTI transmission of HIV can be made.

The use of historical controls was considered and found to be unacceptable because existing epidemiological data for the host countries are inadequate for this purpose. We agree with the commentary on Recommendation 5 of the WHO Geneva panel that:

(r)andomized controlled trials offer the best evaluation of new treatment regimens. The use of historical controls is strongly discouraged, due to the wide changes with time in the study population (differences in the distribution of disease stages), the circulating viral strains, the diagnostic tools used for the ascertainment of the HIV infection status of infants (antibodies in earlier cohorts compared to direct viral markers in more recent cohorts), and the treatment practices (increased use of zidovudine

¹ A useful exploration of these events is contained in an article written by Jon Cohen and published in Science, Vol. 269, pp. 624-626, 4 August 1995.

in HIV-infected pregnant women with AIDS-related symptoms and/or CD4+ lymphocyte counts).

The WHO guidelines clearly indicate that the in-country health care capabilities of each country in which maternal-infant HIV transmission research is to be conducted must be used to define the type of research which is ethical and therefore permissible in that country. If a country will be able to afford only very minimal increments in the resources directed toward improved perinatal care for HIV-infected pregnant women and their children, then trials like those focused on vitamin A and other micronutrients are ethical, permissible, and desirable.

In other countries, such as Thailand, the situation is far more complex. Thailand is a country that may be able to afford a simplified AZT/076-like regimen. However, Thai researchers, physicians, and public health officials are understandably interested in seeing a number of issues addressed before any AZT is placed in general use in HIV-infected pregnant women in their country: (1) Is a much simplified 076-like regimen (e.g., initiation of prenatal treatment at 36 weeks of pregnancy, oral instead of intravenous AZT during labor and delivery, elimination of AZT given to the infant) effective in reducing transmission? (2) What adverse outcomes related to AZT use will be seen in Thai populations? Will adverse effects not seen in the U.S. and Europe occur in Thailand? (3) Is AZT administered orally to Thai women safe and well-tolerated? Do Thai women metabolize AZT such that the dose used is the right one to use in all Thai HIV-infected pregnant women? and, (4) How does the type of HIV seen in Thailand (which has demonstrable differences from the type seen in the U.S.) respond to AZT?

Seeking answers to these questions are two studies, one supported by CDC and one supported by NIH. The CDC-Thai study will determine how well tolerated and how effective a very simple AZT regimen is in a population of women who are infected with a subtype of HIV predominantly different from that observed in the U.S. and who also have co-factors for transmission that may differ from those seen in American populations. Because it is a two-arm, placebo-controlled clinical trial, the CDC-Thai study will provide rapid answers to many of the important questions noted above. It also will enable the Ministry of Health and physicians in Thailand to make better-informed decisions about the use of a much-simplified AZT regimen for general use in HIV-infected pregnant women.

Complementing the CDC-Thai study is an NIH-Thai study to determine how much additional benefit, as compared to how much additional cost and adverse effect, is occasioned by small increments in treatment complexity. The NIH-Thai study has four arms, each a modest increment over the treatment arm in the CDC-Thai study. However, even the most complex arm of the NIH-Thai study is *not* identical to the treatment arm of 076. The NIH-Thai study will benefit from the baseline that is established by the CDC-Thai study.

Since the NIH-Thai study provides some level of AZT to all participants, the data from the CDC-Thai study would be particularly important for interpretation of results if the outcomes were the same for each of the four arms. Taken together, these two studies will provide a broad range of

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information about the likely value of AZT as a strategy to interrupt maternal-infant transmission of HIV.

In an analysis of the spectrum of studies supported by the NIH and CDC in Africa and Asia, it is clear that we have adhered to international guidelines, including the recent WHO guidelines which address specifically the ethical conduct of research in the post-076 era. The primary consideration in decisions about the appropriate conduct of research has been this: Once the research is completed at a given site, will the population which the study participants represent be able to profit from what is learned from that research?

The International Ethical Guidelines for Biomedical Research Involving Human Subjects that were prepared by the Council for International Organizations of Medical Sciences (CIOMS) in collaboration with WHO are:

...intended to indicate how the ethical principles embodied in the Declaration [of Helsinki] could be effectively applied in developing countries.

To evaluate interventions that they could not implement realistically would be exploitive of those in the participant country since there would be no likelihood of meeting requirement 15 of the *Guidelines* that obliges:

...any product developed [through] such research will be made reasonably available to the inhabitants of the host community or country at the completion of successful testing...

Therefore, we have determined that the more compelling ethical argument is against using a regimen that if found to be superior in the study could not possibly be used in the prevention of maternal-infant transmission of HIV in the host country. Turning once again to Malawi for example, health officials there refused to permit the conduct of a study involving a full course regimen of AZT (such as that used in ACTG 076) because they believed it would be unethical to undertake such a study in Malawi given that its very limited resources and poor health infrastructure make the introduction of AZT as standard treatment for HIV-infected pregnant women unfeasible. Instead, the health officials wanted research on alternative treatment approaches that might reduce maternal-infant transmission of HIV. The justification and ethical foundation for the NIH- and CDC-supported studies incorporate the reality that the clinical trials are examining other alternatives that could actually be used for the majority of HIV-infected pregnant women and mothers in the countries in which the clinical trials are being carried out. The process of ethical review of these trials has been rigorous. It has included community and scientific participation and the application of the U.S. rules for the protection of human research subjects in reviews by the relevant institutional review boards (IRBs) in the U.S. and in the countries where the clinical trials are carried out. Support from local governments has been obtained and each active study has been and will continue to be reviewed by an independent Data

07/17/97 THU 11:29 FAX 202 690 0333
and Safety Monitoring Board. These studies are in compliance with broadly accepted principles of ethics of international research, in which the need to take into account the reality of available and feasible health care is a consideration of substantial importance.

In summary, these studies all address an urgent need in the countries in which they are being conducted. They have been developed with extensive in-country input and participation, and they are consistent with widely accepted principles and guidelines of bioethics. Our perspective and our decision to support these trials rest heavily on local support and approval. In this regard, we point to the words of Edward K. Mbidde, Chair, AIDS Research Committee, Uganda Cancer Institute, in a letter, dated May 8, 1997, to the Director, NIH:

These are Ugandan studies conducted by Ugandan investigators on Ugandans. [Elsewhere in the letter he discusses Ugandan ethical review.] Due to lack of resources we have been sponsored by—organizations like yours [NIH]. We are grateful that you have been able to do so.

There is a mix up of issues here which needs to be clarified. It is not NIH conducting the studies in Uganda but Ugandans conducting their study on their people for the good of their people.

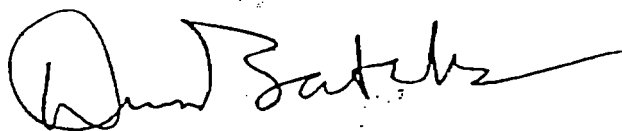
The issues surrounding these studies are, indeed, complex and subject to some disagreement. However, final judgments about their appropriateness must be heavily weighted in favor of decisions made at the local level, as long as those decisions are consistent with international standards and those of the U.S. We know of no other way to realistically and rapidly address the gravity of mother-to-infant transmission of HIV in the developing world and the current lack of a proven, feasible intervention against it, than to continue the studies on which our two agencies have embarked.

DATED: JUL 15 1997



Harold Varmus

Director, National Institutes of Health



David Satcher

Director, Centers for Disease Control and Prevention

Appendix attached

NATIONAL SECURITY COUNCIL

ID 9703257

REFERRAL

DATE: 15 MAY 97

Daniel Montoya

MEMORANDUM FOR: REED, B

DOMESTIC POLICY COUNCIL

DOCUMENT DESCRIPTION:

TO: PRESIDENT

SOURCE: MOSELEY-BRAUN, CAROL

DATE: 30 APR 97

SUBJ: HHS FUNDING OF US AIDS TESTING IN AFRICA

*TO Aids
policy
office
5/17*

REQUIRED ACTION APPROPRIATE ACTION

DUE DATE:

COMMENT:

FOR

John W. Ficklin
JOHN W. FICKLIN

NSC RECORDS MANAGEMENT OFFICE

Cheney 5-16-97

THE WHITE HOUSE

WASHINGTON

July 22, 1997

Dennis R. Roth
10004 Beach Mill Road
Great Falls, VA 22066

Dear Mr. Roth:

I would like to thank you for sending us the information regarding CEL-SCI's quest in formulating an AIDS vaccine. Such news is very exciting for all of us, as the fight against HIV/AIDS is one we are all in together.

As you know, the President is committed to developing an AIDS vaccine. He has announced several initiatives to make this a reality, such as supporting high-level international collaborations, a center dedicated to AIDS vaccine research at the NIH, and outreach to scientists, pharmaceutical companies, and patient advocates to maximize the involvement of both the public and private sectors in the development of an AIDS vaccine. We, as an administration and a nation, must remain dedicated to the development of an effective vaccine.

I truly appreciate the many hours you have put into this research. Thank you again for keeping us informed on the latest in the search for an AIDS vaccine.

Sincerely,

A handwritten signature in black ink, appearing to read "Sandra L. Thurman". The signature is fluid and cursive, with the first name "Sandra" being more prominent.

Sandra L. Thurman

Director

Office of National AIDS Policy

THE WHITE HOUSE
WASHINGTON

July 22, 1997

The Honorable Carol Moseley-Braun
United States Senate
Washington, DC 20510

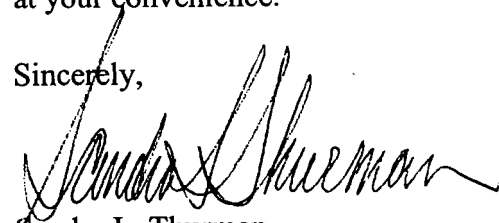
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Please feel free to call me at 632-1215 if you have any questions. I am available to visit with you at your convenience.

Sincerely,



Sandra L. Thurman
Director
Office of National AIDS Policy

Enclosure



THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

JUL 15 1997

Sidney M. Wolfe, M.D.
Director
Public Citizen's Health Research Group
1600 20th Street, NW
Washington, DC 20009-1001

Dear Dr. Wolfe:

On April 22 you wrote to me regarding clinical trials of medical interventions designed to discover methods to reduce maternal-infant transmission of human immunodeficiency virus (HIV) in developing countries. During the process of the development of my response, you wrote to President Clinton on this same matter and provided him with some additional information. I note in both letters your conclusion that the experimental designs for some of these studies are unethical because they do not meet the standard of health care that would be required were they to be conducted in the United States. This letter and its enclosure are in response to both your letter to me and your letter to the President.

Your letters raise issues about how best to seek safe and effective methods to prevent HIV infection in newborns in developing countries whose health care systems lack the substantial level of services and resources available to citizens of industrialized countries. All parties are in agreement that, before initiating any intervention seeking to identify such methods, it is essential to ensure that the intervention being studied is ethically and scientifically acceptable to the developing countries, offers sufficient ~~promise to justify~~ the involvement of human subjects, and is realistically adoptable if the intervention is shown to be sufficiently safe and effective. I have reviewed your letters with Dr. Harold Varmus, Director, National Institutes of Health (NIH), and Dr. David Satcher, Director, Centers for Disease Control and Prevention (CDC). In addition, Dr. Harold Shapiro, Chair of the National Bioethics Advisory Commission, has received copies of your letters.

At my request, Drs. Varmus and Satcher conducted a rigorous assessment of the previous reviews of the needs, resources, and health care capabilities of the developing countries involved. They also reviewed the process of scientific development and ethical assessment leading up to and guiding the current conduct

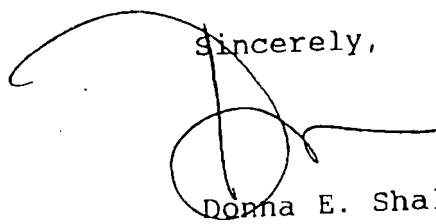
07/17/97 THU 11:23 FAX 202 696 8338
Page 2 - Sidney M. Wolfe, M.D.

of these clinical trials. These two distinguished scientists and public health leaders have concluded that researchers in the host countries and the United States are carrying out scientifically meritorious and ethically sound experimental designs, providing effective protection of human research subjects, and faithfully adhering to approved research protocols that are consistent with the recommendations of the World Health Organization and approved by all of the countries involved. I enclose a copy of their report. Please note that the two CDC-supported protocols referenced in the report had significant procedural shortcomings that have been addressed.

I endorse the assessment of Drs. Varmus and Satcher and therefore have concluded that the pertinent NIH- and CDC-sponsored clinical trials should continue. Three facts weighed heavily in my judgment. First, there is the demonstrated, urgent need for feasible interventions for preventing maternal-infant transmission of HIV in developing countries. Second, in industrialized as well as in developing countries, historical controls and national or local health statistics do not provide an adequate baseline against which to compare the outcomes of new HIV interventions. Third, the ACTG 076 zidovudine (AZT) regimen is presently not feasible as the standard of care in many developing countries because it is too logistically complex and resource-intensive and, therefore, inappropriate for use as a comparison arm of an HIV trial at this time.

Clinical trials in developing countries present a variety of extraordinarily difficult choices. I recognize that not every one of us would make the same decisions in every instance; yet, lack of unanimity on issues as complex as these is neither infrequent nor necessarily reflective of errors in decision-making. With respect to the clinical trials designed to reduce HIV infections in newborns in developing countries, I am satisfied that the choices are being addressed through a sound synthesis of knowledge, compassion, and prudence. As this Department proceeds to sponsor these and other clinical trials in developing countries, I assure you that we and our collaborators in those countries will remain committed to the simultaneous achievement of improved medical care, meritorious science, and assiduous protection of human research subjects.

Sincerely,



Donna E. Shalala

Enclosure

THE CONDUCT OF CLINICAL TRIALS
OF MATERNAL-INFANT TRANSMISSION OF HIV
SUPPORTED BY THE UNITED STATES DEPARTMENT OF
HEALTH AND HUMAN SERVICES
IN DEVELOPING COUNTRIES

A SUMMARY OF THE NEEDS OF DEVELOPING COUNTRIES,
THE SCIENTIFIC APPLICATIONS, AND THE ETHICAL CONSIDERATIONS
ASSESSED BY THE NATIONAL INSTITUTES OF HEALTH AND
THE CENTERS FOR DISEASE CONTROL AND PREVENTION
1994-1997



JULY 1997

THE CONDUCT OF CLINICAL TRIALS OF
MATERNAL-INFANT TRANSMISSION OF HIV
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1994-1997

For the past three years the United States Department of Health and Human Services (HHS), through its National Institutes of Health (NIH) and Centers for Disease Control and Prevention (CDC), has been engaged in the development and conduct of clinical trials designed to identify feasible interventions for preventing maternal-infant transmission of HIV in developing countries. The Director, NIH, the Director, CDC, and other senior scientists and administrators within the NIH and CDC, at the request of the Secretary, HHS, conducted a thorough assessment of the previous reviews of the needs, resources, and health care capacities of these developing countries and the process of scientific development and ethical evaluation leading up to and guiding the current conduct of these clinical trials. As an added measure, comments of a number of experts in biomedical ethics and the biosciences outside of NIH and CDC were also sought and considered. Based on this assessment, NIH and CDC have determined that, although these are complex matters, the studies have the potential to be of enormous value to the developing countries and are scientifically well-founded and ethically acceptable.

The NIH/CDC assessment addressed three major questions related to these clinical trials. What is the need for these studies? Are the studies adequately designed to examine options for treatment that will meet that need? Is the involvement of human subjects in these studies consistent with the internationally accepted principles of autonomy, justice, and beneficence as implemented by the United States Federal Policy for the Protection of Human Subjects, including the equitable selection of subjects, obtaining of voluntary informed consent, and employing the input, review, and authorization of the appropriate ethical and other bodies in the U.S. and in the developing countries where the research is being conducted?

THE NEED

One regimen of antiretroviral therapy has been shown to reduce substantially the likelihood of maternal-infant transmission of HIV. The identification of this successful regimen was the result of the National Institutes of Health's AIDS Clinical Trials Group protocol 076 (ACTG 076 or 076) in 1994. In spite of this knowledge, approximately 1,000 HIV-infected infants are born each day, the vast majority of them in developing countries. This occurs, in part, because the regimen proven to be effective is simply not feasible as a standard of prevention in much of the developing world.

There are two reasons for this lack of feasibility. First, to follow the regimen that has proven efficacy requires that the women be reached early in prenatal care; be tested for and counseled concerning their HIV status; comply with a lengthy oral treatment regimen; receive intravenous administration of the antiretroviral zidovudine (ZDV or AZT) during labor and delivery; and refrain from breast-feeding. Additionally, the newborns must receive 6 weeks of oral AZT therapy. During and after the time the mother and infant are treated with AZT, both must be carefully monitored for adverse effects of exposure to this drug. In the developing world countries that are the sites of these studies, these requirements could seldom be achieved, even under the infrequent circumstance when women present early enough for the screening and care requirements of the 076 therapeutic regimen to be implemented. Second, the wholesale drug costs for the AZT in the 076 regimen are estimated to be in excess of \$800, an amount far greater than these developing countries could afford as standard care. For example, in the developing country of Malawi, the cost of AZT alone for the 076 regimen for one HIV-infected pregnant woman and her child is more than 600 times the annual health care budget allocation for one person. Less complex and expensive alternatives are urgently needed to address the staggering impact of maternal-infant transmission of HIV in developing countries.

In June 1994, after the results of ACTG 076 were released, the World Health Organization (WHO) convened a group of researchers and public health practitioners from around the world in Geneva. This international panel called for the use of the 076 regimen in the industrialized world, where it is feasible, but immediately called for the exploration of alternative regimens that could be used in the developing world, stating that logistical issues and cost would preclude the widespread application of the 076 regimen. The WHO panel called for international coordination of research efforts to develop simpler, less costly drug regimens. This coordination continues in the form of meetings two to three times per year of the UNAIDS Informal Working Group on Prevention of Mother to Child Transmission of HIV. As a result, there is a global research agenda addressing the need to devise efficacious regimens that can be safely and widely implemented in the developing world.

THE STUDY DESIGNS

The NIH- and CDC-supported studies of maternal-infant transmission of HIV in developing countries are designed to meet the critical need just described. The panel convened by WHO in Geneva stated in Recommendation 6 of its *Recommendations from the Meeting on Prevention of Mother-to-Infant Transmission of HIV by Use of Antiretrovirals, Geneva 23-25 June 1994* (attached as an appendix to this report):

Since the ZDV regimen studied in ACTG 076 is not applicable in those parts of the world where most MTI [mother-to-infant] transmission of HIV occurs, placebo-controlled trials offer the best option for obtaining rapid and scientifically valid results.

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The WHO panel went on to explain in its commentary on the recommendation:

Most of MTI transmission of HIV occurs in the developing world, where the ZDV regimen used in ACTG 076 is not applicable because of its cost and operational requirements. In those parts of the world, the choice of a placebo for the control group of a randomized trial would be appropriate as there is currently no effective alternative for HIV-infected pregnant women.

For each individual study there has been careful consideration of the specific needs of and treatment feasibility within the country in which it would be implemented. NIH, CDC, collaborating U.S. institutions, and the host countries will continue to monitor each study and any changes in the countries that may have an impact on study design. It is an unfortunate fact that the current standard of perinatal care for the HIV-infected pregnant women in the sites of the studies does not include any HIV prophylactic intervention at all. Nor does the standard of care for these HIV-infected women include the combination therapies recommended and used for some HIV-infected women in the U.S. However, the inclusion of this regrettable, but real, performance-site standard in the form of placebo controls provides the direct comparison of standard and new intervention that is needed to form the basis for rational policy decisions and will result in the most rapid, accurate, and reliable answer to the question of the value of the intervention being studied compared to the local standard of care.

The NIH- and CDC-supported studies are designed in a manner consistent with the still-pertinent recommendations of the WHO panel and have been developed in on-site collaboration with the health ministries, physicians, and researchers of the host countries. There is strong support for the design of the NIH- and CDC-supported studies, including the placebo arms, within the countries where the clinical trials are being carried out, in part because the studies are assessing regimens that might realistically be employed to decrease mother-to-infant transmission, taking into account the health care resources and operational capabilities of these countries.

