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DEPARTMENT OF HEALTH AND HUMAN SERVICES

declined / discussed with
Office of the Secretary
Office of Public Health and Science

NOV 12 1999

Ms. Sandra Thurman
Director
Office of National AIDS Policy
Executive Office of the President
736 Jackson Place, NW
Washington, DC 20503

Assistant Secretary for Health
Surgeon General
Washington, D.C. 20201

Dear Ms. Thurman,

I would like to invite you to participate in a follow-up discussion to the August 3rd meeting of community leaders sponsored by Assistant Secretary for Health and Surgeon General, Dr. David Satcher, and my office. At that meeting, the goals of The Leadership Campaign on AIDS (formerly named Project LEAD) were discussed, along with a candid dialogue around implementation issues of the joint Administration-Congressional targeted HIV/AIDS initiative. I would like to reconvene this group to continue our discussion and to benefit from your deliberations of the past few months.

In the intervening months, many steps have taken place to move the FY99 initiative forward. A constructive discussion has taken place within the Department around approaches to strengthening the infrastructure of minority community based organizations (CBOs) and the delivery of targeted, effective technical assistance. There have also been a number of meetings and activities associated with The Leadership Campaign on AIDS (TLCA) that I want to update you on, both to get your feedback and seek input on future directions and activities.

I will convene this meeting on December 13, 1999 from 1:00 p.m. to 2:30 p.m. in Room 729G of the Hubert H. Humphrey Building, 200 Independence Ave., S.W., Washington DC. I hope your schedule will permit your participation. Logistical information will be forwarded to you within the next two weeks.

Also, I would like to draw your attention to an important activity that will take place prior to our December meeting. On November 30, 1999, Dr. Satcher will host *The Surgeon General's African American Community HIV/AIDS Satellite Conference*. The Satellite conference will address important messages around HIV prevention and antiretroviral treatments, including issues of adherence and the management of side effects. I am pleased that many of you are planning to participate in this event in your local areas. Fostering and facilitating honest communication around these issues is a critical part of providing leadership to our communities. I encourage you to share the enclosed flyer with your colleagues and communities.

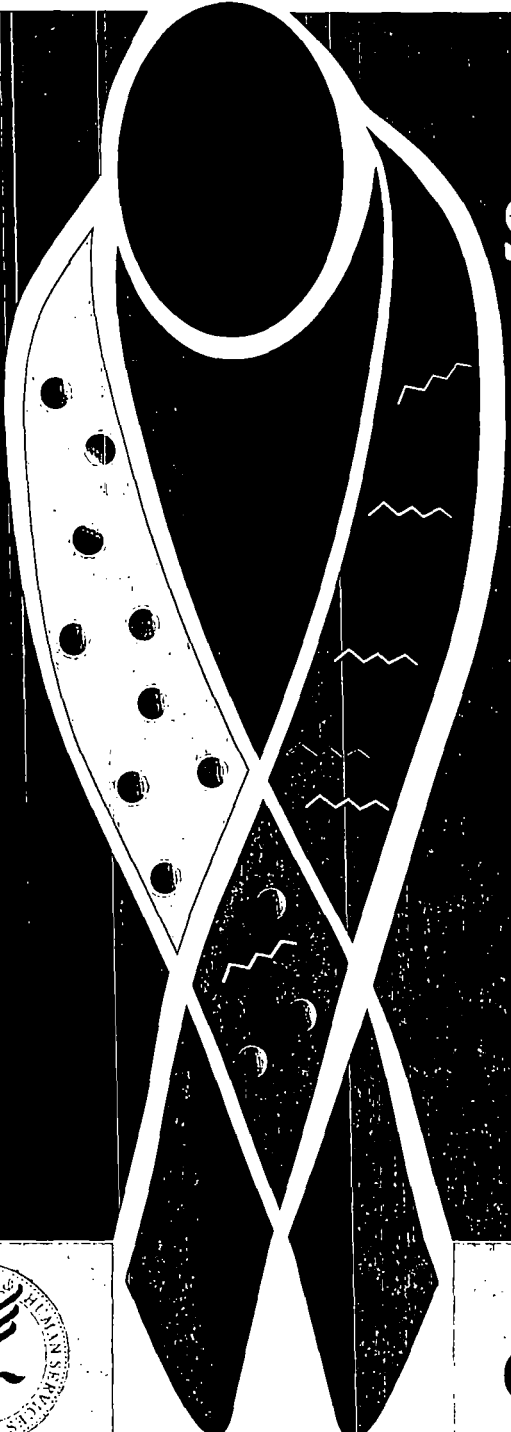
I appreciate your continued support and longstanding commitment to addressing HIV/AIDS, and I look forward to meeting with you on December 13.

Sincerely yours,

Eric P. Goosby, M.D.
Director, Office of HIV/AIDS Policy
Office of Public Health and Science

enclosure

U.S. Public Health Service



Surgeon General's American Community HIV/AIDS

satellite
conference

November 30, 1999
4:30 - 6:00 pm ET



The
Leadership
Campaign
on **AIDS**

Telecast live from: Charles R. Drew University of Medicine and Science,
Howard University College of Medicine, Meharry Medical College, Morehouse School of Medicine,
and Tuskegee University

Obtain Satellite Conference information and register a down link site via:

Internet:

<http://www.surgeongeneral.gov>

Toll free telephone number:

1-877-657-4254

Fax:

301-657-4258

View the Satellite Conference Internet Webcast on Nov. 30 at:

<http://www.blackfamilies.com/>

(Over)

The Surgeon General's African American Community HIV/AIDS Satellite Conference

The Event: The Surgeon General's African American Community HIV/AIDS Satellite Conference is being convened on behalf of the Surgeon General by the Office of HIV/AIDS Policy. The event will take place on November 30, 1999, from 4:30 – 6:00 p.m. ET. Its goal is very simple: to get across the message of prevention, new drugs, and adherence.

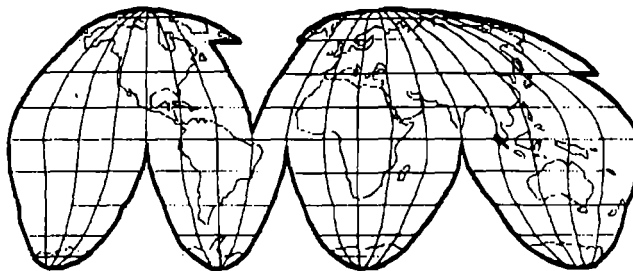
Why Do A Satellite Downlink? To help get the following messages to the African American and other minority community: HIV/AIDS has a devastating impact on minority communities, and specifically the African American community. Prevention is a tool we can support. We have new drugs to combat the infection: take them and adhere to them. **To Register a Down Link go to:** <http://www.surgeongeneral.com>.

Hosts: Four Historically Black Colleges and Universities (Meharry, Howard, Drew, and Morehouse) and the Tuskegee Bio-Ethics Institute are hosting the Satellite Conference. Community-based AIDS Service Organizations that provide care to African Americans living with HIV/AIDS in these HBCU communities and the Macon County Health Department are **also** hosting this event. (Family and Medical Counseling Services, Washington, D.C.; Minority AIDS Project, Los Angeles; Metropolitan Interdenominational Church, Nashville, TN; and Outreach Inc., Atlanta, GA). Each university participates as an interactive site for the conference.

Format for the Event: The conference will link the five primary sites, with one lead host/facilitator. At each site, there will be a site-specific host/facilitator. The Surgeon General will kick-off the satellite conference with a brief message that highlights the conference goals and key messages. Then, at each site, a senior Federal Official will give a brief presentation on prevention, research, care, and adherence. Following this presentation, a person living with HIV will testify about what it means to take the available drugs and adhere to the treatment plan. The presentation will be followed by a question and answer period. There will be a pre- and/or post-conference activity.

To View the Event on the Internet: Go to <http://www.blackfamilies.com/> webpage. This webpage will allow you to watch the conference live on November 30, 1999 at 4:30 p.m. (ET) Instructions on how to view the event will be on the webpage.

For More Information on the Event or to Register a Dowlink Site:
Go to: <http://www.surgeongeneral.gov>



FAX TRANSMISSION SHEET

FROM: Gregory Pappas, MD, PhD
Acting Director
Office of International and Refugee Health
Department of Health and Human Services

PHONE: (301) 443-1774

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E-MAIL: gpappas@osophs.dhhs.gov

TO: Sandra Thurman

CC: Todd Summers

FAX: (202) 456-2438

PAGES: 3

DATE: May 25, 1999

☐ FOR YOUR ACTION

☒ FOR YOUR INFORMATION

☒ AS REQUESTED

☐ AS DISCUSSED

MESSAGE: I am sorry for the delay. Secretary Shalala, Assistant Secretary for Health/Surgeon General Satcher, and a large delegation of DHHS officials including myself were in Geneva last week for the World Health Assembly. DHHS will hold a meeting of relevant agencies later in the week to further develop the response to your request. I will be in touch.

ATTACHED: Memorandum with Attachments



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Office of Public Health and Science
Office of International and Refugee Health
Rockville, MD 20857

DATE: May 25, 1999

TO: Director
Office of National AIDS Policy

FROM: Acting Director
Office of International and Refugee Health
Department of Health and Human Services

SUBJECT: Global AIDS Emergency Working Group

The Department of Health and Human Services (DHHS) has been seriously engaged in a response to the growing emergency of HIV/AIDS in many parts of the world. The crisis in sub-Saharan Africa has been of special concern.

The Assistant Secretary for Health and Surgeon General (ASH/SG) has included Emerging and Reemerging Infectious Diseases (ERIDs) in general and HIV/AIDS in particular under his Global Health Priority. Attached is a column on global HIV/AIDS by the ASH/SG from the *Journal of the American Medical Association (JAMA)* (Tab A).

The three most important agencies in the DHHS response to global HIV/AIDS are the Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA), and the National Institutes of Health (NIH). Attached is a summary of the DHHS response to global HIV/AIDS (Tab B).

DHHS looks forward to its participation in the Global AIDS Emergency Working Group.


Gregory Pappas, M.D., Ph.D.

TAB A

**JAMA**

The Journal of the American Medical Association

Medical News & Perspectives - April 28, 1999
From the Surgeon General

JAMA

The Global HIV/AIDS Epidemic

An enormous human tragedy is unfolding in many less-developed countries because of the spread of HIV/AIDS. Of the 33.4 million HIV-infected people around the world, there are an estimated 22.5 million in sub-Saharan Africa, 6.7 million in South and Southeast Asia, 1.4 million in Latin America, and 665,000 in the United States. Globally, more than 14 million people have died of the disease, including 2.5 million last year.

In many southern African countries, HIV/AIDS has become an unprecedented emergency, with 20% to 26% of people between the ages of 15 and 49 infected. In Botswana, Kenya, Malawi, Mozambique, Namibia, Rwanda, South Africa, Zambia, and Zimbabwe, HIV/AIDS will reduce life expectancy from 64 to 47 years by 2015. The progress of decades of work immunizing children, controlling diseases, and improving nutrition is being negated by HIV/AIDS.

Conditions in many parts of the world promote rapid spread of the HIV/AIDS epidemic. For example, India, with a population approaching 1 billion, has estimated that 3 million to 5 million of its people are infected, and the number of new infections will double every 14 months.

Social and political issues surrounding sex, injecting drug use, and blood transfusion in many countries have created special circumstances in which the disease has been able to spread unchecked. Some less-developed countries also bear a burden of political and economic instability that makes prevention even more difficult. It was only a few years ago that epidemiologists offered projections of disease prevalence for sub-Saharan Africa that were met with disbelief. If the present warnings go unheeded, South Asia, Southeast Asia, and, perhaps, China will follow the disastrous course of sub-Saharan Africa.

More than a decade of experience has taught us how to control HIV/AIDS—we know what works. Many developed countries have successfully checked the spread of the epidemic. While development of therapy and a vaccine continue, prevention must be emphasized. The basic elements of prevention include education, behavior change, voluntary testing and counseling,

prevention of perinatal transmission, and political commitment. Each country must find the mix of methods appropriate to its particular conditions.

Education about HIV/AIDS is necessary but alone does not change the behavior of populations. Promotion of voluntary testing and counseling must complement education. Testing and counseling break the deadly silence around HIV/AIDS and empower individuals to make informed decisions and change behaviors. Breaking the silence also will begin to diffuse the stigma surrounding the disease. We have seen success with behavioral change in Uganda and Thailand, the only two less-developed countries with extensive capacity for voluntary testing and counseling.

It is known that perinatal transmission of HIV can be reduced by more than 50% by using antiretroviral therapy; however, problems with access to these drugs limit their use in some countries. Transmission of HIV through breast-feeding and poor survival of orphans make the avoidance of disease via treatment for perinatal transmission more complex. We continue to work with international organizations, other governments, and pharmaceutical companies to lower costs and expand access to antiretroviral drugs. Current treatment for perinatal transmission (as well as use of antiretrovirals in general) in less-developed countries is also limited by the fact that very few people have been tested for HIV infection.

