FOIA Number: 2018-0758-F

FOIA MARKER

This is not a textual record. This is used as an administrative marker by the William J. Clinton Presidential Library Staff.

Collection/Record Group: Clinton Presidential Records

Subgroup/Office of Origin: National AIDS Policy Office

Series/Staff Member: Todd Summers

Subseries:

OA/ID Number: 21082

FolderID:

Folder Title:
Correspondence - Todd Summers - Outgoing - 12/98

Stack:	Row:	Section:	Shelf:	Position:
S	66	6	2	1

MEMORANDUM FOR KAREN TRAMONTANO

From: Todd Summers
Deputy Director
Office of National AIDS Policy
(202) 456-2437

Date: December 8, 1998

Re: Briefing for meeting with Dr. Scott Hitt, Chair, President's Advisory Council on HIV/AIDS

Dr. Scott Hitt, Chair of the President's Advisory Council on HIV/AIDS (the Council), is scheduled to meet with you this afternoon at 3:00 pm. This meeting was arranged through Richard Socarides in response to a request by Dr. Hitt to meet with the Chief of Staff (who Dr. Hitt believes may be in attendance at this afternoon's briefing).

Dr. Hitt will likely raise issues with you in preparation for a meeting between the President and the Council scheduled for December 18th. He will have met earlier this morning with HHS Deputy Secretary Kevin Thurm.

While he has not shared with us his specific agenda for the meeting with you, we surmise that the following will be raised:

Office of National AIDS Policy (ONAP) Staffing

The Council has been concerned that the Office of National AIDS Policy does not have sufficient staffing. Council members frequently refer to the staffing of ONDCP, although we have explained that ONDCP is created by statute whereas ONAP exists at the discretion of the President.

Here is the current staffing:

Director (Sandra Thurman)	White House employee through OPD
Deputy Director (Todd Summers)	White House employee through OPD
Executive Director of the Council	Agency representative (HHS)
Mathew Murguia	Agency representative (HHS)
Receptionist	Agency representative (HUD)

Funding for the operation of the office comes primarily through HUD, which is therefore the only agency that can provide administrative assistance. Because of its own budget limitations, HUD has been unable to provide more than 1 FTE to the office, which is being used for the receptionist position. Neither the Director nor Deputy Director have assistants.

There are several possible responses:

- **Assign additional FTEs/OGEs to ONAP** - Ms. Apuzzo had submitted a proposal to Mr. Bowles that would have resulted in additional FTEs/OGEs to ONAP but it was apparently not approved
- **COS assists in increasing agency reps** - The COS could agree to assist in securing additional agency representatives by sending letters to all Federal agencies (Mr. Bowles had done this several years ago)
- **Increase ONAP budget** - OMB could support an increase in funding for the Office of the Secretary at HHS with an earmark for funding ONAP (currently, HUD provides approximately $211,000 per year plus 1 FTE)

Access by the Council to the President

Dr. Hitt may raise concern that the Council does not regularly meet with the President. The Council has expressed interest in securing a commitment for an annual meeting with the President at which the Council could provide an update in its recomenndations and the Administration's response.

We suggest that this request be taken under advisement and that the COS agree to carefully consider any request by the Council for a meeting with the President.

Issues to be raised by the Council with the President

The following policy issues are likely to be raised by the Council in its upcoming meeting with the President:

- **Increasing Access to Treatment** - the Council is concerned that current guidelines suggest treatment well before the onset of AIDS; however, access to Medicaid is generally restricted to those who have AIDS. The result is a "catch 22" in which one must become disabled by AIDS in order to qualify for Medicaid, which provides the treatment that could have substantially delayed the onset of AIDS in the first place. Ms. Thurman has established a task force that is working on this issue.
- **National HIV Counseling and Testing Campaign** - the Council is likely to recommend to the President a new, national "get tested" media campaign; they are also interested in having ONAP manage this campaign in much the same way that ONDCP administers its anti-drug media campaign.

- **AIDS Vaccine Development** - the Council will express concern about the pace of the government's work on the President's HIV vaccine initiative (last spring, the President articulated the goal of finding an HIV vaccine within ten years). In particular, the Council is concerned that a Director for the new vaccine research center under construction at NIH has not been hired (the search has been underway for over 14 months).
- **FY2000 Appropriations** - the Council will express strong support for increased AIDS funding in the FY2000 budget to include increases in care, prevention, research, and housing. The FY99 budget was extraordinarily generous to AIDS funding (over $550 million increase in discretionary programs), and created a difficult standard to maintain.

Todd A. Summers
12/14/98 11:24:45 AM

Record Type: Record

To: Karen Tramontano/WHO/EOP

cc: Sandra Thurman/OPD/EOP, Carolyn T. Wu/WHO/EOP
Subject: Update for Hitt Meeting

As we discussed last week, the CDC did issue its draft guidelines for HIV surveillance in which they "advise" states to implement names-based systems. The guidelines do allow for flexibility in that states can use unique identifier systems instead of names, and CDC commits to provide technical assistance regardless of the surveillance system used.

Nevertheless, a number of members of the Council are angry with CDC about the guidelines and feel that the bias toward names is not firmly based on science. Chris Jennings had asked them to either postpone releasing the guidelines until after the Council's meeting with the President or to remove the advisory to use name-based systems. HHS had said that they had revised the documents to reflect a more neutral position and Chris authorized them to go ahead, but in fact HHS had only revised the summary fact sheet (the spin document) and not the actual guidelines. In short, we got rolled by HHS.

Our response is:

- we appreciate the Council's concerns on this
- HHS has committed that comments received on the draft will be fully considered before final guidelines are published
- the guidelines do have important improvements that have been fought for by the community for a long time (their treatment of confidentiality, security, access to anonymous testing, and de-linking partner notification and HIV surveillance systems)
- we are sensitive to the concerns they have
    1. that name-based systems will frighten away those that are historically suspicious of the health care system and therefore create a dangerous impediment to getting tested
    2. that some States may attempt to use the database of HIV-positive individuals for nefarious uses
- Deputy Secretary Kevin Thurm has called a number of Council members and repeated essentially the above

In addition, some Council members and other community advocates are calling on HHS to commit to fighting any attempt by Congress to take away the flexibility to use unique identifiers by mandating name-based systems. We can say that HHS is looking at that.

Meeting with Karen Tramontano 12/14/98

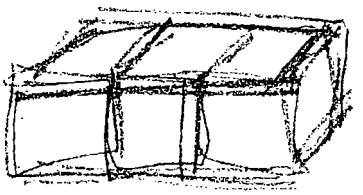
Budget -
Access to Care -
VPOTUS - Medicaid, drug pricing
Get-Tested Initiative
Vaccine Initiative
OVAP

Donna Christian-Green
Shelly Thompson
225-1790

Rafe Pomerantz

Although we've had differences

Marianne O'Sullivan - 6th
→ ~~Alice~~
→ 216-3237



USAID on Thursday
— 3-5 P.M.
— Mezzanine

Sat. 19th.

$38 →
$24

THE WHITE HOUSE

WASHINGTON

MEMORANDUM FOR KRISTIE KENNEY, DEPT. OF STATE

From: Todd Summers
Deputy Director
Office of National AIDS Policy
(202) 456-2437

Date: December 22, 1998

Re: Comments on "1999 U.S. International Response to HIV/AIDS"
S/S 9820322

Attached are specific comments on the above-referenced document. It is our understanding that substantial comments were submitted by other agencies. Therefore, we request review of the amended document before it is released and with adequate time to review and respond accordingly. To facilitate that review, we would appreciate both a finalized document and a "red lined" version showing changes made to that version submitted to us for review.

Re: Clearance of the U.S. Department of State's *1999 U.S. International Response to HIV/AIDS*

From: Todd Summers, Deputy Director, Office of National AIDS Policy

This text is intended to accompany a marked-up version of the above-referenced document.

Executive Summary

Page v. The use of the term "action strategy," implies a listing of steps that each entity (office/agency/department) will undertake in FY 99. No such listing is included in the document. This term should be rephrased, as appropriate.

Page vi. The use of the statement "The one-world nature of life as we know it," may be too colloquial for an official government report.

Page vi. "We look forward to joining this initiative...." What initiative is referenced here?

Page vi. "... this strategy..." What strategy is being referenced here?

Page vi. "We at the State Department will take charge..." While the sentiment is valid, you should consider rewording as "The State Department will coordinate the implementation of the (strategy/initiative) by ...." Take charge is too colloquial, and the use of the term strategy is inconsistent with the title and function of the document.

Page vi. "Safeguard all.... " is a very tall challenge, although noble. It may be more appropriate to "reduce the impact that HIV/AIDS is having across the globe, and work towards the day when HIV is eradicated" or similar.

Page vii. The last paragraph under "A Rapidly Expanding Epidemic," and the first paragraph under "Regional Assessment" repeats the point about not recognizing cultural, religious, etc. belief. Difficulties in HIV prevention are however exacerbated by cultural and religious beliefs -- at least the practices that are considered acceptable and which lead to HIV transmission or hinder the ability to implement prevention and treatment programs.

Page viii. What is the source for the statement that "95% of people with HIV live in the developing world."? This should be stated.

Page viii. Should consider using headers for the discussion of different continents/regions.

Page viii. In the graph, how does HIV indirectly facilitate the spread of TB? This should be explained. AIDS is misspelled as Aids.

Page ix. What is the source for time frames from HIV infection to development of AIDS in developing and developed countries. This should be stated.

Assessment of U.S. Interests

Page 1 Should consider mentioning the HIV blood scandal in Canada?

Page 2 Social and Economic Impact
What is the source for the $500 billion statistic? Should be stated.

Page 2 The statement that some people would have been able to receive treatment for another illness but were not able to do so because of spending on AIDS could be seen as pitting AIDS against other diseases.

Page 2 May need to discuss the impact of AIDS orphans in more detail in the last paragraph in this section.

Page 2 Impact on the Workplace
Do many companies cover the cost of death benefits and funerals, especially in the developing world? This sentence could be deleted.

Page 3 Healthcare Costs
Is the cost of HAART included in the dollar amounts listed?

Assessment of 1995 Strategy

Page 4 should consider changing "more action needs to be taken" to "more action might be taken."

Under Prevent New Infection:

Are you discussing international efforts when you say that the "bulk of U.S. government actions have been in prevention"? Even if you are, this undercuts the U.S. efforts in vaccine development, policy leadership, orphans efforts, and other efforts. If you are focusing on U.S. efforts in general, it undercuts the tremendous investment the U.S. has made in care and treatment, behavior research, etc. One of the principal criticisms of the U.S. relates to supporting access to preventative and therapeutic treatments. This section seems to pass over that issue - a more expansive discussion would be more helpful.

Under Develop Behavioral Prevention Strategies:

Page 4 CDC's name is Centers for Disease Control and Prevention.

Page 5 When referring to "specially" vulnerable men, do you mean men at high risk for infection with HIV?

Page 5 There is a great use of the terms "we," and "our" in the document; an impersonal pronoun is more appropriate.

Page 5 You should spell out "STI" and "NGO" when first used.

Page 5. The term "AIDS prevention" should be changed to "HIV prevention".

Page 6 Under Augment Research

You should include discussion of the new HIV Prevention Trials Network.

Page 6 Safeguard Blood Supply

How bad is the problem? Is there any data which could be included?

Page 6 Provide Access to Health Services and Technologies

Should include discussion about HHS/NIH initiatives on microbicides.

Page 6, last paragraph. Should it be that FDA has approved drugs for opportunistic infections and not "infection related to HIV." Are the number of drugs accurate to date?

Page 7 Address the Adverse Impact ....

Should be people living with "HIV/AIDS" not just AIDS; again in the last paragraph in this section.

Should spell out "NGOs."

Page 7, Provide Care and Support

This section could be strengthened.

Second paragraph. Should be "support to those living with HIV/AIDS," not afflicted.

Page 8 Guarantee Human Rights

Are the guidelines in the resolution voluntary? The statement is that states "may follow" them. Should it be "should follow"?

Page 8 Protect Politico-Military Structures

What is the impact as prepared by the National Intelligence Council?

Page 8 Place HIV/AIDS on the Sustainable....

What were the results of the G 6 - 8 meetings and can they be linked to placement on the agenda of these meetings?

Page 8 Mobilize and Unify .....

Add the Office of National AIDS Policy as first on the list of agencies in the second paragraph in the sentence beginning "In addition...." Also, it would be helpful to mention the 1998 World AIDS Day activities in which the POTUS and Secretary participated.

In the last paragraph on this section, add:

"In addition, the Office of National AIDS Policy coordinates the Interdepartmental Task Force on HIV/AIDS, aimed at developing a coordinated response to the steps laid out in the National AIDS Strategy. ONAP also coordinates the federal response to World AIDS Day, and as a member of the President's Domestic Policy Council, provides ongoing input into the development of the annual federal budget request."

Issue Overview

Page 9 what issue? Per title of section.

Who is the Interagency Working Group? This may need to be explained.

Page 9 Under Effective Interventions

Should be antiretroviral, not antiviral (this occurs throughout the document)

The use of the term "short-term success" may not be able to be validated with research.

The dollar figures used are U.S. dollars?

Rewrite the sentence which starts as "And although antivirals can ..." to delete all wording after "protection to the mother." Use of the term "unborn child" is inappropriate and "protection to the HIV virus" is confusing.

Page 9 HIV Transmission and Prevention

Is the second paragraph of this section needed?

Page 10 first paragraph
It is more accurate to say that cultural, religious and personal beliefs are "challenged" rather that can cause examination of...?

Use the term "male-to-male transmission" rather than homosexual.

Page 11, first paragraph. Should be "accounts for more infections that sexual transmission."

What is the "southern cone"?

Page 12 HIV Drug and Vaccine Development

May need to add a sentence about the restrictions due to the lack of infrastructure and cost of delivering a vaccine.

In the second paragraph in this section, you say steady progress has been made -- is this true for the developing world? Further down in that paragraph, you state that there are already enormous economic costs.

Page 13 Care and Support for HIV Infected .....

The 33.4 million people is worldwide. If so, it should be stated.

Page 13. Women and Health

Is it true that women face greater biologic vulnerability to HIV than males? Is the female reproductive tract more susceptible to infection with HIV than a males anus. Why is a young girl more susceptible than an older women?

Page 13 Donor Coordination

The first paragraph states that there "will be a critical..." Is the need not already critical?

Action Strategy

Please replace the current ONAP description with the one enclosed.

U.S. Department of State

Page 18, last paragraph. Through what mechanisms are post directed?

Second bullet. Should "security/political concerns" be added?

Third bullet. Most countries do not do AIDS research.

Should a bullet be added which states that the U.S. will offer technical assistance in developing responses?

Should delete the paragraph which states that the State Department will convene regular interagency meetings.

Promoting Human Rights.

Has the increase in requests for asylum only been limited to Latin America countries? Does the Justice Department confer with U.S. based immigration groups as well?

US Agency for International Development

Page 20 First paragraph. Remove the words "among key populations." The goal should be among all populations.

Second paragraph. What is PHS in the acronym?

Does USAID's strategy compliment State's strategy?

Last full paragraph on page 20 has a run-on sentence.

The AIDSCAP acronym should be spelled out.

What is meant by "to operationalize the strategic framework"?

Page 21. Under DMELLD. When will the contract start?

Page 21. Under Biomedical Research.

Should be topical microbicide, not vaginal microbicide.

Page 23. Funding

Confused as to why resources will need to be shifted if the policy is to place them where the epidemic is having the greatest impact.

Does this include the $10 million announced by the POTUS on World AIDS Day?

Is the $700 million in FY 98 funds. Remove the exclamation point.

Under Strategy for Specific .....

Remove, "most cost effective" in the first paragraph under Prevention.

Second paragraph. Should say "HIV status", rather than "HIV testing" status, is the same.

This report only refers to confidential testing, and not to anonymous testing. CDC recommends that anonymous testing always be made available as well as confidential testing. We should not be advocating a policy that is different for other countries than what we use in the U.S.

Page 25 AIDS Orphans

Second paragraph is really long.

POTUS event estimated 42 million AIDS orphans, not the 22.9 million stated here.

When will the discussion papers be available?

When will the electronic network be operational?

Page 26 Women and Health

Antiretroviral treatment is not relatively low cost, especially when health expenditures total $10 per year in some countries.

Page 26 Vaccine Research

The second could be interpreted to mean that the U.S. government is more concerned with finding a vaccine for the developing world that for its own citizens.

Should be USAID "will" assist the vaccine development, rather than "can assist."

Page 27 Microbicide Development

Should be topical not vaginal microbicide.

Remove "used by a woman, herself."

Should be consent of "a" sexual partner.

Remove "herself" from "to protect herself from"

Page 29.Reducing Mother-....

Should be Centers for Disease Control and Prevention

Under the bullet "Voluntary... Should be more than 90 percent of HIV infected women, not just 90% of women.

Anonymous versus confidential comment from above.

Department of Defense

Page 45 Who is included in the Tri-service effort? There are four branches so it might be appropriate to know which is not participating.

Should there be a discussion of the Henry M. Jackson Foundation for Medical Research at Bethesda Naval Center?

Role of the Pharmaceutical Industry

Page 48. Although not uniformly available anywhere in the world?

Page 49. Last paragraph. Should it be "but to date, have not involved..."

So many references to Merck and Co. and not other firms makes it sound like a commercial for them..

Page 50. In the "last six months" refers to what time period?

Should add a line that the completion of the trials was also successful because it helped prolong lives, and not just that fact that research was conducted.

Page 51 Vaccine Research
Ivory Coast is referred to in French elsewhere in the document.

Page 51. "One U.S. company" If Merck is named, why is this one not?

Page 51. What is the source for the time line for new vaccine development?

Page 51. Behavior....
Why not name the universities?

Role of International NGO's

Page 53-54. Do any of them promote abstinence as an option?

Page 55 AIDS Orphans.

What are the sources for the 1.5 million children infected with HIV and the 100 million street children alive today?

Replacement Section on Office of National AIDS Policy

In 1993, President Clinton created the Office of National AIDS Policy (ONAP) to provide a national focus and direction to the U.S. government's response to HIV and AIDS. ONAP provides broad guidance for Federal AIDS policy and fosters interdepartmental communication and coordination. ONAP works closely with non-profit and for-profit organizations at the national, state, and community-based levels, as well as internationally, to ensure the broadest input into policy development and implementation. The director of ONAP, Sandra L. Thurman, is a member of the President's Domestic Policy Council, and provides ongoing input into the developing of the Administration's annual budget request to Congress. She serves as the chair of the Interdepartmental Task Force on HIV/AIDS, an intra-governmental coordinating body working to develop a unified approach to HIV/AIDS in the Federal government.

The ONAP director has taken a leadership role in international AIDS issues, having led numerous delegations to Africa, Russia and India to study first-hand the impact that HIV/AIDS is having on developing countries. In December 1998, the President directed the ONAP director to visit South Africa and report back with recommendations on additional measures the United States could implement to assist South Africa in addressing the impact of HIV/AIDS in that country. The ONAP director also participates as an official representative of the United States to UNAIDS.

In addition, ONAP coordinates all Federal World AIDS Day activities, including encouraging each Federal Department/Agency to observe in a public manner World AIDS Day and to host appropriate activities at their headquarters and field offices. This year's World AIDS Day theme was "Be A Force For Chance," and focused on youth.

In 1997, ONAP developed "The National AIDS Strategy," a comprehensive, long-term plan to address the HIV/AIDS epidemic. This Plan contains detailed descriptions of the objectives, goals and budgets of all Federal agencies involved in the Federal response to HIV in six major areas of HIV policy: prevention, research, care and services, civil rights, international activities, and translation of research advances into practices. The Plan identifies key areas for further effort. This Report was developed in consultation with many individuals and groups, public and private, both inside and outside the Federal government.

ONAP also serves as a liaison to the Presidential Advisory Council on HIV/AIDS, which was established by Executive Order to provide advice, information and recommendations to the President, the Administration, and the Secretary of Health and Human Services regarding programs and policies affecting the prevention, services and research needs of people with HIV infection. The Advisory Council has adopted HIV/AIDS in racial and ethnic communities as its primary focus for the remainder of its term. The advisory Council also focuses on appropriations, international issues, prison issues and discrimination.

Action Strategy

White House Office of National AIDS Policy

In 1993, President Clinton created the Office of National AIDS Policy (ONAP) to provide a national focus and direction to the U.S. government's response to HIV and AIDS. ONAP provides broad guidance for Federal AIDS policy and fosters interdepartmental communication and coordination. ONAP works closely with non-profit and for-profit organizations at the national, state, and community-based levels, as well as internationally, to ensure the broadest input into policy development and implementation. The director of ONAP, Sandra L. Thurman, is a member of the President's Domestic Policy Council, and provides ongoing input into the developing of the Administration's annual budget request to Congress. She serves as the chair of the Interdepartmental Task Force on HIV/AIDS, an intra-governmental coordinating body working to develop a unified approach to HIV/AIDS in the Federal government.

The ONAP director has taken a leadership role in international AIDS issues, having led numerous delegations to Africa, Russia and India to study first-hand the impact that HIV/AIDS is having on developing countries. In December 1998, the President directed the ONAP director to visit South Africa and report back with recommendations on additional measures the United States could implement to assist South Africa in addressing the impact of HIV/AIDS in that country. The ONAP director leads the UN global delegation ... **Todd, a little help here, please.**

In addition, ONAP coordinates all Federal World AIDS Day activities, including encouraging each Federal Department/Agency to observe in a public manner World AIDS Day and to host appropriate activities at their headquarters and field offices. This year's World AIDS Day theme was "Be A Force For Chance," and focused on youth.

In 1997, ONAP developed "The National AIDS Strategy," a comprehensive, long-term plan to address the HIV/AIDS epidemic. This Plan contains detailed descriptions of the objectives, goals and budgets of all Federal agencies involved in the Federal response to HIV in six major areas of HIV policy: prevention, research, care and services, civil rights, international activities, and translation of research advances into practices. The Plan identifies key areas for further effort. This Report was developed in consultation with many individuals and groups, public and private, both inside and outside the Federal government.

ONAP also serves as a liaison to the Presidential Advisory Council on HIV/AIDS, which was established by Executive Order to provide advice, information and recommendations to the President, the Administration, and the Secretary of Health and Human Services regarding programs and policies affecting the prevention, services and research needs of people with HIV infection. The Advisory Council has adopted HIV/AIDS in racial and ethnic communities as its primary focus for the remainder of its term. The advisory Council also focuses on appropriations, international issues, prison issues and discrimination.

N:\MURGUIA\ONAPOVER.WPD

THE WHITE HOUSE

WASHINGTON

MEMORANDUM FOR KRISTIE KENNEY, DEPT. OF STATE

From: Todd Summers
Deputy Director
Office of National AIDS Policy
(202) 456-2437

Date: December 22, 1998

Re: Comments on "1999 U.S. International Response to HIV/AIDS"
S/S 9820322

Attached are specific comments on the above-referenced document. It is our understanding that substantial comments were submitted by other agencies. Therefore, we request review of the amended document before it is released and with adequate time to review and respond accordingly. To facilitate that review, we would appreciate both a finalized document and a "red lined" version showing changes made to that version submitted to us for review.

Re: Clearance of the U.S. Department of State's *1999 U.S. International Response to HIV/AIDS*

From: Todd Summers, Deputy Director, Office of National AIDS Policy

This text is intended to accompany a marked-up version of the above-referenced document.

Executive Summary

Page v. The use of the term "action strategy," implies a listing of steps that each entity (office/agency/department) will undertake in FY 99. No such listing is included in the document. This term should be rephrased, as appropriate.

Page vi. The use of the statement "The one-world nature of life as we know it," may be too colloquial for an official government report.

Page vi. "We look forward to joining this initiative...." What initiative is referenced here?

Page vi. "... this strategy..." What strategy is being referenced here?

Page vi. "We at the State Department will take charge..." While the sentiment is valid, you should consider rewording as "The State Department will coordinate the implementation of the (strategy/initiative) by ...." Take charge is too colloquial, and the use of the term strategy is inconsistent with the title and function of the document.

Page vi. "Safeguard all.... " is a very tall challenge, although noble. It may be more appropriate to "reduce the impact that HIV/AIDS is having across the globe, and work towards the day when HIV is eradicated" or similar.

Page vii. The last paragraph under "A Rapidly Expanding Epidemic," and the first paragraph under "Regional Assessment" repeats the point about not recognizing cultural, religious, etc. belief. Difficulties in HIV prevention are however exacerbated by cultural and religious beliefs -- at least the practices that are considered acceptable and which lead to HIV transmission or hinder the ability to implement prevention and treatment programs.

Page viii. What is the source for the statement that "95% of people with HIV live in the developing world."? This should be stated.

Page viii. Should consider using headers for the discussion of different continents/regions.

Page viii. In the graph, how does HIV indirectly facilitate the spread of TB? This should be explained. AIDS is misspelled as Aids.

Page ix. What is the source for time frames from HIV infection to development of AIDS in developing and developed countries. This should be stated.

Assessment of U.S. Interests

Page 1 Should consider mentioning the HIV blood scandal in Canada?

Page 2 Social and Economic Impact
What is the source for the $500 billion statistic? Should be stated.

Page 2 The statement that some people would have been able to receive treatment for another illness but were not able to do so because of spending on AIDS could be seen as pitting AIDS against other diseases.

Page 2 May need to discuss the impact of AIDS orphans in more detail in the last paragraph in this section.

Page 2 Impact on the Workplace
Do many companies cover the cost of death benefits and funerals, especially in the developing world? This sentence could be deleted.

Page 3 Healthcare Costs
Is the cost of HAART included in the dollar amounts listed?

Assessment of 1995 Strategy

Page 4 should consider changing "more action needs to be taken" to "more action might be taken."

Under Prevent New Infection:

Are you discussing international efforts when you say that the "bulk of U.S. government actions have been in prevention"? Even if you are, this undercuts the U.S. efforts in vaccine development, policy leadership, orphans efforts, and other efforts. If you are focusing on U.S. efforts in general, it undercuts the tremendous investment the U.S. has made in care and treatment, behavior research, etc. One of the principal criticisms of the U.S. relates to supporting access to preventative and therapeutic treatments. This section seems to

Under Develop Behavioral Prevention Strategies:

Page 4 CDC's name is Centers for Disease Control and Prevention.

Page 5 When referring to "specially" vulnerable men, do you mean men at high risk for infection with HIV?

Page 5 There is a great use of the terms "we," and "our" in the document; an impersonal pronoun is more appropriate.

Page 5 You should spell out "STI" and "NGO" when first used.

Page 5. The term "AIDS prevention" should be changed to "HIV prevention".

Page 6 Under Augment Research

You should include discussion of the new HIV Prevention Trials Network.

Page 6 Safeguard Blood Supply

How bad is the problem? Is there any data which could be included?

Page 6 Provide Access to Health Services and Technologies

Should include discussion about HHS/NIH initiatives on microbicides.

Page 6, last paragraph. Should it be that FDA has approved drugs for opportunistic infections and not "infection related to HIV." Are the number of drugs accurate to date?

Page 7 Address the Adverse Impact ....

Should be people living with "HIV/AIDS" not just AIDS; again in the last paragraph in this section.

Should spell out "NGOs."

Page 7, Provide Care and Support

This section could be strengthened.

Second paragraph. Should be "support to those living with HIV/AIDS," not afflicted.

Page 8 Guarantee Human Rights

Are the guidelines in the resolution voluntary? The statement is that states "may follow" them. Should it be "should follow"?

Page 8 Protect Politico-Military Structures

What is the impact as prepared by the National Intelligence Council?

Page 8 Place HIV/AIDS on the Sustainable....
What were the results of the G 6 - 8 meetings and can they be linked to placement on the agenda of these meetings?

Page 8 Mobilize and Unify .....
Add the Office of National AIDS Policy as first on the list of agencies in the second paragraph in the sentence beginning "In addition...."

In the last paragraph on this section, add:
"In addition, the Office of National AIDS Policy coordinates the Interdepartmental Task Force on HIV/AIDS, aimed at developing a coordinated response to the steps laid out in the National AIDS Strategy. ONAP also coordinates the federal response to World AIDS Day, and as a member of the President's Domestic Policy Council, provides ongoing input into the development of the annual federal budget request."

Issue Overview

Page 9 what issue? Per title of section.

Who is the Interagency Working Group? This may need to be explained.

Page 9 Under Effective Interventions
Should be antiretroviral, not antiviral (this occurs throughout the document)

The use of the term "short-term success" may not be able to be validated with research.

The dollar figures used are U.S. dollars?

Rewrite the sentence which starts as "And although antivirals can ..." to delete all wording after "protection to the mother." Use of the term "unborn child" is inappropriate and "protection to the HIV virus" is confusing.

Page 9 HIV Transmission and Prevention
Is the second paragraph of this section needed?

Page 10 first paragraph
It is more accurate to say that cultural, religious and personal beliefs are "challenged" rather that

can cause examination of...?

Use the term "male-to-male transmission" rather than homosexual.

Page 11, first paragraph. Should be "accounts for more infections that sexual transmission."

What is the "southern cone"?

Page 12 HIV Drug and Vaccine Development

May need to add a sentence about the restrictions due to the lack of infrastructure and cost of delivering a vaccine.

In the second paragraph in this section, you say steady progress has been made -- is this true for the developing world? Further down in that paragraph, you state that there are already enormous economic costs.

Page 13 Care and Support for HIV Infected .....

The 33.4 million people is worldwide. If so, it should be stated.

Page 13. Women and Health

Is it true that women face greater biologic vulnerability to HIV than males? Is the female reproductive tract more susceptible to infection with HIV than a males anus. Why is a young girl more susceptible than an older women?

Page 13 Donor Coordination

The first paragraph states that there "will be a critical..." Is the need not already critical?

Action Strategy

Please replace the current ONAP description with the one enclosed.

U.S. Department of State

Page 18, last paragraph. Through what mechanisms are post directed?

Second bullet. Should "security/political concerns" be added?

Third bullet. Most countries do not do AIDS research.

Should a bullet be added which states that the U.S. will offer technical assistance in developing responses?

Should delete the paragraph which states that the State Department will convene regular interagency meetings.

Promoting Human Rights.

Has the increase in requests for asylum only been limited to Latin America countries? Does the Justice Department confer with U.S. based immigration groups as well?

US Agency for International Development

Page 20 First paragraph. Remove the words "among key populations." The goal should be among all populations.

Second paragraph. What is PHS in the acronym?

Does USAID's strategy compliment State's strategy?

Last full paragraph on page 20 has a run-on sentence.

