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Angie or Tricia.

FAX TRANSMISSION

NIH OFFICE OF AIDS RESEARCH
BUILDING 31, ROOM 4C02
BETHESDA, MD 20892
301-496-0357
FAX: 301-496-2119

To: Todd Summers **Date:** March 1, 1999

Fax #: 202-456-2438 **Pages:** 6, including this cover sheet.

From: Wendy Wertheimer
and Linda Reck

Subject: NIH AIDS Research in Africa

COMMENTS:

Todd: Here are documents prepared for Chris Jennings before World AIDS Day that sketch out some of the projects we have ongoing in Africa. By the end of the week, we will prepare more detailed information on this research for you.

Prepared by the Office of AIDS Research
November 24, 1998

ACTIVITIES IN AFRICA

(This submission is inclusive of NIH efforts except for those funded by NIAID, which will comprise a separate document developed by NIAID.)

The National Institutes of Health (NIH) supports an comprehensive program of basic, clinical and behavioral research on HIV infection and its associated opportunistic infections and malignancies. The global nature of the HIV AIDS epidemic underscores the critical need to identify interventions that will be of use in developing countries. In this regard, the NIH supports a variety of research efforts conducted in Africa, where the epidemic began and is continuing to ravage many nations. According to the UNAIDS statistics released today, 34 people in sub-Saharan Africa have been infected and almost 12 million of them have already died. Last year alone there were over four million new infections.

Ongoing and planned NIH-supported studies in various parts of Africa are focusing on perinatal intervention studies, testing of potential microbicides and behavioral interventions, protection of the blood supply, and training and infrastructure development. Most of these studies are conducted collaboratively between U.S. and African investigators. In addition, the NIH Institutes and Centers work collaboratively to fund studies in Africa.

Mother to Child Transmission

Preventing transmission from HIV-infected mother to child is a priority of NIH intervention research. Initiation of treatment with zidovudine prior to birth, during delivery, and to the infant has significantly reduced the incidence of maternal-fetal HIV transmission in the United States. However, this protocol is not easily applied in developing countries because of cost factors and lack of health care infrastructure. Simpler and less expensive antiretroviral regimens for interruption of vertical transmission are being tested by NIAID.

Ongoing NIH efforts are designed to identify and test other interventions that can be used effectively and easily in diverse cultural and economic settings to further reduce the incidence of mother to child transmission. These include studies in several countries in Africa:

- NCI-funded study in Malawi to determine the role of vaginal lavage and baby washing in decreasing HIV transmission during birth;

- NICHD-funded studies in Tanzania and Malawi on the effects of vitamin A and multivitamins on decreasing vertical transmission and in Rwanda on whether vitamin A supplementation can effect outcomes for infected children;

- NICHD and NIAID-funded study in Uganda on the use of HIV-1 hyperimmune intravenous immune globulin to decrease transmission;

- NICHD-funded studies in Kenya related to prevention of transmission through breast-milk, including use of formula compared to breastfeeding, early weaning, active/passive immunization during breastfeeding, and the relationship between HIV viral load and transmission;

- NICHD-funded study in South Africa on the role of mucosal immunity in preventing transmission through breastfeeding;and

- NICHD and NIAID-funded study in Kenya to determine the relationship between genital shedding of HIV and intrapartum transmission of HIV.

Prevention Interventions

NIH sponsors an extensive biomedical and behavioral program for the discovery, development, preclinical testing, and clinical evaluation of topical microbicides and other female-controlled barrier methods for prevention of HIV transmission. Population-based research is essential to ensure both the efficacy and acceptability of these interventions to decrease or eliminate HIV transmission. It is an NIH priority to develop safe, reliable, acceptable, and inexpensive contraceptive and non-contraceptive microbicides for the prevention of HIV and other STDs. NIH activities in this area include:

- NICHD-supports several phase 1-3 clinical trials in African nations to determine the safety and efficacy of potential microbicidal substances in various populations including a study of new formulations of Nonoxynol-9 in Kenya.

- In FY 1999, NICHD will initiate new and expand existing programs to accelerate the testing of potential spermicidal microbicides as well as other female-controlled physical barrier methods. Several of these studies will be conducted in Africa.

- NIMH is supporting a study in Uganda on the relationship between sexual behaviors, education, work histories and HIV status in adolescent women. The study will help to develop more effective HIV interventions for this target group in Uganda.

- In FY 1999, NIAID will establish the HIV Prevention Trials Network that will focus on the testing at U.S. and international sites including Africa of various interventions including microbicides. Other ICs will co-fund studies conducted at these sites. NIAID also will expand the Topical Microbicide Program Projects involving multidisciplinary research to develop and test new agents such as PRO2000, lactobacillus and PMPA.

Blood Supply Safety

The NIH is developing with WHO and other Federal government agencies a new initiative

targeted to improve the safety of the blood supply to reduce the incidence of blood-borne transmission of HIV. While this effort is still in the early stages of planning, it is hoped that NIH supported efforts to provide appropriate training for blood transfusion center personnel in HIV testing, including the rapid HIV assays, can ultimately result in protecting the blood supply of African nations.

Research Training

It is critical to the success of international studies that foreign scientists be full and equal partners in the design and conduct of collaborative studies and that they have full responsibility for the conduct of studies in-country. To help build research capacity in developing countries, the FIC funds the AIDS International Training and Research Program (AITRP). The AITRP provides research training to foreign scientists through grants to U.S. universities. During the first nine years of the AITRP, more than 450 scientists from Africa were trained through the program. AITRP is active in Botswana, Cameroon, Cote d'Ivoire, Ethiopia, Kenya, Malawi, Mozambique, Senegal, South Africa, Tanzania, Uganda, Zambia, and Zimbabwe.

Anthony Fauci,11/24/98 1:11 PM -0500,White House request 1

From: Anthony Fauci <AFAUCI@flash.niaid.nih.gov>
To: "Varmus, Harold <hv2b>" <hv2b@nih.gov>
Cc: Anthony Fauci <AFAUCI@flash.niaid.nih.gov>,
Neal Nathanson
<nathansn@mail.med.upenn.edu>
Subject: White House request
Date: Tue, 24 Nov 1998 13:11:18 -0500
MIME-Version: 1.0

Harold:

I am listing below some areas of NIH AIDS research in Africa that can be submitted to Chris Jennings for the President. These all relate predominantly to NIAID activities. I spoke with Neal Nathanson and he will be sending you separately some items that encompass some of the other NIH ICs. If you have any questions, please give me a call.
Tony

Background:

Over the past decade the NIH has supported HIV research in more than 15 African countries. Initial projects focused on development of infrastructure and studies on the epidemiology and the regional characteristic of HIV/AIDS. More recently the research has emphasized the development of cost-effective interventions to control the spread of HIV/AIDS. The targeted interventions include development of HIV vaccines, physical barriers, microbicides and behavioral interventions to prevent sexual transmission, drugs and microbicides to prevent perinatal transmission, and treatment of sexually transmitted diseases (STDs) to reduce susceptibility to HIV infection.

Several important large-scale prevention trials of HIV interventions have been undertaken or completed, such as the following:

* Evaluation of the effect of community treatment of STDs on sexual transmission of HIV. This may provide an inexpensive way to decrease sexual transmission of HIV.

* Studies on the effect of washing the birth canal and the newborn with the common antiseptic chlorhexidine to prevent perinatal transmission in Malawi. Although this study did not have an effect on HIV transmission, it demonstrated a substantial reduction of neonatal bacterial infections.

* Demonstration that peer counseling reduces the risk of HIV infection in factory workers in Zimbabwe.

Anthony Fauci,11/24/98 1:11 PM -0500,White House request 2

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OFFICE OF NATIONAL AIDS POLICY

EXECUTIVE OFFICE OF THE PRESIDENT

THE WHITE HOUSE

FACSIMILE TRANSMITTAL SHEET

TO: Doug Mathies FROM: Jodi Sommers

COMPANY: DATE:

FAX NUMBER: 6-1655 TOTAL NO. OF PAGES INCLUDING COVER:

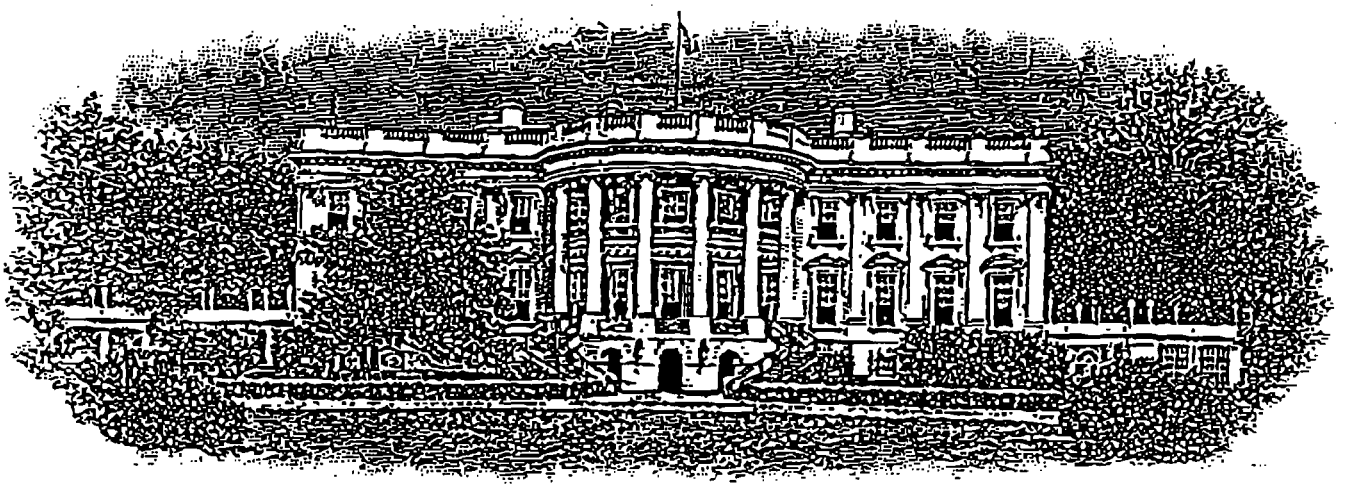
PHONE NUMBER:

RE:

☐ URGENT ☐ FOR REVIEW ☐ PLEASE COMMENT ☐ PLEASE REPLY ☐ PLEASE RECYCLE

NOTES/COMMENTS:

The White House



DOMESTIC POLICY

FACSIMILE TRANSMISSION COVER SHEET

TO: Todd Summers

FAX NUMBER: 6-2438

TELEPHONE NUMBER:

FROM: Sarah Bianchi

TELEPHONE NUMBER: 456-5685

PAGES (INCLUDING COVER): 7

COMMENTS: AGENCIES - NIH - Africa Activities

TELEFAX TRANSMITTAL

Harold Varmus, M.D.
Director, National Institutes of Health
Building 1, Room 126
1 Center Drive, MSC 0148
Bethesda, MD 20892-0148
Fax No. (301) 402-2700
Confirmation Phone No. (301) 496-2433

DATE: November 24, 1998

TO: Chris Jennings
Deputy Assistant to the President
for Health Policy Development

FAX NUMBER: 202-456-5557

PHONE NUMBER: 202-456-5560

NUMBER OF PAGES (INCLUDING COVER PAGE): 6

[ ] **PLEASE CALL TO CONFIRM RECEIPT. THANK YOU.**

REMARKS: As discussed, please feel free to call Dr. Neal Nathanson, Director of the NIH Office of AIDS Research (phone: 301-496-0357), or me if you have questions.