HUMAN RESEARCH SUBJECT PROTECTIONS

The acceptability of the involvement of human subjects in the studies under discussion has been scrupulously reviewed beginning with the first proposal for ACTG 076 which was a placebo-controlled study conducted in the U.S. and France. After the complex 076 treatment regimen was proven successful, the WHO conference in Geneva quickly issued clear guidelines for research taking into account the extremely wide range of health care capabilities that characterize the broad spectrum of countries described by the term developing countries. As mentioned earlier, these matters have been debated in formal discussions, forums, and required reviews in the U.S., in international settings, and in the countries where the clinical trials are or will be

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carried out.¹ Even so, CDC determined that Assurances for performance site countries required by HHS regulations at Title 45, Part 46, Section 103 had not been obtained prior to enrolling subjects. CDC acted immediately to notify OPRR and to address these administrative procedures. The Assurances for the CDC-Thailand and CDC-Cote d'Ivoire studies were conditionally approved by OPRR on July 7, 1997 and July 14, 1997 respectively. CDC amended its human subjects protection administrative procedures to be in full compliance with 45 CFR 46.103.

Arguments against the NIH- and CDC-supported studies appear to rest on the proposition that it is unethical to conduct a clinical trial unless it offers all participants a chance to receive an effective intervention if such is available anywhere in the world, even if it is not available at the site of the clinical trial. Ideally, this would be so for all clinical trials for all therapies. But the reality is that often it is not possible. ~~The very purpose of the NIH- and CDC-supported studies of maternal-infant transmission of HIV in developing countries is to identify interventions other than those of 076 and we agree with the WHO Geneva panel's Recommendation 2 that:~~

It should be emphasized that the results of ACTG 076 are only directly applicable to a specific population. Moreover, the ZDV regimen employed in the ACTG 076 study has a number of features (cost, logistical issues, among others) which limit its general applicability. Therefore, no global recommendations regarding use of ZDV to prevent MTI transmission of HIV can be made.

The use of historical controls was considered and found to be unacceptable because existing epidemiological data for the host countries are inadequate for this purpose. We agree with the commentary on Recommendation 5 of the WHO Geneva panel that:

(r)andomized controlled trials offer the best evaluation of new treatment regimens. The use of historical controls is strongly discouraged, due to the wide changes with time in the study population (differences in the distribution of disease stages), the circulating viral strains, the diagnostic tools used for the ascertainment of the HIV infection status of infants (antibodies in earlier cohorts compared to direct viral markers in more recent cohorts), and the treatment practices (increased use of zidovudine

¹ A useful exploration of these events is contained in an article written by Jon Cohen and published in Science, Vol. 269, pp. 624-626, 4 August 1995.

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in HIV-infected pregnant women with AIDS-related symptoms and/or CD4+ lymphocyte counts).

The WHO guidelines clearly indicate that the in-country health care capabilities of each country in which maternal-infant HIV transmission research is to be conducted must be used to define the type of research which is ethical and therefore permissible in that country. If a country will be able to afford only very minimal increments in the resources directed toward improved perinatal care for HIV-infected pregnant women and their children, then trials like those focused on vitamin A and other micronutrients are ethical, permissible, and desirable.

In other countries, such as Thailand, the situation is far more complex. Thailand is a country that may be able to afford a simplified AZT/076-like regimen. However, Thai researchers, physicians, and public health officials are understandably interested in seeing a number of issues addressed before any AZT is placed in general use in HIV-infected pregnant women in their country: (1) Is a much simplified 076-like regimen (e.g., initiation of prenatal treatment at 36 weeks of pregnancy, oral instead of intravenous AZT during labor and delivery, elimination of AZT given to the infant) effective in reducing transmission? (2) What adverse outcomes related to AZT use will be seen in Thai populations? Will adverse effects not seen in the U.S. and Europe occur in Thailand? (3) Is AZT administered orally to Thai women safe and well-tolerated? Do Thai women metabolize AZT such that the dose used is the right one to use in all Thai HIV-infected pregnant women? and, (4) How does the type of HIV seen in Thailand (which has demonstrable differences from the type seen in the U.S.) respond to AZT?

Seeking answers to these questions are two studies, one supported by CDC and one supported by NIH. The CDC-Thai study will determine how well tolerated and how effective a very simple AZT regimen is in a population of women who are infected with a subtype of HIV predominantly different from that observed in the U.S. and who also have co-factors for transmission that may differ from those seen in American populations. Because it is a two-arm, placebo-controlled clinical trial, the CDC-Thai study will provide rapid answers to many of the important questions noted above. It also will enable the Ministry of Health and physicians in Thailand to make better-informed decisions about the use of a much-simplified AZT regimen for general use in HIV-infected pregnant women.

Complementing the CDC-Thai study is an NIH-Thai study to determine how much additional benefit, as compared to how much additional cost and adverse effect, is occasioned by small increments in treatment complexity. The NIH-Thai study has four arms, each a modest increment *over* the treatment arm in the CDC-Thai study. However, even the most complex arm of the NIH-Thai study is *not* identical to the treatment arm of 076. The NIH-Thai study will benefit from the baseline that is established by the CDC-Thai study.

Since the NIH-Thai study provides some level of AZT to all participants, the data from the CDC-Thai study would be particularly important for interpretation of results if the outcomes were the same for each of the four arms. Taken together, these two studies will provide a broad range of

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information about the likely value of AZT as a strategy to interrupt maternal-infant transmission of HIV.

In an analysis of the spectrum of studies supported by the NIH and CDC in Africa and Asia, it is clear that we have adhered to international guidelines, including the recent WHO guidelines which address specifically the ethical conduct of research in the post-076 era. The primary consideration in decisions about the appropriate conduct of research has been this: Once the research is completed at a given site, will the population which the study participants represent be able to profit from what is learned from that research?

The International Ethical Guidelines for Biomedical Research Involving Human Subjects that were prepared by the Council for International Organizations of Medical Sciences (CIOMS) in collaboration with WHO are:

...intended to indicate how the ethical principles embodied in the Declaration [of Helsinki] could be effectively applied in developing countries.

To evaluate interventions that they could not implement realistically would be exploitive of those in the participant country since there would be no likelihood of meeting requirement 15 of the *Guidelines* that obliges:

...any product developed [through] such research will be made reasonably available to the inhabitants of the host community or country at the completion of successful testing...

Therefore, we have determined that the more compelling ethical argument is against using a regimen that if found to be superior in the study could not possibly be used in the prevention of maternal-infant transmission of HIV in the host country. Turning once again to Malawi for example, health officials there refused to permit the conduct of a study involving a full course regimen of AZT (such as that used in ACTG 076) because they believed it would be unethical to undertake such a study in Malawi given that its very limited resources and poor health infrastructure make the introduction of AZT as standard treatment for HIV-infected pregnant women unfeasible. Instead, the health officials wanted research on alternative treatment approaches that might reduce maternal-infant transmission of HIV. The justification and ethical foundation for the NIH- and CDC-supported studies incorporate the reality that the clinical trials are examining other alternatives that could actually be used for the majority of HIV-infected pregnant women and mothers in the countries in which the clinical trials are being carried out. The process of ethical review of these trials has been rigorous. It has included community and scientific participation and the application of the U.S. rules for the protection of human research subjects in reviews by the relevant institutional review boards (IRBs) in the U.S. and in the countries where the clinical trials are carried out. Support from local governments has been obtained and each active study has been and will continue to be reviewed by an independent Data

and Safety Monitoring Board. These studies are in compliance with broadly accepted principles of ethics of international research, in which the need to take into account the reality of available and feasible health care is a consideration of substantial importance.

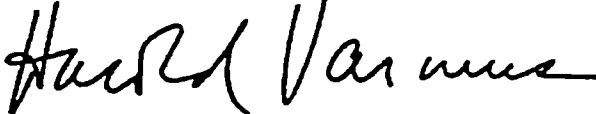
In summary, these studies all address an urgent need in the countries in which they are being conducted. They have been developed with extensive in-country input and participation, and they are consistent with widely accepted principles and guidelines of bioethics. Our perspective and our decision to support these trials rest heavily on local support and approval. In this regard, we point to the words of Edward K. Mbidde, Chair, AIDS Research Committee, Uganda Cancer Institute, in a letter, dated May 8, 1997, to the Director, NIH:

These are Ugandan studies conducted by Ugandan investigators on Ugandans. [Elsewhere in the letter he discusses Ugandan ethical review.] Due to lack of resources we have been sponsored by— organizations like yours [NIH]. We are grateful that you have been able to do so.

There is a mix up of issues here which needs to be clarified. It is not NIH conducting the studies in Uganda but Ugandans conducting their study on their people for the good of their people.

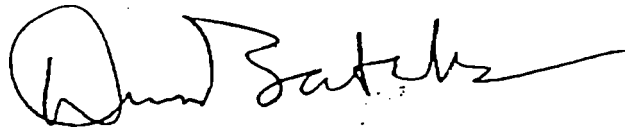
The issues surrounding these studies are, indeed, complex and subject to some disagreement. However, final judgments about their appropriateness must be heavily weighted in favor of decisions made at the local level, as long as those decisions are consistent with international standards and those of the U.S. We know of no other way to realistically and rapidly address the gravity of mother-to-infant transmission of HIV in the developing world and the current lack of a proven, feasible intervention against it, than to continue the studies on which our two agencies have embarked.

DATED: JUL 15 1997



Harold Varmus

Director, National Institutes of Health



David Satcher

Director, Centers for Disease Control and Prevention

Appendix attached

NATIONAL SECURITY COUNCIL

ID 9703257

REFERRAL

DATE: 15 MAY 97

Daniel Montoya

MEMORANDUM FOR: REED, B

DOMESTIC POLICY COUNCIL

DOCUMENT DESCRIPTION:

TO: PRESIDENT

SOURCE: MOSELEY-BRAUN, CAROL

DATE: 30 APR 97

SUBJ: HHS FUNDING OF US AIDS TESTING IN AFRICA

*TO Aids
policy
office
5/17*

REQUIRED ACTION APPROPRIATE ACTION

DUE DATE:

COMMENT:

FOR

John W. Ficklin
JOHN W. FICKLIN

NSC RECORDS MANAGEMENT OFFICE

Ch. Ficklin 5-16-97

THE WHITE HOUSE

WASHINGTON

July 22, 1997

Dennis R. Roth
10004 Beach Mill Road
Great Falls, VA 22066

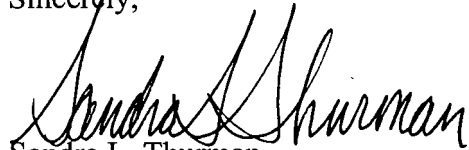
Dear Mr. Roth:

I would like to thank you for sending us the information regarding CEL-SCI's quest in formulating an AIDS vaccine. Such news is very exciting for all of us, as the fight against HIV/AIDS is one we are all in together.

As you know, the President is committed to developing an AIDS vaccine. He has announced several initiatives to make this a reality, such as supporting high-level international collaborations, a center dedicated to AIDS vaccine research at the NIH, and outreach to scientists, pharmaceutical companies, and patient advocates to maximize the involvement of both the public and private sectors in the development of an AIDS vaccine. We, as an administration and a nation, must remain dedicated to the development of an effective vaccine.

I truly appreciate the many hours you have put into this research. Thank you again for keeping us informed on the latest in the search for an AIDS vaccine.

Sincerely,

A handwritten signature in black ink, appearing to read "Sandra L. Thurman", written in a cursive style.

Sandra L. Thurman

Director

Office of National AIDS Policy

THE WHITE HOUSE

WASHINGTON

July 22, 1997

FILE COPY

Dennis R. Roth
10004 Beach Mill Road
Great Falls, VA 22066

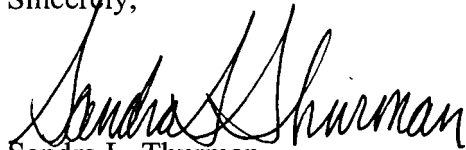
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I truly appreciate the many hours you have put into this research. Thank you again for keeping us informed on the latest in the search for an AIDS vaccine.

Sincerely,



Sandra L. Thurman

Director

Office of National AIDS Policy

July 15, 1997

Sandy Thurman
Office of AIDS Policy
The White House, 1600 Pennsylvania Ave.
Washington, D. C. 20500

Dear Ms. Thurman

I have spent hundreds of hours researching AIDS vaccines and I thought that you might be interested to learn that it may be a small, biotech company, CEL-SCI Corporation located in Alexandria, VA, that actually may have the best AIDS vaccine candidate and may be first to test their vaccine in a phase III preventive AIDS vaccine trial. It is possible that a preventive AIDS vaccine may be developed long before President Clinton's ten year deadline. I'll give you a call sometime next week so we can talk about this.

In late May President Clinton made a commitment that the US would develop a PREVENTIVE AIDS VACCINE within ten years. One of the basic problems to overcome in developing a successful preventive AIDS vaccine is that the human immunodeficiency virus (HIV) and especially the viruses' surface proteins have a very high mutation rate. Since almost all of the present AIDS vaccine candidates are designed to "recognize" surface protein targets, their high mutation rate unfortunately makes these vaccine targets rapidly "unrecognizable". Clinical trial results to date on preventive AIDS vaccines have been so discouraging that most of the companies now developing AIDS vaccines have switched focus hoping to gain some success by testing their vaccine candidates as a therapeutic treatment for HIV or AIDS patients.

Another basic problem to overcome in developing a successful preventive AIDS vaccine is HIV's great variability. There are nine (9) different HIV-1 subtypes for which collectively well over 100 different HIV strains have now been characterized. The surface protein variability between different subtype strains can be 50% or greater. Therefore HIV variability greatly compounds the "recognition" problem making the development of a broad effective preventive AIDS vaccine even more difficult. Almost all preventative AIDS vaccine candidates to date have shown very minimal, if any, protection when tested against a different strain (from which the AIDS vaccine candidate is derived) of the HIV-1 subtype B (the predominant subtype in the US and Western Europe).

The purpose for this letter is to inform you that a company that I follow as a stock analyst (one of the few companies still working on a preventive AIDS vaccine), recently announced what I believe may be "breakthrough" results. Their vaccine candidate has shown the ability to recognize the "consensus sequence" of four of the nine major HIV-1 subtypes: A, B, C, and E. As noted above, subtype B is predominant in the US and Western Europe and is also found in parts of Thailand and Brazil. Subtype C is predominant in Africa and India and is also found in parts of Asia and Brazil.

This is one of the few preventive AIDS vaccine candidates that is not based on HIV surface protein target identification. Instead "HGP-30", this vaccine candidate, is based on a well conserved protein sequence (peptide) from the INTERNAL p17 HIV-1 CORE PROTEIN. HIV-1 core proteins have a lower mutation rate

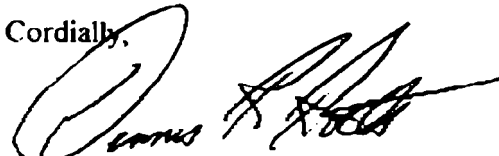
than the virus's surface proteins and there are fewer identified different HIV-1 core protein strains (than surface protein strains) for the nine different HIV-1 subtypes.

CEL-SCI Corporation, the company testing HGP-30, is located Alexandria VA. Items number 5 - 7 (on pages 2 - 4) of the enclosed June 4th six page CEL-SCI update report provide more information on this promising HIV-1 preventive AIDS vaccine candidate.

CEL-SCI should begin a phase II preventive AIDS vaccine clinical trial during Q4 in Africa. The Company could be in a position to know whether they will commence a much larger phase III clinical trial by July or August of next year. This could put them ahead of Pasteur-Merieux-Connaught, the wholly owned vaccine unit of Rhone-Poulenc Inc., a multibillion dollar French pharmaceutical company, which in early June, announced the beginning of a phase II preventive AIDS vaccine trial here in the US which is scheduled to last for two years.

If you would like further details, please contact CEL-SCI directly at (703) 549-5293. Mr. Geert Kersten is the CEO.

Cordially,



Dennis R. Roth
10004 Beach Mill Road
Great Falls, VA 22066
(703) 759-7873

Enclosure: Six page update report on CEL-SCI Corporation dated June 4, 1997



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CONTINUED STRONG BUY RECOMMENDATION - CEL-SCI CORPORATION

Suitable For Risk Oriented Investors Able To Tolerate Substantial Price Volatility

Closing Price \$4.25 June 4, 1997

Dennis R. Roth (703) 893-8080: Home (703) 759-7873

AMEX:	HIV	FYE 9/30	Sales MM	EPS
52 Week Range	\$2.75 - 14.375	1995A	\$0.424	(\$0.89)
12 Month Target Price	\$10 \$15	1996A	\$0.322	(\$0.98)
Shares Outstd FD/Float	10.2Mil/7.5Mil	No Financial Projections Have yet Been Made		
Daily T/Vol. 30 days	141,300			
Institutions/Mgmt. Own	1%/5%			
Cash & Inv./Ann. burn rate	\$6.8mil/\$5 Mil(3/31)			
Market Cap	\$43.35 Million			
Cash/share	\$0.67			
Long Term Debt	\$ -0-			

CEL-SCI HAS MADE ENCOURAGING PROGRESS ON MANY FRONTS SINCE OUR FEBRUARY '97 BUY RECOMMENDATION. WE EXPECT THE STOCK'S PRICE TO BEGIN APPRECIATING AS CLINICAL TRIAL RESULTS BEGIN TO COME IN OVER THE NEXT 6 MONTHS FROM THE NEW MULTIKINE HEAD AND NECK CANCER CLINICAL TRIAL PROTOCOL RECENTLY INITIATED IN ISRAEL AND FROM THE HIV MULTIKINE CLINICAL TRIAL NOW ENROLLING IN CALIFORNIA AT THE AIDS ReSEARCH ALLIANCE.

1. Phase I/II Clinical Trial Protocol Recently Begun In Israel.

Results from this head and neck cancer protocol should be quickly assessable. It should only take about four weeks per patient to assess tumor response to Multikine treatment. Other advantages of this protocol are: (1) patient acquisition should be easier because it addresses a much broader patient population (approximately 80% of all patients diagnosed with head and neck cancer have either stage 2, 3, or 4 tumors), (2) the protocol stipulates that these patients must not have had any prior treatment (radiation, chemotherapy or surgery) for their cancer so their immune systems are much more intact than is the case for the advanced cancer patients enrolled in the Canadian/U. S head and neck cancer trial (begun Q3, '96). Ten patients will be enrolled at this center.

Approximately TWO THIRDS of the worlds malignant tumors are TOO BIG to be surgically removed. In a prior pilot phase I/II Florida intrastate head and neck cancer trial in four advanced head and neck cancer patients, three of four patients experienced significant tumor shrinkage in the first few weeks. Patients 1 and 2, after 63 days or 3 cycles of Multikine treatment, experienced maximum tumor regression of respectively 82% and 94%. The endpoints for this recently begun phase I/II clinical trial is to demonstrate drug safety and tumor response to Multikine treatment. To date, Multikine has been very well tolerated in the advanced head and neck cancer patients treated. Head and neck cancer is the fifth most prevalent form of cancer with 500,000 new annual cases worldwide.

2. Enrollment Is Underway At AIDS ReSEARCH ALLIANCE In California For HIV Patients Who Want To Add Multikine's Immune Boosting Therapy To Their Present Combination Anti-Viral HIV Drug Regimens.

The AIDS ReSEARCH ALLIANCE has received a significant number of responses from HIV patients now on combination anti-viral HIV drug therapy. This study will enroll 14 patients who must have stabilized CD4 cell counts of over 400. The endpoints of this trial are twofold. To see if Multikine:

- Is well tolerated in HIV patients,
- Can stimulate an increase in CD4 cell count (a surrogate marker for overall immune system strength) and/or beneficial increases in other immune cell types.

3. The 24 HIV Patient Phase I/II HGP-30 Therapeutic Clinical Trial That Will Be Shortly Completed Will Be Extended With Some Of These Patients Receiving An Additional Booster Injection Of HGP-30 Supplemented With A New Cytokine Adjuvant, GM-CSF (granulocyte/macrophage colony stimulating factor called "Leukine™"), contributed By Immunex Corporation.

