Karen Mulhauser
Mulhauser and Associates
Management & Public Affairs Consultant

April 13, 1999

Ms. Sandra Thurman, Director
The White House Office on National AIDs Policy
736 Jackson Place
Washington, DC 20503

Dear Sandra,

What a pleasure to meet with you today and learn more about your programs and initiatives! I want very much to learn more about your work and consider how I can help advance your efforts. I hope that as you prepare to report your findings from your trip to Africa and seek forums to present your external report, that you will also be considering how we can help bring attention to the Ark Foundation of Africa.

While I am still learning about Rhoi's work and approach, and marvel at her energy, style and drive, I find myself being drawn in deeper and deeper into wanting to help her organization. There is a fresh and authentic quality that is both attractive and seductive. In so many ways, Ark is naive and inexperienced in how to function in this strange town. As I continue to offer guidance, I do not want it to become "polished" and lose the genuine qualities that come with that inexperience, yet they seem eager to know what to do differently. Maintaining that balance will be important. I hope you agree their mission and approach are appropriate.

Within the next week, I will send you additional information about plans for the fundraising reception to be held in late June, hopefully at the Duke Ellington School. This will include two letters: one to potential Host Committee members who will be asked to participate and to sell tickets, and the other to potential Honorary Committee members who will permit us to add their names to the invitation. Your assistance in identifying individuals and organizations to receive such letters is greatly appreciated. I would also be grateful for any suggestions of individuals and organizations who may agree to be sponsors and make larger contributions. There is no doubt in my mind that resources are used wisely and that Rhoi has a good understanding of cost effective approaches to providing needed care and services.

Please let me know how I might be able to assist you in your educational efforts, and if you can assist us. Next week I will become the President of International Development Conference and my client work has included projects with many international development organizations, such as InterAction, CARE, Association for Women in Development, ASHOKA and others.

Sincerely

Karen

Karen Mulhauser

1730 Rhode Island Avenue NW • Suite 712 • Washington DC 20036 • Phone 202.463.0180 • Fax 202.463.0182

Joint United Nations Programme on HIV/AIDS

UNAIDS

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Facsimile

To: Members and participants

Pages: 3

From: Sally G. Cowal
Director
External Relations

Ref.: pcb08

Date: 29 April 1999

Subject: Programme Coordinating Board Meeting – UNAIDS
Geneva, 27 – 28 June 1999

Please find attached for your advance information copies of the letter of invitation and the Provisional Agenda for the meeting of the UNAIDS Programme Coordinating Board in June 1999.

The originals are being despatched by priority mail.

Joint United Nations Programme on HIV/AIDS
UNAIDS
UNICEF • UNDP • UNFPA • UNDCP
UNESCO • WHO • WORLD BANK

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Ambassador Sally Shelton-Colby
Assistant Administrator
Bureau for Global Programs
U.S. Agency for International Development
State Department Building
320 21st Street, N.W.
Washington, D.C. 20523

28 April 1999

Dear Ambassador Shelton-Colby,

In accordance with the recommendations of the second thematic meeting of the Programme Coordinating Board (PCB), we would like to confirm that the next regular session of the Board will be held from **28-29 June 1999** in meeting room 'A' at the offices of the World Meteorological Organization (WMO), 7 bis Avenue de la Paix, Geneva. The session will open at 09h00 on 28 June with registration taking place from 08h15. Simultaneous interpretation will be provided in Chinese, English, French, Russian and Spanish.

We have pleasure in inviting your Government to be represented at this meeting of the PCB and are enclosing herewith the provisional agenda for the meeting. Other documents are being prepared in English and French and will be despatched to participants at the end of May. It would be appreciated if you could inform us of the name of your Government's representative, together with any additional member(s) of your delegation, no later than **14 May 1999**.

We look forward to hearing from you and to meeting your delegation in June.

Yours sincerely,

Sally G. Cowal
Director, External Relations

cc: Ms Sandra Thurman, Director, Office of National AIDS Policy, The White House, Washington D.C. (-fax: (202) 456 2439

Ms Linda Vogel, International Health Attaché, United States Mission to the United Nations Office at Geneva

Permanent Mission of the United States to the United Nations in New York

ENCLS: as mentioned

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Joint United Nations Programme on HIV/AIDS

UNAIDS

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UNAIDS/PCB(8)/99.1
28 April 1999

PROGRAMME COORDINATING BOARD

Eighth meeting
Geneva, 28-29 June 1999

Place of meeting: Conference Room 'A', World Meteorological Organization
7 bis Avenue de la Paix, Geneva

Times of meeting: ***09h00 – 12h30***
14h00 – 17h30

Provisional Agenda

		Reference documents
1.	Opening	
1.1	Opening of the meeting	
1.2	Election of officers	
1.3	Report by the Chairperson of the Committee of Cosponsoring Organizations	
1.4	Report by the NGO representative	
1.5	Adoption of the provisional agenda	UNAIDS/PCB(8)/99.1
2.	Consideration of the reports of the sixth and seventh meetings	UNAIDS/PCB(6)/98.12 UNAIDS/PCB(7)/98.6
3.	Report of Executive Director	UNAIDS/PCB(8)/99.2
4.	UNAIDS Unified Workplan and budget for 2000/2001	UNAIDS/UWB/2000-01
5.	Financial and Budgetary Update	
5.1	Unaudited Interim Financial Management Information on the 1998/1999 biennium	UNAIDS/PCB(8)/99.3
5.2	UNAIDS Operating Reserve Fund	UNAIDS/PCB(8)/99.4
6.	International Partnership against AIDS in Africa	UNAIDS/PCB(8)/99.5
7.	UNAIDS and UN response at country level	
7.1	Prioritization of support by UNAIDS Secretariat	UNAIDS/PCB(8)/99.6
8.	Next PCB meeting	
9.	Other business	
10.	Adoption of decisions, recommendations and conclusions	

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RESOURCE MOBILIZATION & COFINANCING

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TRUST FUNDS AND COFINANCING DEPARTMENT

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FACSIMILE COVER SHEET AND MESSAGE

DATE: April 6, 1999 **NO. OF PAGES:** (including cover sheet) **MESSAGE NO.:**

TO: Ms. Sandra Thurman
Director
Office of National AIDS Policy
The White House
FAX NO.: 456-2439

FROM: Nancy MacCollum-Arnold
Executive Assistant, TFC
TEL. NO.: (202) 473-7230

SUBJECT: **Accelerating an HIV/AIDS Vaccine for Developing Countries: Issues and Options for the World Bank – Meeting on April 7th & 2:30**

Attached please find an Issues Paper prepared by the World Bank's AIDS Vaccine Task Force which will serve as background information for the April 7th consultation meeting to which you have been invited. This meeting will serve as a preparatory meeting for U.S. government agency representatives to exchange views in advance of an international meeting being held in Paris on April 13th. Also attached is the list of participants for the meeting.

The meeting is scheduled to start at 2:30 and will be held at the World Bank in Room MC-13-603. Please go to the Bank's main entrance which is located at 1818 Street, N.W. Your name will be at the Front Desk which will allow security to give you a pass to enter.

If you have any questions please do not hesitate to call me at the above number.

Transmission authorized by:

If you experience any problem in receiving this transmission, inform the sender at the telephone or fax no. listed above.

U.S. Consultation Meeting
On HIV/AIDS Vaccine

April 7, 1999

Participants

Ms. Nancy **Carter-Foster**
Director
Emerging Infectious Diseases
and HIV/AIDS Program
State Department

Dr. David **Stanton**
Epidemiologist
Division of HIV/AIDS
USAID

Dr. Eric **Goosby**
Director, HIV/AIDS Policy
Dept. of Health & Human Services

Ms. Ann **MacNamara**
International Economist
Office of Multilateral Dev. Banks
Department of Treasury

Ms. Margaret (Peggy) **Johnston**
Assistant Director, AIDS Vaccines
National Institute of Health

Ms. Sandra **Thurman**
Director
Office of National AIDS Policy
White House

Bank Side

Geoff **Lamb**, Director, Trust Funds & Cofinancing (Chair)
Dr. Jacob **Gayle** (In-House rep from Center for Disease Control)
Melanie **Marlett**
Martha **Ainsworth**
Amie **Batson**
Jane **Kirby-Zaki**
Sandra **Rosenhouse**
John **Donaldson**

Accelerating an AIDS vaccine for developing countries: Issues and options for the World Bank*

April 1, 1999

Comments welcome. Not for citation.

Contents

* Prepared by Martha Ainsworth, DECRG, Amie Batson, HDNHE, co-chairs of the World Bank AIDS Vaccine Task Force, and Sandra Rosenhouse, LCSHD. The opinions expressed in this discussion paper are those of the authors and reflect the findings and deliberations of the AIDS Vaccine Task Force. The judgments expressed in this paper do not necessarily reflect the views of the World Bank's Board of Directors or the governments they represent. Please address comments to: mainsworth@worldbank.org and abatson@worldbank.org.

Accelerating an AIDS vaccine for developing countries: Issues and options for the World Bank

I. Introduction

The worldwide AIDS epidemic is a human tragedy that is reversing the gains in life expectancy of the last 30 years and exacerbating poverty in developing countries (see Box 1). Worldwide, 33.4 million people are infected with HIV and 13.9 million have already died of AIDS. More than nine out of every ten HIV infections are in developing countries, and two-thirds are in Sub-Saharan Africa. Every day, 16,000 people become infected. AIDS is a fatal infectious disease for which there is no cure and no vaccine. Antiretroviral therapies that have extended the lives of patients in industrialized countries are out of reach in the poorest developing countries because they are too expensive and difficult to administer effectively in these settings. Since 1986, the World Bank has lent $765 million for HIV/AIDS prevention and care in 74 projects in 49 countries, primarily for information campaigns, behavioral change (like raising condom use), and treatment of sexually transmitted diseases.[1]

At present, the best hope for reducing the spread of HIV and its human and economic impacts is through behavioral change—reducing the number of sexual partners among people with many, raising condom use, and enabling safer injecting behavior. Governments like those in Australia and Thailand have shown that these measures *can* have an impact in reducing the spread of HIV on a national scale. Too few countries have shown the level of political commitment necessary for an effective response. The World Bank and its development partners, including the Joint United Nations Program on HIV/AIDS (UNAIDS), are continuing their efforts to raise the level of policy dialogue on AIDS as a development issue, to obtain greater political commitment and more effective programs.

Substantial benefits could be gained in terms of slowing the epidemic through concerted public action on prevention, and this strategy must be vigorously pursued. In addition, countries where HIV is already widespread in the general population urgently need an HIV vaccine to add to their arsenal in the struggle to control the epidemic. A vaccine that is effective and affordable in developing countries would greatly improve the prospects for dramatically reducing the scope of the epidemic, not just in developing countries but the world over. HIV does not respect geographic boundaries and spares no racial, ethnic, or religious group. No country or population is exempt.

[1] In addition, the World Bank has contributed $18 million over the past 13 years to the Global Programme on AIDS and its successor, the Joint United Nations Programme on HIV/AIDS (UNAIDS).

BOX 1: The impact of AIDS on development

The AIDS epidemic has managed to wipe out nearly all of the progress of the last three decades in raising life expectancy in Sub-Saharan Africa. In the hardest-hit countries the lifetime risk of dying of AIDS is 40-50% and life expectancy is 10-20 years less than it would have been in the absence of AIDS.

The demand for AIDS-related health care is overwhelming fragile heath systems. AIDS is exacerbating poverty in the poorest countries. In hospitals in major African cities, half or more of hospital beds are occupied by AIDS patients, displacing patients with conditions that might be cured. Access to the most basic palliative care and treatment of opportunistic infections is severely limited. It is killing prime-age adults—the breadwinners of households who leave behind young orphaned children in the care of relatives or the state. In Northwestern Tanzania, families are coping with the economic impact of AIDS deaths by consuming less, selling assets, drawing on contributions from the extended family, and removing older children from school to work in the home. In coping with this short term shock, the poorest families are sacrificing investments in human capital that are important to the welfare of the next generation.

Source: World Bank (1997), Stover and Way (1998).

Scientists now believe that an effective preventive HIV vaccine is feasible (see Box 2), but this does not make its development a foregone conclusion. Although the public sector often has financed or subsidized basic research for vaccines, it has limited expertise in transforming these discoveries into marketable products. The development of vaccine products and the technology for their manufacture is usually undertaken by the private sector, which can do this more efficiently. In the case of an HIV/AIDS vaccine, both public and private investment is currently small and oriented toward the needs of the richest countries. There are at least two reasons why private investment in an HIV vaccine is likely to be less than the socially optimum amount:

- The technology for an HIV vaccine is an *international public good.* Regardless of which firm or country develops it, the benefits of an HIV vaccine technology will be global. Even those who do not invest in the research and development (R&D) will benefit. Those who invest in the technology will not be able to recoup revenue from many who will benefit. The private sector is unlikely to invest adequately in products tailored to the needs of developing countries or populations in which ability to pay is low.