NIH
Prepared by the Office of AIDS Research
November 24, 1998

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NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

DATE: TIME:

TO: John Novak

ORGANIZATION:

FAX # 202 216 3046

NO. OF PAGES INCLUDING COVER SHEET: 6

FROM: Greg Folkers, M.S.
Special Assistant for Research Reporting
Office of the Director
National Institute of Allergy and Infectious Diseases
National Institutes of Health
Bldg. 31, Room 7A50
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TEL #: (301) 496-2263
FAX #: (301) 496-4409
Cell phone #: (301) 996-7894
E-mail: gfolkers@nih.gov
NIAID URL: http://www.niaid.nih.gov

Dale Lawrence asked me to send you a list of NIH-supported activities in Africa. This is what I have at hand in terms of info - but it is far from complete and covers only the countries where the President will be visiting. I would suggest you contact Karl western tomorrow. GF

NIH EXPENDITURES IN SELECTED AFRICAN COUNTRIES IN FY 1996

	RESEARCH AWARDS*	# RESEARCH AWARDS	RESEARCH TRAINING AWARDS**
BOTSWANA	$ 0	0	$ 0
GHANA	$ 122,000	3	$ 26,743
RWANDA	$ 507,000	3	$ 26,743
SENEGAL	$ 284,000	4	$ 80,231
SOUTH AFRICA	$ 859,000	16	$ 343,652
UGANDA	$1,625,000	4	$ 775,002
TOTAL	$3,397,000	30	$ 1,252,371

*Includes foreign grants and contracts; foreign components of domestic grants; support for researchers in the NIH Visiting Program; and, support for the Fogarty International Center International Research Fellowship Program to provide training of post-doctoral fellows in U.S. laboratories.

**Includes Fogarty International Center (FIC) research training awards to U.S. institutions to work collaboratively with partners in developing countries on HIV/AIDS, Emerging Infectious Diseases, Environmental Health, and Population and Health. Figures are estimates based on level of activity in individual participating countries.

National Institutes of Health
Bethesda, Maryland 20892

Current DMID/NIAID Supported Research Activities in Selected African Countries

Ghana

- Contract for Evaluation of Dichloroacetate as Adjunct Therapy for Severe Malaria (Komfo-Anokye Teaching Hospital (Kumasi, Ghana), University of Florida, and St. George's Hospital (London, UK))
- Participating Center in Multicenter Clinical Trials Network for Study of Severe Malaria in African Children (SMAC) (Komfo-Anokye Teaching Hospital (Kumasi, Ghana))
- Pending: Application for RFP "Malaria: Clinical Research and Trial Preparation Sites in Endemic Areas" submitted by Noguchi Memorial Institute (Legon, Ghana) in collaboration with Naval Medical Research Institute (Rockville, MD)

Uganda

- Tuberculosis Research Unit
  (Makere University (Kampala, Uganda) and Case Western Reserve University)
- Pending: : Application for RFP "Malaria: Clinical Research and Trial Preparation Sites in Endemic Areas" submitted by Makere University (Kampala, Uganda), Kenya Medical Research Institute (KEMRI), Nairobi, Kenya, International Center for Insect Physiology and Ecology (ICIPE), Nairobi, Kenya, and Case Western Reserve University

South Africa

- Cooperative Agreement on "Natural Immunity to *Entamoeba histolytica*"
  (University of Durban and University of Minnesota)
- Investigator-initiated collaborations on "Correlates of Protective Immunity in Tuberculosis" (Groote Schuur Hospital (Capetown), National Institute for Medical Research (Mill Hill, London, UK), and Rockefeller University (New York))

Botswana

- No current activities

Senegal

- No current activities

Tuberculosis

- Tuberculosis Research Unit at Makere University (in collaboration with Case Western Reserve University)

Epidemiology Projects

- Household Contact Study: the primary focus is to develop a systematic approach toward understanding the epidemiology of pulmonary tuberculosis in Uganda where there is a high prevalence of disease.

- Immunology of Childhood Tuberculosis: goal is to understand the effect of active helminth infection on protective immune responses to *M. tuberculosis* infection in children.

- BCG Vaccine Study: examining the adult immune response following BCG vaccination

Immunology Project

- Immunology Pilot study: a longitudinal study to evaluate the potential mechanisms involved in depressed immune response during active tuberculosis. The goal of this work is to identify immunological surrogates of susceptibility or resistance to active tuberculosis.

Clinical Trials Projects:

- *M. vaccae*: A clinical study (nearing completion) examining the safety of heat-killed *Mycobacterium vaccae* as an immunotherapeutic agent against adult pulmonary tuberculosis.

- Microbiology Pilot Study: An ongoing pilot study to evaluate the role of newly developed microbiologic and molecular assays to quantify the rate of bacillary killing and response to standard short course anti-TB chemotherapy in both HIV+ and HIV- adults.

- IL-2: a clinical trial to evaluate the safety, antimicrobial and immunologic activity of supplementing standard anti-tuberculosis chemotherapy with recombinant human IL-2 therapy in adults with pulmonary tuberculosis.

HIV/AIDS:

- Phase I HIV vaccine trial evaluating the Pasteur Merieux Connaught ALVAC vectored vaccine will be starting in early May at the Joint Center for AIDS Research (in collaboration with Case Western Reserve University)

- Two phase III clinical trials of interventions to prevent perinatal transmission of HIV are under way at Mulago Hospital (in collaboration with Johns Hopkins University). One trial is evaluating a new antiretroviral drug nevirapine and the other trial is evaluating HIVIG made from Ugandan plasma.

- A large, community based trial in the Rakai District to evaluate mass treatment of sexually transmitted diseases to decrease susceptibility to HIV infection

- A study to evaluate the acceptability of and participation of stable couples in group counseling to promote condom use for the prevention HIV transmission when one of couples is infected with HIV.

- A series of studies on the treatment and prophylaxis of TB in HIV infected persons.

Botswana

None

Ghana

N01AI75317	STACPOOLE, PETER	EVALUATION OF DCA AS ADJUNCT THERAPY -PROJECT NUMBER..

Senegal

R01AI37466	KIVIAT, NANCY	EPIDEMIOLOGY OF HIV-1 & HIV-2 IN THE -PROJECT NUMBER..
R01AI40898	SCHWARTZ, DAVID H	RESISTANCE TO HIV1 IN VITRO -PROJECT NUMBER..

South Africa

U01AI35840	RAVDIN, JONATHAN I	NATURAL IMMUNITY TO ENTAMOEBA HISTOLY -PROJECT NUMBER..

Rwanda

R01AI23980	ALLEN, SUSAN A	HETEROSEXUAL TRANSMISSION AND THE NAT -PROJECT NUMBER..
R01AI40951	ALLEN, SUSAN A	HETEROSEXUAL TRANSMISSION AND THE NAT -PROJECT NUMBER..

Uganda

R01AI32414	WHALEN, CHRISTOPHER	IMPACT OF TUBERCULOSIS ON HIV INFECTI -PROJECT NUMBER..
R01AI34826	WAWER, MARIA J	SEXUALLY TRANSMITTED DISEASE CONTROL -PROJECT NUMBER..
R01AI39445	JANOFF, EDWARD N	PNEUMOCOCCAL INFECTION AND PROGRESSIO -PROJECT NUMBER..
R01AI40019	LOUIE, LESLIE G	GENETIC CONTRIBUTION OF HOST AND PATH -PROJECT NUMBER..
Z01AI00361	QUINN, T C	INTERNATIONAL STUDIES ON THE ACQUIRED -PROJECT NUMBER..

NIH COMMITMENT TO INTERNATIONAL AIDS RESEARCH

The National Institutes of Health (NIH) represents the largest single public investment in AIDS research in the world. It supports a comprehensive program of basic, clinical, and behavioral research on HIV infection and its associated opportunistic infections and malignancies.

Half of the total NIH AIDS research budget supports basic research that benefits all HIV-infected individuals and those at risk in all parts of the world. Of the remaining half, NIH conducts and supports AIDS research that has important specific international benefits. NIH also supports research that is taking place in international research sites.

NIH will significantly increase the investments in this area in FY 99. The major areas of the NIH AIDS research program of benefit to the international community include:

- Vaccine Research
- Prevention and Treatment of Opportunistic Infections, including Tuberculosis
- Development of Topical Microbicides
- A New Prevention Trials Network
- Prevention and Treatment of HIV Infection in Children
- Training of Foreign Scientists

VACCINE RESEARCH:

FY 98 (est.) - $153 million
FY 99 (est.) - $200 million
This represents a 100% increase since FY 1995.

The President has made the discovery of an AIDS vaccine a national research priority. A safe and effective vaccine is the critical missing element in our armamentarium for the prevention of HIV and ultimate control of the pandemic, and remains one of the highest research priorities. NIH has also pledged to work with other G-8 nations on vaccine research efforts. The toll of the epidemic in poorer countries where therapeutic and prevention interventions are unavailable or unaffordable, as well as in industrialized parts of the world, dictates the important emphasis on vaccine development. In recognition of the need to develop vaccines that are efficacious against a variety of strains found around the world, NIH supports studies analyzing genetic and antigenic variation of HIV and targeted toward eliciting cross-reactive immune responses. The changes that have been implemented in this area over the past few years have enormous potential significance, not only for AIDS but for other diseases as well, as progress made in the development of an AIDS vaccine will certainly have implications for vaccines against other life-threatening illnesses.

Vaccine Clinical Trials

The NIH AIDS Vaccine Evaluation Group, consisting of 6 U.S. sites, is evaluating potential HIV vaccines in phase I and II clinical trials. To date, more than 46 trials with 24 different vaccine candidates and adjuvants have been conducted. In preparation for Phase III trials, NIH supports a domestic and international network of sites that are currently identifying the cohorts of populations at risk for HIV infection and building the infrastructure necessary to conduct large-

scale efficacy trials of potential HIV vaccine candidates when they become available. These efforts involve strengthening in-country research capacity. NIH collaborates with UNAIDS, host country governments, and in-country scientists in vaccine development and preparation for efficacy trials. Sites have been established in Uganda, South Africa, Haiti, Malawi, Thailand, India, Zimbabwe, Zambia, Trinidad and Tobago, Brazil, and Kenya.

New FY99 Initiative: NIH has issued a new Request for Applications for the HIV Vaccine Trials Network Leadership Group. This group will serve as the executive core to lead the vaccine clinical trial effort to set the scientific agenda for future vaccine clinical trials worldwide. The next step will be the issuance of a second RFA shortly that will solicit investigators to conduct the trials in both domestic and international sites. (Funds for this are included in the overall Vaccine increase.)

PREVENTION AND TREATMENT OF OPPORTUNISTIC INFECTIONS, INCLUDING TUBERCULOSIS

FY 98 est. - $75 million
FY 99 est. - $85 million

Tuberculosis (TB) represents the most common human infection in the world and is the attributable cause of one-third of all adult deaths in developing nations. HIV infection confer the greatest known risk for the development of TB, both the reactivation of latent infection and progression to primary disease, and UNAIDS estimates that approximately 30% of all AIDS deaths result directly from tuberculosis. Particularly ominous is the emergence of multidrug resistance. In collaboration with the government of Uganda and the Centers for Disease Control and Prevention, NIH has made significant progress toward practical and affordable prevention measures to reduce the burden of tuberculosis. NIH-supported scientists in Thailand are studying risk factors for infection with *Penicillium marneffei*, a newly-described fungal infection that is the major OI in Thailand and potentially in other Asian nations.

MICROBICIDE RESEARCH

FY 98 est. - $23 million
FY 99 est. - $27 million

The development of safe, effective and acceptable topical microbicides is a global need to protect women around the world from sexual transmission of HIV infection. NIH sponsors a comprehensive biomedical and behavioral program for the discovery, development, preclinical testing, and clinical evaluation of topical microbicides and other female-controlled barrier methods for prevention of HIV transmission. NIH plans to expand the Topical Microbicide Program Projects involving multidisciplinary research to develop and test new agents and will expand contracts and grants for developing and testing spermicidal and non-spermicidal microbicides and other female-controlled barrier methods.