The AIDSCAP acronym should be spelled out.

What is meant by "to operationalize the strategic framework"?

Page 21. Under DMELLD. When will the contract start?

Page 21. Under Biomedical Research.

Should be topical microbicide, not vaginal microbicide.

Page 23. Funding

Confused as to why resources will need to be shifted if the policy is to place them where the epidemic is having the greatest impact.

Does this include the $10 million announced by the POTUS on World AIDS Day?

Is the $700 million in FY 98 funds. Remove the exclamation point.

Under Strategy for Specific .....

Remove, "most cost effective" in the first paragraph under Prevention.

Second paragraph. Should say "HIV status", rather than "HIV testing" status, is the same.

This report only refers to confidential testing, and not to anonymous testing. CDC recommends that anonymous testing always be made available as well as confidential testing. We should not be advocating a policy that is different for other countries than what we use in the U.S.

Page 25 AIDS Orphans

Second paragraph is really long.

POTUS event estimated 42 million AIDS orphans, not the 22.9 million stated here.

When will the discussion papers be available?

When will the electronic network be operational?

Page 26 Women and Health

Antiretroviral treatment is not relatively low cost, especially when health expenditures total $10 per year in some countries.

Page 26 Vaccine Research

The second could be interpreted to mean that the U.S. government is more concerned with finding a vaccine for the developing world that for its own citizens.

Should be USAID "will" assist the vaccine development, rather than "can assist."

Page 27 Microbicide Development

Should be topical not vaginal microbicide.

Remove "used by a woman, herself."

Should be consent of "a" sexual partner.

Remove "herself" from "to protect herself from"

Page 29.Reducing Mother-....

Should be Centers for Disease Control and Prevention

Under the bullet "Voluntary... Should be more than 90 percent of HIV infected women, not just 90% of women.

Anonymous versus confidential comment from above.

Department of Defense

Page 45 Who is included in the Tri-service effort? There are four branches so it might be appropriate to know which is not participating.

Should there be a discussion of the Henry M. Jackson Foundation for Medical Research at Bethesda Naval Center?

Role of the Pharmaceutical Industry

Page 48. Although not uniformly available anywhere in the world?

Page 49. Last paragraph. Should it be "but to date, have not involved..."

So many references to Merck and Co. and not other firms makes it sound like a commercial for them..

Page 50. In the "last six months" refers to what time period?

Should add a line that the completion of the trials was also successful because it helped prolong lives, and not just that fact that research was conducted.

Page 51 Vaccine Research
Ivory Coast is referred to in French elsewhere in the document.

Page 51. "One U.S. company" If Merck is named, why is this one not?

Page 51. What is the source for the time line for new vaccine development?

Page 51. Behavior....
Why not name the universities?

Role of International NGO's

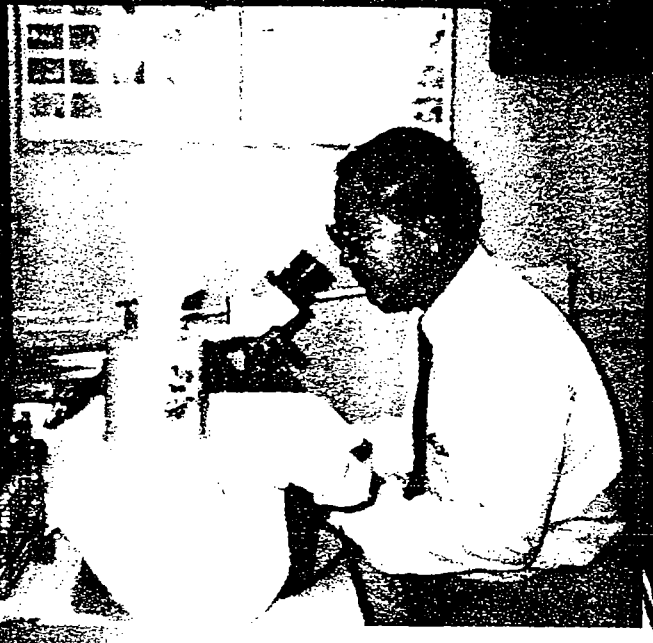
Page 53-54. Do any of them promote abstinence as an option?

Page 55 AIDS Orphans.

What are the sources for the 1.5 million children infected with HIV and the 100 million street children alive today?

U.S INTERNATIONAL RESPONSE TO HIV/AIDS

1999



DEPARTMENT OF STATE PUBLICATION 10589
Bureau of Oceans and International Environmental and Scientific Affairs
Emerging Infectious Diseases and HIV/AIDS Program

Released December 1998

Contents

Executive Summary

The 1999 U.S. International Response to HIV/AIDS (human immunodeficiency virus/acquired immune deficiency syndrome) is part of a continuing effort by the U.S. Government to create positive change in the international fight against HIV/AIDS. It is designed to foster political commitment, develop international partnerships, and provide a directory of public programs that can serve as a model of government policy and resource investments to more effectively meet the challenges posed by the global HIV/AIDS pandemic.

The 1999 report, like its 1995 predecessor, is the product of an interagency effort and provides a framework of effective programs and strategies. It can be used to guide future efforts in the continual battle against HIV/AIDS. It contains a set of U.S. Government priorities for combating the worldwide spread of HIV/AIDS. Participating agencies include the White House Office of National AIDS Policy, the U.S. Department of State, the U.S. Agency for International Development, the U.S. Information Agency, the U.S. Peace Corps, the U.S. Department of Health and Human Services (National Institutes of Health, Centers for Disease Control and Prevention, and the Food and Drug Administration), the U.S. Department of Commerce, the U.S. Department of Defense, the National Intelligence Council, and the U.S. Department of Justice.

The 1999 report reviews the objectives of the 1995 strategy and the accomplishments and difficulties in meeting those objectives. It then examines the remaining challenges confronting the United States and other members of the international community in meeting the many facets of the HIV/AIDS epidemic. And finally, the report includes an action strategy that identifies specific objectives to effectively address HIV/AIDS issues. The action strategy's programs, policies, and activities represent commitments by each agency and have been adopted at the highest level of agency authority. The goals of the 1999 U.S. International Response to HIV/AIDS are to:

- Raise awareness of the issue of international HIV/AIDS;
- Raise the level of priority accorded to stemming the spread of HIV/AIDS by all governments;
- Promote collaboration between governments, international organizations, and the private sector in developing international partnerships to leverage investments of capital and expertise into sustainable programs to fight HIV/AIDS;
- Encourage and support the efforts of UNAIDS and other international organizations;
- Promote respect of human rights for those afflicted with HIV/AIDS; and
- Highlight the special and growing needs of women and children infected with HIV/AIDS.

The 1999 report should not be viewed as a funding directory or as a manual for eradicating the HIV/AIDS epidemic, for this would be an oversimplification of the problem and its solution. Rather, we provide this compilation of government policies, programs, and priorities to further coordinate and share our collective expertise. Through successful, responsible partnerships at home and abroad, we can expand the benefits of the lessons learned and accomplish greater goals.

No member of the global community can afford, either in terms of human suffering or economic costs, to fail to recognize and act to forestall the impending devastation that has already begun to ravage national economies, security, and social infrastructure. It threatens the very fabric of society, regardless of race, creed, or spiritual belief. Disease is the equalizer,

touching all nationalities, all genders, and all ages. It preys hardest on those least able to meet its economic costs, and in the case of HIV/AIDS, on those in their most productive stage of life—between the ages of 20 and 45.

The one-world nature of life as we know it, where people change address and transportation routes, and exchange goods and services over vast distances, links us all in this battle. We must approach the solutions to our collective dilemma in a universal and collaborative way. Only then can we bring to bear the most fervent action and the most specialized resources we each have to offer.

We look forward to each nation joining this initiative at the highest levels, bringing sustainable commitments to see this fight through to its successful conclusion. Our tools are effective, multisectored national policies and programs, underpinned by strong public health infrastructures with effective preventative healthcare as a global priority.

The target audience of this strategy includes governments of both developing and developed nations, international organizations, non-governmental organizations, industry, and the public at large. We at the State Department will take the charge by initiating high-level foreign policy discussions by our ambassadors and other embassy representatives with host country counterparts. We will disseminate and discuss the strategies and encourage leaders to expand HIV/AIDS prevention and mitigation programs.

We will continue to work with international organizations, governments, non-governmental organizations, industry, and others in the private sector to effect this goal as a global priority to reduce human suffering and to safeguard all peoples from the devastation of HIV/AIDS.

Introduction: World AIDS Situation

A Rapidly Expanding Epidemic

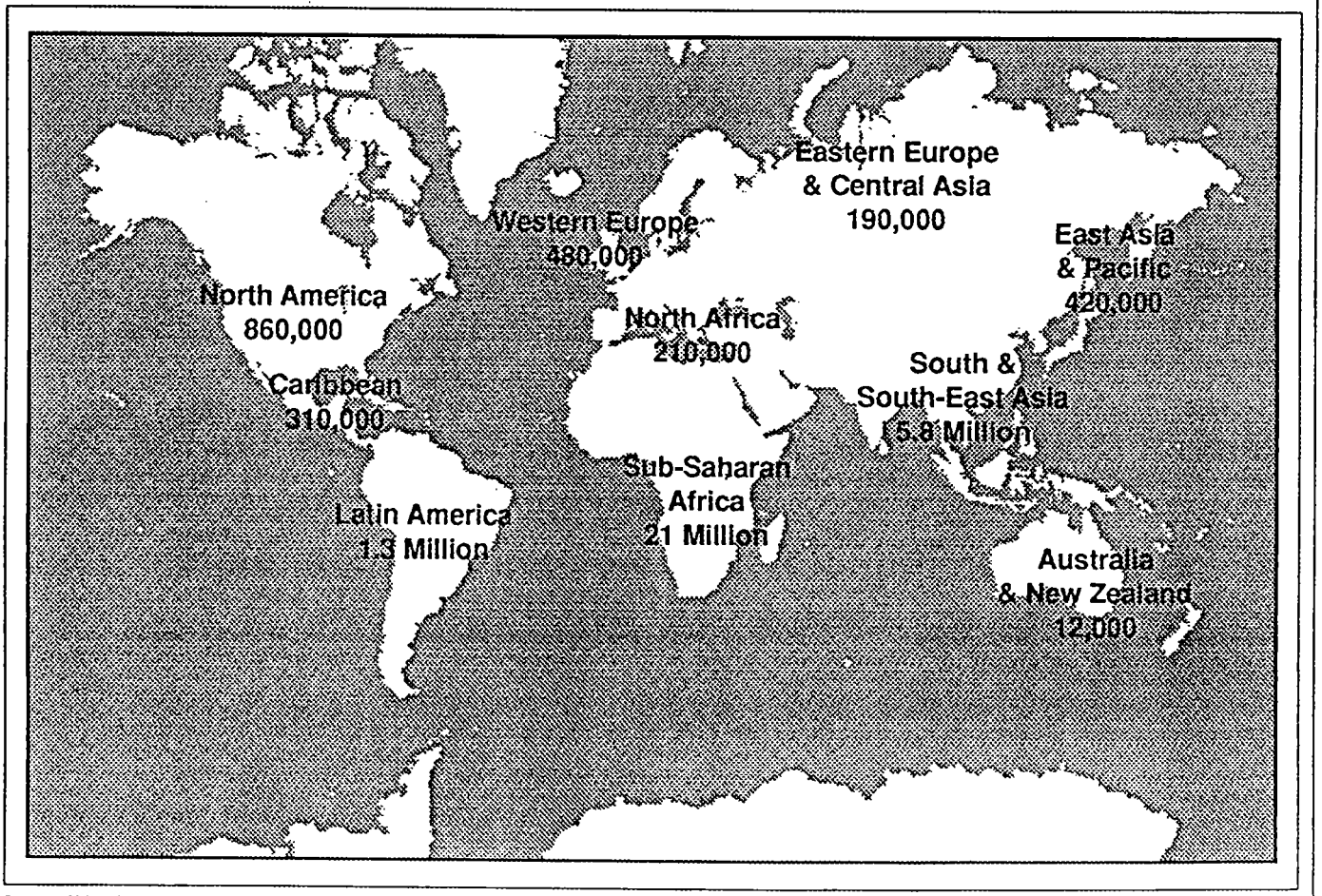
Dire predictions from the 1980s have become the reality of the 1990s, as HIV moves from a nascent state to epidemic disease. HIV/AIDS is insinuating itself into communities previously little troubled by the epidemic and is strengthening its grip on areas where AIDS is already the leading cause of death in adults. The cumulative number of those infected has more than tripled from the 10 million infections estimated in 1990. UNAIDS and the World Health Organization estimate that more than 33 million people are infected with HIV and that 16,000 new infections are acquired every day. An estimated 2.5 million in 1998 alone and 13.9 million people around the world have already lost their lives to the disease. Given the current rate of infection as well as the sheer number of those already infected, the death toll from HIV/AIDS is projected to increase exponentially in the years to come.

HIV/AIDS is a global problem touching virtually every country and every family around the world. It does not recognize nationality, gender, age, or sexual preference. Globally, 1 in every 100 adults 15 to 49 years of age is HIV-infected; at least 80 percent of these infections are due to heterosexual transmission.

Regional Assessment

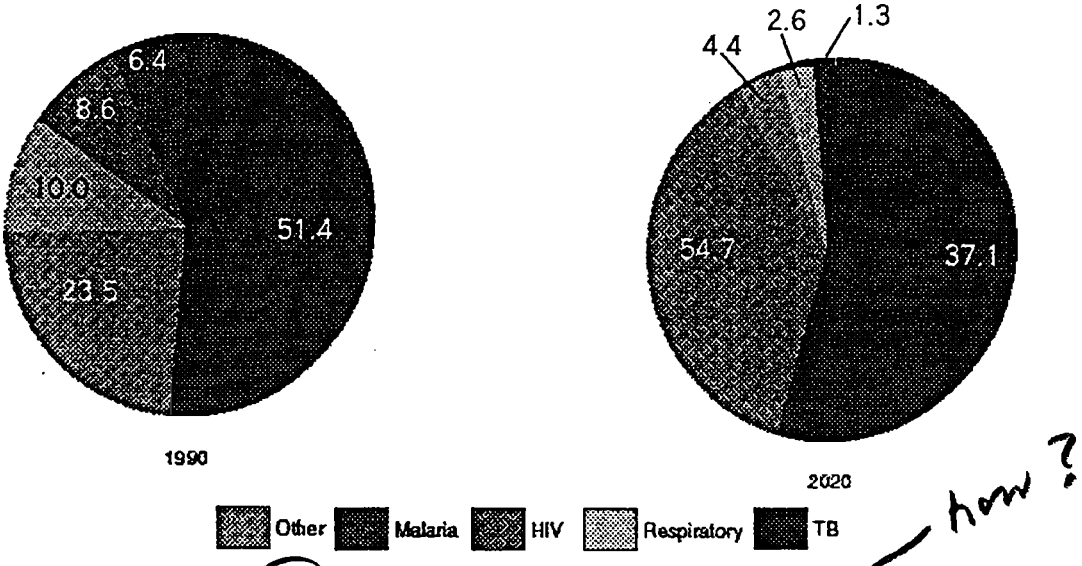
HIV/AIDS ignores international borders, cultural practices, and religious beliefs. HIV/AIDS is resident in humans in every region of the globe, from Sub-Saharan Africa to Asia, the Americas, Eastern

Figure 1. Estimated Number of Adults With HIV/AIDS, by Region, 1997.



Source: UNAIDS data, 1997

Figure 2. Causes of Death From Infectious Diseases Among People Ages 15 to 59, the Developing World, 1990 and 2020.



Between directly causing Aids deaths and indirectly facilitating the spread of TB, HIV will be responsible for up to half of all adult deaths from infectious disease in the year 2020.

Source: Murray and Lopez, 1996

and Western Europe, to the Middle East. However, most HIV infections are concentrated largely in countries least able to afford the care for infected people. In fact, more than 95 percent of people with HIV live in the developing world.

HIV/AIDS is now threatening development gains that local and donor governments, citizens, nongovernmental organizations, and international agencies have worked for decades to achieve. In many sub-Saharan African countries, AIDS has increased infant mortality and reduced life expectancy to levels not seen since the 1960s. Infant and child mortality rates are expected to double and even triple early in the next century. By the year 2010, life expectancy in some sub-Saharan countries could decrease by 30 years or more. In just the last 3 years, 27 countries have seen their HIV infection rates double. AIDS is doubling, or even tripling, death rates among young adults in countries in southern Africa. In Botswana and Zimbabwe, prevalence among young adults has reached 25 percent—one person in four, a historic new high. In South Africa, it is estimated that 3 million people are now living with HIV, and 700,000 were infected in 1997 alone. President Mandela has stated that the South African economy will shrink by 1 percent a year because of AIDS.

Globally, the number of children under 15 who have lived or are living with HIV since the start of the epidemic in the late 1970s has reached approximately 3.8 million—2.7 million of whom have already died. Nearly 600,000 children were infected with HIV in 1998; most were infected before or during birth or through breastfeeding by HIV-infected mothers. From the beginning of the epidemic until the start of 1998, some 8.2 million children around the world lost their mothers to AIDS. In 1997, it is estimated that HIV orphaned 1.6 million children, and 90 percent of the orphans live in sub-Saharan Africa.

An important trend of the 1990s has been the beginning of the shift of the global AIDS problem from Africa to Asia, which will soon have more new HIV infections than any other region of the world. Though the HIV epidemic is a latecomer to Asia and the Pacific, its spread has been swift. Since 1994, almost every country in Asia and the Pacific region has seen HIV prevalence rates increase by more than 100 percent. Nearly 7.2 million people in the region are now believed to be living with HIV. In years to come, that number may grow dramatically. India and China, the two most populous countries on earth, have experienced exponential growth. India, with a population of more than 900

million, had 3–5 million people infected in just the last 3 years, making it the nation with the greatest number of HIV/AIDS-infected individuals. China, the world's most populous nation, will need to act quickly and effectively to avoid following a similar course.

In some countries—like Indonesia and the Philippines—HIV has remained at roughly the same low levels for a number of years. It is these countries that have the greatest potential to avert the epidemic by acting quickly.

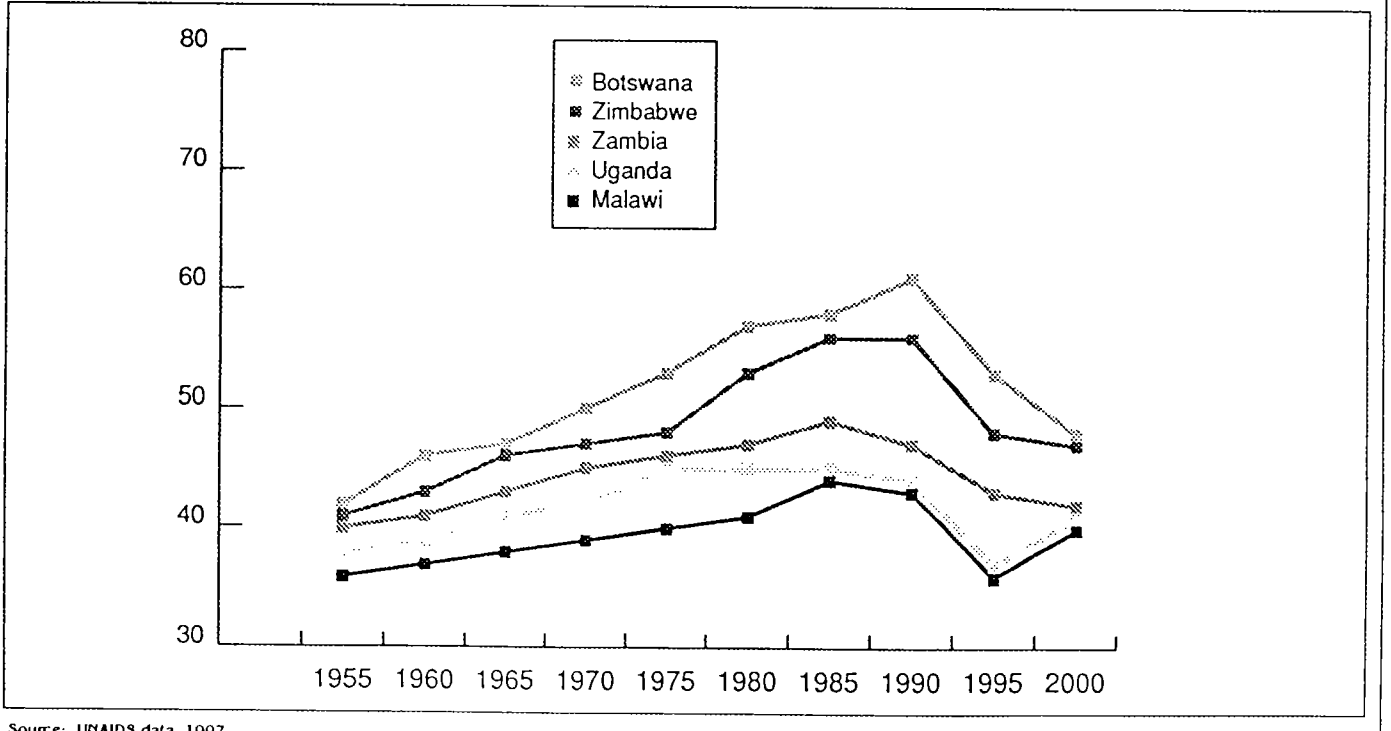
The situation in Latin America is mixed, with prevalence rising rapidly in Mexico, Brazil, Guyana, and Haiti. In other countries, as in many industrialized nations, infection rates have stabilized or are falling. The level of damage sustained by developing nations varies with the maturity of the epidemic and the response of national authorities and local communities to the threat of its spread throughout the population.

In Eastern Europe, though the absolute numbers are lower, many countries have experienced a doubling or tripling of their infections since 1994. Before 1995, the incidence of HIV/AIDS in the former Soviet Union and Eastern Europe was negligible. However, in 1996, 8,000 new HIV cases were reported. The bulk of the spread has been in injecting drug users and the sex partners of injecting drug users, which may provide a conduit for the virus into the general population. In Russia 2,223 cases of HIV were reported in the first 6 months of 1997, and by the year 2000, without appropriate interventions to eliminate illegal intravenous (IV) drug use and to curb high-risk behaviors, as many as 1 million Russians could be infected with HIV.

The long lag time between HIV infection, AIDS, and death—which is 4–5 years in developing countries and 10 years, on average, in developed countries—helps explain why most countries have yet to see the damage the epidemic can do to their social and economic fabric.

Source?

Figure 3. Projected Changes in Life Expectancy in Selected African Countries With High HIV Prevalence, 1955–2000



Source: UNAIDS data, 1997

Assessment of U.S. Interests

In the face of HIV/AIDS, the U.S. Government aims to reduce human suffering and stem further disease transmission. We must remind ourselves that the world looks to and depends on the United States, both for financial support and for the technical expertise to reduce HIV/AIDS transmission. We must continue to take a leadership role in mitigating its devastating individual and social impact of the disease. Focusing our considerable technical and human resources on this pandemic confirms our national ethos to help those in need. Fulfilling this trust, however, is also in the interest of U.S. citizens. This pandemic is the silent enemy of economic growth, national well-being, and stability around the globe, without distinction to borders, nationality, gender, or religion. Further, our hopes of new markets and stable democracies could be threatened by the unbridled spread of HIV in our partner countries. The outbreaks in Russia and the Ukraine are sobering reminders that this danger applies worldwide.

The number of AIDS cases worldwide will continue to rise in the next millennium and will increasingly undermine other projects intended to foster key U.S. policy goals, including democratization, economic development, conflict resolution and peacekeeping, and the promotion of individual and political rights. The AIDS pandemic will overwhelm underfunded and inadequate health delivery systems in much of the developing world and could undo hard-won health, social, and economic gains by nations around the world.

HIV/AIDS is not simply about mustering resources, technological know-how, and collective will to manage and eventually halt the spread of AIDS. The political and economic reverberations of HIV/AIDS demand a far broader response. Its increased incidence among military populations, its transforming of the debates about both North-South issues and gender equity, and its challenges to the central tenets of human rights are all inextricable elements of policy development and implementation.

Security and Political Concerns

Although not an issue of strategic security in the classic sense, the growing incidence of HIV/AIDS internationally and its pervasive impact must reshape U.S. thinking about definitions of security and about U.S. leadership in a changing world. The security implications are due to the fact that the increase in HIV-infected military personnel is gradually weakening the capacity of militaries to defend their nations and maintain civil order, to provide qualified personnel for overseas training, and to have access to a healthy conscription pool.

The high HIV/AIDS infection rate in military personnel of many countries will result in national security threats as militaries are diminished and depleted by the disease. A 1996 UNAIDS report discovered that an astounding 50 percent of Zimbabwe's 50,000 military personnel were infected with the virus. In this instance, a strong correlation found between rank and prevalence rates indicated that as the disease progresses, militaries suffer from debilitated leadership and an inability to meet military needs and commitments.

HIV/AIDS has also emerged as a significant political destabilizing factor. The virus' infiltration into the middle class, ruling elites, and military personnel of developing countries poses unique security threats. In many instances, the spread of HIV/AIDS creates a crippling cycle. Civil strife, refugee flows, urbanization, and poverty all play a role in creating conditions for the rapid spread of HIV. When economies and governments fail, or are chronically enfeebled, health systems falter rapidly. This leaves populations more prone to illness and at greater risk of economic decline. As an example, political instability and disease have reinforced each other in Rwanda and the countries of the former Soviet Union.

Developed countries are not immune to the destabilizing effects of HIV infections. HIV blood test scandals in Germany, France, and Switzerland have resulted in national outcries and triggered the dismissal or prosecution of government and other officials.

Canada ?
blood supply

Social and Economic Impacts

Like the spread of the disease, the economic impact of HIV/AIDS is pervasive and devastating. By the year 2000, the estimated direct (medical) and indirect (loss of labor force and family impact) costs of the disease will exceed $500 billion. Severely affected countries will experience large impacts on their health sector and on the poor. AIDS will affect the health sector in two ways: by increasing demand and by reducing the supply of a given quality of care at a given price. As a result, some HIV-negative people who would have obtained treatment for other illnesses had there been no epidemic will be unable to do so, and total national expenditure on healthcare will increase, both in absolute terms and as a proportion of national product. The net effect will be to increase the price and reduce the availability of healthcare for everyone, which will tend to affect the poor the most. Governments, therefore, will confront tradeoffs along at least three dimensions: treating AIDS versus preventing HIV infection; treating AIDS versus treating other illnesses; and spending for health versus spending for other objectives.

Regionally, a severe HIV/AIDS epidemic will tend to worsen poverty and increase inequality because low-income households will be more adversely affected by an AIDS-related death. Decisions made at the household level to reallocate resources (such as time, labor, housing, and land) to meet costs related to the disease may alter the distribution of income in society and create new groups of poverty. Because HIV is predominantly transmitted sexually, AIDS kills many people in their 20s, 30s, and 40s—their economically most productive as well as child-bearing years.

One important way in which AIDS is likely to exacerbate poverty and inequality is the increase in the number of children who lose one or both parents. Embattled populations are becoming progressively less productive and are burdened with increasing numbers of children orphaned by AIDS. As a result, development in these countries is adversely affected, and they will require increased economic and medical assistance from the community of developed nations. The problems posed by HIV/AIDS will generate additional pressure on North-South transfers of resources, cooperation, and bilateral relations.

Impact on the Workplace

The full social and economic costs to a nation from HIV/AIDS are almost incalculable. Most prevalent among adults in their years of greatest productivity, the economic well-being, particularly of developing nations, will be drastically affected by the presence and spread of HIV/AIDS in the country.

AIDS also affects the workplace, both because of reduced productivity and because HIV-related illnesses can cause increased absenteeism among employees and increased employee costs. Employee turnover related to the disease requires increased training and recruitment costs. In addition to soaring medical costs, corporations incur expenditures related to death benefits and funerals.

The loss of so many working-age adults to illness and death undermines previous achievements in extending life expectancy and increases the burden placed upon the gamut of government and social systems: the education system, healthcare systems, business and industry, communities, and families. Already the HIV/AIDS epidemic is taking a toll on the education systems. Children are being forced to leave school to care for ailing parents who themselves have fallen prey to the disease. When orphaned, children usually abandon school in more immediate need of a livelihood as a means of self-support. That livelihood all too often becomes commercial sex work, selling themselves to survive or to support their remaining siblings or other extended family. This situation already worsened by the growing international financial crisis in Asia, Russia and Latin America, portends an even greater likelihood of increased transmission of HIV/AIDS and other sexually transmitted infections (STIs).

The pool of uneducated and undereducated people due to HIV/AIDS-related causes further threatens to undermine critical economic and business investment, which necessitates a stable, well-educated, and healthy labor pool for production of goods for domestic and international commercial markets. The increased costs of doing business due to increased turnover of employees and additional training and other employee-related benefits and costs could raise the costs of doing business and discourage international investment critical to

stabilizing regional and national economies. This could also mean a reduction in taxes and other production-related revenues generated from tourism and other inputs into a healthy economic climate. At the same time, increased healthcare needs and associated costs for treating HIV/AIDS victims strain national healthcare budgets.

