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OFFICE OF NATIONAL AIDS POLICY

EXECUTIVE OFFICE OF THE PRESIDENT
THE WHITE HOUSE

FACSIMILE TRANSMITTAL SHEET

TO:

FROM: Cheryl Bauerle

COMPANY:

DATE: Aug. 20, 1999

FAX NUMBER: 225-1154

TOTAL NO. OF PAGES INCLUDING COVER: 5

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RE:

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NOTES/COMMENTS:

Please see attached and call me with questions.

Many thanks!

Cheryl Bauerle (456-2959

OFFICE OF NATIONAL AIDS POLICY

EXECUTIVE OFFICE OF THE PRESIDENT

THE WHITE HOUSE

FACSIMILE TRANSMITTAL SHEET

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Please see attached and call me with questions.

Many thanks!

Cheryl Bauerle (456-2959

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INDEPENDENT

July 28, 1999

Ms. Sandra Thurman
Director, Office of National AIDS Policy
The White House
736 Jackson Place, NW
Washington, DC 20503

Dear Ms. Thurman:

On behalf of myself and the members of the Subcommittee on Criminal Justice, Drug Policy and Human Resources, I would like to thank you for taking the time to testify before the subcommittee on the issue of the global HIV/AIDS epidemic. Your testimony assisted our consideration of the challenges faced by the Federal government in determining its role in combating the epidemic.

As mentioned at the close of the hearing, I have also included a set of follow-up questions that I did not get a chance to present to you at the hearing. Please provide the subcommittee with answers to the questions for the record no later than **Friday, August 20, 1999**. The responses and any additional supporting documentation can either be faxed to 202-225-1154, sent electronically to mason.alinger@mail.house.gov, or mailed to:

Subcommittee on Criminal Justice, Drug Policy and Human Resources
B-373 Rayburn House Office Building
Washington, DC 20515

Please feel free to share your ideas and information with my staff and me as we continue to work together on this important topic.

Sincerely,

John L. Mica
Chairman
Subcommittee on Criminal Justice, Drug Policy, and Human Resources

Responses submitted to Subcommittee on Criminal Justice, Drug Policy and Human Resources

Sandra Thurman, Director, Office of National AIDS Policy, The White House

(1) The Office of National AIDS Policy has submitted for the record a copy of the Administration's "Joining Forces for Life" proposal which outlines how the Administration would invest the $100 million increase it has requested in global AIDS funding for FY2000. In addition, we have submitted a copy of the Administration's budget amendment, which outlines our proposed offsets for this essential new funding.

In brief, our investment breakdown is as follows:

- $48 million for prevention;
- $23 million for basic care and treatment;
- $19 million for infrastructure and capacity development; and,
- $10 million for care for children orphaned by AIDS.

As you can see, the Administration's proposal allocates $23 million for basic care and treatment for people living with HIV and AIDS. While the delivery of health care services has not been the traditional role of health related foreign assistance, the suffering brought on by the AIDS pandemic in Africa beckons all host governments, bilateral donors, multilateral institutions, and private-sector partners to do more.

Currently, the overwhelming majority of funding requests related to AIDS treatment coming to us from African governments, USAID missions in Africa, African NGOs, US PVOs working in Africa, and multilateral institutions such as UNAIDS have been for assistance in the care and treatment of AIDS related opportunistic infections, such as tuberculosis, not for anti-retrovirals and protease inhibitors. It is likely that a significant percentage of the care and treatment funding proposed by the Administration would be used for this purpose. For example, The AIDS Support Organization (TASO) has provided basic care and treatment to 50,000 people living with AIDS through satellite clinics and home-care workers throughout Uganda. This effort has not only prolonged life and reduced suffering, it has helped to decrease the stigma of AIDS and to increase the effectiveness of HIV prevention efforts. Such programs should be more widely available throughout Africa, and the Administration's proposal would help to make this possible.

(2) The Administration is not interested in "periodic announcements" or in "raising false hopes". We are interested in working closely with the Congress, the private sector, our G-8 and other allies, multilateral institutions, NGOs, and African governments in the development and implementation of a comprehensive and coordinated HIV/AIDS strategy. We are grateful that the Subcommittee is also committed to such an approach.

The Administration believes that aspects of a comprehensive HIV/AIDS strategy include encouraging the Congress to enact the $100 million in new global AIDS spending for FY2000, pursuing a bipartisan and ongoing resource commitment in FY2001 and beyond, challenging our partners (both public and private) to do their fare share, and supporting compulsory licensing and parallel importing in emergency situations as long as such action is done in accordance with existing international trade laws and agreements. None of these approaches alone, including compulsory licensing and parallel importing, is a panacea, able to eliminate the tremendous suffering brought on by this devastating pandemic. The global AIDS crisis is everyone's problem and everyone must be part of the solution. Should the price of anti-retrovirals and protease inhibitors be dramatically reduced, either through compulsory licensing and parallel importing or through negotiations with the pharmaceutical industry, these treatments will likely remain far beyond the reach of the overwhelming majority of people living with HIV and AIDS in South Africa and across the continent. Most people living with HIV and AIDS in Africa do not know they are HIV+ and many will die before they learn their status or see a health care professional. If we are serious about our desire to reduce this suffering, health care infrastructure and basic health care services are sorely needed. It is this infrastructure that will help to make effective AIDS therapies, and someday an HIV vaccine, accessible once affordable. It is this infrastructure and basic care and treatment that the Administration's proposal seeks to provide.

(3) Yes, the AIDS crisis in Africa is an emergency that demands a united and coordinated response not just from this Administration and this Congress, but from the governments in crisis, the G-8 and other developed nations, the United Nations and other multilateral institutions, NGOs, private corporations, and the pharmaceutical industry.

This response must be comprehensive and coordinated. It must address prevention, care and treatment, caring for children orphaned by AIDS, infrastructure development and accelerating the search for a vaccine.

This type of global response will not come until awareness of the crisis grows. That is why I appreciate the leadership shown by the Subcommittee of Criminal Justice, Drug Policy, and Human Resources in addressing this issue in Congressional hearings. It will help prompt an increasingly positive response from some of the world's most powerful institutions and organizations.

(4) and (5) The office of National AIDS Policy is not on record as opposing parallel imports or compulsory licensing of AIDS treatment drugs by nations that are experiencing major AIDS epidemics. As USTR testified at the Hearing, the Administration "raises no objection to compulsory licensing or parallel importing of pharmaceuticals on the part of South Africa, as long as it is done in a way that complies with TRIPS." We look forward to continuing to work with the government of South Africa and others to expand the availability and accessibility of AIDS care and treatment.

Of course, any effort to expand HIV/AIDS drug availability must include a broad-based effort to expand and improve the health care delivery system in nations where as many as 95% of the people have no access to care and treatment of any kind. This issue is beyond matters of trade law or the price of pharmaceuticals; it demands a dramatic and unprecedented worldwide commitment to the cause - the kind of commitment that can be generated in part by keen and continuing attention by Members of Congress.

(6) I know of no one who has proposed "withholding" drug treatments "from millions now suffering due to fears that new strains of HIV/AIDS might develop". The challenge we all face is how to make HIV/AIDS treatments affordable, accessible, and effective, both here and abroad. I have discussed above how even if drugs are affordable, they are unlikely to be accessible in Africa without a great deal of infrastructure development
(clinics, providers, paraprofessionals, etc.). In addition, in order for drugs to be effective, they must be taken in the manner required and their side effects, often devastating, must be managed. These concerns are real in the United States, and are certainly real in the developing world.

It is true, that protease inhibitors are difficult to take. To be effective, this therapy requires strict adherence to a regimen of 30 or more pills (some of which require intake with large quantities of water), at several precise times each and every day – without exception. This is an extremely complicated therapy for citizens in developing nations that often lack both clean water and access to health care clinics or providers. And it is true, that failure to adhere to the prescribed regimen in this case can do more harm than good. This is not an excuse, it is a reality that must be considered, both here and abroad, when planning and implementing appropriate systems of care for people living with HIV and AIDS. Together, we should do all we can to remove barriers to treatments that can prolong life and reduce suffering, but we should not ignore such barriers or pretend they do not exist.

I look forward to working closely with you on this vitally important effort and thank you again for your interest and commitment.

From Tom Chen

(3). The AIDS crisis in Africa would have brought forth an urgent and immediate response from the world community if the devastation were wrought by a short-term natural disaster, like a flood, hurricane or earthquake. Instead, the disease has spread quietly, but quickly, and we have been too slow to sound the alarm.

We face an international emergency that demands a united and coordinated response not just from this Administration and this Congress, but from the governments in crisis, the G-8, the United Nations, NGOs, private corporations, and the pharmaceutical industry.

And this response must be comprehensive. It must address awareness and prevention, improving health care delivery, caring for orphans, making drugs more effective and affordable, and accelerating the search for a cure.

This type of global response will not come until awareness of the crisis grows. That is why I appreciate the leadership shown by the Subcommittee of Criminal Justice, Drug Policy, and Human Resources in addressing this issue in Congressional hearings. It will help prompt an increasingly positive response from some of the world's most powerful institutions and organizations.

(4). The Office of National AIDS Policy believes that effective and affordable medicines are an essential component of a comprehensive effort to address the AIDS crisis worldwide. While we defer to the USTR for an explanation of United States trade policy, we do believe that a world-wide partnership against this disease – that includes governments, health care professionals, private companies, and pharmaceutical companies in particular – would go a long way toward establishing a safe and effective regime for expanding the availability of medicines in developing nations.

Of course, any effort to expand HIV/AIDS drug availability must include ~~as a first order of business~~ expanding and improving the health care delivery system in nations where as many as 95% of the people have no access to treatment of any kind. This issue is beyond matters of trade law or the price of pharmaceuticals; it demands a dramatic and unprecedented worldwide commitment to the cause – the kind of commitment that can be generated in part by keen and continuing attention by Members of Congress.

