WHAT IS THE U.S. ROLE IN COMBATING THE GLOBAL HIV/AIDS EPIDEMIC?

HEARING

BEFORE THE

SUBCOMMITTEE ON CRIMINAL JUSTICE, DRUG POLICY, AND HUMAN RESOURCES

OF THE

COMMITTEE ON GOVERNMENT REFORM

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WHAT IS THE U.S. ROLE IN COMBATING THE GLOBAL HIV/AIDS EPIDEMIC?

THURSDAY, JULY 22, 1999

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON CRIMINAL JUSTICE, DRUG POLICY,
AND HUMAN RESOURCES,
COMMITTEE ON GOVERNMENT REFORM,
Washington, DC.

The subcommittee met, pursuant to notice, at 11:30 a.m., in room 2154, Rayburn House Office Building, Hon. John L. Mica (chairman of the subcommittee) presiding.

Present: Representatives Mica, Gilman, Mink, Cummings, and Kucinich.

Also present: Representatives Lantos, Norton, Schakowsky, and Sanders.

Staff present: Sharon Pinkerton, deputy staff director; Steven Dillingham and Mason Alinger, professional staff members; Cherri Branson, minority counsel; and Jean Gosa, minority staff assistant.

Mr. MICA. Good morning, I would like to call this meeting of the Subcommittee on Criminal Justice, Drug Policy, and Human Resources to order.

Today's hearing is entitled, What Is the U.S. Role in Combating the Global HIV/AIDS Epidemic?

We will start this morning's hearing, as usual, with opening statements. I will give my opening statement, present a brief video, and then yield to members on our panel. We will then hear from our first panel of witnesses.

We will be joined shortly by our ranking member, but we would like to proceed, because we have a full schedule today.

Today, this subcommittee will address an issue that is unequalled in both its complexity and its urgency. That is, 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 most certainly a humanitarian issue that we cannot ignore.

Our subcommittee was recently reconstituted and vested with oversight of health and trade issues. We are committed to understanding both the nature and magnitude of this epidemic, and also to ensure the proper role of the U.S. Government in combating this disease.

Recently, we held a hearing on another terrible infectious disease, hepatitis B, and the importance of vaccines and properly designated vaccination policies in combating infections and meeting the health concerns of our citizens.

Today and in the future, this subcommittee will perform its oversight responsibility, examining health-related programs and practices that are both promising and also that will save lives.

As we will hear today, the AIDS epidemic is global and horrific. It continues to spread across the globe unabated. We will learn that no area of the world has been harder hit than the continent of Africa, particularly sub-Saharan Africa, where two-thirds of the world's infected population resides.

Other continents and regions are also at risk today. Witnesses will tell us firsthand of the devastating impact 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 also 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 going to do to make certain these new drugs are available to developing countries that need them? Tragically, there are nearly 600,000 African babies newly infected each year; 9 out of every 10 infants infected with HIV at birth or through breast-feeding live in sub-Saharan Africa.

This hearing will also focus on the critical and complicated issues of drug treatment for HIV and 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 other infectious disease. Imagine, in less than two decades, AIDS has become the leading killer out of all known infectious diseases.

As you can see in the chart we have prepared, and I think it is right over here, more than 33.4 million adults and children are estimated to be infected with HIV/AIDS. This disease has already killed 14 million people. Of those, approximately 12 million, almost all are African.

Today, more than 22.5 million Africans are living with HIV/AIDS. Reportedly, 95 percent of Africans with AIDS have not been tested, and 90 percent are unaware that they even 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 is estimated to reach a staggering 500,000. Zimbabwe, a nation of 12 million citizens, reports 600,000 orphans, most being supported by grandparents or other relatives. Uganda, with a population of 20 million people, 10 percent of whom are now HIV-positive, also reports 600,000 children having lost at least one parent, and about a quarter of a million children having already lost both parents.

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

These numbers are devastating, and the personal tragedies 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 issues: What are we doing about this global epidemic, and what should we do about it? Part of that is linked to our trade policy, and part of that is also linked to our health policy.

First, what actions are we now taking 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 also by 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 on this matter, sometimes even contradictory. Should we, through the office of our United States Trade Representative, apply economic pressure 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 and AIDS prevention and treatment in developing nations, rather than imposing rigid licensing and import practices?