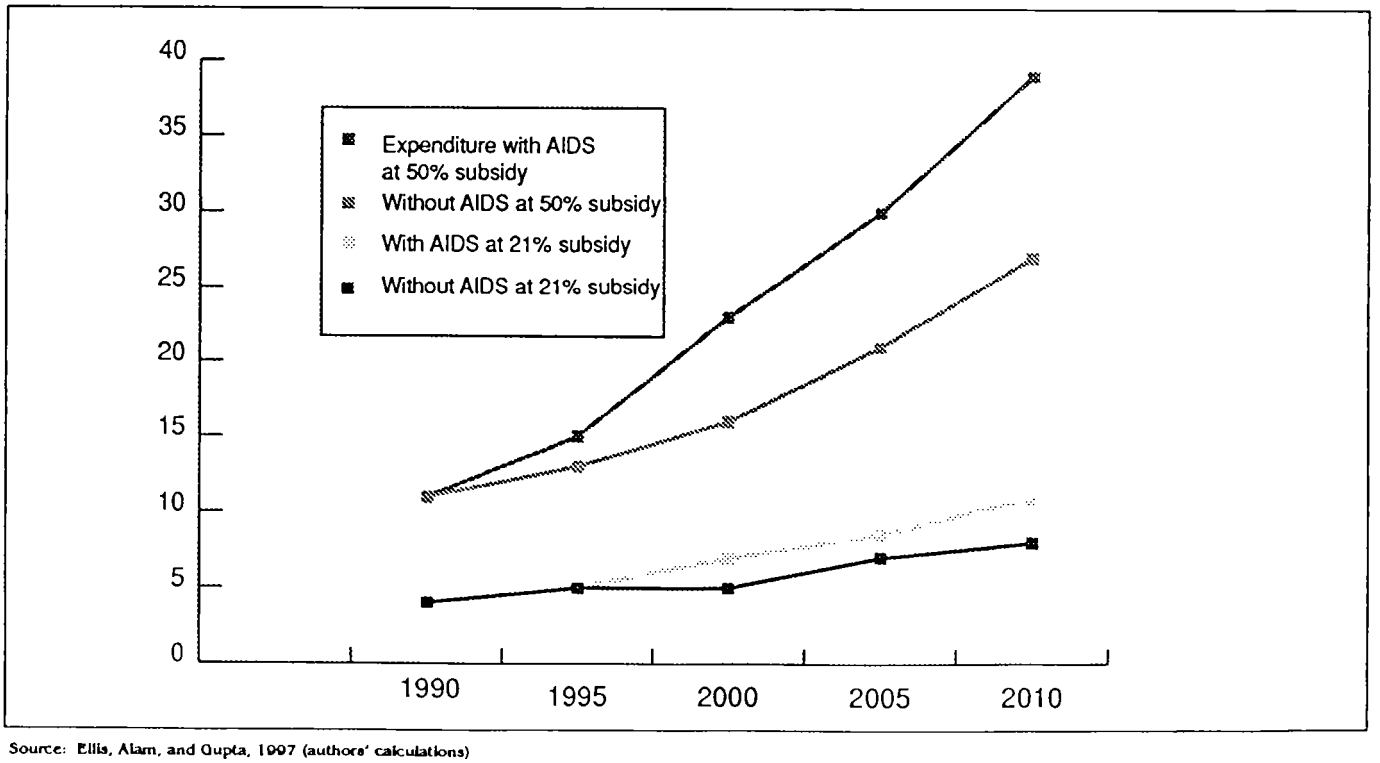
Poorly trained and educated girls and women, with few opportunities for employment in the business sector, may resort to or be sold into prostitution by impoverished family members in an effort to cover family expenses in times of economic hardship. Not only does this lead to an erosion of society, and a further undermining of the roles and status of women, but also leads to the increased transmission of HIV/AIDS, and an exacerbation of the poverty/HIV/AIDS cycle of suffering. With fewer healthy people, and the healthy needed to support the sick, there will be fewer persons available to care for the growing numbers requiring care. They will likely look to the formal healthcare system, in whatever state it may exist, for care and support. And the ever-growing numbers of sick and dying will severely burden inadequate healthcare infrastructures and increase fear and intolerance, which could lead to increased violations of human rights.

Healthcare Costs

Of all the economic and social costs incurred due to HIV/AIDS, healthcare costs are the most easily quantifiable. The World Bank estimates that in the average country, the annual treatment cost of AIDS is about 2.7 times GNP per capita. Spending on AIDS treatment increases with GNP; on average, treating an AIDS patient for 1 year costs about the same as educating 10 primary school students for 1 year. For example, if India maintains its current level of healthcare subsidies, a severe AIDS epidemic would increase government healthcare expenditure by about $2 billion per year by 2010. If subsidies are increased to the 50-percent level, the same-sized epidemic would increase annual government health expenditures by an additional $30 billion (see Figure 4).

Cost of HAART included?

Figure 4. Simulated Impact of a Severe AIDS Epidemic on Health Expenditures, India, 1990–2010.



Source: Ellis, Alam, and Gupta, 1997 (authors' calculations)

Assessment of 1995 Strategy

The July 1995 U.S. International Strategy on HIV/AIDS was structured around three broad categories of goals:

- Prevent new HIV infections;
- Reduce personal and social impact; and
- Mobilize and unify national and international efforts.

The following is a brief review of the progress made on these goals since that time. This review does not constitute an exhaustive analysis of the activities of each agency; rather, it is simply intended to highlight areas of success and identify areas where more action ~~needs to~~ might be taken.

Prevent New HIV Infections

There is not yet a cure for HIV/AIDS, and existing treatment regimens are costly. As such, the bulk of U.S. Government efforts and achievements since 1995 have been in the area of prevention. Under the heading of preventing new HIV infections, the 1995 Strategy laid out several points for action:

- Implement diplomatic initiatives to promote more active involvement on HIV/AIDS issues by national governments;
- Develop behavioral prevention strategies;
- Augment research;
- Safeguard the blood supply;
- Provide access to health services and technologies; and
- Address the adverse impact of poverty and other factors on prevention efforts.

Implement Diplomatic Initiatives on HIV/AIDS Issues by National Governments

As a result of the 1995 U.S. International Strategy on HIV/AIDS, the Department of State, in conjunction with other agencies, has taken numerous diplomatic initiatives to promote more active involvement on HIV/AIDS by national governments. For example, the Department initiated senior staff briefings and high-level directives to engage host government counterparts; placed the issue of HIV/AIDS on multilateral agendas; promoted positions at the Fourth World Conference on Women; included a discussion of HIV/AIDS in Agenda 21 for the International Conference on Environment and Development; placed HIV/AIDS on the G-7 agenda of Finance and Foreign Ministers in 1996 in Lyon; and supported consensus on HIV/AIDS-related Human Rights Commission Resolutions. include '98 WAD

On December 1, 1997—World AIDS Day—Secretary of State Madeleine Albright issued a statement in which she called on nations, private institutions, local and international business, communities, and families to intensify the fight to curb the HIV/AIDS epidemic. In addition, U.S. ambassadors and other embassy representatives were instructed to meet with host country counterparts to brief them on the 1995 U.S. International Strategy on HIV/AIDS and to encourage leaders to expand HIV/AIDS prevention and mitigation programs.

The U.S. Agency for International Development (USAID) has been successful in identifying effective prevention strategies and, through USAID missions and U.S. embassies, publicized successes to government and community health workers so that they may be duplicated elsewhere. Dissemination activities have included producing training curricula; convening workshops; "lessons learned" documentation (electronic, hard copy, CD-ROM, etc.) has been distributed; and most importantly, these best practices have been incorporated into all USAID-assisted programs.

Develop Behavioral Prevention Strategies

Largely, USAID and the Centers for Disease Control (CDC) have supported an ongoing portfolio of behavioral research to identify and monitor risk behaviors and their psychosocial and environmental determinants. CDC scientists have also completed and are disseminating information from several large, multisite intervention trials evaluating one-on-one-, small group-, and community-level behavioral intervention strategies. Approximately six tri-

als evaluating interventions for young gay and bisexual men, young men about to be released from prison, serodiscordant couples (i.e., HIV status is not the same), and HIV-infected persons are now in the formative or implementation phase. Continual research also includes HIV risks to postpartum women and perception and behaviors that influence acceptance of HIV counseling and testing. Finally, CDC established an ongoing database of HIV intervention research literature to facilitate ready identification of scientifically credible intervention models for HIV prevention programs to use.

In the past 5 years, USAID, through work with host country governments and community groups, has provided behavior change services for over 22 million specially vulnerable men, women, and youth, helping them to reduce their risk of HIV infection. To accomplish this task, USAID has trained over 180,000 new dedicated counselors and educators. In addition, with our partner organizations we have improved the clinical management of sexually transmitted diseases (STD's) in more than 22 countries as a significant way to reduce the efficiency of HIV sexual transmission, as well as to restore and protect the health of those specially vulnerable.

Building on this investment in behavioral research, the USAID-funded AIDS Control and Prevention Project (AIDSCAP) project supported more than 20 studies ranging from an intervention trial to define cost-effective approaches to HIV/AIDS education for vocational students in Sao Paulo, Brazil, to a collaborative, AIDSCAP/UNAIDS/WHO multisite efficacy study of the impact of personal risk reduction counseling and HIV testing on sexual-risk behavior. AIDSCAP also built new tools for behavioral research related to HIV/STI. It adapted rapid ethnographic assessment procedures to the STI field. The resulting Targeted Intervention Research (TIR) manual was tested and applied in nine countries in Africa and Southeast Asia. It was used to develop a locally meaningful health education message and to enable developing-country researchers/providers to improve doctor-patient communication by using local language and concepts in STI screening and case management.

USAID's Women and AIDS Research Program, a cooperative agreement with the International Center on Research on Women, supported 17 small behavioral studies on the perceptions and experiences of women and girls around sexuality, HIV/AIDS, and risk reduction. This research has resulted in a dramatic increase in the quality and quantity of knowledge regarding the behavioral, sociocultural, and economic factors that influence women's vulnerability to HIV infection throughout the world. It has brought to the forefront the need to incorporate women and a gender perspective into ~~AIDS~~ HIV prevention programs; has built local NGO and government capacity to deal with gender issues, and in the second phase of the project, has turned the research findings into eight HIV/AIDS interventions, focusing on the special needs and circumstances of women.

USAID's social and behavioral research at the macro level has developed and applied epidemiological and economic projections for HIV/AIDS to improve policymaking. In the Dominican Republic, policy research involving epidemiological models and projections stimulated the President to sign into law legislation to enhance HIV/AIDS prevention efforts. In Brazil, a study of the economic losses associated with high consumer prices for condoms was used successfully by local advocates to convince the Federal Government to reduce taxes on condoms. In South Africa, support for research on the social and economic impact of HIV/AIDS has provided crucial data for policy dialogue concerning the need for private and public investment in HIV/AIDS prevention and care. USAID-funded projects have established formative behavioral research as a prerequisite of technically sound intervention development. Thus, most of our future interventions will contain data collection components that enrich the knowledge base for understanding HIV risk behavior and opportunities for prevention and care.

Finally, behavioral research is one of the core mandates of Horizons, USAID's new global leadership and operations research project managed by the HIV/AIDS division. Through mechanisms under USAID's HIV/AIDS strategic objective, USAID is initiating intervention research on a range of behavioral topics, including improving risk reduction interventions for women and girls; promoting effective STI care-seeking behavior by men as well as women; supporting culturally appropriate counseling and testing; strengthening community mobilization and empowerment for HIV prevention, care, and support; improving methods for personal HIV risk assessment; and understanding the economic and societal pressures that increase sexual risk behavior.

Augment Research

The U.S. Government has made large strides toward improving HIV behavioral prevention strategies and providing access to health services and new technologies to stem mother-to-infant, or vertical, transmission through the National Institutes of Health (NIH's) HIVNET initiative. CDC has pledged to emphasize the eradication of perinatal HIV transmission through research, training, and pilot projects. CDC is actively involved in ongoing research on using antiviral therapy (AZT) in pregnant women to prevent perinatal HIV transmission. In 1995 NIH pledged to place a high priority on following up initial studies on methods to prevent HIV transmission from mother to fetus, including AZT and micronutrient treatment (vitamin A) during pregnancy and on further defining the context of their use. To this end, it is notable that the results from USAID's Clinical Trials Group 076 in 1994 and the recent Thailand trial findings in 1998 highlight the dramatic success of AZT in reducing the risk of perinatal HIV transmission.

The National Institute of Allergy and Infectious Disease (NIAID) is supporting additional perinatal prevention trials in Malawi, Zambia, South Africa, Zimbabwe, Uganda, Ethiopia, and Thailand. These trials address questions about breastfeeding transmission, STD treatment, microbicides, and promising new antiretroviral immune agents to decrease perinatal transmission to as low a rate as possible in international settings. Between 1995–1997, the National Institute of Child Health and Human Development (NICHD) also increased its support for international perinatal transmission studies by more than 90 percent. With support from the Office for AIDS Research (OAR), NIAID, NICHD investigators, and Fogarty International Center grantees are undertaking pilot studies directed at implementing short-course AZT therapy in a number of developing countries.

The Department of Defense continued in its cooperation with other countries in the quest for the identification of an HIV/AIDS vaccine and the identification of "best practice" for the treatment of HIV/AIDS. The Department of Commerce, U.S. Patent and Trademark Office, developed a homepage that provides a searchable database with the full-text and images of patents related to AIDS research.

Safeguard Blood Supply

The Food and Drug Administration (FDA) has worked with manufacturers to facilitate the development of new testing methodologies and other approaches to assure the safety of the blood supply. FDA is also collaborating with international organizations such as the World Health Organization (WHO) and the International Council for Harmonization (ICH) to harmonize biological standards on blood safety and is actively involved in training others in their specialty. Additionally, USAID has directly supported improvements in healthcare infrastructure by providing advocacy and leadership in the area of blood safety and universal precautions.

Provide Access to Health Services and Technologies

Toward the goal of providing greater access to health services and technologies, USAID is supporting female condom distribution and market research in over 15 countries. The USAID Population, Health and Nutrition (PHN) Center has developed a global research agenda for determining the net public health value of providing the female condom through public- and private-sector outlets. USAID supports several grants to non-governmental organizations, as well as epidemiological and biomedical research administered by the NIH, CDC, and World Health Organization's Global Programme on AIDS. Specific areas of research include female-controlled vaginal spermicides and microbicides, female condoms, the economic impact of HIV/AIDS, inexpensive STD diagnostics, and novel testing and counseling strategies.

FDA has also been instrumental in securing greater access to health services and technologies. FDA has worked with manufacturers to facilitate the rapid development of new agents to prevent and treat HIV-related conditions and medical devices to prevent transmission, through streamlining the FDA review and drug certification process for HIV/AIDS therapies. FDA has approved 12 distinct drugs for the treatment of HIV/AIDS and 25 drugs for the treatment of infection related to HIV.

Address the Adverse Impact of Poverty and Other Factors on Prevention Efforts

In 1996, USAID redesigned its HIV/AIDS strategic objective to better reflect the experience gained to date in prevention activities and to respond more effectively to the growing and changing worldwide epidemic. Representatives of host governments, international development organizations, NGOS, the private sector, affected communities, people living with AIDS, and USAID Mission and Regional Bureau staff participated in a series of activities resulting in recommendations to expand the scope of USAID's response to the epidemic.

The revised Strategic Objective (SO) states: "to increase the use of improved, effective and sustainable responses to reduce HIV transmission and to mitigate the impact of the HIV/AIDS epidemic." This new strategy is based on the need for continued and expanded efforts to prevent HIV transmission and a new focus on mitigating the disease's impact on people and their communities, while more closely studying its social, economic, and policy impacts.

Included in the revised strategy is a directive to "develop and promote approaches that address key contextual constraints and opportunities for prevention and care interventions." HIV/AIDS prevention and management efforts are often hampered by the policies, norms, and financial constraints under which they operate. USAID will address these environmental constraints by effectively communicating the economic, social, and health costs of HIV/AIDS to key policymakers and budgetary and decisionmakers; promoting the elimination of barriers that inhibit the flow of HIV/AIDS prevention and management information and services to youth, women, people living with AIDS (PLWH) and other vulnerable groups; developing and promoting effective strategies for providing basic care and support services for PLWH; and supporting initiatives to dedicate increased resources for HIV/AIDS prevention and management.

Reduce Personal and Social Impact

The 1995 Strategy called for a greater consideration of the problems HIV/AIDS poses that go beyond the medical and health implications. The strategy stipulated that in order to mitigate the impact of HIV/AIDS on the individual and society, the following broader issues must be taken into account:

- Providing care and support;
- Guaranteeing human rights;
- Protecting politico-military structures at risk; and
- Placing HIV/AIDS on the sustainable development agenda

Provide Care and Support

In an effort to provide greater care and support, USAID was active in advocating a strategy of "prevention to care," which included access to counseling and testing, reducing stigma, improving psychosocial and basic medical support for HIV-positive persons, and selected interventions for survivors. USAID and NIH have studies underway to find ways to limit progression of HIV disease in infected children and to increase childhood survival in developing countries, particularly Africa and Asia.

Providing care and support to those ~~afflicted~~ living with HIV/AIDS reaches beyond the health sector. As such, increased attention has been given to the social and economic impact of HIV/AIDS. The USAID Regional Missions support a range of studies on the social, economic, and community impact of HIV/AIDS in Africa, Asia, and Latin America, ranging from studies on the social and economic impact of HIV/AIDS in Southern Africa to studies of collaboration between traditional and biomedical healers in managing HIV/AIDS in Zambia and Senegal. At the request of the Assistant to the Vice President for National Security Affairs, the National Intelligence Council (NIC) Office of Transnational Issues recently published a study assessing the social and economic impact of AIDS in the sub-Saharan Africa region.

Guarantee Human Rights

In the area of human rights, the State Department and other U.S. Government representatives took diplomatic initiatives to promote and safeguard protection under the law for persons living with HIV/AIDS with regard to access to healthcare, employment, education, travel, housing, and social wel-

fare in all appropriate fora. The U.S. Government supported consensus on the UN Commission on Human Rights' biennial resolution "The Protection of Human Rights in the Context of the Human Immunodeficiency Virus (HIV) and Acquired Immune Deficiency Syndrome (AIDS)." The resolution sets out guidelines states may follow in dealing with the health crisis and human toll of AIDS and HIV. The resolution also asks the Secretary General to solicit input from countries, specialized agencies, and related governmental and nongovernmental organizations in order to provide a progress report to the Commission on followup. The next session of the Commission at which the HIV/AIDS resolution will be considered will take place in March 1999. In addition, the Department of State continues to include HIV/AIDS-related discrimination and human rights abuses in regular embassy reporting.

Protect Politico-Military Structures

The Department of Defense furthered its efforts to protect politico-military structures at risk by continuing to conduct military-to-military educational programs on HIV/AIDS, which are expected to contribute to changes in high-risk behavior and an overall decrease in rates of infection in foreign militaries. Additionally, the National Intelligence Council prepared a national estimate on the impact of HIV/AIDS on military establishments. ~~And,~~ USAID funded, through AIDSCAP, a global initiative called the Civil-Military Project on HIV/AIDS to provide network collaboration and information sharing opportunities among civilian and military populations in Africa, Asia, Latin America, the Caribbean, and Eastern and central Europe.

Place HIV/AIDS on the Sustainable Development Agenda

The Department of State is directly responsible for placing health and HIV/AIDS on the international agenda as elements of sustainable development. Health—including a discussion of HIV/AIDS—was a part of the discussions for Agenda 21 for the International Conference on Environment and Development and continues to be a part of the USAID programs for development assistance. The Department of State also placed HIV/AIDS on G-7 the agenda of Finance and Foreign Ministers in 1996 in Lyon.

Mobilize and Unify National and International Efforts

The 1995 International Strategy called for increased collaboration and unification of U.S. Government HIV/AIDS prevention and mitigation efforts and stated that "strengthened collaboration within and among countries is an essential component to improving efforts to combat global HIV/AIDS."

In this vein, the Department of State has been active in diplomatic prevention efforts. In particular, at the Fourth World Conference on Women, the Department of State successfully promoted major tenets of the 1995 International Strategy on HIV/AIDS. U.S. positions in support of the strategy were adopted at the Beijing conference. In addition, the Department of State, USAID, and others continue to work with UNAIDS and other international organizations on the goal of unifying international efforts to mitigate and prevent HIV/AIDS.

Through public diplomacy, the U.S. Information Agency (USIA) continues to share with foreign publics key policies and a variety of American Federal and local government and nongovernment organizational activities that contribute to HIV awareness, prevention, and treatment programs in the United States and abroad. An example of USIA efforts is the campaign mounted to bring attention to the December 1, 1997 World AIDS Day.

The White House Office of National AIDS Policy (ONAP) took further steps toward unifying national efforts. Representatives from State, USAID, ONAP Director's Office, the Department of Health and Human Services (DHHS), and others worked together collaboratively and met several times to develop a National AIDS Strategy.

Areas for Continued or Future Action

- Strengthening public health infrastructures;
- Making AIDS treatment more accessible and affordable;
- Addressing the adverse impact of poverty and other factors on prevention efforts;
- Protecting human rights; and
- Improving collaboration and donor coordination through sharing both technical and financial resources.

Issue Overview

An Interagency Working Group of the U.S. Government agreed to the following issues as those most relevant for action through agency programs. They are HIV transmission prevention, vaccine research, and mitigation of the impact of HIV/AIDS. Within these larger issues are several other issues of importance, including treatment equity, behavioral research, behavioral change intervention, AIDS-orphaned children, women and health, microbicide development, and donor coordination. This section provides an overview of these issues.

Effective Interventions

Antiretroviral Drugs

New breakthroughs in the development of multidrug therapies and antiviral used to reduce the perinatal transmission of the disease from mother to fetus or newborn are providing a larger arsenal of weapons with which to fight the HIV/AIDS epidemic. Potent new combinations of antiretroviral drugs have reduced viral load in patients and have proved to be one of the major scientific advances of 1996. However, the relative short-term success of potent three-drug combinations, due to the development of drug resistance and the extreme costs and difficulty in the treatment regimen, undermines the long-term prospects for continued success and their widespread availability beyond the developed world.

While drug therapies may extend and improve the quality of life for HIV/AIDS patients, they are not a cure for the HIV/AIDS virus and are not available to all who need them. Nor have they been proven successful for everyone and often cause severe negative side effects. The costs of antiretroviral therapy range from $10,000 to $15,000 per person per year and require an established public health infrastructure that can assure compliance with a continuous, comprehensive, and vigorous treatment regimen, making the treatments impractical and unwise for much of the developing world.

In addition to cost, drug-resistant strains of HIV emerge if an individual's viral replication is not completely suppressed by antiviral treatment. As a result, the viral load increases and disease progression may occur. The therapies have not been proven successful for everyone, and they often cause severe negative side effects. The misconception that antiretroviral therapy is a cure may work against prevention of transmission if individuals believe they are no longer contagious and continue high-risk behavior. And although antivirals can prevent mother-to-child transmission of the disease, they provide no protection to the mother ~~carrying both the unborn and the HIV/AIDS virus~~. The potential emergence of drug-resistant strains combined with the emergence of mutated strains of the virus and the need for more widespread availability of prevention and treatment measures demand that all efforts for vaccine research and transmission prevention be redoubled immediately.

HIV Transmission Prevention

HIV transmission can be reduced and the socieconomic impact of AIDS alleviated with effective development and implementation of improved policies, strategies, and coordinated programs, underpinned by strong commitment and involvement from national, state, provincial, and local governments.

Now, as more accurate numbers are tabulated to show the presence and rate of infection, it is evident that the fight to end HIV/AIDS will be long and will require the sustained partnerships of all affected. HIV/AIDS is a multisector problem that can be solved only with interventions comprised of well-planned sustainable programs, which address legal, social, and economic inequities as well as a new array of problems unique to HIV/AIDS. The effort requires the collaborative expertise of international organizations, governments, industry, and nongovernmental organizations.

There exists no single, standardized set of interventions in HIV/AIDS prevention programming. Specific regional strategies must include an appropriate mix of programs proven to be effective for the vulnerable populations being addressed. Taken into account must be the available resources and local risk behaviors and approaches that would be tailored to cultural attitudes and belief systems.

Preventing sexual transmission requires comprehensive and persuasive education to convince people to change deeply ingrained sexual behaviors, a difficult and complex task that can cause examination of cultural, religious, and personal beliefs. But prevention works.

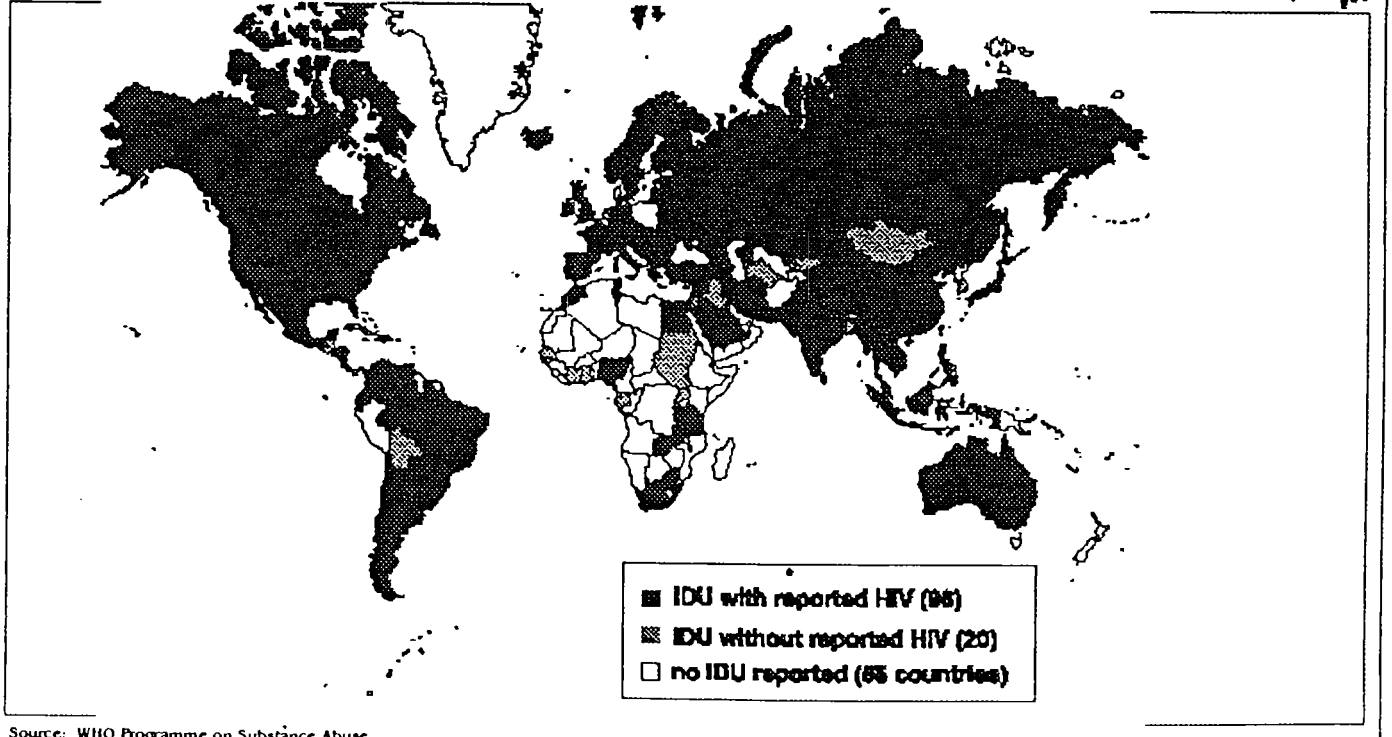
There is good evidence that HIV infection rates are stabilizing or decreasing in places where focused and sustained prevention programs have engendered significantly safer behavior. This is not just the case in developed countries in Europe and the Americas. It is true around the world. For example, surveillance testing in urban areas of Uganda over the past 5 years reveals a 40-percent drop in HIV prevalence among pregnant women. This decline in HIV infection is particularly striking in young women and is associated with delayed first sexual intercourse, increased condom use, and fewer sexual partners.

In Thailand, annual surveys of young men showed both substantial reductions in risk behavior and decreases in HIV infection levels. Between 1991 and 1995, visits to sex workers reported by these men were cut by almost one-half; and those who reported not using a condom on the last visit dropped from nearly 40 percent in 1991 to slightly over 5 percent in 1995. As a result, HIV prevalence among this group has decreased from 8 percent in 1992 to less than 3 percent in 1997. The first signs of an HIV turnaround are also being seen among young people in northern Tanzania. In areas with active prevention programs, prevalence in young women fell by 60 percent over a period of 6 years.

Other methods of preventing HIV transmission also may have an important impact on slowing the pandemic. For example, researchers are developing and testing topical microbicides, substances that a woman could use in her vagina before sex to prevent the transmission of HIV and other sexually transmitted diseases. USAID, UNAIDS, and others also have facilitated more widespread use in Africa of the female condom. These interventions may help women to protect themselves in situations where they are unable to avoid sex with partners who are HIV-infected or are unable to persuade their partners to use a condom.

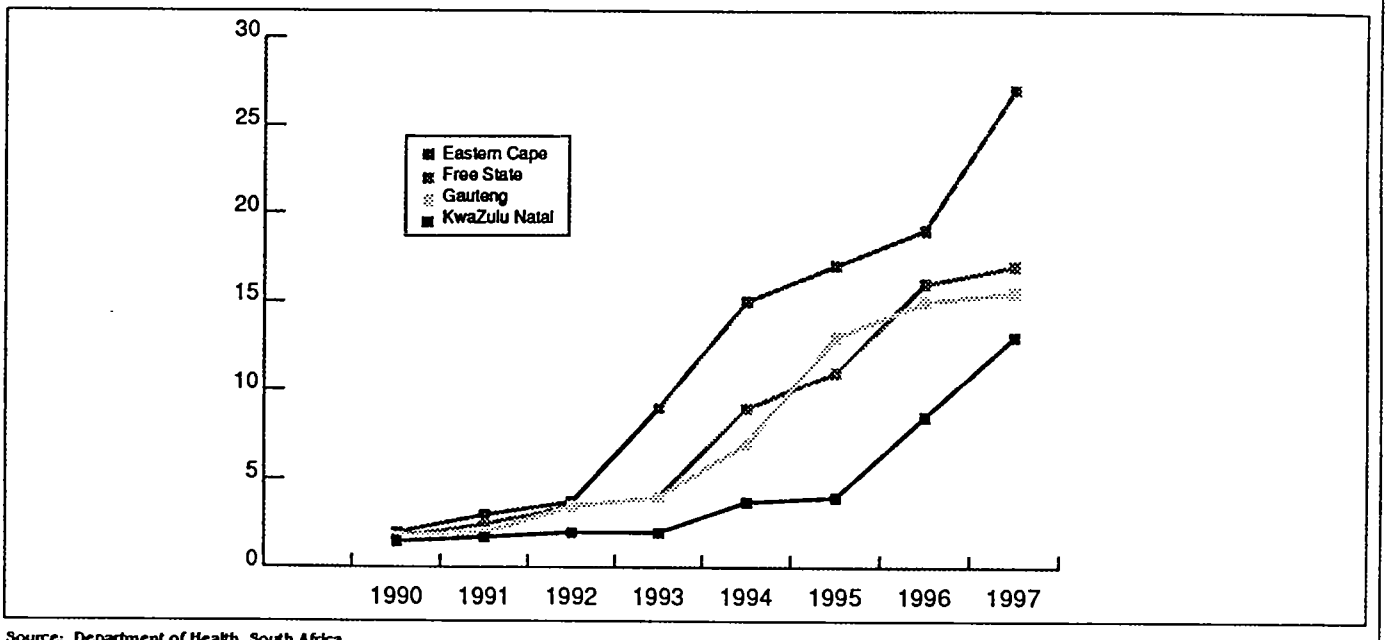
However, to prevent HIV transmission it is no longer sufficient to focus solely on sexual transmission as the only route of HIV infection. While sexual transmission, both heterosexual and homosexual, is still the primary means of transmission, there are many other routes which, if ignored, will continue to raise transmission rates, resulting in further spread of the deadly virus.