PREVENTION TRIALS NETWORK
FY 99 est. - $20 million

NIH sponsors an extensive biomedical and behavioral program for the discovery, development, preclinical testing, and clinical evaluation of interventions to prevent HIV transmission, slow disease progression, and limit disease mortality. These intervention programs include the development of topical microbicides and other barrier methods, behavioral interventions, strategies to reduce perinatal transmission, adherence and compliance to treatment regimens, and prevention of sexually transmitted diseases. A new initiative will begin in FY 1999. NIH has issued an RFA for a new Prevention Trials Network. This network is designed to conduct research on promising and innovative biomedical/behavioral strategies for the prevention or reduction of HIV transmission among at risk adult and infant populations. The research will include: (1) evaluation of a broad range of interventions designed to reduce adult and perinatal transmission of HIV; and (2) basic laboratory studies which address viral and host factors related to risk of transmission, mechanisms of transmission and/or modes of action of successful prevention strategies; and (3) testing of microbicides. The next phase will be to solicit investigators to compete for sites in this network.

PREVENTION AND TREATMENT OF HIV INFECTION IN CHILDREN
FY 98 est. - $18 million
FY 99 est. - $20 million

Preventing transmission from HIV-infected mother to child is a priority of NIH intervention research. Initiation of treatment with zidovudine prior to birth, during delivery, and to the infant has significantly reduced the incidence of maternal-fetal HIV transmission in the United States. However, this protocol is not easily applied in developing countries because of cost factors and lack of health care infrastructure. Simpler and less expensive antiretroviral regimens for interruption of vertical transmission are being tested by NIH. To reduce transmission further, NIH research is pursuing studies to better understand the timing, mechanisms, and risk factors of perinatal transmission; whether specific strains are more likely transmitted; the potential benefit of Caesarean section; risk factors associated with breast feeding; and the role of co-infection and other factors. New initiatives in this area will be pursued in a variety of programs, including the new Prevention Trials Network.

TRAINING OF FOREIGN SCIENTISTS
FY 98 est. - $ 10 million
FY 99 est. - $ 12 million

It is critical to the success of international studies that foreign scientists be full and equal partners in the design and conduct of collaborative studies and that they have full responsibility for the conduct of studies in-country. To help build capacity in developing countries, the NIH funds the AIDS International Training and Research Program (AITRP). The AITRP provides research training to foreign scientists through grants to U.S. universities. The program has provided training in the U.S. for more than 1400 scientists from developing countries in Africa, Asia, and Latin America, and over 600 training courses have been conducted in 60 countries. NIH will increase the number of trainees and sites in FY 99.

RESEARCH CONDUCTED IN INTERNATIONAL SITES

It is important to point out that included in the total investment in international AIDS research, more than $62 million in FY 99 is estimated to be research that will be conducted in international sites and involving foreign scientists.

w/Todd's Comments in Red

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Statement of
Anthony S. Fauci, M.D.
Director
National Institute of Allergy and Infectious Diseases
National Institutes of Health

Field Hearing on AIDS
Senate Appropriations Committee
Subcommittee on Labor, HHS, and Education

The Honorable Arlen Specter, Chairman

San Francisco, California

July 9, 1999

I am pleased to appear before you today to discuss the human immunodeficiency virus (HIV) epidemic, recent developments in HIV research, and the many challenges that remain in the fight against HIV and the acquired immunodeficiency syndrome (AIDS).

The Scope of the Epidemic

AIDS was recognized eighteen years ago this summer, and continues to exact an enormous toll here and throughout the world, in both human and economic terms. In the United States, an estimated 650,000 to 900,000 people are living with HIV, more than 200,000 of whom are unaware of their infection. In this country, 688,200 cumulative cases of AIDS and 410,800 AIDS-related deaths were reported to the Centers for Disease Control and Prevention (CDC) through 1998.

Despite an encouraging downturn in the overall number of new AIDS cases and AIDS-related deaths in the United States during the past three years, the rate of new HIV infections in this country – approximately 40,000 per year – continues at an unacceptably high level. Of these newly infected individuals, the CDC estimates that half are people younger than 25 who were infected sexually.

Unlike the early days of the HIV/AIDS epidemic in this country, the virus now affects minority populations disproportionately. The rates of AIDS cases (per 100,000 population) reported in 1998 in the United States were 66.4 for African-Americans, 28.1 for Hispanics, 8.2 for Whites, 7.4 for American Indians/Alaska Natives and 3.8 for Asian/Pacific Islanders. Women are increasingly affected: the proportion of U.S. AIDS cases reported among adult and adolescent females more than tripled from 1985 to 1998, from 7 percent to 23 percent.

In the developing world, the HIV/AIDS epidemic continues to accelerate, notably in sub-Saharan Africa, southeast Asia and on the Indian sub-continent. There are also signs of burgeoning epidemics in Russia and the Former Soviet Union nations. As of the end of 1998,

more than 33 million people worldwide were living with HIV/AIDS, 43 percent of them female, according to estimates by the Joint United Nations Programme on HIV/AIDS (UNAIDS). An estimated 5.8 million new HIV infections occurred worldwide during 1998 – approximately 16,000 new infections each day. More than 95 percent of these new infections occurred in developing countries. In 1998, HIV/AIDS was the fourth leading cause of mortality worldwide, resulting in an estimated 2.3 million deaths.

Beyond the human tragedy of HIV/AIDS, the economic costs of the epidemic are staggering, posing a significant impediment to the growth and stability of many countries. A 1999 WHO publication **Removing Obstacles to Healthy Development** estimates the annual economic burden of HIV to be $14 billion in prevention and health care costs alone. In many countries, the epidemic is decimating a limited pool of skilled workers and managers, and will likely wipe out gains in development by slashing life expectancy. According to UNAIDS, life expectancy in the nine countries in Africa with the highest HIV prevalence rates will fall, on average, 17 years by 2015.

HHS Spending on HIV/AIDS

Clearly, HIV remains one of the greatest threats to global health, and requires a sustained commitment by the many partners in AIDS research and prevention, including federal, state and local health agencies, foreign governments, UNAIDS, the World Bank, non-governmental and philanthropic organizations, academia, industry, and the activist community. In this regard, overall funding for AIDS-related programs within the U.S. Department of Health and Human Services (HHS) has increased by 122 percent under the current Administration. The FY 2000 President's Budget includes $8.2 billion in total HIV/AIDS funding within HHS.

The Ryan White CARE Act, which helps states and highly impacted communities provide primary and supportive services to people living with HIV and AIDS, was funded at over $1.4 billion in Fiscal Year 1999. President Clinton has proposed an increase of approximately $100

million for FY2000 in recognition of the critical role that the CARE Act continues to play in helping people access and maintain themselves in care.

_____At the National Institutes of Health (NIH), HIV/AIDS funding increased 67.5 percent from FY 1993 to FY 1999; the FY 2000 President's budget includes $1.834 billion in HIV/AIDS research funding at the NIH.

The Success – and Limitations -- of Antiretroviral Therapy

In the United States and other developed countries, new AIDS diagnoses and deaths have fallen significantly during the past three years. In the United States, the age-adjusted death rate from AIDS declined 47 percent from 1996 to 1997, according to the National Center for Health Statistics; similar decreases have been noted in western Europe and Australia. These trends are probably due to several factors, particularly the increased use of potent, albeit expensive anti-HIV drugs, generally administered in combinations of three or more agents. Such combinations are known as "highly active antiretroviral therapy" or HAART. Sixteen anti-HIV drugs are now licensed by the Food and Drug Administration, 10 of which are approved for pediatric use.

Consensus guidelines have been developed for the use of HAART in adults and adolescents; separate treatment guidelines have been formulated for pediatric patients, as well as for the use of antiretroviral drugs in HIV-infected pregnant women. These guidelines are regularly updated on the World Wide Web (see http://www.hivatis.org) and when appropriately applied have greatly improved the prognosis for HIV-infected individuals and markedly reduced the risk of HIV transmission from mother to baby.

Unfortunately, many HIV-infected individuals have not responded adequately to current medications, cannot tolerate their toxicities, or have difficulty complying with treatment regimens that involve extremely complicated and demanding dosing schedules, large numbers of pills, and myriad interactions with other drugs and foods. This can be particularly difficult for those who are

struggling to maintain the basic necessities of life like housing and food, which are the very people in the path of this epidemic.

_____Even in patients who are successfully treated with HAART and have extremely low bloodstream levels of HIV, the virus persists in sanctuaries where the drugs cannot reach it or in a latent form upon which drugs have no effect. In addition, the emergence of HIV strains resistant to current drugs is a ~~widespread and~~ growing problem. Although there is evidence of immune system reconstitution in certain patients who receive combination antiretroviral therapy, the goals of completely "rebuilding" the immune system or eradicating the virus from its hiding places in the body appear unlikely with current approaches to treatment.

Therefore, the development of a next generation of therapies remains a priority. Currently, all licensed antiretroviral medications are directed at one of two viral enzymes, reverse transcriptase or protease. Many new drug targets and novel treatment strategies are now being pursued, including drugs that prevent the virus from entering a cell, approaches to "purging" the virus from its hiding places in certain cells and tissues, and methods to boost an infected person's immune response.

The Critical Role of HIV Prevention

In developing countries where *per capita* health care spending may be only a few dollars a year, anti-HIV therapies are frequently beyond the reach of all but the privileged few, underscoring the urgent need for effective, low-cost tools of HIV prevention that can be used in these settings as well as in the United States.

Researchers have shown that several approaches to HIV prevention can reduce the number of new infections when properly executed, including education and behavior modification, the social marketing and provision of condoms, treatment of other sexually transmitted diseases, drug abuse treatment (for example, methadone maintenance for injection drug users), and the use of antiretroviral drugs to interrupt the transmission of virus from mother to infant.

For example, in one of the true "success stories" of HIV research, the rate of mother-to-child transmission of HIV in the United States has been cut to negligible levels among women and infants treated with an extended regimen of AZT therapy developed by NIH-supported investigators. Subsequent studies by CDC, NIH and others have shown that substantially shorter regimens of antiretroviral drugs, which would be more feasible in resource-poor settings, can also reduce perinatal HIV transmission significantly.

Other methods of preventing HIV transmission may also help slow the HIV/AIDS epidemic. For example, researchers are developing and testing topical microbicides, substances that a woman could use in her vagina before sex to prevent the transmission of HIV and other sexually transmitted diseases. UNAIDS and others also have facilitated the widespread use in Africa of the female condom. These interventions may help empower women to protect themselves in situations where they are unable to avoid sex with HIV-infected partners, and/or cannot persuade their partners to use a condom.

HIV Vaccine Development

Historically, vaccines have provided safe, cost-effective and efficient means of preventing illness, disability and death from infectious diseases. The development of a safe and effective vaccine for HIV infection remains the "holy grail" of AIDS research, and a necessary tool to bringing the HIV epidemic under control. To speed the pace of HIV vaccine discovery, many public and private agencies have dramatically increased the resources devoted to HIV vaccine research. For example, at the NIH, HIV vaccine funding rose from $100.5 million in FY 95 to an estimated $194.1 million in FY 1999. As part of this expanded effort, NIH has awarded numerous grants to foster innovative research on HIV vaccines and to conduct clinical trials of candidate HIV vaccines. To date, more than 3,000 non-infected volunteers have enrolled in more than 50 NIH-supported HIV vaccine studies (including two "phase II" intermediate-sized trials), involving 27 vaccines. In addition, NIH has established the Dale and Betty Bumpers

Vaccine Research Center within the NIH intramural research program to stimulate multidisciplinary vaccine research.

As part of a broad portfolio of research, recent NIH-supported studies have assessed so-called "vectored vaccines": harmless viruses (e.g. canarypox) which are genetically altered to make HIV proteins. These vaccines have been administered to volunteers in combination with a separate vaccine made of a purified HIV protein. Results have been encouraging: in phase I and phase II studies, the combination approach has appeared safe and evoked several types of immune responses that may have a role in protection from HIV. NIH-funded researchers are now comparing three different vectors, as well as other HIV proteins to determine which combination produces the most vigorous immune response.

Meanwhile, a large-scale study of a vaccine based on the surface proteins of two HIV strains was recently undertaken in the United States by a private company, with an additional phase III study to be conducted in collaboration with CDC in Thailand. NIH will collaborate with the company in evaluating the immunological responses to the vaccine.