(5). The Office of National AIDS Policy understands that the United States Government has a duty to defend U.S. economic interests (and that includes the commercial interests of its corporations). But we believe that that duty must be balanced against the humanitarian, social, political, and national security interests represented by a health crisis of this dimension.

Therefore, the Office of National AIDS Policy finds regrettable the language in last year's foreign aid bill that cuts off all U.S. assistance to the Central Government of South Africa "until the Secretary of State reports in writing to the appropriate committees of the Congress on the steps being taken by the United States Government to work with the Government of the Republic of South Africa to negotiate the repeal, suspension, or

Should the price of anti-retrovirals and protease inhibitors be dramatically reduced, either through cl and pi or through negotiations with the pharmaceutical industry, these treatments will likely remain far beyond the reach of the overwhelming majority of people living with HIV and AIDS in South Africa and across the continent. Most Africans live on $1 per day. Most people living with HIV and AIDS in Africa do not know they are HIV+ and many will probably die before they learn their status or see a health care professional. If we are serious about our desire to reduce this suffering, health care infrastructure and basic health care services are sorely needed. It is this infrastructure that will help to make access to effective AIDS therapies, and someday an HIV vaccine, accessible once affordable. It is this infrastructure and basic care and treatment that the Administration's proposal seeks to provide.

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I look forward to working closely with you on this vitally important effort and thank you again for your interest and commitment.

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OFFICE OF NATIONAL AIDS POLICY

EXECUTIVE OFFICE OF THE PRESIDENT

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FACSIMILE TRANSMITTAL SHEET

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NOTES/COMMENTS:

This is the Feinstein language in the African Growth and opportunity Act. It is fairly benign and was passed by UC in the Senate. It is not in the House version of the bill.

When Congress returns the bills will go to conference —

This was a much bigger issue when we were on the ~~TRIPS~~ Plus plan.

Call if you have questions! ST

736 Jackson Place
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(202) 456-2437
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Statement of John Y. Killen, Jr., M.D.
Director

Division of AIDS
National Institute of Allergy and Infectious Diseases
National Institutes of Health

Before the
Committee on Government Reform
Subcommittee on Criminal Justice, Drug Policy and Human Resources

July 22, 1999

Mr. Chairman and Members of the Committee, I am pleased to appear before you today to discuss the human immunodeficiency virus (HIV) epidemic, recent developments in HIV research, and the many challenges that remain in the fight against HIV and the acquired immunodeficiency syndrome (AIDS).

The Scope of the Epidemic

AIDS was recognized eighteen years ago this summer, and continues to exact an enormous toll throughout the world, in both human and economic terms. In the United States, the rate of new HIV infections—approximately 40,000 per year—remains unacceptably high, despite an encouraging downturn in new AIDS cases and AIDS-related deaths.

In the developing world, the HIV/AIDS epidemic continues to accelerate, notably in sub-Saharan Africa, southeast Asia and on the Indian sub-continent. There are also signs of expanding epidemics in Russia and other New Independent States of the former Soviet Union. As of the end of 1998, more than 33 million people worldwide were living with HIV/AIDS, according to estimates by the Joint United Nations Programme on HIV/AIDS (UNAIDS). An estimated 5.8 million new HIV infections occurred worldwide during 1998—approximately 16,000 new infections each day. More than 95 percent of these new infections occurred in developing countries. Alarmingly, in 27 developing countries, HIV prevalence more than doubled between 1995 and 1997. In 1998, HIV/AIDS was the fourth leading cause of mortality worldwide, resulting in an estimated 2.3 million deaths.

Beyond the human tragedy of HIV/AIDS, the economic costs of the epidemic are staggering, posing a significant impediment to the growth and stability of many countries where the epidemic is decimating a limited pool of skilled workers and managers as well as young

people at the peak of their productive years. According to UNAIDS, life expectancy in the nine countries in Africa with the highest HIV prevalence rates will, for the first time in many years, decline an average of 17 years by 2015 due to HIV/AIDS.

Clearly, HIV remains one of the greatest threats to global health, and requires a sustained commitment by the various partners in AIDS research and prevention: U.S. and foreign government agencies, UNAIDS, non-governmental and philanthropic organizations, academia, industry, and the activist community.

Antiretroviral Therapies

As noted above, new AIDS diagnoses and deaths have dropped significantly in the United States in the past two years, and the same is true in other developed countries. These trends are probably due to several factors, particularly the increased use of potent, albeit expensive, combinations of HIV drugs. Sixteen antiretroviral drugs are now licensed in the United States, and several new agents are in various stages of clinical testing. Consensus guidelines have been developed for the use of anti-HIV medications that, when appropriately applied, have greatly improved the prognosis for HIV-infected individuals.

Unfortunately, many HIV-infected individuals have not responded adequately to the medications, cannot tolerate their toxicities, or have difficulty adhering to complex dosing schedules and substantial pill burdens. In addition, the ability of HIV to mutate and become resistant to the current drugs is a persistent threat. Although there is evidence of immune system reconstitution in certain patients who receive combination antiretroviral therapy, the goals of completely "rebuilding" the immune system or eradicating the virus from the body appear unlikely with current approaches to treatment.

For these reasons, the development of the next generation of therapies remains a priority. Currently, all licensed antiretroviral medications are directed at one of two viral enzymes, but many new strategies are being pursued, including drugs that prevent the virus from entering a cell and approaches to boosting an infected person's immune response.

HIV Prevention

In developing countries, where *per capita* health care spending may be only a few dollars per year, use of antiviral drugs is in most cases not a feasible option. These treatments are both costly and complex, and most developing nations lack the financial resources and the health

infrastructure necessary to support their use. Therefore, the identification of effective, low-cost tools for preventing HIV infection is crucial to slowing the epidemic.
~~In developing countries where *per capita* health care spending may be only a few dollars per year, use of antiretroviral drugs is largely out of the question, because combination therapy and attendant care may cost upwards of $15,000 per year. Therefore, the identification of effective, low-cost tools for preventing HIV infection is crucial to slowing the epidemic.~~

Researchers have shown that many scientifically proven approaches to HIV prevention can reduce the number of new infections, including: education and behavior modification, the social marketing and provision of condoms, needle exchange, treatment of other sexually transmitted diseases, and the use of antiretroviral drugs to prevent the transmission of virus from mother to infant.

Prevention of Mother-to-infant transmission

In early 1994, the NIH-funded clinical trial known as ACTG 076 showed that mother-to-infant transmission rates could be reduced by as much as two-thirds by treating HIV-infected pregnant women and their newborn babies with an intensive regimen of AZT (zidovudine). Unfortunately, cost and many logistical issues preclude the widespread application of the ACTG 076 regimen in the developing world.

To surmount these barriers, NIH and CDC-supported researchers have been collaborating with the health ministries and scientists of several developing countries on research to identify simpler, less costly ways to prevent mother-to-infant transmission of HIV.

Several recently reported studies, including two in Thailand and the Ivory Coast (both supported by the CDC), have shown that shorter regimens of AZT can also be beneficial, reducing transmission by between 37 and 51 percent. Despite these promising advances,

widespread implementation of these proven regimens in most developing countries has not occurred because of their expense and their dependence on an infrastructure of good prenatal care.

Last week NIAID reported on the exciting results of a study ~~in~~ conducted jointly with Ugandan scientists that could have profound implications for the epidemic in children worldwide. This study showed that just two doses of the antiretroviral drug nevirapine—one oral dose administered to the mother at the onset of labor and one to her baby shortly after birth—reduced the risk of maternal-infant transmission of HIV by nearly 50 percent when compared with a similar brief course of AZT. What makes this finding so significant for the worldwide epidemic is that nevirapine is extremely inexpensive and easy to administer; the regimen costs approximately $4 and is 70 times cheaper than the prveiously studied regimens of short course zidovudine, can be delivered orally, and does not require a chain of refrigeration~~.~~

Topical Microbicides

Other methods of preventing HIV transmission also may have an important impact on slowing the epidemic. For example, researchers are developing and testing topical microbicides, substances that a woman could use in her vagina before sex to prevent the transmission of HIV and other sexually transmitted diseases. These interventions may help empower women to protect themselves in situations where they are unable to avoid sex with partners who may be HIV-infected or to persuade their partners to use a condom. Several studies have been conducted or are underway in Africa using a variety of products.

HIV Vaccine Development

The development of a safe and effective vaccine for HIV infection remains the ultimate goal of AIDS research, and a key step toward bringing the HIV epidemic under control around the world. To hasten HIV vaccine discovery, many public and private agencies have dramatically increased the resources devoted to HIV vaccine research. For example, at the National Institutes of Health (NIH), HIV vaccine funding increased by 93 percent between FY 1995 and FY 1999. We estimate that approximately $200 million will be spent by the NIH in FY 2000 on HIV vaccine research.

As part of this expanded effort, NIH has awarded numerous grants to foster innovative research on HIV vaccines, and is invigorating and reorganizing its vaccine clinical trials effort. In addition, NIH has established the Dale and Betty Bumpers Vaccine Research Center within the NIH intramural research program to stimulate multidisciplinary vaccine research.

Since 1988 more than 3000 healthy volunteers have enrolled in 52 (50 phase I and two phase II) NIAID-supported studies involving 27 vaccines. Recent studies supported by the NIH in collaboration with several vaccine manufacturers have assessed so-called "vectored vaccines": harmless viruses (e.g. canarypox) that are genetically altered to make HIV proteins. Results have been encouraging: in phase I and phase II studies, this combination approach has appeared safe and evoked several types of immune responses that may have a role in protection from HIV.

Additional phase II trials of the combination vaccine concept will open later this year in Brazil, Haiti, and Trinidad and Tobago. These studies, as well as additional data that emerge from basic research, will provide the information to determine which products will advance into larger-scale testing. An exciting development for AIDS vaccine research was the initiation of the first AIDS vaccine study in Africa this spring. This NIH-supported phase I

study, which is being conducted in Uganda, is designed to help determine whether it will be possible to design vaccines that work against more than one strain of HIV.