Figure 5: HIV and Injecting Drug Use (IDU), 1997.



Source: WHO Programme on Substance Abuse

Figure 6: HIV Prevalence Among Pregnant Women, Selected Provinces, South Africa, 1990–1997.



Source: Department of Health, South Africa

Injecting drug use, for example, is another prevalent mode of HIV transmission. In many countries, drug injecting accounts for more HIV infections than sex. According to UNAIDS, three-quarters of cases recorded in Malaysia, Vietnam, southwest China, northeast India, and Myanmar are among injecting drug users. In Western Europe, if one counts infections passed on to the sex partners and infants of drug users, drug injection accounts for 44 percent of AIDS cases. In the southern cone countries of Africa it accounts for nearly a third. In Eastern Europe the picture is even more alarming. Some 87 percent of HIV infections in Belarus, for example, are among drug injectors. In the Russian Federation, most infections were spread sexually until 1995, and injection drug use was virtually unheard of. However, in 1996 and 1997 confirmed infections in drug users accounted for four out of every five newly-diagnosed infections.

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

Integration of the use of proper procedures for blood safety and universal infection control is effective in reducing blood-borne HIV transmission in health programs. Developing and applying intervention strategies, within existing health programs, to decrease transmission by other routes, such as perinatal and by blood, is absolutely integral to the decrease of HIV transmission rates.

The case of mother-to-child transmission is estimated to be the source of 5–10 percent of the total of new HIV infections in many developing countries, with almost 600,000 children infected in 1998. Compounding the situation is the fact that over 1.5 million HIV-infected women become pregnant each year. The majority of these are in Africa and Asia.

A recent USAID-funded clinical trial conducted by the Centers for Disease Control and Prevention with the Thailand Ministry of Health found that HIV transmission from mother to child could be reduced by 50 percent by giving the drug AZT to mothers during the last 4 weeks of pregnancy and during labor and delivery. Trials show that antiretroviral pills given to pregnant women during the last week prior to and during labor, combined with safe alternatives to replace breastfeeding, cut overall vertical transmission of HIV to 9 percent. This compares with the norm in developing countries of up to 35 percent.

While preventing HIV transmission is necessary to curb the ever-growing epidemic, countering the increasing rates of opportunistic infections is also essential. HIV-related increases will occur in the progression of dormant tuberculosis (TB) infection to infectious TB diseases in individuals infected with both diseases. Programs to address other STI's, which exacerbate or are exacerbated by HIV/AIDS, must be implemented along with more comprehensive, accurate, and inexpensive diagnostic testing and counseling. In Tanzania, the "Mwanza study" showed that using simple, realistic syndromic management to treat sexually transmitted infections within a study population reduced the number of new infections by an impressive 42 percent.

Prevention of and reduction in transmission rates are key to slowing the HIV/AIDS epidemic; however, it is important to note that should HIV transmission cease tomorrow, the continual impact of AIDS cases following the natural course of HIV will remain great for many years to come. Therefore, tailored combinations of programs designed to mitigate the devastation wreaked by HIV/AIDS, as well as prevention of transmission, are needed for an effective sustainable response to the deadly epidemic.

HIV Drug and Vaccine Development

A number of new research advances indicate progress against AIDS and open new areas of investigation. Protease inhibitors, a new class of drugs used in combination with other antiretroviral therapies, have been shown to remarkably diminish the amount of HIV in an infected individual. Receptors for molecules called chemokines have been identified as critical cofactors for HIV infection, providing us with an entirely new set of targets for anti-HIV therapies and new approaches for vaccine development. The challenge now is to develop more effective drugs and to prepare for the possible emergence of drug-resistant strains of the virus.

Despite these advances, the end of the pandemic is not in sight. The new drugs, while promising, are not a panacea. It is not known how long the benefits of the drugs will last. There are many for whom the new drug regimens have not been effective or for whom the side-effects are not tolerable. The challenge now is to develop more effective drugs and to prepare for the possible emergence of drug-resistant strains of the virus.

Developing a vaccine or vaccines that are safe and effective in preventing HIV infection in exposed individuals is a major public health priority in the national and international effort to combat this epidemic. A safe and effective vaccine for HIV infection remains the "holy grail" of AIDS research and an important step toward bringing the HIV epidemic under control. The goal is a preventive vaccine to slow and eventually end the HIV pandemic and to protect the individual from HIV infection and/or disease.

Without a vaccine, AIDS will soon overtake TB as the leading infectious cause of death in the world. Vaccines may be the cost-effective way to prevent HIV infection worldwide. Therefore, an affordable, safe, and effective vaccine that is also easily delivered and acceptable to various populations at risk is urgently needed. President Clinton called for the development of an HIV/AIDS vaccine by 2007, inviting international scientific collaboration to meet this goal.

Mitigating the Impact of HIV/AIDS

Mitigation of HIV/AIDS impact will need to focus primarily on three main areas, while maintaining adequate surveillance and flexibility to address other issues as they may arise. Programs for mitigation should address care and support for HIV-infected individuals, dependency and orphanhood resultant of HIV/AIDS deaths, and the pandemic's affect on women and health.

Due to investments in biomedical research, steady progress has been made in improving the care of people with HIV or AIDS. For example, the usefulness of a tuberculosis prophylaxis has been confirmed that will now allow more effective action against this coepidemic. Widespread access to highly effective antiretroviral therapy has significantly prolonged life and improved the quality of life for people living with HIV in the Western world and has resulted in a spectacular decline in AIDS death in these countries. But because of the high cost and complexity of these drug regimens, most infected individuals in the developing world have no access to these latest therapies—and often not even to simple treatments to fight their infections and diminish their pain. The absence of affordable therapies in developing countries, where 90 percent of the epidemic is concentrated, will only exacerbate the already enormous human and economic costs of AIDS. It also risks becoming a major contributing factor to social and political insta-

bility in those countries, with hundreds of thousands to millions of infected and affected citizens.

More needs to be done to document and improve understanding of the nature, magnitude, prevention, and mitigation of HIV/AIDS-related adverse socioeconomic impacts in the different levels and sectors of society. Surveillance of the disease itself, as well as tabulation of infection rates, is absolutely necessary to ensure that programs are implemented and that funds are used adequately. Including HIV/AIDS sentinel surveillance in regional and national surveillance for emerging and reemerging infectious diseases will serve both to better follow the epidemic and strengthen surveillance systems worldwide. Linking surveillance systems will not only serve to better understand the path of the disease but will also ensure that all information is available and encourage information sharing of effective strategies worldwide.

Care and Support for HIV-Infected Individuals

With 33.4 million people infected with HIV and with infection rates on the rise, the need to create comprehensive care systems is great. The numbers of HIV-infected individuals and people living with AIDS-related illnesses will be so large that governments and donor agencies will have to have developed cost-effective intervention strategies to improve the accessibility and quality of care and support services for HIV-infected individuals. They also will need strategies to reduce the adverse socioeconomic consequences of AIDS. Healthcare for HIV/AIDS-infected individuals must be designed and administered in an equitable manner. It must also be in agreement with human rights, as stipulated by the International Guidelines for HIV/AIDS and Human Rights: that vulnerability to HIV/AIDS be reduced; that those infected with HIV/AIDS live a life of dignity without discrimination; and that the personal and societal impact of HIV infection is alleviated.

AIDS-Orphaned Children

During the 12th World AIDS Conference in Geneva, the problems posed by this issue were referred to as a "massive social time bomb" as the number of children affected by AIDS, including those who are orphans or caring for sick parents, continues to escalate. By the year 2000, 15.6 million will have lost their mothers or both of their parents in 23 countries heavily affected by HIV/AIDS. Largely as a result of the pandemic, that number will increase to 22.9 million by 2010. When paternal orphans are included, the total number of orphans from all causes is projected to increase from 34.7 million in 2000 to 41.6 million in 2010 in these 23 countries.

HIV has often caused huge increases in death rates among younger adults—just the age when people are forming families and having children. This inevitably leads to an increase in orphans. In rural areas of east Africa, 4 out of every 10 children who have lost one of their parents by age 15 have been orphaned by HIV/AIDS.

The loss of a parent poses tremendous challenges for a child. These children may suffer from depression, malnutrition, lack of immunizations or healthcare, increased demands for labor, loss of schooling, forfeiture of inheritance, forced migration, homelessness, vagrancy, starvation, crime, and increased exposure to HIV infection.

The growing number of children who lose parents will, in turn, have a profound impact on their societies. With children who have lost parents eventually comprising up to one-third of the population under age 15 in some countries, this outgrowth of the HIV/AIDS epidemic will create a lost generation—a sea of youth who are disadvantaged, vulnerable, undereducated, and lacking both hope and opportunity. The creation of such a large and disaffected demographic "youth explosion" could propel some of these societies to significant unrest and destabilization over the long term. The threat to the prospects for economic growth and development in the most seriously affected countries is considerable.

Women and Health

One of the most striking trends in the HIV/AIDS pandemic during the past decade has been its rapid spread among women. Worldwide, women are becoming infected at faster rates than men, and the total number of HIV-positive women is fast approaching that of men. Young women are particularly vulnerable, and it is estimated that 70 percent of women infected with HIV are between the ages of 15 and 24.

Women and girls face greater biological vulnerability than males. The female reproductive tract

than? more so than a males AIDS?

is more susceptible to infection with HIV and other STDs, a susceptibility that is particularly great in young girls. Sexual transmission of the virus is four times more efficient from men to women than from women to men; the immaturity of the sex organs of girls and younger women raises their biological vulnerability even higher. Nine in ten women are becoming infected through heterosexual intercourse.

But social and economic forces can play an even greater role in increasing women's risk of acquiring HIV infection. The imbalance of power between men and women in most cultural settings limits women's ability to protect themselves. Many women and young girls are forced to accept sexual partnerships that put them at high risk of contracting the virus and are unable to insist on condom use by their partners. More than half the young women in a Malawi study reported coercion; over 20 percent of young women surveyed in Nigeria reported being forced to have sex. The reasons for forced sexual intercourse range from social pressure through coercion by older men in authority, to having sex with virgins prescribed as a remedy for a range of "illnesses," to outright violence. Young girls are often targeted because they are believed "safe" and uninfected with HIV. Rape has become lethal with the advent of HIV. Adolescent girls face the greatest threat, as their extreme biological vulnerability is amplified by their psychological and cultural subordination and their lack of access to reproductive health information and services.

Topical microbicides are chemical barriers that women can apply to inhibit HIV infection. Although none have been shown to be effective now, microbicides are needed due to the high prevalence of nonconsensual sex, lack of condom use, and need for reproductive choices. Products also are needed to allow conception while preventing infections with HIV and other STDs.

Collaboration is important in addressing both common and individualized concerns for women addressing HIV/AIDS issues. Such collaboration should include the public and private sectors, international organizations, NGOs, the media, and women.

Donor Coordination

While the HIV/AIDS pandemic continues to grow, it is apparent that current worldwide programs and financial resources available to combat this disease are insufficient. An improved worldwide response to the pandemic in the developing world will require enormous increases in resources. Regardless of increases, it is unlikely that there will ever be adequate resources available to effectively meet all the needs associated with HIV/AIDS.

There will be a critical need for developing effective coordination mechanisms within the donor community, multilateral coordinating bodies, the private sector, and host-country governments to ensure that available resources meet the most urgent program needs. The coordination of donor efforts for HIV/AIDS will assure that the limited resources currently available will maximize the comparative advantage donors have in various program areas. For example, some bilateral donors such as USAID may have strength in service delivery programs while other bilateral donors may play important complementary roles in other areas such as policy dialogue and training. Similarly, multilateral donors such as UNAIDS and the World Bank would play important roles in coordinating the efforts of other UN agencies or organizations.

Donor coordination also will become even more important in the future as efforts increase to identify additional resources needed to combat HIV/AIDS. Increasingly, HIV/AIDS is recognized not only as a health problem but also as a development problem that adversely impacts all sectors of a developing country—education, finance, agriculture, and other labor sectors, Therefore, the search for additional financial resources must extend to funds that may be available within the budgets of these other sectors. It may be possible through effective donor coordination/collaboration to mobilize increased private-sector resources for HIV/AIDS prevention and mitigation efforts. A critical need exists for improved collaboration and coordination between those organizations that are performing biomedical research and those who are implementing programs and delivering services. Improved collaboration will allow better exchange of information about the current status, effectiveness, cost, and availability of potentially useful technologies. Likewise, organizations that implement service de-

livery may be able to contribute critical insights during research design to assure that key operational questions can be addressed during initial research endeavors.

To effectively prevent transmissions and mitigate impacts there must be coordination of various programs designed to address the entire spectrum of the epidemic. It has been shown that the key to any effective program or strategy is the full commitment by all involved, particularly the involvement and commitment of government officials at the highest levels. Serious information gaps and lack of leadership and sustained commitment on the part of government and donors have significantly slowed efforts to advance and sustain HIV/AIDS prevention and mitigation programs throughout the world.

In the protracted battle against HIV/AIDS, two of the greatest factors inhibiting effective program planning and implementation are cost and sustainability. Sustainability plays a major role in cost due to the fact that the need for repeated creation, implementation, and staffing of effective programs requires great investment. Therefore, the development of programs that are self-sustaining and easily administered at all levels of implementation is absolutely integral to countering the epidemic.

To design sustainable systems for effective prevention and mitigation, a foundation must be laid to locally train technical workers and to locally plan, manage, and implement programs. Developing linkages between various institutions and international research centers and developing regional networks of health and nonhealth experts involved in fighting HIV/AIDS, who can assist in the review and improvement of regional training curricula, will prove highly beneficial in fighting HIV/AIDS. Planning future programs must involve national and local investment in building professional and institutional capacity to ensure sustainability at all levels of administration. Working with the international community, the collective efforts of all concerned are needed to effectively address the myriad issues involved in addressing this pernicious epidemic.

The U.S. Government calls upon all nations, international organizations, and the public and private sectors to work together in effective partnerships to advance vaccine research efforts and to promote more effective use of limited technical and financial resources in the fight against HIV/AIDS.

Action Strategy

White House Office of National AIDS Policy

Role and Structure

President Clinton created the Office of National AIDS Policy (ONAP) in 1993 to provide the Federal Government with a greater focus on the issues related to the HIV/AIDS pandemic. ~~Numerous national and community based AIDS organizations suggested creating this office~~. ONAP provides broad direction for Federal AIDS policy and fosters interdepartmental communication on HIV/AIDS and also works closely with the AIDS community both in the United States and around the world. The Office Director is a member of the President's Domestic Policy Council.

The Office of National AIDS Policy created the Interdepartmental Task Force on HIV/AIDS to help better facilitate communication among the various departments and agencies of the Federal Government involved.

The Office of National AIDS Policy also functions as a liaison with Presidential Advisory Council on HIV/AIDS. The Council was established by Executive Order to provide advice, information, and recommendations to the President, the Administration, and particularly, to the Secretary of Health and Human Services, regarding programs and policies affecting or affected by HIV/AIDS. It advises the President on what the Administration can and should do to stop the spread of the pandemic; to find a cure and vaccine for HIV; to provide the best possible treatment and care to those who are infected; and to end HIV-related discrimination and intolerance.

The ~~Council~~ is uniquely positioned to play a leadership role in raising ~~unpopular~~ issues, ensuring that no affected populations are forgotten and keeping HIV/AIDS issues in the forefront of Administration priorities.

U.S. Department of State

Agency Mandate Relevant to HIV/AIDS

The Department of State is the lead U.S. foreign affairs agency. It advances U.S. objectives and interests through formulating, representing, and implementing the President's foreign policies. The United States maintains diplomatic relations with some 180 countries and also maintains relations with many international organizations. The Department of State has more than 250 diplomatic and consular posts around the world: country mission components—including embassies and consulates; and delegations and missions to international organizations.

The Department of State implements its mission through overseas posts; in its Washington, D.C. headquarters; and through other offices in the United States. In addition to representing U.S. policy and interests at these posts, the Department of State is the primary provider of foreign affairs information used to formulate policy. Information received from U.S. posts—including in-depth analyses of the politics, economic trends, and social forces at work in foreign countries—is provided to some 60 Federal agencies.

In the area of international health, the role of the Department of State is to develop and coordinate support from other nations and international bodies to raise the level of priority accorded HIV/AIDS and infectious diseases. Through the coordinating efforts of the Bureau of Oceans and International Environmental and Scientific Affairs/Emerging Infectious Diseases and HIV/AIDS Program (OES/E/EID), the Department works with USAID and other Federal agencies to develop the bilateral and multilateral partnerships for international collaborations to address the unique implications of HIV/AIDS and other infectious diseases. Through the diplomatic infrastructure, OES/E/EID negotiates cooperative agreements with other nations to establish a global surveillance and response network. It works with other agencies to enhance awareness and national capacities around the world to prevent, diagnose, report, and respond to the threat of disease.

The Bureau of Population, Refugees and Migration (PRM) coordinates efforts among the Department of State, other U.S. Government agencies, private voluntary organizations, and international agencies to implement a more comprehensive international population policy. PRM's oversight includes broadening population assistance programs to cover a wider range of reproductive health services, including family planning. It also provides assistance to refugees in first-asylum countries.

The Bureau of Democracy, Human Rights, and Labor (DRL) oversees initiatives and policies to promote and strengthen civil society and respect for human and worker rights. DRL ensures that human rights in foreign countries are taken into account in the U.S. policymaking process and submits an annual report to Congress extensively reviewing human rights practices in each country.

The President's Interagency Council on Women, which is chaired by the Secretary of State, is charged with coordinating the implementation of the Platform for Action adopted at the UN Fourth Conference on Women. The Platform recommends actions to increase women's access to appropriate, affordable, and quality healthcare, information, and related services; encourage both women and men to take responsibility for their sexual and reproductive behavior; and undertake gender-sensitive initiatives that address sexually transmitted diseases, HIV/AIDS, and sexual and reproductive health issues.

Agency Strategy for Specific Issues

Promoting Active Involvement by National Governments

The Department of State hopes to bring the message to leaders around the world that HIV/AIDS and infectious diseases are the silent enemies of economic and social development, political stability, and economic productivity. No member of the global community can afford, either in terms of human suffering or economic costs, to fail to recognize or to forestall the impending devastation that has already begun to ravage national economies, security and social infrastructure. Political commitment at the highest level of national government makes the critical difference in stemming the spread of HIV/AIDS. Where such commitment is present,

such as in Uganda and Thailand, the transmission rates are being effectively reduced.

Working through regional bureaus and embassies and missions abroad, the Department's goal is two-fold: to enhance U.S. diplomatic efforts to raise the level of priority by all governments to more effectively meet the challenges of HIV/AIDS and infectious diseases of all kinds and to enhance international collaboration on disease surveillance and response threats to reduce human suffering and to safeguard all peoples from the devastation of HIV/AIDS as a global priority.

HIV/AIDS will be introduced to a greater extent in the U.S. diplomatic and policy dialogue to underscore the recognition of HIV/AIDS as an international problem with political, social, and economic impacts that go well beyond the boundaries of the traditional health sector. Nations should address HIV/AIDS as a pandemic fueled by socioeconomic inequities, human rights issues, and questions of gender status.

The Department of State and senior officials must play a central role in raising the subject of HIV/AIDS in international fora and is redoubling efforts to put the full weight of the U.S. diplomatic infrastructure behind enhanced political commitment for overseas national action.

Recognizing the problem and promoting AIDS education and prevention programs by high-level government officials is vital to the success of AIDS prevention. Posts, through our mission-planning process, will be charged and held accountable for their active interventions to raise awareness with host-government officials. Ambassadors and other foreign policy officials at posts are directed to:

- Urge foreign leaders to openly address the HIV/AIDS pandemic in their own countries;
- Urge other governments to consider the adverse economic and social impact of HIV/AIDS in their countries;
- Urge other governments to increase spending or to reallocate funds to prevent the spread of HIV/AIDS and strengthen AIDS research efforts;
- Emphasize the importance of National AIDS Action Plans, which involve all relevant governmental agencies, ministries, NGOs, and the private sector;
- Encourage foreign leaders to support the Joint U.N. Programme on AIDS (UNAIDS); and
- Incorporate AIDS issues into foreign policy interactions with all government and international organizations.

The Department of State, through formalized briefings as part of our National Foreign Affairs Training Center curricula and by country-specific regional briefing to senior officials, is working to heighten the awareness of the foreign policy implications of HIV/AIDS to the foreign policy community through all available mechanisms.

The Department will convene regular interagency meetings to discuss the international calendar and to develop common approaches on HIV/AIDS and other infectious disease issues.

The Department of State seeks to enhance diplomatic support for HIV/AIDS programs in developing countries and HIV/AIDS vaccine research and policy collaborations with international partners.

Using the HIV/AIDS component of the Common Agenda with Japan as a model, the Department of State and USAID will pursue agreements with other donors to work more closely on HIV/AIDS in priority countries.

Promoting Human Rights

The United States regularly supports UN resolutions before the Commission on Human Rights for the protection of human rights in the context of HIV/AIDS. The resolutions set out guidelines nations may follow in dealing with the health crisis and human toll of AIDS and HIV. The resolutions also asks the UN Secretary General to solicit input from countries, specialized agencies, and related governmental and non-governmental organizations in order to provide a progress report to the Commission on followup. The next session of the Commission at which an HIV/AIDS resolution is expected for consideration will take place in March 1999.

The Department of State will continue to include HIV/AIDS-related discrimination and human rights abuses in regular embassy reporting and in its annual "Country Reports on Human Rights Practices" and represent these interests before the Human Rights Commission.

In Latin American countries, information from post reporting has been correlated with increased requests for asylum and are used by the U.S. Government to consider asylum requests. The Department works closely with the Department of Justice on these issues.

why is this limited to L.A. countries

What about U.S.-based immigration groups

The United States helped to negotiate a partnership arrangement between the Office of the High Commissioner for Human Rights (OHCHR) in Geneva and UNAIDS. It strongly supports OHCHR's efforts to mainstream human rights into the activities of other UN departments and agencies and especially the cooperation this partnership represents in combating the devastating worldwide crisis of HIV/AIDS.

U.S. Agency for International Development

Agency Mandate Relevant to HIV/AIDS

The U.S. Agency for International Development (USAID) is the global leader in developing and implementing international HIV/AIDS/sexually transmitted infections (STI) prevention and control programs. USAID's HIV/AIDS/STI mandate is to achieve a sustainable reduction in HIV/STI transmission among key populations in developing countries and to reduce the impact of the epidemic on individuals, communities, and societies in general. This mandate fits within the broader Agency goal of stabilizing world population and protecting human health in a sustainable fashion.

USAID's regional and bilateral programs are the core of the Agency's HIV/AIDS/STI prevention activities, while the central programs provide complementary technical and programmatic support. The Global Bureau, Office of Health and Nutrition, HIV/AIDS Division (G/PHN/HN/HIV-AIDS) is the Agency unit charged with the primary responsibility for developing program interventions. In collaboration with USAID field missions and other partners and stakeholders, the HIV/AIDS Division has developed a detailed strategic framework that is consistent with the overall Agency mandate and lays out a future-oriented HIV/AIDS/STI program for the next 7–10 years.

USAID's strategy continues to focus on three key approaches to HIV/AIDS prevention, each of which, over time, has had demonstrable impact in multiple country settings:

- Reducing high-risk sexual behavior through behavioral change interventions (BCI). These include not only mass and interpersonal communication strategies but also policy and legislative reforms that enhance communication strategies and campaigns and build awareness and support for health infrastructure change;
- Increasing demand for and access to condoms, mainly through condom social marketing (CSM) programs;
- Treating and controlling sexually transmitted infections (STI) and sexually transmitted diseases (STD).

The first decade of HIV/AIDS programming has revealed that effective, individually focused approaches must be complemented or supplemented by services more attuned to the environment in which individuals live and make sexual and health decisions. This implies greater emphasis on interventions that address couples, parents, and children, social networks, religion, worksites; the interaction of sexual and health beliefs; and the norms, values, and policies that determine the social and sexual context in which people live.

In addition to continuing the three major interventions stated above, the expanded strategy now includes selected basic care and psychosocial support for HIV-infected individuals and their survivors. This will enhance the prevention agenda, and slow the deterioration of economic and social development. The expanded strategy includes increased emphasis on supporting HIV/STI surveillance systems that will assist in our understanding of the growth of the epidemic, as well as allow the assessment of the impact of interventions. There are now innovative initiatives to perform operations research to identify best practice; to expand policy dialogue to include issues such as discrimination and resource allocation; to increase private voluntary organization (PVO) and non-governmental organization (NGO) capacity-building; and to conduct targeted biomedical research.

The expanded strategy responds to concerns raised by many observers (field mission staff, stakeholders, other donors, PVO/NGO representatives, and program evaluators and auditors) that USAID's HIV/AIDS/STI program interventions should concentrate on achieving well-defined program targets and results at country, regional, and G/PHN levels and should be closely coordinated with, and provide technical support to, regional bureau and field mission programs. Likewise, to expand global knowledge of the status of the regional and global HIV/AIDS epidemics, AIDSCAP formed the Monitoring the AIDS Pandemic (MAP) Network of more than 120 HIV/AIDS specialists in 50 countries with its founding partners, UNAIDS and the Harvard School of Public Health.

To operationalize the strategic framework presented above, the HIV/AIDS Division developed a

results-oriented program of grants, cooperative agreements, interagency agreements, and contracts that will continue the Agency's focus on preventing sexual transmission of HIV. This program is accomplished through the following 10 activities:

- **Horizons**: This cooperative agreement with the Population Council (and collaborating partners: International Council for Research on Women; Program for Appropriate Technology in Health; International HIV/AIDS Alliance; University of Alabama; and the Futures Group) will develop and disseminate the most effective ways of combating HIV/AIDS, through operations research, field testing of program interventions, and the review of scientific studies and publications.
- **IMPACT**: This cooperative agreement with Family Health International (and collaborating partners: Program for Appropriate Technology in Health; Population Services International Management Sciences for Health, University of North Carolina; and Institute of Tropical Medicine in Brussels) offers opportunities for field support (technical assistance, training, materials production, support for HIV/AIDS/STI programs, including the development of behavior change communication campaigns and delivery of STD clinical services and HIV/STI care programs, as well as surveillance, monitoring, evaluation, and voluntary testing and counseling) to missions and countries to implement prevention and mitigation programs.
- **AIDSMark**: This cooperative agreement with Population Services International (and collaborating partners: Program for Appropriate Technology in Health; Management Sciences for Health; International Planned Parenthood Federation; International Council for Research on Women; DKT International; and Family Health International) provides support for developing regional and country HIV/AIDS social marketing program interventions. AIDSMark will focus on the social marketing of critical public-health products that are appropriate and timely for the setting (male and female condoms, STI treatment drugs, STD diagnostics, etc.)
- **DMELLD**: This contract will offer field missions access to technical assistance for program design, monitoring, and evaluation. It will also collect technical lessons learned from all components of the portfolio and disseminate these to field missions, cooperating agencies, governments, and international donors.
- **UNAIDS**: (WHO, UNICEF, UNDP, UNICEF, UNFPA, World Bank) USAID is the lead donor to the Joint Coordinated UN Programme on HIV/AIDS (UNAIDS). UNAIDS coordinates UN activities at country level; supports national strategic planning; generates best-practice recommendations; and advocates for increased resources to combat the pandemic.
- **PVO/NGO** Capacity-Building: USAID supports this activity through four separate agreements with the National Council for International Health, International HIV/AIDS Alliance, CDC, and Peace Corps. These organizations focus on building indigenous PVO/NGO capacity through technical assistance, training, technology exchange, and institutional partnering.
- **Operations Research for Implementing the Prevention to Care Continuum**: This activity supports focused operations and applied research and provides selected technical assistance to missions and selected service delivery projects in order to address key questions regarding the prevention to care continuum.
- **Biomedical Research**: USAID provides support for biomedical research for developing selected technologies, including an effective vaginal microbicide to reduce sexual transmission of HIV/STIs; rapid, simple, inexpensive STI diagnostic tests; and realistic interventions to reduce mother-to-child HIV transmission.
- **Policy Reform**: USAID supports policy initiatives that focus on increasing commitment to prevention/care interventions, assisting with resource allocation decisionmaking, discrimination, and other key policy areas that enhance and facilitate prevention and mitigation activities.
- **Strengthening Surveillance Systems**: Through agreements with CDC, the U.S. Bureau of Census, and UNAIDS, consensus guidelines will be finalized on minimum surveillance packages for developing countries based on phase of the epidemic. Technical assistance

to missions and host governments will be available to establish and maintain credible surveillance systems, and operations research will develop and refine methodologies to estimate HIV incidence.

In addition to the strategic framework of the Global Bureau, outlined above, USAID's regional bureaus have also developed HIV/AIDS programs that are tailored to meet the needs of each region and are consistent with the Agency's overall HIV/AIDS strategic objective. Each of USAID's geographic bureaus has its own approach.

Africa Bureau—USAID's Africa Bureau provides leadership in the area of integration of HIV/AIDS activities into ongoing maternal-child health programs. It has been in the forefront for its strong support for developing a solid research and analytical agenda for HIV/AIDS. Topics include information, education, and communication strategies for behavioral change; evaluation of integration strategies; analysis of HIV/AIDS inputs from other development sectors; STD service delivery system strengthening; and monitoring/evaluation. The Africa Bureau also is a strong proponent of sensitizing policymakers to the adverse impact of HIV/AIDS on other development sectors, such as education and agriculture.

Latin America/Carribean Bureau (LAC)—The LAC Bureau's HIV/AIDS strategy focuses on countries where the majority of HIV/AIDS infections occur, e.g., Brazil, Haiti, Mexico. The LAC HIV/AIDS program approaches vary by country depending upon the country's experience level with the epidemic. In some countries, such as those in Central America, USAID's HIV/AIDS efforts stress improving the policy environment, NGO strengthening, and condom promotion. In other countries such as Brazil and Haiti, HIV/AIDS activities focus on targeting high-risk groups such as women, youth, commercial sex workers and men who have sex with men.