Conclusion

As we work to contain the global HIV/AIDS epidemic, it is essential to sustain and enhance our commitment to HIV prevention, to caring for HIV-infected people, to developing the next generation of HIV therapies and prevention tools, and to producing a safe and effective HIV vaccine. Though we have been battling against AIDS for nearly 20 years, we are in no position to let down our guard. On the contrary, if we are ever to hope for a day without AIDS, we will need to sustain and increase our efforts both here in the United States and across the globe.

###

LABORATORY OF MEDICINAL CHEMISTRY
NIDDK, NATIONAL INSTITUTES OF HEALTH
BUILDING 8, ROOM B1-22
BETHESDA, MARYLAND 20892 (USA)

TELEFAX TRANSMISSION COVER SHEET

IF THIS TRANSMISSION IS NOT WELL RECEIVED
PLEASE CALL (301)-496-8099 or 496-1335

DATE: 7-30-99

TO: Ms. Thurman / Cheryl

TELEFAX NUMBER: _____

TELEPHONE CONTACT NUMBER: 202 456 2437

NUMBER OF PAGES TRANSMITTED: 1
(INCLUDING THIS COVER PAGE)

FROM: Keith Crawford, Ph.D.

TELEFAX NUMBER: 301-402-0589

TELEPHONE NUMBER: 301-435-1926

Message:

Dear Ms. Thurman,

My name is Dr. Keith Crawford and I am working with Dr. Rosalyn King, Director of International Programs, Howard University School of Continuing Education. On a recent visit to Ghana, you met with Ms. Clavenda Bright-Parker, President of the West African Pharmaceutical Assn. at the African-African-American Summit. We were eager to begin our HIV intervention program in West Africa but were recently notified that budget reorganization in the United Nations Development Program may jeopardize our initiative. Dr. King and I would like to schedule a meeting to follow up on your discussions with Ms. Bright-Parker and other related issues. Dr. King can be contacted at 301-585-2295, or you can reach me at 301-435-1926 (keithc@intra.niddk.nih.gov). We look forward to continuing our dialogue,

INFORMATION REPORT

Document No. 413730

WHITE HOUSE STAFFING MEMORANDUM

Date: 4/3/00 ACTION / CONCURRENCE / COMMENT DUE BY: ---

Subject: Annual Report on the National Institutes of Health (NIH) AIDS Research Loan Repayment Program (LRP) for FY 1999.

	ACTION	FYI		ACTION	FYI
VICE PRESIDENT	☐	☐	LOCKHART	☐	☐
PODESTA	☐	☐	LEWIS	☐	☐
ECHAVESTE	☐	☐	MARSHALL	☐	☐
RICCHETTI	☐	☐	MOORE	☐	☐
LEW	☐	☐	NASH	☐	☐
BAILY	☐	☐	NOLAN	☐	☐
BERGER	☐	☐	REED	☑	☐
BLUMENTHAL	☐	☐	SPERLING	☐	☐
BRAIN	☐	☐	STREETT	☐	☐
BURSON	☐	☐	TRAMONTANO	☐	☐
CAHILL	☐	☐	UCELLI	☐	☐
EDMONDS	☐	☐	VERVEER	☐	☐
FRAMPTON	☐	☐	_____	☐	☐
IBARRA	☐	☐	_____	☐	☐
JOHNSON, B.	☐	☐	_____	☐	☐
JOHNSON, J.	☐	☐	_____	☐	☐
LANE	☐	☐	_____	☐	☐

REMARKS: Please return this report to the Staff Secretary's Office after review. If you would like a copy of this report to keep, please contact this office. Thank you.

RESPONSE:

THE WHITE HOUSE
CORRESPONDENCE TRACKING WORKSHEET

ID# 413730
OA 3 AM 11:13
PAGE

DATE RECEIVED: 03/21/2000

NAME OF CORRESPONDENT: THE HONORABLE DONNA E. SHALALA

SUBJECT: ENCLOSES THE ANNUAL REPORT ON THE NATIONAL INSTITUTES OF HEALTH (NIH) AIDS RESEARCH LOAN REPAYMENT PROGRAM (LRP) FOR FY 1999

ROUTE TO: OFFICE/AGENCY	(STAFF NAME)	ACTION CODE	ACTION DATE YY/MM/DD	TYPE RESP	C D	DISPOSITION COMPLETED YY/MM/DD
EXECUTIVE CLERK	TIM SAUNDERS	ORG	2000/03/21		C	2000/3/31

ACTION COMMENTS Not for President's transmittal to the Congress

Sean Maloney	A	2000/3/31				/ /

ACTION COMMENTS:

		/ /				/ /

ACTION COMMENTS:

		/ /				/ /

ACTION COMMENTS:

COMMENTS ENCLOSURE

ADDITIONAL CORRESPONDENTS: 0 **MEDIA:** LETTER **INDIVIDUAL CODES:**

REPORT CODES: **USER CODES:**

ACTION CODES:
A - APPROPRIATE ACTION
C - COMMENT/RECOMMENDETION
D - DRAFT RESPONSE
F - FURNISH FACT SHEET
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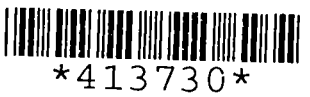
CODE = A
COMPLETED = DATE OF OUTGOING

REFER QUESTIONS AND ROUTING UPDATES TO RECORDS MANAGEMENT (ROOM 72, OEOB) EXT-62590
KEEP THIS WORKSHEET ATTACHED TO THE ORIGINAL INCOMING LETTER AT ALL TIMES AND SEND COMPLETED RECORD TO RECORDS MANAGEMENT.



OFFICE OF THE EXECUTIVE CLERK

CORRESPONDENT: Donna Shalala

Secretary

AGENCY: H. H. S.

DATE OF INCOMING: 3/15/00

ROUTE TO: Tim Saunders

B-413684

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

MAR 15 2000

The President
The White House
Washington, D.C. 20500

Dear Mr. President:

The enclosed Annual Report on the National Institutes of Health (NIH) AIDS Research Loan Repayment Program (LRP) for FY 1999 is submitted pursuant to the requirements of § 487A(b) and § 338B(i) of the Public Health Service Act, as amended (42 USC 288-1(b) and 42 USC 2541-1(i)). This report relates the various activities and accomplishments, actual and projected, of the NIH AIDS Research LRP.

This report was prepared by the National Institutes of Health, Public Health Service.

Sincerely,

Donna E. Shalala

Enclosure

Annual Report to Congress
Fiscal Year 1999

NATIONAL INSTITUTES OF HEALTH
AIDS RESEARCH LOAN REPAYMENT PROGRAM

U.S. Department of Health and Human Services
National Institutes of Health
Office of the Director
Office of Intramural Research
Office of Loan Repayment and Scholarship

PREFACE

Section 338B(i) of the Public Health Service (PHS) Act, as amended, requires an annual report on the National Health Service Corps (NHSC) Loan Repayment Program. Section 487A of the PHS Act authorizes the establishment of a loan repayment program for employees at the National Institutes of Health (NIH) who are engaged in research on acquired immunodeficiency syndrome (AIDS). Section 487A(b) incorporates those provisions of § 338B of the PHS Act that do not conflict with the provisions of the NIH AIDS Research LRP, and thus, an annual report is required for the NIH AIDS Research LRP.

NATIONAL INSTITUTES OF HEALTH
AIDS RESEARCH LOAN REPAYMENT PROGRAM

INTRODUCTION

This Annual Report to the Congress on the NIH AIDS Research Loan Repayment Program (LRP) describes program activities for Fiscal Year 1999, the tenth year under which awards for the LRP have been made.

Report Requirement

Section 338B(i) of the Public Health Service (PHS) Act, as amended, requires the Secretary of Health and Human Services (HHS) to submit to Congress, no later than March 1 of each year, an annual report on the National Health Service Corps LRP, including in such report, with respect to the previous fiscal year, the following:

1. The total amount of loan payments made under the LRP in the year upon which reported;

2. The number and type of health profession training of individuals receiving loan payments under the LRP;

3. The number of applications filed under the LRP;

4. The educational institutions at which such individuals have received their training;

5. The total amount of the indebtedness of such individuals for educational loans as of the date on which the individuals become participants in the LRP;

6. The number of years of obligated service specified in the initial contract;

7. The number and type of health professions that have breached the contract; and

8. The effectiveness of the Secretary in recruiting health professionals to participate in the LRP.

Section 487A of the PHS Act authorizes the establishment of the NIH AIDS Research Loan Repayment Program. Section 487A(b) of the PHS Act incorporates the reporting and administrative requirements found in § 338B(i), as amended.

Legislative Authority

Public Law 100-607, enacted November 4, 1988, requires the Secretary of HHS, not later than one year after the date of the enactment of the Health Professions Reauthorization Act of 1988, to establish and implement a program of loan repayments for appropriately qualified health professionals, who, by contractual obligation, agree to engage in research with respect to AIDS as employees of the NIH. Public Law 103-43, June 10, 1993, reauthorized the NIH AIDS Research LRP. Public Law 105-392 of November 13, 1998, amended § 487A of the PHS Act by increasing the yearly loan repayment authority to $35,000.

NIH AIDS Research LRP Activities

A Notice announcing the implementation of the NIH AIDS Research LRP appeared in the November 8, 1989, issue of the Federal Register. The Office of Management and Budget granted the LRP clearance #0925-0361, with an approval through November 30, 2001.

The NIH AIDS Research LRP provides, for each year of participants' full service, loan repayments to participants' lenders of up to $35,000 a year. These participants are NIH physicians or scientists who are engaged in qualified AIDS research.

The NIH AIDS Research LRP received applications from candidates with the following specialties: anatomy, biochemistry, biology, biomedical science, cell biology, epidemiology, internal medicine, medicine, metabolism, neurology, and pediatrics.

The application packages were reviewed by the National Institutes of Health Loan Repayment Committee (LRC). The LRC is composed of senior scientists from the intramural and extramural research staff, who are appointed by the Director, NIH. In FY 1999, the LRC convened in September. In addition to considering policy questions, the LRC reviewed 11 AIDS Research LRP application packages.

The LRC, in reviewing the application packages, considered the appropriateness of the research assignment with respect to AIDS, the scientific merit of the assignment, and the credentials of the applicant.

The LRC approved all of the 11 IC-endorsed applicants in FY 1999. Obligations of $863,645 were made in FY 1999.

These 11 individuals are serving under contracts to conduct AIDS research at the following Institutes and Centers (ICs) of the NIH:

National Institute of Allergy and Infectious Diseases (NIAID) - $475,191; National Cancer Institute (NCI) - $104,250; and Clinical Center (CC) - $97,300. The 11 researchers include 5 initial two-year contracts and 6 one-year renewal contracts. The NIH AIDS Research LRP also obligated $95,311 for additional Federal, State and local taxes incurred by participants as a result of their loan repayments and $91,593 for increased loan repayment benefits, as authorized in Public Law 105-392.

Awards were made to 5 health professionals entering into initial, two-year service contracts at the following ICs: NIAID (3); NCI (1); and CC (1). One-year, continuation contracts were granted to 6 participants conducting research at the following ICs: NIAID (5) and NCI (1).

The NIH AIDS Research LRP makes payments directly to participants' lenders. In FY 1999, $552,758 was obligated for direct loan repayments to lenders. Loan repayments are disbursed quarterly until the end of the contract period. These payments to lenders represent taxable income to LRP participants. This income is reported to the Internal Revenue Service (IRS) and results in an increase in participants' Federal, State, and local tax liabilities.

The NIH AIDS Research LRP, for the purpose of providing reimbursements for Federal tax liability resulting from loan repayments, makes payments directly to a participant's IRS account in an amount equal to 39 percent of the total amount of loan repayments made for the taxable year involved. The NIH AIDS Research LRP also may make payments to participants for additional Federal, State and local tax liabilities resulting from loan repayment benefits. Thus, in FY 1999, the NIH AIDS Research LRP obligated $310,887 to cover tax reimbursements to be disbursed for qualified participants during FYs 1999 and 2000.