Meanwhile, a large-scale study of a vaccine based on the surface proteins of two HIV strains was recently undertaken in the United States by a private company—VAXGEN. An additional phase III study is being conducted by VAXGEN in collaboration with the CDC in Thailand. NIH will collaborate with the company in evaluating the immunological responses to the vaccine.

Conclusion

Two years ago, President Clinton set a national goal of having a useful HIV vaccine within 10 years. We are well-positioned in our attempt to meet this goal with the extraordinary basic and applied research that is now under way. And just last week, Vice President Gore announced a new, multi-faceted initiative to address the AIDS crisis in Africa and other developing nations. NIH is a partner in this effort and is completely supportive of the initiative's plans to increase our prevention and infrastructure support efforts. As importantly, we support the call by the Vice President to other developed nations to join us in this effort for it is only by working together that we will have any chance of stopping this epidemic.

As we work to contain the global HIV/AIDS epidemic, it is essential that public and private sector partners and other members of the global community redouble their commitment to working together to speed HIV vaccine development, refine prevention efforts, and develop new treatments for those infected with the virus.

Thank you for your attention to this global crisis and for the opportunity to address this ~~subcommittee~~Subcommittee.

DRAFT DRAFT DRAFT

Testimony of

Timothy Dondero, M.D.

Chief

International Activities Branch

Division of HIV/AIDS Prevention

National Center for HIV, STD, and TB Prevention

Centers for Disease Control and Prevention

Before the

U.S. House of Representatives

Committee on Government Reform

Subcommittee on Criminal Justice,

Drug Policy, and Human Resources

JULY 22, 1999

I am Dr. Timothy Dondero, Chief of the International Activities Branch, Division of HIV/AIDS Prevention of the National Center for HIV, STD, and TB Prevention at the Centers for Disease Control and Prevention (CDC). Thank you for the opportunity to testify today about the magnitude of the global HIV/AIDS epidemic and CDC's international HIV/AIDS activities.

I will provide an overview summarizing the magnitude of HIV/AIDS epidemic and the closely intertwined tuberculosis (TB) and sexually transmitted diseases (STDs) epidemics worldwide. I will also highlight a few of CDC's international activities and discuss prevention approaches to reduce the impact of HIV/AIDS globally.

Background: Magnitude of Global HIV/AIDS, STDs and TB Epidemics

The HIV/AIDS epidemic continues to progress. More than 33.4 million people are estimated to be infected with HIV worldwide. Nearly 16,000 new infections occur each day, over 600 new infections every hour. Ninety-five percent of HIV-infected people live in the developing world -- and 95% of the deaths caused by HIV have occurred in developing countries. Unlike in the United States, most infections in the developing world are transmitted through heterosexual intercourse; the second most common route of transmission is from infected mothers to their children. In some areas, especially in Asia and here in the United States, HIV transmission through injection drug use is ~~locally~~ important; but for the world as a whole, drug-related HIV is responsible for only a modest part of the epidemic.

The most heavily impacted area of the world is sub-Saharan Africa, with over two-thirds of the world's infections and nearly 85% of the world's AIDS deaths. The next most affected region is south Asia and southeast Asia, with nearly 10% of the world's infections. These areas, and especially sub-Saharan Africa, are still experiencing explosive HIV epidemics that are taking an

enormous toll in human life and having a profound economic and social impact.

Currently it is estimated that there are 22 million adults and 1 million children living with HIV infection in sub-Saharan Africa and over six million infected persons in Asia. By comparison, the U.S. has an estimated ~~three quarters~~three-quarters of a million persons living with HIV infection. An estimated four million new infections occur in sub-Saharan Africa each year, over six million throughout the world. The number of people losing their lives to AIDS ~~death toll~~ is rapidly rising with an estimated 5,500 deaths from the disease occurring each day in Africa. Without rapid implementation of large scale effective interventions most, if not all, of these national epidemics will continue to grow. Apart from the devastating human tragedy, t~~T~~here are many potential national and international consequences to this critical situation, including effects on political ~~and~~, economic, and military -stability ~~and other factors~~ that ~~could~~ will adversely affect U.S. national interests.

I would like to turn your attention to a figure that graphically illustrates the extremes to which the HIV epidemic has reached in the ~~populations of the~~ developing world. This figure shows the most recently available data (1996-98) for HIV infection in pregnant women from capital cities or major urban centers in Latin America, Asia, and Africa. HIV infection in pregnant women is a reasonable indicator of the levels in young adults in those countries generally and a direct indicator of the risk of mother to child infection.

COULD NOT SEE GRAPH

In the southern-most African countries, HIV has reached epidemic proportions only relatively recently. Botswana now has one of the highest documented rates of HIV infection in the world, with over 40% of ~~child~~ child-bearing women living in cities infected with HIV. Recent reports from four southern African countries, Botswana, Namibia, Swaziland, and Zimbabwe, indicate

that a fifth to a quarter of their entire adult populations aged 19-49 are now HIV-infected. The infection is wiping out recent gains in life expectancy. By the year 2010, for example, demographers project that life expectancy will have fallen from 66 to 33 years in Zambia and from 70 to 40 years in Zimbabwe.

While African countries have been severely affected by HIV disease, other countries including Thailand, Cambodia, and India, have also been impacted by the disease. India has perhaps the largest number of infections of any single country in the world, estimated between 3 and 5 million HIV infected individuals.

Global trends in HIV disease indicate that women are at greater risk than men from heterosexual transmission, and as the HIV epidemic matures in a region, individuals become infected at younger ages and the epidemic moves from high-risk groups to the general population. And infected women are the source of infection for their babies. Without interventions, roughly one quarter of the babies will become infected by the time of birth and an additional 5 to 15% will get infection through breast feeding.

When describing the global magnitude of HIV/AIDS, it is also important to note the interaction between HIV and other diseases, specifically tuberculosis (TB) and sexually transmitted diseases (STDs). The interactions are significant to the control of the HIV epidemic.

Worldwide, 8 million cases of tuberculosis and 3 million deaths occur annually, and 95% of these cases and 98% of the deaths occur in ~~low-income~~low-income countries. Tuberculosis kills more adolescents and adults than any other single infectious disease. The spread of the HIV epidemic has significantly increased the TB epidemic. While some increase in TB is due to demographic shifts in the population, much of the additional TB burden over the last 5 years, especially in Africa, can be attributed to the HIV epidemic. People who have latent, or inactive,

TB infection from exposure earlier in their lives run a high risk of developing active TB if they become infected with HIV, a risk 100 times greater than for someone without HIV infection. This enhancement in TB cases seriously increases the burden on the health care system and specifically on TB control services, already struggling to function in most developing countries, as well as increasing the reservoir of ~~tuberculous~~ tuberculosis infection to be spread to other people. More ominous still is that increased TB in AIDS patients enhances the potential for the spread of multi-drug resistant TB organisms, with negative consequences not only for the geographic areas heavily affected by HIV but for the U.S. and the world generally.

Evidence from epidemiologic studies on four continents has repeatedly linked the presence of sexually transmitted diseases with a two-to-five-fold increased risk for HIV transmission. In 1995, an estimated 333 million cases of four curable STDs (syphilis, gonorrhea, chlamydia, and trichomonas infection) were acquired worldwide, an increase from an estimated 298 million cases in 1990. STDs facilitate HIV transmission by increasing shedding of HIV and also enhance susceptibility to HIV through increasing the likelihood of HIV infection. HIV may also prolong the duration and infectiousness of some STDs, which increases the prevalence of these infections.

But as grim as this HIV, TB and STD situation is, there are ~~actually some glimmers~~ strong symbols of hope. One example is Uganda, where strong political leadership and a well-coordinated prevention campaign have resulted in significant reductions in the number of new HIV infections. ~~though there are some similar if less extensive signs of success in Tanzania, also in east Africa; and, in Cote d'Ivoire and Senegal, both in West Africa. Thailand has also seen improvements in some of it's hardest hit regions.~~

Over the past 4 to 5 years, Uganda, one of the sub-Saharan countries initially most heavily affected by the HIV/AIDS epidemic, has seen significant and encouraging reductions in the incidence and prevalence of HIV infection in its population. Young women attending antenatal

clinics have had a one-third reduction in HIV prevalence between the early 1990's and 1997 (from 32% infected in one area down to 22%), with continuing downward trends. Behavioral studies have shown a two or more year increase in age at first sexual intercourse in youths, a 9% reduction in casual sex, and a 30%-40% increase in condom use. These beneficial trends are attributed to a number of factors simultaneously occurring in Ugandan society.

There has been strong political leadership in efforts to increase AIDS awareness and prevention. The President and the First Lady themselves frequently address HIV-related issues, making them acceptable for public discussion. The Ugandan public is generally aware of HIV, including prevention needs and methods. In addition, Ugandan institutions, including religious groups, help provide a supportive and de-stigmatizing environment. Strong programs also exist for condom social marketing and for screening of transfused blood.

In addition, a very intensive HIV counseling and testing program, technically and fiscally supported by both CDC and USAID, has reached upwards of one-half million persons since 1990 through AIC (AIDS Information Center), a major non-government organization. This internationally acclaimed program, active in urban and rural areas, has functioned as an integral component of national programs for AIDS education and information and has contributed to AIDS surveillance.

There are similar signs of success in Tanzania, also in east Africa; and, in Cote d'Ivoire and Senegal, both in West Africa. Thailand has also seen improvements in some of its hardest hit regions.

Given the magnitude of the epidemic and the continuing explosive risk, and considering the economic and infrastructure realities of the regions of the world most affected, the most critical public health approach is prevention. Providing HIV treatment to the huge numbers of the world's HIV-infected poor people will be difficult in the near future for several reasons. Most

people with HIV infections are not aware that they are infected, and counseling and testing facilities are rare in the most affected developing countries. Most antiretroviral medications are very expensive, even with the reduced prices that UNAIDS has been able to negotiate with the drug manufacturers, and way beyond the $5 to $15 dollar per person annual expenditure on all of health services typical in these countries. Even if the drugs were available, the hospitals and clinical infrastructure are not currently equipped for the diagnostic work and laboratory monitoring most patients would need to really benefit from the treatment. TB screening of HIV-infected people and offering the low cost preventive medications for the other common opportunistic infections is more feasible than the expensive therapy aimed at the HIV virus itself.