Eastern Europe/Newly Independent States (ENI)—HIV/AIDS programs in this region are just beginning as policymakers become increasingly aware of the significance of the skyrocketing problem in this region. HIV/AIDS specific interventions currently are being developed in Russia and Ukraine. HIV/AIDS assessment activities have been completed and initial program plans have been developed. The focus of these early program efforts will be on policy formulation, public education regarding HIV/AIDS prevention, STD/diagnosis and treatment, NGO capacity-building, condom promotion, and targeting high-risk groups such as youth and injecting drug users. USAID-financed HIV/AIDS interventions in other countries of the region remain to be developed. Some beginning HIV/AIDS education and counseling activities exist in countries such as Romania, where HIV/AIDS information is integrated within an overall women's health strategy.

Asia Near East (ANE)—This region has been identified as the site of the next wave of the HIV/AIDS epidemic. The ANE Bureau has developed a regional strategy that includes the funding of an Asia Regional Office in Bangkok, which provides critical technical support to many USAID-mission bilateral programs. The ANE regional strategy depends heavily on the services provided by cooperating agencies through agreements managed by the HIV/AIDS Division of the Global Bureau PHN Center. Many countries, such as Bangladesh, Cambodia, India, Indonesia, Nepal, and the Philippines, have developed full-scale, USAID-financed bilateral HIV/AIDS prevention programs. Other countries will rely on USAID assist-ance provided through the ANE regional bureau in close cooperation with the G/PHN/HIV-AIDS Division. The focus of these regional efforts will be on limiting cross-border and seafarer's HIV/AIDS transmission routes; developing prevention programs in low-prevalence countries; upgrading surveillance systems to improve analysis of HIV/AIDS regional trends; targeting high-risk groups such as commercial sex workers; and working on specialized issues, including the trafficking of women, condom social marketing, HIV/AIDS/STI case management, behavioral change communications, and policy advocacy. Other regionally supported activities include building and strengthening local NGO programs and identifying local sources of HIV/AIDS technical assistance.

Funding

Since 1986 USAID has committed nearly $1 billion for HIV/AIDS/STI prevention and mitigation programs in developing countries, where more than 90 percent of the current and new infections occur. The Agency has maintained an HIV/AIDS annual funding level of approximately $121 million since 1993. These resources are distributed within geographic regions in a pattern that reflects the severity of the pandemic. Approximately 45 percent of the total HIV/AIDS/STI funding goes to Sub-Saharan Africa; 17 percent to Asia/Near East; 12 percent to Latin America/Caribbean; and the remaining 26 percent is provided for worldwide programs, including UNAIDS. If, as experts predict, the severity of the pandemic shifts toward Asia, USAID will need to reconsider resource allocations to reflect the new situation. USAID provides approximately 25 percent of the UNAIDS' budget ($15 million of a total $60 million annual budget).

In spite of the fact that USAID is a major international funder for HIV/AIDS/STI prevention programs in the developing world, the financial resources available to combat the pandemic clearly are inadequate to mount an effective, truly global response in view of the steadily increasing HIV/AIDS/STI infection rates. Approximately $550 million is currently expended per year for HIV prevention and care in the developing world. This includes funding from the international donor community, loans through the World Bank and expenditure by host country governments. By comparison, the annual U.S. expenditure for HIV/AIDS/STI prevention activities domestically is approximately $700 million! In order to deal with the implications of this funding inadequacy, USAID has strategically focused its efforts on key countries and targets its programs to those most likely to transmit or acquire HIV infection. (The emphasis countries for USAID prevention and mitigation programs are listed on page 30.)

Strategy for Specific HIV/AIDS/STI Issues

Prevention

While HIV infection is deadly, it is also preventable. In the developing world, where costly, complex antiretroviral therapies are only accessible to a few, primary prevention remains the best, ~~most cost-effective~~ response to the pandemic. Some 80 percent of infections worldwide are attributed to sexual transmission. Over the past 10 years, in over 70 countries worldwide, USAID's prevention strategy has focused first on promoting and facilitating sustained reduction in sexual risk behavior and, more recently, on modifying environmental conditions, such as poverty and the subordination of women, that provoke or facilitate risk behavior.

The behavioral outcomes that increase protection against sexual transmission of HIV and STI are clear: abstinence, long-term mutual monogamy among seroconcordant partners (i.e., HIV testing status for both partners is the same), reduced rates of partner change (reduced number of partners), and correct, consistent condom use. Unfortunately, only approximately 10 percent of persons in the developing world currently have access to accurate and confidential HIV testing. However, no two countries and target audiences are alike, and USAID has learned that there is no single blueprint for prevention programs to achieve these outcomes. Rather, the agency has established a process for developing and implementing HIV prevention programs in partnership with host-country governments, nongovernmental organizations, technical experts, and intended beneficiaries. This enables USAID-funded services to reach the people at the grassroots level and are shaped to meet the needs of specific target audiences and their cultural, economic, and political environments.

The three pillars of USAID's HIV/AIDS prevention strategy respond to the principal determinants of sexual risk behavior. The first is behavior change communications, that is used to transmit information and to engage people in dialogue about HIV/AIDS, STI, reproductive health, gender power, and sexual norms—because people must understand the risks and means of protection, and must be motivated to act to protect themselves and others. The second is condom social marketing, which uses private-sector advertising and commercial distribution approaches to make condoms more widely and sustainably accessible to people who know and are motivated to use them. The third is improved STI services, including improved and more accessible curative care, partner referral, and prevention counseling, because STI infections are health threats in their own right, and because they significantly increase the risk of HIV transmission and acquisition.

Our three core prevention strategies are supported by policy dialogue, behavioral research, and

monitoring and evaluation. Improving policy dialogue, for example, through assisting community-based organizations and government officials to consult and work together, helps to shape policy and normative environments so that they facilitate rather than impede risk reduction. Behavioral research is essential for identifying and understanding risky behaviors and the populations who practice them, the characteristics and preferences of key audiences, the language and content of messages that will appeal and "speak" to particular audiences, and other site-specific details. Transferring skills in monitoring and evaluation enables USAID and our partners to track our programs, test assumptions, make mid-course corrections, and document the successes and shortcomings of our activities to inform future programming.

In nascent and concentrated epidemics, our programs prioritize work with so-called "high-frequency transmitters," such as sex workers and their clients, other men whose work takes them away from home for long periods (e.g., military, long-distance truckers), or women and men with large, open sexual networks.

USAID programs have developed an array of methods and innovative models for reaching and serving even hard-to-reach populations at risk of HIV, who often include poor, marginalized groups such as street children or people living with HIV/AIDS. Key to the success of the programs are procedures for defining specific audiences and tailoring interventions to fit the need, which have been shared among AIDS and reproductive health researchers worldwide. The AIDSCAP program alone supported over 800 projects in over 45 countries, reaching urban university students to rural traders, secondary school students to factory employees, legions of women attending antenatal care clinics to fledgling networks of people living with HIV, and private medical practitioners and pharmacists to traditional healers.

Whether focused services for localized groups or national programs reaching the general population, behavior change interventions strive for both consistency and dynamism. The most effective programs deliver not one but an array of consistent messages through multiple, mutually reinforcing channels (e.g., newspaper, radio, billboards, community theater). And while coherent, these messages need to move with the public ethos, the stage or readiness of the audience to change, and evolution of the epidemic itself. Thus, new to our programs in the second decade is a more balanced set of messages about HIV/STI prevention, HIV/AIDS care, and clarifying and defending the human rights of people already HIV positive. USAID and ~~our~~ partners across the globe have found that people living with HIV or AIDS are the most convincing educators and advocates in prevention programs, and in high-prevalence settings, communities need help in devising ways to care for families and orphans devastated by HIV/AIDS.

Creating environments where Persons Living with HIV and AIDS (PLWH) can come forward safely to serve as HIV/AIDS educators and community mobilizers requires confronting and overcoming HIV/AIDS stigma, and combating discrimination and oppression of people with or associated with HIV. This has become an important new focus in USAID's strategy for prevention. In addition, the sustainability of programs hinges upon local participation and ownership, and upon resources that require local private-sector and political support. Overcoming HIV/AIDS stigma both facilitates and follows community and policymaker support for HIV/AIDS prevention and care. In short, while carrying forward the successes of the three "pillars" (BCI, CSM, and STI interventions), plus policy dialogue, behavioral research, and monitoring and evaluation activities, USAID's HIV/AIDS prevention strategy has been expanded, based on a decade of field experience that shows the importance of preparing communities and service providers to respond to a range of individual, family, and community needs along the prevention-care continuum.

Care and Support

USAID supports care activities because they improve our efforts to achieve sustainable development, enhance overall public health, and support our efforts to prevent further spread of HIV. Rather than take a narrow biomedical view of care, USAID advocates care and support activities that are broad in nature and are critical to the continued efforts of communities, governments, and donors to promote sustainable development in the face of the HIV/AIDS epidemic. Care and support activities include:

- Protection of basic human rights;
- Psychosocial care of persons infected and affected by HIV/AIDS;
- Palliative care for persons with HIV-related symptoms such as pain, fever, or diarrhea;

- Prevention and treatment of common opportunistic infections;
- Programs that provide economic support to those communities hard hit by HIV/AIDS; and
- Support for foster and extended families for the millions of children who have been orphaned by AIDS.

HIV/AIDS care and support activities enhance sustainable development by shoring up fragile infrastructures. For example, community-based care and retraining of key personnel are essential to preserve the health and education sectors, where in some east African countries up to 40 percent of these workers are already infected with HIV.

HIV/AIDS care and support activities contribute to decreasing secondary epidemics, most notably tuberculosis. The global HIV pandemic is driving a secondary explosion of TB, which is responsible for 35 percent of the deaths of HIV-infected persons in the developing world.

HIV/AIDS care and support enhance all of our primary prevention efforts. Presenting information and education messages to include everyone in the community increases the acceptance, credibility, ownership, and ultimately the response to behavior-change messages. In addition, programs to protect the basic human rights of HIV-infected individuals and those most at risk for infection open the door for implementing far more effective behavior change campaigns. Prevention efforts, to be effective must mobilize those living with HIV/AIDS as spokespeople for change. Ultimately, the person who is carrying the virus, particularly one with multiple sexual contacts, is the single most important recruit for prevention programs promoting reduced risk behavior. If programs appear to abandon people living with HIV/AIDS and their families, or to ignore their needs and concerns, we cannot expect them to be of any help.

USAID is also supporting operational research to determine the most cost-effective ways to provide care and support to persons infected. USAID does not at this time support the large-scale procurement of antiretroviral drugs for developing countries. Using antiviral drugs in treatment regimens similar to those used in the United States would cost approximately $35 billion per year to treat those infected in the developing world. In addition to the enormous cost, these treatments require sophisticated health provider and laboratory infrastructures that do not exist in most of the developing world, where the average health expenditure per person per year is about $10.

AIDS Orphans

The number of children affected by AIDS, including those who are orphans or caring for sick parents, continues to escalate. There has been growing recognition and concern for these children. In a study funded by USAID, "Children on the Brink, Strategies to Support Children Isolated by HIV/AIDS," the U.S. Census Bureau estimated that 15.6 million children will have lost their mothers or both of their parents by 2000 in 23 countries heavily affected by HIV/AIDS. That number will increase to 22.9 million by 2010, largely as a result of the HIV/AIDS pandemic. During the Twelfth World AIDS Conference in Geneva, the problems posed by this issue were referred to as a "massive social time bomb." In 1996, USAID expanded its HIV/AIDS strategic objective to include issues related to care and support of those affected by the disease.

More recently, the Division has supported the development of a series of discussion papers focusing on issues related to care and support of persons affected by HIV/AIDS. Included among these papers is a document entitled "Responding to the Needs of Children Orphaned by HIV/AIDS," specifically focusing on the effect of the disease on youth. These papers provide background information that will be used to develop the HIV/AIDS strategy on care and support. The strategy will influence future related projects conducted by USAID cooperating agencies and missions. In addition, "HORIZONS," the HIV/AIDS operations research project, is currently exploring avenues for conducting research to develop "best practices" for setting up community-based methods of providing care and support to people affected by HIV/AIDS, including children. AIDSCAP supported care projects in Haiti, Tanzania, Nigeria, and India, and IMPACT has expanded the capacity of field projects to support community-based care services. Representatives of the HIV/AIDS division have been actively involved in meeting with other donors and organizations that are working with children and families affected by HIV/AIDS. They are also working on establishing an electronic network to exchange technical information among a wide variety of donors and other organizations. These activities contribute toward

identifying the scope of the problem, sharing information about how to address it, and coordinating activities to do so.

Women and Health

USAID recognizes that women and girls are at the epicenter of the HIV/AIDS epidemic in every community, both as positive agents of change and as individuals in need of services and support. Though not recognized as a key audience for HIV interventions until the early 1990s, in most regions women and girls represent the fastest-growing segment of the HIV+ population.

The impact of HIV/AIDS on women is not solely a function of their greater biological and social vulnerability to infection. It is also because, when family members become ill with HIV disease, the burden of care falls disproportionately on women and girls. Data from a wide range of studies on health and nutrition have confirmed the critical role women can play in improving the health of their families when they have access to information, skills, and some control over resources. USAID's HIV/AIDS programs aim to alert and mobilize communities to respond to the care needs of people living with HIV/AIDS (PLWH) without sacrificing the progress achieved in women's education and economic participation, because that progress is beneficial for all.

Finally, as noted previously, the ability of a relatively low-cost antiretroviral treatment regimen to decrease the risk of mother-to-child transmission (MTCT) has focused attention on another situation where a woman's own health and welfare may be given lower priority than the health of her children and family. By aiming to have all USAID programs examined through a gender lens, and by listening to and involving women at all stages of project identification, design, implementation, and evaluation, the USAID strategy acknowledges the complexity of women's lives and roles, and gives priority to programs and approaches that respond to their expressed concerns.

Vaccine Research

Although USAID lacks the resources to independently fund vaccine research, it has a strong interest in the vaccine development process, and it is uniquely positioned to facilitate the implementation of vaccine trials in developing countries. Because of the tremendous genetic diversity of HIV, one of the greatest challenges facing vaccine developers is to produce a vaccine that can protect against infection with diverse viral isolates. This avoids the need for many isolate-specific vaccines. However, because this type of vaccine may not be developed in the near future, there is concern that initial vaccines will be effective only against those strains of virus found predominantly in North America and Western Europe.

It is the U.S. Government view that vaccine candidates should have broad activity against the most common genetic subtypes of virus for two reasons. First is the issue of impact on the epidemic. Approximately 90 percent of all new HIV infections occur in sub-Saharan Africa and Asia, whereas about 1 percent occur in North America and Europe. In order to have an impact on the growth of the epidemic, candidate vaccines should be targeted to those strains responsible for the most new infections.

The second reason to advocate for vaccines with the broadest possible coverage is to prevent selective pressure for new epidemics. A vaccine that provides protection for only the viral subtypes currently prevalent in a community will reduce transmission of those types of virus while leaving the community vulnerable for a new epidemic caused by subtypes not covered by the vaccine.

USAID can assist the vaccine development processes in the following ways:

- Take the lead in educating stakeholders in developing countries. This task entails explaining the importance of clinical trials; making accurate information widely available; responding to questions; ensuring ethical designs; countering misinformation; and lining up high-level support from both host country and U.S. officials.
- Assist in developing the methodology of community-level interventions; fostering long-term, sustained relations with local communities; measuring indirect effects; and doing impact modeling. By working closely with local communities, USAID could ensure that they are ready to participate in clinical trials.
- Advocate for research on broad-activity vaccines.

Behavioral Research/Behavioral Change Interventions

HIV/AIDS prevention and care hinges upon changes in patterns of risky behavior—be they relating to sex, illicit drugs, or exposure to infected blood through medical waste or unsterile needles, razor blades, and other instruments. Even improvements in STI services will not fulfil their potential impact unless people with STI symptoms and signs change their help seeking behavior, and unless allopathic and traditional practitioners improve their diagnostic and therapeutic practices to recruit people at risk of STI and to satisfy them with their services. Thus, USAID supports behavioral research in our partner countries both to develop new intervention models and to adapt and apply existing models for new settings.

USAID's cooperating agencies conduct behavioral research in:

- Diagnostic studies to define the specific behaviors that put people at risk in a given setting;
- Defining of the distribution of risky behaviors in a population, so as to identify subgroups or target audiences for intervention development;
- Formative research to build understanding of the causes and meanings of risky practices and to pre-test intervention ideas and messages with the intended audience; and
- Testing and documentation of the effectiveness of interventions, where changes in behavior are key outcomes of intervention trials.

Under the AIDS Technical Support Project, completed in 1997, USAID's investment in behavioral research comprised a major increase in the resources available for studying the interactions of culture, health, gender, and sexuality in the developing world. The AIDS Behavioral Research Grants Program, funded jointly with NIH, supported partnerships between U.S. and developing-country NGOs (including universities) to revise and adapt theoretical models of health behavior to strengthen HIV/AIDS behavioral interventions in non-Western settings. The nine studies have provided baseline data for local policy and intervention development. They are also helping to build a more representative, international base for evaluating the roles of culture, society, and behavioral biology in human sexuality and health behavior and for guiding the design of behavior-change interventions appropriate for particular audiences and settings.

USAID-funded projects have established formative behavioral research as a prerequisite of technically sound intervention development. Most of our future interventions will contain data collection components that enrich the knowledge base for understanding HIV risk behavior and opportunities for prevention and care. In addition, the HORIZONS project will extend these achievements through a program of developing research to answer selected research questions in nine thematic areas: 1) STI prevention and management; 2) HIV care and support services; 3) stigma and discrimination; 4) risk assessment and behavior change; 5) policy analysis and change; 6) social marketing and private-sector involvement; 7) NGOs and community mobilization; 8) integration of HIV/STI, family planning, and maternal and child health services; and 9) community mobilization.

In addition to pursuing some relatively new topics in developing countries (e.g., HIV/AIDS stigma), USAID has mandated all projects under the Global Bureau's HIV/AIDS strategic objectives to document and develop knowledge about the following cross-cutting issues: gender inequalities and their effects on risk reduction and program success; the vulnerability of youth; involvement of PLWH in HIV/STI intervention programs; building local NGO and community-based organization (CBO) capacity; links between prevention and care services; sustainability of services; costs and cost-effectiveness of service modalities and models; and methods and costs of taking successful pilot projects to scale.

Microbicide Development

USAID has been a major contributor to the search for a vaginal microbicide. Vaginal microbicides are products that ideally can be used by a woman herself, without the cooperation or consent of her sexual partner, to protect herself from the possibility of acquiring HIV and other sexually transmitted diseases (STDs). The agency has supported laboratory work to identify and test promising compounds, as well as the Women's Health Advocates for Microbicides (WHAM), an innovative group that advocates for the product and promotes international collaboration and involvement of women at all stages of product development.

Most products that have been developed and tested in the past several years have been based on a product known as Nonoxynol-9 (N-9), which, unfortunately, has not proved effective as of this date. In collaboration with the Research Division in the Office of Population, the HIV/AIDS Division is currently supporting a trial of a new microbicide, developed with support from USAID, which has a unique mechanism of action and has been shown to be safe in preliminary studies. The study is expected to continue for approximately 2 years and provide information on safety and effectiveness of the product.

Donor Coordination

Donor coordination is key to the success of the U.S. response to the HIV/AIDS global pandemic. USAID's G/PHN Strategic Objective 4 "to increase the use of improved, effective, and sustainable responses to reduce HIV transmission and to mitigate the impact of the HIV/AIDS pandemic," includes donor coordination and partnership at global, regional, and country levels. USAID has been an active partner with the United Nations in providing financial support for international HIV/AIDS program efforts. Since 1986, USAID has been a major contributor to the WHO Global Program on AIDS. As that program terminated in 1995, USAID support shifted to a new United Nations HIV/AIDS endeavor that officially began in January 1996.

Also, in countries where USAID missions include HIV/AIDS as part of their country strategy, PHN offices coordinate closely with the Joint United Nations Programme and other donors that may be in-country. In addition, there are a series of specific donor coordination activities, including the U.S.-Japan Common Agenda, collaboration with the United Kingdom's Department for International Development (DFID), the European Union (EU), and a number of other selected partners. There are also excellent examples of strong coordination, through funded activities with national governments, PVOs/NGOs, and local organizations.

Capacity-Building

Effective HIV/AIDS programs work to sustain changes in behaviors that contribute to the risk of HIV infection and to establish, improve, and maintain systems and practices to appropriately manage the effects of HIV and AIDS. As HIV/AIDS becomes endemic in many countries, the need for programs to achieve and sustain these results over the long term is heightened. The time period to achieve sustained changes in risk behaviors and manage the effects of HIV will exceed the time frame of many external technical inputs and donor contributions. Therefore, a programming strategy that prioritizes building local capacity within the public and private sector is essential.

The USAID HIV/AIDS program works to build the local public- and private-sector response to HIV/AIDS by increasing political awareness and commitment in local government, and by increasing the technical and managerial capacity of local public, commercial, and nonprofit entities to provide services and commodities required for sustainable HIV/AIDS programs. Within the public sector, USAID and its partners work with government ministries of health and other sectors to increase:

- Political awareness of the effects of HIV and the importance of preventing HIV infection and appropriately caring for those who are infected;
- Technical quality and use of surveillance information in monitoring the epidemic and in program management and evaluation;
- Quality and reach of public-sector services needed in HIV programming, such as STI diagnosis and treatment, logistical systems for commodities (i.e., essential drugs and condoms), and training in counseling and home-based care;
- Collaborations between the public and private sector.

USAID and its partners strengthen the technical and managerial capacity of indigenous NGOs so that they have greater competence in, impact on, and influence over the design, implementation, and evaluation of sustainable HIV/AIDS prevention and care programs. USAID also works to build and improve regional and local networks and coalitions. The networks provide technical support and improve advocacy efforts by building relationships across public- and private-sector institutions.

USAID works to strengthen commercial-sector involvement by increasing the awareness of the potential impact of HIV and by building HIV-prevention programs for the business environment. In addition, some USAID programs work to leverage local commercial markets for condoms and other commodities, such as essential drugs for STI treat-

ment. Sustained local responses to HIV will depend upon public- and private-sector involvements that supplement and complement each other. As we enter the second decade of the HIV/AIDS pandemic, it is clear that the populations requiring HIV prevention and care and support services are changing and increasing. Building the capacity of local institutions to recognize these changes and respond to these increasing demands is critical in order to stem the impact of this pandemic.

Reducing Mother-to-Child HIV Transmission

Mother-to-child transmission (MTCT) is the second leading route of transmission of HIV in the world. Annually, over 590,000 infants are infected by their mothers. This transmission takes place during one of three times: before birth, during labor and delivery, or during breastfeeding.

In February 1998, researchers from the U.S. Centers for Disease Control announced the results of a randomized placebo-controlled study in Thailand. This study demonstrated that a short course of AZT given to HIV-infected women in the last trimester of their pregnancy, plus high doses of AZT during labor, could achieve a 50-percent reduction of transmission of HIV to their infants. Because this compared favorably to a much more costly and complex regimen used in developed countries, the results of the Thai study have raised global hopes that a significant reduction in the number HIV-infected infants can be achieved.

Despite the very exciting results of the Thailand study, a number of questions remain to be answered before the promise of this research can be realized. These are:

- **Breastfeeding:** The Thai study worked with a non-breastfeeding population. Can similar results be achieved in populations that breastfeed? To do so will require that mothers use infant formula in settings where this is not a common practice. What effect will the use of formula have on infectious disease deaths associated with bottle feeding. Will HIV-negative women stop breastfeeding?
- **Voluntary HIV counseling and testing (VCT):** More than 90 percent of women in developing countries do not know they are infected and have little or no access to voluntary, confidential HIV counseling and testing. How can this service be made available at a scale large enough to have a broad impact without sacrificing the quality and confidentiality of the services?
- **Infrastructure and capacity:** Many antenatal care settings in developing countries are struggling to provide basic care for pregnant women. If MTCT programs are added to existing activities, can they be carried out properly; will they achieve in practice what was seen in a clinical trial? Conversely, will the additional burden of MTCT programs compromise the quality of basic antenatal care?
- **Stigma and discrimination:** Stepped up VCT, special antenatal programs, and the use of infant formula all have the potential to reveal a woman's HIV status to the community. Women who reveal their HIV status are at a very high risk of domestic violence, stigmatization and ostracization by family, friends, and community. How can MTCT programs prevent or minimize these negative consequences?

USAID believes that before MTCT initiatives are taken to a large scale, these and other questions need to be answered. We are thus collaborating with UNICEF, UNAIDS, and host-country researchers to conduct a series of operational research studies in two or three developing countries. In 18 to 24 months these studies will give us many of the tools we need to appropriately and effectively use the recent scientific findings.

Impact of USAID Programs—Monitoring and Evaluation

At the country level, we can now point to two major categories of success. In one set of countries (e.g., Senegal, Philippines, Indonesia), early, comprehensive HIV intervention programs, supported by USAID and other donors, have helped curtail and prevent a major epidemic. For example, USAID-supported prevention campaigns that included policy dialogue, behavior change efforts, better treatment of STDs, and improved access to simple technologies like condoms to reduce HIV transmission.

Even more dramatic, we now see another set of countries (e.g., Uganda, Dominican Republic, Thailand) where intensive HIV/AIDS programs were

launched after major epidemics had erupted, yet the numbers of new infections are now actually coming down. For example, sentinel surveillance in Ugandan antenatal clinics shows that the rate of HIV has fallen by 35 percent among young women aged 15–24. In Thailand, USAID supported an intervention study that developed an educational and sexually transmitted infections screening program that was expanded for the entire military. The rate of new infections among military recruits fell from 3 percent to under 1 percent as a result. These are amazing achievements, every bit as significant as the breathtaking progress in HIV treatment in the United States.

Our ability as a global community to achieve these reductions in new infections is predicated on a basic lesson learned from the past 10 years of program implementation: We can reduce unsafe sexual behavior in a sustainable way. We now have ample evidence that public health programs can affect change in the most private and basic of human behaviors, sex. While it is impossible to attribute declining national HIV rates to any single program, USAID-funded research has shown that people are responding to widespread, consistent education messages about HIV/AIDS prevention and care and to dramatic increases in the availability of key tools and services.

USAID's evaluation research in poor urban neighborhoods in the Dominican Republic where our program works found that rates of sexually active youth declined from 73 percent in 1993 to 30 percent in 1996, and rates of participation in "transactional sex" (exchanging food, money, school fees, etc., for sex)—declined from 27 percent to 7 percent among males. The proportion of Ugandan girls who have ever had sex declined by almost half between 1989 and 1995. Over half of young sexually active Ugandans report using condoms in their last sexual contact; this rate was close to zero at the outset of the epidemic. In Bali, Indonesia, USAID's peer education project with sexually active 15- to 25-year-olds led to an increase in consistent condom use from 22 percent to 72 percent.

operates?

USAID's HIV/AIDS-Assisted Countries

Africa Regional	Asia Near East Regional	Eastern Europe/ Newly Independent States Regional	Latin America/ Caribbean Regional
Benin	Bangladesh	Russia	Bolivia
Congo (Kinshasa)	Cambodia	Ukraine	Brazil
Ethiopia	Egypt		Dominican Republic
Ghana	India		El Salvador
Kenya	Indonesia		Guatemala
Madagascar	Laos		Haiti
Malawi	Morocco		Honduras
Mali	Nepal		Jamaica
Niger	Philippines		Mexico
Nigeria	Vietnam		Nicaragua
Senegal			Peru
South Africa			
Tanzania			
Uganda			
Zambia			
Zimbabwe			

U.S. Information Agency

Agency Mandate Relevant to HIV/AIDS

The U.S. Information Agency's (USIA) mission is to promote the national interest and national security of the United States through understanding, informing, and influencing foreign publics regarding U.S. foreign and domestic policies (including HIV/AIDS policies). It acts to broaden dialogue between American citizens and institutions and their counterparts abroad. USIA's public diplomacy strategy regarding USAID's policies extends throughout the year and employs a full range of public diplomacy tools. These include:

- Distributing policy information to foreign media, academics, and other government and civic opinion-makers through U.S. Information Service (USIS) posts at U.S. embassies abroad;
- Arranging speaking tours and programs/seminars abroad for U.S. experts on AIDS issues.
- Broadcasting policy information on Voice of America (VOA) radio and USIA television services and providing foreign publics with language-version news clips, editorials, and interactive dialogues featuring prominent U.S. experts and "best practices" of American individuals and communities meeting the challenge posed by AIDS and other infectious diseases. For example, VOA gave worldwide coverage to World AIDS Day last December 1 in all 52 languages in which VOA broadcasts.
- Publishing policy statements and analysis on the USIA International Homepage, which includes frequently updated information for USIS field officers to use to alert foreign leaders, NGOs, journalists, and healthcare specialists to the threat of AIDS-related health issues and responsibilities of the international community. This information is supplemented with timely reports highlighting American and foreign achievements and cooperative efforts in combating AIDS.
- Publishing a USIA electronic journal on "Infectious Diseases/The Global Fight." The 40-page journal features commentaries by Dr. Anthony Fauci, U.S. Surgeon General Dr. David Satcher, and USAID Director J. Brian Atwood, among other articles.
- Organizing briefings by senior U.S. AIDS experts for foreign journalists at USIA's Foreign Press Centers in Washington D.C., New York, and Los Angeles (as appropriate).
- Developing U.S. programs for international visitors, including discussions and briefings on AIDS policies and issues, such as treatment, prevention, and research efforts.

Funding

The funding level dedicated to HIV/AIDS programs by USIA is difficult to assess. Much of the programming conducted by the Agency is electronic, e.g., VOA broadcasts, WORLDNET TV programming, and the electronic journal (published in November 1996). There is no specific budget for these programs, other than staff salaries and overhead expenses. However, in addition to these programs, USIA exchanges under the Fulbright, International Visitor, and U.S. Speaker programs budgeted $655,200 in FY–1998 on HIV/AIDS programs. This figure has been relatively constant since 1995.

Agency Strategy for Specific Issues

The U.S. Information Agency is a multifaceted public diplomacy organization that uses its multilingual electronic and print media outlets and its educational and exchange programs to give broad support to policies aimed at combating HIV/AIDS.

U.S. Peace Corps

Agency Mandate Relevant to HIV/AIDS

Peace Corps' efforts in HIV/AIDS education and prevention is divided into three spheres of activities: (1) education efforts targeting Peace Corps employees; (2) education efforts targeting Peace Corps volunteers (hereinafter "volunteers"); and, (3) prevention efforts conducted by Peace Corps volunteers targeting the people in the countries in which the volunteers are serving. The focus of this document is on the third sphere—the work that the volunteers do in the communities in which they serve. To date, the Peace Corps' HIV/AIDS prevention and education activities are being conducted in 48 countries around the world.