There have been a number of studies that have demonstrated the synergy of GM-CSF with vaccines. In addition, according to the AIDS ReSEARCH ALLIANCE in their Winter/Spring '97 edition of Searchlight, page 23, "recent studies have demonstrated the ability of recombinant (synthetically produced) GM-CSF to increase the efficacy of peptide-based tumor vaccines." GM-CSF primes dendritic cells, which are the most efficient antigen presenting cells (APCs), to better recognize foreign antigen and, at the same time, GM-CSF also increases the number of APCs. Therefore, it is hoped that this novel vaccine adjuvant will increase the immunogenicity of HGP-30 stimulating an immune response that is better able to recognize the human immunodeficiency virus (HIV). Majority owned by American Home Products, Immunex (IMNX-\$35.25) is a Seattle, WA based biotech company with estimated fiscal '97 sales of approximately \$160 million. This trial should commence shortly. Each patient will receive 1 booster shot of HGP-30 along with GM-CSF. The study is expected to be completed during the fall of '97.

4. Phase I Prostate Cancer Clinical Trial Continues With The Possibility That A Phase II Prostate Cancer Study Will Begin During Q4 '97.

The phase I trial scheduled to enroll up to 15 prostate cancer patients who had failed hormonal therapy continues. We believe that a phase II prostate cancer trial may be commenced during Q4 '97. The current trial is being conducted at the Thomas Jefferson Medical Center in Philadelphia. Prostate cancer is the second most prevalent cancer in men.

5. HGP-30 AIDS Vaccine Candidate Produces Antibodies That Recognize Four Major HIV Subtypes

On May 4, at the 9th Annual Meeting of the National Cooperative Vaccine Development Groups held at NIH, CEL-SCI presented evidence that its HGP-30 vaccine candidate induced antibodies in humans and in mice that recognized the corresponding regions of four different major HIV-1 subtypes or clades: A, B, C and E. All HIV-1 isolates belong to one of two groups. The "M" group has eight HIV-1 subtypes and the "O" group has only one "outlier" subtype. Each of these major HIV-1 subtypes has a number of different "strains" (the number of strains indicated below as of 1994 are those strains for which protein sequences have been analyzed).

The Nine Major HIV-1 Subtypes, Strains Per Subtype And The Countries In Which These Subtypes Predominate

SUBTYPE	STRAINS	COUNTRIES IN WHICH SUBTYPES PREDOMINATE
A	31	Parts of Africa
B	26	Dominant in the US, Western Europe and found in parts of Thailand and Brazil
C	7	Dominant in Africa and India and found in parts of Asia and Brazil
D	10	Parts of Africa
E	31	Parts of Africa and Thailand (subtypes A and E have the same gag p17
F	4	Parts of Africa consensus sequence)
G	3	Parts of Africa
H	2	Parts of Africa
O	3	Parts of Africa (the "outlier" subtype)

CEL-SCI's HGP-30 AIDS vaccine candidate is a synthetic copy of a 30 amino acid sequence or peptide which is a portion of the p17 HIV-1 core protein from subtype B, SF2 strain (one of 26 strains in subtype B).

CEL-SCI last year announced that HGP-30 produced a 78% protection rate in a hu-PBL-SCID mouse model versus a 13% spontaneous protection rate against challenge by a different strain of subtype B (the LAI strain) than the SF2 strain from which the HGP-30 amino acid sequence is derived. No other vaccine candidate has shown protection against a

different HIV strain, let alone a 78% protection rate. It is especially encouraging to see a strong antibody response generated by CEL-SCI's HGP-30 subunit synthetic vaccine candidate that is cross reactive (antibodies produced bind well) with other major HIV subtypes or clades which predominate in other countries on other continents. This is an indication that CEL-SCI's HGP-30 vaccine candidate may confer very broad protection as an HIV preventive vaccine. There is no risk of contracting HIV from an HGP-30 immunization.

The above discussed antibody cross reactivity against the different HIV-1 A, B, C and E subtypes was accomplished against these subtypes' "consensus" sequences. The consensus sequence for each of these subtypes corresponds to the same 30 amino acid sequence of the HIV-1 p-17 core protein represented by HGP-30 (for subtype B, strain SF2). The consensus sequence for each major subtype is constructed by using the amino acids (represented by each of the 30 capital letters) that appear most frequently (for each of the 30 positions) considering all the existing strains under each subtype. Note that the individual amino acids of the different HIV subtype consensus sequences that are underlined indicates a variance in that subtype's consensus sequence from the specific amino acid found at that same location in HGP-30. The percentage variation ranged from 10% to 33% for this sequence in these other subtypes. HIV surface protein amino acid (aa) sequences have been shown to vary by as much as 50%, or higher. Therefore, we believe that HGP-30, based on a conserved sequence of the p17 core protein, has a better chance of protecting against more HIV-1 subtypes than other AIDS vaccine candidates based on HIV surface protein sequences.

HGP-30's p17 Amino Acid Sequence Similarity To The Consensus Sequences For The HIV-1 A, B, C & E Subtypes

	86	90	95	100	105	110	115																								
HGP-30	Y	S	V	H	Q	R	I	D	V	K	D	T	K	E	A	L	E	K	I	E	E	E	Q	N	K	S	K	K	K	A	% Variation
Subtype B	Y	C	V	H	Q	K	I	E	V	K	D	T	K	E	A	L	E	K	I	E	E	E	Q	N	K	S	K	K	K	A	10
Subtype C	Y	C	V	H	K	G	I	E	V	R	D	T	K	E	A	L	D	K	I	E	E	E	Q	N	K	I	Q	Q	K	T	33
Subtypes A & E	W	C	V	H	Q	R	I	E	V	K	D	T	K	E	A	L	D	K	I	E	E	V	Q	N	K	S	O	O	K	T	27

The other important consideration, in addition to similarity of amino acid sequence, is obviously the immunogenicity of the particular amino acid sequence selected. What immune responses does a particular peptide sequence generate in humans? HGP-30 contains two cytotoxic T cell areas or epitopes (amino acids "aa" 93 -101 and aa 86 - 92 with the latter being identified as common to HIV sero positive long term non-progressors) as well as T4 (CD4) helper T cell and B cell (antibody) epitopes. HGP-30 was the first AIDS vaccine candidate to document the production of CD8+ (targeted) cytotoxic killer T cells (Proc. of the Nat. Academy of Sciences, 8/90). It also has been shown to induce antibodies which recognize HGP-30 and HIV-1 p17 in ELISA assays. Continuing research from different sources indicates that of the two primary possible immune responses:

1. An antibody or humoral response;
2. A cell mediated response,

ONLY ONE, at any given time, is the DOMINANT immune response. Once the HIV successfully invades the host's cells, it is beyond the reach of almost all antibody defenses. Only with a killer T cell or an antibody dependent cell mediated cytotoxicity (ADCC) response can the HIV infected cells that are a continuing source of new HIV virions be targeted and destroyed so that the host's immune system can once again gain the upper hand. Most AIDS researchers believe that a killer T cell response is necessary for long term survival for HIV patients. Therefore HGP-30 is an excellent PREVENTIVE AIDS VACCINE candidate because it:

- Has two KILLER T CELL epitopes and generates antibody isotypes indicative of an ADCC response,
- Has a "LIMITED" mutation rate giving it the ability to cross react with a number of different HIV subtypes.

6. Crossreactivity Between HGP-30 Immunized Animal And Human Serum And The four HIV A, B, C, and E Subtypes Was Time Dependent And Reactivity Was Increased In The Animal Models By The Use Of Other Newer Vaccine Adjuvants That Are Currently Being Tested As Part Of Other Vaccine Formulations To Prevent Other Diseases

HGP-30, to increase its size and immunogenicity, uses a carrier (Keyhole Limpet Hemocyanin "KLH") and Alum, currently the only FDA approved adjuvant. After receiving two HGP-30 immunizations on days 0 and 14, mice generated cross reactive antibodies in a time dependent manner with the highest response rates for some HIV subtypes or clades being better at 42 days than at 28. With HGP-30, the highest levels of antibody cross reactivity compared to controls were for:

- Human sera (4 subjects): HIV subtypes A, B and E and to a somewhat lower degree to C
- Mouse sera (27 mice, 6-7 per subgroup): HIV subtypes B, C with lower but significant responses to A and E

HGP-30's ability to specifically generate antibody isotypes IgG2a (mouse antibodies) and IgG3 (human antibodies) indicates that this vaccine candidate will induce a desired cell mediated immune response. HGP-30's ability to cross react with serum containing the different HIV-1 subtypes A, B, C, and E indicates that HGP-30 will induce a desired cell mediated immune response with at least four of HIV-1's most significant subtypes. Two of these four subtypes B and C predominate respectively in the US and Western Europe (subtype B) and Africa and India (subtype C). Subtypes A, B and E are found in parts of Africa, Asia, Thailand and Brazil.

Newer and more immunogenic (but not yet approved) adjuvants have been tested in a number of vaccine clinical trials over the last five years. These new vaccine adjuvants may be approved by the FDA and could be used with vaccine booster injections. CEL-SCI tested two of the newer adjuvants (instead of alum) in mice that had received two or more HGP-30/KLH immunizations with the vaccine constructs:

- Monophosphate lipid MPL[®](S/E) by Ribi Immunochem Research Inc. and
- Novosomes[®] Nonphospholipid liposome by Novavax either alone or supplemented with lipid A or Vitamin E,

Isotype antibody analysis showed that Ribi's MPL[®] (SE) generated a much higher IgG2a response for HIV subtypes A, B, C and E than alum. Novosomes, supplemented with Vitamin E, produced by far the best results with antibody isotype IgG2a cross reacting with subtypes B and C and to a lower degree for subtype A and E compared to alum. Alum, used as the adjuvant for HGP-30, did best at generating both IgG2a in mice and IgG3 in humans with HIV subtype B.

To summarize, CEL-SCI's HGP-30 HIV vaccine candidate (a synthetic peptide copy of amino acids 86 - 115 of the p17 core protein from subtype B; strain SF2) appears capable of generating an antibody response which broadly cross reacts (successfully binds) with corresponding "consensus" sequences of the p17 core protein derived from the HIV-1 subtypes A, B, C and E that vary from HGP-30 by up to 33%. According to the human serum tests, HLA antigen distribution apparently did not play a factor in subtype antibody crossreactivity.

7. CEL-SCI Is Planning To Start A Foreign Phase II 50 - 70 Patient HGP-30 HIV Vaccine Clinical Trial During Q4 '97 And Assuming That The Enrollment Rates And Initial Response To The HGP-30 Vaccine Candidate Are As Expected, A 2,500 Patient Phase III HGP-30 Preventive Vaccine Clinical Trial Would Be Initiated Sometime During Q4 '98.

HGP-30's safety must again be established in a new, different "other country" population that might have different HLA antigen distribution than the population previously tested with HGP-30. Assuming all goes well in the foreign phase II trial, it is likely that CEL-SCI could become THE FIRST COMPANY to ever conduct an HIV PHASE III preventive AIDS vaccine clinical trial (presently projected to start during Q4, '98). This would have to be viewed as a rather extraordinary accomplishment and would be a big surprise to the investment community considering CEL-SCI's size and resources compared to the size and resources of the competition which include very large pharmaceutical companies in the vaccine development business such as Merck, SmithKline Beecham, and Pasteur-Merieux Connaught, to name a few.

8. A Summary of CEL-SCI's Products And Scheduled Clinical Trials

CEL-SCI's three technologies help the immune system fight disease more effectively:

MULTIKINE: Is a mixture of naturally produced cytokines and therefore more closely resembles the cytokine mix (in terms of types and proportion) generally produced by a healthy person's immune response.

HGP-30 AIDS VACCINE CANDIDATE: Is a potential preventive vaccine/therapeutic treatment against HIV. HGP-30 has been tested in over 60 patients. It also is the only AIDS vaccine to ever have shown protection against a challenge by a different strain of HIV and the level of protection (78%) it achieved is the highest protection level ever published in the hu-PBL-SCID mice model.

L. E. A. P. S.™ (Ligand Epitope Antigen Presentation System) HETEROCONJUGATES: Is a "Platform Technology" that COMBINES a synthetic antigenic peptide (that is a copy of a disease epitope which triggers a specific disease immunogenic response) with a synthetic Ligand (binding peptide) which will SELECTIVELY STIMULATE a TH1 cell mediated, a TH2 humoral antibody or a mixed TH1/TH2 immune response. Administered infrequently, like vaccines, L.E.A.P.S. Heteroconjugates may provide a new class of products to treat and/or prevent a variety of difficult to treat or drug resistant diseases such as HIV/AIDS, herpes simplex, malaria, and tuberculosis.

Table Summarizing Multikine™ And HGP-30 Clinical Trials In Progress Or Planned

Product/ Disease	Vaccine or Therapeutic	Clinical Trial Classification	# of Patients # of Centers	Start Or Estimatd. Start Date*	Projected Comp. Date	Location
<u>Multikine™**</u> Head & neck cancer	Therapeutic	Phase I/II failed chemoth. radiatn. surgery	up to 30 at up to 5 center	Q3/96 - Q1/97	'98	Canada/U. S.
Head & neck cancer	Therapeutic	Phase I/II no prior treatmt	ten patients	Q2 '97	Q4 '97	Israel
HIV	Therapeutic	Phase I used in combinatn. with anti-viral drugs	14 -AIDS Res. Alllan.	Q2 '97	Q4 '97	U. S.
Prostate Canc.	Therapeutic	Phase I	up to 15 one center	Q4 '96	Q4 '97	U. S.
<u>HGP-30***</u> HIV	Vac. Booster GM/CSF	Phase I Booster Extensn	6 - 9 patients	Q3 '97*	Q4 '97	U. S.
HIV/AIDS	Vaccine	Phase II	50 - 70 One center	Q4 '97*	Q2 '99	Africa

* Estimated start date

** Granted Canadian HPB approval 3/95 and U. S. FDA IND status 2/96 for head & neck and prostate cancer study:

*** Clinical trials have been conducted under a California Food and Drug Branch intrastate approval

In addition to the above clinical trials, CEL-SCI will complete this month a 24 patient HGP-30 HIV/AIDS phase I/II therapeutic clinical trial that tested the safety and immune boosting effect of HGP-30 in HIV infected individuals. Results should be reported sometime during the next 60 - 90 days.

On June 5th CEL-SCI Began Trading On The American Stock Exchange Under The New Symbol "HIV"

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THE WHITE HOUSE

WASHINGTON

THE PRESIDENT INTRODUCES INITIATIVES TO FULFILL HIS COMMITMENT TO DEVELOP AN AIDS VACCINE

Today President Clinton challenged the nation to commit itself to the goal of developing an AIDS vaccine within the next ten years. The President also announced a number of important initiatives to help fulfill this commitment, including high-level international collaboration, a dedicated research center for AIDS vaccine research at the National Institutes of Health (NIH), and outreach to scientists, pharmaceutical companies, and patient advocates to maximize the involvement of both the private and public sectors in the development of an AIDS vaccine. The President has already taken steps to enhance the possibility of developing an AIDS vaccine by increasing funding for NIH vaccine research and development over 33 percent in the last two years. The initiatives the President announced today, which build on an exceptional commitment to develop better ways to prevent, diagnose, treat, and eventually cure AIDS, include:

- **A New NIH AIDS Vaccine Center.** A dedicated intramural HIV vaccine research and development center is being established at the National Institutes of Health. This vaccine center, which will be fully operational within the next several months, is uniting outstanding scientists in immunology, virology, and vaccinology to join in a highly-collaborative effort to develop an AIDS vaccine. Bringing together a broad array of researchers in an intensely-focused environment has been a successful way of developing vaccines in the past.
- **A Global AIDS Vaccine Research Initiative.** The United States is proposing that the leaders of the eight major industrialized nations meeting at the Denver Summit in June agree to support a worldwide AIDS vaccine research initiative. The proposal calls for each nation to make a commitment to provide the necessary investments in their country to accelerate research toward the development of an HIV/AIDS vaccine as a scientific and public health priority. Joint meetings of key scientists from participating nations will address research progress, identify scientific gaps and opportunities, and design collaborative programs.
- **A Challenge to Pharmaceutical Manufacture Industry to Invest in Innovative Research to Develop an AIDS Vaccine.** We can only be successful in developing an AIDS vaccine if private and public sectors make this goal a priority. The President is challenging the pharmaceutical industry to join the government in a partnership to realize this important goal.

Background on HIV/AIDS. HIV/AIDS remains a global public health threat. More than 29 million men, women and children around the world have been infected with HIV -- more than 3 million infections occurring within the last year. Without an effective vaccine, AIDS will soon overtake tuberculosis and malaria as the leading cause of death among persons between 25-44 years of age. Between 650,000-900,000 Americans are estimated to be living with HIV disease, and over 300,000 Americans have already died from AIDS.

Clinton Administration Accomplishments on HIV/AIDS. The Clinton Administration has made a sustained commitment to addressing the HIV epidemic through investments in prevention, research and treatment.

- **Increased funding for the NIH vaccine by 33 percent.** Funding for NIH vaccine research and development has increased over 33 percent in the last two years -- from \$111.1 million in FY 1996 to \$148 million proposed in the President's FY 1998 budget.
- **Funding for AIDS research, prevention and care increased by more than 50 percent in the first four years of the Clinton Administration.** Funding for AIDS Drug Assistance Programs (ADAP), which help low-income people purchase needed therapies, has tripled, while funding for the Ryan White CARE Act increased 158 percent. The approval of new AIDS drugs has greatly accelerated, with 16 new AIDS drugs and two diagnostic tests.

THE WHITE HOUSE
WASHINGTON

FILE COPY

July 22, 1997

The Honorable Carol Moseley-Braun
United States Senate
Washington, DC 20510

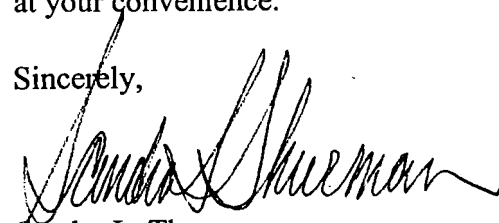
Dear Senator Moseley-Braun:

The President has asked me to respond to your letter drafted on April 30, 1997 regarding the use of placebos in AZT trials in developing countries.

I would like to share a letter written by Secretary Shalala to Dr. Sidney Wolfe at Public Citizen's Health Research Group that addresses your concerns to the President. I have also included a report entitled "The Conduct of Clinical Trials of Maternal-Infant Transmission of HIV Supported by the United States Department of Health and Human Services in Developing Countries, A Summary of the Needs of Developing Countries, The Scientific Applications, and the Ethical Considerations Assessed by the National Institutes of Health and the Centers for Disease Control and Prevention 1994-1997," July 1997.

Please feel free to call me at 632-1215 if you have any questions. I am available to visit with you at your convenience.

Sincerely,



Sandra L. Thurman
Director
Office of National AIDS Policy

Enclosure



THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

JUL 15 1997

Sidney M. Wolfe, M.D.
Director
Public Citizen's Health Research Group
1600 20th Street, NW
Washington, DC 20009-1001

Dear Dr. Wolfe:

On April 22 you wrote to me regarding clinical trials of medical interventions designed to discover methods to reduce maternal-infant transmission of human immunodeficiency virus (HIV) in developing countries. During the process of the development of my response, you wrote to President Clinton on this same matter and provided him with some additional information. I note in both letters your conclusion that the experimental designs for some of these studies are unethical because they do not meet the standard of health care that would be required were they to be conducted in the United States. This letter and its enclosure are in response to both your letter to me and your letter to the President.

Your letters raise issues about how best to seek safe and effective methods to prevent HIV infection in newborns in developing countries whose health care systems lack the substantial level of services and resources available to citizens of industrialized countries. All parties are in agreement that, before initiating any intervention seeking to identify such methods, it is essential to ensure that the intervention being studied is ethically and scientifically acceptable to the developing countries, offers sufficient promise to justify the involvement of human subjects, and is realistically adoptable if the intervention is shown to be sufficiently safe and effective. I have reviewed your letters with Dr. Harold Varmus, Director, National Institutes of Health (NIH), and Dr. David Satcher, Director, Centers for Disease Control and Prevention (CDC). In addition, Dr. Harold Shapiro, Chair of the National Bioethics Advisory Commission, has received copies of your letters.