CDC's Role in International HIV Activities

CDC focuses its international efforts by offering assistance to countries with the greatest public health need; conducting collaborative research and training on preventive interventions; serving as partners in global initiatives; and responding to national U.S. interests. We apply U.S. scientific advances in other countries, such as rapid HIV testing, prevention of mother-to-infant HIV transmission, refinement and installation of HIV diagnostic and research techniques, assisting in technical aspects of HIV surveillance, testing and counseling, applications of simple prevention of opportunistic infections, computerization of prevention and service providing groups, and studying the interactions of HIV and TB. ~~Some~~ Many of these activities involve a partnership with NIH, USAID, UNAIDS, and other international organizations. We also apply lessons learned in other countries to domestic disease control efforts.

CDC has a strong international field station structure in Cote d'Ivoire, Uganda, Kenya, and Botswana in Africa and Thailand in Asia, as well as a long history of providing technical assistance to these and many other countries. In addition to these sites, we have resident advisors relating to HIV and its associated diseases stationed in several places, including India, Bolivia, Indonesia, Vietnam, South Africa, and Mali (a number of these through USAID), and offer many short-term consultations on issues including surveillance, epidemiological assistance, training,

program management, blood supply protection, laboratory capacity building, and -prevention efforts.

At the global level, CDC assists by enhancing the capacity of the UN agencies committed to combating the epidemic through making technical experts available to UNAIDS, UNICEF, and WHO on both a long-term and a short basis. CDC also collaborates extensively with the US Agency for International Development (USAID), the World Health Organization (WHO), the Joint UN Programme on HIV/AIDS (UNAIDS), the United Nations Children's Fund (UNICEF) and the World Bank, as well as ministries of health around the world to provide both long and short term technical assistance and expertise.

Approach to the Epidemic: Prevention

One of the most critical needs in effective HIV/AIDS prevention is political will and political leadership within the country addressing, acknowledging, and focusing resources on HIV/AIDS prevention and control efforts. This key element of effective prevention can be provided only by the leadership in the country itself, though international partners and diplomatic missions can help to encourage and support this effort.

Critical to effective prevention is a well operating surveillance system. This is important so that the extent and trends of the epidemic can be monitored, prevention programs can be targeted and evaluated, priorities can be determined rationally, and the reality and extent of the epidemic can be acknowledged.

Sexual risk and transmission is addressed through behavior modification through the influence of culturally appropriate information and education, HIV counseling and testing, condom availability and social marketing, counseling and peer outreach to those at increased risk, and treatment of sexually transmitted infections. USAID and CDC, as well as other international agencies, provide technical assistance in these areas, but much more is needed. The cost of HIV

prevention is less expensive than treating the infection afterwards.

Prevention of mother-to-child transmission is now possible with the recent discoveries through the work of CDC and others that short-course administration of the antiretroviral drug AZT to pregnant women can provide a 50% reduction in transmission. Recent findings of an NIH-supported study of an even shorter and less expensive drug regimen -- one dose of the antiretroviral nevirapine to the mother in labor and one to the baby shortly thereafter -- offer even greater opportunities for reducing the likelihood of mother-~~infant~~-to-child transmission.~~prevention. Even with the cost of~~

HIV testing and counseling, -and ~~administration~~ the use of antiretroviral drugs for prevention, ~~such prevention is~~ are highly cost effective strategies. However, establishing prevention programs in settings where antenatal services may be weak is an operational challenge. In order to identify effective interventions, CDC is providing technical assistance to UNICEF pilot projects of mother-to-child HIV prevention in a number of sub-Saharan African countries.

Treating opportunistic infections of people living with AIDS~~patients~~, such as TB, is relatively inexpensive, dramatically lessens the impact of HIV and can improve quality of life. Approximately 2 billion people (one-third of the world's population) are infected with *Mycobacterium tuberculosis*, the cause of TB. TB is the cause of death for one out of every three people with AIDS worldwide. The high level of risk for dual HIV and TB infections underscores the critical need for targeted TB screening and preventive treatment programs for HIV-infected people and those at greatest risk for HIV infection. However, basic voluntary HIV counseling and testing services are generally not yet available for the tens of millions of persons living with HIV in Africa, who could benefit from these inexpensive and effective treatments.

Of course, o~~O~~ne of the most important prevention methods will be an effective vaccine. ~~Unfortunately, no vaccine is yet available.~~ A number of research groups are working on vaccine

development ~~including, prominently,~~ with the National Institutes of Health playing a leading role. Two field trials are currently underway, one of these in a developing country -- Thailand, and more are anticipated soon. Developing an effective and affordable vaccine is an extremely high priority for us and the entire Administration, but for the time being the other approaches to HIV prevention are all that we have. These approaches will remain essential even when a vaccine becomes available.

Antiretroviral therapies are a major piece of the prevention puzzle because they offer not only the possibility of prolonged life for ~~an~~ people living with HIV ~~infected~~ and AIDS ~~individual~~ but ~~because they~~ may also prevent mother-to-child HIV transmission and ~~may~~ reduce transmission of the virus from an infected person through sexual contact. However, as ~~I~~ previously mentioned, antiretoviral drugs are not widely available in developing countries, and their cost, unfortunately, competes for the limited resources available for other health services including HIV prevention.

[DO THE FOLLOWING CONCERNS RELATE TO PREVENTATIVE ANTIVIRAL THERAPIES (AZT AND NPV) OR TO HIGHLY-ACTIVE ANTIVIRAL COMBINATION THERAPY? SOME DISTINCTION SHOULD BE MADE.]

There are numerous current barriers to use of antiretroviral therapy of HIV/AIDS in developing countries, aside from the cost of the drugs themselves. These include lack of adequate health services and laboratory capability. Another serious consideration regarding extended therapy with antiretroviral drugs is that inappropriate treatment predisposes patients to development of drug resistant HIV. The appearance of drug resistance has already been found in Uganda after relatively few months of antiretroviral drug use. Since antiretroviral therapy is likely to be needed for a lifetime, the risk of developing of resistant HIV strains through inconsistent or partial treatment becomes a public health concern.

~~Antiretroviral therapy may become more affordable as partnerships are established among international agencies, governments and drug companies. Other cost reducing factors may include reduced drug dosages and reduction in drug prices.~~

In conclusion, ~~unless a consorted effort is undertaken to bring forth the political will, resources and expertise to implement effective prevention and treatment programs, the outlook for the global AIDS epidemic is bleak.~~ The situation is dire. AIDS is an epidemic of Biblical proportion, and has already caused untold pain and suffering. Yet there is hope. We can slow this epidemic as we work toward the development of a vaccine and a cure. That will require a response by the developing world that is of significantly higher magnitude than that currently underway.

The Administration's initiative announced last week by Vice President Gore is a welcome step. Through this effort, CDC will be able to increase its assistance to many of the public health experts in southern Africa in the areas of prevention and surveillance. We welcome and support this leadership, and hope that members of this Committee fully support the request for an additional $100 million called for by the Administration.

Those of us with experience working on public health issues in developing countries fully understand that there will be no simple solutions to the AIDS pandemic. While drug therapies will be critical for both prevention and care, much more will have to be done to enhance prevention initiatives and to support the development of basic health infrastructures.

We look forward to a full partnership with Congress in our efforts to end this terrible epidemic. Thank you for allowing me the opportunity to appear before this Subcommittee.

Statement of John Y. Killen, Jr., M.D.
Director

Division of AIDS
National Institute of Allergy and Infectious Diseases
National Institutes of Health

Before the
Committee on Government Reform
Subcommittee on Criminal Justice, Drug Policy and Human Resources

July 22, 1999

Mr. Chairman and Members of the Committee, I am pleased to appear before you today to discuss the human immunodeficiency virus (HIV) epidemic, recent developments in HIV research, and the many challenges that remain in the fight against HIV and the acquired immunodeficiency syndrome (AIDS).

The Scope of the Epidemic

AIDS was recognized eighteen years ago this summer, and continues to exact an enormous toll throughout the world, in both human and economic terms. In the United States, the rate of new HIV infections—approximately 40,000 per year—remains unacceptably high, despite an encouraging downturn in new AIDS cases and AIDS-related deaths.

In the developing world, the HIV/AIDS epidemic continues to accelerate, notably in sub-Saharan Africa, southeast Asia and on the Indian sub-continent. There are also signs of expanding epidemics in Russia and other New Independent States of the former Soviet Union. As of the end of 1998, more than 33 million people worldwide were living with HIV/AIDS, according to estimates by the Joint United Nations Programme on HIV/AIDS (UNAIDS). An estimated 5.8 million new HIV infections occurred worldwide during 1998—approximately 16,000 new infections each day. More than 95 percent of these new infections occurred in developing countries. Alarmingly, in 27 developing countries, HIV prevalence more than doubled between 1995 and 1997. In 1998, HIV/AIDS was the fourth leading cause of mortality worldwide, resulting in an estimated 2.3 million deaths.

Beyond the human tragedy of HIV/AIDS, the economic costs of the epidemic are staggering, posing a significant impediment to the growth and stability of many countries where the epidemic is decimating a limited pool of skilled workers and managers as well as young

people at the peak of their productive years. According to UNAIDS, life expectancy in the nine countries in Africa with the highest HIV prevalence rates will, for the first time in many years, decline an average of 17 years by 2015 due to HIV/AIDS.

Clearly, HIV remains one of the greatest threats to global health, and requires a sustained commitment by the various partners in AIDS research and prevention: U.S. and foreign government agencies, UNAIDS, non-governmental and philanthropic organizations, academia, industry, and the activist community.