NATIONAL INSTITUTES OF HEALTH
AIDS RESEARCH LOAN REPAYMENT PROGRAM

ACTIVITIES FOR FISCAL YEAR 1999

1. The total amount of loan payments made under the Loan Repayment Program

2. The number and type of health profession training of individuals receiving loan payments under the Loan Repayment Program

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National Institutes of Health
AIDS Research Loan Repayment Program

Obligations Made Toward Qualified Loans
Fiscal Year 1999

Professional Degree(s)	Number	Loan Payments	Tax Reimbursements
M.D.	8	$313,319	$122,195
Ph.D.	1	68,545	26,732
M.D., M.P.H.	1	70,000	27,300
Ph.D., D.O.	1	35,000	13,650
			95,311[1]
		65,894[2]	25,699[2]
	11	**$552,758**	**$310,887**

[1]The NIH AIDS Research LRP also made obligations for Federal, State and local tax reimbursements of $95,311 in FY 1999.

[2]The NIH AIDS Research LRP also made obligations of $91,593 for increased loan repayment benefits, as authorized in Public Law 105-392.

3. The number of applications filed and the health disciplines represented of individuals receiving loan repayments - the number count below includes participants with multiple health disciplines. There were 11 applications filed in FY 1999 that were approved for loan repayments. These participants represent the following health disciplines:

Internal Medicine	5	Anatomy	1
Biochemistry	1	Cell Biology	1
Pediatrics	1	Metabolism	1
Analytical Chemistry	1	Epidemiology	1
Biology	1	Biomedical Sciences	1

4. The educational institutions at which such individuals received their training - the participants in the NIH AIDS Research LRP received their professional degrees at the following institutions:

Doctor of Medicine (M.D.) -

George Washington University
Georgetown University (2)
Mount Sinai School of Medicine
Rush Medical College
University of Chicago
University of Miami
University of Washington, Seattle
Wayne State University

Doctor of Philosophy (Ph.D.) -

Morehouse School of Medicine
University of Oregon

Master of Public Health (M.P.H.) -

Columbia University

Doctor of Osteopathy (D.O.) -

University of New England

5. The total amount of indebtedness for educational loans for the applicants accepted into the NIH AIDS Research LRP in FY 1999 equals $861,258.

6. Initial contracts were executed for 5 health professionals to cover a minimum of two years of obligated service and for 6 health professionals to cover one year of obligated service. To date, 109 individuals have completed the minimum two-year service period, 42 individuals have completed service periods of three years, 12 individuals have completed service periods of four years, 2 individuals have completed five years of service, and 1 individual has completed six years of service.

7. No individuals have breached their contractual obligations.

8. The NIH AIDS Research LRP is designed to counter the growing economic disincentives to embark on research careers and to provide an incentive to engage in AIDS research as employees of the NIH. The NIH AIDS Research LRP has been publicized through the Academic Research Information System, Biomedical Science Report, The Journal of the Student National Medical Association, Journal of AIDS, Science Magazine, and The New Physician, and at the following scientific meetings and symposia: the All Nations Alliance for Minority Participation Research Conference; the American Federation for Clinical Research; the American Medical Student Association; the American Society for Clinical Investigation; the American Federation for Clinical Research; the American Indian Science and Engineering Society; the American Medical Student Association's annual meeting; the American Society for Clinical Investigation; the Association of American Medical Colleges; the Biomedical Sciences Minority Health Professions Foundation; the Boricua Latino Health Organization; the Health Professions Financial Aid Administration Professional Development; the Hispanic Association of Colleges and Universities; the National Association of Advisors for Health Professionals; the National Association of Hispanic Nurses; the National Hispanic Medical Association; the National Medical Association; the National Minority AIDS Council; the National Minority Research Symposium; the Society for the Advancement of Chicanos and Native Americans in Science; and the Student National Medical Association. Some individuals accepted into the NIH AIDS Research LRP would have accepted research training or research positions elsewhere if not for the financial incentives of the loan repayment program. Additionally, some researchers who received loan repayment benefits through renewal contracts otherwise would have left the NIH for other career research opportunities.

Dale and Betty Bumpers
VACCINE RESEARCH CENTER
National Institutes of Health

"Vaccines
For
Life"™

February 2, 2000

Sandra Thurman
Director, Office of National Aids Policy
736 Jackson Place
Washington, D.C. 20503

Dear Sandra,

I wanted to follow up with you regarding the plans for the proposed White House conference on pharmaceutical involvement in vaccine development. As we had discussed, I have worked with Gordon Douglas to draft an outline that may be helpful for the meeting. In particular, the VRC would like to facilitate implementation of ideas that may arise during the meeting. A copy of the outline of these notes is attached. At the suggestion of Douglas Elmendorf, I am also forwarding copies to various members of the Executive office who may be involved in this meeting. Please don't hesitate to contact me if you have any questions.

I also look forward to visiting with you to tour the VRC when it is convenient for you to come to Bethesda.

Best wishes.

Sincerely,

Gary Nabel, M.D., Ph.D.

Cc: Ken Bernard
Laura Ephros
Doug Elmendorf
Chris Jennings

40 Convent Drive, Bethesda, Maryland 20892-3005

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

National Institutes of Health
Vaccine Research Center
40 Convent Drive
Bethesda, Maryland 20892-3005
Telephone (301) 496-1852
FAX (301) 480-0274

February 3, 2000

Some thought on the White House Meeting with pharmaceutical company CEOs and subsequent (follow-up) meeting with VRC:

White House Meeting

Invitees:

1. Large vaccine company CEOs: Merck, Smith Kline-Beecham, American Home Products, Aventis (Rhone-Poulene).
2. Small vaccine company (biotech) CEOs- suggest 3 or 4: Aviron, Chiron, Merrimmune
3. Other large company CEOs (e.g., Glaxo, Wellcome)

Objective:

To enlist the support of pharmaceutical companies to meet a national goal of developing new, safe and effective vaccines for the prevention of HIV/AIDS, TBC, malaria, and other important diseases.

Key Messages for the White House to Deliver:

1. The Administration (government) recognizes the importance of these diseases and their world-wide mortality and morbidity:

HIV/AIDS	3 million
TBC	2 million
Maleria	1.5 million

   (Annual rates from W.H.O. moratlity figures)
2. The Administration recognizes that new vaccines are developed by having a strong basic research program for each of these diseases and also by having the capacity to take several projects into clinical development and continue to completion.
3. The Administration acknowledges that the NIH does a superb job of supporting basic research, and that basic research yields important leads for vaccine development (translational research). This realization comes with the understanding that the FDA effectively assesses the safety and efficacy of new vaccines, while the CDC provides the epidemiological data required for vaccine development.

4. The Administration recognizes that most of the resources needed for development

(facilities, technical expertise, and management experience) reside in the private sector.

5. Therefore, the Administration wishes to enlist the support of the private sector in achieving these goals.

Role of the Private Sector:

1. To encourage major vaccine companies to initiate or intensify existing efforts toward development of vaccines for these important diseases.
2. To enlist other pharmaceutical companies into vaccine development.
3. To encourage small biotechnology companies to begin development of potential vaccines.
4. To foster "hand-offs" (cooperative agreements) between NIH sponsored research and large or small private companies to promote new vaccine development.

Anticipated Industry Response:

1. From the companies already active- we're doing all we can.
2. From those not currently involved- mostly interest, not commitment.
3. If the atmosphere is "open", they may discuss real issues of concern such as: Will there be pricing restraints of some kind? Who is going to keep the vaccine for the developing world? Will the onus be on the companies to donate vaccine or sell at extremely low cost?
4. Discussion of possible interactions and needs:
    a. Direct government funding of vaccine development by private companies.
    b. Direct funding of manufacturing capacity capital.
    c. Purchase of vaccine by third party (Gates Foundation or other Foundations via W.H.O.
    d. Companies will want to know what the "playing field" will look like once a vaccine is licensed and ready to be commercialized.

Outcome:

Follow-up meeting to address specific issues of "hand-off" (cooperative agreements) of vaccine leads discovered by NIH research.

1. Sponsored by VRC.
2. Invite CEOs of vaccine divisions of large companies and CEOs of smaller companies.

Other suggestions:

Invite Bill Gates (Sr.?), because of new role in vaccine funding.

Concerns:

1. Willingness of CEOs to listen because of criticism of drug pricing for Medicare recipients and fears of government price controls.
2. Willingness of Gates to cooperate because of anti-trust judgment.
3. The White House will want to add to the invitee list, but it dilutes, with the exception of some additional foundations and Scientific experts.

Follow-up Meeting

Objective:

To discuss details of "hand-off" leads resulting from NIH sponsored research to private companies for development; to obtain "buy-in" process.

Invitees:

CEOs of small biotech companies and CEOs of vaccine divisions of large companies who attended White House Meeting.

Key Messages from VRC:

1. Process for selecting companies to develop leads:
   2. Bidding
   3. Ensure that development will proceed vigorously by imposing penalties for inaction.
   4. Details of arrangement
   5. Role of direct government funding for research required for manufacturing patent.
6. Overview of VRC research.

Responses From Industry:

1. Willingness to participate.
2. Issues, concerns, potential barriers to success of programs.

Follow-up:

This will depend on the outcome of the meeting; that is if major obstacles or barriers are identified that requires further work, a subsequent meeting may be necessary.

Concerns:

Need to work out details of industry-government partnership so that the meeting can be very specific and real concerns can be identified and addressed.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

D·NIH

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Vaccine Research Center
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Bethesda, Maryland 20814-3005
Telephone (301) 496-1852
FAX (301) 480-0274

November 18, 1999

Sandra L. Thurman
Director
Office of National AIDS Policy
736 Jackson Place
Washington, DC 20503

Dear Sandy,

I am writing to ask if you have any further knowledge about the White House Conference on Vaccines announced by the President earlier this fall. We had discussed the possibility of involving the Vaccine Research Center, possibly with Secretary Shalala, to assist in planning and to ensure follow-up and continuity regarding any plans that might be developed. We have recruited individuals into the center with significant pharmaceutical experience, and we have been discussing formats that might maximize its productivity. I would be delighted to share these ideas with you and to help in the planning of the conference.

On another note, I would like to invite you to visit the NIH campus at your convenience for a hard-hat tour of the Vaccine Research Center. We might also use the occasion to talk about the status of our recruiting efforts and future plans and concerns. I look forward to hearing from you and I hope that you are otherwise well. Best wishes.

Sincerely,

Gary Nabel, M.D., PhD
Director, Vaccine Research Center

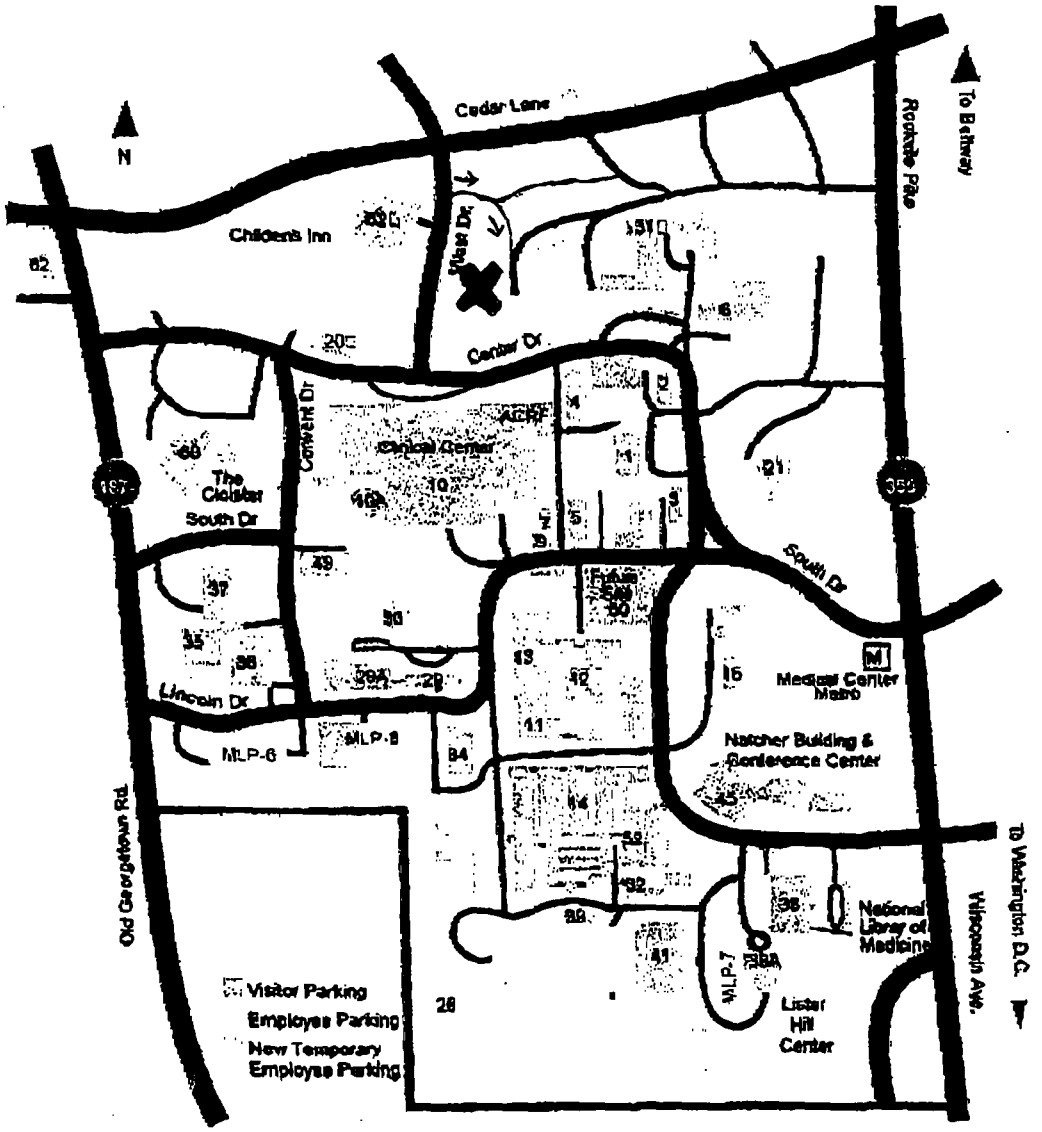
TODD

202 456-2438

Office of Research Services

NIH Campus Parking Map

Use the map key to identify the types of parking, then click on any of the parking areas on the image map below for more information.



National Institutes of Health
Bethesda, MD 20892
For information about this WWW site, please contact ric@nih.gov

Last Updated 05/14/1999 14:17:26

Confirmed (partial attendance in + out)
9/23/99

O-OAR

NATIONAL INSTITUTES OF HEALTH
OFFICE OF AIDS RESEARCH

Neal Nathanson, M.D.
Director

Building 31, Room 4C02
31 Center Drive
MSC 2340
Bethesda, MD 20892
TEL: 301 496 0357
FAX: 301 496 2119

SEP 17 1999

Ms. Sandra Thurman
Director
Office of National AIDS policy
Executive Office of the President
736 Jackson Place, N.W.
Washington, D.C. 20503

Dear Ms. Thurman:

I am pleased to invite you to attend the ninth meeting of the Office of AIDS Research Advisory Council (OARAC) to be held on Thursday and Friday, October 14-15, 1999. The first day of the meeting will be held at the main campus of the National Institutes of Health (NIH) in Building 31C, Sixth Floor, Conference Room 6, beginning at 8:45 a.m. The second day of the meeting will be held at the Doubletree Hotel, 1750 Rockville Pike, Rockville, Maryland on October 15 beginning at 8:45 a.m.

The OARAC will discuss the role of the Federal Government, academia, and industry in AIDS drug discovery and development and clinical evaluation. The tentative agenda is enclosed.

I hope that your schedule will allow you to attend, and I look forward to your participation at the upcoming OARAC meeting. Questions, concerning the meeting may be directed to me or Ms. Linda Reck. Ms. Reck can be reached at (301) 402-8655.

Jack Whitescarver for
Neal Nathanson, M.D.

Enclosure

Office of AIDS Research Advisory Council Meeting

TENTATIVE AGENDA as of 9/14/99

Day One: October 14, 1999

Building 31C, Conference Room 6
National Institutes of Health
Bethesda, MD 20892

Thursday, October 14, 1999 ***Morning Session***

8:45	Welcome and Meeting Overview	*Dr. Charles Carpenter*
	• Approval of Meeting Minutes	
	• Conflict of Interest Statement	*Dr. Neal Nathanson*
9:00	Introduction to Therapeutics Sessions	*Dr. Manuel Navia*
	"What Are the Roles of the Federal Government, Academia, and Industry in AIDS Drug Discovery and Development and Clinical Evaluation?"	
9:15	Drug Discovery:	
	• Report of the Review of NCI's Developmental Therapeutics Program–AIDS Component	*Dr. Jack Edwards*
	▸ NCI/NIAID Implementation Plan	*Drs. Ellen Feigal and Carl Dieffenbach*
	▸ Discussion	*OARAC Discussant: Dr. Manuel Navia*
	• Role of Academia in AIDS Drug Discovery and Development	*Dr. Dennis C. Liotta*
	• Discussion	*OARAC Discussant: Dr. Manuel Navia*
10:45	**BREAK**	
11:00	Future Therapeutic Approaches:	
	• Eradication of HIV by Future Drug Regimens	*Dr. Robert Siliciano*
	• Immune Reconstitution/Immunomodulating Approaches	*Dr. H. Clifford Lane*
	• Therapeutic Immunization Approaches	*Dr. Fred Valentine*
	• Discussion	*OARAC Discussant: Dr. Deborah Cotton*
12:15	**LUNCH**	

Thursday, October 14, 1999 — *Afternoon Session*

1:15 Therapeutics:

• Metabolic Complications Associated with HIV Disease and Its Treatments	*Dr. Kathleen Mulligan*
• An Overview of the Prevalence Study to Define the Fat Distribution and Body Changes Associated with HIV Disease	*Dr. Carl Grunfeld*
• Drug Resistance	*Dr. Scott Hammer*
• Future Directions of Adult AIDS Clinical Trials Group Protocols	*Dr. Constance Benson*

BREAK

• Overview of ACTG/CPCRA Recompetition	*Dr. Jack Killen*
• Discussion	*OARAC Discussants: Drs. Melanie Thompson, Susan Buchbinder, and Michael Lindsay*

4:00 Discussion of Questions to OARAC — *Dr. Manuel Navia*

5:00 **ADJOURN**

Day Two: October 15, 1999

Doubletree Hotel
Rockville, MD 20852

Friday, October 15, 1999 ***Morning Session***

8:30	Review of Agenda	*Dr. Charles Carpenter*
8:45	Discussion of Report of Panel on Scientific Boundaries for Review	*Dr. P. Frederick Sparling* *OARAC Discussant: Dr. Charles Carpenter*
10:15	**BREAK**	
10:30	Report from the Working Group to Review the NIH Perinatal, Pediatric, and Adolescent HIV Research Priorities	*Presenter: Dr. John Modlin* *OARAC Discussant: Dr. Michael Frank*
11:00	Report of the Focal Group Review of the Centers for AIDS Research Program	*Dr. Diane Griffin*
	• NIH Response to Report	*Dr. Neal Nathanson*
11:30	Report from NIAID, DAIDS on the Status of the Prevention Trials Network and Vaccine Trials Network Initiatives	*Dr. Jack Killen* *OARAC Discussants: Drs. Buchbinder and Booth and Mr. Snow*
12:00	Administrative Reports	
	• Report of the OAR Deputy Director	*Dr. Jack Whitescarver*
12:30	**ADJOURN**	

NATIONAL INSTITUTES OF HEALTH
OFFICE OF AIDS RESEARCH

Jack Whitescarver, Ph.D.
Acting Director

Building 2, Room 4E04
Two Center Drive
MSC 0250
Bethesda, MD 20892
TEL: 301 496 0357
FAX: 301 496 2119
E-mail: whitesj@od.nih gov

Dear Colleague:

I am pleased to enclose the *National Institutes of Health Fiscal Year 2002 Plan for HIV-Related Research.* The Plan represents input from hundreds of individuals: NIH Institute Directors; NIH scientists and program staff; representatives of sister agencies; non-Government experts in ethics, research, prevention, and treatment of HIV/AIDS, including participants from academia, foundations and industry; and AIDS community representatives.

The Plan presents research objectives in five Scientific Areas of Emphasis and four Areas of Special Interest that cut across and reinforce the scientific program of the NIH. I would like to call to your attention a new Area of Special Interest within the Plan: International Research. This area highlights research that addresses the global AIDS epidemic in developing countries. In addition, we have continued the Area of Special Interest on Racial and Ethnic Minorities.

Through the Plan, four major themes emerge: international research priorities to address needs in developing countries; research to target the disproportionate impact of AIDS on minority populations in the United States; therapeutic research to treat those who are already infected; and prevention research to reduce HIV transmission in the United States and around the world.

This Plan will shape the NIH investments in biomedical and behavioral research and provide the framework to translate our research findings to benefit populations desperately in need, both here and abroad. It has also been posed on the Internet at www.nih.gov/od/oar.

Sincerely,

Jack Whitescarver

Jack Whitescarver, Ph.D.
Acting Director

Enclosure

Paul G. Hand - carried.

THE WHITE HOUSE

WASHINGTON

MEMORANDUM FOR NEAL NATHANSON, M.D., DIRECTOR, OFFICE OF AIDS RESEARCH, NATIONAL INSTITUTES OF HEALTH

From: Sandra L. Thurman
Director, Office of National AIDS Policy

Date: October 12, 1999

Subject: The Presidential Advisory Council on HIV/AIDS comments on the draft report "Recommendations for Change at the NIH's Center for Scientific Review

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The Presidential Advisory Council on HIV/AIDS met on October 4-5, 1999 at which time the draft report "Recommendations for Change at the NIH's Center for Scientific Review" was discussed. The Council has made recommendations supporting the continuation of the specific HIV/AIDS Integrated Review Group and the HIV/AIDS specific study sections. These comments were submitted to Dr. Ellie Ehrenfeld, Director of the NIH Center for Scientific Review (see attached).

A coordinated research agenda remains critical to our efforts to end the global HIV/AIDS pandemic, and as such I support the recommendations of the Council. I hope that you find the recommendations useful and they are taken into consideration by the NIH. Future updates on the status of this process would be useful and appreciated. Thank you.

PRESIDENTIAL

ADVISORY

COUNCIL ON

HIV/AIDS

October 7, 1999

Memorandum for Dr. Ellie Ehrenfeld, Director, NIH Center for Scientific Review

From: R. Scott Hitt, M.D., Chair

RE: PACHA's position on the draft report "Recommendations for Change at the NIH's Center for Scientific Review"

The Presidential Advisory Council on HIV/AIDS met on October 4-5, 1999 at which time the draft report "Recommendations for Change at the NIH's Center for Scientific Review" was discussed.

It is our understanding that a significant restructuring of the manner in which NIH reviews and ultimately funds research grant applications is currently being proposed. With respect to HIV/AIDS, the draft report to the NIH Center for Scientific Review recommends that the HIV/AIDS Integrated Review Group (IRG) is dismantled and the component study sections dispersed.

The HIV/AIDS pandemic is far from over, with approximately 16,000 people infected worldwide each day, and 40,000 infected each year in the U.S. The Presidential Advisory Council on HIV/AIDS strongly recommends the continuation of the specific HIV/AIDS Integrated Review Group and the HIV/AIDS specific study sections, for the following reasons:

1) HIV/AIDS research requires an integrated approach across multiple disciplines, including basic immunology and virology, as well as clinical and complex behavioral aspects. A coordinated research agenda in this area requires an HIV/AIDS specific IRG.

2) The expedited review process through the designated HIV/AIDS IRG is critical to development of the most efficient solutions required for the HIV/AIDS pandemic.