Treatment of other sexually transmitted diseases (STDs) is important to control the spread of HIV. One of the reasons HIV has spread so rapidly in Africa is that so many STDs go untreated. Untreated STDs break down natural barriers that prevent transmission. Access to even basic treatment for STDs remains a problem for many less-developed countries.

Perhaps most important in the global battle against HIV/AIDS is political commitment. Leaders at the national, provincial, and local levels of government must speak out about HIV/AIDS and encourage businesses and nongovernmental organizations to commit to work against the disease. I was encouraged by US Vice President Al Gore and Deputy President Thabo Mbeki of South Africa, who put the HIV/AIDS threat at the top of the international agenda at the recent meeting of the United States-South Africa Joint Commission. They set an important example for leaders in developed and less-developed countries.

American medicine and public health have an important role to play in the global battle against HIV/AIDS by supporting international organizations such as the Joint United Nations Program on HIV/AIDS, the World Health Organization, and the World Bank.

HIV/AIDS can be likened to the plague that decimated the population of Europe in the 14th century. While the modern epidemic affects people of all age groups, those of working age are at highest risk, posing potentially dire economic, social, and political consequences for the global community. Unfortunately, the world continues to devote greater attention and resources to traditional national security issues such as wars, postponing notice of an epidemic that, if left to spread unchecked, will kill more people than any of the terrible conflagrations that have so marked this century.

—David Satcher, MD
Surgeon General of the United States and Assistant
Secretary,
Department of Health and Human Services

(JAMA. 1999;281:1479)

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TAB B

Centers for Disease Control and Prevention

The U.S. Department of Health and Human Services (DHHS) is committed to working in partnership with others to reverse the toll that HIV/AIDS is taking on millions of lives by halting the further spread of HIV and mitigating its effects on those already infected through research, prevention, service delivery and education efforts. Scientists at DHHS have contributed significantly to international progress in understanding how HIV infection is transmitted, how it affects the body, and how to treat and prevent it. As new information becomes available, increased knowledge about this disease and better ways to treat and prevent it should be forthcoming to address this critical health problem.

As the Nation's prevention agency, CDC integrates prevention science, research and practice. Through basic and laboratory research, epidemiologic research, and surveillance, behavioral, communications, and social science research, CDC supports a comprehensive approach to issues which impact prevention. CDC collaborates with governmental and non-governmental organizations, international and domestic, awarding grants to national organizations, state and local health departments, community-based organizations and other institutions to support prevention activities based on science. This integration of science and practice is consistent across all of CDC's Centers, Institutes, and Offices supporting prevention science activities. These include the National Center for HIV, STD and TB Prevention (NCHSTP), the National Center for Infectious Disease (under which falls the Division of AIDS, STD, and TB Laboratory Research), the National Center for Chronic Disease Prevention and Health Promotion (under which falls the Division of Adolescent and School Health and the Division of Reproductive Health), the Office of Women's Health and the Public Health Practice Program Office (which ensures the quality of laboratory testing).

In FY-1998, DHHS received more than \$6.8 billion dollars for HIV/AIDS activities. The majority of these funds (nearly two-thirds) were distributed for care and treatment of Americans through the Health Care Financing Administration (HCFA) authorized under Medicaid and Medicare programs and through the Health Resources and Services Administration (HRSA) authorized under the Ryan White Care Act. Funding for international collaborative HIV/AIDS activities is limited within the offices and agencies within DHHS, with no formal budget allocation for international activities. Therefore, only a tiny percentage of HIV/AIDS funds are allocated for international HIV/AIDS activities.

CDC has two programmatic approaches to international collaboration in HIV/AIDS prevention: field-based research collaborations and limited CDC-based technical assistance, training, and project management.

Field-Based Research

Epidemiology of HIV. Field-based research provides collaborative assistance to Côte d'Ivoire, Uganda, South Africa and Thailand. Studies are designed to increase the

understanding of the epidemiology of HIV and to evaluate intervention methodologies in the host country and the United States. Because of the variation in the virus itself throughout the world, CDC, through two of its centers in Côte d'Ivoire and Thailand, conducts international surveillance of the genetic diversity of HIV research collaborations in numerous countries throughout the world.

Perinatal Transmission. Earlier this year, researchers from CDC and the Ministry of Public Health in Thailand announced dramatic findings that offer real hope for extending perinatal prevention successes to many developing nations. Researchers found that a short course of AZT given late in pregnancy and during delivery reduced the rate of HIV transmission to infants of infected mothers by half and is safe for use in the developing world. CDC is continuing collaborative research in West Africa to establish the longer term efficacy of short course zidovudine for populations in whom safe alternatives to breast feeding may not be available.

Microbicide Development. CDC has also supported international collaboration on the development of microbicial products, as well as international studies in acceptability of microbicides in Zimbabwe and Thailand. In addition, a number of domestic and international activities have included research about the potential impact of including information on microbicides, once available, as part of the prevention messages about condoms. CDC participates with NIH and FDA in the International Working Group on Microbicides, which also includes UNAIDS, the Population Council and some industry representatives.

Prophylaxis of Opportunistic Infections. In Côte d'Ivoire, a placebo controlled trial of cotrimoxazole in patients in treatment for tuberculosis showed a significantly reduced mortality in immuno-suppressed patients taking the active drug. The recently completed trial of preventive therapy for tuberculosis in Uganda, conducted by Case Western Reserve University in collaboration with Ugandan colleagues was supported by CDC as well.

Vaccine Research. CDC has a number of research activities related to the development of HIV vaccines. This includes participation in efficacy trials in the United States and Thailand, as well as in the development of novel candidate vaccines in collaboration with academic centers. In addition, behavioral research and communication efforts about vaccine related issues are ongoing. CDC expertise in vaccine implementation will be a valuable resource once candidates become available.

Technical Assistance

In addition, CDC provides both long and short term technical assistance internationally. Long-term technical assistance and management capacity has been established by CDC field assignees to Uganda and South Africa, working in conjunction with USAID, as well as India and Vietnam. In addition to these field-based staff, CDC provides short-term technical assistance and training to numerous countries including Brazil, Russia, The

Republic of South Africa, and Mali, and to international organizations including UNICEF, UNAIDS, and WHO.

Training

In conjunction with these technical assistance activities, CDC provides training in the areas of epidemiology, evaluation, prevention methodologies and other technical areas through an extensive program of training based in Atlanta as well as at field sites in Thailand and Côte d'Ivoire. CDC has also designed a program, in collaboration with USAID, to link U.S.-based community organizations and their prevention interventions with counterparts in developing countries. This was established in order to provide a mechanism to share relevant experiences, provide materials and resources, and training opportunities across countries. Other activities will support USAID-assisted countries with access to CDC epidemiologic and surveillance expertise.

Other Activities

Although not specific to HIV/AIDS, it is important to note that CDC's international work focuses heavily on strengthening public health infrastructure, and such work can contribute to sustainable HIV/AIDS control. For example, the CDC established field epidemiology training programs in developing countries. Epidemiology is the cornerstone of public health science, and trained epidemiologists are valuable countries to detect, monitor and help control their key public health programs. Secondly, CDC has established a sustainable management development program to provide practical training in management of public health programs in developing countries.

Recognizing the urgency of the epidemic and its impact on many domestic issues, CDC is committed to HIV/AIDS research within, as well as outside of, U.S. borders. To understand HIV/AIDS at a global level, research must address issues and conditions unique to different countries and communities within countries. Many developing countries severely affected by the epidemic lack the research capacity, public health infrastructure, and financial and human resources to respond to the epidemic. CDC's international research underscores the importance of developing and implementing diverse interventions to address issues among varied populations and to do so quickly and cost-effectively.

Food and Drug Administration

The Food and Drug Administration (FDA) is the only agency within the U.S. Public Health Service whose responsibilities are regulatory in nature. Its purview is product-driven and encompasses products worth approximately 25 percent of the U.S. gross national product. FDA activities respond to product applications--the agency reviews what is brought to it.

FDA's level of commitment to prevention, diagnosis, and treatment of HIV/AIDS is broad-based. FDA, like all of its component agencies in the U.S. Public Health Service, is committed to finding more and better ways to prevent, diagnose, and ultimately cure HIV/AIDS. FDA performs research and review involving AIDS therapeutic and diagnostic vaccine products. Major research priorities include: (1) new more sensitive blood safety testing for HIV; and (2) methods, standards, and studies on mechanisms of action of new AIDS therapeutics and vaccines.

Funding

FDA and its budget is organized around the products within its regulatory framework and is not, generally, a grant-making institution nor an entity organized in terms of line items for particular diseases or disease groups. FDA does not have a specific international budget allocation.

Prevention

Medical Devices. FDA has an ongoing responsibility to help ensure the safety and effectiveness of AIDS-related medical devices through its regulatory activities. This includes sampling and testing of medical gloves and latex condoms; reviewing submissions to market devices that reduce the risk of HIV transmission, including donor screening tests; conducting HIV-related regulatory research involving medical devices; and evaluating the role of devices in the transmission of bloodborne infections.

FDA has cleared for marketing over 280 needle and intravenous cannulas with safety features that reduce the risk of sharps injuries to healthcare workers. Among sharps containers FDA has recently cleared for marketing are devices that electrically oxidize all types and sizes of needles immediately after use, further reducing the risk from used needles.

As condoms remain the best means of protection against the transmission of HIV and other sexually-transmitted diseases, FDA must be vigilant in its regulation. FDA is working to develop better tests for condom strength and is investigating the barrier capability of condoms manufactured of different materials.

Blood and Blood Products. FDA is responsible for ensuring the safety of the U.S. blood supply. Regulatory mechanisms designed to ensure blood safety include establishing

policies; approving authority for blood products and establishments; and surveilling and enforcing blood safety standards. The blood safety system FDA has established consists of five layers of overlapping safeguards that start at the blood collection centers and extend to the manufacturers and distributors of the blood products made from donated blood.

The first level of precautions seeks to eliminate high-risk donors by encouraging those whose blood may pose a health hazard to exclude themselves, and by evaluating their behavioral and medical history as a basis for deferral. The second safeguard entails constant updating of a list of unsuitable donors and checking donors' names against the list to prevent using their blood. The third consists of testing the blood for such bloodborne agents as HIV, hepatitis, and syphilis. The fourth safeguard FDA enforces is a quarantine of donated blood until tests and other control procedures establish its safety. Finally, the blood collection centers are obligated to investigate incidents, audit their systems, and correct deficiencies. FDA also sets quality and safety standards for blood-derived products such as viral inactivation of clotting factor concentrates and immune globulins.

Treatment Equity

Therapeutic Agents. FDA is responsible for approving safe and effective drugs and biologics used in the United States for treating HIV infection, AIDS, and AIDS-associated opportunistic infections. FDA is also responsible for regulating the investigation of new drugs. It places special emphasis on ensuring the most timely and efficient premarketing review possible of products that offer promise for diagnosing, treating, or preventing HIV and HIV-related illnesses. FDA has approved 37 applications for products to treat HIV/AIDS. Twelve drugs are antiretroviral agents that are used to treat the virus, and the remaining 25 are used to treat opportunistic infections that can complicate HIV infection. In addition, FDA is responsible for monitoring the safety of the drugs and biologics post marketing and places special emphasis on ensuring that new safety information is disseminated widely and in a timely manner.

Vaccine Research

Within the framework of the Public Health Service-wide vaccine program for prevention and therapy, FDA is continuing its efforts to guarantee that any promising products for immunization against HIV will receive expedited regulatory review, and when appropriate, will be approved in the shortest possible time.

Diagnostic Capability

Diagnostic Reagents and Test Kits. FDA conducts a variety of regulatory, testing, and research activities to approve for marketing satisfactory test methodologies for detection of HIV. FDA has approved 2 HIV-1 Antigen tests; 20 anti-HIV-1 assays; 3 anti-HIV-2 assays; 1 anti-HIV assay on urine; 1 anti-HIV testing service using home collection; 1

anti-HIV-1 oral specimen collection device; and 1 HIV-1 viral load assay. FDA currently is facilitating development of gene-based screening tests.

National Institutes of Health

The National Institutes of Health (NIH) supports a comprehensive program of basic, clinical, and behavioral research on HIV infection and its associated opportunistic infections and malignancies. Each of the 24 NIH Institutes and Centers is involved in some HIV/AIDS-related research activity consistent with its individual mission. NIH is the world's leading biomedical research institution, supporting more than 5,000 individual HIV/AIDS research projects at more than 500 research institutions across the nation and around the world. NIH has played a leadership role in the discovery and characterization of HIV and continues to lead research to determine the pathogenesis of AIDS. Findings from NIH-sponsored studies have resulted in significant advances in the treatment of HIV infection and its related illnesses and prevention of the opportunistic infections that cause morbidity and mortality of HIV-infected individuals.

The NIH AIDS program supports biomedical and behavioral research necessary to identify therapeutic regimens, behavioral interventions, and vaccine candidates to treat and prevent HIV infection and its associated illnesses in the United States and internationally. The global nature of the AIDS epidemic underscores the critical need to identify interventions for developed and developing nations that prevent HIV transmission, disease progression, and mortality. Continued collaboration with international organizations and other nations is required to achieve these priorities. Research capacity-strengthening in foreign countries is a critical element to NIH's efforts to address HIV/AIDS, and in this regard, NIH supports a strong research training program with partners in 100 countries.