Is it necessary for AIDS-stricken developing nations to rely on periodic pronouncements of intentions to provide limited foreign aid from the United States? And I wrote this before, I guess, the announcement recently of $100 million, I believe, being offered by the Vice President and the administration.

Can nations in need and the pharmaceutical industry negotiate a solution that meets the growing health and humanitarian needs, while also ensuring that a reasonable profit is made to support future drug development?

These are all tough questions that this Nation and this Congress must address, as we are, in fact, the world's foremost economic power; a world leader in science, technology and trade.

The second question is what should we do about the epidemic? In answering this question, let me share with you one description of a crisis and possible response that was highlighted recently in a national television news segment. This takes several minutes, but I think it is worth our time. It is not a scientific piece, but it does show us, firsthand, the situation.

With Members' forbearance, I would like to show it.

We will play that tape.

[Videotape played.]

Mr. MICA. I would say that this news video is very short and superficial. It illustrates the tragedy of the epidemic, raises a number of questions, and also presents us with a dilemma: Does drug treatment delivery in developing countries pose significant risks of new strains of AIDS?

I hope we will learn more about this issue today, and about some of the trade and health implications mentioned. I am convinced that we cannot leave ourselves to do nothing to help these nations

and these people, and I cannot believe that there is no other recourse for us but to watch millions of people die without treatment.

Here in the United States, while AIDS continues to spread, AIDS deaths have dropped recently by 47 percent, primarily due to new drug treatments that prolong lives and allow people to remain productive, and the availability within our market of these treatments. I hope that we can do much more for other nations and our trading partners who are now 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 percent 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 our country because she cannot acquire the drug treatment in her native Africa that she needs.

The survey also found that more than 80 percent of Americans see AIDS as a bigger problem today than they did 10 years ago, despite advances in treatments. The United States plays a vital role in the global economy, and we also remain a Nation at risk. Recent data indicates that the infection rate among American women is increasing more rapidly than among males. As I said at the beginning, African Americans are 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 proceed expeditiously. We also should assist, not hinder, developing nations and our trading partners in their efforts. I cannot fathom that we simply wait while the epidemic reaches the multiples of the 14 million AIDS casualties who have already died from this horrible disease. The millions of infected babies, orphaned children, new infections each year, and deaths that occur internationally without treatment are simply unacceptable. This crisis demands our immediate attention from this government, and more than a Band-Aid approach.

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

I look forward to the testimony of our witnesses, and we have many of them today. This is a topic that has raised a great deal of interest and attention, rightfully so, because it is the greatest health threat facing the world.

I wish to thank my colleagues in Congress for sharing their ideas with the 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 that we have a moral and humanitarian responsibility to publicly air this incredible human tragedy, and our response should be done both as a Congress and as a civilized Nation. Years from now, and millions of deaths later, we must not be accused of turning our backs on this great holocaust.

[The prepared statement of Hon. John L. Mica follows:]

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 <u>should</u> 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.

Mr. MICA. I am pleased at this time to yield to our distinguished ranking member, the gentlewoman from Hawaii, Mrs. Mink.

Mrs. MINK. Thank you, Mr. Chairman. I do not have an opening statement, but I do want to join you in your remarks, and certainly lend my support to this inquiry, and to join you in expressing hope that as a result of the hearings and the testimony today, we can be guided to a policy for this country that can adequately meet this terrible need.

I want to particularly extend a welcome to our distinguished witnesses today, and look forward to their comments. Thank you, Mr. Chairman.

Mr. MICA. Thank you.

I am also pleased that we are joined by the gentleman from California, Mr. Lantos, who is not a member of the subcommittee, but the full committee. We are so pleased to have him join us for the subcommittee hearing this morning.

Mr. LANTOS. Thank you very much, Mr. Chairman. Let me first commend you for holding this extremely important hearing.

The other committee on which I serve, the House Committee on International Relations, held a hearing on the spread of AIDS in the developing world on September 18, 1998, and I would be grateful if my formal statement before that committee could be entered in the record.

Mr. MICA. Without objection, so ordered.

Mr. LANTOS. Mr. Chairman, the word "historic" is often overused, but it certainly is not overused in this instance.