3) The continuation of specific HIV/AIDS study sections allows for the assembly of review teams with specific expertise required for optimal scientific review of the multiple, diverse, yet linked aspects of HIV/AIDS research.

4) HIV/AIDS has been declared a national emergency among populations of color in the U.S., and remains the cause of untold financial and human suffering throughout the world. Until this pandemic has ended, it is the societal obligation of the U.S. in general, and the NIH in particular, to assure that HIV/AIDS research is conducted in the most efficient, comprehensive, ethical and rapid

736 Jackson Place, NW
Washington, DC 20503

manner. Dissolution of the specific HIV/AIDS IRG and the uncertainty of the related study sections will impede this goal.

I hope that you find these comments useful. They will also be submitted via the public comment process.

Thank you.

Presidential Advisory Council on HIV and AIDS

Stephen N. Abel, DDS
Mr. Terje Anderson
Ms. Regina Aragon
Barbara Aranda-Naranjo, PhD, RN
Ms. Judith Billings
Mr. Charles Blackwell
Mr. Nicholas Bollman
Jerry Cade, MD
Lynne M. Cooper, D. Min.
Rabbi Joseph Edelheit
Mr. Robert Fogel
Ms. Debra Fraser-Howze
Ms. Kathleen Gerus
Ms. Phyllis Greenberger
Nilsa Gutierrez, MD
Mr. Bob Hattoy
Mr. B. Thomas Henderson
R. Scott Hitt, MD, Chair
Michael Isbell, JD
Mr. Ronald Johnson
Mr. Jeremy Landau
Alexandra Mary Levine, MD
Mr. Steve Lew
Mr. Miguel Milanes
Ms. Helen Miramontes
Rev. Altagracia Perez
Michael Rankin, MD
Mr. H. Alexander Robinson
Ms. Debbie Runions
Mr. Sean Sasser
Mr. Benjamin Schatz
Ms. Denise Stokes
Rep. Charles Quincy Troupe
Bruce Weniger, MD

NYU Medical Center

10/26/99

Department of Environmental Medicine

Memorandum

Dear Dr. Thurman -

Please excuse the "generic" cover letter, but keep me in mind for any positions open "down South."

Thank you,

- Steve

Called, said
no pos. available
11/4

NEW YORK UNIVERSITY SCHOOL OF MEDICINE

Department of Environmental Medicine

650 First Avenue, 5th Floor, New York, NY 10016-3240
Telephone: (212) 263-
Facsimile: (212) 263-1095

October 1, 1999

To Whom It May Concern:

I would like to introduce myself as a Columbia University doctoral candidate preparing to defend my dissertation within the next few months. It is with great enthusiasm that I begin to embark on my post-doctoral professional career in research.

I have an extensive history conducting HIV/AIDS research, contributing to the scientific literature for more than 10 years. I have chosen to work full time in my field of interest, during academic study, to circumvent the need for post-doctoral training upon completion of my degree. This has proven difficult--yet rewarding--as I contemplate future employment prospects.

I have enclosed my curriculum vitae and a National Institutes of Health Biographical Sketch to represent my interest in working with your organization. Please call me after reviewing these materials so that I may understand any potential interest in my background from within your establishment.

I hope to enjoy the future pleasures of working without the prior burdens of academia. I appreciate your taking the time (in advance) to review the enclosed materials.

Sincerely yours,

Stephen P. Titus

Stephen P. Titus, M.Phil., M.P.H.
NYU School of Medicine, Asst. Research Scientist
Columbia University, Doctoral Candidate (A.B.D.)
252 East 61st Street, #2HS
New York, NY 10021-8583
(212) 838-3924
e-mail: spt1@columbia.edu

BIOGRAPHICAL SKETCH

Provide the following information for the key personnel in the order listed on Form Page 2.
Photocopy this page or follow this format for each person.

NAME	POSITION TITLE
Stephen Philip Titus, M.Phil., M.P.H.	**Asst. Research Scientist, HIVNET Coordinator**

EDUCATION/TRAINING (*Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.*)

INSTITUTION AND LOCATION	DEGREE (*if applicable*)	YEAR(s)	FIELD OF STUDY
Boston University Boston, MA College of Arts & Sciences	B.A.	1988	Psychology, Biology
Columbia University New York, NY The Joseph L. Mailman School of Public Health	M.P.H.	1989	Health Policy/Management
Columbia University New York, NY The Joseph L. Mailman School of Public Health	M.Phil.	1994	Sociomedical Sciences
Columbia University New York, NY The Joseph L. Mailman School of Public Health Graduate School of Arts & Sciences Teacher's College, Dept. of Social & Organizational Psych.	Ph.D.	Defend 1999	Sociomedical Sciences Social Psychology

RESEARCH AND PROFESSIONAL EXPERIENCE: Concluding with present position, list, in chronological order, previous employment, experience, and honors. Include present membership on any Federal Government public advisory committee. List, in chronological order, the titles, all authors, and complete references to all publications during the past three years and to representative earlier publications pertinent to this application. If the list of publications in the last three years exceeds two pages, select the most pertinent publications.

Professional Experience:

1983-1984	Data Base Manager/List Compiler **New England Business Service.** Groton, MA
1984-1985	Telephone Survey Interviewer **KRC, Inc.** Cambridge, MA
1984-1988	Longwood Trauma Center/Emergency Ward Patient Liaison **Brigham & Women's Hospital.** Boston, MA
1985-1988	Admitting/Scheduling/Financial Coordinator for Inpatients, Outpatient Clinics and the Emergency Ward **Boston University Medical Center.** Boston, MA
1987-1988	Directed Study Researcher **Boston University Department of Psychology.** Boston, MA
1987-1988	Health Policy Advisor **Massachusetts Alliance for the Mentally Ill.** Boston, MA
1988-1989	Patient Representative/Census Manager **Columbia-Presbyterian Medical Center.** New York, NY
1988-1990	Graduate Research Assistant: The Role of New York State Community Health Centers in the Prevention and Management of HIV Infection (Robert Wood Johnson Foundation, Ina Labiner) **Community Health Care Association of New York State, Inc.** New York, NY
1989-1992	Staff Associate/Doctoral Researcher: Harlem Longitudinal Health/Multidimensional AIDS Research Study (NIDA, Dr. Ann F. Brunswick) **Columbia University's Joseph L. Mailman School of Public Health.** New York, NY
1990-1992	HIV-Antibody Testing Counselor **Columbia University Mental Health Division.** New York, NY
1992-Present	Asst. Research Scientist & Study Coordinator: NIAID/NIDA and HIVNET Vaccine Preparedness and Phase II Safety and Immunogenicity Trial of Live Recombinant Canarypox ALVAC-HIV VCP205 with or without HIV-1 SF-2 RGP120 in HIV-1 Uninfected Adult Volunteers (NIAID, Dr. Michael Marmor & Dr. Don Des Jarlais) **NYU School of Medicine, Mt. Sinai-NYU Medical Centers/Health System.** New York, NY

Public Advisory/Expert Committees and Honors:

1993	Consultant: Tobacco Litigation Conference **Northeastern University**. Boston, MA
1993	Excellence in Social Psychology: Oral Examination **Teacher's College Department of Social & Organizational Psychology/Columbia University**. New York, NY
1996	Panel Member: National Community Advisory Board/Community Constituency Group External Review **N.I.H., National Institutes Allergy and Infectious Diseases**. Bethesda, MD
1995 & 1997	Fellowship: Sociomedical Sciences **Columbia University's Graduate School of Arts & Sciences**. New York, NY

Professional Societies: AIDS Action Foundation, American Psychological Association, American Public Health Association, Association for Social Sciences in Health, Columbia University's Center for Socio-cultural Research on Drug Use and HIV Center for Clinical & Behavioral Studies, International AIDS Society, New York Academy of Sciences, New York State Public Health Association, New York University's Center for AIDS Research, and the Public Health Association of New York City.

Publications: (* - Publications in the last three years.)

Dissertation:

Titus S. Social Psychology in the 'AIDS of Reason:' The Epistemology of Cognitive Behavioral Theory and Harm Reduction among New York City Injection Drug Users Participating in HIV-1 Vaccine Research. New York, NY: Columbia University Executive Committee, Graduate School of Arts & Sciences. 1999/2000.*

Rayman I, Titus S, Estilo M. The Role of New York State Community Health Centers in the Prevention and Management of HIV Infection: A Status Report. New York, NY: Community Health Care Association of New York State. 1989.

Brunswick A, Messeri P, Titus S. Predictive Factors in Adult Substance Abuse: A Prospective Study of African American Adolescents. In M. Glantz and R. Pickens (Eds.) Vulnerability to Drug Abuse. Washington, DC: American Psychological Association. 1992; 419-472.

Brunswick A, Aidala A, Dobkin J, Howard J, Titus S, Banaszak-Holl J. HIV-1 Seroprevalence and Risk Behavior in an Urban African American Community Cohort. American Journal of Public Health. Oct. 1993; 83(10): 1390-1394.

Titus S, Marmor M, Des Jarlais D, Kim M, Wolfe H, Beatrice S. Bleach Use and HIV Seroconversion Among New York City Injection Drug Users. Journal of Acquired Immune Deficiency Syndromes. 1994; 7: 700-704.

Marmor M, Wolfe H, Titus S, Des Jarlais D. Knowledge and Practices Among Injecting-Drug Users of Bleach Use for Equipment Disinfection--New York City, 1993. MMWR. 43: 24; June 24, 1994; 439-446.

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Titus S. Letters to the Editor, Re: "In the Path of a Killer (Nation, July 28)." TIME Magazine. August 18, 1997. 3.*

Marmor M, Alcabes P, Titus S, Frenkel K, Krasinski K, Penn A, Pero R. Low Serum Thiol Levels Predict Shorter Times-to-Death Among HIV-Infected Injection Drug Users. AIDS. 1997; 11: 1389-1393.*

Des Jarlais D, Vanichseni S, Marmor M, Buavirat A, Titus S, Raktham S, Friedmann P, Kitayaporn D, Wolfe H, Friedman S, Mastro T. "Why I Am Not Infected With HIV": Implications for Long-Term HIV Risk Reduction and HIV Vaccine Trials. Journal of Acquired Immune Deficiency Syndromes and Human Retrovirology. 1997; 16: 393-399.*

Publications (cont.): (* - Publications in the last three years.)

Brunswick A, Titus S. Heroin Patterns and Trajectories in an African American Cohort (1969-1990). In J. Inciardi and L. Harrison (Eds.) Heroin in the Age of Crack-Cocaine. Volume 6: Drugs, Health, and Social Policy Series. Newbury Park, CA: Sage Publications. 1998; 77-108.*

Titus S. Letters to the Editor, Re: "Hillary Clinton's Muddled Legacy (Op-Ed, August 25). New York Times. August 28, 1998: Vol. CXLVII; No. 51,263. Pg. A24.*

Titus S. Letters to the Editor, Re: "John Bartlett: An American Hero (July)." OUT Magazine. October 1998. 22*

Titus S. Letters to the Editor, Re: "After Suicide, Harvard Alters Policies on Graduate Students (news article, Oct. 21)." New York Times. October 27, 1998: Vol. CXLVIII; No: 51,323. Pg. A22.*

Titus S. Science Times Letters to the Editor, Re: "Crossing Flaming Swords over God and Physics (Science Times, April 20)." New York Times. April 27, 1999: Vol. CXLVIII; No: 51,505. Pg. F3.*

Titus S. NYT Letters to the Editor, Re: "Hillary Clinton's Muddled Legacy (Op-Ed, August 25). We the People 1998. Fort Lee, NJ: Publishers Plus. 1999.*

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Alcabes P, Marmor M, Krasinski K, Vogler M, Titus S, Des Jarlais D. Hepatitis B and C Seroprevalence Among New York City Drug Injectors: Evidence for Maturational, Period, and Cohort Effects. Public Health Reports. (1999, submitted for review).*

Des Jarlais D, Marmor M, Friedman P, Titus S, Aviles E, Perlis T, Deren S, Torian L, Glebatis D, Murrill C, Monteroso E, Friedman S. HIV Incidence Among Injecting Drug Users in New York City, 1992 to 1997: Evidence for a Declining Epidemic. Journal of the American Medical Association. (1999, submitted for review).*

Marmor M, Penn A, Berger Z, Titus S, Levin R, Maslansky R. Opiate Users Are At Reduced Risk of Death from Ischemic Heart Disease. The Lancet. (1999, submitted for review).*

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Presentations: (* - Presentations in the last three years.)