The NIH AIDS program includes collaborations with numerous international organizations. Ongoing and planned efforts include collaborations with the following organizations: UNAIDS, in planning for the initiation of international vaccine clinical trials; the Pan American Health Organization (PAHO) for studies on heterosexual transmission of HIV infection and tuberculosis prophylaxis; the World Health Organization (WHO) in the Antibody Serologic Project; WHO as one of three AIDS reagent centers; and WHO for support of several international workshops and conferences.

In addition, since its inception in 1996, NIH has collaborated with UNAIDS through mutual representation on advisory and coordinating bodies, frequent exchange of information, and collaboration on specific efforts, such as vaccine development, ethical issues related to clinical trials, and research training and infrastructure in developing countries. In this regard, the National Institute of Allergy and Infectious Diseases (NIAID) and the Fogarty International Center (FIC) have been designated UNAIDS Collaborating Centers. Additionally, NIAID and the National Institute of Child Health and Human Development (NICHD) have collaborated with UNAIDS on the Working Group on Prevention of Mother to Child Transmission of HIV.

The NIH Office of AIDS Research (OAR) is located within the Office of the Director of NIH and is responsible for the scientific, budgetary, legislative, and policy elements of the NIH AIDS research program. Congress provided in the NIH Revitalization Act of 1993 broad authorities to the OAR to plan, coordinate, evaluate, and fund all NIH AIDS research. The OAR is responsible for developing an annual comprehensive plan and budget for all NIH AIDS research. The OAR supports trans-NIH Coordinating Committees to assist in these efforts in the following areas of program emphasis: Therapeutics, Vaccines, Natural History and Epidemiology, Behavioral and Social Sciences, Etiology and Pathogenesis, Training and Infrastructure, and Information Dissemination.

The OAR promotes collaborative research activities in both domestic and international settings. These research studies are conducted by the Institutes and Centers of the NIH, including the NIAID, National Cancer Institute (NCI), NICHD, National Institute of Mental Health (NIMH), National Institute on Drug Abuse (NIDA), and FIC.

A report by a group of non-government scientists and AIDS community representatives who were convened to evaluate the NIH AIDS research program, has had a significant effect on almost every aspect of the AIDS research program--in setting the scientific agenda, refocusing priorities, and shaping the AIDS research budget. The recommendations in the "Report of the NIH AIDS Research Program Evaluation Working Group of the Office of AIDS Research Advisory Council" (also known as the "Levine Report") helped frame the OAR's final distribution of the NIH AIDS appropriations for fiscal years (FY) 1997 and 1998. In addition, the Levine Report significantly influenced the priority setting that occurred in the development of the FY-1999 NIH Plan for HIV-Related Research and Budget, which the OAR is congressionally mandated to develop in concert with the annual NIH AIDS research budget request. The priorities established by the Levine Report will have an impact not only on government-supported research but on the research agendas of industry and private research organizations in the United States and abroad.

The report articulated the importance of coordinating international HIV/AIDS research efforts with other agencies, international organizations, and other governments. Further, it listed as one of several high priorities "domestic and international studies testing the efficacy of joint behavioral and biomedical strategies for combined control of HIV and other sexually transmitted diseases and combined control of HIV and other adverse health consequences of injection drug use."

The FY-1998 and FY-1999 NIH AIDS research priorities include the following:

- A continued increased emphasis on fundamental science, particularly investigator-initiated research;
- A comprehensive effort, including several important new research initiatives, to develop new vaccine candidates and bring them to clinical trials as soon as

possible, including a refocusing on the importance of international collaboration at the earliest stages of vaccine development and testing;

- An augmentation of research efforts to better understand the human immune system; and
- An emphasis on prevention science research, including enhanced domestic and international studies of risk-taking behavior and the development on strategies to avert infection, such as microbicides, female-controlled barriers, and STD treatment and prevention.

International AIDS Funding (in thousands of dollars)

	FY-1995 Actual	FY-1996 Actual	FY-1997 Actual	FY-1998 Estimate	FY-1999 Estimate
NCI	5,876	3,415	5,641	5,674	5,775
NIDCR	--	--	782	816	901
NINDS	2,103	1,923	973	973	973
NIAID	21,112	21,691	24,892	26,958	29,958
NIGMS	--	--	92	89	84
NICHD	2,263	3,302	4,151	4,400	4,700
NIMH	4,301	3,894	3,512	3,656	3,912
NIDA	1,839	140	--	500	500
NCRR	677	590	418	499	588
FIC	9,108	9,694	10,312	10,611	11,305
Totals	\$47,279	\$44,649	\$50,773	\$54,176	\$58,696

Prevention

NIH-sponsored programs targeting the development and evaluation of various preventive interventions have resulted in marked changes in sexual and drug-using behaviors associated with HIV transmission among at-risk populations, including difficult-to-reach and socially disenfranchised populations in the U.S. and abroad. NIH programs have

demonstrated that behavioral interventions targeting behaviors can be developed and implemented, including those designed to delay or prevent initiation of sexual activity and drug use. These studies have demonstrated that multifaceted risk-reduction programs, including those providing drug treatment, outreach, and education on HIV risk, and sterile injection equipment, can produce significant and sustained decreases in HIV risk behavior among injection drug users. Prevention research has shown that interventions must be culturally and ethnically directed in order to successfully reach targeted populations. NIH also is studying community-level interventions as an important way to effect behavioral change on a larger scale.

Preventing vertical transmission from HIV-infected mother to child is a priority of NIH intervention research. Implementing the ACTG 076 protocol has significantly reduced the incidence of maternal-fetal HIV transmission in the United States. Ongoing efforts are designed to identify and test other interventions that can effectively and easily be used globally to further reduce the incidence of vertical transmission of HIV. NIH-funded scientists are actively studying the timing and mechanisms by which HIV is transmitted from mother to baby so that more effective interventions can be developed to block mother-to-child transmission.

NIH also has sponsored several international conferences on the prevention of perinatal transmission. The second Global Strategies Conference on Prevention of HIV Transmission from Mother to Infant will be held in September 1999 in Montreal Canada. It will bring investigators from developing countries together with investigators from more developed countries to plan future collaborative strategies for the prevention of mother to infant HIV transmission.

NIH international efforts in prevention research and related training and research capacity-building include the following:

- Studies of the role of viral shedding in infectivity for both sexual transmission and mother to child transmission;
- Studies in several developing countries in Africa, Asia, and Latin America to evaluate interventions for reducing mother-to-child transmission of HIV that may be used in diverse cultural and economic settings, such as the use of short courses of treatment with zidovudine, nutritional supplements, HIV-1 hyperimmune intravenous immune globulin, vaginal cleansing, and studies of breastfeeding;
- Development of safe, effective, and acceptable condoms, microbicides, and other female-controlled barriers;
- Studies in Africa on the efficacy of STD treatment and prophylaxis on reducing sexual transmission of HIV; and
- Development of behavioral interventions to reduce the risk factors associated with HIV transmission, including injection drug use and various sexual behaviors.

In response to the Levine Report recommendation for developing a Prevention Science Agenda that combines behavioral and biomedical intervention research, the NIH sponsored several agenda setting activities, including a 1998 Workshop on International HIV/AIDS Prevention Research Opportunities. The goal of the Workshop was to encourage research that would be feasible and relevant for developing countries with limited resources. Representatives from 37 countries severely affected by the epidemic participated in the workshop to develop a "Basic Prevention Package," a list of HIV prevention interventions that would be important in developing countries, and a listing of "Priorities for International HIV Prevention Research." Another outcome of the workshop was a better understanding of the HIV prevention planning process. More information on this workshop may be found at <http://hivinsite.ucsf.edu/ari>.

Behavioral Research/Behavioral Change Interventions

NIH supports an extensive portfolio of behavioral and social science research on HIV infection and AIDS. These studies have demonstrated the important interaction of biological, psychological, and social factors that contribute to HIV prevention, transmission, and disease progression among individuals and population groups. Findings from these studies have significantly contributed to the understanding of human behaviors that affect HIV transmission risk and to the development of successful interventions to encourage sustained behavioral change. NIH-sponsored behavioral and social science research includes research related to the following goals:

- Developing, implementing, and evaluating behavioral and social interventions to reduce HIV transmission;
- Strengthening the understanding of the determinants, trends, and processes of HIV-related risk behaviors and the consequences of HIV infection;
- Developing and evaluating behavioral strategies for preventing or ameliorating the negative physical, psychological, and social consequences of HIV infection; and
- Improving the research methodologies employed in behavioral and social science research.

NIH-supported studies are ongoing, either independently or linked with biomedical studies, in countries in Africa, Asia, and Latin America.

Vaccine Research

The development of a safe and effective HIV vaccine is of the highest priority for the NIH, and NIH has pledged to work with the other G-8 nations on vaccine efforts. NIH supports a broad program of basic, preclinical, and clinical research on the discovery and development of HIV vaccine candidates. Basic research on HIV and the immune system provides crucial information for developing potential vaccines. Various strategies for

stimulating a protective immune response against HIV infection are being explored through basic research, animal model research, and clinical trials. 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. While the goal of preventive vaccines is to end the HIV pandemic by protecting individuals from HIV infection, vaccines also may serve as immunomodulators to improve immune function and slow disease progression in infected individuals and may prevent them from infecting others.

To accelerate the development of NIH's AIDS vaccine effort, the AIDS Vaccine Research Committee (AVRC), chaired by Dr. David Baltimore, was established. Specific areas of basic research relating to HIV vaccines efforts have been identified by the AVRC and a new, special initiative supporting innovative research in these scientific areas has been funded during the last 2 years to advance this research field. To further HIV vaccine research in the NIH intramural programs, the Vaccine Research Center is being constructed with completion targeted for 2000.

The NIH supports an AIDS Vaccine Evaluation Group (AVEG), which consists of six sites nationwide that are actively evaluating potential HIV vaccines in phase I and II clinical trials. To date, the AVEG has conducted or initiated more than 46 trials with 24 different HIV vaccine candidates. All vaccine candidates to date in AVEG phase I trials have been shown to be safe and well tolerated. In preparation for phase III clinical 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 by training foreign scientists and health professionals. NIH collaborates with UNAIDS, host country governments, and in-country scientists in vaccine development and preparation for efficacy trials. Eleven sites have been established in Africa, Asia, and Latin America.

Treatment Equity

In an effort to identify options for clinical management of HIV-infected patients that would be useful in resource-poor settings, NIH is supporting studies on the use of isoniazid and rifampin to prevent active tuberculosis in PPD-positive, HIV-infected patients in Uganda. In addition, NIH-supported scientists in Thailand are studying risk factors for infection with *Penicillium marneffei*. These NIH-trained scientists also are working with the pharmaceutical industry in Asia on developing therapeutics for *P. marneffei* infection.

Women and Health

NIH supports an extensive portfolio of basic, clinical, and behavioral research focusing on women and HIV/AIDS. HIV-infected women experience some complications of HIV disease that are unique or more prevalent in them than in men, such as vaginal and

esophageal candidiasis, chronic herpes simplex infections, other STDs, and cervical dysplasia. NIH-sponsored programs target studies on the natural history and epidemiology of the disease in women through a number of studies in Africa, Asia, and Latin America.

Studies on the etiology and pathogenesis of HIV infection and disease progression in women are ongoing. These studies focus on the role of STDs and other factors in acquiring HIV infection and the pathogenic mechanisms associated with HIV disease progression. Studies on biologic determinants of infectiousness and susceptibility are important areas under investigation. Specific attention is being given to the possible correlation between the level of cell-free or cell-associated HIV in blood, semen, urine, cervical/vaginal secretions or oral fluids, and the probability of transmission. In addition, NIH-funded researchers are investigating the cellular and molecular aspects of mucosal immunity and other infectious diseases as cofactors, as they impact HIV susceptibility and transmission. Results from these studies are critical to developing safe and efficacious AIDS vaccines and microbicides.

A critical area of concern is the impact of HIV on cervical cancer. Co-infection with human papilloma virus (HPV) is common in HIV-infected women, and HPV has been shown to act synergistically with HIV to increase expression of individual viral genes. A study in Africa is examining the natural history of cervical neoplasia in women infected with HIV-1 and HIV-2 and the role of HPV as a risk factor.

Of similar critical importance is a current NIH-sponsored multi-site international trial to determine any possible increase in risk acquisition of HIV through heterosexual contact by uninfected women who use hormonal contraceptives. Other studies are planned to examine the possible effects of steroidal hormones on early, acute HIV infection and later progression to AIDS among hormonal contraceptive users, and on the possible effect of steroidal hormone use on the infectiousness of HIV-infected women.

NIH-supported behavioral and social science research that relates to or focuses on women include studies on (1) determinants of HIV risk and prevention; (2) specific elements of social and cultural life that contribute to HIV risk and protective behaviors; (3) the development of appropriate interventions to reduce risk behaviors; (4) community-level interventions; (5) acceptability of both biomedical and behavioral interventions among different individuals and communities; (6) the behavioral aspects of the adoption of new HIV prevention technologies, such as microbicides and the female condom; and (7) social and psychological factors influencing treatment adherence and compliance as well as participation in clinical trials.