- The private sector is unlikely to invest adequately in products tailored to the needs of developing countries or populations in which ability to pay is low.

At the current pace it is likely to be several decades before an effective vaccine becomes available in OECD countries, let alone in developing countries. An HIV/AIDS vaccine that is effective and affordable in developing countries is even less likely to become a reality if private actors are left to respond to existing incentives.

In April 1998, the World Bank set up an institution-wide Task Force to examine ways in which it could help accelerate the development of an AIDS vaccine for developing countries, as one element of its broader program to combat AIDS. The AIDS Vaccine Task Force has consulted with numerous experts and sponsored studies both the pharmaceutical industry and of the potential demand for an AIDS vaccine. It has also examined and discussed a range of possible Bank responses, including financial instruments that could be used to assure future markets for an HIV vaccine in developing countries. This work is ongoing, and country-specific case studies will shortly be launched.

BOX 2: The scientific challenges of an HIV/AIDS vaccine

The development of a safe and effective AIDS vaccine poses several scientific challenges. A successful vaccine must elicit immune responses capable of blocking infection by sexual, intravenous, and mother-to-child transmission. It must be capable of stimulating immune responses like antibodies, which may be effective at neutralizing free virus particles, as well as cellular immune responses, which destroy incoming virus-infected cells. In addition, the tremendous geographic diversity of the subtypes of HIV worldwide suggest that mixtures or "cocktails" of vaccines may be required for universal protective immunity. Finally, there is a lack of understanding of which anti-HIV immune responses are required for generating protective immunity against HIV and therefore which components of HIV are necessary for an effective AIDS vaccine.

Despite these challenges, there is now broad agreement within the scientific community that an effective AIDS vaccine is possible. First of all, a small but growing number of people who have been repeatedly exposed to HIV have remained uninfected and have elicited anti-HIV immune responses that could explain their resistance to infection. Second, there are now several candidate vaccines that have protected monkeys from infection and/or disease caused by the simian immunodeficiency virus (SIV), which is very similar to HIV. Third, some candidate vaccines already in clinical trials have induced strong anti-HIV immune responses in human volunteers. Finally, vaccines have successfully been developed against several other viruses—measles, mumps, rubella, polio, hepatitis B, and rotavirus, for example—with much less knowledge of their fundamental biology and pathogenesis than HIV.

This paper reviews what the AIDS Vaccine Task Force has learned to date about the nature of the problem of under-investment in an HIV/AIDS vaccine for developing countries, and summarizes some of the approaches under consideration. Its objective is to launch a discussion within the World Bank, and – critically – with its bilateral and multilateral partners, on the best course of action for the institution, given its mandate, its comparative advantages in relation to the other agencies involved in the international effort, and the likely effectiveness of alternative measures for accelerating the development of an HIV/AIDS vaccine for developing countries.

II. Worldwide investment in an HIV/AIDS vaccine

Total global research and development (R&D) for preventive HIV vaccines in both the public and private sectors in 1998 was on the order of only US$300 million.[2] Most of this is public expenditure and is focused on basic research, as opposed to applied research and vaccine

[2] Estimate by International AIDS Vaccine Initiative (IAVI). The United States National Institutes of Health budgeted $180 million for HIV/AIDS vaccine research in fiscal year 1999 (OAR 1998).

development. Privately funded R&D on HIV vaccines was probably less than $50 million per year and fewer than 200 scientists in the private sector worldwide are dedicated to AIDS vaccine-related work, some of it subsidized by the public sector (Batson and Whitehead 1999). Progress has been slow. While more than 25 candidate vaccines have been developed and tested for safety and immune response in small groups of volunteers, only one firm has embarked on Phase III clinical trials of an HIV vaccine—the stage at which a vaccine is tested for efficacy in a large human population.[3]

There are 10 or more subtypes of HIV in the world. Research to date has focused on a vaccine for HIV subtype (or clade) B, which is the predominant strain in North America, Europe, Australia, and Japan. However, the predominant subtypes in Subsaharan Africa and Asia—where the epidemic has hit hardest—are subtypes A, C, D, and E. There is no guarantee that a vaccine based on subtype B will be effective against these other subtypes. Further, cellular immunity—which is thought to be important for protection against HIV—is influenced by the genetic makeup of the individual. Even if a vaccine is not specific to a subtype of the virus, the effectiveness could vary across populations. An HIV/AIDS vaccine for use in developing countries should also be inexpensive and easily administered (preferably oral). Other important characteristics include: a minimum number of doses, preferably one; long-term immunity; heat tolerance; and long shelf life. The vaccine should be as efficacious as possible.[4] In addition, since it would be costly to test every potential recipient for HIV before being vaccinated, the preventive vaccine should not be harmful to people who are already infected.

According to the International AIDS Vaccine Initiative (IAVI), less than $5 million per year is being spent on AIDS vaccines that are specifically designed for use in developing countries. One efficacy trial for a clade B/E vaccine is underway in Thailand; the only other ongoing efficacy trial is in the United States.[5] In it's 1998 "Scientific Blueprint", IAVI laid out a research plan that was most likely to result in an AIDS vaccine for world use by 2007. The plan was costed at $350-$500 million over this period (IAVI 1998).

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[3] Many of these candidates, while safe, have a low probability of being effective because of poor immunogenicity. Nevertheless, it is difficult to know whether laboratory assays will predict the effectiveness in human beings. There are at least a half dozen of these that warrant additional clinical study and efficacy trials (Peggy Johnston, IAVI, personal communication).

[4] Vaccine efficacy is defined as one minus the ratio of the incidence of infection in vaccinated and unvaccinated groups of people. However, efficacy as measured in vaccine trials is not the only factor affecting the impact of a vaccine on community levels of infection (McLean and Blower 1995). The duration of immunity, the level of infectiousness and incubation period of HIV among vaccinees are also key variables. "...in areas of moderate to high transmission, low-efficacy vaccines administered at high coverage levels could act to significantly reduce the endemic prevalence of HIV-1"(Anderson and Garnett 1996). Haber, Watelet and Halloran (1995), point out that a vaccine that is not efficacious at an individual level but that reduces the infectiousness of HIV (the probability of transmission) among those vaccinated could have an important effect in reducing infection in the population. Anderson, Swinton, and Garnett (1995) find even that a low-efficacy vaccine that protects for only a few years "...can save many lives if significant coverage is maintained over many years."

[5] VaxGen is supporting a trial of a bivalent B/E gp120 envelope vaccine in Thailand and is also conducting a US trial of the same type of vaccine.

In contrast to the limited funds spent on AIDS vaccine development, an estimated $2 billion annually is being spent worldwide on research for AIDS treatment, much of it in the private sector.[6] There is far more certainty for the private sector about the profitability of this research. There are more than 33 million people infected worldwide, almost all of them adults who would be willing to pay some amount for treatment when they fall ill. Three million of those infected live in industrialized countries where purchasing power is high. The global market for drugs for AIDS and related infections in 1995, before the widespread introduction of combination therapies that include protease inhibitors, was estimated at $1.3 billion annually. In 1996, it was estimated that protease inhibitors alone might bring in $755 million per year in revenue by 2000, but this is surely an underestimate.[7] Middle-income countries are also becoming important purchasers of expensive antiretrovirals, which must be taken continuously for the rest of the patient's life at a cost of $7,000-$12,000/year. In 1998, Brazil spent $400 million on antiretroviral drugs for treating AIDS patients.[8]

III. The potential market for an AIDS vaccine in developing countries

There are 2.5 billion adults of reproductive age in developing countries who are not infected with HIV, including 260 million in the hardest-hit region, Sub-Saharan Africa. This is the number of people who might benefit today from an AIDS vaccine. However, this is not the same as the "demand" for the vaccine, which is the number of doses that would be purchased by government and private individuals. The demand for an AIDS vaccine in developing countries will depend, among other things, on:

- the characteristics of the vaccine, in terms of its efficacy for relevant strains of the virus, its safety, the number of doses to infer immunity, and its ease of administration in the conditions in developing countries;
- the price of the vaccine;
- levels of income in developing countries and the willingness of international donors to purchase the vaccine for the poorest countries or the poorest people;
- the perceived vulnerability of different populations to becoming infected, their potential for spreading the virus, and their political clout;[9] and
- the costs and capacity of the public and private sectors to administer the vaccine.

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[6] The US National Institutes of Health budgeted $482 million for research on therapeutics and $526 million for research on etiology and pathenogenesis of HIV/AIDS in FY 1999, out of a total AIDS research budget of $1.73 billion.

[7] Business Week (1996)

[8] Preliminary 1998 figures (423.3 million reais) (Brazil AIDS control program website).

[9] The political climate is a key factor affecting demand. Political pressure could force the hand of government—even if the vaccine is very expensive—to guarantee access to an HIV vaccine to everyone. For example, some Latin American governments must provide expensive triple-drug antiretroviral therapy to all AIDS patients who ask for it, irrespective of the cost. On the other hand, if the vaccine is perceived to be less than 100% safe, people who are at relatively low risk of contracting HIV may refuse to be vaccinated, lowering demand. These reactions are difficult to anticipate.

The relation between the price of an HIV vaccine and the number of doses purchased is not known. Childhood vaccines are provided at very low prices to the public sector in developing countries and free to the population. The price of all four basic childhood vaccines[10] combined is less than US$1 per child. Nevertheless, even at these low prices, coverage is far from universal—about 70-80 percent of children under one year of age. The initial price of an HIV/AIDS vaccine is likely to be much higher, measured in dollars or tens of dollars, not cents. Delivery costs—estimated at about $14 per child in the poorest developing countries for the childhood vaccines[11]—could also be higher for HIV, since delivery systems for immunization of other groups in the population, like young adults, may have to be set up. Thus, only a share of all who could benefit from an HIV vaccine will ever be vaccinated.

Global spending on childhood vaccines is estimated at $4 billion annually, of which spending in low- and middle-income countries accounts for about $200 million, most of it financed by the public sector. But this may not be a good guide to potential spending for an HIV/AIDS vaccine. First, the current market for childhood vaccines in developing countries represents a "maintenance" phase, as older children were immunized in previous years. When an HIV/AIDS vaccine becomes available, there will be initial large "catch up" demand, since none of the population will have been previously immunized. Second, AIDS is almost always fatal and it primarily affects prime-age adults. While most childhood vaccines are purchased by or for government programs, adults (even poor adults) may be more willing to pay for an HIV vaccine than for childhood immunizations. No study has attempted to measure the public or private demand response to hypothetical HIV vaccines of different prices or characteristics in a developing country setting.

Historically, vaccines become available and affordable for developing countries after the market in OECD countries has matured. Only after substantial saturation of the OECD market do competition and over-capacity generate the willingness among firms to sell their product at marginal prices that are affordable in developing countries. For example, the hepatitis B vaccine appeared in 1982 but did not effectively become available in developing countries for 10-15 years, when its price had dropped from $150 to about $2-4 for the 3-dose vaccine series. Thus, even when a new product becomes available in OECD countries, it often takes many years for the product to become available and affordable in developing countries.

IV. Why isn't industry investing?

A study commissioned by the World Bank AIDS Vaccine Task Force of industry's perspective on HIV/AIDS vaccine R&D concluded that companies do not believe there will be a realistic commercial return on the required investment for an HIV vaccine in developing countries (see Box 3). There are two important contributing factors.

[10] BCG, oral polio vaccine (OPV, 4 doses), diptheria-pertussis-tetanus (DPT, 3 doses), and measles.

[11] UNICEF/WHO (1996).

BOX 3: Industry's perspective on HIV vaccines

The World Bank and the International AIDS Vaccine Initiative (IAVI) recently commissioned a study of the factors affecting private sector research and development of an AIDS vaccine. The study team interviewed 15 companies and seven international experts on AIDS vaccine development. Of the firms interviewed, two were large firms involved in AIDS therapy, six were large vaccine manufacturers, and seven were smaller biotechnology firms that specialize in early stage research. Biotechnology firms eventually sell their technological discoveries to larger pharmaceutical companies that have the infrastructure, resources, and technical know-how to conduct clinical trials and large-scale production. Only one of the interviewed firms was involved in Phase III efficacy trials for an HIV vaccine, four were involved in Phase I and II early clinical trials, and seven were in pre-clinical stages of an AIDS vaccine. Two firms were very large and not involved in HIV vaccine work, and a third had discontinued work on an HIV vaccine. In each firm, senior managers and/or CEOs were interviewed.