At my request, Drs. Varmus and Satcher conducted a rigorous assessment of the previous reviews of the needs, resources, and health care capabilities of the developing countries involved. They also reviewed the process of scientific development and ethical assessment leading up to and guiding the current conduct

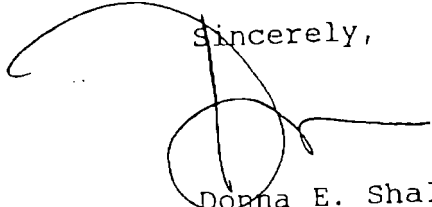
Page 2 - Sidney M. Wolfe, M.D.

of these clinical trials. These two distinguished scientists and public health leaders have concluded that researchers in the host countries and the United States are carrying out scientifically meritorious and ethically sound experimental designs, providing effective protection of human research subjects, and faithfully adhering to approved research protocols that are consistent with the recommendations of the World Health Organization and approved by all of the countries involved. I enclose a copy of their report. Please note that the two CDC-supported protocols referenced in the report had significant procedural shortcomings that have been addressed.

I endorse the assessment of Drs. Varmus and Satcher and therefore have concluded that the pertinent NIH- and CDC-sponsored clinical trials should continue. Three facts weighed heavily in my judgment. First, there is the demonstrated, urgent need for feasible interventions for preventing maternal-infant transmission of HIV in developing countries. Second, in industrialized as well as in developing countries, historical controls and national or local health statistics do not provide an adequate baseline against which to compare the outcomes of new HIV interventions. Third, the ACTG 076 zidovudine (AZT) regimen is presently not feasible as the standard of care in many developing countries because it is too logistically complex and resource-intensive and, therefore, inappropriate for use as a comparison arm of an HIV trial at this time.

Clinical trials in developing countries present a variety of extraordinarily difficult choices. I recognize that not every one of us would make the same decisions in every instance; yet, lack of unanimity on issues as complex as these is neither infrequent nor necessarily reflective of errors in decision-making. With respect to the clinical trials designed to reduce HIV infections in newborns in developing countries, I am satisfied that the choices are being addressed through a sound synthesis of knowledge, compassion, and prudence. As this Department proceeds to sponsor these and other clinical trials in developing countries, I assure you that we and our collaborators in those countries will remain committed to the simultaneous achievement of improved medical care, meritorious science, and assiduous protection of human research subjects.

Sincerely,



Donna E. Shalala

Enclosure

THE CONDUCT OF CLINICAL TRIALS
OF MATERNAL-INFANT TRANSMISSION OF HIV
SUPPORTED BY THE UNITED STATES DEPARTMENT OF
HEALTH AND HUMAN SERVICES
IN DEVELOPING COUNTRIES

A SUMMARY OF THE NEEDS OF DEVELOPING COUNTRIES,
THE SCIENTIFIC APPLICATIONS, AND THE ETHICAL CONSIDERATIONS
ASSESSED BY THE NATIONAL INSTITUTES OF HEALTH AND
THE CENTERS FOR DISEASE CONTROL AND PREVENTION
1994-1997



JULY 1997

THE CONDUCT OF CLINICAL TRIALS OF
MATERNAL-INFANT TRANSMISSION OF HIV
SUPPORTED BY THE UNITED STATES DEPARTMENT OF HEALTH
AND HUMAN SERVICES IN DEVELOPING COUNTRIES

A SUMMARY OF THE NEEDS OF DEVELOPING COUNTRIES,
THE SCIENTIFIC APPLICATIONS, AND THE ETHICAL CONSIDERATIONS
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1994-1997

For the past three years the United States Department of Health and Human Services (HHS), through its National Institutes of Health (NIH) and Centers for Disease Control and Prevention (CDC), has been engaged in the development and conduct of clinical trials designed to identify feasible interventions for preventing maternal-infant transmission of HIV in developing countries. The Director, NIH, the Director, CDC, and other senior scientists and administrators within the NIH and CDC, at the request of the Secretary, HHS, conducted a thorough assessment of the previous reviews of the needs, resources, and health care capacities of these developing countries and the process of scientific development and ethical evaluation leading up to and guiding the current conduct of these clinical trials. As an added measure, comments of a number of experts in biomedical ethics and the biosciences outside of NIH and CDC were also sought and considered. Based on this assessment, NIH and CDC have determined that, although these are complex matters, the studies have the potential to be of enormous value to the developing countries and are scientifically well-founded and ethically acceptable.

The NIH/CDC assessment addressed three major questions related to these clinical trials. What is the need for these studies? Are the studies adequately designed to examine options for treatment that will meet that need? Is the involvement of human subjects in these studies consistent with the internationally accepted principles of autonomy, justice, and beneficence as implemented by the United States Federal Policy for the Protection of Human Subjects, including the equitable selection of subjects, obtaining of voluntary informed consent, and employing the input, review, and authorization of the appropriate ethical and other bodies in the U.S. and in the developing countries where the research is being conducted?

THE NEED

One regimen of antiretroviral therapy has been shown to reduce substantially the likelihood of maternal-infant transmission of HIV. The identification of this successful regimen was the result of the National Institutes of Health's AIDS Clinical Trials Group protocol 076 (ACTG 076 or 076) in 1994. In spite of this knowledge, approximately 1,000 HIV-infected infants are born each day, the vast majority of them in developing countries. This occurs, in part, because the regimen proven to be effective is simply not feasible as a standard of prevention in much of the developing world.

There are two reasons for this lack of feasibility. First, to follow the regimen that has proven efficacy requires that the women be reached early in prenatal care; be tested for and counseled concerning their HIV status; comply with a lengthy oral treatment regimen; receive intravenous administration of the antiretroviral zidovudine (ZDV or AZT) during labor and delivery; and refrain from breast-feeding. Additionally, the newborns must receive 6 weeks of oral AZT therapy. During and after the time the mother and infant are treated with AZT, both must be carefully monitored for adverse effects of exposure to this drug. In the developing world countries that are the sites of these studies, these requirements could seldom be achieved, even under the infrequent circumstance when women present early enough for the screening and care requirements of the 076 therapeutic regimen to be implemented. Second, the wholesale drug costs for the AZT in the 076 regimen are estimated to be in excess of \$800, an amount far greater than these developing countries could afford as standard care. For example, in the developing country of Malawi, the cost of AZT alone for the 076 regimen for one HIV-infected pregnant woman and her child is more than 600 times the annual health care budget allocation for one person. Less complex and expensive alternatives are urgently needed to address the staggering impact of maternal-infant transmission of HIV in developing countries.

In June 1994, after the results of ACTG 076 were released, the World Health Organization (WHO) convened a group of researchers and public health practitioners from around the world in Geneva. This international panel called for the use of the 076 regimen in the industrialized world, where it is feasible, but immediately called for the exploration of alternative regimens that could be used in the developing world, stating that logistical issues and cost would preclude the widespread application of the 076 regimen. The WHO panel called for international coordination of research efforts to develop simpler, less costly drug regimens. This coordination continues in the form of meetings two to three times per year of the UNAIDS Informal Working Group on Prevention of Mother to Child Transmission of HIV. As a result, there is a global research agenda addressing the need to devise efficacious regimens that can be safely and widely implemented in the developing world.

THE STUDY DESIGNS

The NIH- and CDC-supported studies of maternal-infant transmission of HIV in developing countries are designed to meet the critical need just described. The panel convened by WHO in Geneva stated in Recommendation 6 of its *Recommendations from the Meeting on Prevention of Mother-to-Infant Transmission of HIV by Use of Antiretrovirals, Geneva 23-25 June 1994* (attached as an appendix to this report):

Since the ZDV regimen studied in ACTG 076 is not applicable in those parts of the world where most MTI [mother-to-infant] transmission of HIV occurs, placebo-controlled trials offer the best option for obtaining rapid and scientifically valid results.

The WHO panel went on to explain in its commentary on the recommendation:

Most of MTI transmission of HIV occurs in the developing world, where the ZDV regimen used in ACTG 076 is not applicable because of its cost and operational requirements. In those parts of the world, the choice of a placebo for the control group of a randomized trial would be appropriate as there is currently no effective alternative for HIV-infected pregnant women.

For each individual study there has been careful consideration of the specific needs of and treatment feasibility within the country in which it would be implemented. NIH, CDC, collaborating U.S. institutions, and the host countries will continue to monitor each study and any changes in the countries that may have an impact on study design. ~~It is an unfortunate fact~~ that the current standard of perinatal care for the HIV-infected pregnant women in the sites of the studies does not include any HIV prophylactic intervention at all. Nor does the standard of care for these HIV-infected women include the combination therapies recommended and used for some HIV-infected women in the U.S. However, the inclusion of this regrettable, but real, performance-site standard in the form of placebo controls provides the direct comparison of standard and new intervention that is needed to form the basis for rational policy decisions and will result in the most rapid, accurate, and reliable answer to the question of the value of the intervention being studied compared to the local standard of care.

The NIH- and CDC-supported studies are designed in a manner consistent with the still-pertinent recommendations of the WHO panel and have been developed in on-site collaboration with the health ministries, physicians, and researchers of the host countries. There is strong support for the design of the NIH- and CDC-supported studies, including the placebo arms, within the countries where the clinical trials are being carried out, in part because the studies are assessing regimens that might realistically be employed to decrease mother-to-infant transmission, taking into account the health care resources and operational capabilities of these countries.

HUMAN RESEARCH SUBJECT PROTECTIONS

The acceptability of the involvement of human subjects in the studies under discussion has been scrupulously reviewed beginning with the first proposal for ACTG 076 which was a placebo-controlled study conducted in the U.S. and France. After the complex 076 treatment regimen was proven successful, the WHO conference in Geneva quickly issued clear guidelines for research taking into account the extremely wide range of health care capabilities that characterize the broad spectrum of countries described by the term developing countries. As mentioned earlier, these matters have been debated in formal discussions, forums, and required reviews in the U.S., in international settings, and in the countries where the clinical trials are or will be

carried out.¹ Even so, CDC determined that Assurances for performance site countries required by HHS regulations at Title 45, Part 46, Section 103 had not been obtained prior to enrolling subjects. CDC acted immediately to notify OPRR and to address these administrative procedures. The Assurances for the CDC-Thailand and CDC-Cote d'Ivoire studies were conditionally approved by OPRR on July 7, 1997 and July 14, 1997 respectively. CDC amended its human subjects protection administrative procedures to be in full compliance with 45 CFR 46.103.

Arguments against the NIH- and CDC-supported studies appear to rest on the proposition that it is unethical to conduct a clinical trial unless it offers all participants a chance to receive an effective intervention if such is available anywhere in the world, even if it is not available at the site of the clinical trial. Ideally, this would be so for all clinical trials for all therapies. But the reality is that often it is not possible. ~~The very purpose of the NIH- and CDC-supported studies of maternal-infant transmission of HIV in developing countries is to identify interventions other than those of 076 and we agree with the WHO Geneva panel's Recommendation 2 that:~~

It should be emphasized that the results of ACTG 076 are only directly applicable to a specific population. Moreover, the ZDV regimen employed in the ACTG 076 study has a number of features (cost, logistical issues, among others) which limit its general applicability. Therefore, no global recommendations regarding use of ZDV to prevent MTI transmission of HIV can be made.

The use of historical controls was considered and found to be unacceptable because existing epidemiological data for the host countries are inadequate for this purpose. We agree with the commentary on Recommendation 5 of the WHO Geneva panel that:

(r)andomized controlled trials offer the best evaluation of new treatment regimens. The use of historical controls is strongly discouraged, due to the wide changes with time in the study population (differences in the distribution of disease stages), the circulating viral strains, the diagnostic tools used for the ascertainment of the HIV infection status of infants (antibodies in earlier cohorts compared to direct viral markers in more recent cohorts), and the treatment practices (increased use of zidovudine

¹ A useful exploration of these events is contained in an article written by Jon Cohen and published in Science, Vol. 269, pp. 624-626, 4 August 1995.

in HIV-infected pregnant women with AIDS-related symptoms and/or CD4+ lymphocyte counts).

The WHO guidelines clearly indicate that the in-country health care capabilities of each country in which maternal-infant HIV transmission research is to be conducted must be used to define the type of research which is ethical and therefore permissible in that country. If a country will be able to afford only very minimal increments in the resources directed toward improved perinatal care for HIV-infected pregnant women and their children, then trials like those focused on vitamin A and other micronutrients are ethical, permissible, and desirable.

In other countries, such as Thailand, the situation is far more complex. Thailand is a country that may be able to afford a simplified AZT/076-like regimen. However, Thai researchers, physicians, and public health officials are understandably interested in seeing a number of issues addressed before any AZT is placed in general use in HIV-infected pregnant women in their country: (1) Is a much simplified 076-like regimen (e.g., initiation of prenatal treatment at 36 weeks of pregnancy, oral instead of intravenous AZT during labor and delivery, elimination of AZT given to the infant) effective in reducing transmission? (2) What adverse outcomes related to AZT use will be seen in Thai populations? Will adverse effects not seen in the U.S. and Europe occur in Thailand? (3) Is AZT administered orally to Thai women safe and well-tolerated? Do Thai women metabolize AZT such that the dose used is the right one to use in all Thai HIV-infected pregnant women? and, (4) How does the type of HIV seen in Thailand (which has demonstrable differences from the type seen in the U.S.) respond to AZT?

Seeking answers to these questions are two studies, one supported by CDC and one supported by NIH. The CDC-Thai study will determine how well tolerated and how effective a very simple AZT regimen is in a population of women who are infected with a subtype of HIV predominantly different from that observed in the U.S. and who also have co-factors for transmission that may differ from those seen in American populations. Because it is a two-arm, placebo-controlled clinical trial, the CDC-Thai study will provide rapid answers to many of the important questions noted above. It also will enable the Ministry of Health and physicians in Thailand to make better-informed decisions about the use of a much-simplified AZT regimen for general use in HIV-infected pregnant women.

Complementing the CDC-Thai study is an NIH-Thai study to determine how much additional benefit, as compared to how much additional cost and adverse effect, is occasioned by small increments in treatment complexity. The NIH-Thai study has four arms, each a modest increment *over* the treatment arm in the CDC-Thai study. However, even the most complex arm of the NIH-Thai study is *not* identical to the treatment arm of 076. The NIH-Thai study will benefit from the baseline that is established by the CDC-Thai study.

Since the NIH-Thai study provides some level of AZT to all participants, the data from the CDC-Thai study would be particularly important for interpretation of results if the outcomes were the same for each of the four arms. Taken together, these two studies will provide a broad range of

information about the likely value of AZT as a strategy to interrupt maternal-infant transmission of HIV.

In an analysis of the spectrum of studies supported by the NIH and CDC in Africa and Asia, it is clear that we have adhered to international guidelines, including the recent WHO guidelines which address specifically the ethical conduct of research in the post-076 era. The primary consideration in decisions about the appropriate conduct of research has been this: Once the research is completed at a given site, will the population which the study participants represent be able to profit from what is learned from that research?

The International Ethical Guidelines for Biomedical Research Involving Human Subjects that were prepared by the Council for International Organizations of Medical Sciences (CIOMS) in collaboration with WHO are:

...intended to indicate how the ethical principles embodied in the Declaration [of Helsinki] could be effectively applied in developing countries.

To evaluate interventions that they could not implement realistically would be exploitive of those in the participant country since there would be no likelihood of meeting requirement 15 of the *Guidelines* that obliges:

...any product developed [through] such research will be made reasonably available to the inhabitants of the host community or country at the completion of successful testing...

Therefore, we have determined that the more compelling ethical argument is against using a regimen that if found to be superior in the study could not possibly be used in the prevention of maternal-infant transmission of HIV in the host country. Turning once again to Malawi for example, health officials there refused to permit the conduct of a study involving a full course regimen of AZT (such as that used in ACTG 076) because they believed it would be unethical to undertake such a study in Malawi given that its very limited resources and poor health infrastructure make the introduction of AZT as standard treatment for HIV-infected pregnant women unfeasible. Instead, the health officials wanted research on alternative treatment approaches that might reduce maternal-infant transmission of HIV. The justification and ethical foundation for the NIH- and CDC-supported studies incorporate the reality that the clinical trials are examining other alternatives that could actually be used for the majority of HIV-infected pregnant women and mothers in the countries in which the clinical trials are being carried out. The process of ethical review of these trials has been rigorous. It has included community and scientific participation and the application of the U.S. rules for the protection of human research subjects in reviews by the relevant institutional review boards (IRBs) in the U.S. and in the countries where the clinical trials are carried out. Support from local governments has been obtained and each active study has been and will continue to be reviewed by an independent Data

and Safety Monitoring Board. These studies are in compliance with broadly accepted principles of ethics of international research, in which the need to take into account the reality of available and feasible health care is a consideration of substantial importance.

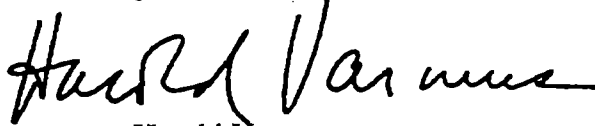
In summary, these studies all address an urgent need in the countries in which they are being conducted. They have been developed with extensive in-country input and participation, and they are consistent with widely accepted principles and guidelines of bioethics. Our perspective and our decision to support these trials rest heavily on local support and approval. In this regard, we point to the words of Edward K. Mbidde, Chair, AIDS Research Committee, Uganda Cancer Institute, in a letter, dated May 8, 1997, to the Director, NIH:

These are Ugandan studies conducted by Ugandan investigators on Ugandans. [Elsewhere in the letter he discusses Ugandan ethical review.] Due to lack of resources we have been sponsored by organizations like yours [NIH]. We are grateful that you have been able to do so.

There is a mix up of issues here which needs to be clarified. It is not NIH conducting the studies in Uganda but Ugandans conducting their study on their people for the good of their people.

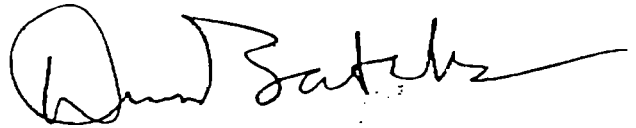
The issues surrounding these studies are, indeed, complex and subject to some disagreement. However, final judgments about their appropriateness must be heavily weighted in favor of decisions made at the local level, as long as those decisions are consistent with international standards and those of the U.S. We know of no other way to realistically and rapidly address the gravity of mother-to-infant transmission of HIV in the developing world and the current lack of a proven, feasible intervention against it, than to continue the studies on which our two agencies have embarked.

DATED: JUL 15 1997



Harold Varmus

Director, National Institutes of Health



David Satcher

Director, Centers for Disease Control and Prevention

Appendix attached

NATIONAL SECURITY COUNCIL

ID 9703257

REFERRAL

DATE: 15 MAY 97

Daniel Montoya

MEMORANDUM FOR: REED, B

DOMESTIC POLICY COUNCIL

DOCUMENT DESCRIPTION:

TO: PRESIDENT

SOURCE: MOSELEY-BRAUN, CAROL

DATE: 30 APR 97

SUBJ: HHS FUNDING OF US AIDS TESTING IN AFRICA

*TO Aids
Policy
Office
5/17*

REQUIRED ACTION / APPROPRIATE ACTION

DUE DATE:

COMMENT:

FOR

John W. Ficklin
JOHN W. FICKLIN

NSC RECORDS MANAGEMENT OFFICE

Ch. Ficklin 5-16-97

THE WHITE HOUSE

WASHINGTON

July 21, 1997

Sean Sasser
878 Peachtree St., N.E. #311
Atlanta, GA 30309

Dear Mr. Sasser:

Let me first offer my congratulations to you for your appointment to the Presidential Advisory Council on HIV and AIDS and then let me thank you for agreeing to take on this important responsibility.