Microbicide Development

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. 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 a safe, inexpensive, reliable, and acceptable microbicide for the prevention of HIV and other STDs.

The development of screening assays to test compounds and agents for their microbicidal/spermicidal activity, as well as developing suitable animal models for safety and efficacy-testing of potential microbicides, are vital parts of the developmental efforts supported by NIH in this field of research. Close collaboration with industry is important in conducting the important phase I through III clinical testing of these agents in various populations and to ensure their eventual availability. While a number of microbicidal substances have been clinically tested in phase I and II studies to date, a safe, effective, and acceptable microbicide has yet to be identified. NIH has placed a high priority on developing an efficacious microbicide and continues to look at new compounds, as well as other barrier interventions. In FY-1999, NIH will establish a Prevention Trials Network that will focus on the testing at U.S. and international sites of various interventions, including microbicides, the expansion of the Topical Microbicide Program Projects involving multidisciplinary research to develop and test new agents and the expansion of programs targeting the developing and clinical testing of spermicidal microbicides and other female-controlled barrier methods.

Other Activities

Basic biomedical and behavioral research has significantly contributed to advances in AIDS research. Findings from basic research have provided the scientific basis for developing potential AIDS drugs, vaccine candidates, and effective behavioral interventions to halt the AIDS epidemic.

The NIH has the primary responsibility for the Federally-supported clinical trials evaluating potential treatment regimens against HIV infection and its associated opportunistic infections and malignancies. NIH supports an extensive network of more than 100 clinical trial sites, including adult and pediatric units in major domestic medical centers and community-based primary care settings. More than 50,000 patients have been enrolled to date in these studies that have involved evaluating more than 200 different drugs. The enrollment and accrual in these clinical trials of women, minorities, children, adolescents, injection drug users, and other populations is a high priority for the NIH.



National Institutes of Health
National Institute on Drug Abuse
Bethesda, Maryland 20892

NOV 22 1999

Ms. Sandra L. Thurman
Director, White House Office
of National AIDS Policy
736 Jackson Place, N.W.
Washington, D.C. 20503

Dear Ms. Thurman:

Thank you for providing the Letter of Welcome to the meeting participants at the Second Annual Meeting of the Global Research Network on HIV Prevention in Drug-Using Populations held on August 26-28, 1999, in Atlanta, Georgia. The meeting was co-sponsored by the National Institute on Drug Abuse (NIDA), National Institutes of Health (NIH); the Office of AIDS Research, NIH; the Centers for Disease Control and Prevention (CDC); the World Health Organization (WHO), Substance Abuse Department; the Joint United Nations Programme on HIV/AIDS (UNAIDS); and Health Canada. As a result of the generous contributions made by co-sponsors, approximately 60 HIV/AIDS prevention researchers from 26 countries received travel and housing support to attend the meeting.

Preliminary feedback and reports of the meeting indicate that it was a great success. The meeting provided an opportunity to: 1) identify emerging issues in the epidemic with implications for HIV, HBV, and HCV prevention; 2) discuss the nature, status, and effectiveness of HIV prevention efforts among injecting drug users in different countries; 3) increase research capacity through collaborative efforts nationally and internationally; and 4) plan the Third Annual Meeting of the Global Research Network on HIV Prevention in Drug-Using Populations in South Africa and the role of the Network in the 13th World AIDS Conference, both to be held in July 2000, in Durban, South Africa. Participants at the meeting shared and presented an overview of research and evaluation findings related to HIV prevention/intervention, rapid assessment response, and emerging issues for their region. Information was also shared on the best practices and status of existing prevention networks that focus on HIV interventions for drug users.

NIDA is currently discussing plans for the *Second Annual Report of the Global Research Network on HIV Prevention in Drug-Using Populations* and will share it with you upon completion. Enclosed for your information are: 1) the *Inaugural Meeting Report of the*

Page 2 – Ms. Sandra L. Thurman

Global Research Network on HIV Prevention in Drug-Using Populations held on June 25-26, 1998, in Geneva, Switzerland, and 2) the Meeting Program of the Second Annual meeting held on August 26-28, 1999, in Atlanta, Georgia.

Sincerely,

A handwritten signature in black ink, appearing to read 'Alan Leshner', with a stylized flourish extending to the right.

Alan I. Leshner, Ph.D.

Director

Enclosures

**Social &
Scientific
Systems**

declined / per
Deborah

November 30, 1999

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

Dear Ms. Thurman:

I am writing on behalf of the Office of HIV/AIDS Policy (OHAP), U.S. Department of Health and Human Services to invite you to a meeting with Eric Goosby, M.D., Director of OHAP. This meeting is scheduled for December 13, 1999, from 8:30 a.m. -10 a.m. (the same day and location as your meeting with the Surgeon General). The location will be Room 727E in the Hubert Humphrey Building.

Attached please find logistical information for the meeting with a response form. Please indicate your availability on the response form, and fax it back to me at (301) 913-0351. I would appreciate receiving the response form by Friday, December 3.

If you have any questions or concerns about logistical arrangements for the meeting, please don't hesitate to contact me. I can be reached by phone at (301) 986-4870 or by email at acb@s-3.com.

Sincerely yours,



Ann Borlo

Attachment

The Leadership Campaign on AIDS (TLCA) (formerly known as Project LEAD)

December 13, 1999

Logistical Fact Sheet

Meeting Date: Monday, December 13, 1999

Time: 8:30 - 10:00 a.m. (Room 727E) - Dr. Goosby
1:00 p.m. - 2:30 p.m. (Room 729G) - Dr. Satcher

Meeting Location: U.S. Public Health Service
Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, DC 20201
Phone: 202-690-5560
Fax: 202-690-7560

**Ground
Transportation:** *To reach the Hubert Humphrey Building:*

■ **From BALTIMORE/SILVER SPRING:**

By Automobile: Take 95 South to 495 toward Silver Spring. Exit at Georgia Avenue South. Bear right when Georgia Avenue splits to 16th Street. Follow 16th Street to K Street. Turn left on K Street and follow it to 7th Street, turn right on 7th Street. Follow 7th Street to Independence Avenue and turn left. The Hubert Humphrey Building is on the right.

By Metro: Board the **Red Line** heading toward Shady Grove. Transfer at Metro Center to the **Orange/Blue Line** toward New Carrollton (Orange) or Addison Road (Blue). Exit the **Orange/Blue Line** at Federal Center Southwest. Exit the station at Third Street, S.W. turn left and walk approximately one block toward the 2nd Street, S.W. The Hubert Humphrey Building is located at 200 Independence Avenue, S.W.

Ground Transportation (continued):

■ From BETHESDA:

By Automobile: Take Wisconsin Avenue south toward Washington, DC. Turn left at M Street, N.W. Continue around Washington Circle to Pennsylvania Avenue, N.W. Take Pennsylvania Avenue to 17th Street. Turn right on 17th Street. From 17th Street, turn left on Constitution Avenue. Follow Constitution Avenue to 7th Street, turn right. Proceed to Independence Avenue, turn left. The Hubert H. Humphrey Building is on the right.

By Metro: Board the **Red Line** heading toward Wheaton. Transfer at Metro Center to the **Orange/Blue Line** toward New Carrollton (Orange) or Addison Road (Blue). Exit the **Orange/Blue Line** at Federal Center Southwest. Exit the station at Third Street, S.W. turn left and walk approximately one block toward 2nd Street, S.W. The Hubert Humphrey Building is located at 200 Independence Avenue, S.W.

■ From NORTHERN VIRGINIA

By Automobile: Take 95 North to 395, exit at 14th Street, S.W. Follow 14th Street to Independence Avenue and turn right. Continue to 200 Independence Avenue, S.W. The Hubert H. Humphrey Building is on the right.

By Metro: Board the **Orange Line** heading toward New Carrollton. Exit the **Orange Line** at Federal Center Southwest. Exit the station at Third Street, S.W. turn left and walk approximately one block toward the 2nd Street, S.W. The Hubert Humphrey Building is located at 200 Independence Avenue, S.W.

Parking:

Parking is available at the Colonial Parking Garage on Third Street at the rate of \$11.00 per day.

**Contact
Information:**

For meeting questions, please contact:

Mr. Miguel Gomez
Office of Public Health and Science
U.S. Public Health Service
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, DC 20201
Phone: 202-690-5560
Fax: 202 690-7560
E-mail: mgomez@osophs.dhhs.gov

For logistical questions, please contact:

Ms. Ann Borlo
Social & Scientific Systems, Inc.
7101 Wisconsin Avenue, Suite 1300
Bethesda, MD 20814
Phone: 301-986-4870
Fax: 301-913-0351
E-mail: aborlo@s-3.com

The Leadership Campaign on AIDS (TLCA)
(formerly known as Project LEAD)

December 13, 1999

RESPONSE FORM

(please print)

Name

- ☐ I WILL be able to participate in the meeting.
- ☐ I WILL NOT be able to participate in the meeting.

Please return this form by December 3, 1999, to:

Ann Borlo
Social & Scientific Systems, Inc.
7101 Wisconsin Avenue, Suite 1300
Bethesda, Maryland 20814
Phone: (301) 986-4870, ext. 346 / **Fax: (301) 913-0351**

Office of HIV/AIDS Policy

Office of Public Health and Science
U.S. Public Health Service/DHHS
200 Independence Avenue, S.W.
Washington, D.C. 20201
Tel. (202) 690-5560



☐ Room 736-E

Fax. (202) 690-6584

☐

Room
736-E

Fax.
(202) 690-7560

TO: Sandy Thurman
202-456-2438

~~CONFIDENTIAL~~

DETERMINED TO BE AN
ADMINISTRATIVE MARKING
INITIALS: Q DATE: 05/02/14

FROM: ERIC GOOSBY, M.D.
202-260-8863

Thanks

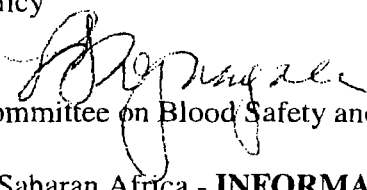


DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary
Office of Public Health and ScienceAssistant Secretary for Health
Surgeon General
Washington, D.C. 20201

DATE: June 9, 2000

TO: Eric P. Goosby, M.D.
Director, Office of HIV/AIDS Policy

FROM: Stephen D. Nightingale, M.D. 
Executive Secretary, Advisory Committee on Blood Safety and Availability

SUBJECT: Needs of Blood Programs in sub-Saharan Africa - **INFORMATION**

The World Health Organization has estimated that 80% of the world's population has access to only 20% of the global supply of safe blood, and that as many as 13 million of the 35 million units of blood that are transfused annually throughout the world are not tested for HIV or hepatitis. For these reasons, WHO has designated blood safety the theme for World Health Day 2000, and a major focus of its efforts in the developing world over the next five years.

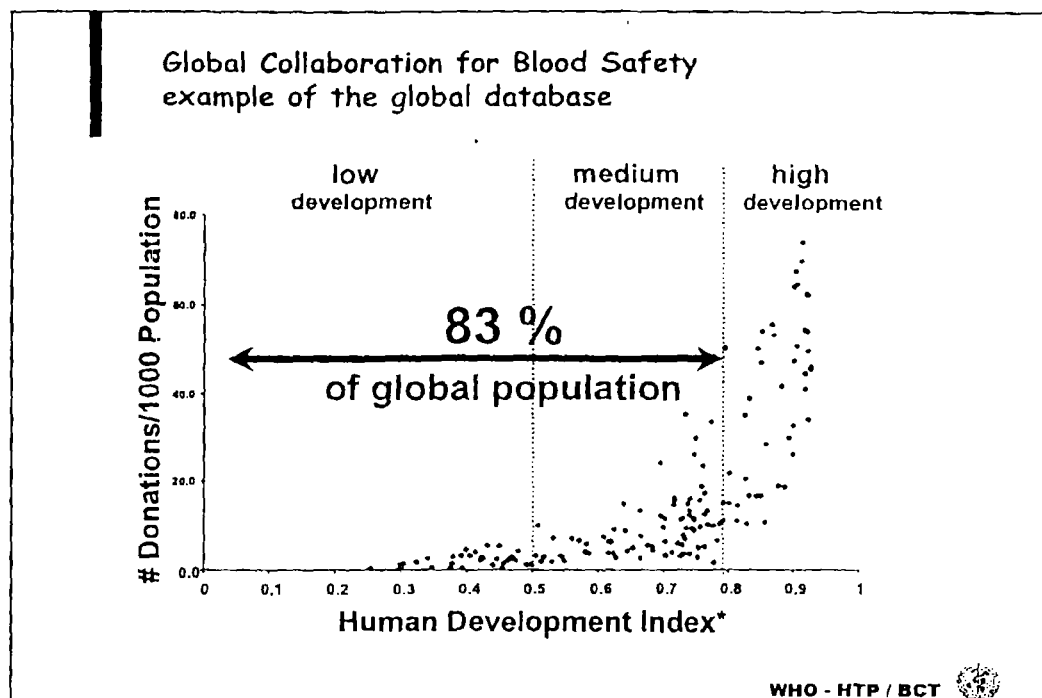
Use of blood in developing countries is only known approximately, and demand for blood even more so. Donation rates in countries with a low human development index is approximately 18 times lower than in countries with a high development index (Figure). In countries such as the United States, half of all blood is used for patients over age 65 (joint replacement, cardiac surgery, and cancer therapy account for most of this use). For individuals under 65, the majority of blood use is for cancer therapy, complications of childbirth, trauma, and inherited diseases such as sickle cell anemia and thalassemia. In developing countries, blood use in urban medical centers may approach the pattern of developed countries, but blood use in the countryside would be primarily for trauma, complications of childbirth, and inherited blood diseases. In areas infested with malaria or intestinal parasites, treatment of anemia due to these infections also generates demand for blood transfusions. As economic development of the countryside proceeds, the pattern of blood use would be expected to change toward the urban pattern.

