FIRST LADY HILLARY RODHAM CLINTON
TALKING POINTS FOR MEETING ON AIDS IN AFRICA
THE WHITE HOUSE
SEPTEMBER 7, 1999

Jim 11:30

Palliative care
infrastructure. service delivery

Carol
Condition Assistance
Incentives

Wolfenson
Horizontal line of credit for AIDS

Recommendation
Research agenda
- public/private partnership
- primary prevention (domestic + global)
- capacity development
public health practitioners.

Nell Weiss
M&E
Retrofitting into RH + Rep programs

Rawlings
AIDS on the agenda

BMS
PA Training
- rural nurses
- fellows

- Welcome -- and thank you all for coming to what I hope will be a very interesting and productive discussion. We are very pleased to be joined this morning by many leaders from the Administration, international organizations, foundations, businesses, and the AIDS community. [Their presence is a testament to the impact the AIDS pandemic has on every sector of society – and to the responsibility we all have to end it.]

- It is my hope that this meeting will lead to new initiatives, new resources, new thinking, and new partnerships to fight – and ultimately win – the war against HIV/AIDS in Africa and around the world.

- Every day, we are reminded of the breakthroughs we've had in this fight– from drug therapies that are improving life to education campaigns that are empowering people to prevent the disease. We know what works. But, we also know that far too many people are still being left behind.

- Just a week ago in Atlanta, we heard that the rate of HIV infections is no longer declining in the U.S. And, each and every day, AIDS claims the lives of more than 5,500 men, women, and children in Africa. In the next few years, that number will more than double. The AIDS epidemic in Africa is a crisis of biblical proportions. We are facing an emergency. And what we see in Africa today, we will likely see one day in India, in Southeast Asia, and the Newly Independent States if we don't act now.

- In Uganda, I saw firsthand what can be accomplished when the governments and citizens join forces to beat this disease. I went to the AIDS Information Center and saw countless billboards educating people to protect themselves against AIDS. I remember a song some of them sang: Ugandans are fighting to ensure that AIDS cannot win. And, it's working. From 1992 to 1998, the percentage of sexually active teenage girls who were HIV positive declined by almost two thirds.

- That example was on the minds of the African health ministers who came together last week at a W.H.O. meeting in Namibia. They declared war on HIV/AIDS and made a commitment to stop the devastation plaguing their citizens and countries. And we must work hand in hand with them.

- AIDS is not somebody else's problem. Our work against this deadly disease must be part of all our development efforts – especially those affecting women and children. Because, as we speak, the AIDS epidemic is turning back the clock on the development we've seen in Africa. It is undermining entire economies, trade, civil society, and stability. It is decreasing life expectancy by up to 20 years in some countries and turning millions of children into orphans.

- I know that the people in this room have worked tirelessly to make great progress in the battle against AIDS. But, as you know better than anyone, the challenge before us is far greater than the collective actions taken so far. And that's why your continuing leadership is so important.

- We are pleased to be joined this morning by many leaders of our Administration, who have worked on this problem from every perspective -- health, financial, international, and development. They include the Secretary of Health and Human Services, Donna Shalala; the Secretary of the Treasury Larry Summers; USAID Administrator Brady Anderson; our Surgeon General, Dr. David Satcher; Undersecretary of State, Frank Loy; Leon Fuerth, the Assistant to the Vice President for National Security Affairs; and Sandy Thurman, the Director of the White House Office of National AIDS Policy.

- As many of you know, the Administration has asked for an additional $100 million next year to fight the global battle against AIDS. This new initiative represents the largest increase ever in the international AIDS budget. And it would allow us to more than double our efforts in sub-Saharan Africa.

- We can also take heart in the recent Cologne Agreement, which will more than double the debt relief provided to countries that need it most. This means that eligible nations such as Uganda and Tanzania will now be allowed to use their freed up resources on social sector spending – including, for the first time, activities to prevent HIV/AIDS. We will work with the International Monetary Fund, the World Bank, and UNAIDS to encourage Uganda, Tanzania, and other eligible countries to develop HIV/AIDS pilot projects – and provide an example to other indebted nations struggling against this disease.

Cologne relief

- And I am very pleased that we are joined here by key representatives of our multilateral organizations, including Jim Wolfenson and Jan Piercy from the World Bank and Peter Piot from UNAIDS. [When we hear Dr. Piot talk about the work that UN agencies are doing to combat AIDS around the world, we are reminded of yet one more reason why we must support the United Nations and pay our dues.]

- We are also very fortunate to have with us the National Association of People with AIDS and the Global AIDS Action Network – two non-governmental organizations that serve on the frontlines of this battle.

- We are also joined this morning by representatives of foundations that have provided great leadership in the fight against HIV/AIDS. I want to thank the Rockefeller Foundation, the Gates Foundation, and the Open Society Institute for their generous contributions. I also want to thank the Kaiser Family Foundation, which comes here with a new commitment to match funding dedicated to preventing AIDS among adolescents in South Africa. And I want to thank the MacArthur Foundation, which will be bringing foundations together at the end of this year to discuss even more ways they came meet this challenge.

- I am also very pleased to be joined by Black Entertainment Television and Bristol Myers Squibb, who are not only making great contributions – but also reminding us of critical role that all businesses can play.

- Because just imagine what we could accomplish if, over the next few years, we could bring to this table every business, government leader, foundation, NGO, multilateral organization, and citizen. Think of the millions of people in Africa and all over the world whose lives and futures we could save – if we could find the will and the way.

- We will never give up until the day when we meet our ultimate goal – and find a cure that reaches every single man, woman, and child on this planet. But, until then, we must do everything in our power to prevent HIV and heal those it strikes in Africa and all over the world.

- And I hope that over the next hour or so we will think creatively about the ways that we can work together to do just that.

## GUIDANCE FOR DISCUSSION

**Introduce Dr. Peter Piot,** Executive Director, Joint UN program on HIV/AIDS in Geneva: For brief overview of epidemic and the specific challenges we face as we move into the next century.

**Call on Donna Shalala** for her thoughts on where we need to go in the health sector

**Call on Lawrence Summers** for his thoughts on where we need to go in the international financial sector

**Call on James Wolfensohn** for his thoughts on directions for the International Financial Institutions

**Follow on with open discussion with foundations and corporations and others**

### Issues -- Incorporating AIDS into specific sector portfolios:

Prevention activities: Engagement of leadership. Stigma reduction. Education. Mother to child transmission prevention.

Care and treatment: Provision of basic medical care, including treatment of TB and other opportunistic infections.

Infrastructure development: including financing and debt relief

### Next Steps

- Foundation meeting called by MacArthur Foundation. Could they take a leadership role with other foundations?
- Business Leader's meeting coordinated by VP and Commerce. Could Bristol Myers have a role in helping with pharmaceutical companies?
- Could BET help organize a communications forum to discuss increased AIDS activities internationally?
- Follow on the Cologne Intitiative: Demonstration project in Africa on Debt for AIDS prevention activities.
- New UN activities
- Other (as come up in the open discussion).

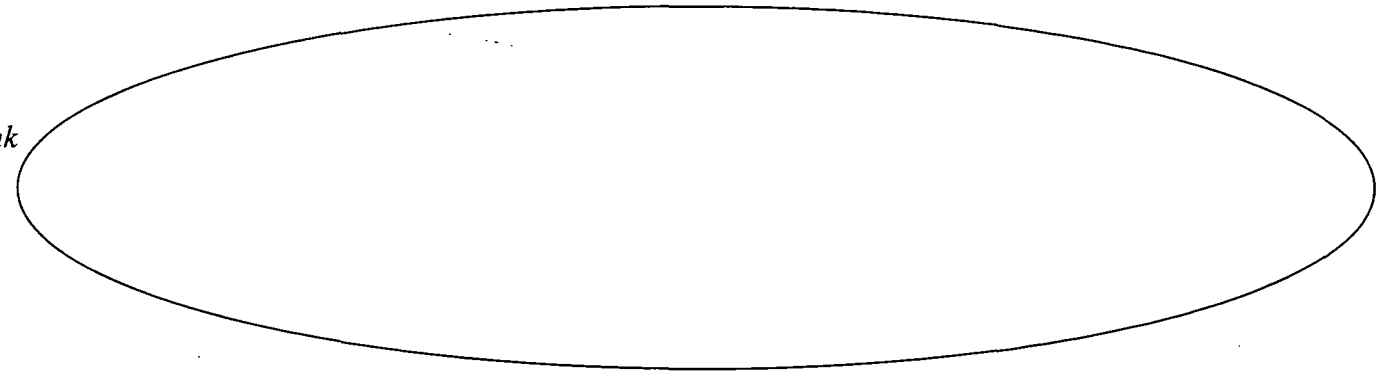
$1/65 ml prevention (97) in SSA

Challenges –
1.– Sustain political commitment
2- Social policy adjustments
education of girls
3- do things differently | community level
partnerships
4– Strengthen technical capacity in country
5- research – V, microbicides,