Antiretroviral Therapies

As noted above, new AIDS diagnoses and deaths have dropped significantly in the United States in the past two years, and the same is true in other developed countries. These trends are probably due to several factors, particularly the increased use of potent, albeit expensive, combinations of HIV drugs. Sixteen antiretroviral drugs are now licensed in the United States, and several new agents are in various stages of clinical testing. Consensus guidelines have been developed for the use of anti-HIV medications that, when appropriately applied, have greatly improved the prognosis for HIV-infected individuals.

Unfortunately, many HIV-infected individuals have not responded adequately to the medications, cannot tolerate their toxicities, or have difficulty adhering to complex dosing schedules and substantial pill burdens. In addition, the ability of HIV to mutate and become resistant to the current drugs is a persistent threat. Although there is evidence of immune system reconstitution in certain patients who receive combination antiretroviral therapy, the goals of completely "rebuilding" the immune system or eradicating the virus from the body appear unlikely with current approaches to treatment.

For these reasons, the development of the next generation of therapies remains a priority. Currently, all licensed antiretroviral medications are directed at one of two viral enzymes, but many new strategies are being pursued, including drugs that prevent the virus from entering a cell and approaches to boosting an infected person's immune response.

HIV Prevention

In developing countries, where *per capita* health care spending may be only a few dollars per year, use of antiviral drugs is in most cases not a feasible option. These treatments are both costly and complex, and most developing nations lack the financial resources and the health

infrastructure necessary to support their use. Therefore, the identification of effective, low-cost tools for preventing HIV infection is crucial to slowing the epidemic.
~~In developing countries where *per capita* health care spending may be only a few dollars per year, use of antiretroviral drugs is largely out of the question, because combination therapy and attendant care may cost upwards of $15,000 per year. Therefore, the identification of effective, low-cost tools for preventing HIV infection is crucial to slowing the epidemic.~~

Researchers have shown that many scientifically proven approaches to HIV prevention can reduce the number of new infections, including: education and behavior modification, the social marketing and provision of condoms, needle exchange, treatment of other sexually transmitted diseases, and the use of antiretroviral drugs to prevent the transmission of virus from mother to infant.

Prevention of Mother-to-infant transmission

In early 1994, the NIH-funded clinical trial known as ACTG 076 showed that mother-to-infant transmission rates could be reduced by as much as two-thirds by treating HIV-infected pregnant women and their newborn babies with an intensive regimen of AZT (zidovudine). Unfortunately, cost and many logistical issues preclude the widespread application of the ACTG 076 regimen in the developing world.

To surmount these barriers, NIH and CDC-supported researchers have been collaborating with the health ministries and scientists of several developing countries on research to identify simpler, less costly ways to prevent mother-to-infant transmission of HIV.

Several recently reported studies, including two in Thailand and the Ivory Coast (both supported by the CDC), have shown that shorter regimens of AZT can also be beneficial, reducing transmission by between 37 and 51 percent. Despite these promising advances,

widespread implementation of these proven regimens in most developing countries has not occurred because of their expense and their dependence on an infrastructure of good prenatal care.

Last week NIAID reported on the exciting results of a study ~~in~~ conducted jointly with Ugandan scientists that could have profound implications for the epidemic in children worldwide. This study showed that just two doses of the antiretroviral drug nevirapine—one oral dose administered to the mother at the onset of labor and one to her baby shortly after birth—reduced the risk of maternal-infant transmission of HIV by nearly 50 percent when compared with a similar brief course of AZT. What makes this finding so significant for the worldwide epidemic is that nevirapine is extremely inexpensive and easy to administer; the regimen costs approximately $4 and is 70 times cheaper than the prveiously studied regimens of short course zidovudine, can be delivered orally, and does not require a chain of refrigeration.

Topical Microbicides

Other methods of preventing HIV transmission also may have an important impact on slowing the epidemic. For example, researchers are developing and testing topical microbicides, substances that a woman could use in her vagina before sex to prevent the transmission of HIV and other sexually transmitted diseases. These interventions may help empower women to protect themselves in situations where they are unable to avoid sex with partners who may be HIV-infected or to persuade their partners to use a condom. Several studies have been conducted or are underway in Africa using a variety of products.

HIV Vaccine Development

The development of a safe and effective vaccine for HIV infection remains the ultimate goal of AIDS research, and a key step toward bringing the HIV epidemic under control around the world. To hasten HIV vaccine discovery, many public and private agencies have dramatically increased the resources devoted to HIV vaccine research. For example, at the National Institutes of Health (NIH), HIV vaccine funding increased by 93 percent between FY 1995 and FY 1999. We estimate that approximately $200 million will be spent by the NIH in FY 2000 on HIV vaccine research.

As part of this expanded effort, NIH has awarded numerous grants to foster innovative research on HIV vaccines, and is invigorating and reorganizing its vaccine clinical trials effort. In addition, NIH has established the Dale and Betty Bumpers Vaccine Research Center within the NIH intramural research program to stimulate multidisciplinary vaccine research.

Since 1988 more than 3000 healthy volunteers have enrolled in 52 (50 phase I and two phase II) NIAID-supported studies involving 27 vaccines. Recent studies supported by the NIH in collaboration with several vaccine manufacturers have assessed so-called "vectored vaccines": harmless viruses (e.g. canarypox) that are genetically altered to make HIV proteins. Results have been encouraging: in phase I and phase II studies, this combination approach has appeared safe and evoked several types of immune responses that may have a role in protection from HIV.

Additional phase II trials of the combination vaccine concept will open later this year in Brazil, Haiti, and Trinidad and Tobago. These studies, as well as additional data that emerge from basic research, will provide the information to determine which products will advance into larger-scale testing. An exciting development for AIDS vaccine research was the initiation of the first AIDS vaccine study in Africa this spring. This NIH-supported phase I

study, which is being conducted in Uganda, is designed to help determine whether it will be possible to design vaccines that work against more than one strain of HIV.

Meanwhile, a large-scale study of a vaccine based on the surface proteins of two HIV strains was recently undertaken in the United States by a private company—VAXGEN. An additional phase III study is being conducted by VAXGEN in collaboration with the CDC in Thailand. NIH will collaborate with the company in evaluating the immunological responses to the vaccine.

Conclusion

Two years ago, President Clinton set a national goal of having a useful HIV vaccine within 10 years. We are well-positioned in our attempt to meet this goal with the extraordinary basic and applied research that is now under way. And just last week, Vice President Gore announced a new, multi-faceted initiative to address the AIDS crisis in Africa and other developing nations. NIH is a partner in this effort and is completely supportive of the initiative's plans to increase our prevention and infrastructure support efforts. As importantly, we support the call by the Vice President to other developed nations to join us in this effort for it is only by working together that we will have any chance of stopping this epidemic.

As we work to contain the global HIV/AIDS epidemic, it is essential that public and private sector partners and other members of the global community redouble their commitment to working together to speed HIV vaccine development, refine prevention efforts, and develop new treatments for those infected with the virus.

Thank you for your attention to this global crisis and for the opportunity to address this ~~subcommittee~~Subcommittee.

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Testimony of

Timothy Dondero, M.D.

Chief

International Activities Branch

Division of HIV/AIDS Prevention

National Center for HIV, STD, and TB Prevention

Centers for Disease Control and Prevention

Before the

U.S. House of Representatives

Committee on Government Reform

Subcommittee on Criminal Justice,

Drug Policy, and Human Resources

JULY 22, 1999

I am Dr. Timothy Dondero, Chief of the International Activities Branch, Division of HIV/AIDS Prevention of the National Center for HIV, STD, and TB Prevention at the Centers for Disease Control and Prevention (CDC). Thank you for the opportunity to testify today about the magnitude of the global HIV/AIDS epidemic and CDC's international HIV/AIDS activities.

I will provide an overview summarizing the magnitude of HIV/AIDS epidemic and the closely intertwined tuberculosis (TB) and sexually transmitted diseases (STDs) epidemics worldwide. I will also highlight a few of CDC's international activities and discuss prevention approaches to reduce the impact of HIV/AIDS globally.

Background: Magnitude of Global HIV/AIDS, STDs and TB Epidemics

The HIV/AIDS epidemic continues to progress. More than 33.4 million people are estimated to be infected with HIV worldwide. Nearly 16,000 new infections occur each day, over 600 new infections every hour. Ninety-five percent of HIV-infected people live in the developing world -- and 95% of the deaths caused by HIV have occurred in developing countries. Unlike in the United States, most infections in the developing world are transmitted through heterosexual intercourse; the second most common route of transmission is from infected mothers to their children. In some areas, especially in Asia and here in the United States, HIV transmission through injection drug use is ~~locally~~ important; but for the world as a whole, drug-related HIV is responsible for only a modest part of the epidemic.

The most heavily impacted area of the world is sub-Saharan Africa, with over two-thirds of the world's infections and nearly 85% of the world's AIDS deaths. The next most affected region is south Asia and southeast Asia, with nearly 10% of the world's infections. These areas, and especially sub-Saharan Africa, are still experiencing explosive HIV epidemics that are taking an

enormous toll in human life and having a profound economic and social impact.

Currently it is estimated that there are 22 million adults and 1 million children living with HIV infection in sub-Saharan Africa and over six million infected persons in Asia. By comparison, the U.S. has an estimated ~~three-quarters~~three-quarters of a million persons living with HIV infection. An estimated four million new infections occur in sub-Saharan Africa each year, over six million throughout the world. The number of people losing their lives to AIDS ~~death toll~~ is rapidly rising with an estimated 5,500 deaths from the disease occurring each day in Africa. Without rapid implementation of large scale effective interventions most, if not all, of these national epidemics will continue to grow. Apart from the devastating human tragedy, t~~T~~here are many potential national and international consequences to this critical situation, including effects on political ~~and~~, economic, and military ~~-~~stability ~~and other factors~~ that ~~could~~ will adversely affect U.S. national interests.

I would like to turn your attention to a figure that graphically illustrates the extremes to which the HIV epidemic has reached in the ~~populations of the~~ developing world. This figure shows the most recently available data (1996-98) for HIV infection in pregnant women from capital cities or major urban centers in Latin America, Asia, and Africa. HIV infection in pregnant women is a reasonable indicator of the levels in young adults in those countries generally and a direct indicator of the risk of mother to child infection.