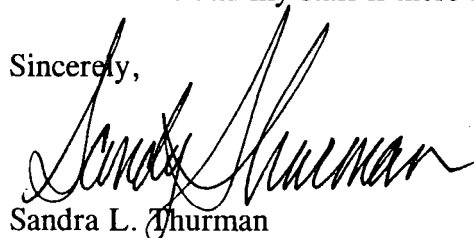
I don't need to tell you how important it is that our government do everything it can to fight this epidemic. Like you, I have spent most of the last fifteen years dedicating my professional and personal life to this battle. Now, as National AIDS Policy Director, I am working hard to ensure the most aggressive response possible.

The President's Council will be an important part of this continuing commitment. No government entity can effectively respond to a national crisis by itself. To attempt to deal with the many aspects of the AIDS epidemic without the direct input of those people who confront it every day would be foolish. I will look to you for advice and counsel on what we are doing right and what we are doing wrong; what we should be doing and what we shouldn't be doing; where our efforts are working and where they are not. And, as this epidemic continues to change, I will need your help in designing new and better ways to respond.

The months ahead will be filled with a lot of hard work but together we will have the satisfaction of knowing that we are doing what we can to respond to the greatest challenge of our day. I look forward to our work together.

I will make sure to keep you informed of my activities and those of my office. Please be sure to contact me and my staff if there is anything that we can do to be of assistance.

Sincerely,



Sandra L. Thurman

Director

Office of National AIDS Policy

THE WHITE HOUSE

WASHINGTON

July 21, 1997

Nilsa Gutierrez, M.D., M.P.H.
702 Penn Ave.
Teaneck, NJ 07666-1611

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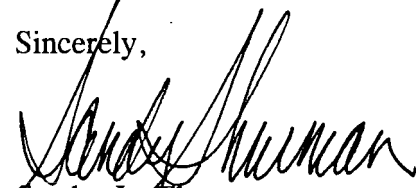
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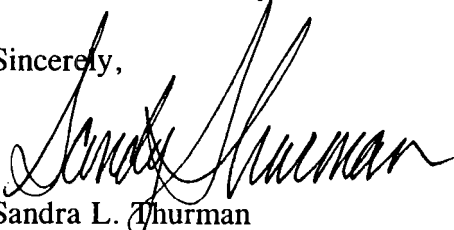
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Sincerely,

A handwritten signature in black ink, appearing to read "Sandra L. Thurman", written in a cursive style.

Sandra L. Thurman
Director
Office of National AIDS Policy

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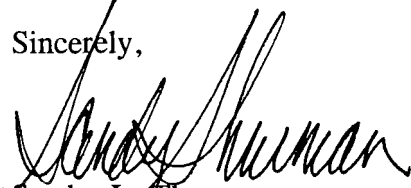
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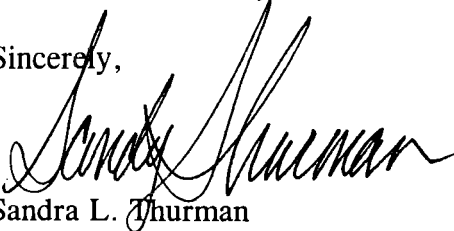
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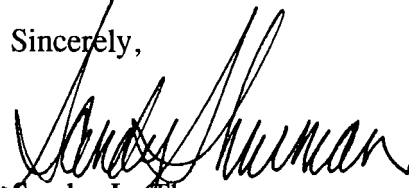
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Sandra L. Thurman
Director

Office of National AIDS Policy

MEMORANDUM FOR THE PRESIDENT

From: Sandy Thurman
Date: July 21, 1997
Subject: Update on HIV/AIDS Issues

This memorandum is to provide you with a quick update on current HIV/AIDS issues.

Background - While the AIDS groups are grateful for the support the Administration has given them in the past, there is considerable anxiety and doubt regarding our ongoing commitment to this issue. This concern began when AIDS programs (including the Ryan White CARE Act) were not included on a small list of discretionary programs that were listed as protected programs in the balanced budget agreement (neither were many other important programs). The community interprets this action to mean that the issue has been "de-prioritized." In addition, following the release of guidelines for AIDS treatment which indicated more aggressive use of triple drug combinations, the Administration did not request any additional dollars in the 1998 budget for ADAP (AIDS Drug Assistance Programs). However, it should be noted that we have continually supported increases in ADAP, including 2 budget amendments last year. All this, combined with the fact that the report the Vice President requested on Medicaid expansion to people with HIV stalled due to indications from HCFA that there is no way to make this budget neutral, and that little visible progress has been made on removing the restrictions on federal funding for needle exchange programs, has made the AIDS community a little irritated with us.

We have been working nonstop with the AIDS groups on these issues. The bottom line is, while we have pending issues, it has been a pretty extraordinary year so far for the AIDS community.

Needle Exchange Programs - The House Appropriations subcommittee for Labor, Health and Human Services marked up their bill on July 15, preserving the authority of the Secretary of HHS to lift the restrictions on use of federal funds for needle exchange programs. HHS does not expect a challenge to this at full committee next week, and is pursuing a strategy of watchful waiting, maintaining a low profile for as long as possible. Most of the AIDS groups accept this strategy as long as the Secretary's authority is not endangered. We held a meeting at the White House last week with the AIDS groups and HHS to facilitate communication on this issue.

Funding Issues - In the House Appropriations subcommittee mark-up, the full \$40 million increase in the Administration's FY 1998 budget request for the Ryan White CARE Act programs was provided, with some reallocation of the increases among Ryan White programs. In addition, the mark up included a \$132 million increase for the Ryan White AIDS Drug Assistance Program (ADAP) in the Chairman's mark. No formal budget amendment was sent forward for this, given the size of the offset. You may want to take this opportunity to formally support this increase.

OMB's position is that it is going to happen anyway, so we might as well take credit for it. The community will obviously appreciate your support.

The House subcommittee increased funds for AIDS prevention by \$5 million (\$12 million below budget request) and an AIDS research increase of \$73 million (\$33 million above budget request). The Senate Labor/HHS subcommittee's 602B allocation is \$200 million below the House's, making it less likely that the Senate will fund AIDS programs at the House levels. In VA/HUD, the Housing Opportunities for People With AIDS (HOPWA) program has been funded at the budget request of \$204 million (an \$8 million increase).

Medicaid Expansion for HIV Infection - On April 9, the Vice President requested that HHS report to him on the feasibility of a Medicaid demonstration project expanding Medicaid eligibility to people with HIV infection prior to the onset of full-blown AIDS. Currently, over 50% of people with AIDS depend on Medicaid for their health care. New AIDS therapies like the protease inhibitor drugs have been effective in delaying disability and reducing hospital costs for many people, raising the question if earlier access to drug therapies and primary care would prove cost-effective for Medicaid as well as other public spending for services to people with HIV/AIDS. HHS briefed the Vice President's office in late May/early June, and is now reworking it to address budget concerns. HHS will probably submit a report in the next few weeks. The report will likely it would be feasible to do a demonstration program limited to several sites but with capped enrollment. It would not be budget neutral and this would represent a break in our longstanding tradition of budget neutrality criteria in Medicaid waivers. There are some at HHS and OMB who believe that it would be preferable for the Administration to support full legislation to change the Medicaid program rather than break our budget neutrality standard, however, this would be expensive.

Model Clinical Practice Guidelines for Treatment of HIV Infection - On June 19, an independent panel of experts convened by HHS and the Kaiser Family Foundation published treatment guidelines for antiretroviral therapy in adults and adolescents. The draft guidelines address a critical need among providers as how to best to use new AIDS drugs most effectively. The guidelines recommend a more aggressive approach to treatment using triple drug combinations at earlier stages of HIV infection, to avert immune system damage.

While these guidelines are not technically a government document, issues of payment for this new standard of care clearly confront us. HHS has stressed that the responsibility for HIV treatment is a shared one with the federal government, states, private and non-profit sectors and individuals each playing an important role. The additional \$132 million in ADAP funding included in the House Appropriation's subcommittee is a good start towards trying to address expanding demand for these new therapies.

Decrease in the AIDS Death Rate - On July 14 the CDC released new figures showing a 19% decrease in the number of AIDS deaths in the first nine months of 1996, compared with the same

period of 1995. In contrast with earlier data, the number of deaths due to AIDS among women decreased 7%, and mortality numbers dropped for all racial groups and categories of HIV transmission. The CDC attributed these findings to greater access to medical care and the development of effective therapies for HIV and associated opportunistic infections. AIDS advocates noted that as AIDS death rates drop, there are increasing numbers of individuals living with HIV who require access to these lifesaving interventions. Clearly, our investment in the AIDS epidemic is beginning to pay off as a significant achievement, given increasing AIDS deaths and infections worldwide. ***It is important to note, however, that there is no evidence that the number of new HIV infections is slowing which means that prevention and education efforts must be reinforced.***

THE WHITE HOUSE

WASHINGTON

July 18, 1997

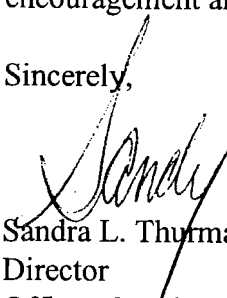
Ms. Cathalene Teahan, R.N.
Georgia AIDS Coalition
P.O. Box 1258
Snellville, Georgia 30278

Dear Ms. Teahan,

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I salute the good work that the Georgia AIDS Coalition has done on behalf of those living with HIV and AIDS, and look forward to working with you in the future. Again, thank you for your encouragement and offer of support.

Sincerely,

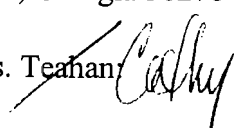

Sandra L. Thurman
Director
Office of National AIDS Policy

THE WHITE HOUSE

WASHINGTON

July 18, 1997

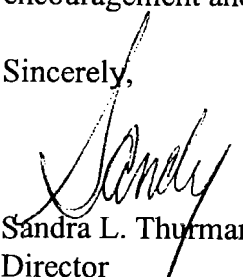
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Sandra L. Thurman
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Office of National AIDS Policy

THE WHITE HOUSE

WASHINGTON

July 15, 1997

Dorothy Keville
Bill Arnold
Co-Chairs
ADAP Working Group
1929 18th Street N.W. #1117
Washington, D.C. 20009

Dear Ms. Keville and Mr. Arnold:

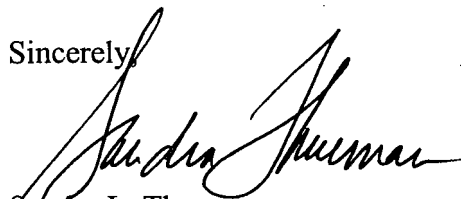
HIV/AIDS has brought forth a remarkable response of courage, compassion and dedication which is reflected in the work of the AIDS Drug Assistance Program and Ryan White CARE Act supported services. These programs have had a positive impact on providing HIV patients with access to the most effective drug therapies. The Clinton Administration remains committed to finding a cure for AIDS and a vaccine to protect us all.

Funding for AIDS research, prevention and care increased by more than 50 percent in the first four years of the Clinton Administration and, over the past two years, funding for NIH vaccine research and development has increased over 33 percent. Drug accessibility continues to be a priority as new, life-sustaining drug therapies are introduced. In response to these developments, funding for the AIDS Drug Assistance Programs has tripled, while funding for the Ryan White CARE Act increased 158 percent.

We recognize the continuing need for HIV prevention programs, vaccine development efforts, and increased access to health care, housing, and research for all people living with HIV and AIDS, including access to the latest developments in HIV therapies. We are dedicated to alleviating the suffering of those living with HIV/AIDS, preventing the spread of the disease, and finding a cure.

I salute the good work that you have been doing on behalf of people living with HIV and AIDS, and look forward to working with you in the future.

Sincerely,



Sandra L. Thurman

Director

Office of National AIDS Policy

THE WHITE HOUSE

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Washington, D.C. 20009

Dear Ms. Keville and Mr. Arnold:

HIV/AIDS has brought forth a remarkable response of courage, compassion and dedication which is reflected in the work of the AIDS Drug Assistance Program and Ryan White CARE Act supported services. These programs have had a positive impact on providing HIV patients with access to the most effective drug therapies. The Clinton Administration remains committed to finding a cure for AIDS and a vaccine to protect us all.

Funding for AIDS research, prevention and care increased by more than 50 percent in the first four years of the Clinton Administration and, over the past two years, funding for NIH vaccine research and development has increased over 33 percent. Drug accessibility continues to be a priority as new, life-sustaining drug therapies are introduced. In response to these developments, funding for the AIDS Drug Assistance Programs has tripled, while funding for the Ryan White CARE Act increased 158 percent.

We recognize the continuing need for HIV prevention programs, vaccine development efforts, and increased access to health care, housing, and research for all people living with HIV and AIDS, including access to the latest developments in HIV therapies. We are dedicated to alleviating the suffering of those living with HIV/AIDS, preventing the spread of the disease, and finding a cure.

I salute the good work that you have been doing on behalf of people living with HIV and AIDS, and look forward to working with you in the future.

Sincerely,



Sandra L. Thurman

Director

Office of National AIDS Policy

THE WHITE HOUSE

WASHINGTON

July 14, 1997

FILE COPY

R. Scott Hitt, MD
Chair
Presidential Advisory Council on HIV/AIDS
Pacific Oaks Medical Group
150 North Robertson Boulevard, Suite 300
Beverly Hills, CA 90211

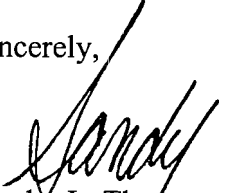
Dear Scott:

I am writing in reference to your May 6, 1997 letter urging the President to take action against the discriminatory policies of certain agencies of the Federal government with regard to those who test positive for HIV.

I am communicating with those agencies to determine the status of their policies toward mandatory HIV testing and hiring of HIV positive applicants. Once I have compiled this information, I will brief the President on my findings so that he may respond to your letter.

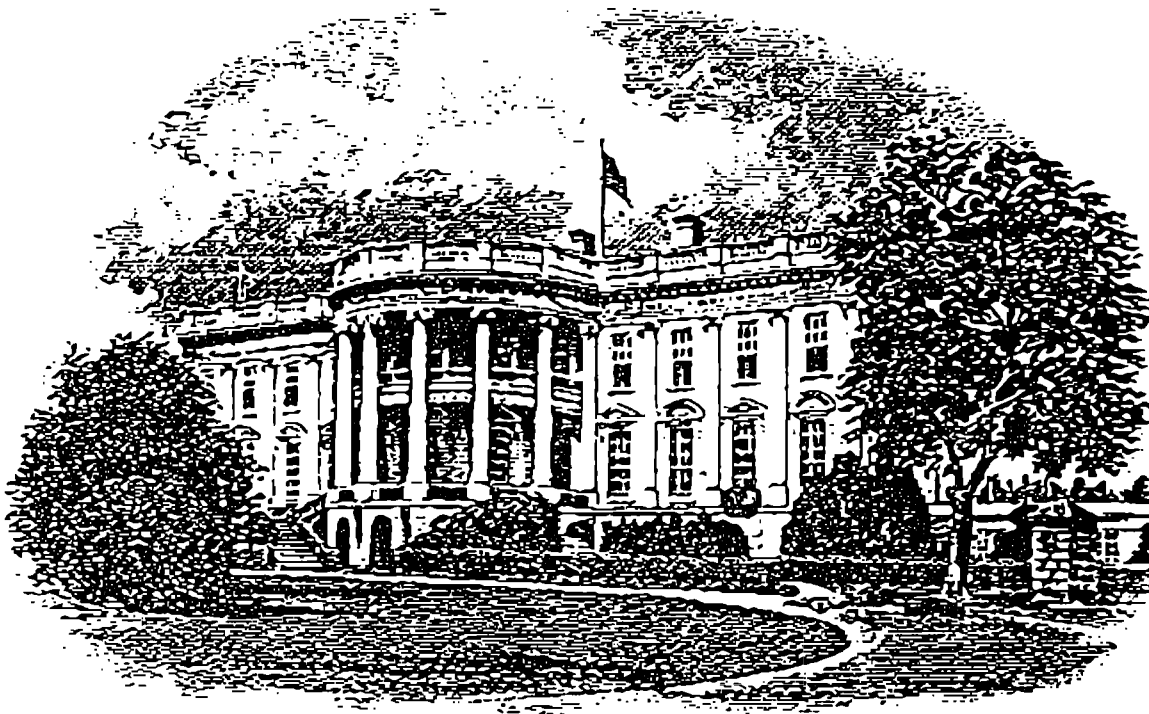
Thank you for your concern, and I will keep you posted.

Sincerely,


Sandra L. Thurman
Director
Office of National AIDS Policy

P.S. I tried to reach you all last week - Call me when you get a chance -

*The White House
Office of Correspondence*



FACSIMILE FROM REUBEN MUSGRAVE
DIRECTOR, PRESIDENTIAL LETTERS AND MESSAGES

TO: SANDY THURMAN, DIRECTOR @ 632-1096
W.H. OFFICE OF AIDS POLICY

DATE: 5/19/97

PAGES TO FOLLOW: 3 4

6-5518 (direct)

RETURN FAX: (202) 456-2993

VOICE: (202) 456-7610

COMMENTS: We have received the attached incoming letter
to answer. I'd appreciate it if you could work with
me to provide some talking points for the POTUS
response. I am also e-mailing you to inform you
of this fax. Thanks very much.

Reuben Musgrave

THE WHITE HOUSE
WASHINGTON

May 6, 1997

*Read in
Rm 94
5/13*

MEMORANDUM FOR BRUCE REED

FROM: Dr Eric Goosby, Acting Director, Office of National AIDS Policy

RE: Presidential Advisory Council on HIV and AIDS

Attached is the Letter to the President from the Council for your transmittal. Please forward.

cc: Elena Kagan

PRESIDENTIAL

May 6, 1997

ADVISORY

COUNCIL ON

HIV/AIDS

The Honorable William Jefferson Clinton
The White House
Washington, D.C. 20500

Dear Mr. President:

On February 7, 1997, the Office of National AIDS Policy Director Patsy Fleming met with representatives of this Council and representatives of several Federal agencies to discuss elimination of discrimination against those infected with HIV. I am writing to you to express our deep concern about the lack of progress by those Federal agencies toward elimination of discriminatory policies. You will remember that almost three years ago you asked this Council to meet with you to discuss issues of major concern regarding HIV/AIDS. One of the most critical issues raised was the previously established policy of several Federal agencies (i.e., the U.S. Foreign Services, the Peace Corps, the Job Corps, the U.S. State Department, and the Military) requiring mandatory HIV testing, and exclusion of those found to be HIV positive.

At that time, you expressed your concern about and disapproval of such policies and instructed your staff to investigate those policies and report back to you. We are dismayed that the February 7, 1997 meeting clearly confirmed that policies requiring mandatory testing and exclusion from entry of all applicants found to be HIV positive continue in these agencies. The policies of these Federal agencies represent a disturbing aberration from the general application of HIV/AIDS employment practices by the vast majority of federal agencies.

We are also concerned that those already employed by such agencies who later test positive face discrimination in assignments, promotions, and career advancement opportunities. Particularly in light of the promise offered by new treatment options, these policies serve to deprive qualified HIV-positive individuals equal employment opportunity and to deprive the federal government of the contributions those individuals could be making as dedicating public servants.

The Honorable William Jefferson Clinton

May 6, 1997

Page two

The Council has little optimism that without your intervention these discriminatory policies might be changed. We would therefore urge, Mr. President, that you renew your instructions for review and reconsideration of such policies. It is only through such action that your commitment "to fight AIDS related discrimination at every turn" contained in your National AIDS Strategy can be realized.

Your Council stands ready to assist in any way you deem appropriate.

Thank you for your consideration and concern.

Sincerely,

A handwritten signature in black ink, reading "R. Scott Hitt". The signature is written in a cursive, flowing style with a large initial "R".