Importance of finance Ministry involvement

**AIDS Convening**
**September 7, 1999**

***Seating Chart***



Dr. Gordon Perkin, *Gates*
Ken Bernard, *NSC*
Charles Heimbold, *BristolMyers*
Donna Shalala, *HHS*
Dr. Peter Piot, *UN/AIDS*
Aryeh Neier, *Open Society*
Stewart Burden, *MacArthur*
Brady Anderson, *AID*

Jan Piercy, *World Bank*
Frank Loy, *State*

Melanne Verveer
Timothy Evans, *Rockefeller*
Gayle Smith, *NSC*

Dr. Drew Altman, *Kaiser*
Leon Feurth, *NSC*
Jim Wolfensohn, *World Bank*
Dr. David Satcher, *HHS*
**HRC**
Larry Summers, *Treasury*
Sandy Thurman, *White House*
Robert Johnson, *BET*

# Joining Forces for LIFE:

**L**eadership and **I**nvestment in **F**ighting an **E**pidemic

*A Global AIDS Initiative*

## I. Increasing the US Government investment in the global battle against AIDS to begin to reflect the magnitude of this rapidly escalating pandemic.

Making a difference in Africa and in other highly impacted areas requires broader political commitment, enhanced community mobilization, and, most urgently, increased resources. In 1998, spending on AIDS in Africa totaled only $165 million. Compared to the ever-escalating need and other health programs, this amount is woefully inadequate. For example, in 1998, over $500 million was spent for basic childhood immunization programs in Africa. Based on our experience in those countries that are starting to demonstrate success, such as Uganda and Senegal, UNAIDS and donors now agree that a minimum of $600 million is needed in sub-Saharan Africa per year for HIV prevention alone ($2 per adult per year).

While we acknowledge the leadership role that the US plays globally and the urgent need to act, clearly an effort to combat AIDS must be driven by many actors including host countries, multi-lateral organizations, and bi-lateral donors, to be successful. In FY1999, the US Government spent $74 million in USAID prevention and care in Africa and $38 million in HHS research and surveillance/prevention. But more remains to be done in sub-Saharan Africa and in other seriously affected parts of the world.

**The Administration proposes to commit an additional $100 million in FY2000 to the global battle against AIDS. This initiative will enable us to move forward on four critically important and interconnected fronts including:**

- **Containing the AIDS Pandemic ($48 million)** Implement a variety of prevention and stigma reduction strategies, especially for women and youth, including: HIV education, engagement of political, religious, and other leaders; voluntary counseling and testing; interventions to reduce mother-to-child transmission (MTCT); and enhance training and technical assistance efforts, including Department of Defense efforts with African militaries.

- **Providing Home and Community-Based Care ($23 million)** Deliver counseling, support, palliative and basic medical care including treatment for sexually transmitted diseases, opportunistic infections (OIs), and tuberculosis (TB) through community-based clinics and home-based care workers. Enhance training and technical assistance efforts.

- **Caring for Children Orphaned by AIDS ($10 million)** Assist families, extended families, and communities in caring for their children through nutritional assistance, education, training, health, and counseling support, in coordination with micro-finance programs.

- **Strengthening Prevention and Treatment by Augmenting Planning, Infrastructure, and Capacity Development ($19 million)** Strengthen host country ability to plan and implement effective interventions. Strengthen the capacity for effective partnerships and the ability of community based organizations to deliver essential services. Strengthen surveillance systems to track the epidemic and target HIV/AIDS programs.

This US Government assistance would be provided through AID ($55 million), HHS ($35 million), and DoD ($10 million). The focus of this funding is HIV prevention, and AIDS care and treatment. In those areas, this initiative represents nearly a doubling of funding in Africa from current levels ($81 million in FY99, which excludes research). The Administration recognizes the fight against AIDS must be sustained to keep pace with this burgeoning epidemic, and is committed to a multi-year effort in this critical area.

**II. Building partnerships with other key stakeholders to maximize our impact on the rapidly expanding pandemic.**

Increasing US investment in the global battle against AIDS is critical, but is not sufficient to achieve the outcomes needed. The commitment of in-country political leaders and of various segments of civil society are key to success. Moreover, resources provided by the US Government need to help leverage, and to be coordinated with, those of other donors, the private sector, and national governments to ensure synergy and to maximize impact. Building partnerships with key stakeholders in support of effective action at the community level is our greatest hope for progress.

**This initiative will pursue a variety of strategic opportunities for challenging other partners to join in an enhanced effort, including:**

- **Leadership Meeting** On September 7, 1999, First Lady Hillary Rodham Clinton will convene a meeting of key US officials, The World Bank, UNAIDS, as well as heads of foundations, corporate CEOs, and others to discuss how best to enhance AIDS prevention and treatment efforts in Africa and around

the world. The meeting will focus not only on leveraging additional resources, but also on establishing priorities, identifying effective public/private partnerships, and identifying targets for action to combat the crisis of HIV/AIDS.

- **African Leaders Summit** We propose hosting a high-level meeting with Africa government and community leaders within the next ten months. This meeting will highlight the critical role of leadership in arresting the epidemic and will work to encourage increased leadership efforts. Topics will include the economic impact of HIV/AIDS, examination of models of success in reducing the transmission of HIV, and addressing the need for increased investment in health programs. Additional topics will include AIDS care and treatment and support for children orphaned by AIDS.

- **UN Conference on Children Orphaned by AIDS** On December 1, 1999 (World AIDS Day), the United Nations in conjunction with the National Black Leadership Commission on AIDS, The White House Office of National AIDS Policy, The Magic Johnson Foundation and a variety of NGOs, will organize a conference to focus attention on the growing number of children orphaned by AIDS worldwide. Special emphasis will be placed on assessing the needs of orphaned children in sub-Saharan Africa and the Americas. Participants will include noted experts on the priority issues identified by UNAIDS, UNICEF, and other UN agencies.

- **Business** The Department of Commerce will facilitate a meeting of business leaders active in Africa to encourage them to increase their efforts to rise to the AIDS challenge. Given the impact that AIDS is having on businesses as well as the overall economic-impact on African countries, such a meeting will seek enhanced business commitment and involvement in AIDS programs.

  The Commerce Department will work with American Chambers of Commerce abroad and other business organizations to publicize the successful AIDS efforts of US firms in Africa and to support others taking similar action. In addition, the Department will direct work to promote closer coordination in Africa between Commercial Service Offices, other USG agencies, the business community, and African NGOs in a united effort to promote corporate partnership in AIDS programs.

- **Labor** The Secretary of Labor will facilitate a meeting of US and African labor leaders, and will be co-chaired by the AFL-CIO. The success of the AFL-CIO and its Solidarity Center in South Africa (supported by USAID) in working with the South African Trade Union Federations to include AIDS as a key labor outreach and policy issue provides a model for similar action elsewhere. Outcomes include assisting labor organizations in educating their members and securing commitments to develop workplace-based AIDS education and prevention programs, including outreach to youth.

- **Religious Leaders Summit** The US government will facilitate a meeting of African, American, and other religious leaders to discuss the important role of communities of faith in the fight against AIDS. In Uganda and Senegal, the involvement of religious communities and leaders had a dramatic impact on the ability of these two countries to reduce HIV incidence and to maintain it at low levels over time. The outcome of such a meeting would be to increase attention to the need for involving religious communities, to mobilize these organizations and leaders in the fight against AIDS, and to identify ways to support their efforts.

- **Diplomatic Initiatives** The Department of State, NSC, and ONAP will work with US and African ambassadors to increase attention to AIDS within the diplomatic community. The NSC, the Department of State, and USAID will work with G-8 and other donors, and challenge them to match the increased investment put forward in this initiative.

"Joining Forces for LIFE: Leadership and Investment in Fighting an Epidemic" is an excerpt from *Report on the Presidential Mission on Children Orphaned by AIDS in sub-Saharan Africa: Findings and Plan of Action*, The White House, June 19, 1999.

THE WHITE HOUSE

Office of the Vice President

**For Immediate Release**
**Monday, July 19, 1999**

**Contact:**
**(202) 456-7035**

## VICE PRESIDENT GORE ANNOUNCES ADMINISTRATION WILL SEEK $100 MILLION INITIATIVE – A RECORD INCREASE -- IN FUNDS TO FIGHT AIDS AROUND THE WORLD

Washington, DC -- Vice President Al Gore today joined Archbishop Tutu, Director of the Office of National AIDS Policy Sandra Thurman, Members of Congress, and leaders of the African-American, religious, children's, and AIDS communities to announce that the Administration will seek the largest-ever budget increase in the global battle against AIDS – a new investment of $100 million. The Vice President also unveiled a new report from the Office of National AIDS Policy that assesses the AIDS crisis in Africa and recommends this investment. In addition, the Vice President announced new efforts to encourage other public and private entities across the world to address AIDS across the world.