Peace Corps does not earmark any of its appropriated budget to a technical area such as HIV/AIDS. Rather, the agency funding is used to recruit, place, and support volunteers—many who then work in HIV/AIDS efforts. Peace Corps does receive funding from USAID through an interagency agreement to support some of its HIV/AIDS activities. In FY-1999, these resources will equal $450,000.

Agency Strategy for Specific Issues

Prevention

The focus of Peace Corps work is in prevention, specifically, targeting women and youth. Since the mid-1980s when HIV/AIDS was first identified, volunteers have been working to help individuals and communities understand the disease and to collectively develop solutions for ways communities can protect themselves and care for those who become ill. In December 1988, the Peace Corps and the Government of the Central African Republic negotiated the first formal agreement to place volunteers in HIV/AIDS education. Since then, the pace of volunteers' involvement has increased dramatically, both in number of volunteers engaged in HIV/AIDS work and in the range of activities.

Peace Corps volunteers work in some health projects focused solely on HIV/AIDS; community health projects that also have an HIV/AIDS prevention component; projects that are not primarily involved with health, e.g., education projects; and community outreach activities undertaken by the volunteers in addition to their main assignment.

The four major programmatic areas that the volunteers work in are:

- NGO and community-based organizations (CBO) development in HIV/AIDS;
- Integrated community health approaches to HIV/AIDS prevention and care;
- Programs for women and girls; and
- Programs for youth, both in and out of school.

The Peace Corps meets these objectives largely through training and educational activities that build host-country capacity in project planning, monitoring/evaluation, and organizational management.

An example of the kind of work that volunteers do is illustrated in the participatory development of a unique, low-cost, content-based approach to English-language instruction, "Teach English, Prevent AIDS" project in Cameroon. Education volunteers, Cameroonian educators, and public health specialists worked together to draft 50 hours of lesson plans. To date the program has provided behavior change education to 300 teachers and 10,800 students, all of whom were also engaged in community-based HIV/AIDS prevention campaigns through the learning process. The manual, published with private-sector support, and the curriculum development process itself are being considered by UNAIDS as an international model for student and community education. The program is sustained as a part of the curriculum and has been adapted by multiple Peace Corps posts to use throughout Africa and the rest of the world.

Volunteers have a viable role to play in HIV/AIDS prevention and education overseas. Most importantly, volunteers are successful in accessing communities that are often not reached by National AIDS Programs and in introducing new innovative education methods to achieve their outreach.

Although not quantified, there is a growing number of volunteers who, based on their experiences overseas, return to the United States and continue to work in HIV/AIDS prevention in their communities. Bringing the lessons home is a valuable contribution that the Peace Corps makes to the domestic efforts in HIV/AIDS work.

U.S. Department of Health and Human Services

National Institutes of Health

Mandate Relevant to HIV/AIDS

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

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

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

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

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

The OAR promotes collaborative research activities in both domestic and international settings. These research studies are conducted by the Institutes and Centers of the NIH, including the NIAID, National Cancer Institute, National Institute of Child Health and Human Development, National Cancer Institute, National Institute of Mental Health, National Institute on Drug Abuse, FIC, and other organizations (see NIH funding chart, page 34).

The "Levine Report," produced by a group of non-government scientists and AIDS community representatives convened to evaluate the NIH AIDS research program, has had a significant effect on almost every aspect of the AIDS research program

—in setting the scientific agenda, refocusing priorities, and shaping the AIDS research budget. The recommendations helped frame the OAR's final distribution of the NIH AIDS appropriations for fiscal years (FY) 1997 and 1998. In addition, the Levine Report significantly influenced the priority setting that occurred in the development of the FY–1999 NIH Plan for HIV-Related Research and Budget, which the OAR is congressionally mandated to develop in concert with the annual NIH AIDS research budget request. The priorities established by the Levine Report will have an impact not only on government-supported research but on the research agendas of industry and private research organizations in the United States and abroad.

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

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

- A continued increased emphasis on fundamental science, particularly investigator-initiated research;
- A comprehensive effort, including several important new research initiatives, to develop new vaccine candidates and bring them to clinical trials as soon as possible;
- An augmentation of research efforts to better understand the human immune system; and
- An emphasis on prevention science research, including enhanced domestic and international studies of risk-taking behavior and the development of strategies to avert infection, such as microbicides, female-controlled barriers, and STD treatment and prevention.

National Institutes of Health

International AIDS Funding

(in thousands of dollars)

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

Strategy for Specific Issues

Prevention

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

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

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

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

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

Behavioral Research/ Behavioral Change Interventions

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

havioral change. NIH-sponsored behavioral and social science research includes research related to the following goals:

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

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

Vaccine Research

The development of a safe and effective HIV vaccine is of the highest priority for the NIH, and NIH has pledged to work with the other G–8 nations on vaccine efforts. NIH supports a broad program of basic, preclinical, and clinical research on the discovery and development of HIV vaccine candidates. Basic research on HIV and the immune system provides crucial information for developing potential vaccines. Various strategies for stimulating a protective immune response against HIV infection are being explored through basic research, animal model research, and clinical trials. In recognition of the need to develop vaccines that are efficacious against a variety of strains found around the world, NIH supports studies analyzing genetic and antigenic variation of HIV and targeted toward eliciting cross-reactive immune responses. While the goal of preventive vaccines is to end the HIV pandemic by protecting individuals from HIV infection, vaccines also may serve as immunomodulators to improve immune function and slow disease progression in infected individuals and may prevent them from infecting others.

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

The NIH supports an AIDS Vaccine Evaluation Group (AVEG), which consists of six sites nationwide that are actively evaluating potential HIV vaccines in phase I and II clinical trials. To date, the AVEG has conducted or initiated more than 30 trials with 19 different HIV vaccine candidates. All vaccine candidates to date in AVEG phase I trials have been shown to be safe and well tolerated. In preparation for phase III clinical trials, NIH supports a domestic and international network of sites that are currently identifying the cohorts of populations at risk for HIV infection and building the infrastructure necessary to conduct large-scale efficacy trials of potential HIV vaccine candidates when they become available. These efforts involve strengthening in-country research capacity by training foreign scientists and health professionals. NIH collaborates with UNAIDS, host country governments, and in-country scientists in vaccine development and preparation for efficacy trials. Eleven sites have been established in Africa, Asia, and Latin America.

Treatment Equity

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

Women and Health

NIH supports an extensive portfolio of basic, clinical, and behavioral research focusing on women and HIV/AIDS. HIV-infected women experience some complications of HIV disease that are

unique or more prevalent in them than in men, such as vaginal and esophageal candidiasis, chronic herpes simplex infections, other STDs, and cervical dysplasia. NIH-sponsored programs target studies on the natural history and epidemiology of the disease in women through a number of studies in Africa, Asia, and Latin America.

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

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

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

Microbicide Development

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

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

Other Activities

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

The NIH has the primary responsibility for the Federally-supported clinical trials evaluating potential treatment regimens against HIV infection and

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

Centers for Disease Control and Prevention

Mandate Relevant to HIV/ADS

The National Center for HIV, STD, and TB Prevention (NCHSTP), as one of seven National Centers within the Centers for Disease Control and Prevention (CDC), is responsible for public health surveillance, prevention research, and programs to prevent and control HIV infection, AIDS, other sexually transmitted diseases (STDs), and tuberculosis (TB). Center staff work in collaboration with governmental and non-governmental partners at community, state, national, and international levels, applying well-integrated multidisciplinary programs of research, surveillance, technical assistance, and evaluation.

NCHSTP translates knowledge about effective methods of preventing HIV/AIDS into nationwide strategies that reach people in communities throughout this country. NCHSTP collects national data on HIV/AIDS incidence and prevalence, and related behaviors; monitors change over time; conducts epidemiological, laboratory, clinical, and behavioral research; and develops and evaluates prevention strategies. NCHSTP works closely with its partners in state and local health agencies, national and community-based organizations, business, and academia to design, test, and disseminate prevention programs that work.

The Division of HIV/AIDS Prevention-Surveillance and Epidemiology (DHAP/SE) conducts surveillance and epidemiologic and behavioral research to monitor trends and risk behaviors and provides a basis for targeting prevention resources. In addition to work within the United States, DHAP/SE is active in surveillance, research, prevention, evaluation, and technology transfer activities in developing countries.

The Division of HIV/AIDS-Intervention Research and Support (DHAP/IRS) conducts behavioral intervention and operations research and evaluation, and provides financial and technical assistance for HIV-prevention programs conducted by state, local, and territorial health departments, national minority organizations, and training agencies.

Funding

In FY–1997 CDC received approximately $634 million in funding for HIV/AIDS prevention and associated research and evaluation; DHAP/IRS received approximately $330 million and DHAP/SE received approximately $102 million. Of this latter total, approximately 10 percent or $10 million was dedicated to international activities.

Agency Strategy for Specific Issues

Prevention

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

Field-based Research

Field-based research provides collaborative assistance to two developing countries. Through collaborative agreements with the Governments of Côte d'Ivoire (Project RETRO–CI) and Thailand (HIV/AIDS Collaboration), DHAP/SE participates in studies designed to increase the understanding of the epidemiology of HIV–1 and HIV–2 infections and to evaluate intervention methodologies in the host country and the United States.

Project RETRO–CI

This project in Côte d'Ivoire is an HIV/AIDS epidemiologic research collaboration between the CDC and the Republic de Côte d'Ivoire, Ministry of Health and Social Affairs. A broad spectrum of epidemiologic research has been conducted at Project RETRO-CI since its inception in 1988. This research has served to define the magnitude of the HIV/AIDS epidemic in Côte d'Ivoire and to describe which subpopulations have been most affected. It also has described the clinical manifestation of HIV–1 and HIV–2 infections; studied in detail the modes of transmission and transmissibility of HIV–1 and HIV–2 by heterosexual, blood product, and mother-

to-child routes; defined causes of death in HIV-infected persons; studied the response to therapy in HIV-infected patients with tuberculosis; and studied the laboratory serologic diagnosis of HIV-1 and HIV–2 infections. The research agenda is now dominated by clinical trials of interventions to prevent transmission of HIV and to reduce HIV-associated mortality.

CDC-Thailand HIV/AIDS Collaboration

The objective of the HIV/AIDS Collaboration is to conduct research and related activities pertaining to HIV infection and AIDS in Thailand, to improve understanding of the disease and the dynamics of its spread in Thailand and to provide a scientific basis for the development, planning, and monitoring of intervention programs to prevent and control HIV infection and AIDS. The collaboration has conducted epidemiologic and laboratory research to examine maternal-child transmission, heterosexual HIV transmission, HIV transmission among injection drug users, HIV transmission via blood, molecular epidemiology of HIV transmission and tuberculosis, and tuberculosis drug reactivity and resistance. Increasingly, the research agenda is oriented toward evaluation on interventions to prevent HIV transmission.

HIV Variant Project

The Division of HIV/AIDS Prevention in collaboration with the National Center for Infectious Diseases, has conducted international surveillance of the genetic diversity of HIV. This investigation has involved establishing research collaborations in numerous countries throughout the world. To date, genetic analysis of HIV variants has been conducted in the following countries: Bahamas, Brazil, Cameroon, Central African Republic, China, Côte d'Ivoire, Honduras, Kenya, Morocco, Thailand, Trinidad and Tobago, Uganda, Uruguay, and Zaire.

Technical Assistance

CDC currently has placed three staff in the field to provide long-term technical assistance and management capacity to two USAID-funded HIV prevention interventions in Uganda and in South Africa. CDC staff works in conjunction with USAID and the host government in the provision of technical expertise to ongoing HIV prevention interventions. CDC has also expanded its field-based technical assistance and training through the placement of a CDC staff person in Vietnam.

In addition to these field-based staff, CDC provides short-term technical assistance and training to numerous countries, including Brazil, Russia, South Africa, and Mali. CDC also plans to provide technical assistance and training to India as part of an HHS memorandum of understanding.

Short-Term Training

In conjunction with these technical assistance activities, CDC provides training in the areas of epidemiology, evaluation, prevention methodologies, and other technical areas through an extensive program of training based in Atlanta as well as at field sites in Thailand and Côte d' Ivoire.

USAID Resource Sharing Agreement

CDC recently signed a resource sharing agreement with USAID which will provide funding for two new international activities. The first activity will develop three pilot programs designed to link U.S.-based community organizations and their prevention interventions with counterparts in developing countries in order to establish mechanisms to share relevant experiences, provide materials and resources, and training opportunities across countries. The second program will provide USAID-assisted countries access to CDC epidemiologic and surveillance expertise.

Strengthening Public Health Infrastructure

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

Food and Drug Administration

Mandate Relevant to HIV/AIDS

The Food and Drug Administration (FDA) is the only agency within the U.S. Public Health Service whose responsibilities are regulatory in nature. Its purview is product-driven and encompasses products worth approximately 25 percent of the U.S. gross national product. FDA activities respond to product applications—the agency reviews what is brought to it and does not establish priorities for spending.

FDA's level of commitment to prevention, diagnosis, and treatment of HIV/AIDS is broad-based. FDA, like all of its component agencies in the U.S. Public Health Service, is committed to finding more and better ways to prevent, diagnose, and ultimately cure HIV/AIDS.

Funding

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

Agency Strategy for Specific Issues

Prevention

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

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

Blood and Blood Products. FDA is responsible for ensuring the safety of the U.S. blood supply. Regulatory mechanisms designed to ensure blood safety include establishing policies; approving authority for blood products and establishments; and surveilling and enforcing blood safety standards. The blood safety system FDA has established consists of five layers of overlapping safeguards that start at the blood collection centers and extend to the manufacturers and distributors of the blood products made from donated blood.

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

Treatment Equity

Therapeutic Agents. FDA is responsible for approving safe and effective drugs and biologics used in the United States for treating HIV infection, AIDS, and AIDS-associated opportunistic infections. FDA is also responsible for regulating the investigation of new drugs. It places special emphasis on ensuring the most timely and efficient premarketing review possible of products that offer promise for diagnosing, treating, or preventing HIV and HIV-related illnesses. FDA has approved 37 applications for products to treat HIV/AIDS. Twelve drugs are to treat HIV infection and 25 are to treat HIV/AIDS-related opportunistic infections.

Vaccine Research

Within the framework of the Public Health Service-wide vaccine program for prevention and therapy, FDA is continuing its efforts to guarantee

that any promising products for immunization against HIV will receive expedited regulatory review, and when appropriate, will be approved in the shortest possible time.

Diagnostic Capability

Diagnostic Reagents and Test Kits. FDA conducts a variety of regulatory, testing, and research activities to approve for marketing satisfactory test methodologies for detection of HIV. FDA has approved 6 HIV–1 antigen tests; 20 anti-HIV–1 assays; 3 anti-HIV–2 assays; 1 anti-HIV–1 assay; 1 anti-HIV–1 testing service; 1 anti-HIV–1 oral specimen collection device; and 1 HIV–1 viral load assay.

U.S. Department of Commerce

Agency Mandate Relevant to HIV/AIDS

The mission of the Department of Commerce is to foster, serve, and promote U.S. economic development and technological advancement. Data collection and analysis programs conducted by the Bureau of the Census and the Bureau of Economic Analysis affect the distribution of funds and other resources for private and public health initiatives, including HIV/AIDS research, treatment, and service programs. The Bureau of the Census maintains the broadest and most current numeric database in the world on HIV prevalence and incidence information for sub-Saharan Africa.

Scientific standards, methodologies, and technologies developed through the programs of the National Institute of Standards and Technology (NIST) affect laboratory procedures and equipment calibration at HIV/AIDS research facilities. The Patent and Trademark Office Biotechnology Examining Groups review and research patent applications for immunological testing apparatus and processes, apparatus for chemical and clinical analysis, immunoassay and pharmaceutical compositions, and apparatus and processes related to sterilization, cell biology, and blood and blood products.

Agency Strategy for Specific Issues

Vaccine Research and Other HIV/AIDS-Related Research

Patent Database. On its homepage on the World-Wide Web, the U.S. Patent and Trademark Office provides a searchable database containing the full-text and images of patents related to AIDS research. This free service is available to anyone with access to the Internet, in the United States or internationally. Currently, there are almost 3,000 U.S. patents available for searching, as well as almost 800 Japanese patent documents and approximately 700 European patent documents in this database. This project was coordinated by the Patent and Trademark Office and the National Science Foundation and developed in cooperation with private and non-profit organizations.

Advanced Technology Program. The Department has funded biotechnology development projects through NIST's Advanced Technology Program (ATP). The ATP is a unique partnership between government and private industry to accelerate the development of high-risk technologies that promise significant commercial payoffs and widespread benefits for the economy. The ATP encourages a change in how industry approaches R&D, providing a mechanism for industry to extend its technological reach of what can be attempted. The ATP supports enabling technologies that are essential to developing new products, processes, and services across diverse application areas. Private industry bears the costs of product development, production, marketing, sales, and distribution.

ATP awards are made strictly on the basis of rigorous peer-reviewed competitions designed to select those proposals that are best qualified in terms of the technological ideas, the potential economic benefits to the nation, and the strength of the plan for eventual commercialization of the results. One project currently being funded through the ATP is a project on the Evolution of a Murine Model for AIDS: Applications to Discovery of Small Molecule and Vaccine Therapeutics. This project aims to provide a small-animal model for research on AIDS therapies and vaccines by developing a variant of HIV-1 that will replicate in mice. This approach will be less expensive than the current practice of using primates and has the potential to accelerate discovery and improve the quality of new AIDS therapies and vaccines.

Accelerated Processing of Patent Applications. The Patent and Trademark Office offers accelerated processing of applications for inventions related to HIV/AIDS.

Trade. The Department of Commerce works closely with the U.S. pharmaceutical and biotechnology sectors in the battle against HIV/AIDS. Commerce is proud that the U.S. industry is one of the leaders in

research and development that produces new medical products to combat HIV/AIDS. Through Commerce trade missions and seminars, the Department works with industry to spread information about new medical products and discoveries in the pharmaceutical and biotech areas. Commerce will work with industry and other governments to create a trade environment that maximizes the exposure of new HIV/AIDS treatments. It will continue to combine efforts with industry, non-governmental organizations (NGOs), and other government agencies in a coordinated effort against the HIV/AIDS epidemic.

HIV/AIDS Surveillance. The U.S. Bureau of the Census, International Programs Center, compiles, evaluates, and analyzes selected health and related data for all countries overseas. With funding from USAID through an interagency agreement. the Health Studies Branch maintains and updates the HIV/AIDS Surveillance Data Base, which is a compilation of information on HIV prevalence and incidence from all available studies from Africa, Asia, Latin America, and some select countries in Europe. Using this information, the Bureau of the Census tracks patterns and trends in HIV infection among subpopulations within countries. This information is then used to estimate AIDS mortality and is incorporated into our world population estimates and projections. These estimates are available from the Census Bureau's International Data Base.

The International Programs Center has been designated a UNAIDS Collaborating Centre and contributed to the development and production of the UNAIDS Epidemiological Fact Sheets.

U.S. Department of Defense

Agency Mandate Relevant to HIV/AIDS

The threat that HIV/AIDS poses to the capabilities and readiness of the U.S. military forces is of great concern. In response to that threat, the military research program was initiated in 1986 to minimize the impact of HIV on military readiness by monitoring the spread of HIV infection in military forces and developing methods to prevent infection. This Tri-Service effort is a highly targeted research program, which addresses the military concerns of HIV. This includes surveilling infection rates and HIV subtypes around the world; developing vaccines and education strategies to prevent infection; and originating clinical studies to slow progression and prevent immune deficiency.

The Military HIV Research Program has as its primary goal the prevention of HIV infection in the fighting force. Once infected, the soldier, sailor, airman, or marine is, irrevocably, a casualty, and that service member and his or her family and the country will feel the effects—physically, emotionally, and economically. Knowledge that HIV infection is possible and that HIV is present in the environment can have deleterious effects on unit morale and cohesion of deployed forces. Preventing HIV decreases casualties and improves unit effectiveness; helps protect the replacement blood supply; and preserves the available recruitment population in the civilian community.

Agency Strategy for Specific Issues

Vaccine Research

The Program's preventive vaccine strategy involves developing several vaccine candidates in concert with industry, academia, and collaborators in Thailand. An initial Phase I safety trial of an HIV recombinant protein vaccine was successfully completed in Thailand in 1997. The vaccine was safe and well tolerated, with immunogenicity similar to that observed in U.S. trials. This current trial is the first of its kind to match the HIV vaccine to the HIV subtype of the population. The Program is conducting the first Phase II vaccine trial with a vaccine prepared from HIV subtype E, which is prevalent in the population of Thailand. The Military Program has a comprehensive vaccine development strategy with clear milestones leading to a large-scale efficacy evaluation of candidate vaccines in the year 2001.

The military research program is highly leveraged through cooperative development initiatives with private industry. In 1998 alone, three new cooperative research and development agreements were established, and two new HIV candidate vaccines have entered Phase I trials at the Walter Reed Army Institute of Research (WRAIR) and the Army overseas laboratory in Thailand.

Cooperation and coordination with other Federal agencies (including NIH/National Institutes of Allergy and Infectious Diseases and the Centers for Disease Control) and international agencies (WHO and UNAIDS) and a strategic alliance with the Royal Thai Government has resulted in an unprecedented opportunity to conduct advanced development and testing of protective vaccines.

Regarding vaccine testing, an initial Phase I vaccine trial of an HIV DNA vaccine began in 1998 with volunteers at WRAIR. Another protocol for an HIV vaccine involving unique boosting strategy with a novel envelope protein also began at WRAIR. The Military Program has secured a commitment from several of its industrial partners to produce large batches of these vaccines and plans to proceed with a large-scale multiple-arm efficacy vaccine trial in Thailand. The possibility of conducting vaccine trials in East Africa is also being investigated where it would be possible to test the effectiveness of vaccines against the subtypes of HIV found in Africa. Continued development and testing of second-generation vaccines with significantly improved biological properties generates optimism for the rapid advancement of vaccines effective against the various HIV subtypes found throughout the world.

In the area of diagnostic and clinical research, the Program is working on post-exposure prophylactic measures to deal with mass casualty situations in HIV-endemic areas overseas involving U.S. military personnel. These emergency situations require using rapid, sensitive diagnostic field tests for HIV, which are currently being developed and evaluated. In a clinical study, the Program has as-

sessed using an HIV gp160 vaccine as therapy for persons already infected with HIV. The results of this long-term, Phase II study involving over 600 volunteers demonstrated that the amount of virus—a patient's viral load—predicts disease progression. In addition, certain antibody responses altered disease progression so that the production of these antibodies will be the target of future vaccine development. In another clinical research project, there is an ongoing effort to monitor the development of resistance to antivirals in patients receiving triple drug therapy. This will assure the most effective use of these drugs while extending the lives and health of HIV infected military healthcare beneficiaries.

Finally, DOD representation and numerous presentations of DOD conducted research have occurred at HIV/AIDS international meetings.

National Intelligence Council

Mandate Relevant to HIV/AIDS

The intelligence community and its various components produce analyses on the scope and impact of HIV/AIDS in response to Presidential decision directives, the needs of their associated agencies, and ad hoc requests from senior policymakers.

Strategy for HIV/AIDS Issues

The National Intelligence Council will produce an assessment on the global threat from infectious diseases, including HIV/AIDS; the capacity of foreign governments and international organizations to deal with such diseases; and the implications for the United States.

The Defense Intelligence Agency's Armed Forces Medical Intelligence Center (AFMIC) will continue to assess systematically worldwide HIV/AIDS incidence and prevalence. AFMIC also will forecast the impact of HIV/AIDS and other infectious diseases on U.S. national security interests and deployed forces. It will also will examine the impact of such diseases on foreign military force readiness, military and civilian healthcare infrastructures and transnational health trends.

Other intelligence community collection and analytical components will focus on HIV/AIDS issues as necessary and upon authorized request.

Role of the Pharmaceutical Industry

Mandate Relevant to HIV/AIDS

In general, the role of the pharmaceutical industry is to find sustainable long-term solutions that will marshal the expertise and resources of all stakeholders to improve the health of those infected with HIV/AIDS, and to help establish balanced approaches to education, prevention, and treatment of HIV/AIDS. Effective responses to the HIV/AIDS challenge must take into consideration all the relevant factors such as available therapies and their applicability for developing countries, medical infrastructure, available resources, disease awareness and prevention initiatives, and national commitment and leadership to make HIV/AIDS a public health priority.

The principal role of the research-based U.S. pharmaceutical industry in confronting HIV/AIDS (in the developing world) is to continue to marshal the expertise and capacity in basic biomedical research and drug development to discover new and more effective treatments, make treatments more affordable and, in the longer term, to develop an effective HIV vaccine.

As corporate entities, the pharmaceutical industry seeks a return on the sizable investment for research and development of new drugs. Annually, the U.S. pharmaceutical industry spends approximately $2 billion on research and development of HIV/AIDS-related drugs. As citizens of the larger global community, however, the industry has a commitment to bring to bear its vast resources to help those in need.

The research-based U.S. pharmaceutical industry is also well-positioned to provide input in the area of national health education and policy through contacts with government and health agencies around the world. This expertise should supplement the responsibilities and expertise of other members of the world health care community, both public and private.

Strategy for Specific Issues

Prevention

Major U.S. companies are active across a broad front to try to improve the quality, delivery, and outcome of HIV/AIDS care in the developing world. The pharmaceutical industry has aggressively pursued prevention and treatment efforts for HIV and related illnesses. Although not uniformly available, the following is a summary of the pharmaceutical sector's efforts.

- A new class of drugs called non-nucleoside reverse transcriptase inhibitors became available for use in combination therapy.
- There are more than 120 new medicines for HIV/AIDS in development, including:
  - 40 antiviral medicines, including new protease inhibitors;
  - 23 medicines to fight AIDS-related cancers such as Kaposis sarcona;
  - 12 vaccines;
  - 12 immunomodulators designed to stimulate the patient's own immune system to fight the HIV virus;
  - 11 anti-infective medicines to fight against such deadly diseases as Pneumocystis carinii pneumonia, a lung infection that affects eight out of ten AIDS patients;
  - 8 antifungal medications aimed at thwarting fungal infections that can prove deadly to people with compromised immune systems; and
  - 5 gene therapies designed to genetically alter cells in patients' bodies to make them more resistant to the HIV virus or to alter the virus itself.
- Two protease inhibitors have been approved to treat children with AIDS.
- A new medicine that combines two widely prescribed AIDS drugs in a single tablet has been approved by the FDA, a first important step toward simplifying the highly effective, but complex, combination drug therapy.
- The treatment of HIV-positive pregnant women with an antiviral drug has shown to be highly effective in preventing transmission of the virus to babies, even in women with advanced AIDS.

- In 1997, a pharmaceutical became the first HIV therapy simultaneously cleared for use both in adults and in children 2 through 13 years of age.
- Recent needle destruction devices that electrically oxidize all types and sizes of needles immediately after use have brought new engineering controls to sharps containment.

In light of this progress, the most beneficial solution to the HIV/AIDS challenge worldwide would be the prevention of new HIV infection via a safe and effective vaccine, especially for those areas of the world where antiretroviral therapy is not yet feasible or practical.

A vaccine, however, will require adequate distribution and supply programs. In some disease areas where vaccines exist, for example, there are insufficient mechanisms for funding and supplying vaccines. To increase the availability of needed pharmaceuticals, the pharmaceutical industry must work with nations to build a cooperative relationship and to develop appropriate expertise and infrastructure to facilitate distribution.

Treatment Equity

The conventional view is that there needs to be greater equity in access to treatments between patients in developed and developing countries. Although this is a straightforward and laudable goal, the issue is complex. In many developing countries, the lack of medical infrastructure and a basic health care system undermine best efforts to make advanced AIDS therapies more widely available. Even if an unlimited amount of drugs were made available, access to HIV/AIDS therapies in the developing world may be thwarted by the lack of basic medical care, poor infrastructure, and the lack of political will and leadership at national levels. In addition to battling the complex HIV/AIDS problem, developing countries are faced with the dilemma of allocating scarce resources to effectively implement prevention, education, and treatment programs and deal effectively with the complex social, cultural, and economic factors involved in improving health.

In many respects, price is not the only issue. Even at a substantially lower price, many of the world's poorest regions still would not be able to obtain optimum clinical benefit from the new treatment drugs, like protease inhibitors or other antiretroviral therapy. This is due in part to the lack of properly trained medical personnel and supporting public health infrastructure, inadequate distribution mechanisms, and other challenges. Using protease inhibitors and other antiretroviral therapy under such circumstances would not only be impractical and potentially ineffective, but even hazardous, as the combination therapies require strict dosage schedules and substantial HIV medical support care to ensure ongoing and uninterrupted use. Inappropriate use of therapy increases the risk of emergence of drug-resistant virus, which exacerbates the impact of HIV/AIDS in affected populations.

To reduce the spread of HIV/AIDS, there is a need for better health infrastructure and government commitment. Government action is required to provide incentives for private individuals and firms to pursue responsible development of new drug therapies and to develop the necessary public health infrastructure. This will permit the development of therapies that are consistent with internationally recognized rights and standards and promote the distribution of safe and effective medical supplies and services.

Improving Infrastructure for HIV/AIDS. The international community at large is working to strengthen public health infrastructures to address a wide array of disease problems. The pharmaceutical industry can and should play a part in addressing infrastructure inadequacies. Clinical trials, with the support and agreement of national governments, can be a vehicle for improvement if they are based on a commitment to make sustainable the infrastructure created for the purpose of conducting such trials. This will provide mutual benefits to both the sponsors and the participating entities.

An example of a successful private/public partnership is the clinical trial of new antiretroviral in Brazil. Brazil's medical community had considerable experience with clinical trials, but to date had involved large-scale studies of HIV infection. Merck & Co, Inc.'s medical department in Brazil worked closely with their colleagues in the United States, Brazilian health and regulatory officials, the clinical investigators, and their staffs to meet the challenges of finding personnel to serve as clinical monitors. They also trained the staff to collect and in-

terpret the data on safety and clinical efficacy correctly; equipped the clinics with the necessary equipment to manage sophisticated clinical tests; expanded the capabilities of the local clinical laboratory to handle the thousands of blood samples from patients; and recruited patients within the trial guidelines, ensuring both that their rights were protected and that their care was delivered appropriately.

As a result, the treatment program has generated almost R$1 billion of savings for the government (R$1.05 equals approximately US$1) and in Sao Paulo, the number of AIDS-related deaths fell by 35 percent in the first half of 1997, compared with the first half of 1996. In Rio de Janeiro, the number of deaths was 21 percent lower. Other ancillary effects include a 20 percent reduction, in the last six months, on government spending for related medication; in Sao Paulo, the use of emergency facilities by AIDS patients fell by 40 percent and one entire floor of an AIDS wing in the city's largest hospital was closed due to insufficient demand; and patients receiving the antiretroviral drugs required less treatment for opportunistic diseases. Another indirect effect of the program is the increased ability for HIV-infected individuals to retain the physical vigor to continue in their jobs.

The successful findings from the clinical endpoint trial played a vital role in making the new therapy available in the countries of the European Union, in Brazil, and elsewhere. For the Brazilian medical community, the completion of the trial was a significant accomplishment. The community had carried to successful completion a complex trial that generated massive amounts of data. The investigators and their teams had solved a variety of logistical and organizational problems and developed the kind of meticulous statistical data on which physicians in Brazil and around the world could, with assurance, base their decisions about HIV/AIDS therapy for their patients

This example demonstrates the power of partnerships among key stakeholders—the private and public sectors, the medical and patient communities—to improve the framework for HIV/AIDS care in the developing world. Examples like this can set the stage for reallocation of government resources to address access to effective new medicines in a more comprehensive way, with confidence that the treatment algorithms will work in the local context.

The industry plans to continue to work in partnership with governments, non-governmental organizations, advocacy groups and academic institutions to lead, support, or initiate projects on AIDS awareness. This can result in a better understanding of the patterns of HIV-related illnesses, caretaking behaviors and determinants of such behaviors among HIV positive individuals. Industry also stands ready to work with governments, international organizations and others to address public health infrastructure needs in developing countries.

At the Twelfth World AIDS Conference in 1998, Merck & Co., Inc., announced a $3 million grant from the Merck Company Foundation to underwrite the Enhancing Care Initiative, coordinated by the Harvard AIDS Institute and the Francois-Xavier Bagnoud Center for Health and Human Rights at the Harvard School of Public Health. The Enhancing Care Initiative will address the issue of HIV/AIDS in the developing world by bringing together the best possible expertise within specific countries, including representatives of the local HIV community, to evaluate the needs of those living with HIV/AIDS. The goal is to customize concrete, practical improvements that will help to advance the quality, delivery and outcomes of HIV care for men, women and children living with HIV/AIDS, not only in the initial countries selected (beginning with Senegal and Brazil), but in a broad range of developing world countries.

The kind of commitment that the pharmaceutical industry is making to this type of responsible partnership is exemplified in industry's efforts in Africa. To help improve the care that African physicians are able to give to their patients with HIV infection, Merck has worked with leading HIV/AIDS treatment specialists at clinical centers in Paris, using a "train the trainer" approach to provide physicians from Uganda, Côte d'Ivoire, and Senegal experience with the best international standards of HIV care. The physicians then disseminate this knowledge to colleagues at home, which over time will improve the level of understanding and expertise in meeting the challenges of HIV/AIDS throughout the medical community in their countries. The information gained from these types of studies can then be used to guide government decisions on making additional resources available to expand programs of HIV/AIDS treatment.

These activities in the private sector complement the initiatives of other stakeholders—including the

HIV community, governments, international organizations, and non-governmental organizations—to help improve medical infrastructures and support the efforts to find long-term, sustainable solutions to the problems of HIV/AIDS faced by countries in the developing world.

Women and Health

Some gender analysis, though limited, has begun. An analysis of data from a protease inhibitor study shows comparable effects on disease progression among men and women as a result of treatment. The study, a clinical endpoint trial of 996 previously untreated HIV patients in Brazil included 277 women (28 percent of total patients), which constitutes one of the largest representations of women in a long-term protease inhibitor study in the world. The objective of the analysis was to determine whether there was consistency of treatment effects across gender in the testing of various new therapies. This type of study is only a beginning. There is a strong need for more research on women's risks, prevention and care needs. Also, funding for women-specific interventions programs needs to be increased.

Vaccine Research

In November 1997, the Pharmaceutical Research Manufacturers of America (PhRMA) reported that twelve vaccines under development from member companies, including the first National Drug Association-preventive AIDS vaccines, were in clinical trials or under review by the U.S. Food and Drug Administration.

Biopharmaceutical research and development companies are involved in the development of therapeutic and preventive vaccines that can induce protective immunity against HIV-1 clades (subtypes) prevalent in different parts of the world.

Industry also must commit to make therapies available where clinical trials are performed. In research programs underway in the Ivory Coast and Thailand, one U.S. company has designed its protease inhibitor clinical trials so that patients in these trials will continue to get access to the therapy after the studies are completed.

Vaccine research is difficult and expensive. The risk of failure is high. Of an initial five thousand compounds in basic research, only one will emerge from the laboratories and actually reach the market. Promising new vaccines require an average of 10 to 15 years of intense study and development. Nonetheless, U.S. pharmaceutical companies active in the HIV/AIDS field remain committed to developing new and innovative vaccines as well as developing combination vaccines, multiple antigens in a single inoculation. For vaccine researchers, the ideal would be converting multidose vaccination regimens into a single time-released shot.

Vital to the continued progress in developing new pharmaceutical defenses against HIV/AIDS is strong intellectual property protection. Intellectual property protection provides the indispensable incentives to invest in pharmaceutical research, which leads to the discovery and development of better treatments for patients with AIDS all over the world. Strong worldwide patent protection is essential to spur pharmaceutical innovation.

Behavioral Research/Behavioral Change Interventions

As part of its ongoing effort to work with partners to improve environments through which health care is delivered in developing countries, PhRMA underwrote AIDS education work in Africa, in partnership with Africare.

In Nigeria, Merck joined forces with WHO in Geneva, Women's Health & Action Research Centre in Benin, Nigeria, the Ford Foundation in Beijing and three U.S. universities in a project that aimed at identifying choices made by Nigerian youth to treat symptoms of sexually transmitted diseases (STDs) and identify targets for improving treatment of STDs. The findings will guide an intervention to reduce the prevalence of STDs and incidence of HIV among Nigerian youth.

Microbicide Development

Pharmaceutical companies are working to develop topical microbicides that women can apply to inhibit HIV infection. Although none have been shown to be effective to date, a potential microbicide that is spermicidal is in later stages of efficacy testing against HIV. Other formulations of microbicide are still in early development and testing.

The pharmaceutical industry realizes that women need microbicides that allow conception, but prevent infection with HIV and other STDS.

Donor Coordination

The pharmaceutical companies sponsor billions of dollars of research and development into new treatments as well as donate products. To facilitate product donations, U.S. research-based pharmaceutical companies created the Product Donations Steering Committee, an organization of innovative companies and key U.S.-based voluntary organizations. The Committee was organized to facilitate experience sharing regarding obstacles to donations and to formulate guidelines for responsibly managing donations.

The Steering Committee has forged a "Statement of Principles" and has taken other actions such as educational meetings and seminars to help insure that donations are carried out and coordinated between the donor company, private voluntary organizations and recipients in a way that assures the highest level of quality and ethics.

Donor coordination requires consideration of what is needed for a successful donation in general. The need for coordination goes far beyond the donors, it extends to all of those involved in the donation process—donors, private voluntary and/or non-governmental development organizations, local ministry of health, governments, field staff, and patients. In addition, coordination of organizations working in any one particular area is needed to avoid overlap, duplication of efforts, and to ensure appropriate coverage.

Sustainability of treatment is crucial and must be considered when planning donor coordination. Sustainability of treatment is contingent on a number of factors: available product supply, program funding, government/minister of health involvement, and recipient fatigue. For diseases like AIDS that require long term treatment and medicines with complex administration protocols, a reliable medical staff is needed to administer the medicines. Failure to ensure proper and continued administration could actually harm the patient. Other requirements for a successful donation include a reliable delivery system on the ground in the recipient country; assurances of adequate and appropriate storage of the medicines; and a system for recording adverse reactions and monitoring patients.

Role of International Non-governmental Organizations (NGOs)

Discussion of Mandate(s) Relevant to HIV/AIDS

Progress in halting the spread of the HIV/AIDS pandemic and its consequences can only be made if public sector efforts are supplemented by private sector involvement in HIV/AIDS prevention and mitigation. Over the past decade, selected non-governmental organizations (NGOs) have demonstrated that they are often in the best position to mobilize communities worldwide for HIV/AIDS prevention and care. Their close relationship with target communities and their experience in community development enables NGOs to work with community members to develop responsive, cost-effective programs. To build effective and sustainable HIV/AIDS programs, it is essential to improve and enhance the performance of these local organizations to provide appropriate HIV prevention and care services.

The functions of NGOs in a democratic society are many: they monitor the action of governments in meeting the needs of poor and disenfranchised populations; are instrumental in building community awareness and support for efforts by international organizations and government agencies; and help to provide a seamless transition from externally sponsored immediate assistance to long-term, domestic assistance.

Strategy for Specific Issues

Prevention

NGOs work to educate the media, private sector, development organizations, multilateral and bilateral institutions, domestic and international AIDS organizations, the U.S. Government, and others about the importance of international HIV/AIDS prevention efforts.

International NGOs in the HIV/AIDS movement also work to create linkages with other health programs, domestic AIDS organizations, and advocacy institutions. The NGO-coordinated strategy for improving and creating linkages with other health programs includes: educating domestic AIDS service organizations on global HIV/AIDS issues to ensure that they will create linkages with indigenous NGOs, and the creation of a working group dedicated to looking at development issues, health, and HIV/AIDS.

NGOs engage in HIV/AIDS behavioral prevention strategies that traverse several levels of impact, highlighting best practices and exemplary behavior change programs. Conference workshops are organized to feature behavior change issues and specific interventions designed on the premise that personal behavior is profoundly influenced by broad contextual factors, including service accessibility and social norms, and that sustained individual behavior change is unlikely unless there is also a change in relevant contextual factors.

Interventions targeting individuals include activities such as peer counseling, couples counseling and testing, and small group interventions. Initiatives at the societal level, such as mass media campaigns and school and workplace interventions, mobilize communities to provide a supportive environment for reducing risk, and support individually-based interventions. Advocacy activities targeting environmental or structural constraints contribute as well. In short, accurate knowledge and sustained behavior change at the community level is directed at the demand side to create understanding and awareness and to spur the adoption of appropriate HIV/AIDS behaviors at the community level.

NGO prevention programs target the population as a whole, as well as groups most vulnerable to HIV, including adolescents, women, refugees, migrant workers, miners, commercial sex workers, and intravenous drug users. For instance, NGO HIV/AIDS prevention projects target young adults with information and services that address their specific issues. Communication material targeting young adults promotes safer sexual behavior, encouraging abstinence as a viable alternative to early sexual activity, and making condoms the right choice for protection when sexual activity does take place. Advice, information, and products are made readily available where youth spend their leisure time. Additionally, NGOs collaborate with traditional condom outlets (~~for example~~, pharmacies) to make

them youth-friendly. Call-in radio shows in India, Zambia, and South Africa invite and respond to young people's questions about sex and send out additional, youth-oriented information booklets to interested callers. A comic book is used in Haiti to encourage teens to discuss sexual matters with their parents. Youth-oriented "photonovellas" in Bolivia capture in print the same stories portrayed in popular TV miniseries on unwanted pregnancies, STIs, and HIV/AIDS.

Over the last 15 years, NGOs have targeted women in their prevention strategies as well. NGO initiatives encourage women to purchase condoms and to insist on their use with partners. Women in Cameroon and Côte d'Ivoire can purchase condoms in self-service shops where the anonymity of a checkout counter is preferred over direct interaction with sales staff. In Burkina Faso, the Griottes, an organized union of female historians and storytellers, go door to door to talk about AIDS with women. Women street vendors do the same in Haiti, where free samples are included in boxes of female hygiene products.

Further, international NGOs have worked collaboratively to open markets for female condoms in developing countries, and to create a video training program on their benefits and use. NGOs have also collaborated with UNAIDS to communicate with local governments, NGOs, and health providers in developing countries about this product and to assess their demand and technical assistance needs for starting or sustaining female condom projects.

Recognizing that injecting drug use has played a critical role in fueling the epidemic in various regions, particularly in some countries in Asia, Eastern Europe, and the Commonwealth of Independent States, NGOs support at least three major prevention components, including: early implementation of prevention initiatives while HIV prevalence is low; community outreach to injecting drug users (IDUs) to provide HIV/AIDS information and help develop trust between IDUs and health care providers; and widespread provision of sterile injection equipment.

Workplace Interventions

For over 5 years, labor unions have conducted an ongoing effort in the U.S. to combat the scourge of HIV/AIDS and STDs through unique programs of workplace peer education. Despite vast cultural differences, two things nearly all people the world over share in common are the need to work and the need to receive medical care. People, rich or poor, uneducated or educated, active in community organizations or not, are best reached where they work. This is particularly true in developing countries and among workers who are most at risk of contracting HIV/AIDS. Truckers, transit workers, miners, and others whose jobs require them to travel through porous borders are the ones most often associated with the spread of HIV/AIDS. Few ways exist to reach these people other than through their jobs and at their place of employment.

What began as a practical effort to cope with issues of occupational safety and health at the beginning of the AIDS pandemic has now become a deep commitment to share the special strengths of labor movements worldwide to open a new front in a global war against this tragic disease. Now more than ever, a mounting body of evidence suggests that the workplace peer education strategy can respond to program needs with practical low-technology methods to help arrest the explosion of HIV/AIDS infection rates in developing nations.

Social Marketing

An example of a specific HIV/AIDS prevention and mitigation methodology utilized by NGOs to make condoms available to low-income people in developing countries is a technique called social marketing. Condom social marketing involves the distribution of condoms to lower-income persons by marketing through the existing local commercial and NGO infrastructures. NGOs procure products using donor funding or obtain them directly from donors; establish an office and a distribution system in the developing country, often acting as its own distributor; and sell the products, through the existing wholesale and retail network in the country. Products are branded and attractively packaged, and sold at low prices making them affordable to the poor. Since this retail price is often lower than even the manufacturing cost, donor contributions are a vital element of the social marketing process.

A key ingredient to successful social marketing is effective communications to stimulate demand and encourage the adoption of appropriate health practices. This is done through both brand advertising and generic educational campaigns, using a mix of strategies and channels, such as mass media and interpersonal communications, to reach the

targeted audience. Activities range from brand advertising informing the public that a quality product is available and where it can be purchased, to generic educational efforts that help people understand why changing behavior is necessary and important.

A project in Côte d'Ivoire provides an illustration of communications initiatives designed to effect behavioral change. Saturation-level brand promotion informs the public about condoms and that their use protects against contracting HIV/AIDS. That activity is complemented by producing and broadcasting a popular and award-winning television soap opera, *SIDA dans la Cité* (AIDS in the City). The multipart program engages viewers in a gripping drama about a family in which the father is diagnosed with AIDS because he was unfaithful and did not use protection. This dual approach, based on research and testing, recognizes that people learn in different ways and a variety of messages will more effectively reach a larger audience.

In Guinea, local religious leaders now use their mosques to preach messages on marital fidelity and abstinence—all part of the national campaign in Guinea to prevent HIV/AIDS. In seven countries, mobile video units, equipped with camcorders and large screens, take health messages to the rural countryside. In Tanzania, these video-equipped vehicles show films that educate about AIDS, encourage fidelity, and promote condoms. These multimedia presentations are extremely popular among entertainment-starved populations; in Pakistan and Bolivia mobile video units have attracted audiences of thousands of people.

Some of the other communications activities used by NGOs include point-of-sale material; radio call-in shows, soap operas, documentaries, profiles and other programs; television documentaries, debates, and other informational programs; musical songs and videos; cinema ads and trailers; theater troupe presentations and puppetry; product demonstrations and information distribution at work places, community meeting places, and special events; print materials, posters, brochures, cartoons, and inserts; informational kiosks and peer education activities at special and sporting events, and in high traffic areas throughout communities; and providing information to and training to those with the ability to reach larger, affected populations.

Treatment Equity

The international NGO community recognizes that very few people living with HIV in the developing world have access to many life prolonging drugs, including basic antibiotics. As the number of people living with HIV/AIDS continues to reach alarming levels, programs dedicated to providing services to these individuals are drastically needed. Recognizing that prevention has been a priority for most multilateral, bilateral, and private voluntary organizations (PVOs), NGOs advocate for the development and inclusion of programs focused on care that address the needs of people living with AIDS and their family members. Care programs should include access to appropriate life-saving therapeutic treatments, development of counseling and related services, and the development of human rights projects to curb discrimination against persons affected by HIV/AIDS.

The coordinated NGO strategy that emphasizes the necessity of creating care projects and monitors the development of these projects includes: offering seminars and workshops on the prevention to care continuum and arranging meetings with PVOs and multi- and bilateral institutions. NGOs can also be advocates and work to broaden the policy dialogue on issues such as drug pricing, calling for price reductions, and aggressively working through all available private and public networks to engender an informed and supportive policy environment to effect change.

An example of a strategy to improve treatment equity is the use of mechanisms such as private sector leveraging to help communities and governments tap into additional financial resources.

AIDS-Orphaned Children

Currently, the future of millions of children is threatened because of HIV/AIDS. In addition to the estimated 1.5 million children infected with HIV, a growing number of children are being orphaned as a result of AIDS-related adult mortality. Young people whose family controls are lacking may seek emotional support and security through sexual relations, thereby increasing their risk of HIV infection. In addition, they may be abused and forced into prostitution. Children living in the streets are forced to fend for themselves, with few options for

survival. With an estimated 100 million street children alive today, the implications for the spread of HIV are alarming.

To avoid infection, children need a supportive, enabling environment that provides them not only with knowledge about how to protect themselves, but also with the motivation and the power to do so. Care is also essential for the survival of children. NGOs have worked with local collaborators to develop a methodology for orphan assessment, which identifies priority needs of orphans and their caretakers. Activities are also focused on orphan care and support, which include care, counseling services, and vocational training. In addition, income-generating activities with NGOs, mobilization of local resources, and psychosocial support and training are supported by NGOs at the country level. Finally, in response to the growing number of children left parentless due to HIV/AIDS, NGOs have made efforts to highlight this crisis through conference workshops, briefings, and media articles.

Women and Health

The international NGO community works to bring attention to the growing vulnerability of women to HIV/AIDS through: workshops at domestic and international conferences, briefings for government leaders, media articles, and monthly E-mail broadcasts.

NGOs have worked tirelessly to:

- Promote access to reproductive health services, such as family planning and antenatal care, that protect the health of women and their families.
- Encourage earlier access to treatment through the development of voluntary HIV counseling and testing services.
- Promote improved treatment by encouraging early management of symptoms and treatment of opportunistic infections.
- Improve STI case management at the clinic level and to make services, including drugs, more accessible to populations at risk.
- Promote dialogue between men and women.
- Expand women's prevention efforts through female condom studies.
- Educate younger women about reproductive health, providing the information they need to make informed choices about abstinence, the initiation of sexual activity, selection of partners, and the use of condoms and other available protection methods.

Vaccine Research

Spending allocated to research in both the public and private sector has increased over the past few years. However, NGOs point out that issues concerning the allocation of funding and the ethics surrounding some of the clinical trials being conducted require continuing attention. While therapeutic development, particularly antiretroviral and protease inhibitors, have been the primary focus in the United States for the past several years, NGOs stress that increased focus must be directed toward vaccine development that will clearly benefit the developing world. This underscores the President's commitment to the development of an HIV/AIDS vaccine in the next 10 years. As such, the NGO community recognizes that it is extremely necessary to apply pressure to public institutions and private industry to ensure that a vaccine will be developed and can be made available for global use.

Through briefings, seminars, and workshops, the international NGO community will continue to provide venues for debate on the ethics of individual clinical trials as to whether the trials meet the United Nation's Internal Review Board's standards. Additionally, NGOs will continue to monitor and report on spending and profits generated by the development of vaccine, antiretrovirals, therapeutic interventions and prophylaxsis by private pharmaceutical companies.

Microbicide Development

The NIAID-funded HIVNET consortium is directly involved in microbicide development and plays a key role in the design, implementation and monitoring of vaginal microbicide studies. NGOs are involved in clinical trials of vaginal microbicides to evaluate efficacy and acceptability in preventing STIs, HIV, and pregnancy. More than 200 scientific publications on barrier methods have been produced, including a monograph for the 1994 International Conference on Population and Development in Cairo.

Three existing trials are Phase I safety and acceptability studies of candidate products taking place both in the United States and at seven international sites in six countries. A fourth trial, a Phase III non-Oxynol (N-9) efficacy study in Zimbabwe and Malawi (two sites), is currently in the final planning stages and the first phase of study enrollment is expected to get under way in early 1999.

A randomized control trial evaluating the impact of N-9 film on the transmission of HIV and STIs in Cameroon has been completed. Results showed N-9 film was safe but did not protect against HIV/STI. Methodological and operational lessons learned from this study have influenced directions of new microbicide development. Other related research includes a number of clinical trials of vaginal microbicides with STI infection as the primary study endpoint, and HIV infection as a secondary endpoint.

Donor Coordination

NGOs play a role in facilitating dialogue among multilateral donors, such as UNAIDS, bilaterals, including USAID, and private funding bodies in order to maximize donor effectiveness and minimize overlap.

In addition, at the country level, NGOs develop programs that complement those of other donors. For instance, NGOs collaborate with the World Bank on specific technical areas such as STI research, and work jointly with UNAIDS and the World Health Organization (WHO) on the development of guidelines for behavioral data collection needs of national HIV/AIDS/STI programs.

Role of International Organizations

Mandates Relevant to HIV/AIDS

Where possible, the U.S. Government works closely with international organizations to leverage both human and financial resources for the greater benefit of those in need. International organizations are uniquely positioned to provide support for HIV/AIDS prevention and mitigation efforts worldwide. The U.S. Government provides direct assistance to these important institutions and supports the critical role international organization's play in the international fight against HIV/AIDS. The role of international organizations is characterized as follows:

- International organizations have a wide funding base and are able to provide significant financial backing and multisectoral support.
- International organizations are able to effect cooperation without political ramifications or restrictions that bind local and national governmental actors.
- International organizations are nonpartisan.
- International organizations are able to bridge gaps between countries and donor nations and provide a fora to bring various international players together on issues.

UNAIDS

The Joint United Nations Programme on HIV/AIDS (UNAIDS), an international organization created specifically to address the HIV/AIDS pandemic, was established as an independent UN agency on January 1, 1996. UNAIDS brings together the efforts of five UN organizations: United Nations Children's Fund (UNICEF), United Nations Development Programme (UNDP), United Nations Population Fund (UNFPA), United Nations Educational, Scientific, and Cultural Organization (UNESCO), World Health Organization (WHO), and the World Bank. The primary focus of UNAIDS is to strengthen the capacities of national governments for an expanded response to HIV/AIDS. UNAIDS will achieve this objective through work at national, regional, and global levels in the following four mutually reinforcing areas: policy development and research, technical support, advocacy, and coordination.

Prevention

Testament to the multisectoral reach of UNAIDS are its numerous prevention efforts, ranging from collaboration with the religious sector to assessment of the cost-effectiveness of HIV prevention strategies. Examples of the range of UNAIDS prevention strategies are detailed below.

Recognizing that truly effective prevention efforts must begin at a young age, UNAIDS activities target school-aged children through outreach and prevention efforts. In 1997, UNAIDS published a position paper on integrating HIV/STD prevention in the school setting; produced a technical update on learning and teaching about AIDS at school; and participated in the organization of seminars on school-based AIDS education at the three regional conferences on AIDS held in Côte d'Ivoire, Peru, and the Philippines.

Within the religious sector, UNAIDS employs a two-pronged prevention approach. The first is to promote the exchange of ideas and training for community-based prevention and care programs. The second is to encourage religious institutions to strengthen life-skills training approaches for HIV education in schools operated by their congregations. UNAIDS also collaborates with the Roman Catholic organization CARITAS International and is supporting a forum of religious leaders in Africa.

UNAIDS' efforts to reduce risk and vulnerability in institutional settings, such as prisons and workplaces, have largely focused on strengthening national and regional networks and facilitating information exchange on effective programming. A joint undertaking with the Civil-Military Alliance to Combat HIV/AIDS, and its regional affiliates, helps to establish and strengthen AIDS programs with military services in Africa, Asia, and Latin America.

To prevent intravenous transmission, UNAIDS works to strengthen regional HIV/injecting drug use harm reduction networks, focusing on exchanging lessons learned and sharing technical resources. In the area of sexual transmission, UNAIDS' principal efforts in 1997 and 1998 have been identification and dissemination of best practices in HIV prevention and care, strengthening of regional networks, and development of tools and guidelines to facilitate project development. UNAIDS has sup-

ported specific initiatives in the Asia-Pacific region, central and Eastern Europe, and west and central Africa. With regard to men who have sex with men, UNAIDS is building several regional networks of experts in HIV prevention.

Finally, to assess the efficiency and effectiveness of HIV prevention efforts, UNAIDS has initiated a number of studies evaluating the cost-effectiveness of HIV prevention strategies. The studies have led to the preparation of costing guidelines for such strategies; a UNAIDS' point-of-view document on cost-effectiveness analysis; and three computerized models covering blood safety, prevention programs for sex workers, and school education, all of which will be published in 1998.

Treatment Equity

Recognizing that there are often insurmountable barriers to obtaining access to available HIV/AIDS treatment, UNAIDS and the WHO Action Program on Essential Drugs are developing an operational plan to improve access to drugs for HIV infection. UNAIDS supported several consultations on this subject in Senegal and during the AIDS conference in Abidjan. UNAIDS also is supporting preparation of case studies on treatment equity and access to care and drugs in Asia, Latin America and the Caribbean, and West Africa; and, in collaboration with the Ministries of Health and a number of pharmaceutical companies, UNAIDS is initiating pilot projects to improve access to drugs of interest to people living with HIV/AIDS, in Chile, Côte d'Ivoire, Uganda, and Vietnam.

Further, UNAIDS is currently collaborating with local partners to document case studies on the process of introducing antiretrovirals in Argentina, Brazil, Colombia, and Mexico, where the drugs have been made available despite resource constraints. The objective of the studies is to assess the extent to which their introduction was successful, and to learn about difficulties encountered in introducing the new technology. These lessons can serve as a learning tool for other countries.

Women and Health

UNAIDS coordinates the Informal Working Group on Mother-to-Child Transmission of HIV, which focuses on the coordination and design of clinical trials on the prevention of HIV transmission from mothers to their children. UNAIDS also supports the Ghent International Working Group on Perinatal Transmission of HIV, sponsored by the European Union, which conducts studies on the acceptability of prenatal voluntary counseling and testing in the context of ongoing clinical trials in Africa, as well as cost-effectiveness studies related to the use of AZT and alternatives to breastfeeding.

Vaccine Research

In collaboration with the WHO Global Program for Vaccines and Immunization, UNAIDS is supporting a project to promote the development of a novel vaccine approach—the International AIDS Vaccine Initiative (IAVI)—whose mandate is to accelerate progress toward an AIDS vaccine for use in developing nations where the epidemic is spreading most rapidly. IAVI is designed to complement, not compete with, existing AIDS vaccine programs, which have emphasized basic research. IAVI's strategy consists of accelerated product development and human testing through international collaboration. In addition, UNAIDS, WHO, and the Council for International Organizations of Medical Sciences are developing a guidance document for ethical standards in the conduct of HIV vaccine trials.

Behavioral Research/Behavioral Change Intervention

In the area of behavioral prevention, UNAIDS, USAID, and WHO collaborated to assist in the multisite voluntary counseling and testing (VCT) study carried out from 1995 to 1997 in Kenya, Tanzania and Trinidad and Tobago. The study concluded that VCT significantly reduces sexual risk-taking behavior and does not increase such negative life events as disintegration of relationships and discrimination.

Another behavioral intervention project combined the efforts of UNAIDS, UNESCO, UNICEF, and the World Bank in the development of communication strategies and regional networks for national AIDS and health-promotion programs.

Microbicide Development

UNAIDS advocates for the development of vaginal microbicides and serves as the Secretariat for the International Working Group on Microbicides. In 1996–1997, UNAIDS launched a multicenter

study on the efficacy of COL–1492 in preventing HIV infection and sexually transmitted diseases among female sex workers in Benin, South Africa, and Thailand. In addition, preparatory work is proceeding in Côte d'Ivoire and Senegal. A first interim analysis is expected in 1999 but final results will not be available before the end of 2001. It is hoped that microbicides will also be useful in preventing HIV infection in men.

UNAIDS' Cosponsors

Although the majority of HIV/AIDS activities on the part of UNAIDS' cosponsors fall under the rubric of UNAIDS, there are continuing independent cosponsor efforts to prevent and mitigate the impact of HIV/AIDS:

- UNESCO is developing curriculum and teacher training in India, and planning seminars in Nepal and Cambodia;
- UNFPA is focusing on integration of HIV/STD prevention in family life/reproductive health programs in more than 150 countries;
- WHO is integrating school-related health services for adolescents with action-research projects in six African countries, as well as integrating HIV/STD prevention into the "Health-Promoting Schools Network" in six regions. WHO also supports the Government of China in extending HIV/STD education in all schools in the most-affected southern provinces;
- UNICEF is developing youth-friendly health services and promoting life-skills education which integrate AIDS information.
- UNDP is preparing a series of issue papers on gender and the HIV epidemic.
- UNICEF is developing resource materials for integrating gender awareness into adolescent sexual health programs.
- UNESCO is implementing a project to reduce the rate of HIV transmission among women by empowering them with awareness, knowledge, and skills.
- WHO is providing technical support to an International Center for Research on Women (ICRW) project on reproductive-health rights of HIV-positive women.

In addition, since 1995, WHO, joined later by UNAIDS, has supported the PETRA study, in South Africa, Tanzania, and Uganda, to test the efficacy of a short-term regimen of AZT and 3TC for reducing the risk of mother-to-child transmission of HIV.

Finally, after the results of the Thai/CDC trial on mother-to-child transmission, UNICEF-WHO-UNFPA-UNAIDS set up an international initiative to demonstrate the feasibility of prevention of mother-to-child transmission of HIV in some of the countries worst-affected by HIV infection. Under this initiative, pilot interventions are being implemented in the following countries: Zimbabwe, Zambia, Uganda, Côte d'Ivoire, Burkina, Honduras, Vietnam, Cambodia, Thailand, Botswana, and Rwanda.

The World Bank

The World Bank—one of the six UNAIDS cosponsors—is an example of an international organization that provides direct assistance to client governments in the form of loans, technical assistance, and policy guidance. The World Bank's comparative advantage lies in its ability to engage in dialogue with client governments, enabling the creation of an environment for the development of sustainable and multisectoral prevention and care programs, and in its capacity to finance large national programs to combat HIV.