The study recommended that the World Bank pursue activities to guarantee a profitable developing country market for an AIDS vaccine, which could be influential to private R&D in the long run. The World Bank should also consider making short-run investments that will speed the access of developing countries to an AIDS vaccine when it becomes available. Enhanced lending for existing vaccines in developing countries and investments in infrastructure necessary to implement them quickly will help to demonstrate that viable LDC markets exist. The study also recommended that the World Bank consider activities in the short term that will accelerate the pace and relevance of HIV vaccine clinical trials in developing countries.

Source: Batson and Whitehead (1999, forthcoming).

The potential market is perceived to be small

Private investment in research on an HIV/AIDS vaccine is based mainly on firms' assessment of the potential market in high-income, OECD countries. There are two points of view. Some firms believe that there will be substantial demand for a safe and efficacious HIV vaccine of the order of magnitude of that for the hepatitis B vaccine. Other firms believe that because HIV is spreading slowly in the developed world and therapies have been successful in extending the life of patients, the OECD market will be small at the outset and slow to develop. Firms that believe there is a potential OECD market are investing in HIV vaccine R&D.

With only one exception, the Task Force's study of industry found that the potential market for an AIDS vaccine in developing countries was not cited as a factor in R&D investment decisions, nor is it a factor in decisions on investing in most products. The more involved a firm already was in developing country markets, the lower was its estimate of the potential sales of an HIV/AIDS vaccine in those markets. Even firms that anticipated some developing country demand expected that their R&D costs will be recouped in the OECD market. Acceptance of market segmentation for the purpose of pricing—price "tiering", enabling firms to maintain high prices in OECD markets while charging marginal costs in developing countries—will be critical if firms are to introduce an HIV vaccine in developing country markets for a price that these

countries could reasonably afford. Based on their experience to date, the firms cited lower-than-expected uptake of new vaccines developed since the 1970s, like hepatitis B, yellow fever, and Hib[12], as evidence that work on future "high-priority" vaccines may not necessarily be rewarded by adequate sales.

The late-stage development costs of an HIV vaccine are high and the probability of success uncertain

There are many steps in bringing new vaccines to the market, which under normal circumstances can take a decade or more (see Box 4). The normally very long time horizon for developing a commercial product—from 10 to 30 years—means that the commercial benefits of developing an AIDS vaccine are far in the future and thus highly discounted in making investment decisions. In the case of an HIV/AIDS vaccine, there has been no good animal model and the correlates of immune protection remain unknown. As a result, the science has been challenging and the level of industrial investment low. More than a decade after the effort to develop an HIV vaccine was launched, there is only limited clinical testing underway and no scientific consensus on the best approach. Safety issues have prevented the testing of live attenuated or whole killed vaccine candidates in humans. While there are a few novel approaches in the early phase of testing, only one recombinant vaccine candidate globally has entered an efficacy trial.

A large-scale trial is needed to show the efficacy of any given vaccine candidate, but because of the huge expense of such trials ($10-30 million) industry is unwilling to pay for them unless there is a high degree of certainty that the vaccine will be efficacious. The main approaches for an HIV/AIDS vaccine at present have few or no current vaccine analogues, which means there is still a large degree of uncertainty about their efficacy in a large trial, even after safety and immunogenicity are demonstrated. HIV vaccine efficacy trials in industrialized countries are particularly expensive because the incidence of HIV is low and the sample size would have to be very large. Trials in developing countries with higher HIV incidence could be smaller, but there are hidden costs such as political barriers and inadequate infrastructure. Since levels of protection against different strains of HIV cannot be assumed, it is highly likely that vaccines based on different strains will have to be tested in areas where those strains are prevalent. The additional costs of expanding the trial of a single vaccine candidate beyond one OECD country to include a vaccine for multiple strains of HIV in additional sites has been estimated at $100 million. Further, efficacy trials usually involve some limited investment in manufacturing process and plant, investment that is lost if an efficacy trial does not result in a commercial product.

[12] Haemophilus influenzae type B.

BOX 4: Vaccine clinical trials

Once a vaccine has been shown effective in animal models, it must be tested in people. These studies, called clinical trials, determine the safety, immunogencity, and efficacy of candidate vaccines. They provide the data necessary for regulatory agencies to decide whether or not a product should be licensed for use in their market. Before a vaccine will be recommended globally, efficacy studies are also required in different epidemiological sites (Asia, Africa, Europe, North America, Latin America). Often, governments will also require efficacy studies be repeated in their own country before agreeing to license a product. There are three types of human clinical trials that must be conducted without exception before a vaccine will be considered for licensure.

Phase I: Safety Phase I trials determine the safety and preliminary dosing studies of a vaccine candidate in a small sample of 10-30 people. They are generally conducted in healthy adults at low risk of HIV infection, take six months to one year, and cost about $1-3 million.

Phase II: Immunogenicity. Phase II trials measure the safety and immune response in a larger sample of several hundred volunteers. They measure whether the vaccine candidate is stimulating the immune function or some other marker that may be indicative of protection. These studies are usually conducted in persons at high risk of HIV infection, typically take 6-24 months, and cost roughly $2-4 million.

Phase III: Efficacy. In the third and final phase before licensure, the efficacy of the vaccine candidate in protecting against disease is tested in a large population (5,000 to over 50,000 people). Efficacy is measured as the difference between rate of disease in people who receive the vaccine and in others who receive a placebo. The lower is the incidence of the disease in the population or the smaller is the anticipated impact of the candidate vaccine, the larger must be the sample of people who participate to demonstrate an effect. These studies take 2-4 years and can cost $10-30 million, depending on the size of the study.

A high level of efficacy does not guarantee an equivalent level of effectiveness when a vaccine is offered in the field. Efficacy trials typically select healthy volunteers and administer the vaccine or placebo under very carefully controlled conditions. Neither of these are assured in field conditions in developing countries. In a number of instances, so-called "Phase IV" "effectiveness" trials have been conducted to demonstrate the true costs and effectiveness of vaccines in typical field conditions.

V. What can the World Bank do?

The mission of the World Bank is to alleviate poverty and to promote economic growth. It pursues these objectives through three traditional channels—lending to developing country governments, engaging in policy dialogue, and conducting economic research.[13] In the case of an HIV vaccine, the World Bank objective is not only to ensure that a vaccine is developed, but also to guarantee the broad and early access of developing countries to a vaccine adapted to their needs. The World Bank does not lend money to the private sector of any country. However, the International Finance Corporation (IFC)—the World Bank group's investment bank for developing countries—can lend directly for private sector projects in developing countries. International Development Association (IDA) credits are available to the poorest countries on

[13] In fiscal year 1997, total World Bank commitments to developing countries amounted to $14.5 billion in IBRD lending and $4.6 billion in IDA credits. Since 1970, total World Bank lending for health, nutrition, and population (HNP) amounted to $14.7 billion. Over the years 1995-98, average annual lending for HNP was $1.6 billion.

highly concessionary terms. With the exception of a small amount of money provided through the Development Grant Facility (about $130 million per year), the World Bank does not make grants to developing countries or institutions.

Given its institutional mandate, what can the World Bank do to accelerate the development and availability of an HIV vaccine for developing countries? There is a range of possibilities that warrant consideration. First and foremost, the Bank can engage governments in policy dialogue, pointing out the economic impact of AIDS, the need for prevention, the issues surrounding development of an HIV/AIDS vaccine in developing countries, and actions that will promote the process. Such a dialogue will condition the effectiveness of any other instruments or mechanisms that the Bank might propose to accelerate an AIDS vaccine, and can also help to broaden and reinforce the commitment within governments and thereby buttress the work of agencies with a more specialized health focus. Beyond this, the Bank can seek to influence the private R&D investment for an AIDS vaccine through existing and future financial mechanisms or instruments. There are two strategies for this: "push" activities directly contribute to increasing R&D for an AIDS vaccine in the short run, and "pull" activities that provide incentives for private R&D by raising the expectation of a future return on these investments. An example of "pull" activities are different types of "assurances" on the size and profitability of a future market for vaccines in developing countries should a safe, effective, and low-cost vaccine be developed. A successful strategy is likely to incorporate intense policy dialogue accompanied by both "push" and "pull" interventions.[14]

Policy dialogue

The World Bank can play a crucial role in accelerating global HIV/AIDS vaccine development by elevating the seriousness of the AIDS epidemic in the dialogue with developing country policymakers, raising the level of political commitment to support HIV/AIDS vaccine research and development, and helping to forge partnerships between developing countries, industry, and international donors. The Bank's credibility and access to treasury and finance officials, as well as development/health leaders, puts it in a strong position to engage all actors in the policy dialogue, and reinforce the efforts of specialized agencies.

To raise the support for AIDS vaccine development, policymakers must first be convinced that AIDS is a serious development issue that will set back investments in all sectors of the economy if not addressed as early as possible with effective prevention efforts.[15] Since there is no HIV/AIDS vaccine and no cure for AIDS, the highest priority must be to prevent HIV in the most cost-effective manner, using existing proven interventions to change behavior. Policymakers also need to understand that an AIDS vaccine will be a useful, even critical,

[14] For a more detailed discussion of the specific "push" and "pull" instruments and issues of implementation, see the Background paper by Rosenhouse (1999).

[15] The Bank is in fact already engaged in this dialogue through current lending operations and analytic contributions, such as *Confronting AIDS* (World Bank 1997). These efforts could be reinforced.

prevention tool, but its availability at an affordable price and in a form that can be effective in developing countries cannot be assumed. Without the proactive involvement of developing countries themselves, it could easily be 20-30 years before an affordable vaccine becomes available for their needs. Partnerships between governments, industry, and civil society can pave the way for ensuring broad access to an effective and affordable vaccine by fostering political support and greater research and development for AIDS vaccines in developing countries with appropriate and transparent locally-determined safeguards. Vaccine development is a protracted process in which multiple candidates will have to undergo multiple efficacy trials in populations where the vaccine will be applied. While there are always risks involved in such endeavors, the developing countries bear very high risks of inaction.

"Push" interventions

Both basic research and clinical testing are essential in developing a new vaccine. In the case of HIV/AIDS, the basic research strategy is well funded by national research institutions in industrialized countries. Clinical testing and development of a marketable vaccine product has always involved the private sector. Push interventions lower the costs and risks of private R&D for an HIV/AIDS vaccine, either through direct subsidies or by lowering transactions costs.

1. Direct support for vaccine research

The most direct way of accelerating R&D for an HIV/AIDS vaccine in developing countries is to directly subsidize the relevant scientific research. However, as previously noted, the World Bank has very limited ability to confer grants and the grants that are awarded are small. Further, the World Bank does not have the capacity to evaluate the merits of alternative scientific approaches for developing an AIDS vaccine.

Nevertheless, the World Bank has supported HIV vaccine research indirectly through participation in the International AIDS Vaccine Initiative (IAVI), an international non-profit, non-governmental organization set up by the Rockefeller Foundation in 1996. IAVI's mission is to ensure the development of safe, effective, accessible preventive HIV vaccines for use throughout the world. Its objective is to stimulate investment and demand for HIV vaccines that will benefit the whole world, including developing countries. IAVI works with both the public and private sectors, pursuing this objective through advocacy, targeted support to R&D for novel vaccine approaches, and measures that reduce obstacles to private investment. Last year, it launched two vaccine development partnerships in sub-Saharan Africa. The World Bank contribution to IAVI has grown from $200,000 in 1997 to roughly $1 million annually in 1998 and 1999.[16] The World Bank is represented on IAVI's Board of Directors. Given the limited availability of grants from the World Bank (about $20 million in grants is available annually for the health sector), it is unlikely that its own financial contribution could be increased

[16] 1998: $1 million ($400,000 from the Global Forum for Health; $600,000 from the DGF); 1999: $940,000 from the DGF.

substantially under the existing structure.[17] Irrespective of whether additional grant funds could be found, the World Bank could play a role in leveraging contributions to IAVI from international organizations and bilateral donors to accelerate the vaccine product development and testing effort.

2. Reducing the costs or risks of vaccine clinical trials in developing countries

This strategy will accelerate the development of vaccines for developing countries, ensure that whatever product is developed will address the infrastructure and delivery constraints, and encourage investments by industry and donors in the infrastructure that would make immunization possible. Investments and improved collaboration will enhance the capacity of developing country researchers to engage in this type of research and the prospects for eventual local production of vaccines or important components of them.

This would be a new activity for the World Bank, but there are several ways that it might participate using its traditional instruments. This might include: elevating HIV/AIDS vaccines in the policy dialogue with developing country governments and smoothing the way for collaboration with industry for conducting clinical trials (discussed above); lending to developing countries for infrastructure and capacity building that are necessary to conduct vaccine trials; and lending for the finance of vaccine trials themselves in countries where partnerships have been established. In this activity, the Bank would presumably focus on elements that add to what is already being done through its financial contributions to IAVI.

