# Talking Points for Secretary's Briefing of POTUS
# Re: President Mbeki and AIDS

**South Africa currently has the fastest growing AIDS epidemic in the world.**

- South Africa has seen an explosion of HIV infection since the fall of apartheid.
- 4 million South Africans are already HIV+ (1 in 10), with 1,700 new infections each day.
- More than 50% of new infections are among people under the age of 20 (ratio of 6 teenage girls infected for every 1 teenage boy)
- 1999 national antenatal survey projects that nearly 1 in 4 pregnant women are already HIV+
- Recent report indicates that 60-70% of the South African National Defense Force may now be infected, up from estimates of less than 40% just two years ago.
- More than 2 million South African children will be orphaned by AIDS in the next decade.

**Top level leadership is desperately needed in this fight.**

- When Ugandan President Museveni came into power, he made AIDS a top priority. Under his leadership, all government officials were directed to talk about HIV and AIDS in *every* public appearance and all government ministries were required to engage in the fight. It was this multi-sectoral approach that created the "enabling environment" needed to ensure that the resources invested in AIDS achieved real results (a 50% reduction in infection rates). It was this bombardment with a *consistent* message about AIDS from the government and its partners that enabled Uganda to reduce stigma and to make serious progress.
- Although the South African Government has developed a national AIDS plan, appointed a national AIDS council, and increased their AIDS budget, fear, denial, and stigma remain fierce and continue to plague efforts to slow the spread of HIV and to care for those with AIDS.
- President Mbeki is undoubtedly wrestling with the reality that an appropriate assault on AIDS may require not just increased health spending, but a reorientation of national economic priorities. He understands, as others should, that we must simultaneously fight HIV/AIDS and poverty, or the two will combine to have a devastating effect on Africa's future.
- President Mbeki has recently sought input from several dissident scientists who believe that HIV does not cause AIDS. This has set off a firestorm of criticism from both the scientific and AIDS communities. In response, President Mbeki has set up an AIDS Advisory Panel made up of AIDS experts from around the world to consider a variety of topics including whether or not HIV causes AIDS.

**The reach of this debate extends far beyond the borders of South Africa.**

- Support for investing in the AIDS crisis in Africa is based not only on the magnitude of the crisis, but on the belief that there is a *real* opportunity to make a difference. The bipartisan Co-del that traveled to South Africa to look at AIDS was very disturbed by their conversations about AIDS with President Mbeki – but continue to be strong supporters of increased investment. For those who are more skeptical about our ability to slow the spread of HIV in Africa, President Mbeki's recent comments only heightens their anxiety.
- AIDS experts in South Africa and across the continent have expressed concern that some African leaders will wait to see how this debate plays out before taking much needed action. Unfortunately, the one luxury we do not have is time. Each day, 11,000 Africans become HIV+, and the rapid implementation of effective prevention efforts is essential.
- In July, South Africa will host the International AIDS Conference. This is the first time that this conference will take place in the developing world and there is great interest. The organizers are expecting more than 15,000 participants and every major media outlet. While this recent controversy has led some activists to call for a boycott of the conference, it has only increased press interest. It is not clear if President Mbeki will address the gathering, and if so, what he would say. We are all invested in helping to ensure that this conference is productive for both the battle against AIDS and for South Africa generally. But again, we are running out of time.

**We have much in common with South Africa.**

- President Mbeki said in his recent letter to you that a "simple superimposition of Western experience on African reality would be absurd and illogical" and that, "contrary to the West, HIV/AIDS in Africa is heterosexually transmitted". While in the early 1980s in the US, AIDS was largely confined to gay white men, today HIV is spreading most rapidly among women, young people, people of color, and the poor. In fact, the epidemic in the US increasingly parallels the epidemic in South Africa.
- While new treatments have brought health and hope to many in the US, less than 1/2 of people with HIV currently benefit from these promising drugs. Certainly, there is much more we all need to do – together.
- One lesson that is now clear from nearly two decades of painful experience with this epidemic is that one-size-fits-all solutions do not work. We are constantly challenged to target our own HIV prevention and AIDS care programs to keep pace with the changing face of the epidemic here at home. We know that our success, both here and abroad, depends on our ability to support locally controlled and culturally appropriate interventions, designed to meet the particular needs and circumstances of those most at risk. What works in Des Moines, Iowa is no more likely to work in the South Bronx or in South Central LA than it is to work in South Africa. And while the components of an effective HIV/AIDS strategy remain constant (ie. widespread education, voluntary counseling and testing, care and support), how these programs are implemented must be "home-grown" and uniquely tailored.

**There is much that we can learn from each other and much progress that we can make together.**

- We have all learned a great deal from the world's most effective HIV prevention program – which was not implemented in the West, but in Uganda. The US is justifiably proud to have been the major donor in the Ugandan success story and we continue to have great hopes for an enhanced AIDS partnership throughout sub-Saharan Africa.
- As a result of our LIFE initiative, we will be able to double our HIV prevention and AIDS care efforts in Africa, and to nearly triple our investment in the battle against AIDS in South Africa. In addition, the nearly $2 billion per year we spend on HIV/AIDS research, including vaccine development, will continue to bear fruit not just for the US but for our global community.
- It is our hope that this process will assist President Mbeki in his quest to leave no stone unturned in responding to this growing tragedy. While the HIV/AIDS pandemic will continue to raise new and serious questions, we should continue to seek ways to use the knowledge we have gathered and the lessons we have learned for the benefit of the millions whose lives are caught in the crossfire.

# OFFICE OF NATIONAL AIDS POLICY

EXECUTIVE OFFICE OF THE PRESIDENT

THE WHITE HOUSE

## FACSIMILE TRANSMITTAL SHEET

TO: Don Gatto

FROM: Cheryl Bauerle

COMPANY:

DATE:

FAX NUMBER: 647-5007

TOTAL NO. OF PAGES INCLUDING COVER:

PHONE NUMBER:

RE:

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

NOTES/COMMENTS:

Many thanks! Please call me with questions - 456-2959.

Cheryl

736 Jackson Place
Washington, DC 20503
(202) 456-2437
(202) 456-2438 (fax)

**********
*** TX REPORT ***
**********

TRANSMISSION OK

| | |
|---|---|
| TX/RX NO | 1073 |
| CONNECTION TEL | 96474780 |
| CONNECTION ID | P |
| ST. TIME | 05/05 12:51 |
| USAGE T | 01'24 |
| PGS. | 3 |
| RESULT | OK |

**Background**: Last year a controversy developed when South Africa passed its "Medicine's Act" which USTR felt would exceed the scope of international trade agreements (TRIPS) and US trade practice (TRIPS plus). On World AIDS Day (12/1/99) the Administration clarified its policy to state that in countries experiencing a public health emergency, it would not object to compulsory licensing if such a practice: (1) promoted access to essential drugs for people with AIDS; and (2) was done in a manner consistent with TRIPS. During Senate floor consideration of the African Growth and Opportunity Act, Senator Feinstein offered an amendment which sought to codify this policy for all of sub-Saharan Africa. This amendment was passed by the Senate but then dropped in conference.

**Executive Order**: Today's Executive Order takes official action on an important provision that was eliminated from the Senate version of the African Trade bill. It administratively codifies the policy adopted by the Administration in December and the amendment put forward by Senator Feinstein.

**Message**: AIDS is far more than a humanitarian issue. AIDS is a development crisis, an economic and trade crisis, and a security and stability crisis. Winning the battle against AIDS requires moving forward on a variety of fronts simultaneously. Today's action is an integral part of a broad-based Administration effort to stem the rising tide of new HIV infection, and to bring health care and support services to the more than 34 million people around the world who are living with HIV and AIDS – most of whom have no access to these essential services. The Administration is also working hard to:

- secure the $100 million increase in the global AIDS programs that the President included in his FY2001 budget:
- encourage similar increases among other G-8 donors;
- encourage countries receiving debt relief under to HIPC to re-direct these funds into HIV prevention and AIDS care; and
- galvanize enhanced support from the business, foundation, and religious communities.

## Talking Points for Secretary's Briefing of POTUS
## Re: President Mbeki and AIDS

**South Africa currently has the fastest growing AIDS epidemic in the world.**

- South Africa has seen an explosion of HIV infection since the fall of apartheid.
- 4 million South Africans are already HIV+ (1 in 10), with 1,700 new infections each day.
- More than 50% of new infections are among people under the age of 20 (ratio of 6 teenage girls infected for every 1 teenage boy)
- 1999 national antenatal survey projects that nearly 1 in 4 pregnant women are already HIV+
- Recent report indicates that 60-70% of the South African National Defense Force may now be infected, up from estimates of less than 40% just two years ago.
- More than 2 million South African children will be orphaned by AIDS in the next decade.

**Top level leadership is desperately needed in this fight.**

- When Ugandan President Museveni came into power, he made AIDS a top priority. Under his leadership, all government officials were directed to talk about HIV and AIDS in *every* public appearance and all government ministries were required to engage in the fight. It was this multi-sectoral approach that created the "enabling environment" needed to ensure that the resources invested in AIDS achieved real results (a 50% reduction in infection rates). It was this bombardment with a *consistent* message about AIDS from the government and its partners that enabled Uganda to reduce stigma and to make serious progress.
- Although the South African Government has developed a national AIDS plan, appointed a national AIDS council, and increased their AIDS budget, fear, denial, and stigma remain fierce and continue to plague efforts to slow the spread of HIV and to care for those with AIDS.
- President Mbeki is undoubtedly wrestling with the reality that an appropriate assault on AIDS may require not just increased health spending, but a reorientation of national economic priorities. He understands, as others should, that we must simultaneously fight HIV/AIDS and poverty, or the two will combine to ~~wipe out~~ have a devastating effect on Africa's future.

Mbeki

**The reach of this debate extends far beyond the borders of South Africa.**

- Support for investing in the AIDS crisis in Africa is based not only on the magnitude of the crisis, but on the belief that there is a *real* opportunity to make a difference. The bipartisan Co-del that traveled to South Africa to look at AIDS was very disturbed by their conversations about AIDS with [redacted] President Mbeki - but continue to be strong supporters of increased investment. For those who are more skeptical about our ability to slow the spread of HIV in Africa, President Mbeki's recent comments only heightens their anxiety.
- AIDS experts → ~~Our colleagues~~ in South Africa and across the continent have expressed concern that some African leaders will wait to see how this debate plays out before taking much needed action. Unfortunately, the one luxury we do not have is time. Each day, 11,000 Africans become HIV+, and the rapid implementation of effective prevention efforts is essential.
- In July, South Africa will host the International AIDS Conference. This is the first time that this conference will take place in the developing world and there is great interest. The organizers are expecting more than 15,000 participants and every major media outlet. While this recent controversy has led some activists to call for a boycott of the conference, it has only increased press interest. It is not clear if President Mbeki will address the gathering, and if so, what he would say. We are all invested in helping to ensure that this conference is productive for both the battle against AIDS and for South Africa generally. But again, we are running out of time.

**We have much in common with South Africa.**

- President Mbeki ~~has~~ said in his recent testimony that a "simple superimposition of Western experience on African reality would be absurd and illogical" and that, "contrary to the West, HIV/AIDS in Africa is heterosexually transmitted". While in the early 1980s in the US, AIDS was largely confined to gay white men, today HIV is spreading most rapidly among women, young people, people of color, and the poor. In fact, the epidemic in the US increasingly parallels the epidemic in South Africa.