I remember I was a young schoolboy studying European history when I was first introduced to the concept of the bubonic plague. The bubonic plague took place 652 years ago, in the year 1347 in Europe, and it killed about 20 million innocent human beings. I recall as a boy the concept of 20 million people being killed by a disease was mind-boggling and incomprehensible.

More recently, in 1917, another 20 million innocent human beings lost their lives because of the influenza epidemic, and today we are facing the nightmarish impact of AIDS.

I truly believe that if there is any issue before the Congress that deserves full bipartisan support, funding, and cooperation, it is the AIDS epidemic. I want to commend the Clinton-Gore administration for proposing an additional $100 million to deal with this issue.

I also want to commend the First Lady for convening a donors conference earlier in September involving international organizations and other governments capable of making major contributions in dealing with this issue.

The recently released report entitled "Report on the Presidential Mission on Children Orphaned by AIDS in Sub-Saharan Africa," is one of the most sobering pieces of literature issued by any government agency in a long, long time.

We are dealing with millions and soon tens of millions of children in desperately poor countries in Africa who will be orphaned because their parents died of AIDS. I could think of no nobler effort on the part of the wealthy nations of this world than to combine forces to try to mitigate the unspeakable human horror that will be inflicted upon vast numbers of people.

It is always easier to focus on the plight of a single individual or a single family. In recent days, our Nation as a family has focused on the tragedy of the Kennedy family, and rightly so. I think we need to multiply this by millions to begin comprehending the scope of what AIDS is doing to millions and tens of millions of families, particularly in the less developed parts of the world.

I very much look forward to listening to our distinguished witnesses. Again, Mr. Chairman, I want to commend you.

Mr. MICA. Thank you.

Not in order of seniority, but in order of arrival, and she also serves on the full committee, Mrs. Schakowsky from Illinois is recognized.

Mrs. SCHAKOWSKY. Thank you, Mr. Chairman. I wanted to thank you and Representative Mink for allowing me to participate in this very important hearing. I do not have a formal opening statement, and just wanted to tell you that I am here because I am so concerned that the United States play a constructive role in addressing this worldwide pandemic, and I look forward to hearing from all of our witnesses. Thank you.

Mr. MICA. Thank you so much.

Again, in order of arrival, I would like to recognize the very distinguished gentlewoman, the delegate from the District of Columbia, Ms. Norton.

Ms. NORTON. Thank you very much, Mr. Chairman. I appreciate your indulgence. While on the full committee, I am not on the subcommittee, but I have a very special interest in this subject, as does the Congressional Black Caucus, which has devoted a lot of time, effort and energy because of our great concern about this subject, both as it relates to Africa and to the United States.

The video that you showed was a very important one, because it showed what the absence of drugs and prevention can do, and it drew our attention to the reality that there is no one approach that will work here or in Africa.

I am particularly concerned with how we go about dealing with this epidemic. I am interested in the way in which there has been an emphasis on drugs and drug therapy.

I represent the District of Columbia, where there is a runaway AIDS epidemic. You indicated that deaths from AIDS have gone down. That does not include African Americans. Indeed, this disease has now transmitted itself such that whereas it was stereotypically seen as a gay disease before, it could properly be called a black and Hispanic disease today.

When it comes to drug therapy, one of the reasons that deaths from AIDS are not going down, but, indeed, are going up in the African American community is that the drugs are so expensive. Even if they were not, the regimen that it requires is something to behold, the numbers of pills that must be taken, the order of those pills.

Very importantly, the video indicated that we are finding that some strains of AIDS may be resistant to drugs, because if not taken in the proper manner in which they must be taken to be effective, not only do they not help, but they hurt in the worst possible way by perhaps creating a different and more powerful strain of the disease that is even more resistant to drugs.

That is, of course, why the country here and Africa needs to concentrate on prevention. Even if we were to get, as we must, more drugs in Africa, who can believe that any but the elites will have access to those drugs? If we are seriously interested in stamping out AIDS in Africa, it is inconceivable to believe that the drugs could be priced low enough so that anything but the rarest of the upper classes would get them, including the government officials and elites who have AIDS. More power to them. We must get those drugs there. But for goodness sake, black people in this country cannot get the drugs, and poor people do not have the lifestyle that enables them to take the drugs in the order and in the rank and with the regime that is required.