"Pull" interventions

Pull interventions create incentives for increasing private R&D for an HIV vaccine for developing countries by demonstrating or guaranteeing a substantial market in developing countries or other form of financial return on investment.

1. Expanded lending for existing vaccines

Long-term promises to guarantee a market for an HIV vaccine would have greater credibility to industry if the international community found a way to stimulate the market in developing countries for priority vaccines that already exist. World Bank lending for vaccines and immunization programs historically has been relatively small—less than $20 million annually. Until recently, funding by UNICEF and bilateral donors was deemed adequate to finance vaccine purchase and delivery needs of developing countries. However, with the introduction of new vaccines that are more expensive (>$1/dose), this will no longer be the case.

[17] Larger contributions could be sought from the Bank's net income (after any necessary increases in reserves). However, this would require the approval of the entire membership of the World Bank, which would have to weigh the use of net income for funding HIV vaccines against other alternative uses—notably additional resources for IDA, which serves the poorest countries, or the Highly Indebted Poor Countries Initiative (HIPC). Furthermore, as net income is expected to experience a downturn in the next few years, the share for reserves is likely to increase.

The World Bank's institutional commitment to finance existing vaccines and immunization programs is already on the rise. In March 1998, World Bank President James Wolfensohn met with heads of public agencies and the vaccine industry at a meeting on "Vaccine Development and Delivery: Leadership for the 21st Century". The World Bank has launched an immunization demonstration project to explore how loans in 6-8 countries could increase the support for immunization and new vaccines. WHO, UNICEF, and the U.S. Centers for Disease Control and Prevention (CDC) will provide technical expertise on setting the priorities for immunization, structuring the loan component, and monitoring results. Building on the demonstration projects, the World Bank will identify a number of countries each year to target for heightened immunization support. It has committed to work more closely with industry and with other immunization partners such as WHO and UNICEF. The World Bank will also explore ways to increase vaccine financing through new financial instruments.

2. Providing better information on developing country markets

Private firms' decisions to invest in R&D for an HIV vaccine, as with other products, are highly dependent on their perception of some future lucrative market for sale of that product. The study of industry revealed that the investment decisions to date have been based almost exclusively on the potential market in OECD countries. Potential markets in developing countries have not entered their calculations. The level of private demand for the purchase of an HIV vaccine is unknown, and public sector purchase of other "new" priority vaccines in developing countries has been limited. Better information on the characteristics of vaccines that are likely to be demanded in developing countries and on the responsiveness of both public and private purchasers of an HIV/AIDS vaccine may alert firms to an important market segment they might otherwise ignore.

A desk study commissioned by the AIDS Vaccine Task Force reviewed the available information on the potential global demand for an HIV/AIDS vaccine estimated the public sector demand for AIDS vaccines under two different sets of decision rules (Bishai and others 1999). However, the validity of these decision rules is not known and to date there has been no basic research on the public or private willingness to pay for hypothetical HIV vaccines with different characteristics and prices. The process of collecting this information would have the added benefit of raising awareness among developing country policymakers about the current state of vaccine research, the characteristics and price of an HIV vaccine, and issues related to improving the access to a vaccine once it is available. Commissioning this work is within the mandate of the World Bank's AIDS Vaccine Task Force, and with sufficient resources could be included in its work program. Related to this, the World Bank could work with the UNAIDS secretariat and representatives from industry and developing countries to develop a set of priorities and guidelines concerning the optimal characteristics of an HIV vaccine for use in developing countries. Meeting such criteria could be the "trigger" point for market guarantee mechanisms, below.

3. Market assurances[18]

Increased knowledge of the potential developing country market for an appropriate HIV/AIDS vaccine alone is unlikely to be sufficient to change firms' R&D behavior because: (a) the potential commercially viable market may be small; and (b) there is still great uncertainty as to whether the potential market will materialize, given all of the political and economic shocks that can occur (or even development of a cure for AIDS) in the intervening time before an HIV vaccine is introduced. Uncertainty about the future market for an HIV vaccine in developing countries can be substantially reduced through agreements that "guarantee" purchase of a certain number of doses of an appropriate HIV/AIDS vaccine at an agreed-upon price at some future date, if such a vaccine is developed.

There appears to be no precedent for this type of activity in the international community—creating or assuring a future market so that the private sector will develop a technology. The World Bank has some experience with financial guarantees in its operations, but on a shorter time frame than would be necessary for development of an HIV/AIDS vaccine (Rosenhouse 1999). New financial instruments could be developed to meet the need for longer-term market assurances, taking into account different contingencies. Such instruments could be important new mechanisms for generating private investment in other high-priority public goods. In the course of deliberations, the World Bank AIDS Vaccine Task Force identified three main types of market guarantee activity that might be pursued.

(a) Vaccine purchase fund. A fund could be established for the purchase of HIV vaccines for the poorest countries or to provide matching funds provided developing countries themselves. The fund would be capitalized by contributions primarily from industrialized countries, although middle-income countries would also be invited to contribute. The trust fund could be financed now, allowing the fund to accrue interest, or financed in the future through government pledges or promissory notes. The trust fund monies would become available only if and when a vaccine was developed that meets very specific criteria, in terms of its price, effectiveness, and applicability for developing countries. This fund could be managed by the World Bank through an independent facility, according to agreed-upon access rules and a "trigger" mechanism or "contingency clause" that defines when the criteria for a vaccine have been met.

The World Bank has ample experience in setting up and administering trust funds created for specific purposes. The Global Environmental Facility (GEF) and the Heavily Indebted Poor Countries Initiative (HIPC) are two examples. It is also quite experienced in dealing with donor pledges, as they constitute the bulk of IDA's resources. However, the trust funds administered by the World Bank generally disburse soon after they are replenished, and the government promissory notes that finance IDA are valid over a 3-year time frame. An HIV/AIDS vaccine for developing countries could take 10-15 years to develop. The main issue to be addressed is

[18] For a detailed description of existing types of World Bank guarantees, contingent-type loans, and options for market assurances, see Rosenhouse (1999).

whether donors would be willing to commit funds with a 10-15 year lead time, and whether industry believes that these promises will materialize.

(b) Contingent loans and credits. The World Bank could issue IBRD loans[19] and/or IDA credits to developing countries to finance the strengthening the borrower's vaccine delivery capacity and the purchase of HIV/AIDS vaccines when a suitable vaccine is developed. The loans or credits would be agreed to in the present; part or all of the disbursements would be contingent on the development of a viable vaccine—that is, one that meets the same criteria as might be established for the trust fund, discussed above.

The World Bank has some experience in contingent lending. It has made loans to back up government facilities that provide guarantees against commercial and political risk to the private sector. These loans only disburse if claims are made.[20] Contingent loans have also been used to reduce the impact of liquidity shocks on the borrower's banking system in the event of severe capital flight. However, the period over which risk is covered in both cases has never exceeded five years. Given the unknown demand for funds for alternative uses in the distant future by both the World Bank and client countries, the main issues for contingent loans for an HIV/AIDS vaccine are, first, whether the IBRD and IDA would be willing to commit resources with such a long time horizon, and second, whether developing countries would be willing to borrow on a contingent basis so far out into the future.[21] A related issue is whether such "promises to borrow" are viewed as credible promises by firms responsible for investing in R&D for an HIV/AIDS vaccine.

(c) High-profile international public signing of intent. Public visibility can be a powerful incentive for public action and strengthen the commitment of the international community to eventually purchase an HIV/AIDS vaccine for developing countries. The World Bank would coordinate public pledges to purchase an HIV/AIDS vaccine by donors and client countries, in international forums with wide press coverage and attendance of heads of state or other high officials. This would give greater prominence to the problem of generating adequate R&D on technology that is an international public good, in general, and specifically for an AIDS vaccine. It would give greater visibility to governments who commit themselves by providing resources now or in the future.

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[19] International Bank for Reconstruction and Development, the arm of the World Bank that lends primarily to middle-income developing countries at market rates.

[20] The World Bank has made these types of loans when conditions do not permit the involvement of the Multilateral Investment Guarantee Agency (MIGA), which cannot cover short-term non-equity transactions, or IFC, which cannot lend to governments.

[21] While there are disincentives for both borrowers and the Bank, under the existing framework, to commit to future lending, the Bank has recently developed a new lending instrument—the Adaptable Program Loan—that is designed to fund a program of activities to achieve an agreed upon development objective over a long-term horizon. The project is designed as a sequence of loans for phased support of the program, with agreed objectives, triggers, and indicators of outcomes/impacts for each phase of the program. For additional discussion on how the APL might be adapted to the issue of AIDS vaccines, see Rosenhouse (1999).

VI. Issues

As an international institution committed to economic growth and poverty alleviation, the World Bank has a vital interest in the development of a preventive HIV/AIDS vaccine that will stop the spread of a virus that is already having such a huge impact on the poorest countries. Scientists believe that an AIDS vaccine is possible. This note has provided an analysis of the problem of underinvestment in R&D for an HIV/AIDS vaccine, a discussion of the main reasons from the perspective of firms, and a summary of the main mechanisms by which the World Bank might accelerate the development and availability of an AIDS vaccine for developing countries.

The AIDS Vaccine Task Force must now develop proposals to World Bank management and the Board of Directors for the most effective way forward to accelerate an AIDS vaccine for developing countries as part of the Bank's broad strategy to combat AIDS. Such proposals might draw on existing World Bank instruments or propose the development of new ones; it will certainly incorporate a combination of policy dialogue and both "push" and "pull" activities. However, the success of the strategy and any new instruments will depend centrally on the extent to which they are seen as relevant and practical by the World Bank's members, by task managers within the institution, and by industry. New financial instruments can be effective only if there is some demand for them by developing country borrowers and by those who might contribute.

At this stage, therefore, the AIDS Vaccine Task Force is requesting feedback from the development community particularly on the following issues:

1) What are the views of industrialized countries, developing countries, and international institutions on the feasibility, desirability, and potential support for different World Bank options such as those set out in this paper?

2) Are there other ideas or activities that would accelerate development of an HIV vaccine for developing countries in which the World Bank could play a particularly useful role?

3) Are there complementarities between these options and current or planned activities on vaccines by bilateral and multilateral partners – and can these be developed and exploited?

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DATE:	April 7, 1999	**NO. OF PAGES:** 8 (including cover sheet)	**MESSAGE NO.:**
TO:	Todd A. Summers	**FAX NO.:**	202/456-2438
Title:	Deputy Director		
Organization:	Office of National AIDS Policy, The White House		
City/Country:			
FROM:	Jane Kirby-Zaki	**FAX NO.:**	202/477-7019
Title:	Cofinancing Officer	Telephone:	202/458-0576
Dept/Div:		Dept./Div. No.:	
SUBJECT:	**Invitation Package to Consultation Meeting in Paris**		

MESSAGE:

Mr. Summers:

Many thanks again for your participation in today's meeting at the Bank. Enclosed as we discussed is the invitation for the meeting next week in Paris. Please do not hesitate to contact me with any questions.

With best regards,

Jane Kirby-Zaki

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To:	**Ms. Sandy Thurman**	**From:**	David B. Mixner
Fax:	**(202) 456-2439**	**Pages:**	[Click **here** and type # of pages]
Phone:	(202) 456-1414	**Date:**	03/14/99 4/21/99
Re:	**NAACP AIDS Videos Reception**	**cc:**	0

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• **Comments:**

Sandy: Hope this is helpful to you. ....David Mixner

March 14, 1999

TO: Sandy Thurman
FROM: David Mixner
RE: AIDS/NAACP Video Reception

Sandy, it was great to see you on my last visit to Washington. Thank you for taking time in the middle of a snowstorm to meet and discuss launching the NAACP AIDS Video Project at the White House. Just wanted you to have the basic background, key fact and players in this effort so you will be able to answer any questions.

BACKGROUND:

In the middle of last year, I felt that it was essential for Gay men to lean their skills and efforts from our years of unfortunate experience from the AIDS epidemic to the newly impacted communities. Hopefully, by doing so, we could help impart important lessons about this horrible epidemic. About the same time, Mr. Julian Bond and Mr. Mfume made combating AIDS in the African-American community a top priority for the National NAACP. I approach two of my top clients TCI (Telecommunications, Inc) and duPont Pharma about working together in a major project to assist the National NAACP in this effort.