The major obstacles to safe blood in developing countries - unfortunately, in both urban and rural areas - are the use of paid donors or "replacement" donors; the very high rates of transfusion-transmissible diseases in the donor population, and limited funding for both infrastructure and specific tests. The goal of the WHO Global Collaboration for Blood Safety, and of all concerned workers in the field, is to implement the standard of voluntary blood donation throughout the world, albeit in a manner responsive to local customs and resources. In both South Africa and Zimbabwe, for example, successful blood donor pools have been constructed from secondary school students who acquire the habit of repeat donation and retain the habit afterwards (repeat

donors are much safer in all settings studied than occasional donors). Judicious support of such programs, particularly for infrastructure and for performance of specific tests, would enable them to expand their catchment areas and serve as models for the development of other blood centers. An investment of approximately \$500,000 US per annum over a period of 5 to 10 years in each of 20 to 40 blood centers throughout sub-Saharan Africa for the purpose of implementing full volunteer donation and uniform testing of donations could have a substantial impact on the estimated 10% of HIV infections in sub-Saharan Africa caused by blood transfusion.

The blood centers most likely to benefit from this support, at least initially, would be those in urban areas. For rural populations, the infrastructure necessary to insure a safe blood supply will take years to develop. In the interim, a potential solution is the deployment of blood substitutes. The Department of Defense anticipates deployment of the equivalent of 65,000 units of a blood substitute around the world within 5 years, and a private company (Biopure) has begun Phase III clinical trials and construction of a manufacturing facility in South Africa for the commercial deployment of a bovine hemoglobin-based blood substitute. For trauma and obstetrical accidents in rural areas of developing countries, these products could have a substantial impact on mortality. At present, clinical trials remain to be completed. However, the challenge of these trials appears to be no greater than the challenge of determining how to deploy them in developing economies of limited resources and substantial need. A modest investment in efforts to solve this problem could return substantial benefits in the future.

FIGURE



Office of HIV/AIDS Policy

Office of Public Health and Science
Office of the Secretary
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201
Tel. (202) 690-5560



☐ Room 736-E

Fax. (202) 690-6584

Fax. (202) 690-7560

TO: *Sandy -*

FAX: *456-2939*

FROM: Deborah von Zinkernagel
Deputy Director for Policy

(This fax contains _____ page(s) + cover)

*Wanted you to have a heads up
that our Crisis Team Initiative
will be starting 3 new cities
(Atlanta, Newark, LA) in the next few
weeks. We'll probably add Oakland to that
list - still being finalized*

If there are any problems with this transmission, please call Terrie Alvarez at (202) 690-5560

XOX



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Bethesda, Maryland 20892

JUN 14 2000

Ms. Sandra L. Thurman
Director, White House Office of
National AIDS Policy
736 Jackson Place, N.W.
Washington, D.C. 20503

Dear Ms. Thurman: *Sandy*

We are pleased to invite you to give welcoming remarks and, as your time permits, to participate in the Third Annual Meeting of the *Global Research Network on HIV Prevention in Drug-Using Populations* to be held July 5-7, 2000, in Durban, South Africa. The meeting is being co-chaired by Health Canada and the South African Medical Research Council, and co-sponsored by the National Institute on Drug Abuse, National Institutes of Health (NIH); the Joint United Nations Programme on HIV/AIDS; the World Health Organization Substance Abuse Department; the United Nations Office of Drug Control and Crime Prevention; the South African Department of Health; the NIH Office of AIDS Research; the NIH Fogarty International Center; the U.S. Centers for Disease Control and Prevention; and the Office of HIV/AIDS Policy, U.S. Department of Health and Human Services.

The objectives of the upcoming meeting are: 1) to exchange empirically-based quantitative and qualitative research data on drug users and HIV prevention; 2) to promote the global diffusion and application of empirically-based research findings on drug users and HIV prevention; 3) to increase cross-national, regional, and country research capacity by addressing structural, economic, cultural, and attitudinal barriers to effective national and international collaboration, with a focus on Africa; and 4) to discuss the nature, status, and effectiveness of HIV prevention research among users of drugs in different countries, with a focus on Africa.

A meeting description and draft agenda are enclosed for your information. The meeting agenda can easily be changed to accommodate your schedule for you to make remarks any time during the meeting. I hope that your calendar permits your participation and attendance at this important meeting. I look forward to hearing from you.

Sincerely,

Ruth L. Kirschstein, M.D.
Acting Director

Enclosures

Programme

2000 GLOBAL RESEARCH NETWORK MEETING ON HIV PREVENTION IN DRUG-USING POPULATIONS

THIRD ANNUAL MEETING

Royal Hotel
Durban, South Africa

Meeting Objectives

- To exchange empirically-based quantitative and qualitative research data on drug users and HIV prevention
- To promote the global diffusion and application of empirically-based research findings on drug users and HIV prevention
- To increase cross-national, regional and country research capacity by addressing structural, economic, cultural, and attitudinal barriers to effective national and international collaboration, with a focus on Africa
- To discuss the nature, status, and effectiveness of HIV prevention research in drug-using populations in different countries, with a focus on Africa
- To explore other health conditions and consequences of drug use

DAY 1

WEDNESDAY, JULY 5, 2000

8:00 AM – 8:30 AM REGISTRATION

8:15 AM – 9:00 AM WELCOME AND INTRODUCTIONS

Co-Chairs: Donald Sutherland

Health Canada

Charles Parry

Medical Research Council – South Africa

Sponsoring organisations listed alphabetically:

Eugene McCray

Centers for Disease Control and Prevention, U.S.A.

David Kilgour

Health Canada

Swarup Sarkar

Joint United Nations Programme on HIV/AIDS

Salim Abdool Karim

Medical Research Council, South Africa

Melvyn Freeman (sending either Ms. Onica Maphai or

Mr. Sifiso Phakade)

Mental Health & Substance Abuse Programme,

Department of Health, South Africa

Mary Jansen

World Health Organisation

Frank Albert

United Nations Office of Drug Control and Crime Prevention,

United Nations Drug Control Programme, South Africa

Kenneth Bridbord

Fogarty International Center,

National Institutes of Health, U.S.A.

Alan Leshner

National Institute on Drug Abuse,

National Institutes of Health, U.S.A.

Neal Nathanson
Office of AIDS Research
National Institutes of Health, U.S.A.

Eric Goosby
Office of HIV/AIDS Policy,
U.S. Department of Health and Human Services

9:00 AM – 9:15 AM **MEETING OVERVIEW:**
(historical perspective of GRN, meeting goals and objectives)

Speaker: Donald Sutherland
Health Canada

DAY 1 OBJECTIVES:

- Summarise current knowledge of HIV/drug use prevention research and evidence-based interventions.
- Update HIV/drug use research from Africa
- Discuss challenges posed for conducting effective HIV/drug use prevention research, focus on Africa

9:15 AM – 12:00 PM **A GLOBAL PERSPECTIVE OF HIV PREVENTION RESEARCH IN DRUG USING POPULATIONS**
(Synthesis papers providing an overview of major HIV/IDU research and interventions. Presentations will be used for the GRN meeting proceedings and will also be given at the Prevention Works Satellite Meeting)

Chair: Paul A. Gaist

9:20 AM – 9:40 AM **Recent Trends in the Global Epidemiology and Ethnography of Injection Drug Use and HIV**
(Identify trends in the global epidemics over the past year based on research studies emphasising 3-4 key findings)

Speaker: Richard H. Needle
Office of HIV/AIDS Policy and
National Institute on Drug Abuse, U.S.A.

9:40 AM – 10:00 AM **Identification and Critical Assessment of Intervention Strategies and Approaches**

Speaker: M. Suresh Kumar
Punarjeevan Drug Treatment Centre, India

10:00 AM – 10:20 AM Critical Assessment of Lessons Learned and Best Practices

Speaker: Don DesJarlais
Beth Israel Medical Center, U.S.A.

10:20 AM – 10:40 AM **BREAK**

10:40 AM – 11:00 AM Evidence in the Effectiveness of Harm Reduction and Other Applied Prevention Practices

Speaker: Judith Honti
Central-Eastern European Harm Reduction Network

11:00 AM – 11:20 AM Collection of Global Evidence to Formulate New Research Questions and Direct Capacity Building
(how to access and assess global information, tools, and resources to inform research and capacity building)

Speaker: Swarup Sarkar
Joint United Nations Programme on HIV/AIDS

11:20 AM – 12:00 PM Discussion
(Outcome: conclusions that can be drawn from research to date and implications for countries with emerging HIV/drug use epidemics)

Moderators: Andrew Ball
World Health Organization

Nandi Siegfried,
Medical Research Council, South Africa

12:00 PM – 1:00 PM **LUNCH**

1:00 PM – 4:00 PM **RESEARCH EXPERIENCES FROM AFRICA ON HIV AND DRUG USE**
(using specific examples of research conducted, address how to identify and tackle emerging epidemics. describe sub-epidemics, surveillance issues, approaches/methods and new data. The speaker should also suggest program implications of findings. Audience is challenged to provide feedback)

Co-chairs: Moruf Adelekan
Gayatri Jayaraman

- 1:00 PM – 1:20 PM** Preventing HIV and Other Blood Borne Diseases among Drug Using Populations in Nigeria – Implications for Research, Practice and Policy
- Speaker: Michael Ekpo*
Federal Neuropsychiatric Hospital, Calabar, Nigeria
- 1:20 PM – 1:40 PM** The Drug Use and HIV Situation in Relation to the Civil Conflict in Sierra Leone
- Speaker: Ahmed B.S. Kamara*
International Organisation on Good Templars, Sierra Leone
- 1:40 PM – 2:00 PM** Harm Reduction as an Alternative Strategy in the Prevention of Drug Abuse and HIV/AIDS in Kenya
- Speaker: Maurice Odek-Ogunde*
United States International University, Kenya
- 2:00 PM – 2:20 PM** Substance Use in the Context of HIV Disease Pandemic – an Emerging Issue in Tanzania
- Speaker: Paul Kilonzo*
Muhimbili Medical Centre, Tanzania
- 2:20 PM – 2:40 PM** **BREAK**
- 2:40 PM – 3:00 PM** High Levels of Injection Drug Use in Mauritius
- Speaker: Vimla (Moruf or Gaya to finalize)*
Ministry of Health – Mauritius
- 3:00 PM – 3:20 PM** Alcohol and Sexual Risk Behaviour in Zimbabwe
- Speaker: Godfrey Woelk*
University of Zimbabwe Medical School,
Department of Community Medicine
- 3:20 PM – 3:40 PM** HIV among Arrestees in Cape Town, Durban and Gauteng, South Africa
- Speaker: Charles Parry*
Medical Research Council, South Africa

3:40 PM – 4:00 PM Drugs and HIV among Sex Workers in Durban, Cape Town,
and Johannesburg, South Africa

Speaker: Ted Leggett
Centre for Social & Development Studies,
University of Natal, South Africa

4:00 PM – 5:00 PM **COMMENTARY ON HIV/DRUG USE PREVENTION
RESEARCH IN AFRICA**

Panel Discussion

*(provide feedback on HIV/drug use prevention research needs
in Africa, lessons learnt from research in other countries, how
to make use of existing knowledge to move the interventions to
reduce transmission of HIV among drug users in national
programmes, areas for GRN involvement)*

Moderator: Moruf Adelekan

*Panelists: Sam Friedman, Jimmy Dorabjee, Edna
Oppenheimer, Graciela Touze, Myat Razak*

5:00 PM **ADJOURN**

DAY 2

THURSDAY, JULY 6, 2000

8:30 AM – 8:45 AM **WELCOME AND REVIEW OF DAY-1**

*Co-Chairs: Donald Sutherland
Charles Parry*

DAY 2 OBJECTIVES:

- Discuss methodologies that can be used for cross-regional or cross-national comparisons of HIV/IDU epidemiology and trend assessment
- Discuss the natural history of drug use highlighting the links between substance abuse and transmission of HIV and other blood borne pathogens and potential avenues for research and interventions
- Discuss challenges of translating research into practice

8:45 AM – 10:30 AM **ROLE OF SURVEILLANCE IN HIV/INJECTION DRUG
USE PREVENTION RESEARCH**

*(discuss collection and use of surveillance data to assess
population trends in drug use and HIV. HIV prevention
questions are triggered by surveillance. Common indicators for
comparability between regions, countries, lessons learnt)*