I am a little frustrated by the emphasis on drugs and with so little emphasis on preventing this disease, because I do not believe that the drugs are the answer in the African American community here; it is pitiful to think that the drugs will do anything for the epidemic in Africa going on today.

It is very important that we are finally having a subcommittee look at this issue, so that we can get the full range of the problems out there. I would hope that we see a change on the House floor this year, because there is a controversy that began in this House with a provision of the foreign operations bill that cutoff all United States aid to the central Government of South Africa. That aid was not to be restored until the State Department submitted a report describing what it was doing to force a change in the South African Medicines Act. That is the act that would allow South Africa to import drugs at lower drug prices, making them available in that country.

I am for that, as much as I think that is a drop in the ocean, compared to what we think the epidemic means in South Africa and in the rest of Africa today. That provision was put in the bill by Representative Frelinghuysen from New Jersey, where many of the pharmaceutical companies are based. He has threatened to write a tougher provision in the law this year.

If we are serious about providing drugs and making them more readily available in Africa, there is something that this committee and this House can do this year, and that is to make sure that the Frelinghuysen amendment no longer requires the State Department to fight the South African Medicines Act that would allow them to import drugs at lower prices.

Thank you, Mr. Chairman.

Mr. MICA. I thank the gentlewoman.

I am pleased to recognize a member of our subcommittee, the gentleman from Ohio, Mr. Kucinich.

Mr. KUCINICH. Thank you, Mr. Chairman, members of the committee, and Members of Congress who are participating in this. I certainly want to welcome our colleagues, Mr. Berry and Mr. Jackson, as well as the gentlewoman who is participating from Malawi.

Mr. Chairman, when we look at some of the background materials which this committee was provided with in preparation for today's hearing, some of the things that cannot help but jump out at us are things such as: As goes Africa, so will go India, Southeast Asia, and the newly independent states, and by 2005, more than 100 million people worldwide will be HIV-positive.

This report from the White House states that

AIDS in sub-Saharan Africa, notes the United Nations, is the worst infectious diseases catastrophe since the bubonic plague. Deaths due to AIDS in the region will soon surpass the 20 million people in Europe who died in the plague of 1347 and more than 20 million people worldwide who died in the influenza academic of 1917. Over the next decade AIDS will kill more people in sub-Saharan Africa than the total number of casualties lost in all wars of the 20th century combined.

Mr. Chairman and fellow committee members and members of the panel, I am very appreciative that the Chair has called this meeting so that we can continue an inquiry into the horrific spread of AIDS and HIV across Africa and Asia. At a time when 47 million people around the globe are living with the epidemic of HIV affecting their lives, and perhaps, more tragically, one-quarter of all children in many sub-Saharan countries have lost both their parents to this terrible disease, this hearing is timely and important in addressing this emergency.

The United States must do everything in its power to counter this deadly disease by playing the leading role in helping to combat the problem.

Appearing to be the hardest hit by the AIDS epidemic have been the populations of the developing countries. Currently 95 percent of those living with AIDS are in developing countries, and the disease tends to be most prevalent among those aged between 25 and 44 years. This has serious implications for the functioning of economic systems, in addition to the more obvious health and humanitarian consequences.

It is obvious that this situation will not be ignored, and therefore, it lends even greater importance to the work of our chairman and the ranking member in seeing that this hearing has been facilitated.

Though 95 percent of new HIV infections occur in developing countries, more than 90 percent of the resources spent on HIV and AIDS prevention and care are devoted to people in industrialized countries. The developing countries simply cannot afford the high cost involved in the supply of these treatments, often lacking the qualified physicians or infrastructure needed to bring the drugs to those in need. Vital drugs are often kept artificially high in their prices by the pharmaceutical industry, which, as we know, is a very lucrative sector with average profits of close to 20 percent last year.

However, there is an option which may avoid this problem and enable countries in need to access these drugs vital to many of their citizens. Parallel imports allow expensive patented drugs to be sold through a third country at a more reasonable price. These imports are not in violation of WTO rules, contrary to the drug companies' complaints, and are deemed legal transactions in the world economy.