R. Scott Hitt, MD

Chair, on behalf of the members of
the Presidential Advisory Council
on HIV and AIDS

Presidential Advisory Council on HIV and AIDS

Stephen N. Abel, D.D.S.
Mr. Terje Anderson
Ms. Judith Billings
Mr. Nicholas Bollman
Mr. Tonio Burgos
Jerry Cade, M.D.
Rabbi Joseph Edelheit
Mr. Robert Fogel
Ms. Debra Fraser-Howze
Ms. Kathleen Gerus
Ms. Phyllis Greenberger
Mr. Bob Hattoy
Mr. B. Thomas Henderson
R. Scott Hitt, M.D., Chair
Michael Isbell, J.D.
Mr. Ronald Johnson
Mr. Jeremy Landau
Alexandra Mary Levine, M.D.
Mr. Steve Lew
Ms. Helen H. Miramontes
Rev. Altagracia Perez
Michael Rankin, M.D.
Mr. H. Alexander Robinson
Ms. Debbie Runions
Mr. Benjamin Schatz
Mr. Richard W. Stafford
Ms. Denise Stokes
Ms. Sandra Thurman
Bruce Weniger, M.D.

THE WHITE HOUSE
WASHINGTON

July 14, 1997

John M. Seiber
Public Policy Coordinator
Caring for Babies with AIDS
P.O. Box 351535
Los Angeles, CA 90035

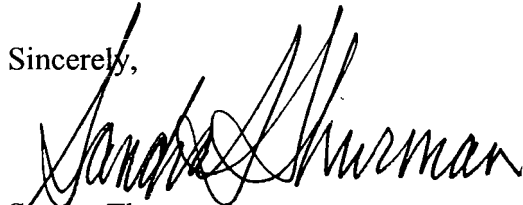
Dear Mr. Seiber:

Thank you for your congratulations and for including information about Caring for Babies with AIDS. I am fully committed to fighting for adequate HIV-related information, housing and care for children, infants and pregnant women.

The combined work of CBA's Residential Program and the Family Support Services Program have greatly assisted many HIV affected families and I commend you on your efforts to help these families remain together.

I appreciate your taking the time to write and look forward to working with Caring for Babies with AIDS and other advocates to help insure proper care and protection for children and families living with HIV and AIDS in Los Angeles and around the country.

Sincerely,

A handwritten signature in black ink, appearing to read "Sandra Thurman", written over a horizontal line.

Sandra Thurman
Director
Office of National AIDS Policy

THE WHITE HOUSE

WASHINGTON

July 14, 1997

R. Scott Hitt, MD
Chair
Presidential Advisory Council on HIV/AIDS
Pacific Oaks Medical Group
150 North Robertson Boulevard, Suite 300
Beverly Hills, CA 90211

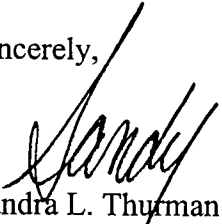
Dear Scott:

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I am communicating with those agencies to determine the status of their policies toward mandatory HIV testing and hiring of HIV positive applicants. Once I have compiled this information, I will brief the President on my findings so that he may respond to your letter.

Thank you for your concern, and I will keep you posted.

Sincerely,


Sandra L. Thurman
Director
Office of National AIDS Policy

P.S. I tried to reach you all last week - Call me when you get a chance -

Withdrawal/Redaction Marker

Clinton Library

DOCUMENT NO. AND TYPE	SUBJECT/TITLE	DATE	RESTRICTION
001a. letter	Sandra Thurman to Individual living with HIV re: Past collaboration (Personal) [partial] (1 page)	07/14/1997	b(6)

COLLECTION:

Clinton Presidential Records
National AIDS Policy Office

OA/Box Number: 19399

FOLDER TITLE:

Correspondence - Sandra L. Thurman - Outgoing - 7/97

2018-0764-F

jm2098

RESTRICTION CODES

Presidential Records Act - [44 U.S.C. 2204(a)]

- P1 National Security Classified Information [(a)(1) of the PRA]
- P2 Relating to the appointment to Federal office [(a)(2) of the PRA]
- P3 Release would violate a Federal statute [(a)(3) of the PRA]
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- P5 Release would disclose confidential advice between the President and his advisors, or between such advisors [(a)(5) of the PRA]
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PRM. Personal record misfile defined in accordance with 44 U.S.C. 2201(3).

RR. Document will be reviewed upon request.

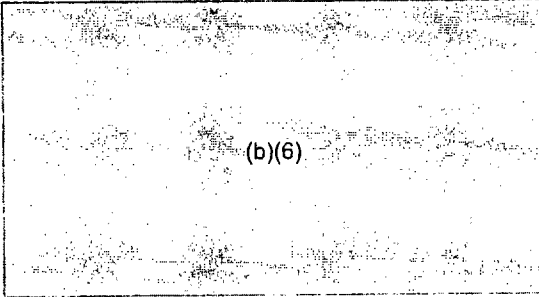
Freedom of Information Act - [5 U.S.C. 552(b)]

- b(1) National security classified information [(b)(1) of the FOIA]
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- b(7) Release would disclose information compiled for law enforcement purposes [(b)(7) of the FOIA]
- b(8) Release would disclose information concerning the regulation of financial institutions [(b)(8) of the FOIA]
- b(9) Release would disclose geological or geophysical information concerning wells [(b)(9) of the FOIA]

THE WHITE HOUSE
WASHINGTON

July 14, 1997

FILE COPY



[0019]

Thank you for your letter of congratulations on my recent appointment. It is with great excitement that I embark upon this challenge to steer the course of the nation's AIDS policy. I have the utmost confidence that our efforts will be successful, knowing that there are involved individuals like yourself working to overcome the HIV/AIDS epidemic.

I was happy to hear from you as I have many fond memories of our work together with the CAEAR Coalition. Please stay in touch and let me know if there is anything I can do for you.

Again, thank you for your letter and your support.

Sincerely,



Sandra L. Thurman
Director
Office of National AIDS Policy

Hope all is well—

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DOCUMENT NO. AND TYPE	SUBJECT/TITLE	DATE	RESTRICTION
001b. letter	Individual living with HIV to Sandra Thurman re: Past collaboration (Personal) [partial] (1 page)	04/10/1997	b(6)

COLLECTION:

Clinton Presidential Records
National AIDS Policy Office

OA/Box Number: 19399

FOLDER TITLE:

Correspondence - Sandra L. Thurman - Outgoing - 7/97

2018-0764-F

jm2098

RESTRICTION CODES

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- b(8) Release would disclose information concerning the regulation of financial institutions [(b)(8) of the FOIA]
- b(9) Release would disclose geological or geophysical information concerning wells [(b)(9) of the FOIA]

April 10, 1997

(b)(6)

[0016]

Sandra Thurman, Director
Office of National AIDS Policy

Dear Sandy,

Congratulations! I was thrilled to read of your appointment in the HIV/AIDS information off the internet that my husband prints (enclosed FYI). I can say 'I knew her when'.

You may not remember me; we met over the last several years at CAEAR Coalition meetings. From your history there, and stories I have been told, I often wished I could have taken "the Sandy Thurman course on AIDS lobbying" to improve my own efforts.

As a person living with HIV, I am confident in your ability to meet this newest challenge. Though our meetings have been brief, your energy and sense of purpose and urgency with regard to HIV/AIDS issues is immediately apparent.

You certainly have our support in Kansas City. If there is anything I can do for you, please let me know.

Sincerely,

(b)(6)

Clinton Chooses New AIDS Office Director

REUTERS 

Tuesday, April 08, 1997 5:43:00 AM EDT

WASHINGTON (Reuter) - President Clinton Monday named Sandra Thurman director of the Office of National AIDS Policy, which coordinates federal policy and programs to combat the disease.

Thurman, who worked on Clinton's election campaigns in 1992 and 1996, was executive director of AID Atlanta, which provides health and support services to people with HIV and AIDS, from 1988 to 1993.

She has spent the past four years with The Task Force for Child Survival and Development at Atlanta's Carter Center, focusing on child immunization and the eradication of polio.

Announcing the appointment at a White House ceremony, Clinton praised Thurman for her work on AIDS, particularly at AID Atlanta, which tripled in size during her tenure.

"Her experience in running a large, community-based organization makes her especially well-equipped to build the partnerships we need throughout our country, where beating the AIDS epidemic will take this kind of teamwork," Clinton said.

Elizabeth Birch, executive director of the Human Rights Campaign gay interest group, praised Thurman in a statement, saying: "She brings the right mix of leadership, political skills and commitment to the fight against HIV and AIDS."

Others were less pleased, with a spokesman for the ACT UP AIDS group, Wayne Turner, denouncing Thurman as the fourth in a series of "ineffective, no-name bureaucrats" in the job.

Some groups have been pressing Clinton to name a more senior official and to upgrade the position to Cabinet status. Thurman will replace Eric Goosby, the office's interim director, who succeeded Patsy Fleming and Kristine Gebbie.

AIDS (Acquired Immune Deficiency Syndrome) is caused by HIV (Human Immuno-deficiency Virus) and attacks the body's immune system. There is no known cure for the disease.

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Additional sources of information

[Tell Me More - From Infoseek](#)





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(e-mail: ASD0523@why.net)

<http://www.serve.com/ASD0523/>

President and Chief Executive Officer
Don Maison, Esq.
(e-mail: dmaison@why.net)

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Co-Founders

Michael R. Merdian (1956-1993)
Daryl Moore (1960-1988)

April 9, 1997

Ms. Sandy Thurman
National AIDS Policy Director
The White House
1600 Pennsylvania Avenue
Washington, D.C. 20500

Dear Sandy:

Congratulations! I could hardly believe my eyes when I opened the *Miami Herald*, saw your photo with the President and read of your appointment. (I was in Satellite Beach visiting my aunt for two days.) And shur-nuff, there you were in *The New York Times*, *USA Today* (aka "McPaper"), *The Atlanta Constitution*, *The Atlanta Journal*, and our own hometown rag, *The Dallas Morning News*.

Good luck to you in your new endeavor. Let me know if there is ever anything I can do to help out. And I look forward to your first royal visit to the Dallas AIDS arena, such as it is.

I'll miss you at AIDSWatch this year. I'll always remember "Sandy Thurman from The Carter Center" and "Sandy Thurman from AIDAtlanta," as the situation warranted. Keep the President on his toes; we have a long way to go before it's over, I'm afraid, and the media messages of late have not been helpful. I'm glad to know we have one from the trenches at the top.

Sincerely yours,

Don Maison



- Housing
- Education
- Advocacy

A Community Housing Development Organization
An Equal Opportunity Employer



THE WHITE HOUSE

WASHINGTON

July 14, 1997

Kathy L. Cerra
CAEAR Coalition Executive Committee
HIV+ Co-Chair Kansas City EMA
1208 N.E. 74th St.
Kansas City, MO 64118-2137

Dear Ms. Cerra,

Thank you for your letter of congratulations on my recent appointment. It is with great excitement that I embark upon this challenge to steer the course of the nation's AIDS policy. I have the utmost confidence that our efforts will be successful, knowing that there are involved individuals like yourself working to overcome the HIV/AIDS epidemic.

I was happy to hear from you as I have many fond memories of our work together with the CAEAR Coalition. Please stay in touch and let me know if there is anything I can do for you.

Again, thank you for your letter and your support.

Sincerely,



Sandra L. Thurman
Director
Office of National AIDS Policy

Hope all is well -

THE WHITE HOUSE

WASHINGTON

July 14, 1997

Robert W. Cooper
1350 N. Third Ave
Upland, CA 91786-3228

Dear Mr. Cooper:

Thank you for your letter and your concern.

Today, more than ever, the HIV/AIDS epidemic is threatening our youth. With nearly half of all new HIV infections occurring among people under the age of 21, the need for youth-oriented prevention efforts is greater than ever.

Our young people need to know the link between substance abuse and HIV/AIDS. We need to help our young people understand that they have the power to protect themselves through education and prevention. It is up to us all to put an end to these twin epidemics.

Again, thank you for your concern and activism.

Sincerely,



Sandra L. Thurman

Director

Office of National AIDS Policy

THE WHITE HOUSE
WASHINGTON

July 14, 1997

Terry M. Stone
Executive Director
Northwest AIDS Foundation
127 Broadway East , Suite 200
Seattle, WA 98102-5786

Dear Mr. Stone:

Terry

It was great to meet you last April, and to get your letter of congratulations.

I share your excitement about my appointment to this position at such a pivotal point in the HIV/AIDS epidemic. As we enter in to this new era, let me reiterate how important I believe it is for this office to stay in close contact with the AIDS community. The Northwest AIDS Foundation has a strong history as a caring, productive AIDS services organization, and I look forward to working with you.

Again, thanks for your letter and I look forward to seeing you again soon.

Sincerely,

Sandra

Sandra L. Thurman
Director
Office of National AIDS Policy

THE WHITE HOUSE

WASHINGTON

July 14, 1997

John M. Seiber
Public Policy Coordinator
Caring for Babies with AIDS
P.O. Box 351535
Los Angeles, CA 90035

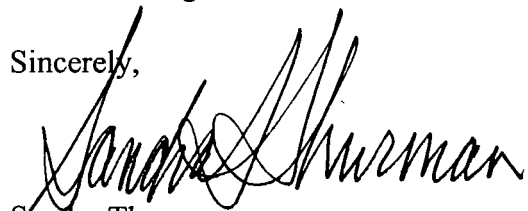
Dear Mr. Seiber:

Thank you for your congratulations and for including information about Caring for Babies with AIDS. I am fully committed to fighting for adequate HIV-related information, housing and care for children, infants and pregnant women.

The combined work of CBA's Residential Program and the Family Support Services Program have greatly assisted many HIV affected families and I commend you on your efforts to help these families remain together.

I appreciate your taking the time to write and look forward to working with Caring for Babies with AIDS and other advocates to help insure proper care and protection for children and families living with HIV and AIDS in Los Angeles and around the country.

Sincerely,

A handwritten signature in black ink, appearing to read "Sandra Thurman", written over a horizontal line.

Sandra Thurman
Director
Office of National AIDS Policy

THE WHITE HOUSE

WASHINGTON

July 14, 1997

Paul Cooper
Universal Music Group
70 Universal City Plaza
Universal City, CA 91608

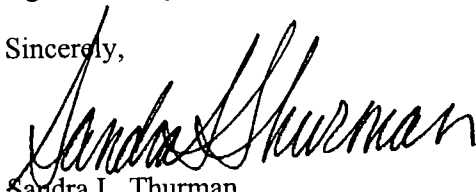
Dear Mr. Cooper:

Thank you for your letter of congratulations and your offer of support.

It is with great excitement that I embark upon this challenge to steer the course of this nation's AIDS policy. I am confident that our efforts will be successful, knowing that there are those out there like yourself who are dedicated to furthering the public/private partnerships which are essential to the fight against HIV/AIDS.

Again, thank you for your encouragement.

Sincerely,

A handwritten signature in dark ink, appearing to read "Sandra L. Thurman", written over a horizontal line.

Sandra L. Thurman
Director
Office of National AIDS Policy

THE WHITE HOUSE
WASHINGTON

FILE COPY

July 14, 1997

Paul Cooper
Universal Music Group
70 Universal City Plaza
Universal City, CA 91608

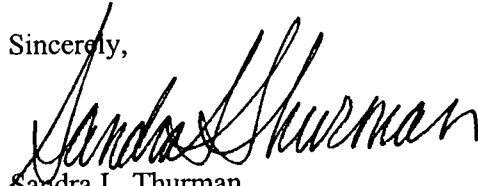
Dear Mr. Cooper:

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Again, thank you for your encouragement.

Sincerely,



Sandra L. Thurman
Director
Office of National AIDS Policy



PAUL COOPER

April 8, 1997

Ms. Sandra Thurman
Director - Office of National Aids Policy
750 17th Street, N.W.
Room 600
Washington DC 20502

Dear Ms. Thurman,

I want to congratulate you on your newly appointed position as Director - Office of National Aids Policy.

I am very aware of the large obstacles you have before you and I want to let you know that if there is anything I can do to alleviate some of the pressures that may arise, please feel free to call me at 818/777-4561. I have been very active in a variety of fund-raising capacities and may prove useful to you when dealing with different functions.

Once again, good luck and I look forward to speaking with you in the near future.

Best Regards,

PC:djv

UNIVERSAL MUSIC GROUP

70 UNIVERSAL CITY PLAZA UNIVERSAL CITY CA 91608 TEL 818 777 4561 FAX 818 777 6439

MEMORANDUM FOR BRUCE REED

From: Sandy Thurman
Date: July 9, 1997
RE: Needle Exchange Meeting Tomorrow

In preparation for tomorrow's meeting with community folks to discuss needle exchange, I thought it would be helpful to provide some comments and suggestions.

At this point, the AIDS activist community is very upset about a number of issues they feel reflect a lack of the Administration's concern around AIDS:

1. AIDS programs not designated as "protected" in the recent budget arrangement with Congress;
2. No request for a FY97 supplemental appropriation for the AIDS Drug Assistance Program (ADAP);
3. No amended FY98 budget request for Ryan White programs (including ADAP);
4. No action by the Secretary of HHS to remove the restriction on federal funding of needle exchange programs.

Their overarching concerns will influence the context in which they discuss needle exchange; it is also likely that the Secretary's decision not to amend the FY98 AIDS budget request will be raised.

A unified and supportive stance by Administration officials at the meeting is important. I would like to make two recommendations during the meeting for which I'll seek your public support:

1. That the Administration move from "if we are going to remove the restriction" to "when and how we are going to remove the restriction" (as late as possible but prior to any revocation by Congress of the Secretary's authority to remove the restriction);
2. That I offer to help in the work necessary to educate some Members of Congress on the need to respond to this issue based on the science, which leads us to a conclusion that needle exchange is a critical component of comprehensive AIDS prevention campaigns (HHS will need to task Drs. Varmus and Goosby to join me in this effort, as well as in preliminary meetings with General McCaffrey); and
3. That I tell the community at the start of the meeting that we will set aside some time at the end of the meeting to hear their concerns about the FY98 budget.

Prior to tomorrow's meeting, I will chat with you briefly to script this meeting. I have a call in to Kevin to insure that he and the Secretary are comfortable with this strategy; however, he hasn't

returned my calls (what a surprise!) - I may need your help on this!

Withdrawal/Redaction Marker

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DOCUMENT NO. AND TYPE	SUBJECT/TITLE	DATE	RESTRICTION
002a. letters	Sandra Thurman to Citizen re: Views on AIDS (Personal) [partial] (2 pages)	07/08/1998	b(6)

COLLECTION:

Clinton Presidential Records
National AIDS Policy Office

OA/Box Number: 19399

FOLDER TITLE:

Correspondence - Sandra L. Thurman - Outgoing - 7/97

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jm2098

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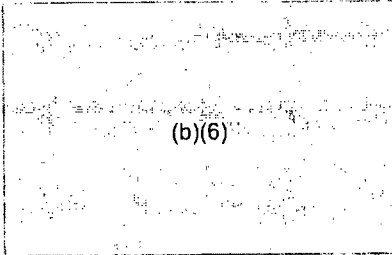
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- b(9) Release would disclose geological or geophysical information concerning wells [(b)(9) of the FOIA]

THE WHITE HOUSE
WASHINGTON

July 8, 1998



[0029]

Thank you for your letter expressing your concerns about the HIV/AIDS epidemic in the United States.

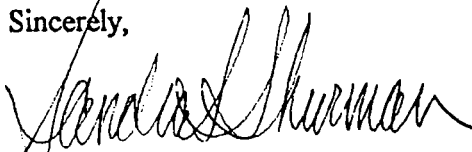
As of December 1997, more than 641,000 Americans had been diagnosed with AIDS. Of all new HIV infections, more than one-half are attributed to intravenous drug use, and more than 25 percent are in young people under the age of 25 years old. In women, more than 45 percent of all cases are attributed to sexual contact. According to the Centers for Disease Control and Prevention, in 1997, fewer than 50% of all AIDS cases are attributed to men who have sex with men.

Globally, the United Nation's AIDS Program (UNAIDS) estimates that 40 million individuals are infected with HIV. More than 90 percent of worldwide AIDS cases are attributed to heterosexual contact.

Now, more than ever, it is extremely important for all Americans to educate themselves on how HIV is and is not transmitted, and to clearly understand which activities place an individual at risk for infection with HIV -- unprotected sexual intercourse with an HIV infected individual, and the sharing of an HIV infected needle for drug injection -- the two leading causes of HIV infection in the U.S.

Again, thank you for your concern.

Sincerely,



Sandra L. Thurman

Director

Office of National AIDS Policy

(b)(6)

Thank you for your letter expressing your concerns about the HIV/AIDS epidemic in the United States.