I arranged a meeting between Mr. Leo Hindery (CEO of TCI) and Mr. Bond and agreement was reached that such a project was not only exciting but also needed. On January 12th, there was a meeting with representatives of TCI, duPont Pharma, the National NAACP and myself in Baltimore. Ms. Caya Lewis who is in charge of Health Issues for the NAACP is in charge of the Project for the NAACP. At that meeting, it was agreed that the following would happen:

-That TCI and duPont Pharma would finance three AIDS video targeting the African-American community dealing with prevention, treatment, testing and patients rights. One video would address the males, another women and the final one teenagers.
-TCI would make available its numerous resources, provide funds and oversee production. duPont Pharma under the direction of Executive Vice President Laurent Fischer and Marcus Parr would make a direct grant and provide it AIDS network for research and fact-finding. The videos overall would be totally under the direction and ownership of the National NAACP.
-close to a half million dollars will be spent by the two corporations to make these videos
-TCI immediately agreed that each of the videos would be shown on everyone of its cable systems that include Washington, Baltimore,

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Pittsburgh, Seattle, San Francisco, Chicago, Portland, etc. guaranteeing from the beginning a wide distribution.
-I then contacted Cable Positive (the cable industries response to AIDS) and they agreed to be a cosponsor of this effort and to distribute over 900 copies to all their key systems, programmers (including such networks as HBO, MTV and BET) and other members of their organization.
-TCI will finance 7000 copies of each video tape (a total of 21,000 copies) for use by the National NAACP so they can send copies to each of their chapters, key AIDS service organizations and prominent churches in the African-American community.

Since that meeting, enormous progress has been made and the following has happen:

-TCI brought on its consultant Glenn Morey of Morey/ Mahoney Advertising to oversee the production under TCI Executive Vice-President Grace deLatour and their media relations person Mark Duke.
-Glenn Morey immediately hired Donna Dewey an Academy Award winning Producer. She won her Best Documentary Short Oscar for "A Story of Healing". Ms. Dewey agreed to produce the three video tapes.
-In Addition, Mr. Mustapha Khan, agreed to become Director. Mr. Khan has a long and distinguished career as an award-winning director including for PBS American Playhouse, Sesame Street, Numbers Alive and prime time specials for HBO.
-weeks of intensive interviews have been conducted around the country in the African-American community to determine what the message needed to be in the tapes.
-shooting has started and the tapes will be completed by June 1st.
-the NAACP is working with its Image Awards people to have African-American celebrities participate in the tapes.

PROPOSAL:

All parties involve, would like to officially launch the "premiere" of these tapes in June so that the publicity and exposure will be widespread by the time of the 90th National NAACP Convention in mid-July. We want to hit hard the mainstream media, specialized press and feature page writers. The story to be told is a compelling one of corporate American, the National NAACP, supported by the gay

AIDS community and prominent filmmakers all joining forces to create a major national program to stop AIDS in the African-American community. It is powerful coalition and powerful story.

We would like to have the Administration launch the premiere of these tapes at the White House. We would like to do so because it would guarantee even a greater audience for the distribution of these tapes and also celebrate the power of "community" coming together for a common good. Here is are suggestion for such a reception:

-That the event be held at the White House in June with hopefully the participation of either the President, the First Lady or the Vice-President.
-We would show a five-minute segment comprised of different sections of the videos at the event.
-The President, First Lady or the Vice-President would give a brief presentation on what this project means and the excitement of all these different elements coming together to save lives.
-Mr. Bond or Mr. Mfume would make brief remarks.
-The reception list would include the corporate participants, key officials of the National NAACP, members of the Congressional Black Caucus, leaders of AIDS service organizations, key cable industry leaders from Cable Positive and key Administration AIDS officials.

Sandy, this would be an extraordinary event and ensure that millions would see these important tapes. Please let either Caya Lewis or I know what to do to assist you in making this happen.

Looking forward to working with you on this effort.

"Paul S. Zeitz" <zeitz @ zamnet.zm>
04/06/99 02:03:11 PM

Record Type: Record

To: Michael Iskowitz <MEIskowitz @ aol.com>, Sandra Thurman/OPD/EOP

cc:
Subject: Gratitude and Ideas

Sandy and Michael:

Greetings from Zambia!! I wanted to express my deep heartfelt gratitude for your successful Presidential Mission to Zambia. It was extraordinarily exciting for me to watch the news on the night of your departure and see President Chiluba saying the right thing, in the right way, FINALLY!!! Your consecutive visits to Zambia have clearly encouraged the President to speak out!!! FOR THE FIRST TIME!! This could be a historic turning point in Zambia's pandemic.

Over this past weekend, I had a plethora of ideas flashing through my mind regarding your Mission. After seeing you again, I feel very comfortable sharing the ideas below.....please know that these are my own ideas and that they have NOT been discussed with or cleared by anyone!!!

Context

1) Mobilizing Resources for African Health Development

Several tactics/rationale have been taken by various stakeholders that are interested in expanding the resource envelope of USG and international efforts to accelerate health development in Africa. These include:

a) Humanitarian--a prime rationale for US health assistance to Africa. This frequently leads to small incremental increases in Congressional allocations.
b) Protecting US domestic interests--protecting the US from invading "ebola" viruses is being portrayed. This led to the Infectious Disease Initiative--totalling $50 million per year and really a trade-off with exisiting resources.
c) Economic Growth---this is the least developed rationale. As mentioned in the Harvard papers, Professor Jeff Sachs stated, "A frontal attack on poor Africa's health status may now be the most important single strategy for economic development for the continent." This fits into the broader USG objectives of making the world safe for democratic governance and capitalism.

As I'm sure you've observed during your African tours, the current health development paradigm is NOT WORKING in most African settings. The problems far exceed the ability of African governments to combat. The international community is basically throwing salt on a gaping wound!! Incrementalism will surely lead to more of the same!!! The only way to expect substantial improvements in the current health crisis is for their to be a paradigm shift---a bold, unprecedented partnership between the G7 and the poor nations of Africa. USG leadership is definately required for this to occur.

While HIV-AIDS is definately the most urgent health crisis in Africa---other pandemics are also devastating African populations: malaria, tuberculosis, malnutrition, unabated population growth,

maternal mortality etc and are major hindrances to economic growth. Only a comprehensive effort to address these inter-related problems will succeed in addressing any of them. Vertical approaches tend to fail in most African settings because of financial and human resource constraints.

Recommendations

1) Form USG Interagency Working Group to Develop the "African Health and Development Partnership Initiative (AHDPI)" as part of President Clinton's Parternship for Economic Growth and Opportunity in Africa. Members of the Working Group could include: White House, Department of State, Department of the Treasury, OMB, Department of Defense, USAID, Department of Health and Human Services (NIH, CDC, FDA), Department of Labor. The Working Group would charged with developing a Presidential Decision Directive which defines roles and responsibilities of USG agencies to work together to accelerate health development in Africa.

2) Convene Congressional Hearings in the House and Senate. Bipartisan panelists could include representatives from USG agencies, Non-governmental organizations, UN Agencies, African countries, religious groups, US Universities, the Global Health Council etc. Members of the Presidential Mission could also participate. Presentations could be designed to suggest modifications in the Economic Growth and Opportunity Act that is before Congress.

3) Demonstrate USG committment/leadership for accelerating health development in Africa by ensuring POTUS or FLOTUS participation in the XIth ICASA Conference which will be held in September 1999.

4) Form Interagency Working Group to Develop Debt Swap for Health Mechanisms which can be implemented by the USG, other G7 nations, and the multilateral institutions. As large scale Congressional allocations for accelerating health development in Africa are unlikely in the current political environment, developing debt swaps for health, is the only way to increase the level of resources currently needed to address the health crisis in Africa. If a signficant portion of the $70 billion of existing debt could be be swaped for health, then huge gains could be made. Debt swap mechanisms need to developed. This working group should also make recommendations for the most expeditious way of ensuring implementation. The basic premise is:

a) African Target country develops health development/HIV-AIDS response plan of Action
b) In partnership, African Target country and lending country/institution develop a debt swap plan that shift payment of debt towards supplementary domestic investment in health. The debt swap plan is based on agreed upon performance milestones (conditionalities) that support the the target country Plan of Action. These performance milestones should include measurement of health improvements in health impact.
c) Debt swaps depends upon effective implementation African target country plans--thus building on and sustaining African ownership of the problems.

The recommendations of this Working Group could be submitted to the G7/8 summits, to the United Nations, and for use in modifying/improving the Congressional Economic Growth and Opportunity Act.

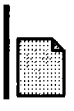
5) Support the formation of an African Committee for Economic Growth in order to involve African leadership (governmental and non-governmental) in the development and review of proposals emerging from the above mentioned working groups. This Committee would represent:
a) a strong effort by participating African countries to help themselves by accelerating health development and stimulating economic growth;
b) promoting the maximum cooperation among African nations;
c) optimizing financial stability within African nations and between regional trading partners.

6) Launch Public Relations Promoting the Critical Role of the USG in Accelerating African Health Development. To garner the support of the American public for a new approach to African development, a concerted public relations campaign is required. This campaign could include health and medical associations, religious groups, African-American leadership, globalization of economic growth advocates etc

That's all for now!! Thanks for allowing me to share in your PASSION FOR ACTION!!!

Yours faithfully,

Paul S. Zeitz

 - att1.htm

NATIONAL INSTITUTES OF HEALTH
OFFICE OF AIDS RESEARCH

Neal Nathanson, M.D.
Director

Building 31, Room 4C02
31 Center Drive
MSC 2340
Bethesda, MD 20892
TEL: 301 496 0357
FAX: 301 496 2119
E-Mail: nathansn@od.nih.gov

APR 8 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 pleased to enclose copies of the National Institutes of Health Fiscal Year 2000 Plan for HIV-Related Research. The Plan represents a unique collaborative process among hundreds of individuals: NIH Institute Directors; NIH scientists and program staff; non-Government experts, including scientists from academia, foundations, and industry; and AIDS community representatives.

The Plan represents the collective efforts and the collective hopes of all of us that through a coordinated, well-planned, strong research program, we can break new ground and open new avenues to achieve our goal of preventing and curing AIDS.

The Plan has also been posted on the Internet at www.nih.gov/od/oar.

Neal Nathanson

Enclosures

Lynne Varner <lvarner @ seattletimes.com>
04/19/99 01:38:21 PM

Please respond to lvarner@seattletimes.com

Record Type: Record

To: Sarah T. Holewinski/OPD/EOP

cc:
Subject: Re: Test message

Good morning Sarah,
I'm just checking in to see if you have anything to pass along on my project about AIDS orphans. I want to narrow my research down to a single country where the problem is particularly acute. Any suggestions?

Also, if Sandy could tell me briefly about the governmental structure over there, because I'm wondering, in reporting about AIDS orphans, is there foster care or orphanages or is it less structured than that? Hope to hear from you soon. Thnx.

Sarah_T._Holewinski@opd.eop.gov wrote:

> >From Sandy Thurman's Office...

Lynne Varner <lvarner @ seattletimes.com>
04/16/99 06:26:28 PM

Please respond to lvarner@seattletimes.com

Record Type: Record

To: Sarah T. Holewinski/OPD/EOP

cc:
Subject: Re: Test message

Got it. thnx.

Sarah,
I've been able to narrow down my field of interest a little more. Specifically, I'm applying for an Ethel Payne Fellowship to study in Africa for one month in the year 2000. My background is education and children reporting so my fellowship proposal will center around this. Currently I'm interested in going to Africa to report on AIDS orphans or the push to educate young girls about condoms and other AIDS preventative measures.
I'd be interested in any U.S.-sponsored initiatives since my story should be of general interest or in some way be connected to U.S. policy. I'm interested in the southern region of Africa, particularly South Africa, Zimbabwe, Botswana, Zambia or Uganda.

What I would like from Sandy is direction. What country would best tell the story of measures taken to prevent AIDS from spreading among increasingly younger girls. Perhaps there are efforts to stem prostitution? Orphanages to care for young children after their parents die of AIDS?

Any help you could give would be great.

Sarah_T._Holewinski@opd.eop.gov wrote:

> >From Sandy Thurman's Office...

Karen Mulhauser

Mulhauser and Associates

1730 Rhode Island Avenue, N.W., Suite 712
Washington, D.C. 20036
(PH) 202-463-0180, (FAX) 202-463-0182
kmulhauser@consultingwomen.com

FAX MEMO

TO: Sarah
FAX: 456-2439
RE: Ark Foundation, AIDS crisis in Africa
PAGES: 6
DATE: 4-8-99

I look forward to meeting you and Sandra at your office on April 13 at 3:30 pm. I appreciate the opportunity to learn more about the work of your office and to talk about the assistance I have been asked to provide for the Ark Foundation of Africa. I am particularly interested in learning more about your Africa trip with the Congressional delegation and what kinds of things you were able to accomplish and learn. I understand that Ron Dellums is leaving in a few days for Africa to also learn about and address the AIDs crisis.

The time seems to be right to try to build some synergisms and create as many opportunities as possible to educate Americans about the crisis. I want to assist you as well as the Ark Foundation and Ron Dellums by encouraging collaborations where the goals are similar.