Co-chairs: Maristela Monteiro & Nicholas Crofts

8:45 AM – 9:05 AM **Estimating the Global Burden of Infections with Blood Borne
Pathogens Associated with Unsafe Injections**

Speaker: Yvan Hutin

9:05 AM – 9:25 AM **Rapid Situation Assessment on Injection Drug Use in Buenos
Aires, Argentina**

Speaker: Diana Rossi

9:25 AM – 9:45 AM **A Multicentre Rapid Assessment of Injection Drug Use in India**

Speaker: Luc Samson

9:45 AM – 10:05 AM **Assessment of Injecting Drug Use and HIV-Related Risks**

Speaker: Jihane Tawilah

10:05 AM – 10:25 AM **UNDCP/UNAIDS – Global HIV Prevalence Update**

Speaker: Peter Ghys

10:30 AM – 10:45 AM BREAK

**10:45 AM – 12:30 PM SOCIAL, ECONOMIC AND POLITICAL FACTORS
ASSOCIATED WITH CHANGING PATTERNS OF
DRUG USE AND HIV: CONSEQUENCES AND
IMPLICATIONS FOR PREVENTION**

*(discuss what we have seen, learnt, and the link between
substance abuse, driven by natural evolution, economics,
behaviour, etc. and injecting)*

Co-Chairs: Stephanie Strathdee & Kenneth Bridbord

**10:45 AM – 11:05 AM Drug injecting, rapid HIV spread, and the risk environment;
assessment and response**

Speaker: Tim Rhodes

11:05 AM – 11:25 AM Patterns of HIV spread associated with drug trafficking

Speaker: Chris Beyrer

11:25 AM – 11:45 AM The Nigerian Experience

Speaker: A.O. Akinhanmi

Neuropsychiatric Hospital and WHO Collaborating Centre for
Research and Training, Nigeria

11:45 AM – 12:30 PM Discussion

(extract implications for research, prevention and policy)

12:30 PM – 1:30 PM LUNCH

**1:30 PM – 3:30 PM CHALLENGES OF TRANSLATING EVIDENCE-BASED
HIV PREVENTION RESEARCH FINDINGS INTO
PROGRAM PRACTICE AND POLICY CHANGE**

*(how research was translated using case studies, how
researchers can best meet the needs of programme
implementers/policy makers)*

Co-Chairs: T. Stephen Jones & Rey Chad Abdool

**1:30 PM – 1:50 PM The challenges of transferring effective research-based HIV
behavioural and social interventions into prevention
programme practice.**

Speaker: Mary Spink Neumann

Centers for Disease Control and Prevention, U.S.A.

- | | |
|--------------------------|--|
| 1:50 PM – 2:10 PM | Title TBD (Asia)
<i>Speaker: (to be suggested by UNAIDS)</i> |
| 2:10 PM – 2:30 PM | Title TBD (Russia)
<i>Speaker: Wim Landman</i> |
| 2:30 PM – 2:50 PM | Title TBD (Brazil)
<i>Speaker: Fabio Mesquita</i>
Faculdade de Medicina da USP, Departamento de
Informatica Medica, Brazil |
| 2:50 PM – 3:10 PM | Title TBD (The role of regional networks in translation of
best practices and informing future research)
<i>Speaker: Allan Clear</i> |
| 3:10 PM – 3:30 PM | Plenary Reaction Session |
| 3:30 PM – 3:45 PM | BREAK |
| 3:45 PM – 5:00 PM | DISSEMINATION OF RESEARCH FINDINGS AND
CAPACITY BUILDING

<i>Co-Chairs: Neo Morojele & Richard Needle</i>
Medical Research Council, South Africa |
| 3:45 PM – 4:05 PM | Title (TBD)
<i>Speaker: Alex Wodak</i> |
| 4:05 PM – 4:35 PM | Building the capacity and knowledge base for policy and
programmes at the national and international levels

<i>Speaker: Alan Leshner</i>
National Institute on Drug Abuse, U.S.A. |
| 4:35 PM – 5:00 PM | Discussion |
| 5:00 PM | ADJOURN |

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DAY 3 (GRN 'OPEN' SESSION)
FRIDAY, JULY 7, 2000

- | | |
|--------------------------|---|
| 9:00 AM – 1:00 PM | FUTURE CHALLENGES AND RESEARCH
PRIORITIES
<i>Co-Chair: Henry Francis</i>
<i>(introductory remarks and summary of Days 1 and 2)</i> |
|--------------------------|---|

- 9:15 AM – 9:25 AM** **Co-Sponsoring Organization's Remarks**
Speaker: David Kilgour
 Health Canada
- 9:25 AM – 9:45 AM** Use of rapid assessment and response to identify research priorities

Speakers: Marital Monteiro
 World Health Organisation

Moruf Adelekan
 University of Ilorin, Nigeria

 Discussion
- 9:45 AM – 10:15 AM** Challenges of translating evidence-based prevention research
Speaker: T. Stephen Jones (or other suggestion)
 Centers for Disease Control, U.S.A.

 Discussion
- 10:15 AM – 10:45 AM** HIV Tools: A Toolkit for Exploring the Cost, Impact, and Cost-Effectiveness of HIV Prevention Activities among IDU
Speaker: Lilian Kumaranayake
 London School of Tropical Medicine and Hygiene, U.K.

 Discussion
- 10:45 AM – 11:00 AM** **BREAK**
- 11:00 PM – 11:30 PM** Ethical issues in HIV/drug use prevention and research
Speaker: Aart Hendriks

 Discussion
- 11:30 AM – 12:30 PM** Accessing Non-Traditional Populations

 International perspectives on HIV and substance abuse in prisons
Speaker: Kate Dolan

 Discussion

Adolescent, HIV, and Drug Abuse
Speakers: Andrew Ball & Neo Morojele

12:30 PM – 1:00 PM General Discussion and Conclusions

1:00 PM **ADJOURN**

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2000 Global Research Network on
HIV Prevention in Drug Using Populations
Third Annual Meeting
Durban, South Africa • July 5-7, 2000

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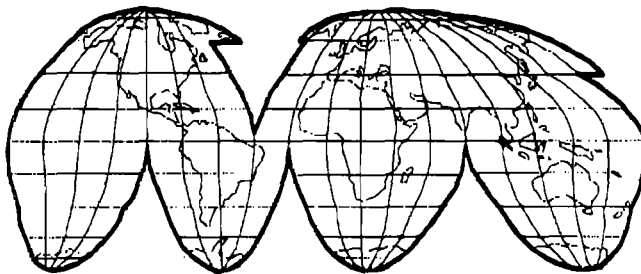
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PAGES: 3

DATE: May 25, 1999

☐ FOR YOUR ACTION



FOR YOUR INFORMATION



AS REQUESTED



AS DISCUSSED

MESSAGE: I am sorry for the delay. Secretary Shalala, Assistant Secretary for Health/Surgeon General Satcher, and a large delegation of DHHS officials including myself were in Geneva last week for the World Health Assembly. DHHS will hold a meeting of relevant agencies later in the week to further develop the response to your request. I will be in touch.

ATTACHED: Memorandum with Attachments

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

Office of the Secretary

Office of Public Health and Science
Office of International and Refugee Health
Rockville, MD 20857

DATE: May 25, 1999

TO: Director
Office of National AIDS Policy

FROM: Acting Director
Office of International and Refugee Health
Department of Health and Human Services

SUBJECT: Global AIDS Emergency Working Group

The Department of Health and Human Services (DHHS) has been seriously engaged in a response to the growing emergency of HIV/AIDS in many parts of the world. The crisis in sub-Saharan Africa has been of special concern.

The Assistant Secretary for Health and Surgeon General (ASH/SG) has included Emerging and Reemerging Infectious Diseases (ERIDs) in general and HIV/AIDS in particular under his Global Health Priority. Attached is a column on global HIV/AIDS by the ASH/SG from the *Journal of the American Medical Association (JAMA)* (Tab A).

The three most important agencies in the DHHS response to global HIV/AIDS are the Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA), and the National Institutes of Health (NIH). Attached is a summary of the DHHS response to global HIV/AIDS (Tab B).

DHHS looks forward to its participation in the Global AIDS Emergency Working Group.


Gregory Pappas, M.D., Ph.D.

TAB A



JAMA
The Journal of the American Medical Association

Medical News & Perspectives - April 28, 1999
From the Surgeon General

JAMA

The Global HIV/AIDS Epidemic

An enormous human tragedy is unfolding in many less-developed countries because of the spread of HIV/AIDS. Of the 33.4 million HIV-infected people around the world, there are an estimated 22.5 million in sub-Saharan Africa, 6.7 million in South and Southeast Asia, 1.4 million in Latin America, and 665,000 in the United States. Globally, more than 14 million people have died of the disease, including 2.5 million last year.

In many southern African countries, HIV/AIDS has become an unprecedented emergency, with 20% to 26% of people between the ages of 15 and 49 infected. In Botswana, Kenya, Malawi, Mozambique, Namibia, Rwanda, South Africa, Zambia, and Zimbabwe, HIV/AIDS will reduce life expectancy from 64 to 47 years by 2015. The progress of decades of work immunizing children, controlling diseases, and improving nutrition is being negated by HIV/AIDS.

Conditions in many parts of the world promote rapid spread of the HIV/AIDS epidemic. For example, India, with a population approaching 1 billion, has estimated that 3 million to 5 million of its people are infected, and the number of new infections will double every 14 months.

Social and political issues surrounding sex, injecting drug use, and blood transfusion in many countries have created special circumstances in which the disease has been able to spread unchecked. Some less-developed countries also bear a burden of political and economic instability that makes prevention even more difficult. It was only a few years ago that epidemiologists offered projections of disease prevalence for sub-Saharan Africa that were met with disbelief. If the present warnings go unheeded, South Asia, Southeast Asia, and, perhaps, China will follow the disastrous course of sub-Saharan Africa.

More than a decade of experience has taught us how to control HIV/AIDS—we know what works. Many developed countries have successfully checked the spread of the epidemic. While development of therapy and a vaccine continue, prevention must be emphasized. The basic elements of prevention include education, behavior change, voluntary testing and counseling,

prevention of perinatal transmission, and political commitment. Each country must find the mix of methods appropriate to its particular conditions.

Education about HIV/AIDS is necessary but alone does not change the behavior of populations. Promotion of voluntary testing and counseling must complement education. Testing and counseling break the deadly silence around HIV/AIDS and empower individuals to make informed decisions and change behaviors. Breaking the silence also will begin to diffuse the stigma surrounding the disease. We have seen success with behavioral change in Uganda and Thailand, the only two less-developed countries with extensive capacity for voluntary testing and counseling.

It is known that perinatal transmission of HIV can be reduced by more than 50% by using antiretroviral therapy; however, problems with access to these drugs limit their use in some countries. Transmission of HIV through breast-feeding and poor survival of orphans make the avoidance of disease via treatment for perinatal transmission more complex. We continue to work with international organizations, other governments, and pharmaceutical companies to lower costs and expand access to antiretroviral drugs. Current treatment for perinatal transmission (as well as use of antiretrovirals in general) in less-developed countries is also limited by the fact that very few people have been tested for HIV infection.

Treatment of other sexually transmitted diseases (STDs) is important to control the spread of HIV. One of the reasons HIV has spread so rapidly in Africa is that so many STDs go untreated. Untreated STDs break down natural barriers that prevent transmission. Access to even basic treatment for STDs remains a problem for many less-developed countries.

Perhaps most important in the global battle against HIV/AIDS is political commitment. Leaders at the national, provincial, and local levels of government must speak out about HIV/AIDS and encourage businesses and nongovernmental organizations to commit to work against the disease. I was encouraged by US Vice President Al Gore and Deputy President Thabo Mbeki of South Africa, who put the HIV/AIDS threat at the top of the international agenda at the recent meeting of the United States-South Africa Joint Commission. They set an important example for leaders in developed and less-developed countries.

American medicine and public health have an important role to play in the global battle against HIV/AIDS by supporting international organizations such as the Joint United Nations Program on HIV/AIDS, the World Health Organization, and the World Bank.

HIV/AIDS can be likened to the plague that decimated the population of Europe in the 14th century. While the modern epidemic affects people of all age groups, those of working age are at highest risk, posing potentially dire economic, social, and political consequences for the global community. Unfortunately, the world continues to devote greater attention and resources to traditional national security issues such as wars, postponing notice of an epidemic that, if left to spread unchecked, will kill more people than any of the terrible conflagrations that have so marked this century.

—David Satcher, MD
Surgeon General of the United States and Assistant Secretary,
Department of Health and Human Services

(*JAMA*. 1999;281:1479)

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TAB B

Centers for Disease Control and Prevention

The U.S. Department of Health and Human Services (DHHS) is committed to working in partnership with others to reverse the toll that HIV/AIDS is taking on millions of lives by halting the further spread of HIV and mitigating its effects on those already infected through research, prevention, service delivery and education efforts. Scientists at DHHS have contributed significantly to international progress in understanding how HIV infection is transmitted, how it affects the body, and how to treat and prevent it. As new information becomes available, increased knowledge about this disease and better ways to treat and prevent it should be forthcoming to address this critical health problem.

As the Nation's prevention agency, CDC integrates prevention science, research and practice. Through basic and laboratory research, epidemiologic research, and surveillance, behavioral, communications, and social science research, CDC supports a comprehensive approach to issues which impact prevention. CDC collaborates with governmental and non-governmental organizations, international and domestic, awarding grants to national organizations, state and local health departments, community-based organizations and other institutions to support prevention activities based on science. This integration of science and practice is consistent across all of CDC's Centers, Institutes, and Offices supporting prevention science activities. These include the National Center for HIV, STD and TB Prevention (NCHSTP), the National Center for Infectious Disease (under which falls the Division of AIDS, STD, and TB Laboratory Research), the National Center for Chronic Disease Prevention and Health Promotion (under which falls the Division of Adolescent and School Health and the Division of Reproductive Health), the Office of Women's Health and the Public Health Practice Program Office (which ensures the quality of laboratory testing).

In FY-1998, DHHS received more than \$6.8 billion dollars for HIV/AIDS activities. The majority of these funds (nearly two-thirds) were distributed for care and treatment of Americans through the Health Care Financing Administration (HCFA) authorized under Medicaid and Medicare programs and through the Health Resources and Services Administration (HRSA) authorized under the Ryan White Care Act. Funding for international collaborative HIV/AIDS activities is limited within the offices and agencies within DHHS, with no formal budget allocation for international activities. Therefore, only a tiny percentage of HIV/AIDS funds are allocated for international HIV/AIDS activities.

CDC has two programmatic approaches to international collaboration in HIV/AIDS prevention: field-based research collaborations and limited CDC-based technical assistance, training, and project management.

Field-Based Research

Epidemiology of HIV. Field-based research provides collaborative assistance to Côte d'Ivoire, Uganda, South Africa and Thailand. Studies are designed to increase the

understanding of the epidemiology of HIV and to evaluate intervention methodologies in the host country and the United States. Because of the variation in the virus itself throughout the world, CDC, through two of its centers in Côte d'Ivoire and Thailand, conducts international surveillance of the genetic diversity of HIV research collaborations in numerous countries throughout the world.

Perinatal Transmission. Earlier this year, researchers from CDC and the Ministry of Public Health in Thailand announced dramatic findings that offer real hope for extending perinatal prevention successes to many developing nations. Researchers found that a short course of AZT given late in pregnancy and during delivery reduced the rate of HIV transmission to infants of infected mothers by half and is safe for use in the developing world. CDC is continuing collaborative research in West Africa to establish the longer term efficacy of short course zidovudine for populations in whom safe alternatives to breast feeding may not be available.

Microbicide Development. CDC has also supported international collaboration on the development of microbicidal products, as well as international studies in acceptability of microbicides in Zimbabwe and Thailand. In addition, a number of domestic and international activities have included research about the potential impact of including information on microbicides, once available, as part of the prevention messages about condoms. CDC participates with NIH and FDA in the International Working Group on Microbicides, which also includes UNAIDS, the Population Council and some industry representatives.

Prophylaxis of Opportunistic Infections. In Côte d'Ivoire, a placebo controlled trial of cotrimoxazole in patients in treatment for tuberculosis showed a significantly reduced mortality in immuno-suppressed patients taking the active drug. The recently completed trial of preventive therapy for tuberculosis in Uganda, conducted by Case Western Reserve University in collaboration with Ugandan colleagues was supported by CDC as well.

Vaccine Research. CDC has a number of research activities related to the development of HIV vaccines. This includes participation in efficacy trials in the United States and Thailand, as well as in the development of novel candidate vaccines in collaboration with academic centers. In addition, behavioral research and communication efforts about vaccine related issues are ongoing. CDC expertise in vaccine implementation will be a valuable resource once candidates become available.

Technical Assistance

In addition, CDC provides both long and short term technical assistance internationally. Long-term technical assistance and management capacity has been established by CDC field assignees to Uganda and South Africa, working in conjunction with USAID, as well as India and Vietnam. In addition to these field-based staff, CDC provides short-term technical assistance and training to numerous countries including Brazil, Russia, The

Republic of South Africa, and Mali, and to international organizations including UNICEF, UNAIDS, and WHO.

Training

In conjunction with these technical assistance activities, CDC provides training in the areas of epidemiology, evaluation, prevention methodologies and other technical areas through an extensive program of training based in Atlanta as well as at field sites in Thailand and Côte d'Ivoire. CDC has also designed a program, in collaboration with USAID, to link U.S.-based community organizations and their prevention interventions with counterparts in developing countries. This was established in order to provide a mechanism to share relevant experiences, provide materials and resources, and training opportunities across countries. Other activities will support USAID-assisted countries with access to CDC epidemiologic and surveillance expertise.

Other Activities

Although not specific to HIV/AIDS, it is important to note that CDC's international work focuses heavily on strengthening public health infrastructure, and such work can contribute to sustainable HIV/AIDS control. For example, the CDC established field epidemiology training programs in developing countries. Epidemiology is the cornerstone of public health science, and trained epidemiologists are valuable countries to detect, monitor and help control their key public health programs. Secondly, CDC has established a sustainable management development program to provide practical training in management of public health programs in developing countries.

Recognizing the urgency of the epidemic and its impact on many domestic issues, CDC is committed to HIV/AIDS research within, as well as outside of, U.S. borders. To understand HIV/AIDS at a global level, research must address issues and conditions unique to different countries and communities within countries. Many developing countries severely affected by the epidemic lack the research capacity, public health infrastructure, and financial and human resources to respond to the epidemic. CDC's international research underscores the importance of developing and implementing diverse interventions to address issues among varied populations and to do so quickly and cost-effectively.

Food and Drug Administration

The Food and Drug Administration (FDA) is the only agency within the U.S. Public Health Service whose responsibilities are regulatory in nature. Its purview is product-driven and encompasses products worth approximately 25 percent of the U.S. gross national product. FDA activities respond to product applications—the agency reviews what is brought to it.

FDA's level of commitment to prevention, diagnosis, and treatment of HIV/AIDS is broad-based. FDA, like all of its component agencies in the U.S. Public Health Service, is committed to finding more and better ways to prevent, diagnose, and ultimately cure HIV/AIDS. FDA performs research and review involving AIDS therapeutic and diagnostic vaccine products. Major research priorities include: (1) new more sensitive blood safety testing for HIV; and (2) methods, standards, and studies on mechanisms of action of new AIDS therapeutics and vaccines.

Funding

FDA and its budget is organized around the products within its regulatory framework and is not, generally, a grant-making institution nor an entity organized in terms of line items for particular diseases or disease groups. FDA does not have a specific international budget allocation.

Prevention

Medical Devices. FDA has an ongoing responsibility to help ensure the safety and effectiveness of AIDS-related medical devices through its regulatory activities. This includes sampling and testing of medical gloves and latex condoms; reviewing submissions to market devices that reduce the risk of HIV transmission, including donor screening tests; conducting HIV-related regulatory research involving medical devices; and evaluating the role of devices in the transmission of bloodborne infections.

FDA has cleared for marketing over 280 needle and intravenous cannulas with safety features that reduce the risk of sharps injuries to healthcare workers. Among sharps containers FDA has recently cleared for marketing are devices that electrically oxidize all types and sizes of needles immediately after use, further reducing the risk from used needles.

As condoms remain the best means of protection against the transmission of HIV and other sexually-transmitted diseases, FDA must be vigilant in its regulation. FDA is working to develop better tests for condom strength and is investigating the barrier capability of condoms manufactured of different materials.

Blood and Blood Products. FDA is responsible for ensuring the safety of the U.S. blood supply. Regulatory mechanisms designed to ensure blood safety include establishing

policies; approving authority for blood products and establishments; and surveilling and enforcing blood safety standards. The blood safety system FDA has established consists of five layers of overlapping safeguards that start at the blood collection centers and extend to the manufacturers and distributors of the blood products made from donated blood.

The first level of precautions seeks to eliminate high-risk donors by encouraging those whose blood may pose a health hazard to exclude themselves, and by evaluating their behavioral and medical history as a basis for deferral. The second safeguard entails constant updating of a list of unsuitable donors and checking donors' names against the list to prevent using their blood. The third consists of testing the blood for such bloodborne agents as HIV, hepatitis, and syphilis. The fourth safeguard FDA enforces is a quarantine of donated blood until tests and other control procedures establish its safety. Finally, the blood collection centers are obligated to investigate incidents, audit their systems, and correct deficiencies. FDA also sets quality and safety standards for blood-derived products such as viral inactivation of clotting factor concentrates and immune globulins.

Treatment Equity

Therapeutic Agents. FDA is responsible for approving safe and effective drugs and biologics used in the United States for treating HIV infection, AIDS, and AIDS-associated opportunistic infections. FDA is also responsible for regulating the investigation of new drugs. It places special emphasis on ensuring the most timely and efficient premarketing review possible of products that offer promise for diagnosing, treating, or preventing HIV and HIV-related illnesses. FDA has approved 37 applications for products to treat HIV/AIDS. Twelve drugs are antiretroviral agents that are used to treat the virus, and the remaining 25 are used to treat opportunistic infections that can complicate HIV infection. In addition, FDA is responsible for monitoring the safety of the drugs and biologics post marketing and places special emphasis on ensuring that new safety information is disseminated widely and in a timely manner.

Vaccine Research

Within the framework of the Public Health Service-wide vaccine program for prevention and therapy, FDA is continuing its efforts to guarantee that any promising products for immunization against HIV will receive expedited regulatory review, and when appropriate, will be approved in the shortest possible time.

Diagnostic Capability

Diagnostic Reagents and Test Kits. FDA conducts a variety of regulatory, testing, and research activities to approve for marketing satisfactory test methodologies for detection of HIV. FDA has approved 2 HIV-1 Antigen tests; 20 anti-HIV-1 assays; 3 anti-HIV-2 assays; 1 anti-HIV assay on urine; 1 anti-HIV testing service using home collection; 1

anti-HIV-1 oral specimen collection device; and 1 HIV-1 viral load assay. FDA currently is facilitating development of gene-based screening tests.

National Institutes of Health

The National Institutes of Health (NIH) supports a comprehensive program of basic, clinical, and behavioral research on HIV infection and its associated opportunistic infections and malignancies. Each of the 24 NIH Institutes and Centers is involved in some HIV/AIDS-related research activity consistent with its individual mission. NIH is the world's leading biomedical research institution, supporting more than 5,000 individual HIV/AIDS research projects at more than 500 research institutions across the nation and around the world. NIH has played a leadership role in the discovery and characterization of HIV and continues to lead research to determine the pathogenesis of AIDS. Findings from NIH-sponsored studies have resulted in significant advances in the treatment of HIV infection and its related illnesses and prevention of the opportunistic infections that cause morbidity and mortality of HIV-infected individuals.

The NIH AIDS program supports biomedical and behavioral research necessary to identify therapeutic regimens, behavioral interventions, and vaccine candidates to treat and prevent HIV infection and its associated illnesses in the United States and internationally. The global nature of the AIDS epidemic underscores the critical need to identify interventions for developed and developing nations that prevent HIV transmission, disease progression, and mortality. Continued collaboration with international organizations and other nations is required to achieve these priorities. Research capacity-strengthening in foreign countries is a critical element to NIH's efforts to address HIV/AIDS, and in this regard, NIH supports a strong research training program with partners in 100 countries.

The NIH AIDS program includes collaborations with numerous international organizations. Ongoing and planned efforts include collaborations with the following organizations: UNAIDS, in planning for the initiation of international vaccine clinical trials; the Pan American Health Organization (PAHO) for studies on heterosexual transmission of HIV infection and tuberculosis prophylaxis; the World Health Organization (WHO) in the Antibody Serologic Project; WHO as one of three AIDS reagent centers; and WHO for support of several international workshops and conferences.

In addition, since its inception in 1996, NIH has collaborated with UNAIDS through mutual representation on advisory and coordinating bodies, frequent exchange of information, and collaboration on specific efforts, such as vaccine development, ethical issues related to clinical trials, and research training and infrastructure in developing countries. In this regard, the National Institute of Allergy and Infectious Diseases (NIAID) and the Fogarty International Center (FIC) have been designated UNAIDS Collaborating Centers. Additionally, NIAID and the National Institute of Child Health and Human Development (NICHD) have collaborated with UNAIDS on the Working Group on Prevention of Mother to Child Transmission of HIV.

The NIH Office of AIDS Research (OAR) is located within the Office of the Director of NIH and is responsible for the scientific, budgetary, legislative, and policy elements of the NIH AIDS research program. Congress provided in the NIH Revitalization Act of 1993 broad authorities to the OAR to plan, coordinate, evaluate, and fund all NIH AIDS research. The OAR is responsible for developing an annual comprehensive plan and budget for all NIH AIDS research. The OAR supports trans-NIH Coordinating Committees to assist in these efforts in the following areas of program emphasis: Therapeutics, Vaccines, Natural History and Epidemiology, Behavioral and Social Sciences, Etiology and Pathogenesis, Training and Infrastructure, and Information Dissemination.

