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The Subcommittee on Criminal Justice, Drug Policy & Human Resources

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
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PANEL THREE

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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

ONE HUNDRED SIXTH CONGRESS

Congress of the United States

House of Representatives

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OPENING STATEMENT

Chairman John L. Mica

July 22, 1999

Today, this Subcommittee will address an issue that is unequalled in its complexity and its urgency. It is the issue of the global HIV / AIDS epidemic and the role of the United States in combating this terrible affliction. This growing problem is both a trade issue, a health issue and certainly a humanitarian issue that we cannot ignore.

Our Subcommittee, recently reconstituted and vested with oversight of health and trade issues, is committed to understanding the nature and magnitude of this epidemic, and to ensuring a proper role by the United States in combating the disease. Recently, we held a hearing on another terrible infectious disease - Hepatitis B - and the importance of vaccines and properly designed vaccination policies in combating infections and meeting the health needs of our citizens. Today, and in the future, this Subcommittee will perform its oversight responsibility of examining health-related programs and practices that are promising and that will save lives.

As we will hear today, the AIDS epidemic is global and horrific, and it continues to spread across the world unabated. We will learn that no area of the world has been hit harder than the continent of Africa, particularly sub-Saharan Africa, where two-thirds of the worlds' infected population resides. Other continents and regions also are at risk. Witnesses will tell us first-hand of the devastating impacts of the epidemic in Africa, including economic, health and humanitarian consequences. They will reveal some of the terrible consequences to themselves and their loved ones.

We will hear about recent developments in vaccine research and its hopefully not-so-distant potential for preventing the spread and transmission of HIV / AIDS. Recent studies show that women are now being infected at a greater rate than men. I am encouraged by recent press accounts that a new, more affordable drug is being developed which may significantly reduce the incidence of AIDS transmission from an infected mother to her unborn child. But a question still remains: What are we doing to make sure these new drugs get to the developing countries that need them? Tragically there are nearly 600,000 new infections each year among African babies. Nine of every 10 infants infected with HIV at birth or through breastfeeding live in sub-Saharan Africa.

This hearing also will focus on the critical and complicated issue of drug treatment for HIV /AIDS. How can we treat such a large and growing population?

The World Health Organization and affiliated organizations recently announced that AIDS kills more people worldwide than any infectious disease. Imagine, in less than two decades, AIDS has become the leading killer of all infectious diseases.

As you can see on the chart we have prepared, more than 33.4 million adults and children are estimated to be infected with HIV / AIDS. This disease has already killed 14 million people, approximately 12 million in Africa. Today, more than 22.5 million Africans are living with HIV / AIDS. Reportedly, 95% of Africans with AIDS have not been tested, and 90% are unaware that they have the disease.

The tragedy resulting from this killer disease in Africa is almost inconceivable. Zambia, for instance, has one of Africa's largest orphan populations. In 1990, it was home to approximately 20,000 orphans. By next year, the number will reach an estimated 500,000.

Zimbabwe, a nation of 12 million citizens, reports 600,000 orphans, with most being supported by grandparents or other relatives.

Uganda, with a population of 20 million and a population that is 10% HIV positive, also reports 600,000 children having lost at least one parent, and about 250,000 children having lost both parents.

Today, we will hear the testimony of a mother from the African nation of Malawi, where reportedly 20% of the population is HIV positive and life expectancy has dropped below 40 years of age.

These numbers are staggering and the personal tragedies are unimaginable. AIDS now infects 6 million people annually around the world, and the number continues to climb.

This nation, which leads the world in science and technology, as well as world trade, must address two important questions: (1) What are we doing about this global epidemic? (2) What should we do about it?

First, <u>what actions are we now taking</u> to combat the international spread of this disease? From all appearances, not nearly enough. The administration's AIDS czar has acknowledged that the epidemic has been met with indifference by Americans and their government. We cannot afford to let this indifference continue. I am heartened to learn that some in the administration are now speaking out on the issue, even though our trade policies to date have been unclear and contradictory.

Should we, through the Office of the U.S. Trade Representative, apply economic pressures or withhold assistance to nations such as South Africa, when that nation attempts to engage in self-help to combat its national health emergency? Can we identify better approaches to expanding HIV / AIDS prevention and treatment in developing nations, than imposing rigid licensing and import practices? Is it necessary for AIDS stricken developing nations to rely upon periodic pronouncements of intentions to provide limited foreign aid from the United States?
Can nations in need and the pharmaceutical industry negotiate a solution that meets the growing health and humanitarian needs, while ensuring that a reasonable profit to support future drug development?

Again, these are the pressing questions that this nation must address as the world's foremost economic power and a world leader in science and technology.

The second question is what should we do about this global epidemic? In answering this question, let me share with you one description of the crisis and possible response that was highlighted recently on a national television news segment. [Show ABC News video tape; July 8, 1999]

While I admit that this news video is short and perhaps superficial, it does illustrate the tragedy of the epidemic and presents a possible health dilemma: does drug treatment delivery in developing countries pose significant risks of new strains of AIDS? I hope that we will learn more about this issue today. I am not convinced that we do nothing to help these nations, and that there is no recourse but to watch millions of people die without treatment.

Here in the United States, while AIDS continues to spread, our AIDS deaths recently dropped by 47%, primarily due to new drug treatments that prolong lives and allow people to remain productive. I hope that we can do more for other nations and our trading partners in need. It is clear that many developing nations cannot progress economically until solutions to this crisis are found.

In a recent survey of American citizens, almost 90% of those surveyed nationwide say that it is safest and cheapest to fight infectious diseases at their source, which is most often in the developing world. In fact, today we will hear from a witness who is in this country because she cannot acquire the drug treatment she needs in her native Africa. The survey also found that more than 80% of Americans see AIDS as a bigger problem today than 10 years ago, despite treatment advances.

The United States plays a vital role in the global economy, and we remain a nation at risk. Recent data indicates that the infection rate among American women is increasing more rapidly than among males, and that African-Americans are at least six times more likely to contract HIV / AIDS than others.

These are some of the reasons that the solution to combating the global HIV/AIDS epidemic is complex and will not be achieved as quickly as we all hope. Yet I am convinced that, through a better understanding of this international health crisis, we can improve our treatment and prevention efforts both domestically and internationally.

It is imperative that vaccine research proceeds expeditiously. We also should assist, not hinder, developing nations and trading partners in their treatment efforts. I cannot fathom that we simply wait while the epidemic reaches multiples of the 14 million AIDS casualties who already have died. The millions of infected babies, the millions of orphaned children, the millions of new infections each year, and the millions of deaths that will occur internationally without treatment, are simply unacceptable. This crisis demands immediate attention by our government, and more than a "Band-Aid" approach.

Today, it is my hope that as we learn more about this crisis, we can begin to formulate a more effective response. It confounds me that we dedicate substantial government resources to learn whether global warming exists, while tens of millions are facing certain death from an immediate and growing crisis where real science and can save lives.

I look forward to the testimony of our witnesses on the greatest health threat facing the world in many centuries, and the role this nation should assume in combating it. I wish to thank my colleagues in Congress for sharing their ideas with this Subcommittee on this topic. I also want to commend those witnesses with this disease who have the courage to discuss publicly this most sensitive and pressing health issue.

Finally, I believe we have a moral and humanitarian responsibility to publicly air this incredible human tragedy and our response both as Congress and a civilized nation.

Years from now and millions of deaths later we must not be accused of turning our backs on this great holocaust of disease.

STATEMENT OF CONGRESSMAN HENRY A. WAXMAN
GOVERNMENT REFORM SUBCOMMITTEE ON CRIMINAL
JUSTICE, DRUG POLICY & HUMAN RESOURCES
HEARING ON THE U.S. ROLE IN COMBATTING THE GLOBAL HIV/AIDS EPIDEMIC

THURSDAY, JUNE 21, 1999
2154 RAYBURN HOB

Mr. Chairman, the topic of today's hearing is of tremendous importance to the health and security of all Americans. The HIV/AIDS epidemic knows no borders. Ending it requires us to sustain our global leadership in research and increase our ongoing support for the prevention, treatment and education efforts of other Nations and multilateral organizations, such as the World Health Organization.

I regret that this hearing only focuses on U.S. trade policies towards South Africa. It is an important, but limited topic. I hope that our inquiries in the future will extend to the adequacy of U.S. foreign assistance to combat HIV/AIDS and work of our Public Health Service in providing technical assistance to other countries. In that regard, I applaud this week's announcement by the Administration of an additional $100 million to combat HIV/AIDS in Africa and abroad.

But recent attention has focused instead on the actions taken by the U.S. Trade Representative regarding the South African Medicines Act of 1997. We should begin with a question — Why did South Africa adopt this law?

The South African law is meant to expand access to HIV/AIDS drugs. According to South African Health Minister Nkosazana Zuma, [HAW - pronounced "NOH-koh-sa-ZAN-na ZOO-ma"] one in eight South

African adults is HIV-positive. In the past year and a half alone, the prevalence of HIV has increased by a third to affect 3.4 million South Africans.

And if we look beyond South Africa's borders, 70 percent of all new HIV infections and 90 percent of all AIDS deaths occur in Subsaharan Africa. Yet only 1 percent of all HIV/AIDS drugs are sold in this region of the world.

No one questions the need to sustain a rigorous international regime of intellectual property protections. This is why the United States was signatory to the Uruguay Round Agreement. That is why we abide by TRIPS, the Agreement on Trade-Related Aspects of Intellectual Property Rights.

But I am concerned by the unusually aggressive and confrontational posture taken by our country towards the South African Medicines Act of 1997. According to the State Department's February 1999 report, U.S. opposition to the law began before its enactment, a position taken by "the State Department with the full support of USTR, Commerce/US Patent and Trademark Office and pharmaceutical industry representatives."

I find this statement notable for two reasons. First, the State Department invests the drug industry with the status of a sister agency of the United States Government. Second, the Department of Health and Human Services and the White House Office of National AIDS Policy are conspicuous in their absence from the statement.

In this same report, the State Department proudly asserts that, "The U.S. Government has made clear that it will defend the legitimate interests and rights of U.S. pharmaceutical firms."

I dearly hope that an impartial observer could also conclude that this Administration and this Congress dedicate the same vigor and energy to ending the HIV/AIDS epidemic as to defending the rights of the prescription drug industry. I hope the Administration's $100 million announcement signals a reconsideration of the apparent disregard for public health considerations in the State Department's February report.

In light of the palpable threat which South Africa faces from the HIV/AIDS epidemic, I believe we can do far more to help countries such as South Africa cope with the disastrous impact of AIDS by being less adversarial and confrontational. I would ask our foreign policy and trade agencies to consider the very real possibility that it is their position — and not the South African law — which will ultimately prove inconsistent with TRIPS.

Finally, I am concerned by the apparent failure of USTR and the State Department in their opposition to the South African law to consult with the agencies directly responsible for our public health response to the HIV/AIDS epidemic — the Department of Health and Human Services and the White House AIDS advisor, Sandy Thurman, who joins us today.

I thank the Chair for convening this hearing. I welcome our witnesses and look forward to their testimony on these issues.

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News from the office of

Congressman Marion Berry

First Congressional District of Arkansas

FOR IMMEDIATE RELEASE
July 22, 1999

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TESTIMONY OF
THE HONORABLE MARION BERRY
BEFORE THE COMMITTEE ON GOVERNMENT REFORM
SUBCOMMITTEE ON CRIMINAL JUSTICE,
HUMAN RESOURCES AND DRUG POLICY
WHAT IS THE UNITED STATES' ROLE IN
COMBATING THE GLOBAL HIV/AIDS EPIDEMIC?

July 22, 1999

I applaud Chairman Mica for holding this hearing today concerning the global HIV/AIDS epidemic. Over 14 million people have died of the disease. In many southern African countries 25 percent of the population between the ages of 15 and 49 are infected. By 2005, the death toll is projected to be 13,000 people per day.

The United States Surgeon General, David Satcher, recently writing for the *Journal of the American Medical Association*, likened AIDS to the plague that decimated the population of Europe in the 14th Century. I also agree with Surgeon General Satcher's comment that "perhaps most important in the battle against HIV/AIDS is political commitment. Leaders at the national, provincial, and local government must speak out about HIV/AIDS and encourage businesses and nongovernmental organizations to commit to work against the disease."

I have worked as a pharmacist and now serve as co-chairman of the House of Representatives Prescription Drug Task Force that I founded along with Jim Turner and Tom Allen. I am familiar with issues involving the cost and availability of prescription drugs in our country, and I believe these same issues are critical to improving health care and access to prescription drugs in developing nations.

-MORE-

I am optimistic that one day a combination of government and private research will lead to a vaccine for HIV and eventually a cure. It is tremendously important that governments have policies in place that encourage investment in preventing and treating the disease. Successful government policies will encourage both research and development for finding new cures, and providing access to the technology for those who need it.

Developing a cure for AIDS would be a monumental breakthrough, but even that wouldn't solve all the problems we face. Modern treatments for AIDS have cut in half the number of patients dying from the disease in the U.S. However, the number of deaths resulting from the disease continues to rise rapidly in Africa. Additionally, almost three times as many people, most of them in tropical countries of the world, die of preventable, curable diseases as die of AIDS.

I welcome the Administration's proposal to increase the U.S. investment in fighting HIV/AIDS in Africa by $100 million. The new funding would go primarily to prevention, providing child care for children of whose parents have AIDS and to offer counseling and support for those with AIDS. I'm sure the help will be appreciated, but noticeably it will not help one more patient get life-saving medicines that are now available.

It is important that we help developing countries have health care systems in place that have the resources and infrastructure to provide an adequate level of care. Countries will also be much better equipped to provide needed medications if they can be acquired in the marketplace at a reasonable price. The U.S. government could play a major role in helping countries obtain medicines at a fair price if U.S. trade negotiators promoted free trade and playing by the rules of international trade agreements.

Over three million South Africans are HIV positive, including 45 percent of its military. One in five South African pregnant women test positive for HIV. Access to affordable medicine is also a critical issue for the elderly and others suffering from chronic diseases and medical conditions. Prescription drugs are not currently an option for many patients in South Africa, where the drugs often cost more than they do in the United States. The 1997 per capita income in South Africa was estimated to be only $6,200 annually.

To address the problem, President Mandela and the South African Government enacted a law in 1997 to reform the country's prescription drug marketplace. The law amends the South African Medicines Act to allow prescription drugs to be purchased in the international marketplace where prices are lower. It would also allow compulsory licensing in some cases. Regulations implementing the law have not come forward while the law is being constitutionally challenged in South African courts by drug makers in their country.

-MORE-

However, the pharmaceutical industry has persuaded the United States government to work to have the South African law repealed. In February, the United States Department of State released a report titled, *U.S. Government Efforts to Negotiate the Repeal, Termination or Withdrawal of Article 15(c) of the South African Medicines and Related Substances Act of 1965.*

While special interest groups have tried to convince members of Congress and the Administration that implementation of the South African Medicines Act would cause violations of international intellectual property rights agreements, I have seen no evidence that such violations are likely to occur. Compulsory licensing is not an assault on intellectual property rights. Instead, it is part of the copyright and patent systems which enable the interest of the public to be served. Compulsory licensing is permitted under Article 31 of the WTO Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS). In fact, French law authorizes compulsory licensing when medicines are "only available to the public in insufficient quantity or quality or at abnormally high prices." Only three months ago the United States House of Representatives voted 422 to 1 to continue the practice of compulsory licensing for television broadcast signals as part of the Satellite Home Viewer Act of 1999.

In addressing the global HIV/AIDS epidemic it is imperative that we examine the trade policies of our country to ensure we are promoting what is in everyone's best interest.

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Statement by Congressman Jim McDermott on The Impact of the Global HIV/AIDS Pandemic Before the Criminal Justice, Drug Policy, and Human Resources Subcommittee of the Government Reform Committee

July 22, 1999

Mr. Chairman, by now, we are all familiar with the arithmetic of the HIV/AIDS pandemic. There are more than 33.4 million people worldwide infected by HIV/AIDS, and about 16,000 new cases every day. Last year, 600,000 children died because of HIV/AIDS and another 8.2 million were left motherless. By 2010, life expectancy in some regions will drop by over 30 years down to the mid-twenties. The numbers are truly staggering, but they only allude to greater problems. Problems that will be with us for generations, regardless of how successful we are in developing vaccines or new drug therapies.

The sheer scope of this epidemic has altered both the social and the economic realities in many of the hardest hit areas. For instance, in South Africa, where almost ten percent of the population has been infected, the government has said that economic growth will slow by a full percent annually because of AIDS. UNAIDS has stated that in the developing world, infection rates are as high as four times higher in the military than in the civilian world. This will soon lead to a major destabilization of militaries throughout the developing world, as military leadership erodes the ability of nations to meet their security needs and commitments. If the United States is to help maintain global security, then we as a nation must realize that HIV/AIDS could have a massive and very negative affect on global stability.

Underneath these global concerns are the day to day decisions that individuals, communities and governments have to make. For example, a recent State Department report sums up the governmental healthcare crisis in this way, "Governments will confront trade-offs along at least three dimensions; treating AIDS versus preventing HIV; treating AIDS versus treating other illnesses; and spending for healthcare versus spending on other objectives." The general health of the developing world has suffered a setback unlike any other. Individuals and families are going bankrupt paying for funerals and communities are losing their future as the young die before the old.

It is at this point when we must realize that this downward spiral is threatening more and more of the world. Africa has been the hardest hit, but now there is evidence that Asia is on the brink and will soon be plunged into a crisis many times worse than Africa. And while the numbers are not quite as large, Europe too seems poised to see a sharp upturn in infection rates. It is at this point when we must realize that this downward spiral will not stop at our borders.

For more information on the current state of the pandemic, I commend you attention to the recent State Department report that can be viewed at:

http://secretary.state.gov/www/briefings/statements/1999/ps990316.html

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SUBCOMMITTEE ON CRIMINAL JUSTICE, HUMAN RESOURCES AND DRUG POLICY

HEARING ON THE ROLE OF THE UNITED STATES IN COMBATING THE GLOBAL HIV/AIDS EPIDEMIC

STATEMENT OF CONGRESSMAN BERNIE SANDERS (I-VT)

July 22, 1999

Mr. Chairman, first let me thank you for calling this hearing today on the pressing issue of the role of the United States in combating the global spread of HIV and AIDS. At a time when scientists are discovering many breakthrough drugs which attempt to treat the AIDS virus, it is a tragedy that millions of people worldwide are unable to afford them. What is perhaps even more tragic is the fact that this problem could be easily remedied were it not for the intense lobbying by multinational pharmaceutical companies who strive not to help those in need, but instead look to make large scale profits. While more than 3 million people in South Africa alone are currently infected with the HIV virus, some drug companies are making profits of over $3 billion dollars per year at the people's expense This has to change.

Today HIV and AIDS are ravaging the global population. South Africa has a populace of 3.2 million infected citizens, which is nearly almost 10 percent of the total population. By its own governmental estimates, 20 percent of pregnant South African women are HIV-positive, creating millions of orphaned children each year. At the same time, the military has an infection rate of over 45 percent. This dire situation is expected to plunge the life expectancy a full twenty years, from 60 to 40 years by the year 2008.

Unfortunately, the circumstances found in South Africa are not isolated occurrences. There are many countries all over the world which are currently experiencing similar epidemics. Thailand is faced with more than 800,000 infected people, tens of thousands of which have not yet reached adolescence. In less than a year, China's infected population is projected to reach one million. And the Middle East has seen the number of HIV cases double in the past two years.

But the rates of HIV infection are only part of the problem with which we are now faced. The real complication lies not in the lack of medicines which can be found on the market to treat and lessen the effects of this terrible disease, but in the lack of affordable options to those countries and people which need to import such drugs. As it stands, countries like South Africa, Thailand and Israel are forced to pay exorbitant prices for prescription drugs like AZT. While methods to obtain lower-cost drugs are available under a World Trade Organization agreement called TRIPS (Trade Related Aspects of

International Property Rights), drug companies and the U.S. government are blocking South Africa, Israel, and Thailand from taking these WTO-approved steps to get these drugs to treat their citizens. In effect, this is barring the people in these countries from obtaining the medication they need to slow the AIDS outbreak.

It is deeply disturbing to look closely at these facts. While 90 percent of all AIDS deaths are from sub-Saharan African countries, less than one percent of the world's AIDS drugs are sold there. Why? Because in countries like South Africa, where the annual per capita income is a meager $2,600, AIDS drugs can cost up to $1,000 for a month's supply. This is outrageous.

Much of the blame for this problem lies at the feet of the pharmaceutical companies. Rather than lowering prices and helping save millions of lives every year, these companies are hiking up their prices and charging top dollar for their products. They place profit above human life. For example, AZT costs only 42 cents for 300 mg on the world market. However, the retail price is bumped up to $6 for the same amount here in the United States. When you apply those retail prices to millions of people, it is easy to see why some countries are unable to afford the drugs from the companies, despite the TRIPS agreement.

And what happens to countries who practice "parallel importing," and do not purchase their AIDS drugs from drug companies, instead looking to buy them through cheaper sellers, often times other countries? Under direct pressure from the pharmaceutical industry, they are punished by the U.S. State Department. Countries who buy their prescription drugs elsewhere are penalized by the United States. These countries are faced with having their preferential tariff treatment withheld, and being placed on the "watch list" as free trade violators, all because the pharmaceutical companies do not wish to lose any of their tremendous profits.

And what makes this situation even more appalling is the fact that parallel importing is legal under a 1995 WTO agreement. This agreement clearly states that countries may take measures to reduce the costs of importing prescription drugs, including purchasing them from other nations. But the pharmaceutical industry has lobbied so extensively that the State Department is buckling under their hold and aggressively disciplining countries that do not buy their prescription medicines through drug companies. Thus far, South Africa, Israel and Thailand have seen actions taken against them simply for trying to find an affordable way to save their citizens from AIDS and other diseases.

It is high time that we take action to stop this injustice. That is why I offered an amendment to the State Department Authorization bill yesterday which would have made it easier for countries like South Africa to purchase affordable AIDS prescription medication. My amendment would have stopped the State Department from pursuing disciplinary actions against countries that seek to find cheaper ways to import these drugs. Unfortunately, it was defeated by a vote of 117 to 307.

The pharmaceutical industry, which spent more money lobbying Congress than any other industry in the last election cycle, won this week's fight. But I assure you they will not win the battle. I will continue to fight to lower prescription drug costs in our nation and throughout the world in order to save the lives of those people living with AIDS and other diseases.

Testimony by

Sandra Thurman
Director, Office of National AIDS Policy

Before the

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

July 22, 1999

Mr. Chairman and other members of this Subcommittee, I am very pleased to be with you today to talk about the global AIDS pandemic. Your interest in addressing this crisis is very much appreciated.

My colleagues from the National Institutes of Health and the Centers for Disease Control and Prevention will lay out for you a vivid picture of the depth of this tragedy, and describe for you some of the work their agencies are supporting to address the many challenges before us. I would like to use this time with you to talk about the human dimension of the AIDS pandemic, and to share with you my experiences of the reality behind the many statistics you will hear today.

AIDS is a plague of Biblical proportion, and it is claiming more lives than all armed conflicts in this century combined. While many of us have witnessed its devastation firsthand, it is almost impossible to describe the grip that AIDS has on villages across Africa and on communities around the world. Twelve million men, women and children in Africa have already died of AIDS.

Today and everyday, AIDS in Africa buries more than 5,500 men, women and children – and that number will more than double in the next few years. AIDS is now the leading cause of death among all people of all ages in Africa – and among young adult African-American men in the United States.

And the epidemic rages on. Each day, 11,000 people in Africa become HIV infected – one every 8 seconds. Most of these new infections are among young people under the age of 25. And by 2005, more than 100 million people worldwide will have been infected with HIV. Without our help, without your help, the pace of these deaths will continue to accelerate.

And in a host of different ways and from a variety of different vantagepoints, it is children who are caught in the crossfire of this relentless epidemic. In Africa, an entire generation is in jeopardy. In many sub-Saharan Africa countries, between one-fifth and one-third of all children have already been orphaned by AIDS. And the worst is yet to come. Within the next decade, more than 40 million children will have lost one or both parents to AIDS. 40 million. That is about the same number as all children in public school in this country. Left unchecked, this tragedy will continue to escalate for at least another 30 years.

In just a few short years, AIDS will wipe out decades of hard work and steady progress in improving the lives and health of families throughout the developing world. In endemic regions, infant mortality will double, child mortality will triple, and life expectancy will be cut by 20 years or more.

For millions and millions of families, for large regions of the developing world, and in some cases for entire nations, AIDS is an engine of destruction that is pushing them to

the brink of disaster. Not only do millions of precious lives hang in the balance, but so too do the economic viability and political stability of their homelands.

AIDS is a trade and investment issue. Both in terms of exports and natural resources, Africa is a critical partner to the US economic engine. And a successful fight against AIDS is fundamentally important to our ability to sustain and improve our economic ties to Africa. Skilled workers are taken in the prime of their lives, forcing their companies to find and train new employees to take their place. As workers get sick, they can no longer afford to buy or produce products, so the economies of their countries suffer.

According to the *Economist* magazine, recent studies have found that AIDS is seriously eroding the economies of many of our partner nations. In Namibia, AIDS cost the country almost 8% of its GNP in 1996. By 2005, Kenya's GNP will be over 14% smaller than it would have been without AIDS.

Similarly, in Tanzania, The World Bank has predicted that its GNP will be 15 to 25% lower as a result of AIDS. The South African government has estimated that this epidemic costs the country 2% of its GNP each year, a situation that will only worsen without strong intervention.

AIDS is also a security and stability issue. The prevalence of HIV in the armed forces of many African countries is staggeringly high. The *Economist* has estimated the HIV prevalence in armed forces in the Congo range between 50 to 80%. Other recent

reports have projected that the South African military and police are also heavily impacted by HIV. Moreover, as these troops participate in an increasing number of regional interventions and peacekeeping operations, the epidemic is likely to spread.

Extremely high levels of HIV infection among senior officers could lead to rapid turnover in those positions. In countries where the military plays a central or strong role in government, such rapid turnover could weaken the central government's authority. For those countries in political transition, this kind of instability could slow or even reverse the transition process. This is a dynamic that deserves serious attention not only in Africa, but in the Newly Independent States of the Former Soviet Union, and in India where AIDS is intensifying its deadly grip.

The South African Institute for Security Studies has also linked the growing number of children orphaned by AIDS to future increases in crime and civil unrest. The assumption is that as the number of disaffected, troubled, and under-educated young people increases, many sub-Saharan African countries may face serious threats to their social stability. Without appropriate intervention, many of the 2 million children projected to be orphaned by AIDS in South Africa alone will raise themselves on the streets, often turning to crime, drugs, commercial sex, and gangs to survive. This seriously effects stability and promotes the spread of HIV among these highly vulnerable young people.

Yet my message to you today is not one of hopelessness and desolation. On the contrary, I hope to share with you a sense of optimism. For amidst all of this tragedy, there is hope. Amidst this terrible crisis, there is opportunity: the opportunity for us—working together—to empower women, to protect children, and to support families and communities throughout the world in our shared struggle against AIDS.

The United States has been active in the struggle. The Administration has taken an active role in sounding the alarm on the AIDS crisis in Africa, and in ensuring that the United States supports African efforts to combat this deadly disease.

Since 1986, this nation has contributed over $1 billion to the global fight against AIDS. More than 50% of those funds have been used to address the epidemic in sub-Saharan Africa. Overall, nearly half of all of the development assistance devoted to HIV care and prevention in the developing world has come from the US. The United States has also been the leading supporter of the United Nation's Joint Program on AIDS—UNAIDS—contributing more than 25% of its budget.

It is a strong record of engagement and one of which we can be proud; but unfortunately it has not kept pace with this terrible pandemic. We have done much, but there remains much more that we and the other developed nations can and must do.

In that spirit, on World AIDS Day 1998, the President directed me to lead a fact finding mission to sub-Saharan Africa and to report back with recommendations for an

enhanced US battle plan for our global fight against AIDS. I was pleased to lead that Presidential Mission during the Easter recess – accompanied by members and staff from both parties and chambers – to witness firsthand both the tragedies and triumphs of AIDS in Africa. In response to the findings of that trip, both the President and the Vice President agreed that we needed to respond to do more immediately and worked to develop an initiative to address this growing pandemic. This week, the Administration announced a broad new initiative to invest $100 million in the FY2000 budget for this effort.

This initiative provides for a series of steps to increase US leadership through support for effective community-based solutions and technical assistance to developing nations. This effort more than doubles our funding for programs of prevention and care in Africa, and challenges our G8 and other partners to similarly increase their efforts. This initiative is a significant increase in the US government's investment in the global battle against AIDS and it begins to reflect the magnitude of this rapidly escalating pandemic.

A critical component of this initiative is a commitment to seek an additional $100 million in Fiscal Year 2000 funds to help support this battle. Four key investments have been identified:

- $48 million will be used for prevention. Specifically, we hope to implement a variety of prevention and stigma reduction strategies, especially for women and youth, including: HIV education, engagement of political, religious, and civic

leaders, voluntary counseling and testing, interventions to reduce mother-to-child transmission, and enhanced training and technical assistance programs.

- $23 million will support home and community-based care. This will help create and enhance counseling and support systems, and help clinics and home health workers provide basic medical care (including treatment for related illnesses like STDs and TB)
- $10 million will go for the care of children orphaned by AIDS. This will allow us to continue efforts that are being started this fiscal year through funds supported by Representatives Callahan and Pelosi and their colleagues. We hope to improve our ability to assist families and communities in caring for their orphaned children through nutritional assistance, education, training, health, and counseling support, in coordination with micro-enterprise programs.
- And $19 million will be used to strengthen prevention and treatment infrastructure. These funds will help to increase the capacity for the effective delivery of essential services through governments, NGOs, and the private sector. We also need to enhance surveillance systems so that we can better track the epidemic and target HIV prevention efforts.

This assistance will come through the combined work of three Federal agencies: the US Agency for International Development would utilize $55 million, HHS would invest $35 million, and the Department of Defense the remaining $10 million.

Some of the other key components of this initiative include an increase in our efforts to include the AIDS epidemic in our foreign policy dialogue, both to support political leadership in countries hardest hit and to promote an increased response by our developed nation partners. We are also taking steps to increase our coordination with the private sector and the many non-governmental organizations working in endemic regions, including religious organizations.

We hope that this initiative will receive the broad-based bipartisan support it deserves. AIDS is not a democratic or republican issue – it is a devastating human tragedy that cries out to all of us for help.

You will find a more complete description of this initiative and the problems it seeks to address in the report released by the Administration earlier this week. I have submitted a copy to this Subcommittee and would like to request that it be included in the record as part of my remarks.

Let me conclude by thanking this Subcommittee for its interest in this issue, and offer my continued assistance as you seek ways to respond to this terrible tragedy. Not too many years ago, the Reverend Martin Luther King, Jr. said:

> We are caught in an inescapable network of mutuality, tied in a single garment of destiny. Whatever affects one directly affects all indirectly.

Last week, Archbishop Tutu expressed the same sentiment through an African proverb:

When one steps on a thorn and it goes into the toe, the whole body bends to pull it out.

We are one world – and in many ways – Africa's destiny is our destiny. Every day, another 16,000 people around the world are infected with HIV, and 90% of those live in our poorest nations. There is hope, but that hope will only be realized if we act. We are not at the beginning of the end of AIDS, but rather at the end of the beginning. Our resolve to stop this epidemic must be strengthened, our resources significantly increased, our determination made clear. Let us hope and pray that we have the foresight and the fortitude to seize this opportunity.

I thank the Chairman and this Committee for allowing me to be with you here today.

Release Upon Delivery

STATEMENT OF

JOHN Y. KILLEN, M.D.

DIRECTOR

DIVISION OF ACQUIRED IMMUNODEFICIENCY SYNDROME

NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

NATIONAL INSTITUTES OF HEALTH

BEFORE THE

COMMITTEE ON GOVERNMENT REFORM

UNITED STATES HOUSE OF REPRESENTATIVES

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. This week Vice President Gore reinforced the Administration's commitment to combating AIDS worldwide by announcing a proposal to spend an additional $100 million in FY 2000 on prevention and treatment strategies, community-based care and assistance for children orphaned by AIDS.

Today, I will focus on NIH's role in the development of treatment and prevention strategies for HIV/AIDS.

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 antiretroviral drugs is, in most cases, not feasible. Most developing nations lack the financial resources and health care delivery infrastructure necessary to support their appropriate use. Therefore, the identification of effective, low-cost tools for preventing HIV infection is crucial to slowing the epidemic.

Researchers have shown that many approaches to HIV prevention can reduce the number of new infections, including: education and behavior modification, the social marketing and provision of condoms, treatment of other sexually transmitted diseases and the use of antiretroviral drugs to prevent the transmission of virus from mother to infant. NIH has been pursuing these approaches to prevention both domestically and internationally through the HIV Network for Prevention Trials (referred to as HIVNET), and will continue to do so through a follow-on initiative, the NIAID Prevention Trial Network.

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 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 and the Health Ministry of Uganda reported on the exciting results of a study in Uganda that could have profound implications for the epidemic in children worldwide. This study showed that just two doses of the antiretroviral drug nevirapine—one 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 AZT.

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 NIH, HIV vaccine funding increased by 93 percent between FY 1995 and FY 1999.

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 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 CDC in Thailand. NIH will collaborate with the company in evaluating the immunological responses to the vaccine.

Research Training

Training is a critical component of an international AIDS research and prevention program. Currently, the Fogarty International Center is working with several NIH Institutes to build HIV/AIDS research training and capacity in developing countries. Over the past decade, the AIDS International Training and Research Program, an arm of NIH's vaccine research effort, has trained in the U.S. over 1,500 scientists from nearly 100 nations. This capacity-building effort has expanded research capabilities in a number of developing counties and has facilitated many NIH international HIV/AIDS research initiatives.

Conclusion

Two years ago, President Clinton set a national goal of having an effective 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 strengthen 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.

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Public Health Service

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TESTIMONY OF

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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 be a challenge. 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 percent 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, 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 percent of the world's AIDS deaths. The next most affected

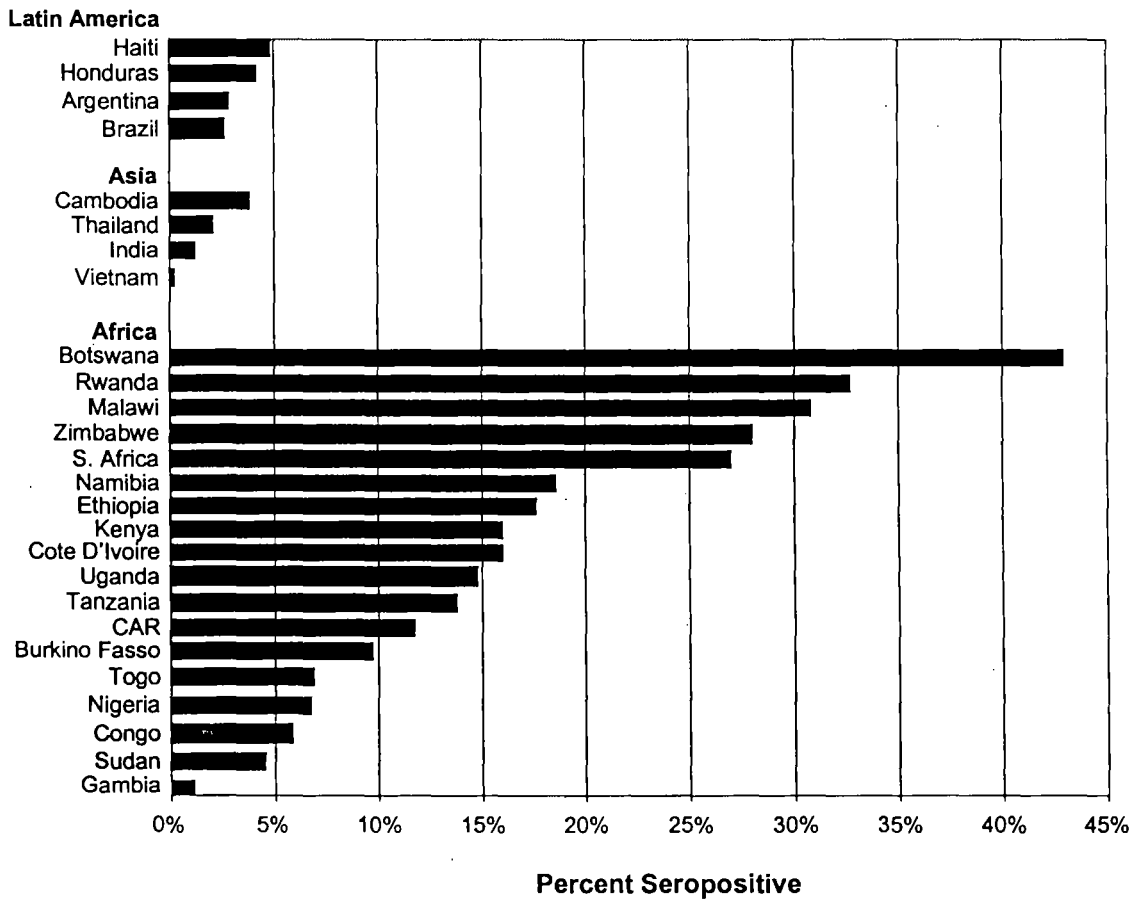
region is south Asia and southeast Asia, with nearly 10 percent of the world's infections. These areas, and especially sub-Saharan Africa, are still experiencing explosive HIV epidemics that are taking an enormous toll in human life and having a profound economic and social impact.

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 in the range of 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 AIDS death toll is rapidly rising with an estimated 5,500 deaths from the disease occurring each day in Africa. Rapid implementation of large scale effective interventions by global partners will be essential to any strategy to contain these national epidemics. This will be key to addressing the many potential national and international consequences of this critical situation, including effects on political and economic stability and other factors that could affect global interests.

I would like to turn your attention to a figure that graphically illustrates the extremes 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.

Figure 1: Percent of Pregnant Women with HIV Infection in Urban Areas

Source: Health Studies Branch, International Programs Center, U.S. Bureau of the Census; Research Note No. 26, February 1999.



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 percent of 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 can then pass the infection to their babies. Without interventions, roughly one quarter of the babies will become infected by the time of birth and an additional 5 to 15 percent will get the 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 percent of these cases and 98 percent of the deaths occur in countries with low per capita income.

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 infection to be spread to other people. More ominous still is that increased TB in AIDS patients enhances the potential for the spread of 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 penetration of the virus into the body. HIV may also prolong the duration and increase the 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 of hope. One example of effective action can be seen in Uganda; there are also early signs of success in

Tanzania, Cote d'Ivoire and Senegal. Thailand has also seen improvements in some of its 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 percent infected in one area down to 22 percent), with continuing downward trends. Behavioral studies have shown a two or more year increase in age at first sexual intercourse in youths, a 9 percent reduction in casual sex, and a 30 to 40 percent increase in condom use. These beneficial trends are attributed to a number of factors simultaneously occurring in Ugandan society.

An important element of Uganda's AIDS control efforts is a very intensive HIV counseling and testing program fiscally supported by USAID with CDC technical expertise, which 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 has been strong political leadership in efforts to increase AIDS awareness and prevention in Uganda. The President and First Lady of Uganda themselves frequently address HIV-related issues, making these 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.

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 antiretroviral HIV therapies 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 far greater than the $5 to $15 dollar per person annual expenditure for all 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. Many drugs also require refrigeration and must be administered under dietary restrictions. TB screening of HIV-infected people and offering the low cost preventive medications for this and 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 who seek assistance; conducting collaborative research and training on preventive interventions; serving as partners in global initiatives; and responding to national U.S. interests. Although our geographic focus is limited and focused, we assist in the application of U.S.

scientific advances within other countries, such as rapid HIV testing, prevention of mother-to-child HIV transmission, refinement and installation of HIV diagnostic and research techniques, assisting in technical aspects of HIV surveillance, counseling and testing, applications of simple prevention of opportunistic infections, computerization of health information systems, and studying the interactions of HIV and TB. Some of these activities involve a partnership with USAID. 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 knowledgeable in HIV and its associated diseases stationed in several places, including India, Bolivia, Indonesia, Vietnam, South Africa, Malawi, and Mali (a number of these through USAID). CDC also offers many short-term consultations on issues including surveillance, epidemiological assistance, training, program management, laboratory capacity building, and prevention efforts.

At the global level, CDC makes technical experts available to UNAIDS, UNICEF, WHO, and the World Bank on both a long-term and a short basis, enhancing the capacity of the UN agencies committed to combating the epidemic. CDC also collaborates extensively with the US Agency for International Development (USAID), the National Institutes of Health (NIH), 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.

The President recently submitted a Budget Amendment containing a multilateral initiative to address the global HIV/AIDS epidemic, which includes an additional $100 million in FY 2000 from the United States Government. This initiative will focus primarily on prevention of HIV/AIDS and treatment of related infections, providing support to nations with a high prevalence of HIV/AIDS and a demonstrated commitment to fighting HIV/AIDS.

Under this initiative, CDC will expand its role internationally by assisting with the establishment of surveillance systems to understand the health impact of the disease, and by providing additional technical assistance and training to both improve and expand prevention and treatment programs.

Approach to the Epidemic: Prevention

One of the most critical needs in effective HIV/AIDS prevention is political will and public health leadership within the country in their efforts to acknowledge, effectively address, and focus 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 an adequate surveillance system. This is important so that the extent and trends of the epidemic can be monitored, prevention programs can be targeted and evaluated, program priorities can be determined rationally, and the reality and extent of the epidemic can be acknowledged.

In general, sexual risk for HIV transmission is addressed by reducing risky behavior through the provision of culturally appropriate information and education, HIV counseling and testing, condom availability, counseling and peer outreach to those at increased risk, and treatment of sexually transmitted infections. However, the optimal configuration of HIV prevention services must be determined within the cultural, demographic, and social context surrounding the HIV epidemic within the host country. 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 up to a 50 percent reduction in transmission. Important 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 mother-infant prevention. Even with the cost of HIV counseling and testing and administration of antiretroviral drugs, such prevention is highly cost effective. However, establishing prevention programs in settings where antenatal services may be weak is an operational challenge. 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 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 as well as for those at greatest risk for HIV infection. The high morbidity and mortality associated with HIV and TB co-infections highlights the need for basic HIV counseling and testing services which 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 TB treatments.

Another 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, the National Institutes of Health. 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 Administration priority, 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 HIV-infected individual but because they also prevent mother-to-child HIV transmission and may reduce transmission of the virus from an infected person through sexual contact. Antiretroviral 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. 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 resistant HIV strains through inconsistent or partial treatment becomes a global public health concern.

In conclusion, while there are a few countries we can point to demonstrating improvement in the HIV/AIDS epidemic, continued leadership and expertise are necessary to implement effective prevention and treatment programs. Without these, the outlook for the global AIDS epidemic remains grim.

Thank you for allowing me the opportunity to appear before this Subcommittee.

Adults and children estimated to be living with HIV/AIDS as of end 1998

Total: 33.4 million

UNAIDS

WAD-EN 1998

World Health Organization

Statement of Peter Lurie, MD, MPH
Public Citizen's Health Research Group
Before the Committee on Government Reform
Subcommittee on Criminal Justice, Drug Policy, and Human Resources
US House of Representatives
July 22, 1999

Recently, the pharmaceutical industry has questioned compulsory licensing[1] and parallel imports[2] on the grounds that these measures might 1. lead to the development of strains of the human immunodeficiency virus (HIV) that are resistant to currently available medications; and 2. result in decreased pharmaceutical company research and development (R&D). This testimony will address these two claims in turn.

The Viral Resistance Argument

Tom Bombelles, Assistant Vice President International for the Pharmaceutical Research and Manufacturers of America (PhRMA) has recently asserted: "Just giving people drugs without the proper treatment can create drug-resistant strains of HIV. It can make people sicker, not better. And that threatens AIDS patients everywhere around the world."[3]

The potential development of resistance to anti-HIV drugs is a serious public health concern, one that threatens to undermine the enormous gains that have been made in treatment for HIV infection in this country. But before one can address the validity of the HIV-resistance argument directly, one must acknowledge the following aspects of compulsory licensing and parallel importing that transcend viral resistance:

The compulsory licensing and parallel import proposals do not *require* any country to engage in these practices. Rather countries are left to decide for themselves if they wish to use these mechanisms. But preventing compulsory licensing and parallel imports in blanket fashion robs developing countries of that choice.

The compulsory licensing and parallel import mechanisms proposed by South Africa, for example, do not only involve AIDS drugs or those for infectious diseases. The "resistant strain" argument is thus being used to prevent improved access to lifesaving drugs even for non-infectious diseases such as heart disease and cancer. Drugs like simvastatin, to lower cholesterol, and ranitidine, for ulcers, could be substantially reduced in price.

Fluconazole is a drug that treats an often-fatal complication of HIV infection, cryptococcal meningitis, rather than HIV itself. Its price could be dramatically reduced by either compulsory licensing or parallel importing. Two 150 mg fluconazole tablets sell for $23.50 in Italy, where its patent is protected, compared to $0.95 in India where the patent is not recognized.

Let me now turn to the HIV-resistance argument directly.

For a patient to be worse off due to the development of viral resistance, one would have to believe that a patient who is partially adherent to anti-HIV therapy and who consequently develops a resistant HIV strain is worse off than one who is not treated with anti-HIV drugs at all. But there is no evidence to support that assertion. First, many patients who are not fully adherent with anti-HIV therapy do not develop drug resistance. Second, even for those who might develop resistance, the change to the viral genetic material that confers resistance is likely to be different than one that would confer greater aggressiveness. Mutant microorganisms generally reproduce less efficiently than non-mutants. A recent review in the Journal of the American Medical Association points out that, in the absence of therapy, strains from untreated people (which are primarily non-resistant) are likely to reproduce more rapidly than resistant strains and so will come to dominate the resistant strains over time.[4] There is also some evidence that HIV strains resistant to zidovudine are more difficult to transmit to uninfected people.[5]

The decision to prescribe or not prescribe effective medication should be a matter between a patient and his or her doctor. Two authors, writing in the American Journal of Public Health, have argued that, "it would be very difficult to justify denial of access to protease inhibitors [specific drugs for HIV infection] in the face of expressed patient preference for treatment except in the presence of clear and compelling evidence that a patient could not or would not be adherent."[6] But opposing compulsory licensing and parallel imports is a blunt instrument indeed: because of high costs, physicians and patients would be unable to make that case-by-case assessment[7] and patients would instead be denied drug simply on the basis of their residence. Assuming that all residents in developing countries are incapable of adherence is both insulting and historically inaccurate.

Developing countries are also not monolithic when it comes to public health capacity, and it is condescending to lump them all together in order to justify withholding effective treatments. Clearly there are enormous differences between developing countries and within them. For example, very impoverished African countries such as Zimbabwe, Zambia, Uganda, Botswana, Senegal and Cote d'Ivoire are planning to provide anti-HIV drugs for HIV-positive women to prevent HIV transmission to their infants.[8] Other countries, such as Brazil, already provide complex anti-HIV drug regimens to their HIV-positive populations.

The solution to the development of drug resistance due to patient difficulty in adhering to the often-complex AIDS drug regimens is not denial of drug, but rather interventions to improve adherence. (In fact, high drug prices are one of the causes of non-adherence, as poor patients may take partial drug courses to save money.) Such interventions have had substantial success with tuberculosis in developing countries,[9] including with HIV-infected populations.[10] Has anyone suggested leaving developing country tuberculosis or malaria patients untreated to prevent the development of resistance?

Lack of adherence to anti-HIV drugs is a problem in the United States as well. Even in the controlled setting of a clinical trial, non-adherence rates of 25% have been observed.[11] Should we therefore apply the same logic to some populations in the United States? Imagine if someone tried to make that argument with respect to all drug users or particular socioeconomic sectors of the United States.

Is the real concern that resistant strains from the developing world will enter the United States? If so, is the pharmaceutical industry really arguing that Africans should remain untreated so that Americans can live longer?

It is true that pharmaceutical company pricing practices are not the only reason that anti-HIV drugs are unavailable in most developing countries. The lack of health care infrastructure is a very important impediment to drug delivery. But pricing is an important, and in this case partially correctable, part of the problem. One reason that the HIV counseling and testing infrastructure in developing countries is weak is that, in the absence of affordable therapies, there are only limited reasons to improve it. But, if effective therapy were more widely available, there would be an incentive to improve the infrastructure to detect undiagnosed HIV infection.

In sum, on both policy and virological grounds, the possible emergence of drug-resistance strains provides no support for arguments against compulsory licensing and parallel imports.

The R&D Scare Card

Tom Bombelles of PhRMA has also asserted that "compulsory licensing creates an active disincentive to research-based pharmaceutical industry involvement in the international effort to improve public health in developing countries, as companies will choose not to develop medicines which will not be patent-protected. Such disincentives are more likely to drive patients and the availability of medicines further apart."[12] This seems to argue that patients in developing countries should wait patiently without existing drugs because of prohibitively high prices while companies develop other drugs that may eventually be affordable in developing countries. The history of international drug development teaches us that this is likely to be an empty promise.

Once again, the pharmaceutical industry is playing its R&D Scare Card. This is an empty threat: pharmaceutical company R&D expenditures almost doubled between 1990, when Congress imposed price restraints on Medicaid drugs, and 1995.[13] R&D represented a median of 11.4% of sales for the top 10 pharmaceutical companies (ranked by revenue) in 1998.[14] In contrast, profit (net income) represented a median of 18.6% of sales by those same companies in 1998.

Furthermore, the pharmaceutical industry is the most profitable in the United States, whether measured by return on sales, assets or equity.[15] Since 1989, pharmaceutical company return on equity has been at least 1.7 times the median of all U.S. industries.[16]

Given the extraordinary profits generated by the pharmaceutical industry, and its failure to make many critical medications affordable for developing country patients, we urge you to call the R&D Scare Card bluff.

Conclusion

Neither the viral resistance nor the R&D scare card arguments provides support for opposing legal trade measures such as compulsory licensing and parallel importing. Furthermore the sub-Saharan African market represents a scant 1.4% of the global pharmaceutical market. The explanation for the pharmaceutical companies' opposition to compulsory licensing and parallel importing is to be found elsewhere: in their desire to not have their irrational pricing practices exposed. We suggest that providing potentially lifesaving drugs to residents of developing countries should have a higher priority.

1. Compulsory licensing allows local production of patented medications with a royalty to be paid to the patent holder.

2. Parallel importing allows countries to find the lowest price for a particular drug on the international market, rather than being required to purchase from the manufacturer at a higher price.

3. World News Tonight with Peter Jennings (6:30 PM Eastern Time), July 8, 1999 (rush transcript).

4. Hirsch MS, et al. Antiretroviral drug resistance testing in adults with HIV infection: implications for clinical management. JAMA 1998;279:1984-91.

5. Wahlberg J, et al. Apparent selection against transmission of zidovudine-resistant human immunodeficiency virus type 1 variants. J Infectious Disease 1994;169:611-4.

6. Bayer R, Stryker J. Ethical challenges posed by clinical progress in AIDS. Am J Public Health 1997;87:1599-602.

7. Bangsberg D, et al. Protease inhibitors in the homeless. JAMA 1997;278:63-5.

8. Lurie M, et al. Denying effective antiretroviral drugs to HIV-positive pregnant women -- the national government's flawed decision. S Afr Med J 1999;89:621-3.

9. Wilkinson D, et al. Directly observed therapy for tuberculosis in rural South Africa, 1991 through 1994. Am J Public Health 1996;86:1094-7.

10. Davies GR, et al. Twice-weekly, directly observed treatment for HIV-infected and uninfected tuberculosis patients: cohort study in rural South Africa. AIDS 1999;13:811-7.

11. Kastrissios H, et al. The extent of non-adherence in a large AIDS clinical trial using plasma dideoxynucleoside concentrations as a marker. AIDS 1998;12:2305-11.

12. Bombelles T. Remarks before Presidential Advisory Council on HIV/AIDS, Washington, DC, June 7, 1999.

13. Pharmaceutical Research and Manufacturers Association. Pharmaceutical Industry Profile 1999, Washington, DC 1999.

14. Based on 1998 Annual Reports.

15. Fortune 500. Fortune Magazine, April 26, 1999, p. F-27.

16. Sager A, Socolar D. Winning affordable prescription drugs for all Americans: problems, causes and solutions. Boston University School of Public Health, 28 June, 1999.

June 22, 1998
Oral Testimony of Eric Sawyer
Director, HIV/AIDS Human Rights Project
On the
Role of the US Government in Combating the Global AIDS Crisis
To the
Subcommittee on Criminal Justice, Drug Policy and human Resources

Mr. Chairman, Members of the Committee, Ladies and Gentlemen,

I have but a few minutes to speak about a global public health crisis that has been evolving for twenty years and is unprecedented in human history. At present 14 million people have died from AIDS -- more than died during the Black Plague or all the world wars of the last 100 years. And we are of course still counting, and will be for some time.

So allow me briefly to introduce myself and then focus my remarks on aspects of this crisis that may not yet have come to your attention.

My name is Eric Sawyer. I live in New York City and am Director of the HIV/AIDS Human Rights Project. I am also one of the founders of ACT UP New York: an AIDS activist coalition formed in 1987 to focus media attention on the lack of governmental action with respect to AIDS, and to advocate for access to medical treatments for AIDS and related opportunistic infections.

I am also a person who has been living with AIDS for nearly twenty years, thanks to my privileged access to a sophisticated and expensive regimen known as "salvage therapy". This regimen includes daily doses of five anti-retroviral drugs, including two protease inhibitors. At the present time my viral load is undetectable and my CD-4 count has risen to its highest level in a decade. I have not been this well in ten years, and I am happy to be alive, and happy to be here today.

But I am also extremely sad, because I represent less than two percent of those for whom HIV/AIDS has become a manageable disease. There are nearly forty million men, women, and children with HIV/AIDS in the world today, and for 98% percent of them this disease remains-- there is no other term for it-- a death sentence.

It certainly was a death sentence for one of my heroes Auxcillia Chimusoro. Auxcillia was a brilliant woman from Zimbabwe, full of life and energy. She had just found out she was HIV infected in 1991, when her husband and infant child died of AIDS. She quickly started the first support group in her country for women living with HIV, by coming out as HIV positive and opening her home to others. Her bravery was rewarded with a fire-bombing and the beating of her children at school. Auxcillia responded by starting a sewing project to give other AIDS widows in her village an alternative to the exchange of sex for income or food. She also went on to start a project to care for AIDS orphans.

To access health care Auxcillia traveled over night on three different buses to reach a doctor who could treat her. While Auxcillia discovered her HIV infection 10 years after I began showing symptoms, today she is dead and I am alive and that is wrong. Auxcillia Chimusoro deserves to

be alive and with us here today. The world is a poorer place because of her loss and the loss of millions of others like her.

And even if we were all-- governments, NGO's, researchers, activists, pharmaceutical companies-- to come together on this very day in pursuit of a common goal, their will be millions and millions more, like Auxcillia, who will die before their time. Make no mistake about it: we are witnessing a global crisis of unprecedented proportions, that will leave a fossil-like imprint on human civilization for decades to come. The very existence of this congressional committee hearing, therefore, is in my view of historic importance, and I urge you to consider all the testimony you hear today with the courage, compassion, and concern.

In the few minutes I have left, I wish to zero in on pricing issues specifically with regard to those drugs that treat AIDS-related opportunistic infections.

The point is this: the kinds of combination therapies I am privileged to have access to are far beyond the resources of most men, women, and children in developing countries and they are furthermore difficult to administer and supervise in developing world conditions.

But these treatments, in my view, are not the most important ones we should be looking at. The first priority for extending the lives of people living with HIV/AIDS in the developing world should be providing access to very inexpensive drugs that treat and prevent the development of opportunistic infections that that kill most people with AIDS.

In this regard I am especially troubled that the pharmaceutical companies are focusing the attention of the treatment access debate on their most over-priced and difficult-to-administer anti-retroviral drugs: their triple-therapy cash cows.

What would have far more important and immediate benefits to people with HIV and AIDS in the developing world would be access to the inexpensive drugs used to treat and prevent AIDS-related opportunistic infections.

A few brief examples: Most people with AIDS die of treatable and preventable infections such as tuberculosis, pneumonia, fungal infections, and dehydration due to diarrhea. Prior to the introduction of triple-therapy regimens, significant reductions in AIDS-related death rates were achieved here in the United States through the application of inexpensive drugs to these and other infections.

What are the actual costs today of some of these drugs?

--TB prophylaxis costs $15 per year in a WHO program in Uganda.

--PCP prophylaxis in HHS programs costs as little as $24 per year.

-- NTZ, a wide-spectrum anti-parasitic drug for diarrhea, and some of the older generic anti-fungal drugs cost less than the Uganda TB treatments.

Thus, for under $70 per year, many fatal AIDS related opportunistic

infections can be prevented, delaying the deaths of people with AIDS for several years. Generic production of these treatments and bulk buying can even further reduce costs.

In other words: a partial remedy to the global AIDS crisis-- in the form of prolonging the lives of millions of people while the search for a vaccine goes on and hopefully intensifies-- is already at hand. That is the importance of the implementation of trade policies such as compulsory licensing and parallel importing. These policies will drive price reductions by introducing generic equivalents into the market place.

At the same time while we gear up efforts to dramatically expand access to cheaper drugs for opportunistic infections we can start to look at trade policies like compulsory licensing and parallel importing, or two tiered pricing systems, to reduce the price of the more expensive and complex triple therapies. Such efforts are already underway in India- proof that it can (and must) be done. In India, generic versions of AZT cost $34.00 per month-- as compared to the $250.00 charged by Glaxo-Wellcome.

For too long, in my view, the US Government has allowed the commercial interests of the pharmaceutical industry to drive trade policy and has, frankly, avoided meaningful debate about what our public policy should be with respect to global public health issues such as AIDS. What is our responsibility as Americans, I would ask, to the health of our planet? Now that we have the global village, do we really understand what it means to live-- and far to often-- to die in it? What should our response be? Should it be one hundred million dollars, as Vice President Gore recently announced? This is a welcome initiative but it is also a drop in the vast ocean of suffering created by AIDS and other infectious diseases.

What is required of us, I believe, is a comprehensive and compassionate policy that is driven and informed by a vision of our responsibilities as Americans in a planetary society. It is time for us to realize that the public health of South Africa is also the public health of the United States. And it is time to act on this realization by challenging greed; promoting debate; and recognizing that when it comes to public health, it is never about "them". It is always about us. Health is a human right. This is the great lesson we can learn from AIDS in the world, and if we do, some redemption will emerge, I believe, from this global tragedy.

In conclusion, I would ask this committee to consider the following:

1. Call for Congressional Hearings on the real cost of drug development so as to identify who is actually paying for research and development of essential medicines. I believe you will find that in many cases it is the US taxpayer;

2. Call for Hearings on drug pricing practices and work to pass fair pricing legislation for essential drugs;

3. Pass legislation making it illegal for the US government to use trade sanctions to bullying developing countries into denying it's

people affordable access to essential medicines through legal trade practices like compulsory licensing and parallel importing; and

4. Ask the President to license all US taxpayer-funded medical inventions to organizations like the World Health Organizations or to a multi-national not-for-profit drug distribution venture to facilitate greater access to essential medicines.

My mentor and hero was Jonathan Mann, the architect of the World Health Organizations' Global program on AIDS. Jonathan and his wife, Mary Lou, were tragically killed last September 2 in the crash of Swissair 111, but he has left behind for the global AIDS family, and indeed for all of us a vision of the inextricable link between health and human rights.

I would like to end my remarks with this statement of Jonathan's made at last year's International AIDS Conference in Geneva:

"Our responsibility is historic. For when the history of AIDS and the global response is written, our most precious contribution may well be that at a time of plague we did not flee, we did not hide, we did no separate ourselves."

In this spirit, may we all not separate ourselves, but instead work together to provide every man, women and child with one of their most fundamental rights: health.

Thank you very much.

July 22, 1999
Written Testimony of Eric Sawyer
On the Role of the US Government in Combating the Global AIDS Crisis
To the Subcommittee on Criminal Justice, Drug Policy and Human Resources

Mr. Chairman, Members of the Committee, Ladies and Gentlemen.

My name is Eric Sawyer. I am a person living with AIDS from New York City. I am one of the Founders of ACT UP NY, an AIDS activist coalition formed in 1987 to draw media attention to the lack of governmental action on AIDS and to fight for access to medical treatments for AIDS and related opportunistic infections. We also advocate for the search for a cure for AIDS, and for more effective governmental policies, increased governmental funding and more effective programs to prevent and treat HIV related illnesses. I am also the Director of the HIV/AIDS Human Rights Project.

I have shown symptoms of this disease since 1981, several years before the discovery of the HIV virus. I have had a medical AIDS diagnosis since 1989. I first began AZT mono-therapy in 1987. I have successively taken each new HIV drug almost as soon as they became available in the US market. I currently take five anti-retroviral drugs, including two protease inhibitors, in what is known as a salvage therapy. My current viral load has been undetectable for 21 months and my CD-4 count has risen to its highest level in a decade. I have not been this well in ten years.

What does this mean? This means that I am alive today, -- some 20 years after HIV infection -- because I have had access to the latest medical treatments just as soon as they have become available. Often, I have been a willing participant in clinical trials to approve new generations of therapy.

While I am happy to be healthy and present here today, I am deeply saddened by the absence of many of my friends from developing countries who have died premature deaths. In some cases, I have seen my friends die only a few months after discovering their HIV infection. I am angry the very drugs that saved my life are priced out of the reach of the majority of people in the developing world who need these drugs.

I started working on medical treatment access issue for people living in the developing countries after meeting two of my heroes -- Jonathan Mann and Auxcillia Chimusoro from Zimbabwe, at the Amsterdam International AIDS Conference in 1992. Jonathan Mann, whom the world remembers as the architect of the global fight against AIDS, died fighting for AIDS treatment access in a plane crash on route to Geneva last fall. Not as many people know of Auxcillia.

Auxcillia was a brilliant woman, full of life and energy. She had just found out she was HIV infected in 1991, when her husband and infant child died of AIDS. She quickly started the first support group in Zimbabwe for women living with HIV, by coming out as HIV positive and opening her home to others. Her bravery was rewarded with bullets fired into her home - followed by a fire bombing and the beating of her children at school. She responded by starting a sewing project to give other AIDS widows in her village an alternative to the exchange of sex for income or food. Auxcillia also went on to start a project to care for AIDS orphans.

To access health care Auxcillia traveled overnight on three different buses to reach a doctor who could treat her. While Auxcillia discovered her HIV infection 10 years after I began showing symptoms, Auxcillia died the morning of the opening session of the June 1998 International Conference in Geneva.

Auxcillia deserves to be alive and with us here today. The world is a poorer place because of her loss and the loss of millions of others like her. Trade policies enabling compulsory licensing and parallel importing of AIDS drugs in Zimbabwe might have prolonged Auxcillia's life. As a PWA in the developed world privileged to survive because of access to health care, I have a duty to my brothers and sisters in the developing world to fight for their rights to access these treatments and the hope they hold for an extended future. I owe a debt to them and to their children to fight for their human right to health. And in an increasingly global village, inextricably linked to one global public health - you too owe it them, to their children, and to your children.

A recent survey of 20 African and Southeast Asian Countries by UNAIDS shows that only 4 of 20 countries have, any access to the new Protease Inhibitors that are part of the standard combination therapy. This standard triple therapy that has helped reduce AIDS death rates in the US by almost 50% - costs between $12,000 and $15,000 per year. In many developing countries the average per capita income is less than $2,000 per year. Thus, in most of these countries these treatments are only available to the very rich, in the largest, often capital cities.

Worse than this, the UNAIDS survey shows that Pentamidine, a cheap treatment developed to treat sleeping sickness, which is effective in the treatment of PCP (pneumocystis carinii pneumonia) is available in only one of 20 countries. The price of Pentamidine has increased 500 per cent since it was discovered to be effective against AIDS-related PCP. Bleomycine, a treatment for Kaposis Sarcoma an AIDS related cancer, is available in only three of 20 countries. Most of these treatments are never available in rural areas.

While at current pricing levels these combination therapies seem beyond reach of people in developing countries, these treatments are not the most important drugs for us to be discussing. The first priority for extending the lives of people living with HIV and AIDS is access to inexpensive drugs that treat and prevent the development of the AIDS related opportunistic infections that kill most people with AIDS. It is especially troublesome that the drug companies are focusing the attention of the treatment access debate on their most over-priced and difficult to administer anti-retroviral drugs – their triple therapy cash cows.

What would have far more important immediate benefit to people living with HIV and AIDS would be access to these inexpensive drugs used to treat and prevent AIDS opportunistic infections. Most people with AIDS die of treatable and preventable opportunistic infections like TB, pneumonia, fungal infections and diarrhea related wasting (dehydration). Prior to the introduction of triple therapy significant reductions in AIDS related death rates were achieved in the US through the benefit of these inexpensive drugs to treat and prevent opportunistic infections.

TB prophylaxis for non- MDR-TB costs $15 per year in a WHO program in Uganda. PCP prophylaxis in HHS programs costs as little as $24 per year. NTZ - a wide spectrum anti-parasitic drug (to treat diarrhea diseases) and some of the older generic anti-fungal drugs (that are effective against thrush) costs less than the Uganda TB treatments. Thus for under $70 per year many fatal AIDS related opportunistic infections can be cheaply prevented, delaying the deaths of people with AIDS for several years. Generic production of these treatments and bulk buying can further reduce the costs of these treatments to even more affordable levels.

In the October 1998 UNAIDS report "Access To Drugs: UNAIDS Technical Update" several tables summarize the worlds' best practice treatments of the most common and deadly infectious diseases; the drugs that are effective; their wholesale prices; the proprietary or generic status of their patents; and the obstacles to access in the developing world. Access to these essential treatments for HIV opportunistic infections and the HIV virus are - in almost every case - listed as blocked, most often by high prices or patent limitations.

Trade policies like compulsory licensing and parallel importing can improve the injustice of this unequal access to the more expensive newer essential medicines – like those in the standard triple therapy – by helping to lower the price of essential drugs to levels affordable by individuals living in developing countries. This is achieved by price reduction brought about through the competition that generic equivalents introduce into the market place. Generic versions of AZT produced in India have provided generic versions of AZT that cost $34 for a one month supply – compared to the $250 charged by Glaxo-Wellcome

For years the US government has failed to pursue several proven effective AIDS education and prevent programs because it lacked the political will to take brave positions on controversial issue. Countries like Australia, Holland, Kenya, Switzerland and Uganda have kept HIV infection rates low by introducing proven prevention techniques like massive public condom promotion programs and needle exchange programs. Such programs have kept infection rates tens of times lower in these countries - - because they

did not let moral rhetoric interfere with sound public health policy. It is time that the US government led the charge to implement these proven programs worldwide. The public health of our planet demands this.

For far too long the US government has allowed the commercial interests of the tobacco and pharmaceutical industries to drive trade policy without considering the public health implications of this action. It is time that our government realizes that trade policies often have far-reaching public health consequences. We must stop setting trade policies in a moral and intellectual vacuum that does not consider the related public health implications.

Instead of siding with special interest groups like the pharmaceutical industry and instituting governmental trade sanctions to protect the profits of greedy drug companies, – the US government should be pressuring drug companies to consider two-tier pricing systems that provide access to these essential live-saving medicines at levels affordable to people in the developing world.

While Vice President Gore's recent announcement to seek an additional $100 million dollars appropriation for the US government's global AIDS initiatives in fiscal year 2001 shows that the administration is listening to our demand for increased action, it is a drop in the ocean. Between five and seven million more people will die of AIDS before this allocation is spent, provided Congress agrees to fund the request.

In meetings last month with Sandy Thurman we urged the administration to immediately issue additional licenses to governments like South Africa and Thailand, and to the World Health Organization to produce affordable generic equivalents of the US taxpayer-funded AIDS treatments to which the US government retains some ownership rights. It is our understanding that ddi, d4t, 3tc, Norvir and the cancer drug Taxol are all candidates for such additional licenses. Such action could provide millions of poor people with access to these taxpayer-funded medical inventions. And such actions would not require additional expenditures of tax dollars. Nor would such action require drug company or Congressional approval.

Similarly the administration must abandon its practice of promoting prevention and education programs without accompanying treatment access programs or Human Rights initiatives. It has been demonstrated that the most effective education and prevention programs are those run by HIV infected individuals who can put a face on the illness. In order to encourage infected individuals to risk discrimination and persecution for disclosing their illness, programs are needed to insure that their human rights are protected. Similarly, providing incentives like access to treatment give infected individuals a reason to risk self-disclosure of their illness.

At the Amsterdam Conference Jonathan Mann called for the creation of a global movement to fight for equal international access to health. In that spirit, we in the AIDS activist community are attempting to put governments of the developed world, United Nations Agencies, and the multi-national drug companies on notice. We are outraged that governments, UN Agencies, and multi-national drug companies are engaging in policies that have allowed more than 14 million poor people of color in developing countries to die of AIDS during the first two decades of this pandemic. In the same vein, we believe that the governments of the developed world of contributing to the genocide an additional 34 million more people through government inaction – for our governments are failing to respond appropriately to the pending deaths of tens of millions of people from AIDS. As an American I am outraged that my government is pressuring developing countries not to exercise their right to produce affordable generic versions essential medicines, by imposing trade sanctions to protect the profits of drug companies.

The governments of Thailand, India and South Africa are currently in dispute with our government over compulsory licensing of medicines—the manufacture of essential drugs that waives most of the patent protections companies normally, rightfully claim for their products. The World Trade Organization specifically allows any member state to issue a compulsory license of any product deemed essential for the safety of its populace. The drug companies are angry, of course—their profits are at stake. Drug companies claim that they must protect their current high profit margins to generate funds to re-invest in new drug research. In reality however, most pharmaceutical compounds designed to fight infectious diseases, are invented in the governmental laboratories like those at the National Institutes of Health, and are then given

to the drug companies to test and market. A far higher portion of the profits of drug companies is spent on advertising and marketing expenses than on research and development.