Attached is information about the Ark Foundation, a nonprofit organization committed to improving the conditions in east Africa. Its current focus is on the AIDs crisis with particular attention to the children who are orphaned because of AIDs. The Executive Director, Rhoi Wangila, has just returned from Uganda, Kenya and Tanzania where she visited their projects, and attended many funerals... I have asked her to prepare a brief report that I can share with you and others who may be interested in collaborations and support. It is a small struggling group with a massive task. The Ark's niche is in part defined by the fact that it is administered by Africans who have a comprehensive understanding of the cultural barriers and opportunities for the type of education needed to halt the spread of AIDs.

I have offered to help the Foundation in various ways to help raise money for their programs and to bring their message to the American public. I'm afraid that too many people in the US are beginning to think AIDs is less of a problem and are not giving it the attention it deserves – especially with an entire continent effected as Africa is. Specifically I am:

- organizing a fundraising reception, hopefully on May 27. A host committee of representatives from international development and health related organizations will promote the event and help bring participants. An honorary committee with

members of Congress and others will also be listed. *We are inviting the* Ambassador of Uganda, Ron Dellums and others to speak. It would in fact be wonderful if Sandra could speak as well. A description of the Congressional visit would be very valuable. A singer from Uganda is donating his time for entertainment. The program will be followed by a reception.

- organizing a Capitol Hill briefing. My current plan is to work with the Overseas Development Council as part of its Congressional Staff Forum series for a mid May date. If you are planning a briefing about your visit, we should coordinate. Again, it would be wonderful if Sandra could speak at the Staff Forum.

There will be other activities I want to help the Ark Foundation convene and organize because its message is so important. All ideas and suggestions of collaborators are welcome.

Please do not hesitate to contact me if you have any questions or suggestions. Otherwise, I will see you on the 13th. Please let me know if it would be okay for me to invite Rhoi to join me.

The Ark Foundation of Africa
1505 North Capital N E. Washington D.C. 20001 Tel. 202-832-5420 Fx 202- 636-4244

February 3, 1999

Dear Karen,

Thank you for talking with me yesterday. As an African, I am proud to share with you some of the work we at the Ark Foundation of Africa have been doing to help our fellow Africans. (see attached)

I am in the process of putting together the plans for our conference/dinner on HIV/AIDS in Eastern Africa which is scheduled for the last week of May. Mr. Samite, a well-known Ugandan musician and recording artist in New York, has agreed to perform (songs of Refugee). Can we count on your assistance?

With your Event Preparation experience and contacts with other people in the field, would you be willing to assist?

Seriousness of the HIV Epidemic in Eastern Africa.

What should be done to secure a minimum of well-being to those who are struggling on a daily basis for their survival, with an income of less than $300 a year per household? What can be done in Uganda, Kenya and Tanzania to prevent the unborn and mother-to-child HIV transmission (an increase of 45% since 1997) mostly through breast feeding? This is the only alternative in Africa for proper feeding. What about the 1,970,000 living orphans under 15 years old in these three countries? Eighty-three percent of the world's documented AIDS cases are in Africa.

Studies show that 90% of all children infected with HIV since the beginning of the Epidemic have been born in Africa, where there is a high prevalence of HIV among women of reproductive age. In Kenya alone, over 100,000 babies are born to HIV-infected women every year. "Out of 1.5 million Kenyans who are infected, 70% are youths between 15-25 years," according to the minister of Health. HIV is undermining development in Africa.

I am convinced that we all know and are moved by the same desires, needs and emotions, regardless of the language in which these feelings are expressed. The need to raise more money for HIV outreaches for rural Africa where 3 out of 5 people do not understand the causes of HIV has never been greater. The goal is to open people's minds and hearts to the common threads of human concerns, conveying optimism through vigorous outreaches, and campaign to raise the necessary funds.

Africa means a great deal to me, and I owe it to her. I must therefore, stand-up and advocate for the cause. Please feel free to call me for any additional information. My fingers are crossed in hope of your assistance.

Yours sincerely,

Rhoi Wangila

Rhoi Wangila
Executive Director, AFA

Dear

I am writing to you about the *heart breaking **AIDS** conditions in my homeland of East Africa.*

It is more than clear that sweeping changes are needed if Africa is to **SURVIVE** the challenges of the 21st Century. **Where else can people die like this and we do nothing to affect change?** Few people outside Africa realize that **AIDS** is the most terrifying challenges facing Africans TODAY. HIV is raging through Africa and will continue to do so unless something is done NOW. Families, communities, and nations are being wiped out in dire desperation.

Thousands are dying daily. Consider these facts.

- 83% of all the world's HIV cases are in Africa
- 4 out of 5 deaths for Africans aged 25-34 years are HIV/AIDS-related
- 7 out of 10 pregnant women in Uganda are HIV positive
- 1 out of every 4 walking person in Botswana is HIV positive

While numbers are declining else where in the world, they are sky rocketing in Africa. Response from the international community to this Public Health Emergency has been woefully ineffective. Children are left sick without parents and old people who depended on their children are now hopeless. Villages are left bare. *Relatives and friends are on borrowed time.* ***The future is best imagined than described.***

Why is it so difficult to control this KILLER? The answer is bound up in the Cultural and Social Traditions of Africans. Poverty, Traditional practices, and Lack of Community outreaches play a huge part. Most people in rural Africa are not well informed about the dangers associated with HIV/AIDS.

Can Africa fight this war alone? I don't think so. **WE NEED HELP!** The war against poverty and AIDS can be best fought by native Africans, but it is too much for us. The Ark Foundation, Inc, (AFA) is committed to improving the health, social, and economical conditions of East Africans. AFA together with missionary volunteers travel to East-Africa where we conduct effective Christian Outreaches. ***Get involved, save lives, we need your help and commitment.*** Thousands of people are dying daily. **It is real.** There is no single family, school, office in Uganda that has not lost a person to AIDS. **NONE.** ***CALL TODAY TO FIND OUT HOW YOU CAN HELP, 202-832-5420***

May the Lord bless you,

[redacted]

[redacted]

The Ark Foundation of Africa Mission and Goals:

The mission of the Ark Foundation of Africa (AFA) is to improve the quality of life of East Africans--- with emphasis on women, youth, and children- by providing assistance through educational and community economic development programs that are replicable, self-sustaining, and poverty alleviating. The Ark Foundation's programs help vulnerable groups, such as the displaced, the unemployed, women, teens, and others affected by wars and AIDS.

AFA believes that the reduction of village poverty and health problems lies within the villagers' ability to become self-sufficient. Thus, AFA supports self-help initiatives of the poor in Uganda, Kenya and Tanzania through the following activities.

AFA develops educational opportunities for poor children and adults by building affordable community schools, providing educational scholarships, and offering adult education programs focusing on literacy and basic health care.

AFA provides community economic development through its micro-enterprise program, which encourages and supports small, private enterprises.

AFA is undertaking a new, pilot project-- Sanitation Y2000-- to control deadly diseases spread via poor sanitary conditions.

In all of its efforts, AFA encourages and supports participatory development- a process through which villagers conceive, design, implement, and participate in evaluating their own development efforts.

AFA works to help poor East-Africans develop and empower their minds, families, and villages so that they can achieve freedom. The major goal is to end dependence on humanitarian aid and develop successful new businesses at the village level.

1: **Educational**
- Scholarship
- Computer Training
- School Supplies
- Building and Refurbishing Learning Institutions

2: **Poverty Reduction**
- Microenterprise
- Community Development
- Youth and Women

3: **Basic Health**
- Sanitation
- HIV/AIDS Education
- Nutrition

Samite of Uganda

Samite's music first and foremost celebrates and preserves his native Baganda culture: his vocals are sung entirely in Luganda, his mother tongue, and the songs are performed on traditional African instruments such as kalimba (finger piano), marimba (wooden xylophone), litungu (seven-stringed Kenyan instrument), and flutes. But with the addition of modern technology and a touch of Western jazz, Samite seamlessly merges the traditional with the contemporary, resulting in a fascinating, unique and highly accessible fusion.

Samite was born and raised in Uganda, where his grandfather taught him to play the traditional flute. His primary schooling was within the King's Courtyard, where the royal musicians played for the king. That daily influence permanently instilled within the young boy the rhythms and patterns of the traditional music of his people. Recognizing his talents, a teacher at his high school in Kampala put a western flute in his hands and helped him to become one of the most highly acclaimed flutists in East Africa.

In 1982, he fled to Kenya as a political refugee, where he played with the Bacchus Club Jazz Band and the renowned African Heritage Band. Increasingly drawn to instruments and rhythms from the traditional Ugandan music scene, he began playing his own music at the Mount Kenya Safari Club in Nairobi.

Emigrating to the United States in 1987, Samite made his home in Ithaca, New York, where he recorded his first tour de force Shanachie release, **Abaana Bakesa** (Dance My Children, Dance). His second release, **Pearl of Africa Reborn** (Shanachie), was recorded at the Hit Factory in New York City. Samite's third U.S. album, **Silina Musango** (Xenophile), reached #2 on the CMJ New World Music Charts in the summer of 1996. He also appears on several Narada and Putumayo compilations. Samite recently signed with Windham Hill Records, and his next album is expected to be released in the summer of 1999.

In the summer of 1997, Samite returned to Uganda for the first time in fifteen years, a trip which was filmed by documentary producer Glenn Ivers. Along the way, the two visited with refugees from Liberia, Rwanda, and Uganda at various locations in Africa. The result is the PBS video **Song of the Refugee**, available through the PBS satellite in January 1998. **Song of the Refugee** tells the true story of African refugees and displaced peoples, and conveys their optimism for the future despite their harrowing past.

Samite is available solo, duo, or trio, the trio including a percussionist and a guitarist. In addition to concerts, he is also available for workshops, children's performances and residencies.

For over ten years, Samite has made his living as Uganda's unofficial musical ambassador to the U.S. One of his goals is to open people's minds and hearts to the common threads of human concerns, conveying optimism through stories and song. "I am convinced that we are all moved by the same desires, needs, and emotions regardless of the language in which those feelings are expressed," says Samite. His major appearances include an amazing concert with the Cornell University choruses; headlining Unicef's Day of the African Child in New York City; the New Orleans Jazz and Heritage Festival; the Houston International Festival; and Woodstock '94, on Peter Gabriel's WOMAD stage.

For bookings and information: *The* **MURRI** *Agency* P.O. Box 586, Hadley, MA 01035 USA 413-527-8180 • Fax 413-527-6240

KAREN MULHAUSER

TUES, APRIL 13TH, 3:30 PM

BRIEFING MATERIAL

OFFICE OF NATIONAL AIDS POLICY

THE UNITED METHODIST CHURCH

WASHINGTON EPISCOPAL AREA
BALTIMORE-WASHINGTON CONFERENCE

April 30, 1999

MEMORANDUM:

TO: Ms. Sandra Thurman, The White House
Fax: 202/456-2439

FROM: Bishop Felton Edwin May

RE: Chattanooga, TN event:

Sandy, thanks for your patience while waiting for the following information.

The Council of Bishops Spring Meeting is being held at:
Chattanooga Marriott Hotel
2 Carter Plaza
Chattanooga, TN 37402
(423) 756-0002; Fax: (423) 265-8735

We have scheduled a Luncheon Meeting with the Africa Bishops for Thursday, May 6, 1999 and are scheduled to be in the *Lookout Mountain* Room. Your speaker will want to check the signs to confirm this.

Following the luncheon, at 1:30 p.m., the Plenary will begin in the Plaza Ballroom. The person you have selected to speak is scheduled to be the 2nd speaker.

The Rev. Joyce L. Alford, Administrative Assistant of the Council of Bishops, can be contacted for any assistance needed for the presentation. The front desk at the Marriott can put your person in touch with her.

Grace and peace.

FELTON EDWIN MAY, BISHOP
NANCY G. DRAKE, ADMIN. SECRETARY

OFFICE: 202/546-3110
FAX: 202/546-3186

110 MARYLAND AVENUE, NE - Suite 311
WASHINGTON, D.C. 20002-5622

FILE

PRESIDENTIAL

ADVISORY

COUNCIL ON

HIV/AIDS

April 8, 1999

MEMORANDUM FOR SANDRA THURMAN, DIRECTOR AND TODD SUMMERS, DEPUTY DIRECTOR

FROM: Daniel C. Montoya, Executive Director

RE: Letter to the President Addressing the Omnibus Appropriations Bill of 1998

Attached is a letter to the President from the Presidential Advisory Council on HIV/AIDS dated April 7, 1999. The letter addresses provisions of the Omnibus Appropriations Bill of 1998 and its potentially negative impact on government sponsored research. Please transmit this letter to the President.

Thank You.