More effective awareness campaigns would be another solution. For too long, we have seen governments involved closing their eyes to the problem, ignoring the sheer scale of the problem, and failing to initiate successful education and prevention programs, similar to those that have proven successful in combating HIV infection in industrialized countries. Programs can be set up with minimum cost, and the benefits reaped in return can far outweigh initial outlays.

Mr. Chairman and the ranking member, I look forward to learning of the ways in which the United States can play a more active role in alleviating this human tragedy. We have the opportunity and the responsibility to make this a healthier world and to help those less fortunate than ourselves. I believe this aim can be achieved if we are willing to keep an open mind. Thank you very much, Mr. Chairman.

Mr. MICA. I thank the gentleman.

[The prepared statement of Hon. Dennis J. Kucinich follows:]

Opening Statement for

Dennis J. Kucinich

Criminal Justice, Drug Policy and Human Resources subcommittee

11.30 am on July 22nd 1999

Mr. Chairman, fellow committee members, and members of the panel, I welcome the committee in holding this important inquiry on the horrific spread of AIDS and HIV across Africa and Asia. At a time when 47 million people, across the globe, are living with the epidemic of HIV affecting their lives and, perhaps most tragic of all, one quarter of all children in many sub-Saharan countries have lost both their parents to this terrible disease, this hearing is both timely and important in addressing this emergancy. The United States must do everything in its power to counter this deadly disease by playing the lead role in helping to combat the problem.

Among the hardest hit by the AIDS epidemic have been the populations of developing countries. Currently 95% of those living with AIDS are in Developing countries, and the disease tends to be most prevalent amongst those aged between 25 and 44 years of age. This has serious implications for the functioning of the economic systems, in addition to the more obvious health and humanitarian implications, it is obvious that this situation can not continue.

Though 95% of new HIV infections occur in Developing countries, more than 90% of resources spent on HIV and AIDS prevention and care are devoted to people in industrialized countries. These countries simply can not afford the high costs involved in the supply of these treatments, and often lack the qualified physicians or

infrastructure to bring the drugs to those in need. These vital drugs are often kept artificially high by the pharmaceutical industry, an incredibly lucrative sector with average profits of close to 20% last year.

However, there is an option which may avoid this problem and enable countries in need to access these drugs, vital to many of their citizens. Parallel imports allows expensive, patented drugs to be sold through a third country at a more reasonable price. These imports are not in violation of WTO rules, contrary to the drugs companies complaints, and are deemed legal transactions in the world economy.

More effective awareness campaigns could be another solution, for too long the governments involved have closed their eyes to the problem, ignoring its sheer scale and failing to initiate successful educational and prevention programs, similar to those that have proved successful in combating HIV infection in industrialized countries. These programmes can be set up with the minimal of costs but the benefits reaped in return far outweigh this initial outlay.

Mr Chairman, I look forward to learning of any way in which the US can play a role in alleviating this human tragedy. We have the opportunity and the responsibility to make this a healthier world, and to help those less fortunate than ourselves, and I believe this aim can be achieved if we keep an open mind.

Mr. MICA. Now I recognize the gentleman from Maryland, Mr. Cummings, for an opening statement.

Mr. CUMMINGS. Thank you very much, Mr. Chairman. I am glad that we are taking this time to address our Nation's role in combating the HIV/AIDS pandemic.

Just this past Tuesday, Congresswoman Nancy Pelosi and I held an AIDS Task Force meeting, which she and I co-chair, to address similar issues.

Since the early 1980's, the AIDS virus has not only plagued and crippled American society, but the global community as well. Just back in December 1997, I visited Zambia, the Ivory Coast, Ghana, and Uganda on behalf of Johns Hopkins University and Hospital, which are located in my district, and had an opportunity to see firsthand the crippling and devastating effects of AIDS.

Today, I want to make sure that we are all singing from the same page. We are holding this hearing, and I think we can easily argue on both sides that something should be done, but if it is politics as usual, I think that is almost criminal, because people are dying as we speak.

As a matter of fact, when I was in Zambia in 1997, I had an opportunity to meet a number of people, some of whom, while I was there, died from AIDS. As a matter of fact, in Zambia, what they do is they have coffins; they sell coffins outside of the hospital. A lot of people going in know that they won't be walking out.