As of December 1997, more than 641,000 Americans had been diagnosed with AIDS. Of all new HIV infections, more than one-half are attributed to intravenous drug use, and more than 25 percent are in young people under the age of 25 years old. In women, more than 45 percent of all cases are attributed to sexual contact. According to the Centers for Disease Control and Prevention, in 1997, fewer than 50% of all AIDS cases are attributed to men who have sex with men. Members of racial and ethnic minority populations continue to be disproportionately impacted by this disease.

Now, more than ever, it is extremely important for all Americans to educate themselves on how HIV is and is not transmitted, and to clearly understand which activities place an individual at risk for infection with HIV -- unprotected sexual intercourse with an HIV infected individual, and the sharing of an HIV infected needle for drug injection -- the two leading causes of HIV infection in the U.S.

Globally, the United Nation's AIDS Program (UNAIDS) estimates that 40 million individuals are infected with HIV. More than 90 percent of worldwide AIDS cases are attributed to heterosexual contact. UNAIDS estimates that 3 million children will be AIDS orphans by the year 2000.

Clearly, there is so much more that we have to do. AIDS is a disease that all caring Americans must be concerned about.

Sincerely,

Sandra L. Thurman
Director
Office of National AIDS Policy

(b)(6)

Withdrawal/Redaction Marker

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DOCUMENT NO. AND TYPE	SUBJECT/TITLE	DATE	RESTRICTION
002b. letter	Citizen to Sandra Thurman re: Views on AIDS (Personal) (1 page)	06/20/1998	b(6)

COLLECTION:

Clinton Presidential Records
National AIDS Policy Office

OA/Box Number: 19399

FOLDER TITLE:

Correspondence - Sandra L. Thurman - Outgoing - 7/97

2018-0764-F

jm2098

RESTRICTION CODES

Presidential Records Act - [44 U.S.C. 2204(a)]

P1 National Security Classified Information [(a)(1) of the PRA]
P2 Relating to the appointment to Federal office [(a)(2) of the PRA]
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DOCUMENT NO. AND TYPE	SUBJECT/TITLE	DATE	RESTRICTION
002c. letter	Citizen to Sandra Thurman re: Views on AIDS (Personal) (1 page)	01/06/1998	b(6)

COLLECTION:

Clinton Presidential Records
National AIDS Policy Office

OA/Box Number: 19399

FOLDER TITLE:

Correspondence - Sandra L. Thurman - Outgoing - 7/97

2018-0764-F

jm2098

RESTRICTION CODES

Presidential Records Act - [44 U.S.C. 2204(a)]

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Withdrawal/Redaction Marker

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DOCUMENT NO. AND TYPE	SUBJECT/TITLE	DATE	RESTRICTION
002d. clippings	re: Citizen's personal views on AIDS [partial] (5 pages)	00/00/0000	b(6)

COLLECTION:

Clinton Presidential Records
National AIDS Policy Office

OA/Box Number: 19399

FOLDER TITLE:

Correspondence - Sandra L. Thurman - Outgoing - 7/97

2018-0764-F

jm2098

RESTRICTION CODES

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(b)(6)

[002d]

To become knowledgeable on the subject of this serious threat to our civilized society, I urge that you read the following books:

- 1) The Myth of Heterosexual AIDS - by Michael Fumento, publ. Regnery-Gateway
Read the footnotes for each chapter... '90, '93
- 2) Deadly Innocence - by Dr. Leonard Horowitz, publ. Tetrahedron Industries, Inc., POB-402, Rockport, Mass. 01966 '94
- 3) The AIDS Cover-Up ? - by Gene Antonio, publ. Ignatius Press, San Francisco '86
note: parts of this book can only be read in half-hour segments.
- 4) And The Band Played On - by Randy Schilts, publ. Penguin Books '87
note: author is gay w/AIDS, contains much dis-info., self-serving, but also contains much factual info.
- 5) AIDS In The Mind of America - by Dennis Altman, publ. Anchor Press, div. Doubleday '86 re. non-medical problems

note: I keep these 5 books in my office library, and when asked or challenged, I have them available for loan. One who fails to read
GOOD books has NO advantage over the person who cannot read...

Hopefully, the TRUTH about homosexuals and AIDS will become common knowledge, but only when TRUTH overcomes political dis-information and widely publicized propaganda and lies promoted by Queer Nation and Act Up which is so accepted by the print and other media.

In the meantime, the TRUTH is known and available, tho not in its 100% pure form, in the above 5 books. You still have to "Sift and Winnow"-the motto of the University of Wisconsin.

- *Dr. Ted Taylor*
Dr. Ted Taylor

ref: "60 Minutes" segment 6-19-94
discloses the falsehoods re.
Kimberly Bergolis et al/Dr. Acer
fiasco as perpetrated by the CDC..!

The TRUTH is finally emerging! With this article, the TRUTH has now risen from 'scant' to now about 85 percent revealed. As more time passes, hopefully, the remaining 15 percent will become widely known. What remains to be told is that the ENZYMIC reaction occurring at the interface between the semen and the mucosal lining of the rectum (due to strong tissue incompatibility between these 2 tissues) results in the formation or genesis of the HIVirus ... within the body of the receptor otherwise known as the "catcher" - not the "pitcher". Not a theory. It is the answer!

THE WALL STREET JOURNAL.

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75 CENTS

Health Hazard

AIDS Fight Is Skewed By Federal Campaign Exaggerating Risks

Most Heterosexuals Face
Scant Peril but Receive
Large Portion of Funds

Less Goes to Gays, Addicts

By AMANDA BENNETT and ANITA SHARPE
Staff Reporters of THE WALL STREET JOURNAL

In the summer of 1987, federal health officials made the fateful decision to bombard the public with a terrifying message: Anyone could get AIDS.

While the message was technically true, it was also highly misleading. Everyone certainly faced some danger, but for most heterosexuals, the risk from a single act of sex was smaller than the risk of ever getting hit by lightning. In the U.S., the disease was, and remains, largely the scourge of gay men, (intravenous drug users, their sex partners and their newborn children.

Nonetheless, a bold public-relations campaign promised to sound a general alarm about AIDS, lifting it from a homosexual concern to a national obsession and accelerating efforts to eradicate the disease. For people devoted to public health, it seemed the best course to take.

But nine years after the America Responds to AIDS campaign first hit the airwaves, many scientists and doctors are raising new questions. Increasingly, they worry that the everyone-gets-AIDS message - still trumpeted not only by government agencies but by celebrities and the media - is more than just dishonest: It is also having a perverse, potentially deadly effect on funding for AIDS prevention.

No Allocation for Gays

The emphasis on the broad reach of the disease has virtually ensured that precious funds won't go where they are most needed. For instance, though homosexuals (and intravenous drug users) now account for 83% of all AIDS cases reported in the U.S., the federal AIDS-prevention budget includes no specific allocation for programs for homosexual and bisexual men. And needle-exchange programs, widely seen as among the most effective methods available in fighting infection among drug users, are denied any federal funding.

Much of the Centers for Disease Control's \$584 million AIDS-prevention budget goes instead to programs to combat the disease among heterosexual women, college students and others who face a relatively low risk of becoming infected. Feder-

ally funded testing programs alone, which primarily serve low-risk groups, account for roughly 20% of the entire budget.

Some scientists charge that tens of thousands of infections a year could be averted if only practical assistance were directed to the right people. Instead of aiming general warnings at non-drug-using heterosexuals, these critics say, the government should use the bulk of its anti-AIDS money to teach homosexual men to avoid unprotected anal sex and to dissuade addicts from sharing infected needles.

"You can't stop this epidemic if you spend the money where the epidemic hasn't happened," says Ron Stall, associate professor of epidemiology at the University of California in San Francisco.

Helene Gayle, who is in charge of AIDS prevention at the CDC, agrees that "increasingly, it is important to shift strategies to meet the epidemic." She says that the CDC, by giving communities more freedom to decide how to spend federal AIDS money, is now seeking to direct more help to those who need it most.

But she defends the CDC's pivotal decision in 1987 to emphasize the universality of AIDS: "One should not underestimate the fear and confusion this disease caused early on," Dr. Gayle says. "We needed to build a base of understanding before we could go for the jugular."

Certainly, powerful political and social forces at work nine years ago made it nearly impossible for health officials to focus attention on those most at risk, a reconstruction of events of that year shows. And though, as Dr. Gayle says, the CDC is now trying to revamp its AIDS-prevention efforts, the same forces that shaped public policy in 1987 are making it difficult for the government to change directions, even now.

Understanding the Risks

By 1987, CDC officials already had a fairly clear picture of where and how AIDS was spreading - and how much risk different groups faced. The disease was proving less likely to be transmitted through vaginal intercourse than many had feared. A major study that was just being completed put the average risk from a one-time heterosexual encounter with someone not in a high-risk group at one in five million without use of a condom, and one in 50 million for condom users.

Homosexuals (needle-sharing drug users and their sex partners) however, were in grave danger. A single act of anal sex with an infected partner, or a single injection with an AIDS-tainted needle, carried as much as a one in 50 chance of infection. For people facing these risks, it was fair to say AIDS was truly a modern-day plague. (See story on page A8.)

A key player in the CDC's earliest AIDS-prevention efforts was Walter Dowdle, a virologist who was a veteran of the war on herpes and had helped create the CDC's anti-AIDS office in the early 1980s. Like most people in his operation, he

Please Turn to Page A8, Column 1

How the Campaign To Combat AIDS Exaggerated Risks

Continued From First Page

understood that AIDS had to be fought hardest in the places it was most prevalent.

But by the spring of 1987, Dr. Dowdle had already been rebuffed repeatedly in efforts to prepare AIDS warnings aimed directly at high-risk groups. TV networks were refusing to air announcements advocating the use of condoms. And Dr. Dowdle had failed in his attempt to disseminate a brochure that mentioned condoms as effective in slowing the spread of AIDS. At the time, all AIDS material had to be cleared by the president's Domestic Policy Council, and the Reagan White House objected to pro-condom messages on moral grounds. The 1986 brochure went into the White House for review and never came out.

Searching for clues about how to proceed, CDC officials began a series of internal meetings at their red-brick headquarters on Clifton Road in Atlanta. They also reached outside for high-powered marketing help, retaining Steve Rabin, then a senior vice president of the advertising giant Ogilvy & Mather. In August, Mr. Rabin, openly gay and deeply committed to the effort, ran focus groups in a half-dozen cities to gauge attitudes toward the disease.

The results were discouraging: In city after city, the focus groups made clear that concern about AIDS hadn't taken hold in much of the country, despite the widely publicized announcement two years earlier that Rock Hudson had the disease. With some exceptions in big cities like New York and San Francisco, homosexuals continued to engage casually in unprotected sex, as did heterosexuals everywhere. The prevailing attitude: It was somebody else's problem.

For gays and drug users, this view was flatly wrong and potentially fatal. Moreover, the focus-group results highlighted a huge policy issue: Would the public support funding for AIDS prevention and research if the majority of heterosexuals believed they and their families were only minimally at risk? Would they be compassionate toward the victims of the disease?

Poll data suggested otherwise. A 1987 Gallup Poll showed that 25% of Americans thought that employers should have the right to fire AIDS victims. In that same poll, 43% felt that AIDS was a punishment for moral decline. In meetings within the CDC, many people, including Messrs. Dowdle and Rabin, expressed particular concern about the growth of housing and job discrimination against people with AIDS.

It was in this environment that the idea of presenting AIDS as an equal-opportunity scourge began to form. Politicians, including Republican Sen. Jesse Helms of North Carolina, were blocking campaigns aimed at gays anyway. And homosexual and minority groups were concerned about being linked too closely with the disease. Some CDC scientists, watching the spread of the disease among heterosexuals in Africa, worried that AIDS might yet make inroads among non-drug-using heterosexuals in the U.S. In any event, CDC officials believed that fighting AIDS was everyone's responsibility, even if everyone wasn't equally at risk of getting it.

"We were drawing on gut instinct," recalls Paula Van Ness, who had come to the CDC after

serving as chief executive of the AIDS Project, a community program in Los Angeles. "The aim was, we thought we should get people talking about AIDS and we wanted to reduce the stigma." Earlier, in Los Angeles, she had reached out directly to high-risk groups: "Don't go out without your rubbers!" warned a motherly woman in one announcement the AIDS Project had sponsored. But now, on the national scene, she too felt that such a direct approach was impossible.

Dr. Dowdle, burned by the response to his earlier, more targeted efforts, agreed with his colleagues that the CDC's best bet was to present AIDS as everyone's problem: "As long as this was seen as a gay disease or, even worse, a disease of drug abusers, that pushed the disease way down the ladder of people's priorities," he says.

After considerable soul-searching and debate, officials fixed on a dramatic approach they believed would do the most good in the long run: a high-powered PR and advertising campaign to spread a sobering yet politically palatable message nationwide.

In subsequent meetings in the summer and fall of 1987, the CDC team developed the idea of filming people with AIDS and building a series of public-service announcements around what they had to say. Subjects wouldn't be identified as gay, and the dangers of intravenous drug use would get little attention.

Early on, the staffers stumbled on their defining slogan when they interviewed the son of a rural Baptist minister. As Ms. Van Ness recalls it, the man said, "If I can get AIDS, anyone can." His remark "wasn't scripted. That's what he actually said." Other similar public-service announcements were prepared, all with the same personal approach. "If you want your audience to be more receptive about this, you had to touch their hearts," Ms. Van Ness says.

The CDC's award-winning campaign, deftly pitched to a general audience, was launched in October 1987 and featured 38 TV spots, eight radio announcements and six print ads. The initial ads steered clear of specific advice on how to avoid

AIDS among heterosexuals largely settled into a world bounded by poverty and poor health care and beset by rampant drug use.

AIDS, instead focusing on the universality of the disease and counseling Americans to discuss it with their families.

It wasn't until the spring of 1988, when the government mailed its "Understanding AIDS" brochure to 117 million U.S. households, that the risks of anal sex (and drug abuse) were underlined. But even this brochure accentuated the broader risk: It featured a prominent photo of a female AIDS victim saying that "AIDS is not a 'we' 'they' disease, it's an 'us' disease."

As public relations, the CDC campaign and par-

LIES !!! Government
LIES...!!

"Political Correctness" as defined by Queer Nation & Act Up and the rest of the 'Gay Lobby' has DICTATED to the American public a set of GOVT. LIES known to BE lies by myself and others who have made the effort to READ, listen, study and LEARN the TRUTH .. which is available, but NOT to the public...

THE WALL STREET JOURNAL until today (85%)

WEDNESDAY, MAY 1, 1996

- my thanks and deep

GRATITUDE to The Wall Street Journal !!

allel warnings from other groups proved to be remarkably effective, particularly because these messages were reinforced by various public agencies and the media. According to one poll, during the last three months of 1989, 80% of U.S. adults said they saw an AIDS-related public-service announcement on television.

Millions of people were thus sold and resold on the message: Though AIDS started in the homosexual population it was inexorably spreading, stalking high-school students, middle-class husbands, suburban housewives, doctors, dentists and even their unwitting patients. (a crime!)

In late 1991, Magic Johnson dramatically boosted the perception that everyone was at risk when he announced that his infection was due to promiscuous heterosexual behavior. Talk shows and magazines pursued the theme relentlessly. Even late last year, Redbook magazine—written for a largely middle-class female audience—carried a major story about married women called, "Could I have AIDS?" In it, the author wrote: "My mind automatically telescopes to AIDS every time I get sick."

Meanwhile, the CDC itself was producing research that made clear that heterosexual fears were exaggerated. And some CDC scientists, including then-epidemiology chief Harold W. Jaffe, publicly railed against the everyone-gets-AIDS message and urged that assistance be targeted to those who most needed it. But his opinion, along with the internal research on which it was based, was typically drowned out by the countervailing mass-media campaign.

Fear of AIDS spread—and remains. Gallup surveys show that by 1988, 69% of Americans thought AIDS "was likely" to become an epidemic, compared with 51% a year earlier, before the PR campaign got in full swing. By 1991, most thought that married people who had an occasional affair would eventually face substantial risk.

Yet, as CDC officials well knew, many of the images presented by the anti-AIDS campaign created a misleading impression about who was likely to get the disease. The blonde, middle-aged woman in the CDC's brochure was an intravenous drug user who had shared AIDS-tainted needles, although she wasn't identified as such in the brochure. The Baptist minister's son who said, "If I can get AIDS, anyone can," was gay, although the public-service announcement featuring him didn't say so.

Ryan White, perhaps the epidemic's most compelling symbol, had been diagnosed in 1984, at the age of 13, after receiving a transfusion from an AIDS-tainted blood-clotting agent used in the treatment of hemophilia. Barred by his school, shunned by neighbors, he emerged with his family as a forceful opponent of discrimination against AIDS

Those who KNOW "Magic" J- KNOW he is a LIAR...

In order to successfully transfuse the HIVirus from one body to another, it MUST be contained, thereby protected, within a RELATIVELY LARGE VOLUME OF BODY FLUID. (see *)

patients. But five years before he died in 1990, the availability of a blood test for the human immunodeficiency virus, which causes AIDS, had nearly eliminated the infection from America's blood-products supply. (Similarly, activist Elizabeth Glaser, who spoke at the 1992 Democratic Convention, was infected through a blood transfusion well before AIDS testing began.) . . . these are the tragic and REAL VICTIMS of GayPri

Meanwhile, Kimberly Bergalis became famous for a particularly rare case: She and five other Florida patients apparently acquired their infections from their dentist, who later died of AIDS. But although the CDC has tracked down and tested thousands of patients of hundreds of HIV-positive doctors and dentists, that single Florida dentist remains the only documented case in the U.S. of a health professional's passing the virus on to patients. (see **

Research continued to show that AIDS among heterosexuals had largely settled into an inner-city nexus, a world bounded by poverty and poor health care and beset by rampant drug use. AIDS was also on the rise in some poor rural communities. Yet government ads typically didn't address the heterosexual group at greatest risk, a group that a CDC researcher would later define as "generally young, minority, indigent women who use 'crack' cocaine, have multiple sex partners, trade sex for 'crack' or other drugs or money, and have [other sexually transmitted diseases] such as syphilis and herpes."

Though scientists and anti-AIDS activists knew that the government-nurtured fear of AIDS among upscale, non-drug-using heterosexuals was exaggerated, not everyone thought this was a bad thing. Indeed, many credited rampant fear with achieving pro-family goals that no amount of moralizing alone could have accomplished. In a 1991 Gallup Poll, 57% of respondents said they believed that AIDS had already made their married friends "less likely to fool around." Singles reported being less apt to have one-night stands and more reluctant to date more than one person.

Moreover, there was no question that even mainstream heterosexuals bore some risk of AIDS and that greater caution would reduce their already-low rate of infection. "I don't see that much downside in slightly exaggerating [AIDS risk]" says John Ward, chief of the CDC branch that keeps track of AIDS cases. "Maybe they'll wear a condom. Maybe they won't sleep with someone they don't know."

The marketing campaign also appeared to be having another key desired effect: to mobilize support for public funding of AIDS research and prevention. Federal funding for AIDS-related medical research soared from \$341 million in 1987 to \$655 million in 1988, the year after the CDC's campaign began. (This year, the figure stands at \$1.65 billion.) Meanwhile, the CDC's prevention dollars leapt from \$136 million in 1987 to \$304 million in 1988; \$584 million was allocated for 1996.

Even the gay community though not specifi-

cally targeted for assistance, began to see the freedom of the everyone-gets-AIDS campaign. "This was a time of decreases in government funding," according to Jeff Amory, who headed the San Francisco AIDS Office in the 1980s. "Meanwhile, AIDS money was increasing."

It took a while before people realized that much of the money pouring in wasn't reaching the groups most at risk. In 1990, Mr. Amory took part in a telephone survey of about 50 HIV/AIDS groups funded by the CDC. Fewer than 10% even mentioned gay men as among their constituencies. (Mr. Amory died in November, after his interview with this newspaper.)

Meanwhile, the rush to testing meant that people at low risk were using up more and more of the available AIDS-prevention money just to discover they weren't infected. In 1994, 2.4 million tests were administered at government-funded locations, more than 10 times the number in 1985. Only 13% of those tests were given to homosexual or bisexual men or intravenous drug users.)

As the CDC's biggest single prevention program, AIDS testing in 1995 accounted for about \$136 million of the agency's total \$589 million AIDS-prevention budget for that year. "It was not efficient or effective in picking up HIV-positive people," says Eric Goosby, director of the HIV/AIDS Policy Office of the U.S. Public Health Service, which oversees the CDC and other health agencies.

Moreover, because treating drug-addiction wasn't directly part of the CDC's mandate, stopping the spread of AIDS among needle-sharing addicts fell "between the cracks," says Dr. James W. Curran, who was director of the anti-AIDS office at the CDC until late last year and is now dean of the School of Public Health at Emory University in Atlanta.

State funding for AIDS prevention—tracking public attitudes toward the disease—was also being directed largely toward low-risk groups, says Patricia E. Franks, a senior researcher at UCSF, who spearheaded a study of California AIDS spending between 1989 and 1992. The study found that while 85% of AIDS cases were concentrated among men who had sex with men, programs targeting this group received only 9% of all state AIDS prevention dollars.

Spending for women, in contrast, grew to 29% of the state money in 1992 from 13% in 1989, even though HIV rates among women of childbearing age held steady at less than one-tenth of 1% from 1988 through 1992.

California health officials say they believe spending on high-risk groups has improved in the past few years. But Wayne Sauseda, director of the California Office of AIDS, concedes that "it's hard to take money away from groups already receiving grants." In California's last three-year state funding cycle, "we were being deluged by proposals from low- and no-risk population groups." Mr. Sauseda says. "We got two proposals for every one from a high-risk group."

Typical of the requests from low-risk groups, he says, were proposals to offer education on college campuses. "No one would say coeds are not at any

* - the tiny, minute volume of body fluid contained WITHIN the lumen of a hypodermic needle, does not qualify as a "relatively large volume of body fluid". Therefore it is unlikely and highly IMPROBABLE that sharing needles transmits the virus. UNPROVEN

(b)(6)

not our first priority."

AIDS officials in other states report similar frustrations. In 1994, the CDC turned to a community-planning process for dispensing AIDS funds, a system that theoretically allows local people to allocate dollars to groups most in need. But various community planners say it has been tough to redirect the funds, in large part because public attitudes have become so entrenched.

In Oregon, for example, many community AIDS workers "are unwilling to acknowledge that youth who are truly at risk [are] young gay men," says Robert McAlister, the state's HIV program manager. Thus, most of Oregon's AIDS-prevention money is still spent on counseling and testing that primarily serves low-risk individuals. "When Magic Johnson made his statement, we got overwhelmed with clients demanding service," Dr. McAlister says. "You start to cut corners. If we try to serve everybody, we wind up serving everybody poorly."

Having helped shape current attitudes and set AIDS-prevention policies in motion, the Centers for Disease Control finds itself in a serious bind. So far, AIDS has killed 320,000 Americans, according to the CDC. Between 650,000 and 900,000 others are currently infected with the virus that causes the illness.

Overall, rates of new HIV infections appear to be declining from their peak in the mid-1980s. Nonetheless, as many as 40,000 people, mostly gay men, (drug users and their sex partners) will contract the virus this year alone. Despite this, the CDC aims its current education campaign, called "Respect Yourself, Protect Yourself," at a broad spectrum of young adults, rather than targeting the high-risk groups. A current focus of the campaign is to discourage premarital sex among heterosexuals.

The CDC also has been emphasizing that women constitute a growing proportion of AIDS cases. But close analyses of the data indicate that the vast majority of these victims are drug users or sex partners of drug users. Also, the data partly reflect a statistical quirk: Because the number of infections among gay men has declined, other groups—such as women—now represent a larger percentage of victims. Yet the infection rate among women not in high-risk groups appears to be holding roughly steady.

Meanwhile, unpublished research by the CDC itself concludes that "the most effective efforts to reduce HIV infection will target injecting drug users on the Eastern seaboard, young and minority homosexual and bisexual men, and young and minority heterosexual women and men who smoke crack cocaine and have many sexual partners."

Numerous studies have shown significant behavior changes in gay men who have been counseled by gay-outreach programs. Susan M. Kegles, a behavioral scientist at UCSF's Center for AIDS Prevention Studies, reports that an eight-month program in Eugene, Ore., reduced (one of the highest-risk acts, unprotected anal intercourse, by 27% in young gay men. The program used leaders in the gay community to demonstrate

by ignorance and distributing
Quest, Pridefest's PrideGuide,
thereby promoting the anal
Feather United Fund member !!!
I have met actually PROMOTE homosexuality by ignorance and distributing
The Wisconsin Light, The Gay Traveler, Quest, Pridefest's PrideGuide,
thereby promoting the anal
Feather United Fund member !!!
sex which causes the incidence of AIDS. Supported as a Red
In Step Mag., the Nat'l. Gay & Lesbian Newsmagazine, The Advocate...thereby promoting the anal
Feather United Fund member !!!

Other studies have shown that drug users need even more intense behavioral counseling to break their addiction. But "only 15% of active drug users are in treatment on any given day, and there are not enough treatment slots to meet the demand from drug users," according to a report by the federal Office of Technology Assessment. Further, the ban of federal funding for needle exchanges continues, even though most reports conclude that locally funded efforts to distribute sterile needles or needle-cleaning supplies have been effective in reducing the spread of infection.

An epidemiologist at UCSF, James G. Kahn, recently created an academic model which, he says, shows that over five years, \$1 million spent in a high-risk population averts 150 infections, compared with two or three infections if the money is spent in a low-risk population. Moreover, he argues that reducing infections in high-risk groups would "almost certainly" benefit low-risk groups by reducing the pool of people who could potentially infect others.

Then there is the separate issue of honesty in government: Shouldn't the public hear the truth, even if there might be adverse consequences? "When the public starts mistrusting its public health officials, it takes a long time before they believe them again," says George Annas, a medical ethicist at Boston University.

Yet many both inside and outside the government fear that speaking more directly about AIDS transmission, and seeking federal programs to match, poses the same dangers it did nine years ago. Congress controls the purse strings, and Sen. Helms, in particular, still monitors every AIDS-related bill. Says a Helms staff member, "We would certainly have a problem" with money going to gay-activist groups or to produce materials that illustrate gay sex acts.

"There is a real concern that funding won't be shifted, it will be cut, that if most people in the U.S. feel they are at very low risk, there will be little support for any AIDS-prevention efforts," says Don Des Jarlais, director of research at the Chemical Dependency Institute of Beth Israel Medical Center in New York. Still, he and many others believe that prevention experts have no choice—and that it is time to fight for programs based on candor. "You can't build a good prevention program on bad epidemiology," he says.

Even back in the 1980s, Stephen C. Joseph, who was commissioner of public health for New York City from 1986 to 1990, blasted the notion that AIDS was making major inroads into the general population.

Today Dr. Joseph, who is assistant secretary of defense for health affairs at the Pentagon, says: "Political correctness has prevented us from looking at the issue squarely in the eye and dealing with it. It is the responsibility of the public-health department to tell the truth." ❖

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Scientists Hone Knowledge of How Virus Spreads

Scientists once feared that the AIDS would become an epidemic among non-drug-using heterosexuals. Today, there is a broad consensus among experts that it probably won't.

"Over 90% of the population is heterosexual, and most people are at zilcho or very low risk," says Lyle Petersen, until recently chief of the CDC branch that estimates the prevalence of HIV, the virus that causes AIDS.

This doesn't mean heterosexuals shouldn't take precautions, including condom use. Cases have been documented of people contracting AIDS after a single heterosexual encounter. Any individual's risk of contracting a disease is very different, and much more specific, than the overall risk to a large group of people.

For a person to become infected with HIV, scientists believe, the virus must pass from the blood, semen or vaginal secretions of an infected person into the cells or bloodstream of another.

People who share infected needles accomplish that quite readily; in one Connecticut study, as many as 70% of drug-users' needles contained HIV, which could be injected directly into the blood of the next user. Between 1% and 2% of injections with HIV-tainted needles appear to result in infection, according to Don Des Jarlais, director of research at the Chemical Dependency Institute of Beth Israel Medical Center in New York.

HIV is also transmitted fairly readily to the receptive partner in anal intercourse, whether that partner is male or female. Scientists believe such transmission occurs largely because the sex practice frequently leads to anal tears and abrasions. Scientists estimate that 0.5% to 3% of such acts with an infected person will lead to infection.

HIV apparently can also infect vaginal cells but, at least in the U.S. and Western Europe, it doesn't appear to do so easily. Studies of couples in which only one partner is infected show that about one in every

1,000 sexual acts results in infection. Women appear to be infected during vaginal sex several times as often as men, although still not, on average, very frequently.

For both men and women, it is much harder to transmit AIDS than to pass on other, less serious sexually transmitted diseases. Some studies suggest that gonorrhea, for example, passes from men to women in as many as 90% of all encounters with an infected person, and from women to men about one-quarter of the time.

There is an insidious link, though, between venereal diseases and AIDS; people with diseases such as syphilis and herpes, which may produce open sores, are much more likely to become infected with AIDS or to transmit the disease to a partner.

Scientists also now believe that most people with HIV are most infectious during two periods: before any symptoms appear and later in the disease, when the person may be very ill. Therefore, many scientists believe, for widespread transmission to take place, infected people have to have sexual contact with a large number of partners in a fairly short period of time.

This is one of the reasons that AIDS spread rapidly among homosexuals in the early days of the epidemic, as gay bathhouses provided the venue for large numbers of sexual contacts. In one San Francisco study published in 1987, for example, nearly 40% of the gay men studied had had 10 or more sexual partners in the previous two years; an additional 25% had had more than 50 partners. Of those reporting more than 50 partners, more than 70% had been infected.

All this also helps explain why AIDS hasn't spread rapidly among non-drug-using heterosexuals in the U.S. but has made bigger inroads in parts of Africa and Asia.

For one thing, prostitution is more widely practiced in the developing world. This means that

random heterosexual encounters in which partners may be infected with a venereal disease are more widespread. "Good studies in Thailand show that roughly one in five men reported visiting a prostitute in the last 12 months," says Bruce G. Weniger, a medical epidemiologist at the CDC who has studied the Asian epidemic.

Even when prostitutes aren't involved, the developing world has a higher incidence of venereal disease; in addition, in some areas, local sexual practices lead to tearing of the skin, which contributes to the more-rapid spread of AIDS, many scientists believe.

In the U.S., the use of prostitutes is low by comparison. In a major survey of sexual practices, centered at the University of Chicago, fewer than 1% of the 3,432 people surveyed said they had paid for sex in the previous year. Even those who think the true rate is much higher don't believe it approaches the level found in developing countries. Moreover, in the U.S., outside of drug-using communities, HIV prevalence among prostitutes isn't as high as in developing countries.

The situation, however, is far different in inner-city neighborhoods where drug use is high, access to good medical care is insufficient and trading sex for drugs is relatively common. A recent study of crack users in New York, Miami and San Francisco, for example, found that more than one-third of the women and 15% of the men had a history of syphilis; more than two-thirds of the women had traded sex for money or drugs. More than 40% of the women who recently had engaged in unprotected sex for pay were HIV positive.

But large surveys that systematically exclude drug users and gay men indicate that the spread of HIV infections in the U.S. has either been leveling off or dropping. In a 1992 CDC study at blood banks, which seek to block high-risk individuals from donating, 0.0067% of blood donors were HIV-

infected, down from 0.0223% in 1985. Moreover, subsequent research shows that the rate has continued to drop.

Further, says the CDC's Dr. Petersen, who studied the blood-bank results, most of the HIV-positive donors turn out, on investigation, to have engaged in some high-risk behavior.

Meanwhile, blood tests of newborns, which indicate the HIV status of the mother, show that the overall percentage of infected women has remained stable nationally for several years, and has actually begun dropping in New York, New Jersey and Florida, three states with very high AIDS rates. Nationally, the HIV-infection rate for women is 1.6 per 100,000 women.

Other surveys support the suggestion that most heterosexuals aren't seriously at risk. The University of Chicago's sexual-practices survey turned up six people out of the 3,432 surveyed who credibly reported themselves HIV positive. Of those six, three were bisexual men, one a woman who injected drugs and one a woman who had had more than 100 lifetime sex partners. (anal sex)

Some scientists argue that the U.S. still faces a big threat from strains of HIV that are much more readily transmitted heterosexually than the strains that exist here today. Max Essex, a professor of virology at Harvard University and chairman of the Harvard AIDS Institute, says his research suggests that such strains are contributing to the extensive heterosexual threat in Africa and Asia.

But after attending a European conference on the topic, Roy Anderson, professor of epidemiology at Oxford University, is unconvinced. "I find it plausible but, as yet, scientifically unsubstantiated" that such strains exist, he says. Even if they do, he adds, they probably won't lead to a heterosexual epidemic in the U.S. or Western Europe.

Male homosexuals make up only 1 to 3 percent of the population (or 2 to 6 percent of the MALE population)...they would like to CLAIM 10 percent ... to make them feel 'better' NOT TRUE

(b)(6)

More and more - and very many researchers have come to the conclusion that receptive anal intercourse (either male or female) is the ONLY risk behavior involved in the incidence of HIV/AIDS infection.

FACTOID: this is the most widely practiced method of birth control in primitive African and other 3rd world countries.

A Question of Odds

Below are rough estimates of the relative risks in the U.S. and Western Europe of various activities that can transmit AIDS. The calculations can't be used as a guide to individual behavior. Risk to any one person depends on many factors that can't be reduced to a single number. Recent research, for example, suggests that the infectiousness of the HIV virus can vary greatly over the life of an infected person; infectiousness is likely to be high both at the very outset of the infection, before symptoms have appeared, and several years later. Also, women may be several times more likely than men to be infected through vaginal intercourse, a distinction that the overall risk figure obscures.

ACTIVITY	RISK	NOTES AND SOURCES
Vaginal sexual intercourse	1 infection per 1,000 acts with HIV-positive partner	Mean per-act risk for unprotected intercourse. Source: Isabelle de Vincenzi, European Study Group on Heterosexual Transmission of HIV, 1994 by Michael Fumento [read - <u>THE MYTH OF HETEROSEXUAL AIDS</u> - Fumento
Receptive anal intercourse ...the <u>ONLY</u> risk behavior	5 to 30 infections per 1,000 acts with HIV-positive partner	With no condom use. Source: Victor DeGruttola, Harvard School of Public Health, 1989 ...partner does NOT NEED to have the HIV/AIDS virus. Many don't.
Intravenous drug injection with infected needle	10 to 20 infections per 1,000 needle uses	Source: Don Des Jarlais, Beth Israel Medical Center, New York ...NOT a likely means of transmission. NOT provable. <u>IV drug users are into a LOT of KINKY things, such as</u> receptive anal intercourse.
Accidental stick in medical setting with infected needle	3 infections per 1,000 sticks	Source: Centers for Disease Control ...highly UN-likely. Latest CDC study disclosed NONE. <u>Sound better to family and friends than admitting to receptive anal intercourse</u>
Transfusion of screened blood ... THIS is the tragic aspect of AIDS.	1 infection per 450,000 to 660,000 donations	Source: Centers for Disease Control/American National Red Cross Homosexuals are known to donate blood at a rate that is 3 to 5 times higher than the general population.

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THE WHITE HOUSE
WASHINGTON

July 6, 1998

Chris and Shan Stevenson
405-A Eagle Heights
Madison, WI 53705

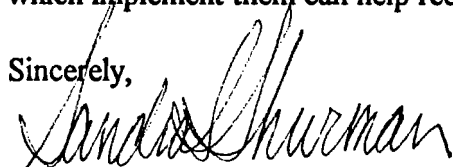
Dear Chris and Shan Stevenson:

Thank you for providing your views about needle exchange funding to our office.

Based on numerous studies conducted by the National Academy of Sciences, the U.S. General Accounting Office, the National Institutes of Health, among a host of other organizations, the Secretary of Health and Human Services has determined that needle exchange programs decrease HIV infection rates in intravenous drug using populations, and that they do not increase drug use in this population. The President has stated that he agrees with this conclusion, but believes that funding of needle exchange programs should be a local decision. The President did not allow for the use of federal funds to support this HIV prevention activity.

I support fully the President's decision and look forward to continuing to educate the American public on the sound scientific principles behind needle exchange programs and how communities which implement them can help reduce HIV infection without increasing drug use.

Sincerely,

A handwritten signature in black ink, appearing to read "Sandra L. Thurman", written over a horizontal line.

Sandra L. Thurman

Director

Office of National AIDS Policy

Todd:
Any comments/changes?

m²

No -

Chris and Shan Stevenson
405-A Eagle Heights
Madison, WI 53705

Dear Chris and Shan Stevenson:

Thank you for providing your views about needle exchange. I am sure you know that the President, based on sound scientific evidence, has endorsed needle exchange programs which are part of a comprehensive HIV prevention program as a viable method for preventing the spread of HIV infection in intravenous drug users. Based on numerous studies conducted by the National Academy of Sciences, the U.S. General Accounting Office, the National Institutes of Health, among a host of other organizations, the Secretary of Health and Human Services has determined that needle exchange programs decrease HIV infection rates in intravenous drug using populations, and that they do not increase drug use in this population. The President has stated that he agrees with this conclusion, but believes that funding of needle exchange programs should be a local decision. The President did not allow for the use of federal funds to support this HIV prevention activity.

I support fully the President's decision and look forward to continuing to educate the American public on the sound scientific principles behind needle exchange programs and how communities which implement them can help reduce HIV infection without increasing drug use.

Thank you for sharing your views with me.

Sincerely,

Sandra L. Thurman
Director
Office of National AIDS Policy

Data Entry Form

Letter ID	Writer First Name	Writer Last Name	Received Date	Subject
10846	Chris & Shan	Stevenson	5/27/98	Needle Exchange Opinion

☐ Response Required?

Response Type	Response Date	Responder ID	Responder Name	Action Promised
			Matthew	
Action Completed	Action Date	Addressed To		

Notes

Sender's Organization	Sender's Street1	Sender's Street2
Sender's City	Sender's State	Sender's Zip

May 16, 1998

Chris Stevenson
405-A Eagle Heights
Madison, Wisconsin 53705

Sandy Thurman
Director—White House AIDS Policy
1600 Pennsylvania Ave.
Washington, D.C. 20500

Dear Ms. Thurman:

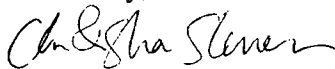
I am currently a graduate student at the University of Wisconsin at Madison, where I study food engineering and rheology. I would like to communicate our strong opinion on a matter of public debate.

It is regarding needle exchange, under the auspices of preventing AIDS from spreading. My wife heard a piece on NPR a couple of weeks back, and was appalled at peoples' thinking. It is our understanding that the Clinton Administration "supports" needle exchange, but not with federal dollars.

We do not believe in needle exchange, and hope that you will take that into consideration in trying to fulfill your responsibilities. What a horrible thing to do. Imagine any parent trying to encourage their children to keep up a bad habit (pick any) but at the same time use every effort to avoid consequences. That is a fairly good analogy, I believe, to make my point, without having to go on for paragraphs. If people want to stop AIDS, we have to teach them sexual abstinence before marriage, complete integrity in marriage, that homosexuality is wrong, and that using drugs is wrong.

Besides the fact that it is a horrible idea, we believe it is very far from the role of our federal government to be involved in this. We hope that you work very hard to prevent this from happening. We look forward to your response.

Sincerely,

A handwritten signature in cursive script that reads "Chris & Shan Stevenson".

Chris & Shan Stevenson

**OFFICE OF NATIONAL AIDS POLICY
EXECUTIVE OFFICE OF THE PRESIDENT**

808 17th Street, N.W., 8th Floor
Washington, DC 20006

Phone: 202-632-1090
Fax: 202-632-1096

FACSIMILE COVER SHEET

TO: Deborah V.

FAX NUMBER: 690-7560

FROM: Sarah

DATE: 8/25/97

PAGES INCLUDING COVER SHEET: 13

COMMENTS: Business Reports to AIDS info —