736 Jackson Place, NW
Washington, D.C. 20503
Telephone: (202) 456-2437
Facsimile: (202) 456-2438

FILE

PRESIDENTIAL
ADVISORY
COUNCIL ON
HIV/AIDS

April 7, 1999

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

Dear Mr. President:

As your Advisory Council on HIV/AIDS, we bring to your attention our concern with two sentences in the Omnibus Appropriations Bill of 1998 which have a potentially tremendous negative impact on publicly funded HIV/AIDS research. These two sentences would allow individuals (and corporations) to use the Freedom of Information Act (FOIA) to gain access to researchers' raw data whenever the research is funded by a federal grant.

The language provides: "That the Director of the Office of Management and Budget amend... Section -.36 of OMB Circular A-1 10 to require Federal awarding agencies to ensure that all data produced under an award will be made available to the public through the procedures established under the Freedom of Information Act." A second sentence allows a "reasonable user fee" to be charged for the release of data. While the intent of this legislation in making information about this research available is laudable, the outcome could have detrimental effects.

On January 6, Representative George Brown (D-CA), ranking Democrat on the House Science Committee, introduced H.R. 88 to repeal this provision, pointing out that the language as stands would require "the premature release of research results." Congressman Brown says his legislation would " protect researchers from harassment."

The Omnibus Appropriations language could have potentially serious and detrimental effects on all government sponsored research - including HIV/AIDS, by allowing:

- Early release of research data, which does not reflect the real and final truth;
- Mis-use of in accurate, partially completed research data;
- Potential for loss of subject confidentiality; and
- Potential loss of valuable time and effort on the part of researchers, who must devote energy to complying with this law, as opposed to performing the research for which funds were granted.

We urge you to support H.R. 88, and to support a similar repeal bill in the Senate.

Sincerely,

R. Scott Hitt, M.D.
Chair

736 Jackson Place, NW
Washington, D.C. 20503
Telephone: (202) 456-2437
Facsimile: (202) 456-2438

cc: The Honorable George Brown
Sandra L. Thurman, Office of National AIDS Policy
Daniel Mendelson, Office of Management and Budget

Presidential Advisory Council on HIV and AIDS

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

PRESIDENTIAL
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COUNCIL ON
HIV/AIDS

April 7, 1999

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

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Sincerely,

R. Scott Hitt, M.D.
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cc: The Honorable George Brown
Sandra L. Thurman, Office of National AIDS Policy
Daniel Mendelson, Office of Management and Budget

FILE

PRESIDENTIAL

ADVISORY

COUNCIL ON

HIV/AIDS

April 8, 1999

MEMORANDUM FOR SANDRA THURMAN, DIRECTOR AND TODD SUMMERS, DEPUTY DIRECTOR

FROM: Daniel C. Montoya, Executive Director

RE: Letter to the President Addressing the "Early Treatment for HIV Act of 1999"

Attached is a letter to the President from the Presidential Advisory Council on HIV/AIDS dated April 7, 1999. The letter addresses the "Early Treatment for HIV Act of 1999." Please transmit this letter to the President.

Thank You.

736 Jackson Place, NW
Washington, D.C. 20503
Telephone: (202) 456-2437
Facsimile: (202) 456-2438

FILE

PRESIDENTIAL

ADVISORY

COUNCIL ON

HIV/AIDS

April 7, 1999

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

Dear Mr. President:

As your Advisory Council on HIV/AIDS, we continue to be concerned by the large number of low-income Americans in the earlier stages of HIV disease who are unable to receive antiviral therapy and medical care because of current Medicaid eligibility restrictions.

We appreciate the hard work of the Health Care Financing Administration, the Office of National AIDS Policy, the Office of the Vice President, the Office of Management and Budget and others in the Administration to try to find ways to extend Medicaid coverage to such individuals within the constraints of a balanced budget agreement.

To assist in that effort, later this month Congresswoman Nancy Pelosi, Congressman Richard Gephardt, Senator Robert Torricelli, and other Members of Congress are preparing to introduce the "Early Treatment for HIV Act of 1999" in both the House and the Senate. This legislation would give states the option of providing Medicaid benefits to this population with full federal participation.

Mr. President, your active support of the "Early Treatment for HIV Act of 1999" could be tremendously helpful in achieving your laudable goal of expanding early access to treatment for low-income, uninsured individuals living with HIV disease.

Medicaid is the largest provider of health coverage to people with AIDS in this country. However, Medicaid eligibility policy has not caught up to current HIV treatment guidelines issued by government health experts more than eighteen months ago. These Public Health Service Guidelines recommend early medical care, and in many cases, the use of antiviral therapy in the earlier stages of HIV infection, before development of symptoms. Yet because Medicaid does not define such individuals as "disabled", many low-income, HIV-infected individuals are currently unable to receive HIV-related drugs and health care through the program.

Research released at the 12th World AIDS Conference in Geneva provides additional evidence that early therapy for individuals infected with HIV

736 Jackson Place, NW
Washington, D.C. 20503
Telephone: (202) 456-2437
Facsimile: (202) 456-2438

saves lives and is cost effective. A University of California San Francisco study found that, "expansion of the U.S. Medicaid system to provide wider access to combination antiretroviral therapy would prevent thousands of deaths and AIDS diagnoses, leading to 8,000 more years of life for persons with HIV" during just the next five-years.

In addition to preventing costly inpatient costs associated with treating HIV-related opportunistic infections, Medicaid expansion would also likely lead to substantial savings in the Supplemental Security Income (SSI) program. Individuals receiving earlier therapy would more likely maintain their health; in many cases, continue working or return to work; and be less likely to require government disability benefits.

For both public health and fiscal reasons, passage of the "Early Treatment for HIV Act of 1999" makes good sense. Powerful new drugs have given many people with HIV infection renewed hope in fighting this disease. It is imperative that federal health care programs catch up with the newest standards set by our nation's health experts.

Thank you for your continuing attention to this important issue. We will appreciate your assistance with the passage of this legislation.

Sincerely,

R. Scott Hitt, M.D.
Chair

cc: The Honorable Nancy Pelosi
The Honorable Richard Gephardt
The Honorable Robert Torricelli
Nancy-Ann Min De Parle, Health Care Financing Administration
Sandra L.Thurman, Office of National AIDS Policy
David Beier, Office of the Vice President
Daniel Mendelson, Office of Management and Budget

Presidential Advisory Council on HIV and AIDS

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ELIZABETH GLASER PEDIATRIC AIDS FOUNDATION

REQUEST FOR APPLICATIONS

TO: Interested Pediatric HIV/AIDS Researchers
FROM: Elizabeth Glaser Pediatric AIDS Foundation
SUBJECT: **Programs for Research in Pediatric HIV/AIDS**
DATE: April 1, 1999

The **Elizabeth Glaser Pediatric AIDS Foundation**, in its commitment to fund basic medical research in pediatric HIV/AIDS, announces the availability of funding for One-year Pediatric Research Grants, Two-year Pediatric Research Grants, Two-year Pediatric Scholar Awards, and Pediatric Short-term Scientific Awards. This granting program is entirely funded and solely directed by the Elizabeth Glaser Pediatric AIDS Foundation.

The Elizabeth Glaser Pediatric AIDS Foundation is especially interested in funding **creative and innovative research ideas not yet suitable for funding by other agencies (e.g., NIH).** All proposals must have direct relevance to pediatric HIV/AIDS and its related issues. **The Elizabeth Glaser Pediatric AIDS Foundation will accept applications from investigators who are previous Foundation awardees.** Established investigators and international applicants at not-for-profit institutions are encouraged to apply. Further, we will consider applications from researchers interested in collaborating with investigators from developing countries. To date, the Elizabeth Glaser Pediatric AIDS Foundation has funded all applications that scored in the fundable range during peer review and met the Foundation's scientific criteria for funding, and we will make every effort to continue this commitment. The Elizabeth Glaser Pediatric AIDS Foundation is especially interested in receiving Letters of Intent which fall within any of the following pediatric research areas, or other areas that have direct relevance to pediatric AIDS:

PP01- Transmission of virus from mother to infant

PP03- Pathogenesis of HIV infection

PP05- Mucosal immunity to HIV (including studies of the pediatric GI tract)

PP07- Characterization of immune response to HIV

PP08- Central nervous system and HIV

PP09- Role of the placenta in facilitation of, or protection from, HIV infection.

PP12- Host genetic factors that increase or decrease susceptibility of the neonate to perinatal HIV infection

PP13 - Vaccine development

PP14- Other critical areas highly relevant to pediatric HIV/AIDS research

PP15- Breast-milk transmission

2950 31st Street, Suite 125, Santa Monica, California 90405 Tel: (310) 314-1459 Fax (310) 314-1469 www.pedAIDS.org

THE ELIZABETH GLASER PEDIATRIC AIDS FOUNDATION IS OFFERING GRANT SUPPORT FOR THE FOLLOWING THREE (3) PROGRAMS

A.---> ONE-YEAR AND TWO-YEAR PEDIATRIC RESEARCH GRANTS

- Provides institutionally affiliated investigators with up to $80,000, U.S., in annual direct costs **for a period of performance not to exceed two years**.
- Applicants must have a full-time academic and/or institutional appointment (organizations must be non-profit).
- While the investigator may apply for a one-year or two-year grant, determination as to the duration of support will be made by the Scientific Advisory Committee during peer review.
- Only one application per investigator will be solicited.
- Renewal applications will be solicited for investigators receiving one-year grants, and will be reviewed **competitively** based on progress delineated in the renewal application. Two-year grants are not renewable.
- Applicants conducting research using **animal models** may apply for **supplemental funds** directly related to the purchase and care of animals; the total **direct cost** for these grants **may not exceed $100,000 per year**, for a period of performance not to exceed two years.
- Indirect cost allowed for these awards is 20% of total direct costs.
- In order to enhance existing research, an investigator may seek funds to support a nested study which is complementary to research currently funded by other institutions.
- Percentage of time spent on active grants, including the application submitted to the Foundation, may not exceed 100% effort.
- Basic Research Grants will be awarded beginning January 1, 2000.

B.--->TWO-YEAR RENEWABLE PEDIATRIC SCHOLAR AWARDS**

- Provides up to $66,000, in direct costs, for two years of salary support towards basic medical research in pediatric HIV/AIDS ($32,000 year one and $34,000 year two). Scholars must agree to spend at least 50% of their time on research in pediatric HIV/AIDS.
- Pediatric researchers with M.D.s must have two to three years of post-doctoral experience to be eligible. This requirement is waived for Ph.D.s and D.V.M.s. Tenured senior investigators are not eligible.
- Awards are renewable for a third year at $36,000. Renewal applications do not go through the Letter of Intent process and are solicited automatically. However, renewals are competitive and are not routinely awarded.
- Only two applications will be accepted from any one sponsor. There is no limit as to the number of applications submitted from one department.
- Scholars must select an experienced sponsor with appropriate qualifications to oversee the proposed research.
- Indirect cost allowed for these awards is 10% of total direct costs.
- Scholar Awards are awarded for a period of two years beginning January 1, 2000.

C.--->PEDIATRIC SHORT-TERM SCIENTIFIC AWARDS **

- Provides $5,000 for any **small project** or portion of a project that can be accomplished in a short period of time. Awards are specifically intended to facilitate exchanges of information and the acquisition of specialized skills within the Foundation's areas of concern.
- Open to qualified pediatric investigators at U.S. and foreign (non-profit) institutions.
- Indirect costs are not allowed on Short-term Scientific Awards.
- Short-term Scientific Awards are given for a one-year period, beginning January 1, 2000 and the project or travel/training may be done at any time within that one-year period.

** SPONSORS

A sponsor for Scholar Awards, or a host for Short-term Awards that involve travel or training must be designated at the time of letter of intent submission. Sponsors or hosts are not required for Short-term Scientific Awards that do not involve travel or training. Letters of Intent must contain the CV of the designated sponsor/host, as well as the CV of the applicant/scholar. To be reviewed, all Scholar Award applications and any Short-term Award applications involving travel or training must designate a sponsor/host.

RESEARCH TOPIC CODES

On the first page of this announcement you will find a list of pediatric research areas with codes. Please assign primary and secondary research codes to your cover sheet in the appropriate box when submitting your letter of intent. Please use only one research topic code per category. If PP14 is used, please provide one or two sentences which explain the relevance of your research to basic medical research in pediatric HIV/AIDS. Also, please use the check box to indicate if your research involves animal models. If you feel there are other basic medical research areas highly relevant to pediatric HIV/AIDS which are not represented here, and you think we should include them in our next RFA, please suggest them on the face sheet. While the Elizabeth Glaser Pediatric AIDS Foundation supports basic medical research using clinical material, we do not support large therapeutic trials or the pharmacologic development of drugs.

SUBMISSIONS FROM THE NIH OR OTHER GOVERNMENT AGENCIES:

Applications from the NIH or other government agencies must submit a clear explanation of why extramural support is needed.