"AIDS in Africa is the worst infectious disease catastrophe in the history of modern medicine," Vice President Gore said. "More than twenty million people are now infected and nearly 500 more become infected each hour. We hope this initiative will not only provide much-needed relief but will inspire decisive action by other countries and institutions – and bring hope to the millions of children and families trapped in this horror." Today, the Vice President:

**RELEASED A NEW REPORT ON THE PRESIDENTIAL MISSION ON CHILDREN ORPHANED BY AIDS IN SUB-SAHARAN AFRICA.** Last December, President Clinton directed the Director of the Office of National AIDS Policy to go on a fact-finding mission to assess the problem of HIV/AIDS in Africa. Today, the Vice President is releasing the report that includes new findings and a plan of action resulting from this mission. The report finds that:

**AIDS in sub-Saharan Africa is one of the largest health crises in the history of the world.** In the past decade, twelve million people in sub-Saharan Africa have died of AIDS -- one quarter of them children -- and each day AIDS buries another 5,500 women and children. Over the next decade, AIDS will kill more people in sub-Saharan Africa than the total number of casualties in all of the wars of the 20th century combined. By 2005, the daily death toll will reach 13,000 people per day.

**Millions of children will be orphaned by this epidemic.** In some areas up to one-quarter of all children already live with an HIV-positive parent. In the next decade, more than forty million children in sub-Saharan Africa will lose a parent to HIV/AIDS.

**This epidemic has a devastating impact on many aspects of life in sub-Saharan Africa.** AIDS is undermining much of the progress in development that has been made in Africa. AIDS is reducing life expectancy by more than 20 years in some countries. Many children are dropping out of school to care for dying parents undermining improvements in education, and AIDS will continue to have a major negative impact on the economy, hitting a range of professionals, from teachers to military to business leaders and therefore undermine its current trade with other nations throughout the world.

**UNVEILED NEW $100 MILLION INITIATIVE TO COMBAT HIV/AIDS ACROSS THE GLOBE.** The Vice President also unveiled a new initiative to double the existing efforts to prevent and treat AIDS. This initiative will be targeted to Africa in addition to other parts of the world where this epidemic is growing. It will help move forward on four critically important and interconnected fronts including:

**Containing the AIDS Pandemic.** A new $48 million initiative will be used to implement a variety of prevention and stigma reduction strategies including: HIV education; engagement of political, religious and other leaders; voluntary counseling and testing; blood supply screening, and, interventions to reduce mother-to-child transmission (MTCT). In addition, the Department of Defense (DoD) will begin new efforts to work with African militaries to provide educational material and training on AIDS prevention.

**Providing Home and Community-Based Care.** This $23 million investment will be used to deliver counseling, support palliative and basic medical care including treatment for sexually transmitted diseases, opportunistic infections, and tuberculosis (TB) through community-based clinics and home-based care workers and enhance training and technical assistance efforts.

**Caring for Children Orphaned by AIDS.** This new $10 million initiative will be used to assist families, extended families, and communities in caring for their children through nutrition, education, health and counseling support, in coordination with micro-finance programs.

**Strengthening Prevention and Treatment by Augmenting Planning, Infrastructure, and Capacity Development.** This $19 million initiative will help strengthen host country ability to plan and implement effective interventions. It will also strengthen the capacity for effective partnerships between local government and community-based organizations. Strengthen local surveillance systems to track the spread of HIV infection, AIDS, and the effects of interventions to enable the best targeting of HIV/AIDS prevention programs.

This United States Government investment would be provided through AID ($55 million), HHS ($35 million) and DOD ($10 million) and will be fully offset.

**ENGAGING OTHER PARTNERS TO ADDRESS THIS CRISIS.** Addressing the crisis of AIDS worldwide will require a broad-based commitment from public and private partners across

the globe. The Vice President also unveiled a series of new initiatives to enhance efforts to address this problem including:

**Multi-lateral Partners Meeting to Enhance Coordination Around the World.** 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.

**A United Nations Conference on Children Orphaned by AIDS.** The United Nations, in conjunction with the National Black Leadership Commission on AIDS, The White House Office of National AIDS Policy, The Magic Johnson Foundation and a variety of NGOs, will organize a conference on World AIDS Day to focus attention on the growing number of children orphaned by AIDS worldwide, with a special emphasis on sub-Saharan Africa.

**New Partnerships with Private Sector Leaders to Address This Crisis, Such As the Religious, Business and Labor Communities.**

-- Given the impact of AIDS on businesses active in Africa as well as the overall economic-impact on African countries, the White House will facilitate a meeting of business leaders to encourage commitment and involvement in AIDS programs, such as workplace education, outreach to communities, and increased funding support for AIDS efforts.

-- The White House will host a meeting of US and African labor leaders, co-chaired by the AFL-CIO, to build on successes in working with the Council of South African Trade Unions to address AIDS.

-- The White House will also facilitate a religious summit of African, American, and other religious leaders to discuss the important role of communities of faith in the fight against AIDS. In Uganda and Senegal it is very clear that the involvement of religious communities and leaders had a dramatic impact on the ability of these two countries to reduce HIV prevalence or to maintain it at low levels over time.

THE WHITE HOUSE
WASHINGTON

# Office of the First Lady

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**From:** CAROL REACH X67265
CELL 202-365-0202

**No. of pages (including cover):** 5

**Comments:**

Draft #1

**FIRST LADY HILLARY RODHAM CLINTON**
**"TALKING IT OVER"/CREATORS SYNDICATE**
**COLUMN FOR PUBLICATION SEPTEMBER 7, 1999**

Twenty years ago, no one had ever heard of the human immunodeficiency virus. Yet today, in sub-Saharan Africa, AIDS is the leading cause of death. The disease buries 5,500 people every day, a number that will more than double in the next few years. More than 22 million adults and 1 million children are living with HIV, and 11,000 new people are infected each day.

Last year on World AIDS Day, my husband spoke publicly about the growing tragedy of children orphaned by AIDS, and directed his Office of National AIDS Policy to lead a fact-finding mission to Africa. What they found is a crisis of global proportions – a human, economic, political and social catastrophe that touches each and every one of us.

Although AIDS kills indiscriminately, the disease is stalking women and young people in Africa disproportionately. More than half of all new HIV infections are among women, shattering families and placing extraordinary burdens on the villages that have been the backbone of the child-rearing tradition.

In addition to isolation and stigma, the disease threatens child welfare in unprecedented ways, restricting access to food, education, health care, housing and clothing. In many places, one-quarter of the children are living with an HIV-positive parent and will be orphaned by the end of this year.

Tragically, the worst is yet to come. During the next decade, more than 40 million children will be orphaned by AIDS. An entire generation of Africa's children is in jeopardy.

AIDS is not only causing unfathomable human suffering, it is also wiping out decades of progress on a host of development objectives. Life expectancy in Zimbabwe has dropped by an unbelievable 25 years. In the coming decade, child mortality will triple. And, despite steady advances in access to education, a rapidly increasing number of children, particularly girls, is dropping out of school to work or care for dying parents. Far too few are finding their way back.

In Lusaka, Zambia, 100,000 children, most orphaned by AIDS, are living on the streets. In an effort to survive, many are forced into crime, sex and drug operations, and we can only assume that HIV is spreading rapidly among them.

Not surprisingly, this extraordinary level of human devastation is jeopardizing economic growth and threatening political stability. Over the

course of the next 20 years, it is predicted that AIDS will reduce the economies of sub-Saharan Africa by 25 percent.

AIDS is not just an African problem. It is not somebody else's problem. It is our problem. If we allow this epidemic to proceed unchecked, we will likely see its effects repeated around the world, particularly in India, Southeast Asia and the Newly Independent States of the former Soviet Union.

We know what we have to do, and now is the time to do it.

Leadership and sustained investment have made, and can continue to make, an extraordinary difference. Uganda's President Yoweri Museveni demonstrated bold leadership early in the epidemic by developing a plan to reduce the stigma and transmission as well as to support those who became sick. As a result, infection rates in urban Uganda have been cut in half.

Over the past decade, the U.S. has invested with the Ugandan government, other donors and non-governmental organizations to provide HIV prevention, care and support. When I was in Uganda I saw the results at the AIDS Information Center I visited and on billboards exhorting Ugandans to protect themselves against the disease.

In July, the Vice President, calling AIDS in Africa the "worst infectious disease catastrophe in the history of modern medicine,"

announced that the administration would seek the largest-ever budget increase in the global battle against AIDS, an increase that would allow us to more than double our efforts in sub-Saharan Africa. In addition, several new initiatives, including a UN Conference on Children Orphaned by AIDS, and a G-7 debt relief agreement that will allow countries to target new resources to combating the disease, will encourage public and private groups around the world to become involved.

As part of this initiative, I convened a meeting at the White House this week of major donors, senior government officials, corporate CEOs, representatives of the World Bank, the United Nations, international foundations and community groups to discuss how best to enhance and coordinate our AIDS efforts in Africa and around the world.

The global battle against AIDS has just begun, and we know the worst is yet to come. But the faces of Africa's children beckon us – especially members of Congress – to act now. It is time to develop the capacity and partnerships we lack, not only too seek a cure, but also to prevent the further spread of this dreadful disease and to treat those who are suffering from it today.

[790 words]

THE WHITE HOUSE

WASHINGTON

# Office of the First Lady

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[790 words]

Sandy Thurman

INTERNATIONAL
INTELLECTUAL
PROPERTY
INSTITUTE

July 29, 1999

Richard Socarides
Special Assistant to the President
The White House
Washington, D.C. 20500

Dear Richard,

Thank you for taking my telephone call this morning about my interest in being included in the September 7 meeting on AIDS in sub-Saharan Africa which is being convened by Hillary Rodham Clinton on September 7. As I explained to you on the phone, since leaving my post as Assistant Secretary of Commerce and Commissioner of Patents and Trademarks at the end of last year, I have formed a nonprofit organization with the principal purpose of assisting developing countries to utilize the global intellectual property system for their benefit.

One of the first issues I was asked to look at by UNAIDS was the controversy surrounding delivery of patented HIV therapies to developing countries. This led to the enclosed paper which has been widely circulated in the world AIDS community. This week my colleague Lee Feldman and I had a very productive discussion with HHS Secretary Donna Shalala about our ideas and she expressed great interest in serious follow-up. The paper also has been shared with Pharma, GlaxoWellcome Corp. and the Merck Corp., who have expressed significant interest in the plan. The essence of the plan is to bring together the global public and private sectors to more efficiently bring to developing countries the benefits of state-of-the-art patented therapies for HIV disease. I believe that this is directly relevant to the September 7 meeting.

I would deeply appreciate your assistance in having the International Intellectual Property Institute invited to participate in the September 7 meeting. I believe that we have a significant contribution to make. With regard to any concern about conflicts of interest or ethical concerns, please be advised that I in no way participated in decision making regarding this issue while I was in the Administration, and have no ethical bar to dealing

201 Massachusetts Ave., NE. Suite C-3 • Washington, DC 20002 • Tel: (202) 544-6610 • Fax: (202) 478-1955 • E: iipi@iipi.org

with the White House or any other Executive Branch department or agency other than the Department of Commerce.

Thank you very much for your interest.

With warm regards,

Bruce Lehman,
President and CEO,
IIPI

Enclosure

THE WHITE HOUSE

WASHINGTON

August 3, 1999

The Honorable Sandy Thurman
Director
National AIDS Policy
1600 Pennsylvania Avenue
The White House
Washington, D.C. 20502

Dear Sandy:

I am pleased to invite you to the White House on September 7, 1999, to join me and a small group of senior representatives from the United States government, multinational institutions, foundations and the corporate sector for a meeting to explore strategies to better address the international AIDS crisis.

This devastating epidemic is an assault on health and development that has few, if any, modern equals. Only 20 years ago we did not know that HIV existed. At the beginning of this decade, who among us would have thought that by 1999 AIDS would be the leading cause of death in sub-Saharan Africa and the fourth leading cause of death worldwide?

In the face of this reality, the President has recently asked for a $100 million increase in funding for international HIV/AIDS programs as the cornerstone of a broad and comprehensive new international initiative to combat the epidemic. This is just a part of the international effort necessary to control the spread of HIV and to deal with the associated problems of patient care.

Today 34 million people worldwide are living with HIV or AIDS. AIDS related diseases have killed 14 million men, women and children- -mostly in Africa where more than 5,000 deaths are reported each day. By 2010, 40 million children will have been orphaned by HIV/AIDS. Economic development in many African countries has come to a stop and the hard won social and health advances of the last 20 years are being reversed by the new realities of the epidemic. These statistics do not begin to describe the personal tragedy for many of those living with HIV/AIDS and their families.

Still there is cause for hope. Throughout the world, heads-of-state are increasingly acknowledging AIDS prevention as a public health and political priority. National HIV/AIDS control strategies have been written, and Uganda and Thailand

have shown that successful national AIDS prevention programs can work. Unfortunately, a serious crisis remains and much more needs to be done. Many developing countries, overwhelmed by human and financial costs, are losing the battle with the epidemic.

I am asking you to join me to help build the momentum necessary to engage all stakeholders in winning the war against HIV/AIDS. Although financial support for AIDS prevention efforts remains the most critical unmet need, this meeting is not intended to be a donors conference. Rather, we will discuss strategies and identify priorities and new partnerships for assisting countries in their HIV/AIDS control efforts.

We will meet at the White House on Tuesday, September 7th. Please plan to arrive at the East Appointments Gate no later than 10:00am. To confirm your participation, please call Katy Button in my office at (202) 456-6266. I look forward to seeing you on September 7th.

Sincerely yours,

Hillary

Hillary Rodham Clinton

Bruce Lehman
201 Mass. Ave., N.E. Suite C-3
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Phone: 202-544-6610
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**IIPI**

# Fax

| | | | |
|---|---|---|---|
| **To:** | Richard Socarides | **From:** | Bruce A. Lehman |
| **Fax:** | 456-6218 | **Date:** | July 29, 1999 |
| **Phone:** | 456-1611 | **Pages:** | 12 including cover sheet |
| **Re:** | White House Aids in Africa meeting | **CC:** | |

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**Comments:**

**Richard,**

**Thanks for taking my call. For some reason my e-mail to you didn't work. So, I'm faxing you the material. This is our proposal. In some ways we are already leapfrogging over this because Shalala is interested in going directly to the full-scale pilot with Uganda as the target. If you want to talk to someone at HHS about this, I suggest Dr. Stuart Nightingale, Associate Commissioner of the FDA for Health Affairs, at 301-827-6610. Donna Shalala put him in charge of follow-up to our meeting. I deeply appreciate your interest and assistance. I look forward to hearing back from you. I will send you a letter re the Hillary Clinton meeting in September.**

**Bruce**

DRAFT

# A PROPOSAL FOR A PILOT PROJECT TO DELIVER PATENTED HIV/AIDS THERAPIES AND OTHER TREATMENTS TO PATIENTS IN DEVELOPING AND LEAST DEVELOPED COUNTRIES

**DRAFT VERSION 1.3**

**PRINTED: 07/29/99 11:35 AM**

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**DRAFT**

***Precis***

The need to better control the spread and treatment of HIV and other diseases such as tuberculosis in the developing countries is a widely known and serious issue that calls for diligent and aggressive attention. This proposal addresses three critical problems:

- the high cost of pharmaceutical treatments,
- the lack of infrastructure needed to effectively deliver treatment and support services to patients, and
- inadequate incentives and assurances needed to stimulate additional subsidies and investments in the impacted countries

This paper proposes a framework of national exhaustion, tiered pricing and subsidization coupled with innovative technology that can achieve sustained and effective service delivery to patients thereby yielding improved outcomes. These measures would remove barriers and create incentives for pharmaceutical companies to actively participate in the delivery of essential therapeutics. Accordingly it should be possible to attain the level of multi-party cooperation and clinical effectiveness needed to build a program that brings meaningful treatments to the developing world.

Pharmacological interventions are a critical component in the management of HIV/AIDS, opportunistic infections and other high-impact diseases in the developing world. Affordability is a critical issue. Yet, efforts to simply restructure the price of pharmaceutical treatments to make them more affordable do nothing to bring the treatment to the patient in need. Affordability does not, by itself, translate into availability. Few developing nations have the service infrastructure needed to properly deliver the full spectrum of HIV and other treatments and critical patient support services that are required over a sustained period of time. Available pharmacological interventions and accessible clinical interventions are the necessary predicates for a successful disease containment program.

This paper discusses the implementation of policies and technologies that would help assure the affordable and effective delivery of pharmaceuticals, treatments and support services resulting in improved outcomes. In particular, the framework:

- Lays a foundation that encourages developing countries to accept national exhaustion of patent rights and support for patent holder rights.
- Discusses how a full spectrum of care can be effectively delivered to patients
- Creates incentives for patent holders to participate in both special pricing models and programs that bring the benefits of the latest innovations to the developing world.
- Helps address the concerns of patent holders that special pricing would lead to the formation of gray markets that erode the fundamentals of their business.
- Helps create an environment where subsidization of pharmaceutical purchases required by the impacted countries can be made with greater assurance that treatments are being delivered in a manner that is clinically effective.

The policies and technologies discussed are not revolutionary, but there is an obvious need for a demonstration project. While a pilot project would necessarily include private industry, three international entities, by virtue of their mandates, should coalesce to shepherd the effort: (a) the World Bank, (b) the World Intellectual Property Organization and (c) UNAIDS.

A successful pilot program will demonstrate the effective case management of patients, a regulated and rational pharmaceutical distribution model and a measurable impact on HIV, opportunistic and other high-impact disease.

DRAFT

In recent years HIV/AIDS and tuberculosis have become the principal public health crisis for a number of countries in the developing world, particularly in sub Saharan Africa. While new advances in drug therapy such as AZT, protease inhibitors, non-nucleoside reverse transcriptase inhibitors and antiretrovirals have drastically lowered morbidity in the United States and developed countries, these therapies are virtually unknown in impacted areas of the developing world. First line therapies for TB are becoming less effective as multiple drug resistant strains evolve. Second line therapeutics and other more complex interventions are often considerably more expensive.

The problem of making effective therapies available in developing and least developed countries stems from several causes. First, of course, is the high cost of treatment. In the United States the annual bill for prescriptions of protease inhibitors usually exceeds $10,000 per patient. This is a price beyond the reach of individuals in countries where annual per capita incomes may be a fraction of this annual cost. Second, these pharmaceuticals require a sophisticated medical infrastructure and level of patient cooperation beyond the capacity of many developing and least developed nations. Finally, the relative poverty of populations in these countries and their resulting inability to stimulate market demand deprives developers of the necessary incentive for investing in solutions. Absent potential consumer demand, the patent system is ill equipped to impel producers of these therapies to risk scarce venture capital.

This paper proposes an integrated policy and technological approach to resolving these difficult problems. The first section outlines a policy based on principles of national exhaustion, tiered pricing and subsidized pharmaceutical purchases. The second section describes technological measures based on sophisticated information systems, established models of patient care and controlled pharmaceutical delivery.

## [redacted]

At the present time developers of state-of-the-art therapies look to the exclusivity, which they enjoy in developed country markets, as the means to command a product price enabling them to amortize the cost of their investment and produce a profit. To the extent that individual patients lack the financial means to pay for these prescription therapies, governments pay the costs.

Until recently, few countries in the developing world offered patent protection to pharmaceutical products. Therefore, the basic market foundation underlying manufacture and distribution of newly developed drugs has not been a factor in making pharmaceuticals available in the developing world. As a result of the Agreement on Trade-Related Aspects of Intellectual Property rights ("TRIPS Agreement") adopted as part of the Uruguay Round of Negotiations, all WTO member countries must begin the process of integrating into the patent-based system of developing and distributing pharmaceuticals. Fear of this change has caused a backlash among public health professionals in the developing world, leading recently to a heated debate in the World Health Organization over a code of conduct, which would conflict directly with the TRIPS agreement.

The TRIPS Agreement allows developing countries until January 1, 2005 to provide product patent protection for pharmaceuticals and least developed countries until January 1, 2006, with a possible extension. Due to fears that patent protection will adversely impact costs, a number of non-

governmental organizations and policy makers in the developing world have begun to look for mechanisms within TRIPS that would allow for compulsory licensing and parallel importing of protected pharmaceutical agents. While this would not address the cost of the fine chemicals used in the production of many of drugs at issue, it could potentially impact the worldwide pricing structure for these products. It is not clear that widespread use of compulsory licensing will significantly impact affordability and certainly it does nothing to address availability. Today, the absence of patent protection in many countries is not providing inexpensive or effective access to patients in need of many of these treatments. Nevertheless, even if it does not impact availability, a large-scale effort to use compulsory licensing to address issues of affordability could have serious impact on the integrity of the international system of patent protection and could undermine the incentives at the heart of a very successful system of innovation. Furthermore, the sophistication of manufacture and delivery of state-of-the-art HIV treatments is beyond the means of most developing countries. Therefore, compulsory licensing could only create reliable sources of supply if countries imported product from generic-producing countries. Again, large-scale importing of products produced under compulsory licenses could have the effect of undermining the cost structure of these same products in countries where parallel import is legal. In other countries, gray markets will likely develop if reliable sources of alternative "low-price" product become available. Accordingly, the challenge is to develop a plan that both harnesses the powers of innovation and investment of product developers and addresses the cost issues of populations in developing and least developed countries.

Such a plan has three components:

1. segregation of territorial markets so that ability to pay can be figured into the pricing of a pharmaceutical product in a developing country;

2. a system of determining price levels appropriate to the ability to pay in such a market;

3. a system of sustainable subsidization to assist the purchase of a pharmaceutical when the ability to pay is out of reach even at a below market price point.

A discussion of each of these three components follows.

***Segregation of Territorial Markets – The Issue of Exhaustion of Rights***

A longstanding controversy in international intellectual property law has been whether a patent holder exhausts his or her rights to control the resale or use of a product in a territorial market different than the one into which the product was first sold. In general patent holders have argued that the principle of national exhaustion applies, meaning that their loss of control after the first sale of a given patented product applies only in the territory of the country in which it was first sold. Opponents support the principle of international exhaustion; meaning that rights to control resale and use of a legally manufactured product exhaust anywhere in the world after the first sale takes place. Consumer groups have generally supported the principal of international exhaustion.

With regard to pharmaceutical products, public health policy makers in the developing world have generally favored the principle of international exhaustion. This is consistent with the point of view that the less control pharmaceutical manufacturers have the fewer difficulties poorer countries will have obtaining and administering needed pharmaceuticals.

However, a practical side effect of international exhaustion is that it is much more difficult for drug manufacturers to consider ability to pay in establishing different price points for different markets. Were pharmaceutical companies to establish significantly lower prices for developing country markets, they would risk having products sold in those markets re-imported into their profit-

generating home markets. These re-imports are generally known by the name "gray market" products. Consumer groups in developed countries such as the United States naturally favor the "gray market" and oppose marketing strategies that result in consumers in their societies subsidizing lower prices in other markets.

Even under a regime of international exhaustion, countries can adopt systems of price controls (discussed in the next section) which reduce the cost of drugs within national markets. The difficulty with this strategy, standing alone, is that drug companies may refuse to manufacture in or export to those markets. And, with full implementation of the WTO/TRIPS agreement, developing countries that wish to be a part of the international trading system will be unable to copy without a license from the patent owner. While the WTO/TRIPS agreement does allow countries to grant compulsory licenses, they can only be granted once some comparatively strict preconditions are met. In any event, therapies such as AZT and protease inhibitors are difficult, if not impossible, to replicate and administer without the cooperation of their developers. This calls for a cooperative relationship between patent holders and licensees rather than a relationship imposed upon them by the state. Therefore, in the post WTO/TRIPS world developing countries may have to reconsider where their self-interest lies in the debate over territorial versus international exhaustion. Effective implementation of the principle of national exhaustion requires its broad acceptance at the international level – in particular among higher-priced countries so that the differential pricing scheme described above may work. If not, it is inevitable that the products placed on the market at a lower, concessional price in one country will find their way into a higher-priced country.

***Setting Price Levels Appropriate to Developing and Least Developed Country Markets***

The market price of sophisticated HIV/AIDS treatments is clearly beyond the reach of consumers in developing or least developed countries. Therefore, a key element in supplying drugs such as AZT and protease inhibitors to these markets must be a method of establishing appropriate price levels likely below the world market price. The use of price controls is not unknown in the pharmaceutical world. Government regulation of prices has been utilized in the past in highly developed countries such as Canada. As an alternative to direct price regulation, the single payer health systems of some European countries operate in such a way as to set prices at a level lower than would be the case where there are multiple consumers. These developed country models should be examined as a basis for establishing below world market price levels appropriate to specific developing and least developed countries. Although producers generally oppose any kind of price controls or non-market price setting, the advantage of such a system for them is that it would open up markets and revenue streams which are currently unavailable to them. Two factors would be of critical importance in gaining their cooperation in such a system. First, they would have to be assured that drugs sold at non-market price points would not find their way into non- regulated markets. This implies both a relationship between a system of national exhaustion and price controls and a need for cooperation between health authorities and patent holders. As discussed above, a broadly accepted system of national exhaustion allows patent owners to consider ability to pay in a given country in setting prices for pharmaceutical products. Price controls are imposed by health authorities also on the basis of ability to pay. Thus, with a system of national exhaustion and cooperation between patent owners and health authorities there should be a convergence between price points set by patent owners and health authorities.

The second factor in obtaining the cooperation of the pharmaceutical producers in a system of price controls would be that developed countries not use such a system as a precedent to establish additional price controls themselves.

***International Subsidization of Pharmaceutical Purchases***

Even assuming a significantly lower price level could be established for HIV/AIDS drugs sold in a given developing country market, few developing or least developed countries enjoy income levels enabling them to pay. This is particularly true in sub Saharan Africa. Therefore, any comprehensive effort to supply state-of-the-art pharmaceuticals to these countries will require a significant program of international subsidization by wealthy states and manufacturers. Given the moral imperative involved, the costs of political destabilization resulting from unchecked epidemics, and the significant risk of new disease strains which could defy treatment and find their way back into the developing world, a program of international subsidization is reasonable. The World Bank has a history of organizing such programs. Along with UNAIDS it could put together a coordinated plan, involving international aid programs of developed countries and private sector humanitarian organizations to supply the necessary funding. Over time it will be necessary to create a subsidization regime that is sustainable. Given an appropriately controlled product delivery infrastructure, such an effort can include long-term price support by manufacturers for imported product and local production facilities.

Of course, in addition to assisting in the coordination of fund raising, UNAIDS has an extremely important role to play in organizing the means to deliver the therapies involved to patients, including the training programs, patient education programs, and the infrastructure for delivering sophisticated pharmaceutical products in general. The last section of this proposal suggests the implementation of a patient care delivery and pharmaceutical distribution system.

***Conclusion: The Need for a Pilot Project Coordinated by Three Specialized Organizations***

The costs and administrative complexity of a global effort to supply new drug therapies to developing and least developed countries are sufficiently high that it would be imprudent to attempt such an effort without testing its feasibility first. Therefore, this proposal is focused on identifying one developing country in a position to host a pilot project.

Together with private industry, three international specialized agencies have the mandate, expertise, and ability to organize the pilot project outlined above. They are the World Bank, the World Intellectual Property Organization and UNAIDS.

Expertise and norm setting authority over international patent law lies with the World Intellectual Property Organization in Geneva. Establishing an international consensus on how rules of territorial exhaustion should apply to developing country pharmaceutical markets clearly are within the jurisdiction of WIPO. UNAIDS, also located in Geneva, has the expertise to develop a program directed at the training and medical infrastructure issues critical to the effective administration of state-of-the-art anti-AIDS pharmaceuticals. Finally, the World Bank is in a position to put together the international effort to raise the funds necessary to subsidize the purchase of patented pharmaceuticals.

## IMPLEMENTING STRATEGY TO MANAGE DISTRIBUTION AND TREATMENTS

The success of this program relies on the ability to successfully deliver drugs to patients in combination with an effective treatment regime. HIV risk management and HIV/AIDS treatments are complex and require sustained therapeutic management. Accordingly, pharmacological therapies alone are insufficient absent other clinical management and support services.

Three major challenges must be met in order to deliver meaningful treatments to patients:

1. An effective clinical case management program must exist to coordinate the delivery of a full spectrum of care (including pharmaceutical therapeutics, HIV and other disease risk management, clinical services, social services, etc.) so as to achieve the maximum clinical benefit
2. A regulated pharmaceutical distribution network to help: (a) control delivery of these specific pharmaceutical products to patients, (b) achieve appropriate utilization, and (c) reduce product diversion and the development of a gray market
3. A multi-tiered, resource optimized, case management infrastructure to coordinate patient care, risk management and the delivery of pharmaceutical product.

### *Resource Optimized Case Management Services*

Supplying pharmaceutical interventions alone will not provide the level of measurable clinical benefit and improved outcomes required to make this proposed program a success. The complexity of the disease necessitates execution of a case management capability to help provide patient support services and appropriate clinical management of each case.

In the developing nations, case management services can be provided by an array of providers arranged in tiers according to level of sophistication and training. Examples are First Nation's programs in Canada that employ local residents as "front line" care workers working under the remote supervision of specially trained nurses and clinicians. Other examples are midwife programs that successfully operate in rural regions throughout Pakistan.

In these programs, local care workers provide the wide array of fairly comprehensive, hands-on support services required by patients during intervals between visits by more highly trained case managers. While not a requirement for this program, rudimentary telemedicine systems can also be implemented. Front line care workers can be remotely supervised and assisted to provide an even higher level of support service.

#### *Case Management Tiers*

Patients require continuous, but varying levels of support over the duration of their treatments. It is reasonable to provide services with the least expensive resource capable of accomplishing the task. Different "tiers" of case management resources and primary care services would be assembled. Each tier would be trained and outfitted to provide services based on the complexity of the support activity and the skill level of the caseworkers in that tier. Patients requiring services beyond the skill/capabilities of the tier are identified and moved to the next tier.

The critical ingredient to managing a tiered care delivery system is an underlying set of protocols and technologies that:

1. help senior case managers properly evaluate the level of support required by a patient at any particular point in time, and

2. help determine how and when services are provided to those patients.

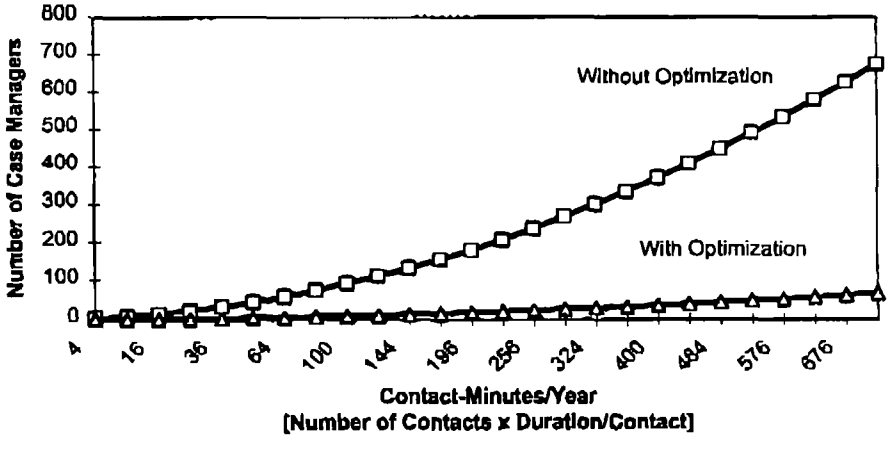
It is envisioned that the most senior nurse case managers and a network of participating clinicians will have access to a sophisticated, but easy to use, modeling and optimization technology. This technology enables the nurse case managers to understand how to schedule interventions with patients and, utilizing geographic overlays, can help them coordinate their rotations (visits with patients). Optimization technology also helps case managers task care coordination by local care workers who perform basic support services. Local care workers can also utilize the system to access case managers when an episode occurs that requires a more complex type of intervention. The infrastructure to implement and operate such a technology in the developing world is currently available and the advanced algorithms and computational platforms employed can be operated remotely where required.

This technology can substantially leverage the population that can be served by one senior nurse case manager. Therefore, it is possible to cost-effectively create a system that uses lower-skilled and lower wage local workers to provide many of the hands-on interventions that would otherwise have to be provided by an expensive nurse case manager. With supervision and occasional visits from more highly trained nurse case managers, patients will be assured of receiving an appropriate level of care sufficient to achieve an improved outcome.

Without the technology, meaningful case management would likely be impossible as it would require hundreds of personnel to support the large number of patients and the level of coordination would overwhelm management's ability to rapidly respond to patient needs. Without a sustained program, the treatment regime collapses and the outcomes are poor.

The following table shows one analysis of the labor required to provide equivalent levels of case management interventions with and without the support of optimization technology.

**Case Managers Needed for 100,000 Cases as a Function of Increasing Contacts and Durations [With and Without Resource Optimization]**



***Regulated Pharmaceutical Distribution Network***

In the industrialized nations, pharmaceuticals are delivered through a homogeneous, well-developed product distribution system. A logistically sophisticated delivery pipeline includes wholesalers, distributors and retailers. In this distribution model, many different parties retain quantities of product as inventory before it is delivered to the consumer. This inventory is often maintained in regional and local warehousing facilities with automated picking systems designed to minimize labor costs. Just-in-time delivery capabilities, eliminate the need to maintain inventory at retail locations where space is very expensive.

This robust model of distribution can not work in countries where the distribution infrastructure does not exist and where there are tremendous opportunities to engage in arbitrage by diverting product from one market to another. It is especially difficult to manage dissemination of pharmaceuticals if:

- the product is sold domestically at a price substantially below the world price
- there are limited inventory management and control systems to track inventory
- there are large quantities of product available in the distribution system that are subject to "inventory leakage" and diversion
- there is no way to ascertain patient utilization to ensure that the product is reaching those patients in need
- the product is manufactured locally under license and excess production is not controlled.

In the developing world, it will be necessary to implement a "pull" distribution model. The underlying premise of a pull distribution system is that product does not enter the local-market distribution pipeline in large quantities, and it only enters the pipeline when there is a known consumer (patient) demand in a controllably small geography. Furthermore, product is paid for in a manner that inhibits the formation of local black markets. A "pull" distribution model operates much like a drop shipment system wherein product is not shipped from the manufacturer or controlled warehouse until the end consumer generates an "order" (much like how a catalog order is processed). Rather than distributing and warehousing the inventory in any quantity, the product is distributed to a geography only in anticipation of a particular order being generated (i.e., a refill is going to come due). Because there is no infrastructure to create the "order", a modeling approach coupled to the case management system is used to determine when demand necessitates re-supply and this generates the insertion order. Orders can be aggregated, but no large stockpiles are allowed. Shipments can be tracked and monitored to the point where it is delivered or administered to the patient or to a local distributor (this does not have to employ a great deal of physical or labor infrastructure). Because of the wide disparity between the value of the product and the income of people who work in the distribution system, there is always the issue of local black market diversion. A number of techniques can be used to reduce the incidence of diversion including paying distributors a percentage of product value for successful delivery to the patient. Another technique is to make the product freely available at the local level, thus reducing its "street value". Product is paid for at the national or regional level where it is easier to implement controls that prevent diversion. By eliminating the street price and paying a commission only for successful delivery to patients, there is less incentive to divert product from patients to be sold on a local black market

### *Coordinating Case Management with Pharmaceutical Supply*

Because the management of HIV and the treatment of AIDS and other high-impact disease requires a clinical and social case management adjunct to patient care, there is an opportunity to implement a drug delivery system that runs concurrently with the case management system. The case management system is approximately aware of the quantities of pharmaceutical and other supplies being used by patients under management and, at the right time, it triggers the insertion of refill orders into the pipeline for ultimate delivery by a visiting case worker or fulfillment by a local pharmacy.

Factors such as the inherent latency of the pipeline and the projected demand for product in a given geography are computed by the optimizer as is the projected interval until each patient is expected to need supplies. The optimizer also computes when case management interventions will be required based on a number of factors including case plans and episodic incidents. The scheduling algorithm then uses the output from these models to calculate when the patient will next see a skilled care worker or case manager. These case managers can be entrusted to arrange the delivery of pharmaceuticals directly to patients in that geography.

Such a system makes it possible to "feed" the distribution pipeline in a much more controlled way and reduce the incidence of untraceable diversion. Other control measures can be implemented to reduce the likelihood of significant quantities of product being outside of control while in the distribution pipe. This approach makes it significantly more difficult for the gray market to assemble and divert meaningful quantities of product and dramatically increases the costs of doing so.

It must be pointed out that even in the developed nations there have been instances of gray market product diversion for "street" resale of products by patients (and others) that need money (e.g., for food or housing). Yet, when drug delivery strategies have been coupled to clinical case management services, appropriate utilization increases and the instances of "street resale" have been significantly reduced. This has been shown to result in better compliance and improved patient outcomes – especially as measured by the incidence of hospital admissions related to opportunistic disease.

Even in those areas where a reliable retail distribution system exists, the technology will help caseworkers oversee and coordinate appropriate drug utilization – a critical factor in managing this disease.

A powerful arsenal of new treatments now exists to help manage the course of HIV and other high-impact disease such as TB. Information management technologies have been developed that make it possible to cost-effectively deliver treatments and the adjunctive patient support needed to improve outcomes. HIV infection is being treated with some real success in the developed world and there is a reasonable expectation that it is now possible to manage the treatment of HIV and other intractable diseases in the developing world. A mandate to create the policy and legal foundation to make these treatments available is forming. There are compelling reasons of global dimension to find a way to bring these capabilities together.

A coordinated pilot program consisting of:

- innovative policies,
- international cooperation and funding

can be combined with

- sophisticated information technology,

- established models of case-managed patient care, and
- controlled pharmaceutical delivery systems

to achieve an affordable and effective effort to stem the course of a pandemic.

THE WHITE HOUSE

WASHINGTON

August 3, 1999

The Honorable Sandy Thurman
Director
National AIDS Policy
1600 Pennsylvania Avenue
The White House
Washington, D.C. 20502

Dear Sandy:

I am pleased to invite you to the White House on September 7, 1999, to join me and a small group of senior representatives from the United States government, multinational institutions, foundations and the corporate sector for a meeting to explore strategies to better address the international AIDS crisis.

This devastating epidemic is an assault on health and development that has few, if any, modern equals. Only 20 years ago we did not know that HIV existed. At the beginning of this decade, who among us would have thought that by 1999 AIDS would be the leading cause of death in sub-Saharan Africa and the fourth leading cause of death worldwide?

In the face of this reality, the President has recently asked for a $100 million increase in funding for international HIV/AIDS programs as the cornerstone of a broad and comprehensive new international initiative to combat the epidemic. This is just a part of the international effort necessary to control the spread of HIV and to deal with the associated problems of patient care.

Today 34 million people worldwide are living with HIV or AIDS. AIDS related diseases have killed 14 million men, women and children- -mostly in Africa where more than 5,000 deaths are reported each day. By 2010, 40 million children will have been orphaned by HIV/AIDS. Economic development in many African countries has come to a stop and the hard won social and health advances of the last 20 years are being reversed by the new realities of the epidemic. These statistics do not begin to describe the personal tragedy for many of those living with HIV/AIDS and their families.

Still there is cause for hope. Throughout the world, heads-of-state are increasingly acknowledging AIDS prevention as a public health and political priority. National HIV/AIDS control strategies have been written, and Uganda and Thailand

have shown that successful national AIDS prevention programs can work. Unfortunately, a serious crisis remains and much more needs to be done. Many developing countries, overwhelmed by human and financial costs, are losing the battle with the epidemic.

I am asking you to join me to help build the momentum necessary to engage all stakeholders in winning the war against HIV/AIDS. Although financial support for AIDS prevention efforts remains the most critical unmet need, this meeting is not intended to be a donors conference. Rather, we will discuss strategies and identify priorities and new partnerships for assisting countries in their HIV/AIDS control efforts.

We will meet at the White House on Tuesday, September 7th. Please plan to arrive at the East Appointments Gate no later than 10:00am. To confirm your participation, please call Katy Button in my office at (202) 456-6266. I look forward to seeing you on September 7th.

Sincerely yours,

Hillary

Hillary Rodham Clinton

# NATIONAL SECURITY COUNCIL

# FAX COVER SHEET

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Washington, D.C.
20504

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(202) 456-9394

**From:** Dr. Kenneth W. Bernard
International Health Affairs

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**To:** Sandy Thurman
**Agency:** National Aids Policy
**Fax Number:** 456-2438
**Date/Time:** September 7, 1999
**No. of pages to follow:** 7

**Message:** As discussed

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DEPARTMENT OF THE TREASURY
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WASHINGTON, DC 20220

**URGENT**

DATE: September 3, 1999 PAGES TO FOLLOW: 1

TO: Ken Bernard, NSC

ADDRESSEE'S FAX NUMBER: 202/ 456-9390 [redacted]

ADDRESSEE'S CONFIRMATION NUMBER: 202/ 456-9298

FROM: Margaret Kuhlow

SENDER'S FAX NUMBER: 202/622-0404

SENDER'S CONFIRMATION NUMBER: 202/622-0656

SPECIAL INSTRUCTIONS/MESSAGE:

Ken, attached please find suggested text describing two sample countries whose social spending programs, including AIDS prevention, could potentially benefit from the deeper debt reduction that would be afforded under the Cologne initiative. If you need to make significant changes, please clear the substance with Bill Schuerch.

Should you need additional information, you can reach Bill Schuerch or Joe Eichenberger through the Treasury operator at 622-1260.

The recently agreed Cologne initiative to expand debt reduction under the Highly Indebted Poor Countries program, or HIPC, could play an active part in increasing AIDS prevention activities in the poorest countries of the world by freeing up resources for health care and public awareness. Two examples of countries at different stages of their battle with AIDS who will benefit from the Cologne initiative are Uganda and Tanzania. Uganda, the first country to receive HIPC debt reduction, is already using funds that would otherwise be used for debt service for increased social sector spending. Uganda's experience in reducing the rate of HIV/AIDS infection demonstrates what can be done with strong political leadership and effective programs in the health sector, primary schools, and more broadly with private organizations and religious groups. Tanzania is just beginning its efforts to combat AIDS. They will soon be eligible for participation in the HIPC program and the Prime Minister recently visited Uganda to gather lessons for Tanzania as they embark on their own AIDS prevention program.

The Cologne agreement will more than double the debt relief to be provided under the HIPC program, freeing up resources for Uganda and Tanzania and other eligible countries to finance basic social sector spending, including more intensive efforts to prevent the spread of AIDS.

For the initial countries eligible for debt reduction under HIPC, we will work with the International Monetary Fund and the World Bank to encourage them to develop pilot projects that integrate AIDS programs more effectively into each country's public health strategies.

# FIRST LADY HILLARY RODHAM CLINTON
# TALKING POINTS FOR MEETING ON AIDS IN AFRICA
# THE WHITE HOUSE
# SEPTEMBER 7, 1999

- Welcome -- and thank you all for coming to what I hope will be a very interesting and productive discussion. We are very pleased to be joined this morning by many leaders from the Administration, international organizations, foundations, businesses, and the AIDS community. [Their presence is a testament to the impact the AIDS pandemic has on every sector of society – and to the responsibility we all have to end it.]

- It is my hope that this meeting will lead to new initiatives, new resources, new thinking, and new partnerships to fight – and ultimately win – the war against HIV/AIDS in Africa and around the world.

- Every day, we are reminded of the breakthroughs we've had in this fight– from drug therapies that are improving life to education campaigns that are empowering people to prevent the disease. We know what works. But, we also know that far too many people are still being left behind.

- Just a week ago in Atlanta, we heard that the rate of HIV infections is no longer declining in the U.S. And, each and every day, AIDS claims the lives of more than 5,500 men, women, and children in Africa. In the next few years, that number will more than double. The AIDS epidemic in Africa is a crisis of biblical proportions. We are facing an emergency. And what we see in Africa today, we will likely see one day in India, in Southeast Asia, and the Newly Independent States if we don't act now.

- In Uganda, I saw firsthand what can be accomplished when the governments and citizens join forces to beat this disease. I went to the AIDS Information Center and saw countless billboards educating people to protect themselves against AIDS. I remember a song some of them sang: Ugandans are fighting to ensure that AIDS cannot win. And, it's working. From 1992 to 1998, the percentage of sexually active teenage girls who were HIV positive declined by almost two thirds.

- That example was on the minds of the African health ministers who came together last week at a W.H.O. meeting in Namibia. They declared war on HIV/AIDS and made a commitment to stop the devastation plaguing their citizens and countries. And we must work hand in hand with them.

- AIDS is not somebody else's problem. Our work against this deadly disease must be part of all our development efforts – especially those affecting women and children. Because, as we speak, the AIDS epidemic is turning back the clock on the development we've seen in Africa. It is undermining entire economies, trade, civil society, and stability. It is decreasing life expectancy by up to 20 years in some countries and turning millions of children into orphans.

- I know that the people in this room have worked tirelessly to make great progress in the battle against AIDS. But, as you know better than anyone, the challenge before us is far greater than the collective actions taken so far. And that's why your continuing leadership is so important.

- We are pleased to be joined this morning by many leaders of our Administration, who have worked on this problem from every perspective -- health, financial, international, and development. They include the Secretary of Health and Human Services, Donna Shalala; the Secretary of the Treasury Larry Summers; USAID Administrator Brady Anderson; our Surgeon General, Dr. David Satcher; Undersecretary of State, Frank Loy; and the Director of the White House Office of National AIDS Policy, Sandy Thurman.

- As many of you know, the Administration has asked for an additional $100 million next year to fight the global battle against AIDS. This new initiative represents the largest increase ever in the international AIDS budget. And it would allow us to more than double our efforts in sub-Saharan Africa.

- We can also take heart in the recent Cologne Agreement, which will more than double the debt relief provided to countries that need it most. This means that eligible nations such as Uganda and Tanzania will now be allowed to use their freed up resources on social sector spending – including, for the first time, activities to prevent HIV/AIDS. We will work with the International Monetary Fund ~~and the~~ World Bank to encourage Uganda, Tanzania, and other eligible countries to develop HIV/AIDS pilot projects – and provide an example to other indebted nations struggling against this disease.

- And I am very pleased that we are joined here by key representatives of our multilateral organizations, including Jim Wolfenson and Jan Piercy from the World Bank and Peter Piot from UNAIDS.

- We are also very fortunate to have with us the National Association of People with AIDS and the Global AIDS Action Network – two non-governmental organizations that serve on the frontlines of this battle.

- We are also joined this morning by representatives of foundations that have provided great leadership in the fight against HIV/AIDS. I want to thank the Rockefeller Foundation, the Gates Foundation, and the Open Society Institute for their generous contributions. I also want to thank the Kaiser Family Foundation, which comes here with a new commitment to match funding dedicated to preventing AIDS among adolescents in South Africa. And I want to thank the MacArthur Foundation, which will be bringing foundations together at the end of this year to discuss even more ways they came meet this challenge.

- I am also very pleased to be joined by Black Entertainment Television and Bristol Myers Squibb, who are not only making great contributions – but also reminding us of critical role that all businesses can play.

- Because just imagine what we could accomplish if, over the next few years, we could bring to this table every business, government leader, foundation, NGO, multilateral organization, and citizen. Think of the millions of people in Africa and all over the world whose lives and futures we could save – if we could find the will and the way.

- We will never give up until the day when we meet our ultimate goal – and find a cure that reaches every single man, woman, and child on this planet. But, until then, we must do everything in our power to prevent HIV and heal those it strikes in Africa and all over the world.

- And I hope that over the next hour or so we will think creatively about the ways that we can work together to do just that.

Record Type: Record

To: Kenneth W. Bernard/NSC/EOP@EOP

cc:
Subject:

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# AIDS Convening
# September 7, 1999

## *Participants List*

**Administration**

First Lady Hillary Rodham Clinton

Secretary Donna Shalala
Department of Health and Human Services

The Honorable David Satcher
Surgeon General

Secretary Lawrence Summers
Department of the Treasury

Administrator Brady Anderson
US Agency for International Development

The Honorable Leon Fuerth
Assistant to the Vice President for National Security Affairs
The White House

The Honorable Sandy Thurman
Director
National AIDS Policy Office
The White House

Ms. Gayle Smith
Senior Director for African Affairs
National Security Council
The White House

Under Secretary Frank Loy
Under Secretary for Global Affairs
Department of State

Melanne Verveer
Assistant to the President and Chief of Staff to the First Lady
The White House

Dr. Ken Bernard
International Health Affairs
National Security Council
The White House

**Multinational Organizations**

Mr. James Wolfensohn
President
World Bank

Ms. Jan Piercy
The Executive Director of the United States
The World Bank

Dr. Peter Piot
Executive Director
Joint United Nations Program on HIV/AIDS

**Foundations**

Dr. Timothy Evans
Team Director for Health Services
The Rockefeller Foundation

Mr. Aryeh Neier
President Soros Foundations Network
Open Society Institute

Mr. Stewart Burden
Senior Program Officer
The John D. and Catherine T. MacArthur Foundation

Dr. Gordon Perkin
President of PATH
William H. Gates Foundation

Dr. Drew Altman
President and CEO
Kaiser Family Foundation

**Corporations/Others**

Mr. Charles Heimbold
Chairman and Chief Executive Officer
Bristol Myers Squibb

Mr. Robert Johnson
Chairman and CEO
Black Entertainment Television

**Observers**

B.A. Rudolph
Chief of Staff to the Administrator
Agency for International Development

Paul Delay
Agency for International Development

Dr. Jim Sherry
United Nations Joint Program on HIV/AIDS

Mr. Eduardo Doryan
Vice President and Head of Network
The World Bank

Ms. Debrework Zewdie
Lead Specialist, Population
The World Bank

Timothy Geithner
Under Secretary for International Affairs
Department of the Treasury

William Schuerch
Deputy Assistant Secretary for International Development, Debt and Environmental Policy
Department of the Treasury

Ms. Debrah Lee
President and COO
Black Entertainment Television

Mr. Ken Weg
Vice Chairman
Bristol Myers Squibb

Dr. Seth Berkley
President
International AIDS Vaccine Initiative
The Rockefeller Foundation

Mr. Terry Anderson
Executive Director of Public Policy
National Association of People with AIDS

Mr. Paul Boneberg
Director
Global AIDS Action Network

Ms. Marsha Martin
Special Assistant to the Secretary
Department of Health and Human Services

Ms. Diane Graham
Special Assistant for Global Affairs
State Department

Ambassador Nancy Powell
Principal Deputy Assistant Secretary for African Affairs
State Department

Richard Socaridies
Special Assistant to the President and Senior Adviser for Public Liaison
Office of the Public Liaison
The White House

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