COULD NOT SEE GRAPH

In the southern-most African countries, HIV has reached epidemic proportions only relatively recently. Botswana now has one of the highest documented rates of HIV infection in the world, with over 40% of ~~child~~ child-bearing women living in cities infected with HIV. Recent reports from four southern African countries, Botswana, Namibia, Swaziland, and Zimbabwe, indicate

that a fifth to a quarter of their entire adult populations aged 19-49 are now HIV-infected. The infection is wiping out recent gains in life expectancy. By the year 2010, for example, demographers project that life expectancy will have fallen from 66 to 33 years in Zambia and from 70 to 40 years in Zimbabwe.

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CDC's Role in International HIV Activities

CDC focuses its international efforts by offering assistance to countries with the greatest public health need; conducting collaborative research and training on preventive interventions; serving as partners in global initiatives; and responding to national U.S. interests. We apply U.S. scientific advances in other countries, such as rapid HIV testing, prevention of mother-to-infant HIV transmission, refinement and installation of HIV diagnostic and research techniques, assisting in technical aspects of HIV surveillance, testing and counseling, applications of simple prevention of opportunistic infections, computerization of prevention and service providing groups, and studying the interactions of HIV and TB. ~~Some~~ Many of these activities involve a partnership with NIH, USAID, UNAIDS, and other international organizations. We also apply lessons learned in other countries to domestic disease control efforts.

CDC has a strong international field station structure in Cote d'Ivoire, Uganda, Kenya, and Botswana in Africa and Thailand in Asia, as well as a long history of providing technical assistance to these and many other countries. In addition to these sites, we have resident advisors relating to HIV and its associated diseases stationed in several places, including India, Bolivia, Indonesia, Vietnam, South Africa, and Mali (a number of these through USAID), and offer many short-term consultations on issues including surveillance, epidemiological assistance, training,

program management, blood supply protection, laboratory capacity building, and -prevention efforts.

At the global level, CDC assists by enhancing the capacity of the UN agencies committed to combating the epidemic through making technical experts available to UNAIDS, UNICEF, and WHO on both a long-term and a short basis. CDC also collaborates extensively with the US Agency for International Development (USAID), the World Health Organization (WHO), the Joint UN Programme on HIV/AIDS (UNAIDS), the United Nations Children's Fund (UNICEF) and the World Bank, as well as ministries of health around the world to provide both long and short term technical assistance and expertise.

Approach to the Epidemic: Prevention

One of the most critical needs in effective HIV/AIDS prevention is political will and political leadership within the country addressing, acknowledging, and focusing resources on HIV/AIDS prevention and control efforts. This key element of effective prevention can be provided only by the leadership in the country itself, though international partners and diplomatic missions can help to encourage and support this effort.

Critical to effective prevention is a well operating surveillance system. This is important so that the extent and trends of the epidemic can be monitored, prevention programs can be targeted and evaluated, priorities can be determined rationally, and the reality and extent of the epidemic can be acknowledged.

Sexual risk and transmission is addressed through behavior modification through the influence of culturally appropriate information and education, HIV counseling and testing, condom availability and social marketing, counseling and peer outreach to those at increased risk, and treatment of sexually transmitted infections. USAID and CDC, as well as other international agencies, provide technical assistance in these areas, but much more is needed. The cost of HIV

prevention is less expensive than treating the infection afterwards.

Prevention of mother-to-child transmission is now possible with the recent discoveries through the work of CDC and others that short-course administration of the antiretroviral drug AZT to pregnant women can provide a 50% reduction in transmission. Recent findings of an NIH-supported study of an even shorter and less expensive drug regimen -- one dose of the antiretroviral nevirapine to the mother in labor and one to the baby shortly thereafter -- offer even greater opportunities for reducing the likelihood of mother-~~infant~~-to-child transmission.~~prevention. Even with the cost of~~

HIV testing and counseling, -and ~~administration~~ the use of antiretroviral drugs for prevention, ~~such prevention is~~ are highly cost effective strategies. However, establishing prevention programs in settings where antenatal services may be weak is an operational challenge. In order to identify effective interventions, CDC is providing technical assistance to UNICEF pilot projects of mother-to-child HIV prevention in a number of sub-Saharan African countries.

Treating opportunistic infections of people living with AIDS ~~patients~~, such as TB, is relatively inexpensive, dramatically lessens the impact of HIV and can improve quality of life. Approximately 2 billion people (one-third of the world's population) are infected with *Mycobacterium tuberculosis*, the cause of TB. TB is the cause of death for one out of every three people with AIDS worldwide. The high level of risk for dual HIV and TB infections underscores the critical need for targeted TB screening and preventive treatment programs for HIV-infected people and those at greatest risk for HIV infection. However, basic voluntary HIV counseling and testing services are generally not yet available for the tens of millions of persons living with HIV in Africa, who could benefit from these inexpensive and effective treatments.

Of course, o~~O~~ne of the most important prevention methods will be an effective vaccine. ~~Unfortunately, no vaccine is yet available.~~ A number of research groups are working on vaccine

development ~~including, prominently,~~ with the National Institutes of Health playing a leading role. Two field trials are currently underway, one of these in a developing country -- Thailand, and more are anticipated soon. Developing an effective and affordable vaccine is an extremely high priority for us and the entire Administration, but for the time being the other approaches to HIV prevention are all that we have. These approaches will remain essential even when a vaccine becomes available.

Antiretroviral therapies are a major piece of the prevention puzzle because they offer not only the possibility of prolonged life for ~~an~~ people living with HIV ~~infected~~ and AIDS ~~individual~~ but ~~because they~~ may also prevent mother-to-child HIV transmission and ~~may~~ reduce transmission of the virus from an infected person through sexual contact. However, as ~~I~~ previously mentioned, antiretoviral drugs are not widely available in developing countries, and their cost, unfortunately, competes for the limited resources available for other health services including HIV prevention.

[DO THE FOLLOWING CONCERNS RELATE TO PREVENTATIVE ANTIVIRAL THERAPIES (AZT AND NPV) OR TO HIGHLY-ACTIVE ANTIVIRAL COMBINATION THERAPY? SOME DISTINCTION SHOULD BE MADE.]

There are numerous current barriers to use of antiretroviral therapy of HIV/AIDS in developing countries, aside from the cost of the drugs themselves. These include lack of adequate health services and laboratory capability. Another serious consideration regarding extended therapy with antiretroviral drugs is that inappropriate treatment predisposes patients to development of drug resistant HIV. The appearance of drug resistance has already been found in Uganda after relatively few months of antiretroviral drug use. Since antiretroviral therapy is likely to be needed for a lifetime, the risk of developing of resistant HIV strains through inconsistent or partial treatment becomes a public health concern.

~~Antiretroviral therapy may become more affordable as partnerships are established among international agencies, governments and drug companies. Other cost reducing factors may include reduced drug dosages and reduction in drug prices.~~

In conclusion, ~~unless a consorted effort is undertaken to bring forth the political will, resources and expertise to implement effective prevention and treatment programs, the outlook for the global AIDS epidemic is bleak.~~ The situation is dire. AIDS is an epidemic of Biblical proportion, and has already caused untold pain and suffering. Yet there is hope. We can slow this epidemic as we work toward the development of a vaccine and a cure. That will require a response by the developing world that is of significantly higher magnitude than that currently underway.

The Administration's initiative announced last week by Vice President Gore is a welcome step. Through this effort, CDC will be able to increase its assistance to many of the public health experts in southern Africa in the areas of prevention and surveillance. We welcome and support this leadership, and hope that members of this Committee fully support the request for an additional $100 million called for by the Administration.

Those of us with experience working on public health issues in developing countries fully understand that there will be no simple solutions to the AIDS pandemic. While drug therapies will be critical for both prevention and care, much more will have to be done to enhance prevention initiatives and to support the development of basic health infrastructures.

We look forward to a full partnership with Congress in our efforts to end this terrible epidemic. Thank you for allowing me the opportunity to appear before this Subcommittee.

FINAL VOTE RESULTS FOR ROLL CALL 322

(Republicans in roman; Democrats in *italic*; Independents underlined)

H R 2415 RECORDED VOTE 21-JUL-1999 12:47 PM
AUTHOR(S): Sanders of Vermont Amendment
QUESTION: On Agreeing to the Amendment

	AYES	NOES	PRES	NV
REPUBLICAN	19	197		5
DEMOCRATIC	97	110		4
INDEPENDENT	1			
TOTALS	**117**	**307**		**9**

--- AYES 117 ---

bPs voted NO 1

Abercrombie	*Gutierrez*	*Rivers*
Allen	*Hall (OH)*	Rohrabacher
Bachus	*Hastings (FL)*	Ros-Lehtinen
Baird	Hayworth	*Roybal-Allard*
Baldacci	*Hilliard*	*Rush*
Baldwin	*Hinojosa*	*Sabo*
Barrett (WI)	*Jackson (IL)*	Sanders
Bartlett	*Johnson, E. B.*	Sanford
Becerra	*Jones (OH)*	Scarborough
Berry	*Kaptur*	*Schakowsky*
Blagojevich	*Kildee*	*Scott*
Bonior	*Kilpatrick*	*Serrano*
Brady (PA)	*Kucinich*	Shays
Brown (FL)	*Lantos*	Shimkus
Brown (OH)	*Lee*	*Shows*
Campbell	*Lewis (GA)*	*Slaughter*
Capuano	*Luther*	Smith (NJ)
Carson	*Maloney (NY)*	*Snyder*
Castle	*Markey*	*Stabenow*
Clay	*McGovern*	*Stark*
Clyburn	*McKinney*	*Strickland*
Coburn	*McNulty*	*Taylor (MS)*
Condit	*Meehan*	*Thompson (CA)*
Conyers	*Meek (FL)*	*Thompson (MS)*
Cox	*Meeks (NY)*	*Tierney*
Cummings	*Miller, George*	*Towns*
Davis (IL)	*Mink*	*Udall (NM)*
DeFazio	*Moakley*	*Velazquez*
Delahunt	*Nadler*	*Vento*