OFF-CYCLE APPLICATIONS

The Foundation has mechanisms to review applications for these programs off-cycle, although off-cycle grants are not routinely awarded. Please contact the Grants Department for more information.

ELIZABETH GLASER PEDIATRIC AIDS FOUNDATION WEB SITE

Please visit our Web site **www.pedaids.org** for more information about the Foundation. This RFA will be available there for downloading by April 1, 1998.

LETTER OF INTENT SUBMISSIONS

Submission of a Letter of Intent is not a guarantee of eligibility to submit a grant application. The LOI review is a screening process which is highly competitive. All Letters of Intent are peer reviewed, and those of the highest caliber will be asked to submit a full grant application. All LOIs must address the direct relevance of the research to pediatric AIDS and/or its related issues. **Applicants will be notified** by September 16, 1999 if they will be asked to submit a full application. Awards will be made in January of 2000 following peer review. For further information regarding our granting programs, please contact the Grants Department at (310) 314-1459, e-mail: research@pedaids.org.

ADMINISTRATIVE REQUIREMENTS

- All Letters of Intent should be addressed to: **The Review Committee.**
- Please use a 12-point font, double-spaced, and .75 margins
- We will not accept revisions to the application after the due date.

LETTER OF INTENT INSTRUCTIONS

Attached is a Letter of Intent (LOI) Cover Sheet. The cover sheet must be used for all LOI submissions. Please check the appropriate box for the type of award for which you are applying. Letters of Intent that arrive late, lack sufficient copies, are incomplete, or exceed page limitations (strictly enforced) will not be reviewed. FAX copies of Letters of Intent are not permitted and will not be considered or acknowledged. Letters of Intent are due no later than 5:00 p.m., **July 22, 1999.** Please prepare the original and 9 **(total of 10) collated and stapled sets** of the Letter of Intent in the following order.

1. **CHECKLIST**... a cover page with the following items should be listed with check marks verifying each item's inclusion in the application submission.
2. **COVER PAGE**... completed, including the research assignment codes.
3. **ABSTRACT**... 200-word lay-language description of the proposal.
4. **DESCRIPTION/RESEARCH PLAN**... three pages or less which should include background and rationale, preliminary studies, specific aims, experimental design, procedures to be used and data analysis. Relate specific aims to long-term objectives. Discuss new methodologies, if any. **Short-term Award applicants** must provide complete discussion of the travel and training of the project to be accomplished; and **Scholar Award applicants** must submit a research plan that reflects their two-year period of performance.
5. **RELEVANCE DESCRIPTION**... a maximum one-page document which addresses the direct relevance of the proposed research and/or training to pediatric AIDS and its related conditions.
6. **BIOGRAPHICAL SKETCHES**...of the investigator and the sponsor/host (required for Scholar Awards and as necessary for Short-term Awards), not more than two pages in length and including not more than 15 relevant and/or recent publications. Biographical sketches for both the applicant and the sponsor/host are required.

Letters of Intent (original & 9 copies) must be received at the address below by 5:00 P.M. on July 22, 1999. NO FAX COPIES ACCEPTED!

ELIZABETH GLASER PEDIATRIC AIDS FOUNDATION
2950 31st Street
Suite 125
Santa Monica, CA 90405
Attn: Trish Devine, Programs Director

Phone: 310-314-1459, FAX: 310-314-1469
E-MAIL: research@pedaids.org

Elizabeth Glaser
Pediatric AIDS Foundation
Letter of Intent Cover Sheet
CYCLE 25
PLEASE TYPE

Please check type of grant:
- ☐ One-Year Basic Research Grant
- ☐ Two-Year Basic Research Grant
- ☐ Scholar Award
- ☐ Short-term Scientific Award

TOTAL COST _____

Foundation Use Only

Research Topic Code
Primary:
Secondary:

PRINCIPAL INVESTIGATOR

APPLICATION TITLE ☐ Check if research involves animal models

Name Degree

Title

Institution

Department

Subdivision

Street, Building, Room

City State Zip

Country Phone FAX

E-mail Address

Signature Date

SPONSOR/HOST INSTITUTION (required for Scholar and Short-term Scientific Awards)

Name Degree

Title

Institution

Department

Subdivision

Street, Building, Room

City State Zip

Country Phone FAX

E-mail Address

Signature

PAST PEDIATRIC AIDS FOUNDATION SUPPORT

Please provide the requested information for all Pediatric AIDS Foundation grants you have received, regardless of support received or its relationship to the current research application. Use additional page if needed.

Grant #	Project Title	Award Amount

Other Priority Research Areas you suggest we include on our next RFA:

ELIZABETH GLASER PEDIATRIC AIDS FOUNDATION

REQUEST FOR APPLICATIONS

2000 Elizabeth Glaser Scientist Awards

A Five-Year Award for Outstanding Scientists to Conduct Research in Pediatric HIV/AIDS

In the mid-1980's, Elizabeth Glaser learned that she and both of her children were HIV positive. She also discovered that there wasn't a national pediatric HIV/AIDS research agenda. Faced with this critical situation, she co-founded in 1988 what is now the Elizabeth Glaser Pediatric AIDS Foundation and called on the research community to focus on issues of pediatric HIV/AIDS.

Elizabeth died in December of 1994; her life is a testament to living with courage. As a way of carrying on her legacy, the Foundation created the *Elizabeth Glaser Scientist Award.* Through these awards, her vision and resolve will continue to inspire researchers to join together and bring an end to pediatric HIV/AIDS.

Scientists are selected on the basis of their knowledge, innovation and ability to carry forward Elizabeth Glaser's vision. The five-year duration of each award is a means of building an invaluable network of scientists who will continue to impact pediatric HIV/AIDS research long after the individual grants have been utilized.

We believe that the greatest potential for success in stopping the growing epidemic of HIV/AIDS lies in collaboration among leading innovators from different fields of research. This is the fifth year of the *Elizabeth Glaser Scientist Award* program. The Foundation has already awarded over $13 million to 19 stellar *Elizabeth Glaser Scientists* who will be the next leaders in the field of HIV/AIDS research. It is our goal that by the turn of the century, all of the*Elizabeth Glaser Scientists* will be working together to ensure that the world's next generation of children are free of HIV/AIDS, and that children already living with HIV/AIDS will grow to enjoy a healthy adulthood.

The *Elizabeth Glaser Scientist Award* is the only named award in AIDS research. The *Elizabeth Glaser Scientist Award* is an international program which provides each investigator with $650,000 (U.S.) in direct cost for a period of five years. An Advisory Board of distinguished scientists selects the awardees and ensures that the program meets its goals. Up to five awards will be given in January of 1999.

2950 31st Street, Suite 125, Santa Monica, California 90405 Tel: (310) 314-1459 Fax: (310) 314-1469 www.pedAIDS.org

ELIZABETH GLASER SCIENTIST AWARD LETTER OF INTENT SUBMISSIONS

ELIGIBILITY

- The *Elizabeth Glaser Scientist Award* provides $650,000 (U.S.) in direct costs for five years of research. Indirect costs are a maximum of 5% of direct costs.
- Each applicant must have an M.D., Ph.D., D.D.S., or D.V.M. degree and be at the Assistant Professor level or above. Full Professors will be considered only under very special circumstances. Endowed chairs are not eligible to apply.
- International investigators are encouraged to apply.
- Applicants must agree to dedicate a percentage of effort to this award that is at least equal to the percentage of funding they receive from the award relative to their other support.
- The Elizabeth Glaser Pediatric AIDS Foundation only accepts grant applications from not-for-profit entities.
- Only one application per investigator will be accepted.
- **All applications must have direct relevance to pediatric HIV/AIDS.**

SUBMISSION FROM THE NIH OR OTHER GOVERNMENT AGENCIES

Applications from the NIH or other government agencies must submit a clear explanation of why they need extramural support.

ELIZABETH GLASER PEDIATRIC AIDS FOUNDATION WEB SITE

Please visit our Web site www.pedaids.org for more information about the Foundation. This RFA will be available there for downloading by April 1, 1999.

PRIORITIES FOR RESEARCH

The Elizabeth Glaser Pediatric AIDS Foundation is especially interested in receiving applications for the research topics listed below. Additionally, we will consider applications in these areas from investigators interested in collaborating with researchers from developing countries. While the Elizabeth Glaser Pediatric AIDS Foundation supports basic medical research using clinical material, we do not fund large therapeutic trials or the pharmacologic development of drugs. Please assign primary and secondary research topic codes to your Letter of Intent cover sheet, in the appropriate box, when submitting your LOI. If your research involves animal models, please check the box on your face page. If PP14 is used, please provide adequate justification of the relevance of your investigations to basic medical research in pediatric HIV/AIDS.

PP01- Transmission of virus from mother to infant

PP03- Pathogenesis of HIV infection

PP05- Mucosal immunity to HIV (including studies of the pediatric GI tract)

PP07- Characterization of immune response to HIV

PP08- Central nervous system and HIV

PP09- Role of the placenta in facilitation of, or protection from, HIV infection

PP12- Host genetic factors that increase or decrease susceptibility of the neonate to perinatal HIV infection

PP13 - Vaccine development

PP14- Other critical areas highly relevant to pediatric HIV/AIDS research

PP15- Breast-milk transmission

LETTER OF INTENT SUBMISSIONS

Submission of a Letter of Intent (LOI) is not a guarantee of eligibility to submit a grant application. The LOI review is a screening process which is highly competitive. All LOIs are peer reviewed, and those of the highest caliber will be asked to submit a full grant application. All LOIs must address the direct relevance of the research to pediatric HIV/AIDS and its related issues.

Attached is a Letter of Intent cover sheet which must be used for all submissions. Please pay particular attention to the page limitations as they will be strictly enforced. FAX copies of LOIs are not permitted and will not be considered or acknowledged. To be considered for solicitation of a full application, please submit the original and 11(total of 12) copies of the Letter of Intent. Letters of Intent that arrive late, lack sufficient copies, are incomplete, or exceed page limitations will not be reviewed. An LOI document consists of the original and 11 (total of 12) collated and stapled sets assembled in the order specified below.

1. **CHECKLIST**...a cover page with the following items should be listed with check marks verifying its inclusion in the application submission.
2. **COVER PAGE**... completely filled out, including the research assignment codes.
3. **ABSTRACT**... 200-word lay-language description of the proposed study.
4. **DESCRIPTION/RESEARCH PLAN** ... three pages or less which should include background and rationale, preliminary studies, specific aims, experimental design, procedures to be used and data analysis. Relate specific aims to long-term objectives. Discuss new methodologies, if any.
5. **RELEVANCE DESCRIPTION**... a maximum one-page document which addresses the direct relevance of the proposed research and/or training to pediatric HIV/AIDS and its related conditions.
6. **BIOGRAPHICAL SKETCH**... of the investigator, not to exceed 2 pages in length, including not more than 15 relevant and/or recent publications.
7. **LETTER OF RECOMMENDATION**...(original plus 11 copies, a total of 12) from applicant's Department Chair. This may be sent under separate cover if need be, but we prefer all materials to be submitted together.

ADMINISTRATIVE REQUIREMENTS

- All Letters of Intent should be addressed to: **The Elizabeth Glaser Scientist Award Advisory Board.**
- Please use a 12-point font, double-spaced, and .75 margins
- We will not accept modifications to the applications after the due date.

DEADLINE

Letters of Intent (original & 11 copies) must be received at the address below by 5:00 P.M. on **June 10, 1999.** NO FAX COPIES ACCEPTED! **Applicants will be notified** by July 27, 1999 if they will be asked to submit a full application. Awards will be made in January of 2000 after peer-review. For further information regarding our programs, please visit our Web site (www.pedaids.org) or contact the Grants Dept.

Elizabeth Glaser Pediatric AIDS Foundation
2950 31st Street, Suite 125
Santa Monica, CA 90405
ATTN: Trish Devine, Programs Director

PH: (310) 314-1459 FAX: (310) 314-1469
E-mail: research@pedAIDS.org

Pediatric AIDS Foundation
Letter of Intent Cover Sheet
Elizabeth Glaser Scientist Award

Foundation Use Only

Research Topic Code
Primary:
Secondary:

☐ Check if research involves animal models

PLEASE TYPE

APPLICATION TITLE:

PRINCIPAL INVESTIGATOR

Name Degree

Title

Institution

Department

Subdivision

Street, Building, Room

City State Zip

Country Phone FAX

E-mail Address

Signature Date

PAST PEDIATRIC AIDS FOUNDATION SUPPORT

Please provide the requested information for all Pediatric AIDS Foundation grants you have ever received, regardless of support received or its relationship to the current research proposal. Use additional page if needed.

Grant #	Project Title	Award Amount

Other Priority Research Areas you suggest we include on our next RFA: