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Ms. Sandy Thurman
The White House
HIV/AIDS Bureau
1600 Pennsylvania Avenue NW
Washington, D.C 20500
USA

Fax: 202-456-2461

Dear Madam,

22 JUL 2000

Acceleration of WHO Regional Office for Africa (AFRO)
Action on HIV/AIDS Prevention and Care

The HIV/AIDS epidemic in Africa is now a disaster that threatens the survival of many communities and sustainable development in the Region. This was vividly illustrated in the discussions at the XIIIth International Conference on AIDS, held in Durban, South Africa. WHO/AFRO is developing a strategy and plan for the acceleration of our support to country's responses to HIV/AIDS, including the needs and concerns highlighted at the Conference.

WHO/AFRO's Regional Programme on HIV/AIDS already provides technical support to countries in the areas of Epidemiological Surveillance of HIV/AIDS and STI; Blood Safety; Prevention and Care for Sexually Transmitted Infections; Clinical and Nursing Care of HIV-related illness and Programme Management. We intend to add Prevention of Mother-to-Child Transmission of HIV and Voluntary Counselling and Testing. We are convinced that effective prevention and care interventions are well known and that tools for their implementation exist. WHO has contributed significantly to the development of approaches that underpin our work in countries.

An important limiting factor in the Region's response to HIV/AIDS has been inadequate financial and human resources. The scope of WHO/AFRO's Regional Programme on HIV/AIDS, with a current activity budget of **US\$ 2,2 million** and a team of 5 experts, is far below the level required for meaningful support to countries, given the scale of the HIV/AIDS epidemic in the Region. Our acceleration of support to Member States will focus on resource mobilisation for countries' activities, within the International Partnership Against HIV/AIDS (IPAA). Limited additional resources will be required to ensure our optimal support to country efforts.

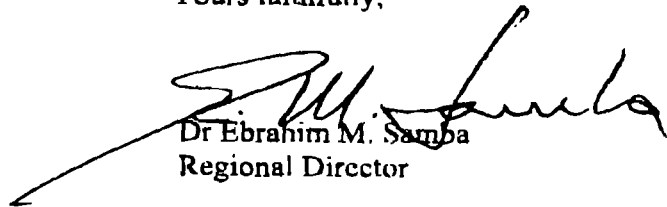
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V6/27/1

I am pleased to share with you an outline of actions that we will undertake to rapidly expand the scope of our collaboration with Member States. Our focus will be on the contribution of the health sector; within the context of multi-sectoral national strategic plans. WHO/AFRO has developed a Framework for accelerating the implementation of the Regional Strategy on HIV/AIDS, which will be discussed by Ministers of Health at the next session of the Regional Committee, from 28 August to 02 September 2000 in Ouagadougou, Burkina Faso. A plan for our accelerated action will be developed and finalised in the context of this discussion.

I would appreciate your comments on this outline and hope for your contribution to the immediate expansion of support to countries. The plan will be shared with you as soon as it is completed, when we shall look forward to further collaboration in its implementation.

Yours faithfully,



Dr Ebrahim M. Samba
Regional Director

**DRAFT OUTLINE FOR THE ACCELERATION OF
WHO AFRO SUPPORT TO
HIV/AIDS PREVENTION & CARE:
RESPONDING TO THE XIIIth INTERNATIONAL
CONFERENCE ON AIDS**

2000-2001

**WHO Regional Office for Africa
Parirenyatwa Hospital
P.O. Box BE 773
Harare
Zimbabwe**

22 July 2000

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Parirenyatwa Hospital-Harare
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12 NOV. 1999

Message No. 569 of 3 pages

From: Dr Ebrahim M. Samba
Regional Director

To: Dr. Peter Piot,
Executive Director,
UNAIDS,
Geneva

Our ref:

Subject: COMMENTS ON THE DRAFT AGENDA OF THE WASHINGTON, DC
MEETING TO CONSIDER THE STRENGTHENING OF TECHNICAL
COOPERATION IN THE INTERNATIONAL PARTNERSHIP
AGAINST AIDS IN AFRICA, NOVEMBER 17-18, 1999.

I have just received a copy of the first draft agenda of the above-mentioned meeting. This is indeed a very rare opportunity for us to mobilize all necessary assistance for sub-Saharan Africa in the battle against this scourge. I therefore feel very strongly, that we shall be losing a great and very rare opportunity of meeting in the White House, if the meeting does not devote attention to the real problems of HIV/AIDS in Africa and spell out what assistance is required from the International Community that constitute the Partnership, and especially from a very benevolent United States Administration.

The concerns of the governments of the African countries, most of which are severely affected by HIV/AIDS, revolve around how to find adequate resources to implement effective HIV/AIDS prevention and control programmes, and mitigate the impact of the epidemic. The present disastrous situation is the result of past denial and long neglect of the opportunities to act against the epidemic.

The first year of the International Partnership has been devoted to advocacy and increasing the awareness of the international community, donors, bilateral agencies and the African governments themselves. Many activities have been undertaken, almost without interruption, since the first meeting of the Partnership, which was held in Annapolis, State of Maryland, USA, in January 1999.

.../2

Copy for information:

Dr. Gro Bruntland, Director-General, WHO, Geneva
Dr. Olive Shisana, Executive Director, CHS/HQ
Dr Sandra Thurman, Director, Office of National AIDS Policy, The White House, Washington DC. ✓

Dr. Peter Piot,
Executive Director
Geneva

Many international and regional meetings have been held in London, Geneva, Maputo, Windhoek, Tripoli, Lusaka, Cairo, and Johannesburg to advocate the Partnership. These meetings have been attended by various groups of highly placed officials and high level decision makers, ranging from heads of international organizations and agencies, to Ministers, Heads of State of all African countries (OAU) and, by no means the least, Donors.

These advocacy activities will reach a climax on December 6-7 1999, when the UN Secretary General will launch the International Partnership in New York. Little more can be done in raising awareness among the African leaders and governments.

The burning issues of great concern, that the Partnership should now seriously begin to deliberate upon, are those concerned with the selection of appropriate interventions, availability of resources, the creation of enabling environment for a successful combat, and the commencement of action against HIV/AIDS at the country and community levels.

The list given hereunder has been compiled from the decisions, conclusions, resolutions and declarations made by African governments, their ministers, higher authorities and heads of state at various forums throughout the past year. The needs identified by them for urgent action and resource allocation are:

1. Care of patients, prevention and treatment of opportunistic infections and tuberculosis in HIV/AIDS patients
2. Prevention and treatment of sexually transmitted infections including the supply of condoms
3. Establishment of voluntary testing and counselling services
4. Availability of diagnostic facilities; reagents, equipment and technical personnel
5. Blood safety measures
6. Training of health and allied workers: epidemiologists, biomedical researchers, social workers
7. Specially designed educational materials for adolescents in and out of school

Dr. Peter Piot,
Executive Director
Geneva

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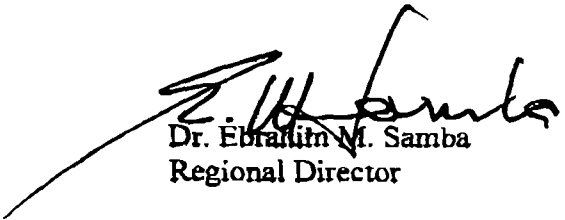
8. Affordable anti-retroviral drugs for the prevention of mother to child transmission of HIV
9. Strengthening the coping capacity of affected rural communities, by introducing measures such as the establishment of viable micro-projects, that can promote better social and economic life and integration, and assure food security.

I therefore recommend that

1. The discussions should aim at setting an ACTION AGENDA.
2. The technical cooperation required from the agencies and partners should be directed towards strengthening institutional and national capacity to plan and implement the above interventions.
3. The support required from the African governments, their partners, the Donors and the International Community, is the provision of adequate resources for the successful launching, implementation and sustainability of the above listed interventions.
4. The directory of national, regional and international experts that is being compiled should contain the names and addresses of persons and institutions with the appropriate skills, competence and resources, who are willing and available to give technical advice or make technical contribution, to one or more of the interventions listed above.

It will therefore be appreciated if you would consider these suggestions when modifying the agenda.

Best regards.



Dr. Ebrahima M. Samba
Regional Director

CONTACT SCIENCE

From David



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May be submitted via e-mail (at science_letters@aaas.org), fax (202-789-4669), or regular mail (Science, 1200 New York Avenue, NW, Washington, DC 20005, USA). Letters are not routinely acknowledged. Full addresses, signatures, and daytime phone numbers should be included. Letters should be brief (300 words or less) and may be edited for clarity or space. They may appear in print and/or on the Internet. Letter writers are not consulted before publication.

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Investing in the World Health Organization

Barry R. Bloom, David E. Bloom, Joel E. Cohen, Jeffrey D. Sachs

No international organization has been more successful in promoting global health and well-being in the past half century than the World Health Organization (WHO). It has been at the forefront of advances that have allowed people to live longer and healthier lives that are far less threatened by infectious diseases. It has also improved access to good quality health care and diminished ignorance about public health, biology, and medicine. These improvements also contribute indirectly to living standards by promoting increased productivity, income, gender equity, and accumulation of human capital.

United States support of WHO has always been justified on grounds of national self-interest and humanitarian concern. Given the disrespect that diseases have for national boundaries, the increasing depth and complexity of our participation in the world economy only reinforce this argument. The case for U.S. support is further buttressed by the phenomenal strength of the U.S. economy and the enormously promising initiatives that WHO is undertaking under the leadership of Gro Harlem Brundtland. She has, in a few months, "reinvented" WHO to better address long-standing and emerging health problems, giving high priority to addressing the health needs of the poor, attacking emerging threats to health, strengthening health systems, and increasing knowledge to be used for decision-making. Preventing malaria and avoidable blindness, reducing addiction to tobacco among the young, controlling tuberculosis, working with the United Nations (UN) AIDS program on HIV prevention and AIDS care, and eliminating as public health problems such diseases as polio, leprosy, guinea worm disease, and Chagas disease are also top priorities for the "new" WHO. However, we regret to note that the United States is over \$35 million in arrears in assessed dues to WHO. Furthermore, the U.S. position of resisting even nominal increases in its contribution to the regular budget of WHO compromises America's vital interest in global health, violates the spirit of American generosity, and represents the antithesis of global leadership.

WHO has two sources of funds for financing its operations: regular budgetary contributions (the assessed contribution) and extrabudgetary contributions. In terms of real purchasing power, WHO's regular budget (\$843 million for the current biennium) has declined by an estimated 20% during the past decade, jeopardizing its ability to carry out its mission and programs. In 1998, the United States gave WHO \$46.1 million in extrabudgetary contributions. Although it is the largest contributor to specific programs, it ranks on both a per-person basis and as a share of gross domestic product far below Norway, Denmark, Sweden, the Netherlands, the United Kingdom, Australia, and Canada. We believe that the United States should reverse this situation. If matched by other donors, a 3.7% increase in our assessed contribution, which would amount to less than \$4 million annually, would allow WHO to cover the price increases and exchange rate fluctuations it can reasonably be expected to face. On economic, political, and humanitarian grounds, U.S. support for WHO must not be allowed to erode.

The U.S. government has vigorously criticized international agencies for ineffectiveness and for failing to exercise leadership in the past and has often said that U.S. support for the UN should be linked to reform and performance. WHO is exemplary in this regard. For example, it has reduced its administrative costs this year by 15%. Given WHO's record of success and its new vision, it is incumbent upon us to pay our arrears and enlarge our financial contribution so that WHO can fulfill its global mandate.

Representatives of all WHO member states will meet at the World Health Assembly in Geneva on 17 to 25 May 1999 to decide WHO's budget and member states' assessments. The United States will express its position at that meeting. We urge readers to contact their congressional representatives to convey their views on U.S. funding of WHO.

B. R. Bloom is professor at Harvard University and dean of the Harvard School of Public Health. D. E. Bloom is professor at Harvard University and deputy director of the Harvard Institute for International Development. J. E. Cohen is Professor of Populations at Rockefeller University and Columbia University, New York. J. D. Sachs is professor at Harvard University and director of the Harvard Institute for International Development.

**U.S. support
for WHO must
not be allowed
to erode.**

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Page 1 of 9 pages

From: Dr Roy Widdus, Global Forum To: Ms Sandy Thurman, Director, Office of AID's Policy, 736
for Health Research, c/o WHO, Jackson Place, Washington, D.C. 20503, USA
Geneva

Your ref.:

Originator:

Fax No.: 202 456 2438

Date: 01 May 2000

Our ref.:

Subject: National Institutes of Health - White House Initiative
on Vaccines for HIV, Malaria and TB Meeting
- Washington, D.C., 22-23 May 2000

Sandy
Dear Ms Thurman,

Attached is a copy of preliminary information on the plans of the US National Institutes of Health to follow-up on President Clinton's 2 March meeting at the White House with pharmaceutical and vaccine company CEOs on the development of vaccines for HIV/AIDS, malaria and tuberculosis. The material includes background to the planned meetings, the topics to be addressed and a tentative agenda for the first, which is to be held at the NIH in Bethesda, MD, USA on 22-23 May 2000.

The organizing committee feel your participation in the meeting would be extremely valuable and therefore extend an invitation. A formal letter of invitation, and information on logistics and hotels will be sent if you indicate that you are available to participate.

If you can accept the invitation, please contact directly Hope Kott of IQ Solutions, the group assisting with the meeting arrangements.

Hope Kott: e-mail <HKott@iqsolutions.com>
tel: 1 (301) 984 1471
fax: 1 (301) 984 1473

If you wish to discuss the meeting please contact:

Roy Widdus, Ph.D., Meeting Consultant, currently at WHO, Geneva, (41 22 791 4469/4369) : emails widdusr@who.int or rwiddus@niaid.nih.gov. (After 8 May 2000 at NIAID/NIH - Tel. 301 496 6752.)

We hope that you will be able to attend and would appreciate a reply as soon as possible so that we can finalize meeting arrangements.

Many thanks.

Roy Widdus

Roy Widdus
Meeting Consultant, NIAID

Draft
2 May 2000

Vaccines for HIV/AIDS, Malaria, and Tuberculosis: Addressing the Presidential Challenge

Background, purpose and agenda

On 2 March 2000 President Clinton met with leaders of the world's major pharmaceutical and vaccine companies, foundations and international organizations at the White House to announce new partnerships to develop and deliver vaccines – including HIV/AIDS, malaria, and tuberculosis vaccines – for developing countries. At this meeting he requested Health and Human Services Secretary Donna Shalala “to convene a meeting of experts from industry, government and academia to address impediments to vaccine development in the private sector and to strengthen public-private partnerships” for these vaccines. The National Institute of Allergy and Infectious Diseases, in collaboration with other NIH Institutes and Centers, other HHS agencies, the Department of Defense and international agencies is organizing, on 22-23 May 2000, the first of a series of workshops to address the relevant issues, a preliminary listing of which is included on the next page.

The primary tasks in the initial discussions will be to identify the technical impediments that currently discourage private sector involvement in the development of these vaccines and ways of strengthening public-private sector collaboration for overcoming them. However, to the extent that the solutions (or the motivation to seek solutions) for these problems may be affected by perceived prospects for introduction or financing of these vaccines, the group will be asked in the first meeting to also identify such issues, for future consideration. Future meetings will consider the problems inherent in the introduction of these vaccines and in their widespread use, including lack of uniformity between countries in regulatory approaches, weak delivery infrastructures and perceived lack of commercially attractive markets in the poorer developing countries where the vaccines are particularly needed.

At the meeting scheduled for 22-23 May 2000 there will be, in addition to plenary sessions, three working groups to address the scientific and technical issues that inhibit the development of vaccines to prevent these three infectious diseases. Each of the three working groups will consist of about 30 individuals. The invitations will ensure that the potential private sector vaccine developers/producers will be well represented in all three groups. A Chair, co-chair and rapporteur(s) will be assigned to each working group. On the evening of Day 1 the Chairs and rapporteurs will meet to prepare conclusions and summary presentations. Each working group will present a brief report on the major unresolved scientific problems to the plenary session on the morning of Day 2 for general comment. Day 2 of the meeting will be devoted to consideration of various approaches through which the public and private sectors could collaborate more effectively to address the challenges identified during Day 1.

Anticipated attendance for the first meeting is approximately 130-140 participants, with substantial involvement of senior executives from pharma/vaccine companies

The list of agenda topics for future meetings that follows on the next page will be supplemented with issues identified in the course of the first meeting.

Vaccines for HIV/AIDS, Malaria, and Tuberculosis: Addressing the Presidential Challenge

Agenda topics

Meeting 1.

Scientific impediments that currently discourage private sector involvement in the development of HIV/AIDS, malaria and tuberculosis vaccines

Ways of strengthening public-private collaboration for overcoming these impediments

Meeting 2 and possible subsequent meetings

Implementing mechanisms for improved public-private and private-private collaboration

Internationally unified regulatory approaches for vaccines for HIV, malaria and tuberculosis as a means of encouraging greater commercial involvement

'Push' mechanisms and incentives to lower the financial costs and risks of product development

'Pull' mechanisms to provide market incentives for product development

Establishing or strengthening the systems in developing countries for delivery of HIV/AIDS, malaria and tuberculosis vaccines as a measure to encourage development.

Creating functioning markets in the middle-income and large, poor developing countries as a measure to encourage vaccine development

Other topics will be added as they are identified

Draft
2 May 2000

**Vaccines for HIV/AIDS, Malaria, and Tuberculosis:
Addressing the Presidential Challenge**

May 22-23, 2000
NIH Campus, Bethesda

Day 0: May 21 2000

: 06:00-07:00 PM Meeting of Chairs and Rapporteurs at Doubletree Hotel on the charge to WGs

Day 1: May 22, 2000

Opening Plenary Session

Chairs: Dr. A.S. Fauci and Mr Kevin Reilly

09:00 AM	Welcome to NIH	Dr. Ruth Kirschstein Acting Director, NIH
09:10 AM	Background to and objectives of the conference	Dr. Anthony S. Fauci Director, NIAID, NIH
09:30 AM	The health and economic impact of HIV/AIDS, malaria and tuberculosis: the potential benefits of vaccination to disease control	Dr. G. Keusch, FIC, NIH
09:45 AM	A perspective on the scientific issues that presently discourage greater involvement in preventive vaccines against HIV/AIDS, malaria and tuberculosis	Dr. Adel Mahmoud Merck Vaccines
10:00 AM	A perspective on the commercial and implementation issues that presently discourage greater involvement in preventive vaccines against HIV/AIDS, malaria and tuberculosis Questions	Dr Jean Stephenne SB Bio
10:30 AM	The importance of public-private partnership for global health	The Honorable Donna Shalala, Secretary, DHHS
10:40 AM	Coffee Break	
11:10 AM	Working Group Sessions: The scientific impediments to vaccine development for HIV/AIDS, malaria and tuberculosis	See below
12:30 PM	Break for lunch	WG chairs should take lunch together to assess progress, need for additional inputs
01:30 PM	Working Group Sessions continue	See below
05:30 PM	End of Working group sessions	
06:00	Reception at the Stone House (ends at 08:00 p.m.)	

Working Group Sessions 11:00 AM to 05:30 PM**HIV/AIDS, Malaria and Tuberculosis Vaccines****Parallel Working Group Sessions**

Summary presentation: Status of vaccine development and barriers

- HIV/AIDS: M. Johnston
- Malaria: J. Cohen
- Tuberculosis: Ann Ginsberg

Background materials on resources:

NIH/DOD/CDC/other
Preparers

- HIV- Rona Siskind
- Malaria-Sarah Landry
- TB-Sarah Landry

International

Preparers:

- HIV/AIDS: J Esparza
- Malaria: H Engers
- TB: U. Fruth

Summary presentations on each vaccine status to respective WGs

Inventories of resources to be available and referred to in summary presentations but not separately presented

Questions for WGs – see also matrix at end of the agenda

- What scientific and technical barriers must be overcome to develop HIV/AIDS, malaria and tuberculosis vaccines?
- Is the available infrastructure for research and efficacy/effectiveness testing (both public and private) sufficient to meet this challenge?
- What administrative, logistical or legal impediments exist that block progress towards the development of HIV/AIDS vaccines?