Delahunt	*Nadler*	*Vento*
DeLauro	*Neal*	Wamp
Dixon	*Oberstar*	*Waters*
Duncan	*Obey*	*Waxman*
Emerson	*Olver*	*Weiner*
Evans	*Owens*	Weldon (FL)
Farr	Paul	*Wexler*
Fattah	*Payne*	*Weygand*
Filner	*Pelosi*	*Woolsey*
Frank (MA)	*Peterson (MN)*	*Wu*
Green (TX)	*Rangel*	*Wynn*

--- NOES 307 ---

Ackerman	Gilman	Ney
Aderholt	*Gonzalez*	Northup
Andrews	*Goode*	Norwood
Archer	Goodlatte	Nussle
Armey	Goodling	*Ortiz*
Baker	*Gordon*	Ose
Ballenger	Goss	Oxley
Barcia	Graham	Packard
Barr	Granger	*Pallone*
Barrett (NE)	Green (WI)	*Pascrell*
Barton	Greenwood	*Pastor*
Bass	Gutknecht	Pease
Bateman	*Hall (TX)*	Petri
Bentsen	Hansen	*Phelps*
Bereuter	Hastings (WA)	Pickering
Berkley	Hayes	*Pickett*
Berman	Hefley	Pitts
Biggert	Herger	Pombo
Bilbray	*Hill (IN)*	*Pomeroy*
Bilirakis	Hill (MT)	Porter
Bishop	Hilleary	Portman
Bliley	Hobson	*Price (NC)*
Blumenauer	*Hoeffel*	Pryce (OH)
Blunt	Hoekstra	Quinn
Boehlert	*Holden*	Radanovich
Boehner	*Holt*	*Rahall*
Bonilla	*Hooley*	Ramstad
Bono	Horn	Regula

Borski	Hostettler	*Reyes*
Boswell	Houghton	Reynolds
Boucher	*Hoyer*	Riley
Boyd	Hulshof	*Rodriguez*
Brady (TX)	Hunter	*Roemer*
Bryant	Hutchinson	Rogan
Burr	Hyde	Rogers
Burton	*Inslee*	*Rothman*
Buyer	Isakson	Roukema
Callahan	Istook	Royce
Calvert	*Jackson-Lee (TX)*	Ryan (WI)
Camp	*Jefferson*	Ryun (KS)
Canady	Jenkins	Salmon
Cannon	*John*	*Sanchez*
Capps	Johnson (CT)	*Sandlin*
Cardin	Johnson, Sam	*Sawyer*
Chabot	Jones (NC)	Saxton
Chambliss	*Kanjorski*	Schaffer
Clayton	Kasich	Sensenbrenner
Clement	Kelly	Sessions
Coble	*Kind (WI)*	Shadegg
Collins	King (NY)	Shaw
Combest	Kingston	*Sherman*
Cook	*Kleczka*	Sherwood
Cooksey	*Klink*	Shuster
Costello	Knollenberg	Simpson
Coyne	Kolbe	*Sisisky*
Cramer	Kuykendall	Skeen
Crane	*LaFalce*	*Skelton*
Crowley	LaHood	Smith (MI)
Cubin	*Lampson*	Smith (TX)
Cunningham	Largent	*Smith (WA)*
Danner	*Larson*	Souder
Davis (FL)	Latham	Spence
Davis (VA)	LaTourette	*Spratt*
Deal	Lazio	Stearns
DeGette	Leach	*Stenholm*
DeLay	*Levin*	Stump
DeMint	Lewis (KY)	*Stupak*
Deutsch	Linder	Sununu
Diaz-Balart	*Lipinski*	Sweeney
Dickey	LoBiondo	Tancredo

Dingell	*Lofgren*	*Tanner*
Doggett	*Lowey*	*Tauscher*
Dooley	*Lucas (KY)*	Tauzin
Doolittle	Lucas (OK)	Taylor (NC)
Doyle	*Maloney (CT)*	Terry
Dreier	Manzullo	Thomas
Dunn	*Martinez*	Thornberry
Edwards	*Mascara*	Thune
Ehlers	*Matsui*	*Thurman*
Ehrlich	*McCarthy (MO)*	Tiahrt
Engel	*McCarthy (NY)*	Toomey
English	McCollum	*Traficant*
Eshoo	McCrery	*Turner*
Etheridge	McHugh	*Udall (CO)*
Everett	McInnis	Upton
Ewing	McIntosh	*Visclosky*
Fletcher	*McIntyre*	Vitter
Foley	McKeon	Walden
Forbes	*Menendez*	Walsh
Ford	Metcalf	Watkins
Fossella	*Millender-McDonald*	*Watt (NC)*
Fowler	Miller (FL)	Watts (OK)
Franks (NJ)	Miller, Gary	Weldon (PA)
Frelinghuysen	*Minge*	Weller
Frost	*Mollohan*	Whitfield
Gallegly	*Moore*	Wicker
Ganske	Moran (KS)	Wilson
Gejdenson	*Moran (VA)*	*Wise*
Gekas	Morella	Wolf
Gephardt	*Murtha*	Young (AK)
Gibbons	Myrick	Young (FL)
Gilchrest	*Napolitano*	
Gillmor	Nethercutt	

--- NOT VOTING 9 ---

Chenoweth	*Kennedy*	Mica
Dicks	Lewis (CA)	Peterson (PA)
Hinchey	*McDermott*	Talent

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ONE HUNDRED SIXTH CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON GOVERNMENT REFORM

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BERNARD SANDERS, VERMONT,
INDEPENDENT

The Subcommittee on Criminal Justice, Human Resources and Drug Policy

HEARING ON

"What is the United States' Role in Combating the Global HIV/AIDS Epidemic?"

Thursday, July 22, 1999, 11:30 a.m.,
Room 2154 Rayburn House Office Building

WITNESS LIST

PANEL ONE

The Honorable Marion Berry (D-AR)
United States Representative

The Honorable Jesse Jackson, Jr. (D-IL)
United States Representative

Ms. Chatinka Nkhoma
Malawi Citizen

PANEL TWO

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

Mr. Joseph Papovich
Assistant U.S. Trade Representative
Services, Investment & Intellectual Property
United States Trade Representative

Dr. John Killen
Director, Division of AIDS
National Institute of Allergy and Infectious Diseases
National Institute of Health

Dr. Timothy Dondero
Chief of the International Activities Branch
Division of HIV/AIDS Prevention
Center for Disease Control and Prevention

PANEL THREE

Dr. Allen Herman
Dean of Public Health
Medical University of Southern Africa

Mr. James Love
Director
Consumer Project on Technology

Dr. Peter Lurie
Medical Director
Public Citizen's Health Research Group

Mr. Eric Sawyer
Executive Director of HIV Human Rights Project
ACT UP New York

Dr. John Siegfried
Senior Medical Officer
Pharmaceutical Research and Manufacturers of America

Paul Thornell@OVP 07/19/99 06:02:06 PM

Record Type: Record

To: See the distribution list at the bottom of this message

cc:

Subject: AIDS Hearing Witnesses

The following people are invited to testify at the House hearing on the U.S. Role in the AIDS Epidemic. There may be one or two others.

Rep. Jesse Jackson, Jr.
Rep. Marion Berry
Eric Sawyer, HIV/Human Rights
Jamie Love, Act-Up
Alan Herman, Medical University of South Africa
Sandy Thurman
Charlene Barshefsky

Message Sent To:

Ron Klain/OVP@OVP
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Kay Casstevens/OVP@OVP
Thomas M. Rosshirt/OVP@OVP
Sarah A. Bianchi/OVP@OVP
Sandra Thurman/OPD/EOP@EOP

Paul Thornell@OVP 07/19/99 06:02:06 PM

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Statement of John Y. Killen, Jr., M.D.
Director

Division of AIDS
National Institute of Allergy and Infectious Diseases
National Institutes of Health

Before the
Committee on Government Reform
Subcommittee on Criminal Justice, Drug Policy and Human Resources

July 22, 1999

Mr. Chairman and Members of the Committee, I am pleased to appear before you today to discuss the human immunodeficiency virus (HIV) epidemic, recent developments in HIV research, and the many challenges that remain in the fight against HIV and the acquired immunodeficiency syndrome (AIDS).

The Scope of the Epidemic

AIDS was recognized eighteen years ago this summer, and continues to exact an enormous toll throughout the world, in both human and economic terms. In the United States, the rate of new HIV infections—approximately 40,000 per year—remains unacceptably high, despite an encouraging downturn in new AIDS cases and AIDS-related deaths.

In the developing world, the HIV/AIDS epidemic continues to accelerate, notably in sub-Saharan Africa, southeast Asia and on the Indian sub-continent. There are also signs of expanding epidemics in Russia and other New Independent States of the former Soviet Union. As of the end of 1998, more than 33 million people worldwide were living with HIV/AIDS, according to estimates by the Joint United Nations Programme on HIV/AIDS (UNAIDS). An estimated 5.8 million new HIV infections occurred worldwide during 1998—approximately 16,000 new infections each day. More than 95 percent of these new infections occurred in developing countries. Alarmingly, in 27 developing countries, HIV prevalence more than doubled between 1995 and 1997. In 1998, HIV/AIDS was the fourth leading cause of mortality worldwide, resulting in an estimated 2.3 million deaths.

Beyond the human tragedy of HIV/AIDS, the economic costs of the epidemic are staggering, posing a significant impediment to the growth and stability of many countries where the epidemic is decimating a limited pool of skilled workers and managers as well as young

people at the peak of their productive years. According to UNAIDS, life expectancy in the nine countries in Africa with the highest HIV prevalence rates will, for the first time in many years, decline an average of 17 years by 2015 due to HIV/AIDS.