- While new treatments have brought health and hope to many here in the US, less than 1/2 of people with HIV currently benefit from these promising drugs. Certainly, there is much more we all need to do – together.
- One lesson that is now clear from nearly two decades of painful experience with this epidemic is that one-size-fits-all solutions do not work. We are constantly challenged to target our own HIV prevention and AIDS care programs to keep pace with the changing face of the epidemic here at home. We know that our success, both here and abroad, depends on our ability to support locally controlled and culturally appropriate interventions, designed to meet the particular needs and circumstances of those most at risk. What works in Des Moines, Iowa is no more likely to work in the South Bronx or in South Central LA than it is to work in South Africa. And while the components of an effective HIV/AIDS strategy remain constant (ie. widespread education, voluntary counseling and testing, care and support), how these programs are implemented must be "home-grown" and uniquely tailored.

**There is much that we can learn from each other and much progress that we can make together.**

- We have all learned a great deal from the world's most effective HIV prevention program – which was not implemented in the West, but in Uganda. The US is justifiably proud to have been the major donor in the Ugandan success story and we continue to have great hopes for an enhanced AIDS partnership throughout sub-Saharan Africa.
- As a result of our LIFE initiative, we will be able to double our HIV prevention and AIDS care efforts in Africa, and to nearly triple our investment in the battle against AIDS in South Africa. In addition, the nearly $2 billion per year we spend on HIV/AIDS research, including vaccine development, will continue to bear fruit not just for the US but for our global community.
- It is our hope that this process will assist President Mbeki in his quest to leave no stone unturned in responding to this growing tragedy. While the HIV/AIDS pandemic will continue to raise new and serious questions, we should continue to seek ways to use the knowledge we have gathered and the lessons we have learned for the benefit of the millions whose lives are caught in the crossfire.

**Q: Just exactly what are the facts about AIDS in Africa?**

- Globally, more than 34 million people are living with HIV, 24 million in sub-Saharan Africa;
- Everyday, 5,500 people in Africa die of AIDS, and that number will more than double in the next few years;
- Last year alone, ten times as many people in Africa died of AIDS (2.2 million) than were lost in all of the continents wars combined (200,000);
- Everyday, 11,000 Africans become HIV+ -- 1 every 8 seconds;
- 16 countries in sub-Saharan Africa already have adult (ages 15-49) infection rates of more than 10%, 9 countries (including South Africa) have adult infection rates of 20% (1 in 5 adults) or more;
- by the end of this decade, more than 40 million African children will be orphaned by AIDS, the same number of children as those living east of the Mississippi River or attending public school in the US;

**Q: Why is AIDS a national security issue?**

- In addition to the classic threats to national security, globalization means that we are facing a host of new threats that know no borders – including AIDS, international crime, and drug trafficking;

- HIV infection rates in militaries, especially those in sub-Saharan Africa, are extremely high. According to the National Intelligence Council report, African armies and recruitment pools already have infection rates between 10-60%. This threatens the stability of these nations and seriously complicates peacekeeping operations.

- High HIV infection rates among professionals, particularly hard hit by AIDS, hurts struggling democracies and those in transition. In Africa, HIV has disproportionately affected civil servants, police, miners, transportation workers, health professionals, teachers, and others. In several sub-Saharan Africa nations, more than 30% of teachers are already infected.

- AIDS has had a devastating impact on economies at both the micro and macro levels. AIDS is striking down skilled workers in their prime, driving up the cost of doing business, and driving down both profits and GNP. Many corporations are already hiring two workers for every one job, assuming that one will die of AIDS. By 2005, Kenya's GDP will be 15% smaller than it would have been without AIDS. As a result of AIDS, South Africa's GNP is already falling by 1-2% per year.

- The South African Security Institute has linked the growing number of children orphaned by AIDS to future increases in crime and civil unrest. As millions of orphaned children seek to raise themselves, exploitation by rogue militias, drug traffickers, and other criminal organizations is a serious concern.

- As a result of AIDS, infant mortality is doubling, child mortality is tripling, and life expectancy is plummeting by 20 years or more in many countries in Africa. According to the National Intelligence Council, infant mortality correlates strongly with social and political instability, particularly in countries that have achieved a measure of democracy.

**Q: Why does AIDS in Africa matter?**

- We are a global community, and a crisis of this magnitude anywhere effects people everywhere. Threats to the public health, to national economies, and to national and regional stability threaten us all.

- AIDS in Africa is much more than a health emergency, it is a development crisis, an economic crisis, and a security and stability crisis.

- We are at the beginning and not the end of this pandemic. By 2005, more than 100 million people worldwide will have been infected with HIV. And these numbers are probably conservative. Throughout this pandemic, global estimates have always turned out to be low. In 1991, the WHO predicted that by 1999 there would be 9 million people with HIV. Tragically, that number turned out to be 24 million.

- What we see in Africa today, we will see in India and the Newly Independent States of the Former Soviet Union tomorrow. According to the National Intelligence Council report, by 2015, Asia will be the epicenter of this pandemic.

- We can help to turn this tide. To fail to do so would be unconscionable. We know what works and have demonstrated this success in Africa. With our help, Uganda waged an all out war on AIDS and reduced their infection rates by more than half. Together with the government of Senegal, we showed that with aggressive prevention efforts, infection rates could be kept low. We now have the chance to work with the global community to bring these successes to scale – and to save millions of lives.

- If we learn our lessons well in Africa – we can apply them immediately to Asia and begin to change the course of this pandemic.

- Last year, the global community raised $80 billion to deal with the Y2K virus. Unfortunately, during the same period, the same donors have committed less than $350 million to deal with AIDS virus. Surely there is more that we can do together.

# AIDS in Africa is a Serious Crisis

But Opportunities Exist for Helping to Save Millions of Lives

**AIDS IN SUB-SAHARAN AFRICA IS SHATTERING FAMILIES AND COMMUNITIES.**

- About 24 million Africans south of the Sahara are HIV infected -- almost 70% of the world's total number infected in a region that accounts for only 10% of the world's population.
- In seven countries in southern Africa, including South Africa, 20% of the adult population (ages 15 to 49) is already infected.
- UNAIDS has declared HIV/AIDS in Africa "the worst infectious disease catastrophe since the bubonic plague."
- In sub-Saharan Africa, each and every day more than 11,000 additional people become HIV+. In South Africa alone, at least 1,600 people a day become HIV+.
- AIDS is now the leading killer in sub-Saharan Africa with 84% (13.7 million) of the 16.3 million AIDS deaths to date.
- There are over 5,500 AIDS related funerals a day in Africa. That number will rise to 13,000 a day by 2005.
- In 1998 in Africa, 200,000 people died as a result of war -- AIDS killed 2.2 million.
- By 2010, more than 40 million children in Africa will be orphaned by AIDS.

**AIDS IS WIPING OUT DECADES OF PROGRESS ON A HOST OF DEVELOPMENT OBJECTIVES IN SUB-SAHARAN AFRICA.**

- According to US Census Bureau, AIDS has already reduced life expectancy Zimbabwe from 65 to 39 years, in Uganda from 54 to 43 years, and in Zambia from 56 to 37years. In the next few years, AIDS will reduce life expectancy in South Africa by a third, from 68 to 45 years.
- In the coming decade, AIDS will double infant mortality (infants under the age of 1) in many sub-Saharan Africa countries and triple child mortality (children ages 1 to 5).

**AIDS IS NOT ONLY CAUSING UNFATHOMABLE HUMAN SUFFERING IT IS JEOPARDIZING THE ECONOMIES, THE STABILITY, AND CIVIL SOCIETY OF MANY SUB-SAHARAN AFRICAN NATIONS.**

- AIDS is a trade and investment issue. At the recent meeting with African trade and finance ministers, Professor Jeffrey Sachs, director of the Harvard Institute for International Development, stated that, "a frontal attack on AIDS in Africa may now be the single most important strategy for economic development."
- According to *The Economist*, a recent study in Namibia estimated that AIDS cost the country almost 8% of GNP in 1996. Another analysis predicts that Kenya's GNP will be 14.5% smaller in 2005 than it would have been without AIDS, and the per capita income will be 10% lower.

- A report released by the World Bank last week states: "The question is, will this pandemic destroy the developing nations' hard earned economic gains or will governments get their act together in time? Clearly time is running out."
- AIDS has hit professionals hard in sub-Saharan Africa, particularly civil servants, engineers, teachers, miners, and military personnel. According to one study in Kigali, Rwanda, 34% of people with post-secondary education were HIV positive, compared to 18% of those with primary education, and civil servants were more than three times more likely to be HIV positive than farmers. Increased benefits and training costs, and disruption due to sick and bereavement leave are seriously affecting both the private and public sectors. Companies like British Petroleum and Barclay Bank told us that they are now hiring two employees for every one skilled job, assuming that one will die of AIDS.
- AIDS is a security issue. According to the Economist, "the estimated HIV prevalence in the seven armies embroiled in the Congo range from 50% for the Angolans to 80% in Zimbabweans". Recent reports confirm that 40% of the South African military is already HIV positive. US military officials have raised this as a serious stability concern.
- A South African anti-crime institute has linked the growing number of children orphaned by AIDS to future increases in crime and civil unrest. Without appropriate intervention, many of the 2 million children projected to be orphaned by AIDS in South Africa will raise themselves on the streets, often turning to crime, drugs, commercial sex, and gangs for survival. This not only effects social stability but also dramatically increases their risk of HIV.

**DETERMINED LEADERSHIP AND PARTNERSHIPS HAVE MADE, AND ARE CONTINUING TO MAKE, AN EXTRAORDINARY DIFFERENCE, SAVING MILLIONS OF LIVES.**

- Uganda has been the world leader in demonstrating that even a country with limited resources and low levels of literacy could turn the tide on a burgeoning epidemic. President Museveni demonstrated bold leadership early on, making every government ministry take the problem seriously, and develop and implement its own plan for reducing stigma and transmission, and caring for those who become sick.
- Uganda has created an enabling environment for donors, such as the US, to be active partners in the battle against AIDS. The US has invested $46 million in HIV prevention and care in Uganda (26% of all donor AIDS funding), and as a result, HIV rates have been slashed by more than half. Through stigma reduction, education, HIV counseling and testing, treatment of STDs, and community based HIV care and support, Uganda has begun to turn the tide.
- Countries such as Zambia, Malawi, Uganda, and Kenya have begun to develop initiatives to respond to the growing number of children orphaned by AIDS. In the longstanding African tradition, communities are finding creative ways to support the village in its efforts to raise its children, but the growing number of orphaned children already overwhelms many of these villages.
- Through micro-finance programs like FINCA (Foundation for International Community Assistance), women are receiving loans, starting small businesses, and with increased household incomes, taking in children orphaned by AIDS. With support of non-governmental organizations, communities are coming together to deal with school fees, nutritional assistance, immunization and oral hydration, counseling, and the range of other needs that arise for orphaned children. These efforts are low cost strategies designed to empower women, protect children, and support extended families and communities in carrying for their own. For a small fraction of the cost of one orphanage bed an entire community of vulnerable children can receive care. The problem is that only a very small number of children receive even this modest level of support.

# OFFICE OF NATIONAL AIDS POLICY

EXECUTIVE OFFICE OF THE PRESIDENT

THE WHITE HOUSE

**FACSIMILE TRANSMITTAL SHEET**

TO: Bob Tasat

FROM: Cheryl Baverle

COMPANY:

DATE:

FAX NUMBER: 690-5673

TOTAL NO. OF PAGES INCLUDING COVER: 5

PHONE NUMBER:

RE:

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

NOTES/COMMENTS:

Pls see attached.

736 Jackson Place
Washington, DC 20503
(202) 456-2437
(202) 456-2438 (fax)

**********
*** TX REPORT ***
**********

TRANSMISSION OK

| | |
|---|---|
| TX/RX NO | 1076 |
| CONNECTION TEL | 96905673 |
| CONNECTION ID | DHHS/ASPA |
| ST. TIME | 05/05 15:51 |
| USAGE T | 02'31 |
| PGS. | 5 |
| RESULT | OK |

**Q1: What does the Order do? How will it help the HIV/AIDS crisis in sub-Saharan African countries?**

**A:**

- Under this Order, beneficiary sub-Saharan African governments will be provided with flexibility to bring life-saving drugs and medical technologies to affected populations.

- They will be provided with this flexibility because the U.S. Government will not seek the revocation or revision of any intellectual property policy in beneficiary sub-Saharan African countries that promotes access to HIV/AIDS pharmaceuticals and that provides adequate and effective intellectual property protection consistent with international intellectual property standards. These standards are established by the World Trade Organization Agreement on Trade-Related Aspects of Intellectual Property Rights or "TRIPS Agreement." [For background information on the TRIPS Agreement, see Q14.]

- In other words, under the Order the United States will not invoke its domestic trade law remedies to get sub-Saharan governments to change their intellectual property laws if two important conditions are met. The first is that the laws in question promote access for HIV/AIDS victims to needed drugs and medical devices and technology. And the second is that the laws must be consistent with the rules established in the TRIPS Agreement.

- In addition, the Order states that the U.S. will take several positive steps to address the HIV/AIDS crisis. These include encouraging all sub-Saharan African countries:

  - to implement policies designed to address the underlying causes of the HIV/AIDS crisis;

  - to promote practices that will prevent further transmission and infection;

  - to stimulate development of the infrastructure necessary to deliver adequate health care services; and

  - to encourage policies that provide an incentive for public and private research on and development of vaccines and other medical innovations that would contribute to combating the HIV/AIDS crisis facing Africa.

**Q2: Why is the President issuing this Order?**

**A:**

- The President is issuing the Order for several reasons. First, he is deeply concerned about the HIV/AIDS pandemic sweeping through Africa. [For details on the pandemic, see Q6.] He has taken numerous steps to fight the spread of AIDS, and this Order is intended to add to the

Administration's efforts in this critical area. [For details on the Administration's efforts in this regard see Q7.]

- Second, the President had hoped that Congress would include provisions in the pending Trade and Development Act of 2000 [containing the Africa-CBI provisions]. Senators Feinstein and Feingold proposed an amendment to the act that would have instructed U.S. trade officials not to take action against sub-Saharan intellectual property laws that are designed to promote access to AIDS drugs and medical technologies and that are consistent with international intellectual property standards. This amendment, though, was not included in the Conference Report for the bill. Thus, building on the work of Senators Feinstein and Feingold, the President decided to issue an Order that will implement the policy.

- Third, for some time [at least since the end of last year] the Administration has been carrying out a policy that essentially is mirrored by the Order. Formalizing this policy through an Executive Order serves to provide specific direction to address the HIV/AIDS crisis in Africa.

- And fourth, the President determined that the Order, operating in conjunction with the Africa-CBI provisions will help our African partners make important advancements. Together, these actions will strengthen African economies, enhance African democracy, and expand U.S.-African trade. They also will enable the United States to forge closer ties with our African allies, broaden export opportunities for our workers and businesses, and promote our values around the world.

**Q3: Will the Order allow foreign countries to steal U.S. AIDS drugs for manufacturing?**

**A:**

- The Order in no way diminishes obligations owed by sub-Saharan countries to the United States with regard to intellectual property protection. The United States will continue to insist that our trading partners, including sub-Saharan African countries, meet their international obligations to provide basic intellectual property protection. This includes patent, copyrights, trademarks and other intellectual property rights.

- The Order makes clear that the minimum degree of protection to be provided by sub-Saharan countries is based on the World Trade Organization TRIPS Agreement. This agreement establishes minimum international norms for patents, copyrights, trademarks, and the like. Countries that fail to meet the standards established in the agreement would not be permitted to take advantage of the Order.

**Q4: Does the Order allow foreign countries to force U.S. companies to sell AIDS drugs below cost?**

**A:**

- The Order does not allow sub-Saharan countries to force U.S. companies to sell AIDS drugs at unfair low prices.

- International rules [under the TRIPS Agreement] establish parameters around governmental compulsory licensing of drugs and other products. These rules expressly require adequate remuneration be provided where compulsory licensing is imposed, among other things. [For details on international rules covering compulsory licensing, see Q12.]

- Because the Order applies only to sub-Saharan African countries that meet their international obligations, our companies will generally be assured of a fair price where compulsory licensing is used.

- [While compulsory licensing is rare with regard to pharmaceuticals, it is a legitimate practice. ]

**Q5: Does the Order mean that U.S. trade actions will be limited only to challenging those laws that are in violation of the TRIPS Agreement, and not where countries chose not to adopt "TRIPS-plus" laws or practices?**

**A:**

Correct, we will not be challenging laws or practices adopted by sub-Saharan African countries dealing with HIV/AIDS as long as they are consistent with the TRIPS Agreement. We will not press for laws or policies that would implement a higher standard than the TRIPS agreement in these situations.

**Q6: Why was the Order necessary? Why African countries and why now?**

**A:**

- The Order recognizes that there is an extraordinary human health crisis occurring now in sub-Saharan Africa. This is one of the gravest health crises in the world.

- The numbers are staggering. Approximately 34,000,000 people in sub-Saharan Africa have been infected with the disease and, of those infected, approximately 11,500,000 have died. Approximately 5,500 people in sub-Saharan Africa die every day from this illness. These deaths represent more than 80 percent of the total HIV/AIDS-related deaths worldwide.

**Q7: Do you believe that this will solve the AIDS crisis in Africa? What else is the Administration doing?**

**A:**

- The Order will not by itself solve the AIDS crisis in Africa. It will, however, give sub-Saharan countries added ability to fight the spread of AIDS. It will give them additional flexibility to determine how best to get drugs and treatments to people who need them.

- Today's action is an integral part of a broad-based Administration effort to stem the rising tide of HIV infection and to help care for the millions of men, women, and children in Africa and around the world who are already sick with AIDS.

- The Administration's comprehensive global AIDS strategy also includes:

  - an intergovernmental working group, chaired by the White House AIDS Office and the National Security Council, charged with coordinating a government-wide response;

  - working to secure a $100 million increase in funding for global AIDS programs that the President included in his FY2001 budget request; last year the President also requested and secured a $100 million increase in our global AIDS effort enabling the USG to more than double its HIV programs in sub-Saharan Africa;

  - encouraging similar increased AIDS-related foreign aid from other G8 countries;

  - encouraging countries in Africa and around the world receiving debt relief under HIPC to redirect these funds toward HIV prevention and AIDS care programs;

  - pushing for a new tax cut to help spur the development and distribution of vaccines for AIDS and other diseases;

  - calling on the World Bank and other multilateral development banks to dedicate additional low-interest loans to expand AIDS education and other prevention programs as well as to build health care infrastructure; and

  - helping to galvanize support from the business, labor, foundation, and religious communities.

**Q8: Is the Administration no longer concerned with the protection of intellectual property rights in Africa?**

**A:**

- The Administration continues to seek full implementation of intellectual property commitments made to the United States by our trading partners.

- In particular, the Administration has pressed many of our trading partners to provide adequate and effective protection consistent with the TRIPS Agreement. These include initiating investigations into suspect practices under Section 301 of the Trade Act of 1974 [the principal U.S. trade investigation and sanctions law] and Special 301 [USTR's annual report to Congress on the most egregious intellectual property practices around the world], as well as initiating dispute-settlement proceedings in the WTO.

- The United States under the Clinton Administration remains the most active enforcer of intellectual property rights in the world. The Order will not prevent future actions against sub-Saharan governments that fail to meet their international obligations. The Order does so by specifically requiring these countries to provide adequate and effective consistent with the TRIPS Agreement. If a country fails to do so, the United States can take action against their offending measures.

- In this way, the Order strikes a proper balance between the need to enable sub-Saharan African governments to promote access to HIV/AIDS pharmaceuticals and medical technologies and the need to ensure that intellectual property rights are protected.

**Q9: What is meant by a beneficiary country?**

**A:**

We mean those sub-Saharan African countries that are determined to be beneficiaries under the Trade and Development Act of 2000 [containing the Africa-CBI provisions]. The Order is limited to beneficiary sub-Saharan countries that could be identified in that act. The countries could include:

(1) Republic of Angola (Angola).

(2) Republic of Botswana (Botswana).

(3) Republic of Burundi (Burundi).

(4) Republic of Cape Verde (Cape Verde).

(5) Republic of Chad (Chad).

(6) Democratic Republic of Congo.

(7) Republic of the Congo (Congo).

(8) Republic of Djibouti (Djibouti).

(9) State of Eritrea (Eritrea).

(10) Gabonese Republic (Gabon).

(11) Republic of Ghana (Ghana).

(12) Republic of Guinea-Bissau (Guinea-Bissau).

(13) Kingdom of Lesotho (Lesotho).

(14) Republic of Madagascar (Madagascar).

(15) Republic of Mali (Mali).

(16) Republic of Mauritius (Mauritius).

(17) Republic of Namibia (Namibia).

(18) Federal Republic of Nigeria (Nigeria).

(19) Democratic Republic of Sao Tome and Principe (Sao Tome and Principe).

(20) Republic of Sierra Leone (Sierra Leone).

(21) Somalia.

(22) Kingdom of Swaziland (Swaziland).

(23) Republic of Togo (Togo).

(24) Republic of Zimbabwe (Zimbabwe).

(25) Republic of Benin (Benin).

(26) Burkina Faso (Burkina).

(27) Republic of Cameroon (Cameroon).

(28) Central African Republic.

(29) Federal Islamic Republic of the Comoros (Comoros).

(30) Republic of Cote d'Ivoire (Cote d'Ivoire).

(31) Republic of Equatorial Guinea (Equatorial Guinea).

(32) Ethiopia.

(33) Republic of the Gambia (Gambia).

(34) Republic of Guinea (Guinea).

(35) Republic of Kenya (Kenya).

(36) Republic of Liberia (Liberia).

(37) Republic of Malawi (Malawi).

(38) Islamic Republic of Mauritania (Mauritania).

(39) Republic of Mozambique (Mozambique).

(40) Republic of Niger (Niger).

(41) Republic of Rwanda (Rwanda).

(42) Republic of Senegal (Senegal).

(43) Republic of Seychelles (Seychelles).

(44) Republic of South Africa (South Africa).

(45) Republic of Sudan (Sudan).

(46) United Republic of Tanzania (Tanzania).

(47) Republic of Uganda (Uganda).

(48) Republic of Zambia (Zambia).

**Q10: What if that legislation is not passed?**

**A:**

- The President will then have the authority to make the determination about the countries to which this policy applies.

**Q11: How do intellectual property rules/laws affect access to AIDS drugs/technology?**

**A:**

- Intellectual property law provides patent owners the exclusive right to make, use, sell, and distribute the patented product, such as patented pharmaceuticals.

- However, limitations do exist. For instance, the TRIPS Agreement explicitly permits countries to adopt measures necessary to protect public health and nutrition, and to promote the public interest in a manner consistent with the Agreement. TRIPS also permits compulsory licensing of patented products under certain conditions.

- Consistent with all of this, the Executive Order requires the U.S. Government to refrain from seeking the revocation or revision of laws or policies that promote access to HIV/AIDS pharmaceuticals, so long as these laws or policies provide adequate and effective intellectual property protection consistent with the TRIPS Agreement.

**Q12: What are compulsory licensing and parallel imports, and how are they affected by the Order?**

**A:**

***Compulsory Licensing***

Under the Order, the United States would not seek to revoke or revise any intellectual property law or policy of a sub-Saharan African country involving compulsory licensing if that law or policy promotes access to HIV/AIDS pharmaceuticals or medical technologies for affected populations in that country and the government implements any compulsory licensing in a manner that adheres strictly to the conditions specified in the TRIPS Agreement.

Compulsory licensing refers to the situation in which a government authorizes third parties (or the government itself) to use the subject matter of a patent without the authorization of the right holder. TRIPS imposes a number of disciplines on compulsory licensing including, for example:

- the requirement that authorization of such use shall be considered on its individual merits (in other words, shall be considered on a case by case basis);
- such use shall be authorized predominantly for the supply of the domestic market;
- the right holder shall be paid adequate remuneration;

- decisions relating to the authorization of such use and the remuneration provided shall be subject to judicial review; and
- such use may only be permitted if, prior to such use, the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and such efforts have not been successful within a reasonable period of time. This last requirement (but not the others) may be waived in a national emergency.

Generally, a government would grant a compulsory license to one or more domestic manufacturer(s) for the purpose of allowing it (or them) to produce a patented drug for sale in the domestic market without the consent of the patent holder.

***Parallel Importing***

- Parallel importing refers to the importation of genuine products without the authorization of the right holder.

- In other words, parallel imports of pharmaceuticals are pharmaceuticals that are produced by, or with the authorization of, the patent holder, but that are diverted from authorized distribution channels and imported into a country without the authorization of the patent holder.

- As a policy matter, this Administration generally does not support policies that allow for the parallel importation of pharmaceuticals because such imports compromise intellectual property rights and raise concerns about the safety and efficacy of imported drugs.

- We realize, however, that HIV/AIDS is a special case that may require special measures. Thus, while we continue to believe compromising intellectual property rights is not the solution to the greater problem of HIV/AIDS, under the Order we will raise no objection to parallel importing of pharmaceuticals on the part of sub-Saharan African countries, as long as it is done in a way that complies with the TRIPS Agreement.

**Q13: What can the Administration do if it is concerned that a law or policy does not meet the conditions set out in the Order?**

- U.S. Government officials will still be permitted to evaluate, determine, and/or express concern about whether such a law or policy promotes access to HIV/AIDS pharmaceuticals or medical technologies or provides adequate and effective intellectual property protection consistent with the TRIPS Agreement.

- U.S. Government officials will still be permitted to consult with or otherwise discuss with sub-Saharan African Governments whether such law or policy meets the conditions set out in the Order.

- The U.S. Government will also remain able to invoke the dispute settlement procedures of the WTO to examine whether any such law or policy is consistent with the Uruguay Round Agreements, including TRIPS.

**Q14: What are the minimum intellectual property protections provided by the TRIPS Agreement?**

**A:**

- The TRIPS Agreement, which came into effect on January 1, 1995, is the most comprehensive international agreement on intellectual property.

- The areas of intellectual property that it covers are: copyright and related rights (i.e. the rights of performers, producers of sound recordings and broadcasting organizations); trademarks including service marks; geographical indications including appellations of origin (e.g., Champagne or Bordeaux); industrial designs; patents; the layout-designs of integrated circuits; and undisclosed information (including trade secrets and test data).

- The TRIPS Agreement provides a number of important overarching principles. For example, the agreement generally requires that intellectual property rights given to foreign nationals must be at least as good as those provided to domestics. It also generally requires that rights given to the citizens of one foreign country must be no worse than those given to other WTO countries.

- In each of the main areas of intellectual property covered by the TRIPS Agreement – i.e., patents or copyrights – the Agreement sets out the minimum standards of protection to be provided by each WTO country. Each of the main elements of protection is defined, namely the types of goods to be protected, the rights to be conferred, permissible exceptions to those rights, and the minimum duration of protection.

- Patents are the area most relevant to AIDS drugs and technology. The TRIPS Agreement requires WTO member countries to make patents available for any inventions in almost all fields of technology without discrimination. Patents are to be conditioned on tests used widely around the world: the novelty, inventiveness and industrial applicability of the product. [There are a number of exceptions to the scope of coverage for patents.] Patent protection generally must be provided for at least 20 years from the date the patent application is filed.

- [Special rules apply to developing countries. The most important one in the present context is that some developing countries may delay providing patent protection for pharmaceuticals until the year 2005. However, these countries must establish procedures that allow inventors to make a filing and "get in line" – thereby preserving their right to file a patent application ahead of competitors for their product in 2005.]

Talking Points on EO Regarding Limitation of Trade Actions
in Connection with Sub-Saharan Measures Promoting Access
to HIV/AIDS Pharmaceuticals and Medical Technologies

- Today the President will sign an executive order that instructs U.S. trade officials to refrain from taking actions against intellectual property laws and policies of sub-Saharan African governments that are designed to increase access to HIV/AIDS pharmaceuticals and medical technologies for people who need them.

- More specifically, the order will limit U.S. trade actions where sub-Saharan measures (a) promote access to HIV/AIDS drugs and technologies and (b) are consistent with the central WTO agreement on intellectual property rules, the Agreement on Trade-Related Aspects of Intellectual Property Rights (or TRIPs).

- The President's action will provide certain sub-Saharan African countries with added flexibility in crafting policies that will promote access to drugs and medical devices for affected populations.

- At the same time, the order ensures that fundamental intellectual property rights of U.S. businesses and inventors will be protected by requiring that beneficiary sub-Saharan African countries comply with applicable WTO rules – most notably the Agreement on Trade-Related Aspects of Intellectual Property Rights.

- Thus, to the extent that sub-Saharan African countries comply with their WTO obligations, they stand to benefit from the order in important ways. However, if they do not, they may face trade actions initiated by the United States.

- In addition, the Order states that the U.S. will take several positive steps to address the HIV/AIDS crisis. These include encouraging all sub-Saharan African countries:

  - to implement policies designed to address the underlying causes of the HIV/AIDS crisis;

  - to promote practices that will prevent further transmission of HIV;

  - to stimulate development of the infrastructure necessary to deliver adequate health care services; and

  - to encourage policies that provide an incentive for public and private research on and development of vaccines and other medical innovations that would contribute to combating the HIV/AIDS crisis facing Africa.

- The President's action today will help combat the worldwide HIV/AIDS epidemic, which has resulted in approximately 34,000,000 people in sub-Saharan Africa being infected and, of those, approximately 11,500,000 have died. These deaths represent more than 80 percent of the total HIV/AIDS-related deaths worldwide.

**Talking Points for Vice President's Speech**
**to the UN Security Council**

- **The UN called AIDS the "most deadly undeclared war in human history".**

In 1998, nearly 3 million people worldwide died of AIDS – more than 10 times the death toll of the war in Bosnia. Already, AIDS has taken more lives than all of the wars of the 20th century combined.

More than 50 million people worldwide have already become HIV+ and that number is expected to double by 2005.

More than 16,000 people become HIV infected each day -- half of whom are under the age of 25 -- with the fastest growing rates of infection now found in India and South Asia.

As UNICEF said today in releasing the State of the World's Children: "There can be little doubt that the same catastrophic combination of stigma, taboo, and silence that continues to fuel the deadly epidemic in sub-Saharan Africa is repeating itself in South Asia."

More than 11 million children have already lost their mother or both parents to AIDS, and by 2010 that number will rise to 40 million in sub-Saharan Africa alone; and

- **AIDS is not just a humanitarian crisis, but a development crisis, an economic crisis, and a security crisis.**

AIDS will double infant mortality, triple child mortality, slash life expectany,

AIDS has been called the "single greatest threat to future economic development in Africa" by the World Bank.

# Questions (Additional)

1) You have mentioned the US Government's leadership in this area. What are our other partners doing in the private sector?

2) If we to double or even triple the USG budget for HIV/AIDS in Africa, what could we achieve?

3) I congratulate you on providing the leadership to move this issue to the forefront of the Administrations agenda. Why has there been such a lack of political will and leadership in Africa to deal with HIV/AIDS? What are you doing to reverse that? Involvement with religious leaders?

4) You have noted the impact that 40 million orphans in Africa will have, as well as the toll on economic and political security. This seems such a daunting challenge. What can we realistically do to respond to these orphan and children-related issues?

5) We have heard the exciting news of nevirapine to prevent mother to child transmission. How fast can we scale up mother to child transmission?

# An AIDS Initiative: Qs & As

**Q**: How is the budget amendment being offset?

- $40 million comes from unspent activities at the Department of Justice for enforcement activities against unlawful diversion of prescription drug medications.

- $30 million in unobligated balances from the National Institutes of Health Buildings and Facilities still available because they were not spent last year.

- $10 million in balances from the Agency for International Development Sustainable Development Assistance Account in appropriate funds that exceeds projected expenditures for development accounts.

- $10 million for general nutrition assistance that is reallocated from International Assistance Programs and prioritized for AIDS orphans.

  $10 million from the Department of Defense from sales of excess raw minerals no longer needed.

**Q:** Are any of these funds being taken from existing AIDS programs, Africa programs, or programs to support orphans?

**A:** None of the funds are being shifted away from AIDS, Africa or programs which provide support to orphans. These funds are additional to what is currently being spent on both AIDS and Africa.

**Q**. You claim that this initiative "more than doubles funding for prevention and treatment in Africa (above its current level of $81 million in FY99)." What does this mean?

**A**. The USG currently spends $112 million on AIDS in Africa in total, $31 million on research and $81 million in prevention and treatment. This initiative is solely for prevention and treatment -- not research -- so it is fair to say that we are more than doubling our prevention and treatment funding.

The $81 million is comprised of $74 million in AID prevention and treatment, and $7 million in HHS/CDC surveillance.

**DRAFT**

July 16, 1999

**Q:** Has funding been allocated for FY2001?

**A:** The difficult battle against AIDS will require sustained attention from the US government, other bilateral and multilateral donors and especially from the African nations themselves for many years. Our goals, which are coordinated with the UNAIDS program goals, are five year goals. We are committed to working towards reaching these important goals.

(IF PRESSED:) We have not made any funding commitments beyond the year 2000. However, recognizing the extreme need, we anticipate future funding commitments will be part of our sustained effort.

**Q:** How will the US Government accomplish the goals described with only $100 million in FY2000?

**A:** The goals are part of a larger strategy to battle AIDS outside the U.S., primarily in Sub-Saharan Africa. Our initiative seeks to link the US comparative advantage in assisting developing countries battle AIDS with that of other bilateral and multilateral donors, as well as on the host countries themselves. The battle against AIDS can not be won by the US alone or in one year. Although US leadership is a critical component of the effort, there must be a substantial effort on the part of other donors and the African nations themselves. The goals of the initiative, developed in coordination with UNAIDS, are part of a five year strategy. The global effort of all parties must be sustained over time to address this urgent problem.

**Q:** How will you ensure that other countries donate and how much funding do you expect in total?

- **A:** This new initiative the United States is committing to today demonstrates the US commitment to and leadership in fighting the AIDS pandemic. The US contribution will seek to leverage the commitment and resources necessary from other bilateral and multilateral donors, and host nations themselves to address this challenge. The US will challenge other developed countries to participate in the global effort to achieve the goals laid out through our initiative and the UNAIDS program. In fact, on September 7, 1999, First Lady Hillary Rodham Clinton will convene a meeting of donors, The World Bank, UNAIDS, international foundations, CEOs and others to discuss how we can best enhance and coordinate our AIDS efforts in Africa and around the world.

**Q:** How did you choose the countries in which to focus your efforts?

**A:** Countries will be chosen based on a combination of factors. There were a number of factors to be considered including the adult HIV prevalence rates, the potential for impact, the rate of

increase in HIV, the status of ongoing programs, the political commitment of governments and the opportunity for innovation. Certainly it is critical that the host country is receptive and committed to investing these types of funds.

**Q:** Will the new treatment for reducing mother to child HIV transmission (nevirapine/Viramune) reduce the cost of this initiative?

**A:** We are excited about the potential of this new drug and will be evaluating how it fits into our treatment plans.

Q. What sorts of activities will the Department of Defense conduct associated with this initiative?

**F.** The Department of Defense already conducts a wide variety of activities aimed at educating its own service members to prevent HIV infection. Upon entry, every service member undergoes training to promote responsible behavior. This training includes in-depth explanation of how an individual does or does not contract HIV. Through questionnaires or examinations, at risk persons are identified and further counseled on an individual basis. Following their initial training, service members receive periodic counseling on an as-needed basis.

The Department of Defense will use this practical experience to help prevent the spread of HIV in Africa. As part of on-going medical exercises and organizational exchanges, DoD will engage with African countries to educate and provide prevention activities to African military personnel.

**Q:** How much of the $100 million goes towards prevention? towards treatment?

**A:** $48 million will primarily go towards prevention and $23 million for treatment of sexually transmitted diseases and opportunistic infections. Of the remaining dollars, $10 million will provide care for children orphaned by AIDS and $19 million will strengthen prevention and treatment by augmenting planning, infrastructure, disease surveillance and capacity development.

**Q:** Is this initiative a response to the recent problems facing the Vice President on international patents in South Africa?

**A:** No. The Administration recognizes the critical nature of this pandemic and is committed to helping the African people combat AIDS.

**Q:** What countries?

**A:** Countries will be chosen based on a combination of factors. The most important factor is the receptivity of host countries to partnering. Other factors to be considered include the adult HIV prevalence rates, the potential for impact, the rate of increase in HIV, the status of ongoing programs, the political commitment of governments and the opportunity for innovation. Some of the countries which are currently under consideration are: South Africa, Nigeria, Kenya, Uganda, Mozambique, Zimbabwe, Senegal, Malawi, Zambia, Rwanda, Cambodia, and India. In addition, two regional programs (West/Southern Africa Programs) may be necessary to target migrant workers, and other trans-border issues.

**Q:** How will you pay for this and other 150 initiatives (e.g., Kosovo, Wye)

**A:** This $100 million AIDS initiative which the Administration is putting forward is fully offset and does not use resources which would otherwise be devoted to the additional urgent international assistance needs. The AIDS initiative is offset through resources from DOJ, DOD, HHS and USAID. (See Question 1.)

# An AIDS Initiative: Qs & As

**Q**: How is the budget amendment being offset?

**A**:

- $40 million in surplus balances from the Department of Justice Drug Enforcement Administration which are derived from user fees primarily on pharmaceutical companies to ensure legal drugs are not diverted for illegal uses.

- $30 million in unobligated balances from the National Institutes of Health Buildings and Facilities, that is a small portion of their unobligated balances, still available because they were not spent last year.

- $10 million in balances from the Agency for International Development Sustainable Development Assistance Account, which will not be spent as anticipated most likely due to changes related to civil strife or the political environment.

- $10 million allocation of funds in International Assistance Programs, from PL 480 Food Aid which have not yet been committed. [Note: Although some may argue that food is being taken away from children, in fact the opposite is true. This allocation of $10 million in FY 2000 will guarantee that the food is directed at some of the most needy children – AIDS orphans. PL 480 had unobligated balances of $22 million and obligated balances of almost $700 million at the beginning of FY 1999, and USAID has recently deobligated over $60 million in funds that are no longer committed for their initial purpose. These funds are likely to carry over into FY 2000 and could provide the $10 million for this initiative.]

- $10 million from the Department of Defense from sales of excess raw minerals no longer needed.

**Q:** Are any of these funds being taken from existing AIDS programs, Africa programs, or programs to support orphans?

**A:** None of the funds are being shifted away from AIDS, Africa or programs which provide support to orphans. These funds are additional to what is currently being spent on both AIDS and Africa.

**Q**. You claim that this initiative "more than doubles funding for prevention and treatment in Africa (above its current level of $81 million in FY99)." What does this mean?

**DRAFT**

July 16, 1999

**AIDS Drugs for Africa**
**June 25, 1999**

*Context: In 1997 South Africa's National Assembly passed legislation granting the Health Minister unspecified powers related to pharmaceutical patents. In response to this legislation, more than 40 companies -- roughly one third from America, one third from Europe, one third from South Africa – challenged the law in South African Court, contending that this law violates the constitution of South Africa. The litigation is still ongoing.*

*At the same time, the U.S. Trade Representative was concerned that the ambiguity in the law could allow for actions in violation of the WTO-TRIPS agreement (the agreement reached by the 134-member WTO on protection of intellectual property). As a result, USTR named South Africa to the 301 Special Watch List. The watch list (which is not attached to sanctions) is the lowest level of three designations included in the report USTR produces every April. The report's purpose is to signal U.S. concern on intellectual property rights protection offered to U.S. goods by U.S. trading partners.*

*The Vice President – in his meeting with Deputy President Mbeki in August 1998 -- proposed that the two work toward a solution within a framework that would include parallel importing and compulsory licensing, so long as they were done consistent with international agreements (TRIPS). But progress of negotiations has been slow because of worries on both sides about prejudicing the outcome of the ongoing litigation.*

*AIDS activists have charged that the Vice President – in order to curry favor with drug companies -- has threatened severe trade sanctions against South Africa. These activists have been given credible airing in the media in spite of underlying facts that disprove their points. Namely: Early in 1999, drug company representatives pushed to raise South Africa's status on the 301 Special Watch List from the lowest level to the highest level. The highest designation – if imposed – would require South Africa to resolve the issue to U.S. satisfaction within a set period of time or face trade sanctions. As reported in a Tuesday, June 22 story in the Baltimore Sun, the Office of the Vice President strongly opposed the drug industry recommendation, and the April 30 report – rather than raising the designation -- kept South Africa on the watch list.*

**AIDS activists have said the Vice President has threatened trade sanctions against South Africa if they go forward with plans to produce lower-cost AIDS drugs. Is that fair?**

- As co-chair of the U.S.-South Africa Binational Commission, the Vice President has made an immense personal investment of time and effort in building better U.S. ties with South Africa – working to improve health, expand trade, build the economy.

- Why would he be trying to undercut his own efforts?

- The Vice President has taken a special interest in South Africa's efforts to fight AIDS, and has kept the crisis clearly in mind as we have worked to resolve our trade differences.

- As Susan Rice, our Assistant Secretary of State for Africa, said in the press this week (Baltimore Sun, Tuesday June 22): the Vice President took the position that the health crisis in South Africa needed to be taken into account, and he led the way led the way in opposing trade sanctions pushed by the pharmaceutical industry.

- These activists – as the Washington Post said in their Thursday editorial – are "manipulating the facts." They should understand that the Vice President is one of the strongest advocates in this administration for the issues they care about.

- They should be working with him instead of against him.

**The Vice President cares nothing for millions who are dying.**

It would be hard to find someone in the U.S. Government with a more active record of support for the fight against AIDS in South Africa.

Since 1995, the Vice President has co-chaired with Deputy President Mbeki the U.S.-South Africa Binational Commission. In that context, he has had a central role in bringing to South Africa the best of American knowledge, effort and ideas in the fight against AIDS.

Under the auspices of the Commission, the U.S. has funded a South African effort to track the disease –you can't fight it if you can't track it. The Commission has also worked to expand awareness and improve prevention.

The Vice President has brought high-level U.S. health officials on his trips to South Africa – Secretary Shalala and Surgeon General Satcher -- where they have spoken with President Mandela's cabinet on the issue of AIDS.

Just a few months ago, Vice President Gore took Surgeon General David Satcher with him to South Africa for another meeting of the Commission.

When Vice President Gore appeared with Deputy President Mbeki last February on national TV in South Africa, he was wearing an AIDS ribbon, done in African beadwork, given to him by Mbeki after the two had spent hours the previous day in a one-on-one discussion on AIDS.

It is hard to believe that the Deputy President would present the Vice President such a gift unless they were united in partnership in the fight against AIDS.

The Vice President and Deputy President Mbeki spent a substantial part of their time at the press conference talking about the importance of raising awareness of AIDS, and the Vice

President urged leaders in every sector of South African society to add their voices to Mr. Mbeki's in the call for greater awareness and action against AIDS.

**During those meetings, did the Vice President threaten trade sanctions against South Africa?**

No, he did not. The Vice President proposed working toward a resolution within a framework that would include compulsory licensing and parallel importing, as long as they were done in line with international agreements.

**What's the basis for the dispute?**

The issue arose in 1997, when South Africa's National Assembly passed legislation granting the Health Minister unspecified powers related to pharmaceutical patents. The ambiguity raised concern that actions taken under that law might not be compliant with the WTO-TRIPS agreement.

In response to this legislation, more than 40 companies -- roughly one third from America, one third from Europe, one third from South Africa – have challenged the law in South African Court, contending that this law violates the constitution of South Africa. This case is now being heard by the South Africa Constitutional Court. The ongoing litigation has slowed efforts to resolve it on a government to government level.

**But didn't the Vice President order a sweeping new review of South African trade laws on April 30, 1999?**

No, he did not. The Baltimore Sun's June 22 story pointed out this fallacy. This charge grows out of a misunderstanding of the United States Trade Representative's Annual 301 report – issued April 30, 1999.

The USTR is mandated by Congress to publish a report every year at the end of April, detailing which of America's trading partners may not be affording full protection to U.S. intellectual property rights. As a result of the passage of amendments to South Africa's Medicines Act, and the provisions that could lead to the loss of U.S. intellectual property rights, the U.S.T.R named South Africa to the "Special 301 watch list." This designation means what it says: "The U.S. is seeing some things that give it concern, signaling that concern to the South African government, and indicating that it will be watching further developments. It is the mildest designation in the report, and is not attached to sanctions.

There are two higher designations on the report -- the priority watch list, and the highest, the priority foreign country list. If a country is named a priority foreign country, it means that the country must -- within a set period of time -- resolve the trade dispute to the satisfaction of the United States or face stiff trade sanctions. South Africa is not close to that status.

**But clearly , the Vice President is in the pocket of the pharmaceutical industry**

No, he is not. The Pharmaceutical Research and Manufacturers argued this spring that the USTR annual report -- due to come out again at the end of April -- should designate South Africa (because of the Medicines Act) as a priority foreign country, the most severe designation. This would have required South Africa to resolve the issue to U.S. satisfaction within a short period of time, or face sanctions and a loss of foreign aid. As reported in the June 22 Baltimore Sun, the Vice President's office strongly opposed the recommendation. The U.S.T.R. agreed, and its April 30, 1999 report renewed South Africa's status on the watch list.

**But the Vice President is trying to stop South Africa from doing things that are legal under WTO/TRIPS.**

No, he is not. The U.S. is seeking clarification of the law – about how it will be implemented. The point of discussions has been to work with South Africa to seek assurances that actions taken under the law will be in line with international agreements.

**So where does the Vice President stand?**

The Vice President believes we need to use all available means to deliver high-quality, affordable medicines to those who need them. And we should do it within the legal limits established by TRIPS. Specifically, the Vice President has no objection to parallel exporting or compulsory licensing of pharmaceuticals in South Africa, so long as it is consistent with TRIPS.

**But all the South Africans want to do is what is already their legal right under TRIPS.**

Section 15c of the Medicines Act gives the Health Minister unspecified powers that could go beyond was has been agreed to under TRIPS.

**But the State Department Report says that the Vice President was part of an effort to put pressure on the South Africans.**

First, the State Department report – dated February 5 -- was written in response to members of Congress who had expressed concern that the U.S. wasn't being tough enough with South Africa. They had already suspended U.S. foreign assistance to the central Government of South Africa, and said they would not restore the aid until they received a State Department report detailing what the U.S. was doing to resolve the issue. They had already rejected an earlier report – apparently for not being tough enough.

Second, the only language in the report that names Vice President Gore comes on pages 6 and 7 – under the heading "The Vice President's Plan for a Negotiated Solution." It reads as follows:

"During the August 1998 U.S.-South Africa Binational Commission meetings in Washington, Vice President Gore made the issue of intellectual property rights protection, and pharmaceutical patents in particular, a central focus of his discussions with Deputy President Mbeki. They agreed on a basis for a mutually satisfactory, Government-to-Government negotiated solution to the impasse."

That is the only mention of Vice President Gore's actions in the entire report.

I- talking points

# AIDS in Africa

## Overview

AIDS is now the leading cause of death among all people of all ages in Africa. More than 12 million people in Africa have already died, and another 22.5 million are now living with HIV/AIDS. Although the region contains only 10% of the global population, it accounts for 80% of AIDS deaths worldwide[1].

AIDS buries more than 5,500 people a day in Africa and by 2005, the daily death toll is expected to reach 13,000. Over the next decade, AIDS will kill more people in sub-Saharan Africa than the total casualties lost in all wars of the 20th Century combined.

Every day, an additional 11,000 people in Africa become HIV positive – one every 8 seconds. Since the World AIDS Day 1998 press conference, 325,000 people in South Africa alone have become infected.

AIDS has already reduced life expectancy in Zimbabwe by a quarter of a century and in Zambia from 56 years to 37. In the next few years, AIDS will reduce life expectancy in South Africa by a third, from 60 years to 40.[2]

UNAIDS has declared HIV/AIDS in Africa "the worst infectious disease catastrophe since the bubonic plague."[3]

## Children

Three million children have already died of AIDS in Africa and each year there are an additional 500,000 new infections among infants. Nine out of every ten infants infected with HIV live in sub-Saharan Africa.

During the next decade, more than 40 million children will be orphaned by AIDS in sub-Saharan Africa. AIDS is wiping out decades of progress in child survival. By 2005, as a result of the epidemic, infant mortality will double and child mortality will triple.

Up to one-quarter of all children in sub-Saharan Africa are already living with an HIV positive parent. In nine sub-Saharan African countries, between one-fifth and one-third of all children will be orphaned by AIDS by the end of this year[4].

According to UNICEF, the AIDS pandemic in sub-Saharan Africa has a more significant impact on child survival and maternal mortality than all other emergencies on the continent.

---

[1] UNAIDS

[2] US Bureau of Census, World Population Reports, 1998.

[2] Global Health Council.

[4] Children's statistics have been taken from the 1997 USAID Report, Children on the Brink: Strategies to Support Children Isolated by HIV/AIDS".

## US – Africa Partnership

There is still time to mitigate the impact of AIDS in Africa.

A strong political commitment to the fight against AIDS is crucial. Governments, NGOs and the commercial sector, working together in a multi-sectoral effort can make a difference.

The recent efforts by many of Africa's leaders, including those of President Mandela, President Mbeki, Ghana's President Rawlings, Zambia's President Chiluba, Namibia's President Nujoma, and many others have helped to publicize the dangers of HIV/AIDS and the need for a united and concerted effort by communities to prevent its further spread and to support those already infected.

Uganda, in particular, has shown that even a country with limited resources and a low literacy level can turn the tide on this burgeoning epidemic. President Museveni demonstrated bold leadership early in the epidemic by requiring every government ministry to develop and implement a plan to reduce AIDS stigma and HIV transmission, and support those who became sick. In so doing, Uganda created an "enabling environment" for donors to assist in this effort.

Over the past decade, the US invested $46 million (26% of donor contributions to AIDS) in partnership with the Ugandan government, other donors, and NGOs to provide HIV prevention, care and support. As a result, HIV rates in Uganda were cut in half.

In South Africa, the United States, through USAID recently committed to fund a $10 million five year program to support the South African government and local NGOs efforts to fight HIV/AIDS.

EXPAND ? ↑

Global partnerships and the dedication of political leaders coupled with sufficient resources can help to stem the tide of the AIDS epidemic in Africa.

## Resources

Since 1986 the United States government has contributed over $1 billion to the global fight against HIV/AIDS. More than 50% of those funds have been dedicated to sub-Saharan Africa. This year the United States will spend $76 million to combat HIV/AIDS in sub-Saharan Africa, including $7 million alone for children orphaned and affected by AIDS.

However, if we as a global community are to keep pace with this burgeoning pandemic, a significant new investment is essential. Since 1993, while the annual incidence of HIV has increased by more than 300%, US funding has remained stagnant.

New funds will enable the US, in partnership with other donors and host countries, to contain the AIDS pandemic through proven prevention campaigns, to care for individuals and families living with AIDS, to support children orphaned by AIDS, and to develop much needed infrastructure and capacity.

# TALKING POINTS
# AFRICAN-AMERICAN/LATINO COMMUNITY

- Nationally, AIDS is the leading killer of African American males and the second leading killer of African American women in the 25-44 age group[1];

- Every hour, seven people are newly infected with HIV; **three of those seven** are African American;

- Through December 1999, African-Americans accounted for
  - 37% of total AIDS cases;
  - 57% of total AIDS cases among women; and,
  - 58% of total AIDS cases among children;

- In the U.S., African Americans represent nearly 13% of the population, yet 47% of new AIDS cases reported in 1999, compared to 23% of new cases in 1982 and 30% of cases in 1990[2];

  - By the year 2005, they will account for 60% of all AIDS cases;

- In the U.S., Latinos represent 11% of the population, yet in 1998 they accounted for 20% of new AIDS cases, compared to 12% in 1982 and 17% in 1990.[3]

- Between 1991 and 1996, AIDS deaths in the African-American community increased by 45% while deaths in Whites decreased by 24%:

- Among women, African American women represent 60% of new cases. African American women represent three times the number of new cases reported for White women.

- Nationally, by 2000, more than 125,000 children will have been orphaned or left behind as a result of losing one or both parents to AIDS – 80% of whom will be Black and Latino;[4]

- Youth of color are over-represented among youth with AIDS. African Americans and Latinos account for 63% of AIDS cases among youth ages 20 to 24.

- Black faith community – becoming more involved, but we need to garner even more support and participation;

---

[1] Kaiser Family Foundation Fact Sheet -- The HIV/AIDS Epidemic in the U.S. (June, 1999)
[2] CDC
[3] Kaiser
[4] BLCA

- IDU & Men who have Sex with Men are leading causes of infection in communities of color representing 52% of the total AIDS cases[5] – continued denial within this community about drug use and homosexuality;

- Surgeon General's Leadership Campaign on AIDS – goes directly to African American leaders to make them step up to the plate;

- Injection drug use accounts for a greater proportion of cases among Latino (29%) and African American (27%) than white men (11%).[6]

- African-Americans are not benefiting from the new anti-retroviral treatments due to lack of access and knowledge.

- According to HHS, 20% of African-Americans do not have a regular source of medical care, and 22% have no private of public health insurance

[5] CDC/HHS Fact sheet

[6] Kaiser Family Foundation Fact Sheet -- The HIV/AIDS Epidemic in the U.S. (June, 1999).

I- Talking pts

Memo
5/26/00

To: Sandra Thurman
From: May Kennedy/Melissa
Re: Suggested talking points, first Ad agency meeting, Wed., 5/28, 1-3 pm:

- Introduce yourself & welcome the ad agency reps and CDC.
- Explain briefly what the ONAP is.
- Mention that there's also a Presidential Advisory Council on HIV/AIDS and that, at their March meeting, PACHA recommended that leaders in the advertising industry be contacted. PACHA's hope was that the private sector could help us by acting quickly to get some state-of-the art prevention messages out.
- We were very excited about the idea, and CDC was too. We sent out only a few invitations to a this initial meeting today, inviting a select group of agencies from across the country that are known for excellence and for thinking outside the box.
- You'll hear shortly from representatives from CDC. They'll explain that, here in the US, a smart, energetic push has the potential to get us to the "tipping point" in our fight against HIV.
- But first, I wanted to put some human faces on the statistics that you'll hear.
- Imagine, if you will, that it's 1998, and you're an 8 year-old girl. You have HIV and you can't find a Girl Scout troupe in New York City that will admit you.
- Now, imagine that it's 1999, you're a 35 year-old accountant in San Francisco. You learned that you were HIV-positive almost 10 years ago. You're one of the lucky ones who responded to the new medications and can pay for them with your medical insurance. But it's never easy. When a man sitting beside you on an airplane asked you what all those pills were for, you told him. He was polite, but when you came back from the men's room, you saw that he had left

his first class seat beside you and moved back to coach. You're can't afford that kind of reaction from your co-workers, so sometimes you miss a daytime dose of your medication. Your doctor says he's beginning to see signs that the medication isn't working as well...

- And finally, imagine that it's the year 2000, and you're a 29 year-old single mother in Chicago. A couple of years ago, you found out that your child's father was using IV drugs. You tried everything you could think of to get him to stop, but he wouldn't or couldn't, so you broke things off. After a lot of struggle, you're working now, and things are looking up. In fact, you recently starting seeing a man who seems to be responsible and who obviously likes your little girl. But he doesn't know you might have been exposed to HIV, and you're afraid of what he'll think of you if bring up the idea of an HIV test...

- In just a few minutes, CDC will give you an overview of the relevant science, but these stories give you the flavor of what we're up against at this point in the epidemic. AIDS stigma has become a serious public health problem. And public health experts don't have all the answers on this one.

- You're the experts at changing attitudes – at reframing. And you know that attitudes take time to change. We need to manage our expectations and be pleased with small, steady improvements. Little things will add up and make a big difference.

- There are no earmarked Federal funds at present to support the kind of national visibility we need, and there will have to be a significant national investment over the next decade if we are to create broad social change. This investment will have to be made by the both public and private sectors, and it has to be a collaborative effort.

- CDC is putting together a formidable public/private partnership to take the next step in the fight against the epidemic. Current partners include members of the music industry, cosmetic companies, pharmaceutical companies, and many others. Participants in Business and Labor responds to AIDS like Levi Strauss and Coca Cola have pledged to do their part.

- We're here today to talk about the advertising component.

- Introductions around the room.

- Now CDC will spend the rest of this hour giving you some background information and then we'll all try to answer questions. Then we'll have an hour for an open discussion about a really provocative advertising challenge. How are we going to fight AIDS stigma without inadvertently sending the message, "HIV isn't so bad anymore so you don't have to continue to wear those condoms" ?

- Introduce Melissa Shepherd, Director of the Office of Communication, Center for HIV, STD and TB Prevention (she'll present on the epi, the targeted campaign that's in its final development stages, the barriers to testing, and what CDC can do).

** Then **you will lead a group discussion**, hoping to get as far as possible down the following list:

1. What kind of campaign could help?

2. How could a cooperative effort could be organized (e.g., would one organization have to nominate a manager/point person? What would the remaining division of labor be, very broadly speaking?)

3. Interest in partnership, resources

4. Timing

5. Next steps

Who's coming to the ad agency meeting:

1. Bob Kuperman, President and CEO, Chiat/Day, Los Angeles

   (the company that did the Taco Bell chihuahua, Energizer Bunny; has the International Olympic Committee account)

2. Mel Ciciola
3. Dianne Ashley, President and Partner, Ciciola & Company, New York

   (small firm, had San Pellagrino account, have helped us a lot with the meeting)

4. Kristen Anderson, account executive
5. Ned Crowley, leading "creative", Leo Burnett, huge firm in Chicago

   (have Coca-Cola, Kellogg, Nintendo and Walt Disney accounts)

6. John Thorpe, partner, Goodby, Silverstein & Parters, San Francisco

   (did the women's soccer team, have E*trade, Budweiser, Pepsi accounts)

7. (May have a last minute addition from Young & Rubicam, big NY firm)

8. From CDC, Melissa, David Holtgrave, and an intern, Erin Dixon.

**Fallon McElligott from Minneapolis and Saatchi & Saatchi, NY made a serious effort to arrange schedules, but couldn't. It might be worthwhile to send them minutes of the meeting.

TP

# Talking Points for Secretary's Briefing of POTUS
# Re: President Mbeki and AIDS

**South Africa currently has the fastest growing AIDS epidemic in the world.**

- South Africa has seen an explosion of HIV infection since the fall of apartheid.
- 4 million South Africans are already HIV+ (1 in 10), with 1,700 new infections each day.
- More than 50% of new infections are among people under the age of 20 (ratio of 6 teenage girls infected for every 1 teenage boy)
- 1999 national antenatal survey projects that nearly 1 in 4 pregnant women are already HIV+
- Recent report indicates that 60-70% of the South African National Defense Force may now be infected, up from estimates of less than 40% just two years ago.
- More than 2 million South African children will be orphaned by AIDS in the next decade.

**Top level leadership is desperately needed in this fight.**

- When Ugandan President Museveni came into power, he made AIDS a top priority. Under his leadership, all government officials were directed to talk about HIV and AIDS in *every* public appearance and all government ministries were required to engage in the fight. It was this multi-sectoral approach that created the "enabling environment" needed to ensure that the resources invested in AIDS achieved real results (a 50% reduction in infection rates). It was this bombardment with a *consistent* message about AIDS from the government and its partners that enabled Uganda to reduce stigma and to make serious progress.
- Although the South African Government has developed a national AIDS plan, appointed a national AIDS council, and increased their AIDS budget, fear, denial, and stigma remain fierce and continue to plague efforts to slow the spread of HIV and to care for those with AIDS.
- President Mbeki is undoubtedly wrestling with the reality that an appropriate assault on AIDS may require not just increased health spending, but a reorientation of national economic priorities. He understands, as others should, that we must simultaneously fight HIV/AIDS and poverty, or the two will combine to have a devastating effect on Africa's future.
- President Mbeki has recently sought input from several dissident scientists who believe that HIV does not cause AIDS. This has set off a firestorm of criticism from both the scientific and AIDS communities. In response, President Mbeki has set up an AIDS Advisory Panel made up of AIDS experts from around the world to consider a variety of topics including whether or not HIV causes AIDS.

**The reach of this debate extends far beyond the borders of South Africa.**

- Support for investing in the AIDS crisis in Africa is based not only on the magnitude of the crisis, but on the belief that there is a *real* opportunity to make a difference. The bipartisan Co-del that traveled to South Africa to look at AIDS was very disturbed by their conversations about AIDS with President Mbeki – but continue to be strong supporters of increased investment. For those who are more skeptical about our ability to slow the spread of HIV in Africa, President Mbeki's recent comments only heightens their anxiety.
- AIDS experts in South Africa and across the continent have expressed concern that some African leaders will wait to see how this debate plays out before taking much needed action. Unfortunately, the one luxury we do not have is time. Each day, 11,000 Africans become HIV+, and the rapid implementation of effective prevention efforts is essential.
- In July, South Africa will host the International AIDS Conference. This is the first time that this conference will take place in the developing world and there is great interest. The organizers are expecting more than 15,000 participants and every major media outlet. While this recent controversy has led some activists to call for a boycott of the conference, it has only increased press interest. It is not clear if President Mbeki will address the gathering, and if so, what he would say. We are all invested in helping to ensure that this conference is productive for both the battle against AIDS and for South Africa generally. But again, we are running out of time.

**We have much in common with South Africa.**

- President Mbeki said in his recent letter to you that a "simple superimposition of Western experience on African reality would be absurd and illogical" and that, "contrary to the West, HIV/AIDS in Africa is heterosexually transmitted". While in the early 1980s in the US, AIDS was largely confined to gay white men, today HIV is spreading most rapidly among women, young people, people of color, and the poor. In fact, the epidemic in the US increasingly parallels the epidemic in South Africa.
- While new treatments have brought health and hope to many in the US, less than 1/2 of people with HIV currently benefit from these promising drugs. Certainly, there is much more we all need to do – together.
- One lesson that is now clear from nearly two decades of painful experience with this epidemic is that one-size-fits-all solutions do not work. We are constantly challenged to target our own HIV prevention and AIDS care programs to keep pace with the changing face of the epidemic here at home. We know that our success, both here and abroad, depends on our ability to support locally controlled and culturally appropriate interventions, designed to meet the particular needs and circumstances of those most at risk. What works in Des Moines, Iowa is no more likely to work in the South Bronx or in South Central LA than it is to work in South Africa. And while the components of an effective HIV/AIDS strategy remain constant (ie. widespread education, voluntary counseling and testing, care and support), how these programs are implemented must be "home-grown" and uniquely tailored.

**There is much that we can learn from each other and much progress that we can make together.**

- We have all learned a great deal from the world's most effective HIV prevention program – which was not implemented in the West, but in Uganda. The US is justifiably proud to have been the major donor in the Ugandan success story and we continue to have great hopes for an enhanced AIDS partnership throughout sub-Saharan Africa.
- As a result of our LIFE initiative, we will be able to double our HIV prevention and AIDS care efforts in Africa, and to nearly triple our investment in the battle against AIDS in South Africa. In addition, the nearly $2 billion per year we spend on HIV/AIDS research, including vaccine development, will continue to bear fruit not just for the US but for our global community.
- It is our hope that this process will assist President Mbeki in his quest to leave no stone unturned in responding to this growing tragedy. While the HIV/AIDS pandemic will continue to raise new and serious questions, we should continue to seek ways to use the knowledge we have gathered and the lessons we have learned for the benefit of the millions whose lives are caught in the crossfire.

I - Q:A

7pm
11/30

**Health and Trade Announcement**
**December 1, 1999**

**Question: What are the implications of the agreement between USTR and HHS?**

**Answer:**

- Under this new arrangement there will be a more directed interaction between USTR and HHS on health-related intellectual property issues.

- When a foreign government expresses concern that U.S. trade law related to intellectual property significantly impedes its ability to address a health crisis, USTR will seek substantive information from HHS on the health conditions prevailing in that country.

- This will enable USTR to ensure that the application of U.S. trade law related to intellectual property, consistent with international trade treaties, is sufficiently flexible to respond to public health crises.

**Question: Does this mean USTR is globalizing its recent understanding with South Africa?**

**Answer:**

- Through consultations with HHS, USTR will ensure that the unique health demands of individual nations are given careful consideration in the application of U.S. trade policy.

- We will make determinations on a case by case basis after a thorough analysis of each individual situation once a foreign government has expressed concerns to us.

**Question: What was the understanding with South Africa?**

**Answer:**

- Under the understanding both governments reaffirmed their shared objective of fully protecting intellectual property rights under the WTO TRIPS Agreement, while addressing the health issues identified by South Africa. This will permit South Africa to engage in compulsory licensing, parallel importing, *inter alia,* consistent with existing international trade law.

**Question: What is the Administration's response to claims that the TRIPS Agreement should be amended because it conflicts with developing countries' efforts to address health issues?**

**Answer:**

- We do not believe that TRIPS interferes with health policy. In fact, HHS and USTR agree that sound public health policy and intellectual property protection are mutually supportive. As seen in the case of South Africa, TRIPS allows the flexibility for developing countries to respond to public health crises.

**Question: What is the U.S. view of proposals to patents on drugs designated by the WHO as essential drugs?**

**Answer:**

O We oppose proposals to deny patents on drugs designated by the WHO as essential. The vast majority of the drugs designated as essential by the WHO are not under patent anywhere in the world.

**Question: We understand that the Thai Government is under pressure to issue compulsory licenses on HIV drugs such as ddI.**

**Answer:**

o The Thai Government has not approached us about the situation you describe. If the Thai Government does indeed approach us on this issue, USTR will certainly consult closely with them and with HHS before determining the best course of action.

**Question: Isn't it true that the USG imposed trade sanctions on Thailand in 1998 because it attempted to reduce the costs of medicines?**

**Answer:**

o Recently there have been articles stating that Thailand enacted a patent law in 1992 in response to U.S. threats to restrict trade preferences.
- In 1993 the USG restored certain trade preferences to Thailand that had been revoked in 1988, pursuant to U.S. trade law, over concerns about the lack of intellectual property protection in Thailand.

O It is important to note that the 1998 IPR action plan and restoration of certain benefits as the USG's attempt to focus the Thai Governments attention on the growing IP problem and to promote cooperation between our governments to improve IPR protection.

I-14

**Sandra Thurman** 06/18/99 05:32:26 PM

Record Type: Record

To: Thomas M. Rosshirt/OVP@OVP

cc:
Subject: Talking Points On Compulsory Licensing

**TALKING POINTS**

The Vice President has absolutely no objection to compulsory licensing of pharmaceuticals in South Africa so long as it is consistent with TRIPS ( Trade Related Aspects of Intellectual Property, from the World Trade Organization ).

In 1997, South Africa's General Assembly passed legislation granting broad powers to the Health Minister with respect to pharmaceutical patents. This has raised serious concern among drug companies. As a consequence, more than 40 companies from around the world have filed suit against the South African government. Unfortunately, the pending law suit slowed negotiations between the United States and South Africa to resolve the issue.

I understand that compulsory licensing has received a lot of attention. However, it's important to look at this issue in the broader context of our Administration's work on the global battle against AIDS -- particularly in Africa.

More than any Administration in the past, our Administration has worked diligently to build a new partnership with Africa. A vital part of this new partnership is helping to respond to this serious and growing pandemic.