So when I look at the AIDS Action Council voting percentages, I really wonder whether this is real or whether we are just sort of going through some motions. Thirty-three million people worldwide are infected with HIV and have full-blown AIDS, and 90 percent of them live in Africa, Asia, and Latin America. Significantly, however, 90 percent of the resources spent on HIV/AIDS prevention and care are devoted to people in industrialized countries.

AIDS and HIV prevention are topics of particular importance to me, as I have seen firsthand the effects that these deadly viruses have on communities, particularly in my home district of Baltimore, where AIDS is the No. 1 killer of our young people, aged 24 to 45, while in the prime of their productive years.

I am encouraged that this important issue is finally receiving the attention by Congress that it deserves, but again, I want to make sure that it is not something simply being politicized, but something that we are, all of us, doing something about.

The introduction of this virus and its incredible widespread growth has caused unmatched devastation. Although we have made great strides in the promotion of AIDS research, awareness, and prevention in our country, we are facing an uphill battle on the global front. That is why I believe efforts like the Vice President's new initiative to combat AIDS in sub-Saharan Africa are a step in the right direction.

However, $100 million is not very much money when we are talking about countries like Zambia, where there are 650,000 orphans, who have been orphaned because of AIDS, and in a country like Zambia, where I personally witnessed people having their teeth extracted with no kind of anesthesia because the country was so poor.

In a country like Zambia, we have people sitting in open-air clinics, sometimes waiting for as long as 2 or 3 days for a nurse practitioner to see them, only so often to be told that they do not even have pills for children's diarrhea. So $100 million is nice, but that does not go very far. And I am just talking about one country.

Mr. Gore's initiative serves to contain the AIDS pandemic on the international level, provide home- and community-based care, offer care for children orphaned by AIDS, and strengthen prevention and treatment by supporting infrastructure, disease surveillance and capacity development. But as I said before, it is a step in the right direction, but it is simply not enough. I strongly believe that it is important for us to critically examine the U.S. role in combating this global epidemic.

In doing so, I look forward to the hearing today and the testimony from the witnesses to discover the best ways to develop initiatives to strengthen the fight against AIDS worldwide and help some people in countries like the Ivory Coast, Zimbabwe, Zambia, Ghana, Uganda address this dreadful disease.

With that, thank you.

Mr. MICA. I thank the gentleman.

[The prepared statement of Hon. Elijah E. Cummings follows:]

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Congressman Elijah Cummings
Subcommittee on Criminal Justice, Drug Policy, and Human Resources
Statement--HIV/AIDS Hearing
July 22, 1999

Thank you, Mr. Chairman.

I would like to thank the Chairman for taking the initiative to schedule this timely hearing on our nation's role in combating the HIV and AIDS pandemic. Just this past Tuesday, Congresswoman Nancy Pelosi and I held an AIDS task force meeting to address similar issues.

Since the early eighties, the AIDS virus has not only plagued and crippled American society, but the global community as well. Nearly 33 million people worldwide are infected with HIV and have

Latin America. Significantly, however, 90 percent of the resources spent on HIV/AIDS prevention and care are devoted to people in industrialized countries.

AIDS and HIV prevention are topics of particular importance to me, as I have seen firsthand the effects that these deadly viruses have on communities, particularly in my home district of Baltimore, Maryland. And I am encouraged that this important issue is finally receiving the attention by Congress that it deserves. The introduction of this virus and its incredible widespread growth has caused unmatched devastation. Although we have made great strides in the promotion of AIDS research, awareness, and prevention in our country, we are facing an uphill battle on the global front.

That is why, I believe that efforts like Vice President Gore's new initiative to combat AIDS in sub-Saharan Africa is a step in the right direction towards fighting AIDS on an international level.

Gore's initiative serves to:

- contain the AIDS pandemic on the international level;
- provide home and community-based care;
- offer care for children orphaned by AIDS; and
- strengthen prevention and treatment by supporting infrastructure, disease surveillance, and capacity development.

I strongly believe that it is important for us to critically examine the United States' role in combating this global epidemic. In doing so, I look forward to hearing the testimony from the witnesses assembled, and to discover the best ways to implement initiatives that would strengthen the fight against AIDS worldwide.

Thank you, Mr. Chairman.

Mr. MICA. I am now pleased to recognize another member of our panel and subcommittee, and also the chairman of our Committee on International Relations.