Most of the World Bank's loans for HIV/AIDS are provided on highly concessionary terms through the World Bank's concessionary lending arm, the International Development Association (IDA). While the approval of new loans for HIV/AIDS fluctuates considerably from year to year, the World Bank is continuing to expand its portfolio of HIV/AIDS projects and loan disbursements, which reflect efforts to implement AIDS control activities. The World Bank has committed over $800 million to HIV/AIDS projects over the past decade, and there are indications that the pace of lending will rise in the next 3–5 years as more clients turn to the World Bank for financial assistance to address HIV/AIDS in their countries.

Additionally, the World Bank incorporates HIV/AIDS components into other loans such as reproductive health and rural development programs. The World Bank's commitment to HIV/AIDS is also reflected in its technical and operational assistance. Further, the World Bank attempts to ensure that HIV/AIDS strategies are effective and appropriate for

the specific challenge facing each country. Although individual governments are ultimately responsible for project implementation, the World Bank works closely with government officials in designing, monitoring, and evaluating HIV/AIDS projects. The World Bank is also increasingly focusing on capacity building as part of country specific responses to HIV/AIDS.

Prevention

The World Bank regularly funds regional prevention projects. For example, in collaboration with UNAIDS, the World Bank is providing grants for initiatives which tackle the AIDS epidemic at the regional level, dealing with cross-border issues such as migration and transport, that are central to the spread of HIV. These regional problems, covering western Africa, southern and eastern Africa, Southeast Asia, and Latin America and the Caribbean, are managed by UNAIDS on behalf of the World Bank. They aim to strengthen regional cooperation and improve the capacity for neighboring countries to consult and work jointly on policy and implementation issues.

The World Bank is also working closely with UNAIDS at the country level in developing programs in a number of nations. Country-level projects are ongoing in India, China, Zimbabwe, and Brazil.

AIDS Orphans

In the area of AIDS-orphaned children, the World Bank supports the production of public service announcements, picture exhibits, and video documentaries to bring attention to the millions of children orphaned by AIDS. In 1997, the World Bank developed a Public Service Announcement, which has been aired on CNN and many other international outlets to highlight the theme of the 1997 World AIDS Campaign: Children Living in a World with AIDS. On World AIDS day 1997, the World Bank hosted a picture exhibit titled: "Dying Branches: The Impact of HIV/AIDS on the Villages of Mpondas, Malawi." The goal of the exhibition was to portray both the vulnerability and resiliency of grandparents who are forced to provide for children who have lost one or both parents in a community devastated by HIV/AIDS. Finally, the World Bank, with UNAIDS, developed an MTV documentary on the 1998 theme for World AIDS Day, entitled "Youth—a Force for Change."

Vaccine Research

The World Bank recognizes that the HIV/AIDS epidemic in many of the World Bank's client countries has increased the priority for developing a preventive vaccine that will be effective and affordable in the developing world. As such, a World Bank task force is exploring the market failures leading to underinvestment in an HIV/AIDS vaccine and examining the feasibility and optimal design of innovative financing instruments. This would stimulate private investment. The task force also is responsible for developing new World Bank instruments that will increase private incentives to invest in related research and development.

Further, the World Bank is part of a global collaboration of organizations that has created and funded the International AIDS Vaccine Initiative (IAVI).

UN Commission on Human Rights

The UN Commission on Human Rights regularly considers resolutions for the protection of human rights in the context of HIV and AIDS. The resolutions set out guidelines nations may follow in dealing with the health crisis and human toll of HIV and AIDS. Resolutions also ask the UN Secretary General to solicit input from countries, specialized agencies, and related governmental and non-governmental organizations in order to provide a progress report to the Commission on follow-up. The next session of the Commission at which an HIV/AIDS resolution is expected for consideration will take place in March 1999.

Conclusion

The 1999 U.S. International Response to HIV/AIDS represents the continued commitment by the United States Department of State working with other Federal agencies, our partners in the international community, non-governmental organizations, and industry to stem the spread of HIV/AIDS. Although this report highlights the U.S. response to the international situation, it serves to intensify U.S. resolve to maintain its leadership role in initiating needed action to forestall unnecessary human suffering and related socioeconomic impacts from HIV/AIDS.

We have defined some of the impending problems which will confront us as a result of the HIV/AIDS pandemic. It is up to all of us to structure solutions in anticipation of their occurrence, knowing that many unavoidable deaths will occur unrelated to our collective actions. Unfortunately, our lack of knowledge about the disease and failure to acknowledge and address it swiftly has given temporary advantage to the disease. Yet new tools for prevention, growing knowledge, and the collaborations of governments, non-governmental entities, industry, and international organizations are making effective interventions possible. While maintaining a strong emphasis on other prevention interventions, it is critical that concerted efforts be focused on the development of a safe and effective vaccine against the many strains of HIV. President Clinton has placed the development of an HIV vaccine on the international agenda and efforts to garner partnerships to meet the 2007 goal will be a priority for our domestic and international research.

Underpinning research and drug development efforts is the need to tackle the ubiquitous problem of inadequate or nonexistent public health infrastructure in many foreign countries. This is at the heart of the problem and the solution of HIV/AIDS and other infectious diseases. Resulting in part from inadequate political commitment to make HIV/AIDS a national priority, this important domestic issue has become an international concern that threatens the health and security of every nation around the world. Any weak link in the global health chain, which binds the nations of the world, weakens us all. We all benefit from enhancing public health infrastructures around the globe. The United States and the international community must strengthen partnerships with all entities that can bring needed resources and expertise to expedite improvement.

The magnitude of the worldwide HIV/AIDS pandemic calls for strong political commitment at the highest levels of government and collaborative support from the full range of in-country technical expertise and the greater international community. This multipartite approach can leverage the vital resources to effectively bring practical solutions to the HIV/AIDS epidemic. Stemming the global spread of HIV/AIDS requires developing and industrialized nations, international organizations, the pharmaceutical industry, and non-governmental organizations to work effectively together for the sake of all concerned.

Appendix A

U.S. Government Contact List for International HIV/AIDS Issues

White House Office of National AIDS Policy

National AIDS Policy Director Sandra Thurman
(202) 456–2437

Deputy Director Todd Summers
(202) 456–2437

U.S. Department of State
(www.state.gov)

Under Secretary for Global Affairs
Under Secretary Frank Loy
(202) 647–6240

Bureau of Oceans and International Environmental and Scientific Affairs—Emerging Infectious Diseases and HIV/AIDS Program
(www.state.gov/www/global/oes/health/index/html)
Director Nancy Carter-Foster
(202) 647–2435
ncarterf@state.gov

Bureau of Democracy, Human Rights, and Labor
Assistant Secretary Harold Koh
(202) 647–2126

Bureau of International Organization Affairs
Deputy Assistant Secretary E. Michael Southwick
(202) 647–9604

U.S. Agency for International Development
(www.usaid.gov)

Office of the Administrator
Administrator J. Brian Atwood
(202) 712–4040

Bureau for Global Programs, Field Support and Research—Center for Population, Health and Nutrition
Deputy Assistant Administrator Duff Gillespie
(202) 712–4120
dgillespie@usaid.gov

HIV/AIDS Division
Division Chief Dr. Paul DeLay
(202) 712–0683

U.S. Information Agency
(www.usia.gov)

Office of the Director
Director Joseph D. Duffey
(202) 619–4742

Office of Strategic Communication
Senior Advisor James W. Kelman
(202) 619–4150

U.S. Peace Corps

Center for Field Assistance and Applied Research
(202) 692–2666

U.S. Department of Health and Human Services
(www.os.dhhs.gov)

Surgeon General and Assistant Secretary for Public Health and Science
Surgeon General and Assistant Secretary David Satcher
(202) 690–7694
(301) 443–4000

Office of HIV/AIDS Policy
Director Eric Goosby
(202) 690–5560

Office of International and Refugee Health
Director Greg Pappas, Acting
(301) 443–1774

National Institutes of Health
(www.nih.gov)

Office of the Director
Director Harold E. Varmus
(301) 496–2433

International Contact:
Director, Office of Extramural Programs
James O'Donnell
(301) 435–2768

Office of AIDS Research
Director Neal Nathanson
(301) 496–0357

National Institute of Allergy and Infectious Diseases
Director Anthony S. Fauci
(301) 496–2263

Division of AIDS
Director John Y. Killen
(301) 496–0545

International Contact:
Assistant Director for International Research
Karl Western
(301) 496–6721
kwestern@mercury.niaid.nih.gov

National Institute of Mental Health
Director Steven Hyman
(301) 443–3673

International Contact:
Associate Director for Prevention Juan Ramos
(301) 443–3533

National Institute of Child Health and Human Development
Director Duane F. Alexander
(301) 496–3454

International Contact:
Office of Science Policy, Analysis and Communications
Associate Director Judith Whalen
(301) 496–1877

National Institute of Environmental Health Sciences
Director Kenneth Olden
(919) 541–3201

International Contact:
Director for International Programs
Chris Schonwalder
(919) 541–4794
schonwa1@niehs.nih.gov

Fogarty International Center
Director Gerard T. Keusch
(301) 496–1415

Centers for Disease Control and Prevention
(www.cdc.gov)

Office of the Director
Director Jeffrey P. Koplan
(404) 639–7000

Office of Global Health
Director Steve Blount
(404) 488–1085

National Vaccine Program Office
Director Robert F. Breiman
(404) 639–4452

National Center for HIV, Sexually Transmitted Diseases and Tuberculosis Prevention
Director Helene D. Gayle
(404) 639–8000

Division of HIV/AIDS Prevention—Surveillance and Epidemiology
Director Kevin DeCock
(404) 639–0900

Division of HIV/AIDS Prevention—Intervention Research and Support
Director David Holtgrave
(404) 639–5200

National Center for Infectious Diseases
Director James M. Hughes
(404) 639–3401

Division of AIDS, Sexually Transmitted Diseases and Tuberculosis Prevention
Director Harold W. Jaffe
(404) 639–4581

National Center for Environmental Health
Director Richard J. Jackson
(770) 488–7000

National Center for Health Statistics
Director Edward J. Sondik
(301) 436–7016

Food and Drug Administration

Office of Special Health Issues
Associate Commissioner Terry Toigo
(301) 827–4460
ttoigo@oc.fda.gov

Office of International Affairs
Director Walter Batts
(301) 827–4480
wbatts@oc.fda.gov

U.S. Department of Commerce
(www.doc.gov)

Bureau of the Census

International Programs Center
Chief Peter O. Way
(301) 457–1390

Health Studies Branch
Chief Karen A. Stanecki
(301) 457–1406

Bureau of Economic Analysis
Office of the Director
Director J. Steven Landefeld
(202) 606–9602
john.landefeld@bea.doc.gov

Trade Development
Assistant Secretary for Trade Development
Michael J. Copps
(202) 482–0309

National Institute of Standards and Technology

Office of the Director
Director Joan Parrott-Fonseca
(202) 482–5061

Office of International and Academic Affairs
Director B. Stephen Carpenter
(202) 975–4119

Patent and Trademark Office

Office of the Assistant Secretary
Assistant Secretary and Commissioner of Patents & Trademarks Bruce A. Lehman
(703) 305–8600

Biotechnology Examining Groups
Director John J. Doll
(703) 308–1123

U.S. Department of Defense

Office of the Deputy Assistant Secretary for Clinical and Program Policy
Director of Health Promotion/ Health Affairs
Lynn Pahland
(703) 681–1703

Walter Reed Army Institute of Research
Division of Preventive Medicine,
Lt. Col. Patrick Kelley
(202) 782–1353

Appendix B

List of Acronyms

AFMIC	Armed Forces Medical Intelligence Center
AIDS	Acquired Immune Deficiency Syndrome
AIDSCAP	AIDS Control and Prevention Project
ANE	Asia/Near East Bureau (USAID)
ATP	Advanced Technology Program
AVRC	AIDS Vaccine Research Center
AZT	Anti-viral Therapy
BCI	Behavioral Change Intervention
CAPS	Center for AIDS Prevention Studies
CBO	Community-based Organization
CDC	Centers for Disease Control and Prevention
CSM	Condom Social Marketing
DFID	Department for International Development, United Kingdom
DHAP/IRS	Division of HIV/AIDS Prevention-Intervention Research and Support (CDC)
DHAP/SE	Division of HIV/AIDS Prevention - Surveillance & Epidemiology (CDC)
DHHS	Department of Health and Human Services
DOC	U.S. Department of Commerce
DOD	U.S. Department of Defense
DOJ	U.S. Department of Justice
DOS	U.S. Department of State
DRL	Bureau of Democracy, Human Rights and Labor (State)
ENI	Eastern Europe/Newly Independent States Bureau (USAID)
EU	European Union
FDA	Food and Drug Administration
FIC	Fogarty International Center (NIH)
G-7	Group of Seven
HIV	Human Immunodeficiency Virus
IAVI	International AIDS Vaccine Initiative
ICH	International Council for Harmonization
ICRW	International Center for Research on Women
IDA	International Development Association
IDU	Intravenous Drug User
IO	International Organization
LAC	Latin America/Caribbean Bureau (USAID)
MTCT	Mother-to-child Transmission
N-9	non-Oxynol-9
NCHSTP	National Center for HIV, STD and TB Prevention (CDC)
NCI	National Cancer Institute
NCIH	National Council on International Health
NCRR	National Center for Research Resources
NGO	Non-governmental Organization
NHLBI	National Heart, Lung and Blood Institute

NIAID	National Institute of Allergy and Infectious Disease
NIC	National Intelligence Council
NICHD	National Institute of Child Health and Human Development
NIDA	National Institute on Drug Abuse
NIH	National Institutes of Health
NIMH	National Institute of Mental Health
NIST	National Institute of Standards and Technology
NOAA	National Oceanic and Atmospheric Administration
OAR	Office for AIDS Research (NIH)
OES/E/EID	Office of Emerging Infectious Diseases and HIV/AIDS, Bureau of Oceans and International Environmental and Scientific Affairs (State)
OHAP	Office of HIV/AIDS Policy (DHHS)
OHCHR	Office of the High Commission for Human Rights
ONAP	White House Office of National Aids Policy
PHN	Population, Health and Nutrition (USAID)
PhRMA	Pharmaceutical Research Manufacturers of America
PHS	U.S. Public Health Service
PHS/OWH	U.S. Public Health Service's Office on Women's Health
PLWH	People living with HIV/AIDS
PRM	Bureau of Population, Refugees and Migration (State)
R&D	Research and development
SO	Strategic Objective
STD	Sexually Transmitted Disease
STI	Sexually Transmitted Infection
TB	Tuberculosis
TIR	Targeted Intervention Research
UNAIDS	United Nations Joint Programme on AIDS
UNDP	United Nations Development Programme
UNESCO	United Nations Educational, Scientific and Cultural Organizations
UNFPA	United Nations Population Fund
UNICEF	United Nations Children's Fund
USAID	U.S. Agency for International Development
USG	United States Government
USIA	U.S. Information Agency
USIS	U.S. Information Service
VCT	Voluntary HIV counseling and testing
VOA	Voice of America
WHAM	Women's Health Advocates for Microbicides
WHO	World Health Organization
WRAIR	Walter Reed Army Institute of Research

MEMORANDUM FOR KAREN TRAMONTANO

From: Todd Summers
Deputy Director
Office of National AIDS Policy
(202) 456-2437

Date: December 8, 1998

Re: Briefing for meeting with Dr. Scott Hitt, Chair, President's Advisory Council on HIV/AIDS

Dr. Scott Hitt, Chair of the President's Advisory Council on HIV/AIDS (the Council), is scheduled to meet with you this afternoon at 3:00 pm. This meeting was arranged through Richard Socarides in response to a request by Dr. Hitt to meet with the Chief of Staff (who Dr. Hitt believes may be in attendance at this afternoon's briefing).

Dr. Hitt will likely raise issues with you in preparation for a meeting between the President and the Council scheduled for December 18th. He will have met earlier this morning with HHS Deputy Secretary Kevin Thurm.

While he has not shared with us his specific agenda for the meeting with you, we surmise that the following will be raised:

Office of National AIDS Policy (ONAP) Staffing

The Council has been concerned that the Office of National AIDS Policy does not have sufficient staffing. Council members frequently refer to the staffing of ONDCP, although we have explained that ONDCP is created by statute whereas ONAP exists at the discretion of the President.

Here is the current staffing:

Director (Sandra Thurman)	White House employee through OPD
Deputy Director (Todd Summers)	White House employee through OPD
Executive Director of the Council	Agency representative (HHS)
Mathew Murguia	Agency representative (HHS)
Receptionist	Agency representative (HUD)

Funding for the operation of the office comes primarily through HUD, which is therefore the only agency that can provide administrative assistance. Because of its own budget limitations, HUD has been unable to provide more than 1 FTE to the office, which is being used for the receptionist position. Neither the Director nor Deputy Director have assistants.

There are several possible responses:

- **Assign additional FTEs/OGEs to ONAP** - Ms. Apuzzo had submitted a proposal to Mr. Bowles that would have resulted in additional FTEs/OGEs to ONAP but it was apparently not approved
- **COS assists in increasing agency reps** - The COS could agree to assist in securing additional agency representatives by sending letters to all Federal agencies (Mr. Bowles had done this several years ago)
- **Increase ONAP budget** - OMB could support an increase in funding for the Office of the Secretary at HHS with an earmark for funding ONAP (currently, HUD provides approximately $211,000 per year plus 1 FTE)

Access by the Council to the President

Dr. Hitt may raise concern that the Council does not regularly meet with the President. The Council has expressed interest in securing a commitment for an annual meeting with the President at which the Council could provide an update in its recomenndations and the Administration's response.

We suggest that this request be taken under advisement and that the COS agree to carefully consider any request by the Council for a meeting with the President.

Issues to be raised by the Council with the President

The following policy issues are likely to be raised by the Council in its upcoming meeting with the President:

- **Increasing Access to Treatment** - the Council is concerned that current guidelines suggest treatment well before the onset of AIDS; however, access to Medicaid is generally restricted to those who have AIDS. The result is a "catch 22" in which one must become disabled by AIDS in order to qualify for Medicaid, which provides the treatment that could have substantially delayed the onset of AIDS in the first place. Ms. Thurman has established a task force that is working on this issue.
- **National HIV Counseling and Testing Campaign** - the Council is likely to recommend to the President a new, national "get tested" media campaign; they are also interested in having ONAP manage this campaign in much the same way that ONDCP administers its anti-drug media campaign.

- **AIDS Vaccine Development** - the Council will express concern about the pace of the government's work on the President's HIV vaccine initiative (last spring, the President articulated the goal of finding an HIV vaccine within ten years). In particular, the Council is concerned that a Director for the new vaccine research center under construction at NIH has not been hired (the search has been underway for over 14 months).
- **FY2000 Appropriations** - the Council will express strong support for increased AIDS funding in the FY2000 budget to include increases in care, prevention, research, and housing. The FY99 budget was extraordinarily generous to AIDS funding (over $550 million increase in discretionary programs), and created a difficult standard to maintain.

GOVERNMENT AND PUBLIC RELATIONS

THE Sheridan GROUP

FAX TRANSMITTAL

DATE: December 10, 1998

TO: Todd Summers

FAX #: (202) 456-2438

FROM: Grayson

2 *PAGES INCLUDING COVER SHEET*

1808 SWANN STREET NW ▪ WASHINGTON DC 20009

December 10, 1998

Todd:

Present yesterday at the meeting in your office, in addition to Tom and myself, were: Eric Hanson and Gary Capistrant from U.S. Strategies.

Grayson

THE
CDM
GROUP,
INC.
5530 WISCONSIN AVE.
SUITE 1600
CHEVY CHASE, MD
20815
(301) 654-6740

December 4, 1998

Todd Sommers
Deputy Director
Office of National AIDS Policy
736 Jackson Place
Washington, DC 20503

Dear Mr. Sommers:

I am contacting you on behalf of the Center for Substance Abuse Treatment (CSAT) to ascertain your current interest in participating in the Field Review of the TIP *Treatment of Persons with HIV/AIDS and Substance Use Disorders* (HIV). You have either been a potential consensus panel member or nominated by CSAT or your peers to review this document.

TIPs are state-of-the-art guidelines on best practices in the field of substance abuse treatment. To date, 28 TIPs have been published and distributed to State Alcohol and Drug Abuse Directors, program administrators, and clinicians.

Field Review is an essential step in a TIP's development. Content experts, such as yourself, perform an in-depth review of the manuscript prior to final clearance by CSAT. Comments received from Field Review will be considered for integration into the final draft.

In an effort to gather the field review comments in the most cost-effective and efficient way possible, this TIP can be reviewed via the Internet. We invite and encourage all reviewers with Internet access to utilize it for field review. We will send each Internet user a hard copy of the draft along with review guidelines, instructions on performing the review, and a user name and password. Internet users can read the hard copy and then access the Internet to insert annotations into the document.

If you do not have Internet Access, if you cannot view the World Wide Web through the Internet, or you do not use a Web browser that supports frames, you can perform a similar review in Microsoft Word on a diskette. Panelists without Microsoft or computer access may type responses onto a blank diskette or plain paper. All of these groups will receive a hard copy of the draft, review guidelines, and instructions for performing the review.

If you agree to review the TIP, you can expect to spend approximately four to five hours. Although there is no monetary reimbursement for the field review process, your participation will be recognized in the published document. This current TIP is planned for field review commencing **January 5, 1999**, and must be returned within three weeks (January 26, 1999). If these requirements fit your schedule, please return the attached Field Reviewer Response Form, with your Field Review Format Preference Form and, if you have not already done so, a Consultant Profile Form. This form identifies and highlights your specific qualifications and expertise in our extensive database.

If you have any questions about TIPs or the field review process, please contact Raquel Ingraham, TIPs Project Manager at (301) 654-6740 or ringraham@cdmgroup.com. Thank you.

Sincerely,

Rose M. Urban

Rose M. Urban, M.S.W., J.D., C.S.A.C.
TIPs Project Director

Enclosures:

Field Reviewer Response Form
Field Review Preference Form
Consultant Profile Form

Field Reviewer Response Form

CENTER FOR SUBSTANCE ABUSE TREATMENT
TREATMENT IMPROVEMENT PROTOCOLS

Treatment of Persons with HIV/AIDS and Substance Use Disorders

Name Todd Summers

PLEASE TYPE OR PRINT!

Please check the appropriate box:

☐ **Yes, I am interested in serving as a Field Reviewer for this TIP.**

☐ **No, I am not available to serve as a Field Reviewer for this TIP; but please keep me in mind as other TIPs topics in my areas of expertise are selected.**

☒ **No, I am not available to serve as a Field Reviewer for this TIP and please remove my information from your database.**

Please return this form by December 23, 1998 to:

Raquel Ingraham, M.S.
TIPs Project Manager
CDM Group, Inc.
5530 Wisconsin Avenue, Suite 1660
Chevy Chase, MD 20815
(301) 654-6740 phone
(301) 656-4012 fax

Please return this page to Raquel R. Ingraham at The CDM Group, Inc. Fax: (301) 656-4012.

TIPs FIELD REVIEW FORMAT PREFERENCE FORM

I. Thank you for participating in the Field Review for the Treatment Improvement Protocol (TIP) *Treatment of Persons with HIV/AIDS and Substance Use Disorders*. Please read the following nondisclosure agreement and indicate your compliance by printing and signing your name in the spaces provided.

1. I understand that the forthcoming document, a Treatment Improvement Protocol (TIP), developed under contract by the Center for Substance Abuse Treatment (CSAT), Substance Abuse and Mental Health Services Administration (SAMHSA), is confidential.

2. I agree not to copy, distribute, or publicize the contents of the material, in any form, until after it is published by the Government Printing Office and distributed by CSAT.

3. I agree to return any hard copies of the TIP sent to me by The CDM Group, Inc., a contractor to CSAT, after I complete my review, which is due two weeks after I receive the draft.

_____ _____

Printed Name Signature

II. Please indicate whether you can perform the review via the Internet or alternative methods by checking the appropriate box.

❑ I can perform the review on the **Internet** (I can view the World Wide Web through the Internet and I use a Web browser that supports frames). By doing so, I will be able to insert annotations within the document.

❑ I cannot perform the review via the Internet, so I will review the document in **Microsoft Word** on a diskette. By doing so, I will be able to insert annotations within the document. (Check one).

I use: ❑ Mac ❑ Windows (❑ 3.1 ❑ 95 ❑ NT)

❑ I cannot perform the review on the Internet or in Microsoft Word, so I will **type my responses,** referencing line numbers in the hard copy of the document. If possible, I will submit my typed comments on a disk (in any format). I understand that only typed responses will be accepted, and I will not be able to submit handwritten responses or any comments on the copy of the draft.

III. Please provide the address and telephone number where you would like to receive the Federal Express package containing everything you will need for your review.

_____

_____

_____

Treatment Improvement Protocols (TIPs)
Consultant Profile

SS#_____ Employer Identification #_____ Male ❑ Female ❑

Mr./Ms./Dr. *(Circle One)* First Name_____ Middle Initial_____ Last Name_____

Degrees, Licensure, and Certifications_____

Name exactly as you would like it to appear in publication_____

Title/Position_____

Organization_____

Branch/Division/Department_____

Work Information

Street_____

City_____ State_____ Zip Code_____

Telephone_____ Fax_____ Email_____

Home Information

Street_____

City_____ State_____ Zip Code_____

Telephone_____ Fax_____ Email_____

Completion of the following information is voluntary.

Race and/or National Origin: *(Check One)*

❑ American Indian or Alaska Native
❑ African American, not of Hispanic origin
❑ White, not of Hispanic origin
❑ Asian or Pacific Islander
❑ Hispanic
❑ Other_____

Please check all areas of expertise that apply to your background and work experience.

Profession	*Expertise*	
❑ Accountant	❑ Adolescents	❑ Legal Issues
❑ Administrator	❑ Alcohol Dependence/Alcohol Abuse	❑ Low Income/Disadvantaged Populations
❑ Clinician/Clinical Supervisor	❑ Client Medical Management	❑ Opioid/Narcotic Addiction/ Treatment
❑ Educator/Trainer	❑ Client (Case) Management	❑ Patient Management
❑ Physician	❑ Criminal Justice Incarcerated/ Non-Incarcerated	❑ Patient Placement Criteria
❑ Nurse/Nurse Practitioner	❑ Cultural Issues/Competency	❑ Poly-drug Abusers
❑ Researcher	❑ Detoxification	❑ Program Evaluation
❑ Statistician	❑ Drug Impaired Infants	❑ Relapse Prevention
❑ Writer/Editor	❑ Dual Diagnosis	❑ Self Help Services/Organizations
❑ Other *(specify)*_____	❑ Family Issues	❑ Training
	❑ Geriatrics	❑ Treatment Planning
	❑ Guideline Development	❑ Women's Issues
	❑ Infectious Diseases	❑ Other *(specify)*_____

Please attach a current CV to this profile and mail both documents to:

Raquel Ingraham, M.S. -- TIPs Project Manager
CDM Group, Inc., 5530 Wisconsin Avenue, #1660, Chevy Chase, MD 20815
(301) 654-6740

THE WHITE HOUSE

WASHINGTON

December 12, 1998

Memorandum for Sally Paxton
Special Associate Counsel to the President
148 OEOB

From: Sandra Thurman(Summers)

Regarding: Certification of Document Request of December 1, 1998.

This certification is in response to the document request from Sally Paxton dated December 1, 1998. By signing this document, I certify that I have directed all the individuals in the Office of National AIDS Policy to search their files as well as the office's files. To the best of my knowledge, these files have been reviewed and all potentially responsive documents have been provided.

On behalf of the Office of National AIDS Policy:

Dep Dir.

Sandra Thurman(Summers)

THE WHITE HOUSE

WASHINGTON

December 1, 1998

MEMORANDUM FOR: ALL EXECUTIVE OFFICE OF THE PRESIDENT STAFF

FROM: SALLY P. PAXTON
SPECIAL ASSOCIATE COUNSEL TO THE PRESIDENT

SUBJECT: DOCUMENT REQUESTS

In an effort to fully comply with document requests generated in connection with a federal civil lawsuit, please search your files and records (whether in hard copy, computer or other form) for documents responsive to the requests listed below. **Every employee** is responsible for searching all of his or her own files and records to ensure a comprehensive search. The head of each office then must provide a signed certification that all employees have searched their files and provided copies of any responsive documents in their possession. Additionally, the Counsel's Office has been working with the staff of the Office of Records Management to find responsive material located in storage. If you believe files that you have sent to Records Management may contain responsive information, please let us know so that we can ensure that all responsive materials are found.

Requests:

1. All documents relating to the White House's release, on or about March 16, 1998, of Kathleen Willey's letters to the President.

2. All documents relating to the release of information from Linda Tripp's security clearance form by the Department of Defense.

3. All documents relating to a March 3, 1998 memorandum from FBI Director Louis Freeh to FBI employees regarding the disclosure of FBI information to persons outside the FBI, including the memorandum itself.

4. All documents relating to the alleged obtaining and public disclosure by Clinton Administration officials of information from the personnel files of political appointees in the Bush State Department, including but not limited to the 1993/1994 report on this subject by State Department Inspector General Sherman Funk, and all documents relating to this subject and Elizabeth Tamposi, Jennifer Fitzgerald, Mark Schulhof, Joe Tarver, and Thomas Donilon.

5. All documents relating to the FBI files matter (*i.e.*, requests to the FBI for access to FBI background investigation files on former Reagan and/or Bush Administration personnel) created between December 19, 1997 and October 27, 1998. You need NOT provide pleadings or deposition transcripts relating to the case *Alexander v. FBI.*

Please provide copies of any responsive documents to Sally Paxton, 148 OEOB, **BY NOON ON TUESDAY DECEMBER 8, 1998.** If you have any questions about any requests or if you need additional time to respond to this directive, please call Sally at extension 65079. Thank you very much for your cooperation.

SUMMERS, TODD A.
WHITE HOUSE OFFICE

DOMESTIC POLICY COUNCIL

736 JACKSON PL

THE WHITE HOUSE

WASHINGTON

December 7, 1998

Memorandum for Sandra Thurman(Summers)

From: Sally Paxton
Special Associate Counsel to the President

Regarding: Certification of December 1, 1998
Document Request Regarding Federal Civil Lawsuit

On December 1, 1998, I circulated to all staff of the Executive Office of the President a document request relating to a federal civil lawsuit. The memorandum requested a response by December 8, 1998. To certify that the files of your office have been searched, please sign the attached certification and return it to me as soon as possible.

Thank you for your cooperation.