When history evaluates the role of the US government in combating the global HIV pandemic, it will no doubt give the US government a failing grade for not responding with a sense of urgency to the worst health crisis to face mankind during the modern age. Current Surgeon General Satcher has stated in the Journal of the American Medical Association that the global AIDS pandemic is worse than the Black Plague of medieval Europe, yet we fail to respond with any emergency actions such as we undertake when storms or fires destroy personal property within our borders. Why do we not respond in the same way to the impending deaths of millions of Africans?

When activists like GHMC Founder Larry Kramer began sounding the alarm about the dangers of AIDS on television programs like the Phil Donahue Show in the early 1980s -- there were less than 400 reported AIDS deaths worldwide. When ACT UP activists like myself started a civil disobedience movement in 1987 to draw public attention to the AIDS crisis -- there were less than 20,000 reported AIDS deaths in the US. There have now been more than 13 million AIDS deaths and there are estimated to be at least 34 million more cases of HIV infection world-wide – with more than 98 per cent of these cases in the developing world where access to the promising therapies are priced out of the reach of all but the very rich. This lack of healthcare access means almost certain death for the majority of these 34 million individuals living with HIV. Public Health experts agree that HIV is fueling the resurgence of diseases like TB and Malaria. What will it take for the US government to respond with a sense of emergency to the global AIDS crisis? Will our government respond when HIV succeeds in facilitating the total melt down in global public health that lurks on the horizon of the not too distance future?

The administration is establishing international trade policy in a moral and intellectual vacuum—where the only thing that matters is the economic impact of trade on Western multinationals. The White House ignores the moral and public health consequences of its trade policies. It is time that the government realized that the trade policies it is trying to unilaterally set have moral implications and resulting public health consequences. What is happening in South Africa proves that the World Health Organization must be involved in any dispute about international pharmaceutical trade issues when access to essential health products is involved. And the World Trade Organization's regulations allowing for compulsory licensing and parallel importing in cases such as these—regulations, which were agreed to by the United States and every other member of the WTO—must not be ignored at the behest of a powerful industry lobby. Whatever the lobby, whatever the pressure, our leaders should have the courage to say no.

The Global Village is much more than a Global Market. Disowning anyone in the village—because they don't buy enough of our merchandise, because they are weak, because they don't look like us, because we are too apathetic to work for their well-being as well as our own—is not just immoral, it is a threat to public health and humanity. In a global village there is one global public health. The hundreds of thousands of international flights circling the globe each year are just glamorous routes by which disease can travel more rapidly around an ever-more crowded planet. Diseases like AIDS, TB and Malaria are spreading rapidly across all borders.

Now that the United States of America has emerged as the only remaining super power, our government must stop abusing its power to protect the profits of industry instead of promoting the human rights and health of people in the developing world. It is time we realize that the public health of South Africa is also the public health of the United States and start acting accordingly. We must not rest until every person with HIV, tuberculosis, and the host of other infectious diseases enjoys equal access to treatments. Access to health is a Human Right!

Statement PhRMA

Testimony By John Siegfried, M.D.
on Behalf of the
Pharmaceutical Research and Manufacturers of America
Before the Subcommittee on Criminal Justice, Drug Policy, and
Human Resources, of the Government Reform Committee
on U.S. Global HIV/AIDS Policy
July 22, 1999

Thank you, Mr. Chairman and members of the Subcommittee, for inviting PhRMA to testify today on the issue of whether the pharmaceutical industry is critical to the effort in combating the HIV/AIDS epidemic. By way of introduction, I am Dr. John Siegfried. I serve in a consultant capacity as Senior Medical Officer for the Pharmaceutical Research and Manufacturers of America. As a PhRMA employee from 1992 to 1998 I lived in the District of Columbia and was a volunteer physician caring for AIDS patients on a regular basis at the Elizabeth Taylor Medical Center of the Whitman Walker Clinic - a leading AIDS facility in the District.

PhRMA is the trade association representing the American research-based pharmaceutical industry. Defined by their commitment to innovative research and development, PhRMA member companies lead the way in the search for new medicines and vaccines that save lives, improve the quality of life, and often provide the most effective and cost-effective health care for patients.

In the area of therapies for HIV/AIDS, the contribution made by the U.S. pharmaceutical industry is nothing short of remarkable. The first reports of a mysterious illness, later identified as HIV/AIDS, appeared in the medical literature in 1981 and the HIV virus was identified in 1983. The first HIV/AIDS treatment was approved only in 1987. Since then 54 medicines have been approved for

HIV/AIDS and associated conditions, and an additional 113 are in development, most of which are being developed by the research-intensive pharmaceutical companies. Government and academic scientists generally led the way in advancing basic knowledge about HIV/AIDS, although pharmaceutical companies have contributed. And the industry has led the way in translating those advances in knowledge into anti-HIV/AIDS medicines to help patients.

Drug discovery and development in the U.S. usually takes 12 to 15 years from the test tube to the pharmacy. The development of 54 medicines within only a decade and a half is thus an unprecedented accomplishment. The National Institutes of Health, particularly the National Institute of Allergy and Infectious Disease with its Division of AIDS, led in advancing our basic knowledge. Pharmaceutical companies led the discovery and development of medicines to help HIV/AIDS patients. And the Food and Drug Administration expedited review and approval of these life-saving medicines.

Equally unprecedented are the results of this effort in the United States, and in many other developed countries. The death rate from AIDS in the U.S. dropped by nearly one-half from 1997 to 1998 - - the largest single year decline in any major cause of death ever. The health of many HIV-positive patients improved. Many have returned, and are returning, to work and leading more productive lives. Often the demand for more expensive secondary and tertiary health care services has declined as a result of newer therapies, providing the most cost-effective health care for HIV/AIDS patients. The new products not only best help many patients, but also can reduce the need for other medicines to treat the diseases associated with AIDS and the need for treatments in hospitals and hospices.

The foundation on which this progress rests is investment in innovative research and development. And it is in the area of applied research and development that the pharmaceutical industry excels. It is the industry's role in this crisis to lead the

way in the discovery and development of pharmaceutical and biotechnology products that can play a critical role in HIV/AIDS treatment and prevention. But not all patients and not all countries can afford them. Effective responses to the HIV/AIDS challenge in developing nations must take into consideration all the relevant factors, including medical infrastructure, available resources, disease awareness and prevention initiatives and, most importantly, national commitment and leadership to make HIV/AIDS a public health priority.

The principal role of the research-based U.S. pharmaceutical industry in confronting HIV/AIDS world-wide is to continue what it does best -- to marshal the expertise and capacity in applied biomedical research and drug development to discover new and more effective treatments. In cooperation and collaboration with scientists in the government and academia, some pharmaceutical companies are also seeking to discover and develop an effective HIV vaccine, which ultimately would be the most effective and cost-effective way to prevent HIV/AIDS and to respond to the global AIDS pandemic.

Investors in pharmaceutical companies seek a return on their investment commensurate with the large risk they assume. The current cost of bringing a pharmaceutical product to market averages $500 million, and only one of five to ten thousand compounds tested ever reaches the marketplace. Additionally, of marketed products, on average only one in three generates revenues that meet or exceed average R&D costs. The U.S. pharmaceutical industry is spending $24 billion on research and development this year, including approximately $2 billion on research and development of HIV/AIDS-related drugs. Over 20 percent of all domestic sales revenues go back into research and development - - the highest proportion of any industry with which we are familiar. Intellectual property protection and market pricing are the keystones of, and are essential to, this research effort.

The research-based U.S. pharmaceutical industry has contacts with government

and health agencies around the world and, therefore, is well positioned to provide input in the area of national health education and policy. This expertise complements and supplements the responsibilities and expertise of other members of the world health care community, both public and private.

Let me give you several examples:

- Bristol-Myers Squibb is spending $100 million over five years in five southern African countries to fund extensive AIDS research trials, improve training for more than 200 physicians, and help non-governmental organizations bolster community AIDS-prevention and treatment programs. The company also has developed a pediatric AIDS program in Mexico - donating drugs to cover all untreated cases of pediatric AIDS in the country and providing physician training and community outreach.

- The Merck Company Foundation is underwriting the Enhancing Care Initiative, an initiative coordinated by the Harvard AIDS Institute and the Francois-Xavier Bagnoud Center for Health and Human Rights at the Harvard School of Public Health. The Enhancing Care Initiative will address the issue of HIV/AIDS in the developing world by bringing together the best possible expertise within specific countries, including representatives of the local HIV community. The goal is to customize specific, practical improvements that will help to advance the quality, delivery and outcomes of HIV care for men, women and children living with HIV/AIDS, not only in the initial countries selected (beginning with Senegal and Brazil), but in a broad range of developing countries throughout the world.

- Glaxo Wellcome is providing deeply discounted prices for AZT, to combat mother-child vertical transmission, in cooperation with UNAIDS. In addition, the company is sponsoring a program called Positive Action. Positive Action's activities are devoted to initiatives and organizations in developing countries. For example, intensive training is provided to developing country community groups and non-government organizations that identify and meet local needs to improve the delivery of HIV/AIDS care. The company also founded the Global Business Council on HIV/AIDS, a consortium of private and public sector groups whose objectives are to advance private sector HIV workplace policies.

These activities in the private sector complement the initiatives of others -- including the HIV community, governments, and international organizations.

Conclusion

Broadening access to modern health care in developing countries, including pharmaceuticals, is a complex challenge. While the HIV/AIDS pandemic creates special challenges, the needs of patients world-wide with tuberculosis, cancer, parasitic and fungal infections does not lag far behind. Many countries lack the broad public health infrastructure necessary to support the use of complex regimens of anti-HIV treatments.

Many AIDS experts, such as Dr. Thomas Coates, Executive Director of the University of California at San Francisco's AIDS Research Institute, have been quoted as saying that delivery of complex, demanding AIDS drugs without the necessary infrastructure and supervision is a "recipe for disaster" Dr. Herman's comments today echo this sentiment. It is neither feasible nor desirable to simply import treatment regimens from other countries into South Africa. This is true for the disease HIV/AIDS and for many other health conditions. These are complex issues that can only be addressed through collaborations involving industry, government, international organizations, patient and medical groups. All are vital to finding workable solutions that will help patients with HIV/AIDS lead better lives and prevent others from contracting AIDS.