As the gentleman from California, Mr. Lantos, pointed out, I think this is the second congressional hearing. He conducted the first congressional hearing on this issue, so I am pleased to recognize the gentleman from New York, Mr. Gilman.

Mr. GILMAN. Thank you. I want to commend you for conducting this hearing on such a critical issue facing not only nations in Africa, but throughout the world and our own Nation as well, and to try to find the best way to combat the HIV/AIDS epidemic.

We still have a long way to go. I am pleased that we heard recently this week, as a matter of fact, that there will be more funds from the administration contributed to this issue, but we have to encourage the international community to work together on this problem. It is a problem that has affected too many lives for too long. We are beginning to see some scientific and medical improvements. Of course, we still have a long way to go it in that direction.

So I commend you for bringing this again to the attention of the Congress. I commend our panelists who are here today, our Members of Congress, Mr. Berry, Mr. Jackson. It is good to have Ms. Nkhoma here from Malawi. We look forward to having the additional panelists from our administration, and we all look forward to working together to see what we can evolve by way of congressional assistance to combat this problem.

Thank you, Mr. Chairman.

Mr. MICA. I thank the gentleman.

I would like to now turn to our panel, they have been waiting most patiently. We have two distinguished Members of the House of Representatives who have joined us today and asked to provide testimony: First, the Honorable Jesse Jackson, Jr., from Illinois, and he is joined by Marion Berry of Arkansas.

Also on the panel, we are pleased to introduce Chatinka Nkhoma, a Malawi citizen, who will also testify.

I might say, just as a preface, that this is an investigations and oversight subcommittee of Congress. We do not swear in other Members of Congress, but we ask all others who testify to affirm and swear that their testimony is truthful.

With that, Ms. Nkhoma, would you stand and be sworn, please? Raise your right hand.

[Witness sworn.]

Mr. MICA. Thank you.

The other ground rule we have is that we try to limit our statements to 5 minutes, and we will be very glad to enter into the record lengthy additional statements or documents that might refer to your testimony.

With those comments, let me welcome our two Members and recognize first in the order of seniority our colleague Mr. Jackson from Illinois. You are recognized and welcomed, sir.

STATEMENT OF HON. JESSE JACKSON, JR., A REPRESENTATIVE IN CONGRESS FROM THE STATE OF ILLINOIS

Mr. JACKSON. Thank you, Mr. Chairman, Chairman Mica, Ranking Member Mrs. Mink. I want to thank you for this opportunity

to address the subcommittee during today's hearings on the U.S. role in combating the global HIV/AIDS epidemic, and the policies and programs that are being pursued internationally.

I want to comment just briefly on the gentlewoman from Washington's concern regarding the Frelinghuysen language. I offered an alternative in the foreign operations subcommittee hearing to the Frelinghuysen language. It was accepted by the committee, and Mr. Frelinghuysen committed to me in full committee that he will not offer it, so we have reversed the Frelinghuysen language, and he has been most accommodating and understanding.

As you are surely aware, Mr. Chairman, HIV/AIDS are rampaging throughout sub-Saharan Africa. While sub-Saharan nations comprise only 10 percent of the world's population, they are bearing the tragic burden of 70 percent of the world's new AIDS cases.

The World Health Organization reports that of the 14 million people who have died of AIDS to date, 12 million have come from this region. In the hardest hit countries, Botswana, Namibia, South Africa, Zimbabwe and Swaziland, infection rates in the 15-to–49 age group are an astonishing 25 percent. In tourist areas, such as Victoria Falls in Zimbabwe, the rates are even higher, 40 percent.

Please allow me to share an additional key finding from the Report on the Presidential Mission on Children Orphaned by AIDS in Sub-Saharan Africa released by the White House on Monday.

Deaths resulting from AIDS in sub-Saharan Africa will soon surpass the 20 million people in Europe who died in the plague of 1347. Over the next decade, AIDS will kill more people in sub-Saharan Africa than the total number of casualties in all wars in the 20th century. Each day 5,500 in the region die of AIDS-related causes. By 2005, the daily death toll will reach 13,000. There are nearly 600,000 new infections each year among African babies; 9 of every 10 infants infected with HIV at birth or through breastfeeding live in sub-Saharan Africa.