The OAR promotes collaborative research activities in both domestic and international settings. These research studies are conducted by the Institutes and Centers of the NIH, including the NIAID, National Cancer Institute (NCI), NICHD, National Institute of Mental Health (NIMH), National Institute on Drug Abuse (NIDA), and FIC.

A report by a group of non-government scientists and AIDS community representatives who were convened to evaluate the NIH AIDS research program, has had a significant effect on almost every aspect of the AIDS research program--in setting the scientific agenda, refocusing priorities, and shaping the AIDS research budget. The recommendations in the "Report of the NIH AIDS Research Program Evaluation Working Group of the Office of AIDS Research Advisory Council" (also known as the "Levine Report") helped frame the OAR's final distribution of the NIH AIDS appropriations for fiscal years (FY) 1997 and 1998. In addition, the Levine Report significantly influenced the priority setting that occurred in the development of the FY-1999 NIH Plan for HIV-Related Research and Budget, which the OAR is congressionally mandated to develop in concert with the annual NIH AIDS research budget request. The priorities established by the Levine Report will have an impact not only on government-supported research but on the research agendas of industry and private research organizations in the United States and abroad.

The report articulated the importance of coordinating international HIV/AIDS research efforts with other agencies, international organizations, and other governments. Further, it listed as one of several high priorities "domestic and international studies testing the efficacy of joint behavioral and biomedical strategies for combined control of HIV and other sexually transmitted diseases and combined control of HIV and other adverse health consequences of injection drug use."

The FY-1998 and FY-1999 NIH AIDS research priorities include the following:

- A continued increased emphasis on fundamental science, particularly investigator-initiated research;
- A comprehensive effort, including several important new research initiatives, to develop new vaccine candidates and bring them to clinical trials as soon as

possible, including a refocusing on the importance of international collaboration at the earliest stages of vaccine development and testing;

- An augmentation of research efforts to better understand the human immune system; and
- An emphasis on prevention science research, including enhanced domestic and international studies of risk-taking behavior and the development on strategies to avert infection, such as microbicides, female-controlled barriers, and STD treatment and prevention.

International AIDS Funding (in thousands of dollars)

	FY-1995 Actual	FY-1996 Actual	FY-1997 Actual	FY-1998 Estimate	FY-1999 Estimate
NCI	5,876	3,415	5,641	5,674	5,775
NIDCR	--	--	782	816	901
NINDS	2,103	1,923	973	973	973
NIAID	21,112	21,691	24,892	26,958	29,958
NIGMS	--	--	92	89	84
NICHD	2,263	3,302	4,151	4,400	4,700
NIMH	4,301	3,894	3,512	3,656	3,912
NIDA	1,839	140	--	500	500
NCRR	677	590	418	499	588
FIC	9,108	9,694	10,312	10,611	11,305
Totals	\$47,279	\$44,649	\$50,773	\$54,176	\$58,696

Prevention

NIH-sponsored programs targeting the development and evaluation of various preventive interventions have resulted in marked changes in sexual and drug-using behaviors associated with HIV transmission among at-risk populations, including difficult-to-reach and socially disenfranchised populations in the U.S. and abroad. NIH programs have

demonstrated that behavioral interventions targeting behaviors can be developed and implemented, including those designed to delay or prevent initiation of sexual activity and drug use. These studies have demonstrated that multifaceted risk-reduction programs, including those providing drug treatment, outreach, and education on HIV risk, and sterile injection equipment, can produce significant and sustained decreases in HIV risk behavior among injection drug users. Prevention research has shown that interventions must be culturally and ethnically directed in order to successfully reach targeted populations. NIH also is studying community-level interventions as an important way to effect behavioral change on a larger scale.

Preventing vertical transmission from HIV-infected mother to child is a priority of NIH intervention research. Implementing the ACTG 076 protocol has significantly reduced the incidence of maternal-fetal HIV transmission in the United States. Ongoing efforts are designed to identify and test other interventions that can effectively and easily be used globally to further reduce the incidence of vertical transmission of HIV. NIH-funded scientists are actively studying the timing and mechanisms by which HIV is transmitted from mother to baby so that more effective interventions can be developed to block mother-to-child transmission.

NIH also has sponsored several international conferences on the prevention of perinatal transmission. The second Global Strategies Conference on Prevention of HIV Transmission from Mother to Infant will be held in September 1999 in Montreal Canada. It will bring investigators from developing countries together with investigators from more developed countries to plan future collaborative strategies for the prevention of mother to infant HIV transmission.

NIH international efforts in prevention research and related training and research capacity-building include the following:

- Studies of the role of viral shedding in infectivity for both sexual transmission and mother to child transmission;
- Studies in several developing countries in Africa, Asia, and Latin America to evaluate interventions for reducing mother-to-child transmission of HIV that may be used in diverse cultural and economic settings, such as the use of short courses of treatment with zidovudine, nutritional supplements, HIV-1 hyperimmune intravenous immune globulin, vaginal cleansing, and studies of breastfeeding;
- Development of safe, effective, and acceptable condoms, microbicides, and other female-controlled barriers;
- Studies in Africa on the efficacy of STD treatment and prophylaxis on reducing sexual transmission of HIV; and
- Development of behavioral interventions to reduce the risk factors associated with HIV transmission, including injection drug use and various sexual behaviors.

In response to the Levine Report recommendation for developing a Prevention Science Agenda that combines behavioral and biomedical intervention research, the NIH sponsored several agenda setting activities, including a 1998 Workshop on International HIV/AIDS Prevention Research Opportunities. The goal of the Workshop was to encourage research that would be feasible and relevant for developing countries with limited resources. Representatives from 37 countries severely affected by the epidemic participated in the workshop to develop a "Basic Prevention Package," a list of HIV prevention interventions that would be important in developing countries, and a listing of "Priorities for International HIV Prevention Research." Another outcome of the workshop was a better understanding of the HIV prevention planning process. More information on this workshop may be found at <http://hivinsite.ucsf.edu/ari>.

Behavioral Research/Behavioral Change Interventions

NIH supports an extensive portfolio of behavioral and social science research on HIV infection and AIDS. These studies have demonstrated the important interaction of biological, psychological, and social factors that contribute to HIV prevention, transmission, and disease progression among individuals and population groups. Findings from these studies have significantly contributed to the understanding of human behaviors that affect HIV transmission risk and to the development of successful interventions to encourage sustained behavioral change. NIH-sponsored behavioral and social science research includes research related to the following goals:

- Developing, implementing, and evaluating behavioral and social interventions to reduce HIV transmission;
- Strengthening the understanding of the determinants, trends, and processes of HIV-related risk behaviors and the consequences of HIV infection;
- Developing and evaluating behavioral strategies for preventing or ameliorating the negative physical, psychological, and social consequences of HIV infection; and
- Improving the research methodologies employed in behavioral and social science research.

NIH-supported studies are ongoing, either independently or linked with biomedical studies, in countries in Africa, Asia, and Latin America.

Vaccine Research

The development of a safe and effective HIV vaccine is of the highest priority for the NIH, and NIH has pledged to work with the other G-8 nations on vaccine efforts. NIH supports a broad program of basic, preclinical, and clinical research on the discovery and development of HIV vaccine candidates. Basic research on HIV and the immune system provides crucial information for developing potential vaccines. Various strategies for

stimulating a protective immune response against HIV infection are being explored through basic research, animal model research, and clinical trials. 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. While the goal of preventive vaccines is to end the HIV pandemic by protecting individuals from HIV infection, vaccines also may serve as immunomodulators to improve immune function and slow disease progression in infected individuals and may prevent them from infecting others.

To accelerate the development of NIH's AIDS vaccine effort, the AIDS Vaccine Research Committee (AVRC), chaired by Dr. David Baltimore, was established. Specific areas of basic research relating to HIV vaccines efforts have been identified by the AVRC and a new, special initiative supporting innovative research in these scientific areas has been funded during the last 2 years to advance this research field. To further HIV vaccine research in the NIH intramural programs, the Vaccine Research Center is being constructed with completion targeted for 2000.

The NIH supports an AIDS Vaccine Evaluation Group (AVEG), which consists of six sites nationwide that are actively evaluating potential HIV vaccines in phase I and II clinical trials. To date, the AVEG has conducted or initiated more than 46 trials with 24 different HIV vaccine candidates. All vaccine candidates to date in AVEG phase I trials have been shown to be safe and well tolerated. In preparation for phase III clinical 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 by training foreign scientists and health professionals. NIH collaborates with UNAIDS, host country governments, and in-country scientists in vaccine development and preparation for efficacy trials. Eleven sites have been established in Africa, Asia, and Latin America.

Treatment Equity

In an effort to identify options for clinical management of HIV-infected patients that would be useful in resource-poor settings, NIH is supporting studies on the use of isoniazid and rifampin to prevent active tuberculosis in PPD-positive, HIV-infected patients in Uganda. In addition, NIH-supported scientists in Thailand are studying risk factors for infection with *Penicillium marneffe*. These NIH-trained scientists also are working with the pharmaceutical industry in Asia on developing therapeutics for *P. marneffe* infection.

Women and Health

NIH supports an extensive portfolio of basic, clinical, and behavioral research focusing on women and HIV/AIDS. HIV-infected women experience some complications of HIV disease that are unique or more prevalent in them than in men, such as vaginal and

esophageal candidiasis, chronic herpes simplex infections, other STDs, and cervical dysplasia. NIH-sponsored programs target studies on the natural history and epidemiology of the disease in women through a number of studies in Africa, Asia, and Latin America.

Studies on the etiology and pathogenesis of HIV infection and disease progression in women are ongoing. These studies focus on the role of STDs and other factors in acquiring HIV infection and the pathogenic mechanisms associated with HIV disease progression. Studies on biologic determinants of infectiousness and susceptibility are important areas under investigation. Specific attention is being given to the possible correlation between the level of cell-free or cell-associated HIV in blood, semen, urine, cervical/vaginal secretions or oral fluids, and the probability of transmission. In addition, NIH-funded researchers are investigating the cellular and molecular aspects of mucosal immunity and other infectious diseases as cofactors, as they impact HIV susceptibility and transmission. Results from these studies are critical to developing safe and efficacious AIDS vaccines and microbicides.

A critical area of concern is the impact of HIV on cervical cancer. Co-infection with human papilloma virus (HPV) is common in HIV-infected women, and HPV has been shown to act synergistically with HIV to increase expression of individual viral genes. A study in Africa is examining the natural history of cervical neoplasia in women infected with HIV-1 and HIV-2 and the role of HPV as a risk factor.

Of similar critical importance is a current NIH-sponsored multi-site international trial to determine any possible increase in risk acquisition of HIV through heterosexual contact by uninfected women who use hormonal contraceptives. Other studies are planned to examine the possible effects of steroidal hormones on early, acute HIV infection and later progression to AIDS among hormonal contraceptive users, and on the possible effect of steroidal hormone use on the infectiousness of HIV-infected women.

NIH-supported behavioral and social science research that relates to or focuses on women include studies on (1) determinants of HIV risk and prevention; (2) specific elements of social and cultural life that contribute to HIV risk and protective behaviors; (3) the development of appropriate interventions to reduce risk behaviors; (4) community-level interventions; (5) acceptability of both biomedical and behavioral interventions among different individuals and communities; (6) the behavioral aspects of the adoption of new HIV prevention technologies, such as microbicides and the female condom; and (7) social and psychological factors influencing treatment adherence and compliance as well as participation in clinical trials.

Microbicide Development

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. 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 a safe, inexpensive, reliable, and acceptable microbicide for the prevention of HIV and other STDs.

The development of screening assays to test compounds and agents for their microbicidal/spermicidal activity, as well as developing suitable animal models for safety and efficacy-testing of potential microbicides, are vital parts of the developmental efforts supported by NIH in this field of research. Close collaboration with industry is important in conducting the important phase I through III clinical testing of these agents in various populations and to ensure their eventual availability. While a number of microbicidal substances have been clinically tested in phase I and II studies to date, a safe, effective, and acceptable microbicide has yet to be identified. NIH has placed a high priority on developing an efficacious microbicide and continues to look at new compounds, as well as other barrier interventions. In FY-1999, NIH will establish a Prevention Trials Network that will focus on the testing at U.S. and international sites of various interventions, including microbicides, the expansion of the Topical Microbicide Program Projects involving multidisciplinary research to develop and test new agents and the expansion of programs targeting the developing and clinical testing of spermicidal microbicides and other female-controlled barrier methods.

Other Activities

Basic biomedical and behavioral research has significantly contributed to advances in AIDS research. Findings from basic research have provided the scientific basis for developing potential AIDS drugs, vaccine candidates, and effective behavioral interventions to halt the AIDS epidemic.

The NIH has the primary responsibility for the Federally-supported clinical trials evaluating potential treatment regimens against HIV infection and its associated opportunistic infections and malignancies. NIH supports an extensive network of more than 100 clinical trial sites, including adult and pediatric units in major domestic medical centers and community-based primary care settings. More than 50,000 patients have been enrolled to date in these studies that have involved evaluating more than 200 different drugs. The enrollment and accrual in these clinical trials of women, minorities, children, adolescents, injection drug users, and other populations is a high priority for the NIH.