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STEPHEN PHILIP TITUS

Curriculum Vitae

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Education/Training

1994 – present Ph.D. Candidate *(A.B.D.)*	**Columbia University in the City of New York** - New York, NY Candidate for the Doctor of Philosophy (Ph.D.) ***Graduate School of Arts and Sciences*** in collaboration with: ***The Joseph L. Mailman School of Public Health*** – Sociomedical Sciences ***Teacher's College*** – Social, Organizational & Counseling Psychology ***Dissertation Title***: "Social Psychology in the 'AIDS of Reason:' The Epistemology of Cognitive Behavioral Theory and Harm Reduction among New York City Injection Drug Users Participating in HIV-1 Vaccine Research."
1989 – 1994 M.Phil.	**Columbia University in the City of New York** - New York, NY Master of Philosophy (M.Phil.) ***Graduate School of Arts and Sciences*** in collaboration with: ***The Joseph L. Mailman School of Public Health*** – Sociomedical Sciences ***Teacher's College*** – Social, Organizational & Counseling Psychology
1988 – 1989 M.P.H.	**Columbia University in the City of New York** - New York, NY Master of Public Health (M.P.H.) ***The Joseph L. Mailman School of Public Health*** – Health Policy & Management
1984 – 1988 B.A.	**Boston University** – Boston, MA Bachelor of Arts (B.A.) ***College of Arts & Sciences*** – *Major*: Psychology, *Minor*: Biology
1980 – 1984 Diploma	**Ayer Senior High School** – Ayer, MA Highest Honors College Preparatory (Diploma)

Research/Professional Experience

9/92 – present

New York University School of Medicine – New York, NY
ASST. RESEARCH SCIENTIST, HIVNET & NIDA PROJECT COORDINATOR
Department of Environmental Medicine
Division of Epidemiology and Biostatistics
Center for AIDS Research – Infectious Disease Epidemiology Unit

Primary responsibilities: Represent P.I. (s) when necessary, study coordination/management, data analyses, manuscript preparation, grant writing, and staff supervision.
Study title: (1) New York University-Beth Israel Community Health Survey/Prevention Project, (2) Vaccine "Jumpstart" Study, (3) Vaccine Preparedness Initiative (VPS), and (4) Phase II (014) Safety and Immunogenicity Trial of Live Recombinant Canarypox ALVAC-HIV VCP205 with or without HIV-1 SF-2 RGP120 in HIV-1 Uninfected Adult Volunteers.
Study description: Longitudinal epidemiological study of HIV-1 infection, seroincidence, and HIV-1 preventive vaccine clinical trials among intravenous drug users (IDUs) and the sexual partners of IDUs recruited at Bellevue, Beth Israel and the Manhattan VA Medical Center. A subcontract, in addition, has been awarded through the HIVNET to study the feasibility of conducting future preventive HIV vaccine trials, focusing on behavioral risk factors, among high risk HIV-negative IDUs and IDU sexual partners.
Principal investigators: Drs. Michael Marmor and Don Des Jarlais
Funding sources: NIDA, NIAID, National Institute on Environmental Health Sciences, NIH Center for Research Resources, and ConEd of NY.

12/89 – 9/92

Columbia University in the City of New York – New York, NY
STAFF ASSOCIATE & DOCTORAL RESEARCHER
The Joseph L. Mailman School of Public Health – Sociomedical Sciences

Primary responsibilities: Study management, data analyses, manuscript preparation, grant writing, and staff supervision.
Study title: Harlem Longitudinal Health Study, Multidimensional AIDS Risk Study
Study description: An ongoing longitudinal epidemiological study of a cohort of African-Americans recruited in Central Harlem using a multi-stage probability sample of households in 1968. The current research focuses, specifically, on behavioral risks associated with HIV infection.
Principal investigator: Dr. Ann Brunswick
Funding source: NIDA

11/88 – 2/90

Columbia University in the City of New York – New York, NY
GRADUATE RESEARCHER
The Joseph L. Mailman School of Public Health – Health Policy & Management in association with ***The Community Health Care Association of New York State, Inc.***

Primary responsibilities: Study development, management, data analyses, and manuscript preparation.
Study title: The Role of New York State Community Health Centers in the Prevention and Management of HIV Infection: A Status Report.

Study description: A mailed questionnaire developed and utilized to conduct a needs-assessment of Community Health Centers in the state of New York. This questionnaire evaluated the degree and extent of resources available to educate, counsel, HIV-antibody test, and treat the population at risk for acquiring HIV infection.
Principal investigator: Ms. Ina Labiner and Dr. Irene Rayman
Funding source: Robert Wood Johnson Foundation, and the USPHS - Region II in collaboration with the Center for Health Policy Studies.

9/88 – 12/99 **Columbia-Presbyterian Medical Center** - New York, NY
PATIENT REPRESENTATIVE & CENSUS MANAGER

Primary responsibilities: Arrange admissions and manage the census at this 1300+ bed facility affiliated with the Columbia University College of Physicians and Surgeons.

6/85 - 9/88 **Boston Medical Center** – Boston, MA
ADMITTING, SCHEDULING & FINANCIAL COORDINATOR

Primary responsibilities: Arrange admissions, manage the census and assisted patients with financial planning at this 380+ bed facility affiliated with the Boston University School of Medicine.

5/85 - 9/85 **KRC Research, Inc.** – Cambridge, MA
TELEPHONE SURVEY RESEARCHER

Primary responsibilities: Conduct telephone survey research for various clients and special interest groups.

5/84 - 9/84 **New England Business Service, Inc.** - Groton, MA
DATA BASE MANAGER & LIST COMPILER

Primary responsibilities: Computer data entry of commercial addresses for business-related mailing lists.

Volunteer Work/Community Service

9/90 - 9/93 **Columbia University Mental Health Division** – New York, NY
HIV-ANTIBODY TEST COUNSELOR

1/88 - 8/88 **Massachusetts Alliance for the Mentally Ill** – Boston, MA
HEALTH POLICY and HOSPITAL MONITORING ADVISOR

9/87 - 5/88 **Boston University Department of Psychology** – Boston, MA
DIRECTED STUDY RESEARCHER

11/84 – 9/88 **Brigham and Women's Hospital** – Boston, MA
LONGWOOD TRAUMA CENTER PATIENT LIAISON

Public Advisory/Expert Committees & Honors

1993	***Northeastern University*** – Boston, MA Consultant: Tobacco Litigation Conference
1993	***Teacher's College/Columbia University*** – New York, NY Excellence in Social Psychology: Oral Examination, Department of Social and Organizational Psychology
1996	***N.I.H., National Institutes of Allergy and Infectious Diseases – Office of AIDS Research*** – Bethesda, MD Panel Member: National Community Advisory Board/Community Constituency Group External Review
1995 & 1997	***Columbia University in the City of New York*** – New York, NY Fellowship: Graduate School of Arts & Sciences, Sociomedical Sciences

Research Interests

Primary interests:	Theoretical and applied Social Psychology using experimental, survey, clinical trial, Epidemiologic, and Bio-statistical methodologies.
Substantive areas:	HIV-related behavioral interventions and preventive vaccines, in addition to life-course research, health psychology and research on minorities, gender roles, addiction and illicit substance abuse.

Research Skills

Multivariate data analyses:	SAS, SPSS, EGRET, LISREL, Paradox
Word processing utilities:	Word for Windows and WordPerfect
Project communications:	FTP, Telnet and Web-based Internet connections
Project presentations:	Harvard Graphics, Lotus, Quattro Pro, Power Point

Affiliations

AIDS Action Foundation
American Psychological Association
American Public Health Association
Association for Social Sciences in Health
Columbia University:
    HIV Center for Clinical & Behavioral Studies
    Center for Socio-cultural Research on Drug Use
International AIDS Society
New York Academy of Sciences
New York State Public Health Association
New York University Center for AIDS Research
NIAID Prevention Research Advisory Council
Public Health Association of New York City

Publications

Dissertation:

Titus S. Social Psychology in the 'AIDS of Reason:' The Epistemology of Cognitive Behavioral Theory and Harm Reduction among New York City Injection Drug Users Participating in HIV-1 Vaccine Research. New York, NY: Columbia University Executive Committee, Graduate School of Arts & Sciences. 1999/2000.

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Titus S. NYT Letters to the Editor, Re: "Hillary Clinton's Muddled Legacy (Op-Ed, August 25). We the People 1998. Fort Lee, NJ: Publishers Plus. 1999.*

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(* - Presentations in the last three years.)

References

R. Gary Bridge, Ph.D.	***Teacher's College, Columbia University*** – New York, NY Associate Professor, Psychology and Education
Ann F. Brunswick, Ph.D.	***Columbia University*** – New York, NY Senior Research Scientist, Sociomedical Sciences
Don Des Jarlais, Ph.D.	***Beth Israel Medical Center*** – New York, NY Director, Chemical Dependency Inst. & Office of Grants Management
Sheila A. Gorman, Ph.D.	***Columbia University*** – New York, NY Professor & Deputy Director, Health Policy & Management
Dale Lawrence, M.D.	***National Institutes of Allergy and Infectious Diseases*** – Bethesda, MD Chief Medical Officer, Vaccine Trials Section
Jackie Liederman, Ph.D.	***Boston University*** – Boston, MA Professor, Psychology
Peter Messeri, Ph.D.	***Columbia University*** – New York, NY Dissertation Advisor, Sociomedical Sciences
Irene Rayman, Ph.D.	***Community Health Care Association of New York State, Inc.*** – New York, NY Former P.I. and Research Consultant
George Seage III, Ph.D.	***Abt Associates, Inc.*** - Cambridge, MA HIVNET Principal Investigator

Written references available upon request.

THE WHITE HOUSE

WASHINGTON

Memorandum for Jack Whitescarver, Ph.D., Acting Director, Office of AIDS Research, NIH

From: Sandra Thurman
Director, Office of National AIDS Policy

Re: Dr. Gaist's work performance for the period of June 1999 through August 2000

As requested by the NIH, this is a note providing an evaluation of Dr. Paul Gaist's work performance for the period of his assignment to the White House Office of National AIDS Policy (ONAP), June 1999 through August 2000.

Overall, Dr. Gaist's work performance during his assignment at ONAP has been outstanding. He is a self-starter and consistently carries out his assigned responsibilities to successful completion. His knowledge and input provides us with invaluable assistance in areas such as international health, HIV prevention, and health science and research. Based on his high level of performance, at my request, his assignment was extended for an additional six months past the original assignment.

During the period of his assignment, Dr. Gaist successfully worked on many projects and issues. To cite only a few, Dr. Gaist:

Organized a White House level briefing on non-vaccine HIV prevention approaches which emphasized behavioral and social science approaches;

Represented the Office and the Director at meetings focused on both domestic and international issues;

Served as a technical expert to and a liaison with the President's AIDS Advisory Council, working directly with both the Council's executive director and members;

Served as the point person for Eastern Europe and Central Asian affairs;

Drafted, reviewed and modified speeches and high level correspondence for the Director;

Gave presentations on international HIV issues, policies and programs to both governmental and non-governmental groups on behalf on the Office and the Director; and,

Served as the ONAP representative on a number of groups including the Africa Work Group at the Center for Strategic and International Studies and small group meetings on Russian health issues at the National Security Council;

In addition, Dr. Gaist continues to be an invaluable "sounding board" and advisor to the Director and other senior staff in the Administration on a range of program, policy, and administrative issues.

In brief, Dr. Gaist's contributions to the Office of National AIDS Policy have been invaluable. It is our hope that our colleagues at OAR will continue to allow us to seek his input on issues that are important to both The White House and NIH.