Supplementary questions to be suggested by Planning Group members for each vaccine

Possible use of the matrix at end of the agenda

05:30 PM WGs adjourn

06:00-08:00 PM Reception

All participants

5

Proposed Working Group Chairs and Rapporteurs

Category	HIV/AIDS	Malaria	TB
Chairs (C) and co-chairs	N. Nathanson (C) W. Makgoba	A. Mahmoud (C) L. Miller	B. Bloom (C) D. Williams
Rapporteurs (with significant back-up from NIH/DOD Staff)	G. Siber M Liu	S. Hoffman G. Brown (tbc)	N. Ganguly D. Young

Day 2: May 23, 2000

Plenary Session: Scientific Impediments to Development of Vaccines for HIV/AIDS, Malaria, and Tuberculosis

Chairs: Dr. Gordon Douglas and Dr. William Makgoba,

	Conclusions of the Working Groups:	
08:00 AM	HIV/AIDS	
08:10 AM	Malaria	
08:20 AM	Tuberculosis	
08:30 AM	Questions, comments and summation	Chair(s)

Plenary Session: How can the collective resources available in the private and public sectors be applied better to accelerate the development of these three vaccines?

Chairs: Mr. Jean-Jacques Bertrand and Dr Charles Hoke

08:45 AM	The NIH Vaccine Research Center A new resource and paradigm for vaccine development	Dr Gary Nabel VRC, NIAID, NIH
09:00 AM	What major companies need and can offer for vaccine development.	Dr. Ed Scolnick Merck and Co
09:15 AM	What emerging companies need and can offer for vaccine development.	Dr. Peter Young AlphaVax Inc.
09:30 AM	An overview of issues in public-private and private-private partnerships: Some models for collaboration and how they have worked	Dr. Maria C Friere OD, NIH
10:00 AM	Break	
10:30 AM	Plenary discussion session: Collaboration mechanisms Where and how can public-private and private-private collaboration accelerate vaccine development for HIV/AIDS, malaria and tuberculosis - Questions, comments and proposals for WGs to consider	Meeting participants
11:45	Working Group sessions: Collaboration mechanisms For each vaccine:	Chairs and rapporteurs as on Day 1
	- What mechanisms for cooperation and collaboration currently exist? - What are their limitations? - What changes to existing mechanisms, if any, would optimize collaboration and harmonization of these research efforts? - Where in the product development pathway are (a) collective action and (b) new resources most needed? - What collaboration mechanisms are most promising for each vaccine?	Use of matrix at end of document to guide discussions to be considered
12:30 PM	Lunch	
01:30 PM	Working Groups continue	

02:30 PM Break

03:00 PM **Plenary: Options for advancing public-private collaboration**
Chair: Dr. Philip Russell and Dr. Gordon Douglas

Reports from WGs

- HIV/AIDS
- Malaria
- Tuberculosis
- Questions

04:00 PM **Summation and next steps**

Dr J. La Montagne
NIAID, NIH

04:15 PM Adjournment

DRAFT: The necessary scientific components of vaccine development

	Desirable scientific under-pinnings			Product related activities			
	Identify the immune mechanisms of protection (to the maximum extent possible, via basic or clinical research)	In vitro assays that predict protective immunity	Identify relevant antigens	Develop and validate antigen delivery systems that induce the desired immune system responses	Production process development	Phase I/II trials for safety and immunogenicity	Efficacy /Phase III trials
Primary scientific impediments							
Areas in which greater public-private or private – private collaboration would significantly accelerate development							
Possible modes of public-private or private – private partnership							