Through the White House AIDS Office, we have lead several recent fact finding missions to sub-Saharan Africa and are now in the process of finalizing an AIDS Initiative for Africa.

This Administration has been a leader in the battle against AIDS and we will continue to be.

I - TP

## Meeting the Needs of Children Orphaned by AIDS (and other children in distress)

**√ Children orphaned by AIDS are at serious risk of not receiving the essential supports that all children need to grow and develop into productive adults.**
These essential supports include:

- **Family security**
  - -- shelter, food, clothing (income, protection against property grabbing)
  - -- identity, sense of belonging (in/formal adoption/foster care, migration)
  - -- protection from exploitation (abuse, neglect, child labor)

- **Educational security**
  - -- formal schooling
    - -- getting into school (particularly girls)
    - -- staying in school (many drop out to care for parents w/AIDs)
    - -- returning to school (orphans often do not return because of discrimination, absence of needed fees, need to work)
  - -- youth development activities (to avoid crime, drugs, early & commercial sex)
    - -- structured recreation
    - -- life skill training
    - -- vocational training and apprenticeships

- **Health/mental health security**
  - -- counseling and support (dealing with death, isolation, stigma)
  - -- nutrition (vitamin supplementation)
  - -- immunization & basic care (ORT)
  - -- HIV prevention (orphans are at very serious risk)

**√ Supporting children orphaned by AIDS means strengthening families, communities, and youth themselves.** Solutions must be low-cost, sustainable, and replicable/expandable to a scale responsive to the magnitude of the projected devastation. Successes to date seem to build on development efforts designed to enhance the ability of families, extended families, and villages (communities) to cope with and meet the needs of their children. These solutions require the active buy-in and participation of individuals and committees at the village level. NGOs, donors, governments and others can help to create an enabling environment for effective action (beyond discrimination, denial, and hopelessness) and to support locally defined and executed programs including microenterprise and income generating activities.

**√ Focusing attention on children orphaned by AIDS can be a catalyst for a more vigorous response to HIV generally.** The only way to slow the number of children orphaned by AIDS is to reduce the transmission of HIV. Until there is an available vaccine, this means more aggressive prevention efforts. In addition, the delivery of low cost treatments for opportunistic infections, STDs, and TB to parents with AIDS can help them to live longer and better lives and enable them to plan for the care of their children when they are no longer able.

Talking Points on EO Regarding Limitation of Trade Actions
in Connection with Sub-Saharan Measures Promoting Access
to HIV/AIDS Pharmaceuticals and Medical Technologies

- Today the President will sign an executive order that instructs U.S. trade officials to refrain from taking actions against intellectual property laws and policies of sub-Saharan African governments that are designed to increase access to HIV/AIDS pharmaceuticals and medical technologies for people who need them.

- More specifically, the order will limit U.S. trade actions where sub-Saharan measures (a) promote access to HIV/AIDS drugs and technologies and (b) are consistent with the central WTO agreement on intellectual property rules, the Agreement on Trade-Related Aspects of Intellectual Property Rights (or TRIPs).

- The President's action will provide certain sub-Saharan African countries with added flexibility in crafting policies that will promote access to drugs and medical devices for affected populations.

- At the same time, the order ensures that fundamental intellectual property rights of U.S. businesses and inventors will be protected by requiring that beneficiary sub-Saharan African countries comply with applicable WTO rules – most notably the Agreement on Trade-Related Aspects of Intellectual Property Rights.

- Thus, to the extent that sub-Saharan African countries comply with their WTO obligations, they stand to benefit from the order in important ways. However, if they do not, they may face trade actions initiated by the United States.

- In addition, the Order states that the U.S. will take several positive steps to address the HIV/AIDS crisis. These include encouraging all sub-Saharan African countries:

  - to implement policies designed to address the underlying causes of the HIV/AIDS crisis;

  - to promote practices that will prevent further transmission of HIV;

  - to stimulate development of the infrastructure necessary to deliver adequate health care services; and

  - to encourage policies that provide an incentive for public and private research on and development of vaccines and other medical innovations that would contribute to combating the HIV/AIDS crisis facing Africa.

- The President's action today will help combat the worldwide HIV/AIDS epidemic, which has resulted in approximately 34,000,000 people in sub-Saharan Africa being infected and, of those, approximately 11,500,000 have died. These deaths represent more than 80 percent of the total HIV/AIDS-related deaths worldwide.

Fourth, we pay a heavy price for the stigma that surrounds AIDS.

We must lift the shroud of secrecy that surrounds AIDS, so that individuals and families living with AIDS will no longer be forced to suffer in silence. For years in America, AIDS remained underground, and people living with AIDS lost their jobs, their homes, their health insurance, and their dignity to the fear mongering and finger pointing of others. Leadership, education, and expansion of civil rights laws can help to bring AIDS into the light, where it can be seen and combated. For Gugu Dlamini, the 36 years old mother in South Africa who was stoned to death by her neighbors for going public with her HIV status, and for the many others too afraid to seek help - together – we must learn to fight AIDS not people with AIDS.

Fifth, this battle will be won or lost at the community level. This is true in Detroit as it is in Durban.

And finally, partnerships among all sectors are essential. AIDS is not just a health problem – it is a development problem, a trade problem, a democracy and a civil society problem, a security problem.

AIDS is everyone's problem -- and everyone must be part of the solution.

Much has been written and said about each of these lessons -- and about what we need to do to turn the tide of this epidemic. It is now time for us to move from paper to practice – and from words to deeds.

Together, we must find ways to affirm that we are a global community and our battle against AIDS in America, in Africa, and around the world is a shared responsibility.

Together, we must join our voices and pool our skills and our resources to begin to keep pace with an epidemic that is out of control.

And together we must push past denial and blame and inevitability -- and toward a sense of real solidarity symbolized by shared commitment, collaboration, and constructive action.

Remember the charge of Reverend Martin Luther King, Sr.:

> "Injustice anywhere is a threat to justice everywhere. We are caught in an inescapable network of mutuality, tied in a single garment of destiny. Whatever affects one directly affects all indirectly."

Can there be any greater injustice than to have a preventable and increasingly treatable disease and to fail to find ways to do what we can to save lives? I think not.

This is a time of great challenge. The destiny of millions of people hang in the balance. I pray that each of us can leave this Summit more confident in our commitment, more invigorated by

Q&A

DRAFT
September 27, 2000 11:27 AM
FOR INTERNAL USE ONLY

# IOM REPORT ON HIV PREVENTION
## Questions and Answers
## September 27, 2000

**Q1. Do you agree that there is a lack of leadership in HIV prevention at the federal level?**

A2 No, not at all. The Clinton-Gore Administration has always supported HIV prevention activities and HHS and its agencies are working to create further strategies for addressing HIV prevention in the United States. HIV prevention efforts in the United States have significantly reduced the incidence of HIV infections.

Both the CDC and the NIH conduct prevention research to assure that prevention efforts are based on sound behavioral and biomedical science. In addition, the CDC supports several community prevention programs, working with local health departments and organizations to provide technical assistance and build capacity in governmental and non-governmental organizations delivering HIV prevention services.

In addition, on June 18, 1998, the National Institute of Mental Health (NIMH) at the NIH announced that the NIMH Multisite HIV Prevention Trial found that even among persons considered hardest to reach, educational sessions that motivate and offer specific strategies to reduce high-risk sexual behaviors can cut those behaviors in half. The National Institute on Drug Abuse at the NIH has also conducted research on understanding the trends in HIV transmission among drug users and their sexual partners, as well as ways to reduce viral spread. As a result, innovative models of outreach have been developed to help stem the spread of HIV among this at-risk population.

The Substance Abuse and Mental Health Services Administration's (SAMHSA) Center for Mental Health Services (CMHS) funds Project Shield, the HIV/AIDS High-Risk Behavior Prevention/Intervention Model for Adolescents/Young Adults and Women Program. Project Shield is a four year, multi-site effort which is developing, implementing and evaluating a community-focused intervention to reduce high-risk behaviors among individuals at high risk for HIV-infection. SAMHSA also supports specialized Targeted Capacity Expansion grants to increase the capacity of minority community-based organizations to provide integrated substance abuse prevention and HIV prevention services.

These are only examples of the work that HHS and its agencies perform to get out the message that prevention works and stop the spread of HIV. Prevention initiatives have helped slow the rate of new HIV infections in the United States from more than 150,000 in the late 1980s to approximately 40,000 today.

Specifically, the number of U.S. infants who acquire AIDS from mother-to-child transmission dropped by 75 percent from 1992 to 1998.

But there is still more to do. We share the view that we must not become complacent in the fight against HIV and the changing demographics of the epidemic call for us to reevaluate our strategies and reexamine the tools and technology at our disposal in the fight to stop the spread of AIDS. That is why we requested that IOM conduct this study, and we welcome this new report as an important contribution to a renewed national commitment to responding to the AIDS epidemic.

**Q2. Has the IOM report caused you to reconsider your policy on needle exchange programs?**

A2. No. The Secretary of Health and Human Services, after consultation with her scientific advisers, determined in 1998 that the scientific evidence shows that needle exchange programs reduce the risk of HIV infection, and do not encourage the use of illegal drugs.

The Administration decided at that time that the best course of action was to have local communities which choose to implement their own programs use their own dollars to fund needle exchange programs, and to communicate what has been learned from science so that communities can construct the most successful programs possible to reduce the transmission of HIV, while not encouraging illegal drug use.

**Q3. What is your policy on abstinence-only programming and has your view changed in light of IOM's recommendation that rules mandating that public funds be used solely for abstinence-only education be removed?**

A3. We believe that abstinence is a key part of our prevention strategy. We also believe that communities, schools, and parents are best able to determine the needs of children - not Washington, and that local governments must be allowed to design programs that are right for them. But it is simply not acceptable - emotionally, physically, and financially – for 14-year-olds and 15-year-olds to be having sex and having children. We must all send the strongest possible message to teens, as the welfare law signed by President Clinton does, that postponing sexual activity, staying in school, and preparing for work are the right things to do.

The "Abstinence Only Education Program," passed as part of the welfare reform bill, enables states to provide abstinence education through activities such as mentoring, counseling, and adult supervision. The program, administered by the Health Resources and Services Administration (HRSA), has a mandatory appropriation of $50 million for each Fiscal Year from 1998 through 2002.

In addition, for more than 12 years, CDC has provided funds for state education agencies and 18 large urban education agencies, as well as a wide range of national non-governmental organizations, to prevent HIV infection among our nation's young people. CDC, through these agencies, has worked to increase the percentage of young people who do not engage in sexual intercourse and to increase the percentage of those who do engage in intercourse to use condoms. We believe that such programs should be locally determined and should be consistent with community values.

**Q4. Do you agree with IOM's recommendations?**

A4. We look forward to carefully reviewing the report and engaging our partners at state health departments, community-based organizations and public health, academic and medical institutions in discussions about the detailed recommendations.

We share the view that we must not become complacent in the fight against HIV and agree that the changing demographics of the epidemic call for us to reevaluate our strategies and reexamine the tools and technology at our disposal in the fight to stop the spread of AIDS. That is why we requested that IOM conduct this study, and we welcome this new report as an important contribution to a renewed national commitment to responding to the AIDS epidemic.

The report makes it clear, first and foremost, that HIV prevention works. I applaud that central finding, as it lends further credence to the fact that scientifically based prevention is core to winning our nation's battle against HIV and AIDS.