Clearly, HIV remains one of the greatest threats to global health, and requires a sustained commitment by the various partners in AIDS research and prevention: U.S. and foreign government agencies, UNAIDS, non-governmental and philanthropic organizations, academia, industry, and the activist community.

Antiretroviral Therapies

As noted above, new AIDS diagnoses and deaths have dropped significantly in the United States in the past two years, and the same is true in other developed countries. These trends are probably due to several factors, particularly the increased use of potent, albeit expensive, combinations of HIV drugs. Sixteen antiretroviral drugs are now licensed in the United States, and several new agents are in various stages of clinical testing. Consensus guidelines have been developed for the use of anti-HIV medications that, when appropriately applied, have greatly improved the prognosis for HIV-infected individuals.

Unfortunately, many HIV-infected individuals have not responded adequately to the medications, cannot tolerate their toxicities, or have difficulty adhering to complex dosing schedules and substantial pill burdens. In addition, the ability of HIV to mutate and become resistant to the current drugs is a persistent threat. Although there is evidence of immune system reconstitution in certain patients who receive combination antiretroviral therapy, the goals of completely "rebuilding" the immune system or eradicating the virus from the body appear unlikely with current approaches to treatment.

For these reasons, the development of the next generation of therapies remains a priority. Currently, all licensed antiretroviral medications are directed at one of two viral enzymes, but many new strategies are being pursued, including drugs that prevent the virus from entering a cell and approaches to boosting an infected person's immune response.

HIV Prevention

In developing countries, where *per capita* health care spending may be only a few dollars per year, use of antiviral drugs is in most cases not a feasible option. These treatments are both costly and complex, and most developing nations lack the financial resources and the health

infrastructure necessary to support their use. Therefore, the identification of effective, low-cost tools for preventing HIV infection is crucial to slowing the epidemic.
~~In developing countries where *per capita* health care spending may be only a few dollars per year, use of antiretroviral drugs is largely out of the question, because combination therapy and attendant care may cost upwards of $15,000 per year. Therefore, the identification of effective, low-cost tools for preventing HIV infection is crucial to slowing the epidemic.~~

Researchers have shown that many scientifically proven approaches to HIV prevention can reduce the number of new infections, including: education and behavior modification, the social marketing and provision of condoms, needle exchange, treatment of other sexually transmitted diseases, and the use of antiretroviral drugs to prevent the transmission of virus from mother to infant.

Prevention of Mother-to-infant transmission

In early 1994, the NIH-funded clinical trial known as ACTG 076 showed that mother-to-infant transmission rates could be reduced by as much as two-thirds by treating HIV-infected pregnant women and their newborn babies with an intensive regimen of AZT (zidovudine). Unfortunately, cost and many logistical issues preclude the widespread application of the ACTG 076 regimen in the developing world.

To surmount these barriers, NIH and CDC-supported researchers have been collaborating with the health ministries and scientists of several developing countries on research to identify simpler, less costly ways to prevent mother-to-infant transmission of HIV.

Several recently reported studies, including two in Thailand and the Ivory Coast (both supported by the CDC), have shown that shorter regimens of AZT can also be beneficial, reducing transmission by between 37 and 51 percent. Despite these promising advances,

widespread implementation of these proven regimens in most developing countries has not occurred because of their expense and their dependence on an infrastructure of good prenatal care.

Last week NIAID reported on the exciting results of a study ~~in~~ conducted jointly with Ugandan scientists that could have profound implications for the epidemic in children worldwide. This study showed that just two doses of the antiretroviral drug nevirapine—one oral dose administered to the mother at the onset of labor and one to her baby shortly after birth—reduced the risk of maternal-infant transmission of HIV by nearly 50 percent when compared with a similar brief course of AZT. What makes this finding so significant for the worldwide epidemic is that nevirapine is extremely inexpensive and easy to administer; the regimen costs approximately $4 and is 70 times cheaper than the prveiously studied regimens of short course zidovudine, can be delivered orally, and does not require a chain of refrigeration.

Topical Microbicides

Other methods of preventing HIV transmission also may have an important impact on slowing the epidemic. For example, researchers are developing and testing topical microbicides, substances that a woman could use in her vagina before sex to prevent the transmission of HIV and other sexually transmitted diseases. These interventions may help empower women to protect themselves in situations where they are unable to avoid sex with partners who may be HIV-infected or to persuade their partners to use a condom. Several studies have been conducted or are underway in Africa using a variety of products.

HIV Vaccine Development

The development of a safe and effective vaccine for HIV infection remains the ultimate goal of AIDS research, and a key step toward bringing the HIV epidemic under control around the world. To hasten HIV vaccine discovery, many public and private agencies have dramatically increased the resources devoted to HIV vaccine research. For example, at the National Institutes of Health (NIH), HIV vaccine funding increased by 93 percent between FY 1995 and FY 1999. We estimate that approximately $200 million will be spent by the NIH in FY 2000 on HIV vaccine research.

As part of this expanded effort, NIH has awarded numerous grants to foster innovative research on HIV vaccines, and is invigorating and reorganizing its vaccine clinical trials effort. In addition, NIH has established the Dale and Betty Bumpers Vaccine Research Center within the NIH intramural research program to stimulate multidisciplinary vaccine research.

Since 1988 more than 3000 healthy volunteers have enrolled in 52 (50 phase I and two phase II) NIAID-supported studies involving 27 vaccines. Recent studies supported by the NIH in collaboration with several vaccine manufacturers have assessed so-called "vectored vaccines": harmless viruses (e.g. canarypox) that are genetically altered to make HIV proteins. Results have been encouraging: in phase I and phase II studies, this combination approach has appeared safe and evoked several types of immune responses that may have a role in protection from HIV.

Additional phase II trials of the combination vaccine concept will open later this year in Brazil, Haiti, and Trinidad and Tobago. These studies, as well as additional data that emerge from basic research, will provide the information to determine which products will advance into larger-scale testing. An exciting development for AIDS vaccine research was the initiation of the first AIDS vaccine study in Africa this spring. This NIH-supported phase I

study, which is being conducted in Uganda, is designed to help determine whether it will be possible to design vaccines that work against more than one strain of HIV.

Meanwhile, a large-scale study of a vaccine based on the surface proteins of two HIV strains was recently undertaken in the United States by a private company—VAXGEN. An additional phase III study is being conducted by VAXGEN in collaboration with the CDC in Thailand. NIH will collaborate with the company in evaluating the immunological responses to the vaccine.

Conclusion

Two years ago, President Clinton set a national goal of having a useful HIV vaccine within 10 years. We are well-positioned in our attempt to meet this goal with the extraordinary basic and applied research that is now under way. As we work to contain the global HIV/AIDS epidemic, it is essential that public and private sector partners redouble their commitment to working together to speed HIV vaccine development, refine prevention efforts, and develop new treatments for those infected with the virus. Thank you for the opportunity to address this subcommittee.

Paul Thornell@OVP 07/20/99 10:17:15 AM

Record Type: Record

To: See the distribution list at the bottom of this message

cc: Ron Klain/OVP@OVP, Melissa B. Ratcliff/OVP@OVP, David W. Beier/OVP@OVP, David R Thomas/OVP@OVP

Subject: AIDS Hearing - PLEASE READ

I have been in contact with Rep. Patsy Mink's staff who covers subcmte. matters for her and tentatively set up a meeting time with him when we could brief other Dem. staff, Weds. at 10:00am on the Hill. In addition, Rep. Tom Lantos, a member of the full committee, has committed to attending the hearing and do whatever is necessary for the VP at the hearing. I have also spoken with Reps. Elijah Cummings, Danny Davis, Eleanor Holmes Norton, and Harold Ford who are on the committee and some other CBC Members at the AIDS event yesterday. They are ready to be supportive, but they need a briefing. In addition, as Rep. Jesse Jackson is testifying (not sure of his approach), we should figure out how to engage him.

Seeing as we need to put our heads together before we take our message to these offices, I would like to try to get everyone together, at least on the phone to discuss things before tomorrow. If this sounds fine, can we aim to meet at 4:00 today somewhere in OEOB?

Message Sent To:

Thomas M. Rosshirt/OVP@OVP
Laura M. Quinn/OVP@OVP
Sarah A. Bianchi/OVP@OVP
Kay Casstevens/OVP@OVP
Sandra Thurman/OPD/EOP@EOP
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Paul Thornell@OVP 07/19/99 11:27:28 AM

Record Type: Record

To: Ron Klain/OVP@OVP, Kay Casstevens/OVP@OVP, Sandra Thurman/OPD/EOP@EOP, Sarah A. Bianchi/OVP@OVP

cc: See the distribution list at the bottom of this message
Subject: Re: House Hearing on AIDS Issue

The Democrats on the subcmte. are: Reps. Patsy Mink (Ranking Democrat); Ed Towns (CBC); Elijah Cummings (CBC); Dennis Kucinich; Rod Blagojevich; John Tierney; and Jim Turner. Charlene Barshefsky is scheduled to testify.

Reps. Tom Lantos, Eleanor Holmes Norton, Carolyn Maloney, Danny Davis and Harold Ford are among the Members on the full committee who are friends. I have spoken with Cummings, Lantos and Ford's office about the hearing to be sure it is on their bosses' schedules. I will call around to other D's on the subcmte to give them a heads-up also. I would like to arrange a briefing on the Hill for the staff of these offices with the relevant players from our end to get them the best info and message points. While all these Members have seen the news hits on this issue, I'm not confident they know our story, so we should do some proactive hand-holding.

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Ron Klain@OVP
07/19/99 10:09:17 AM

Record Type: Record

To: Paul Thornell/OVP@OVP

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Subject: Re: House Hearing on AIDS Issue

Laura: I really want to think about how we kill them on this: work with Stacie on surrogates. People have been dying from AIDS for a decade or more, and the House GOP only gets into the act once they think they can score a political point at Al Gore's expense. The only thing the press hates more than our (Gore) indifference is their (GOP) hypocrisy. Let's use this as a chance to paint that red hot.

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