In nine sub-Saharan countries, from one-fifth to one-third of children will lose one or both parents to AIDS this year. In Lusaka, Zambia, 100,000 children are estimated to be living on the streets, most of them orphaned by AIDS. By next year, 1 million children in Zambia, or one out of three, will have lost one or both parents.

In large part, as a result of AIDS, infant mortality will double, while child mortality will triple over the next decade in many areas of sub-Saharan Africa. AIDS has reduced life expectancy in Zambia to 37 years from 56. In the next few years, AIDS will reduce life expectancy in South Africa by one-third, from 60 years, to 40.

Over the next 20 years, AIDS is estimated to reduce by one-fourth the economies of sub-Saharan Africa. In Malawi and Zambia, 30 percent of teachers are HIV-positive. In Zambia, 1,500 teachers died of AIDS-related causes in 1998 alone.

By 2005, AIDS deaths in Asia will mirror those in Africa. Asia will account for one out of every four infections worldwide by the end of the year. In India, rates of infection are expected to double every 14 months.

Finally, one in seven South Africans has HIV/AIDS, one in seven Kenyans, one in four people in Zimbabwe. United States Surgeon General David Satcher has likened the HIV/AIDS epidemic in Africa to the plague which decimated Europe in the 14th century.

Existing treatments which enable many people with HIV/AIDS in the United States and elsewhere to survive are unavailable to all but a few people in Africa. Lifesaving HIV/AIDS drug cocktails cost about $12,000 a year in many African countries, far out of reach of all but a handful of the growing African population of people with HIV/AIDS. Mr. Chairman, per capita income in sub-Saharan Africa for 750 million people is $500 per year, while the drug cocktails are $12,000 a year.

By comparison, Mr. Chairman, the top three officers in Microsoft have personal assets valued at $140 billion; 43 sub-Saharan Africa countries and 600 million people.

Highlighting the difficulty of AIDS education, there are 1,500 sub-Saharan languages. Even myth, superstition, and rumor hamper the efforts. Most recently in Durbin, South Africa, and I quote from a newspaper article issued in a CNN bulletin,

> The rolling hills and fertile valleys in the province of 8.5 million have spawned a myth of a terrible folk cure, a story that says having sex with a virgin will rid sufferers of the disease. The widespread belief has parents, children, doctors and courts struggling with a wave of rapes, frequently of young girls.

There is a crying need to make life-saving drugs and education more affordable and available, and quickly. South Africa is seeking to lower prices through the use of compulsory licensing and parallel import policies. Both of these measures are consistent with South Africa's obligations under the World Trade Organization's Agreement on Trade-Related Intellectual Property, or TRIPS.

Compulsory licensing would permit generic production of on-patent drugs with reasonable royalties paid to the patent owner. Market competition as a result of compulsory licensing would likely lower pharmaceutical prices by 75 percent or more. Parallel imports would enable the government to shop on the world market for low-priced pharmaceuticals.

Other countries are watching South Africa; if South African policies result in lower drug prices and help alleviate the AIDS epidemic, other African countries are likely to follow with similar lifesaving measures.

Mr. Chairman, I want to ask unanimous consent that all of my remarks be entered into the record, but I do want to close on this brief point.

The chairman in his opening statement said it is a trade issue. The Congress continues to send mixed signals regarding the global HIV/AIDS epidemic. Last week Congress passed by voice vote an amendment, which expresses a sense that addressing the HIV/AIDS crisis should be a central component of America's foreign policy with respect to sub-Saharan Africa. It expresses the sense of Congress that significant progress needs to be made in preventing and treating HIV/AIDS before we can expect to sustain a mutually beneficial trade relationship with sub-Saharan countries.

However, the Committee on Rules defeated a substantive amendment which I offered would have resolved this problem and put an end to the misguided United States policy of bullying South Africa. It would prevent the United States Trade Representative or other agencies from interfering with African countries' efforts to make HIV/AIDS and other medicines available to the sick so long as their intellectual property rules comply with TRIPS.

The Committee on Rules said my AIDS amendment did not belong in a trade bill. However, a sense of Congress resolution did belong in a trade bill. Even the chairman in his opening statement acknowledged that this issue is a trade issue.

Last week, with the Africa Growth and Opportunity Act amendment on HIV/AIDS, the House said its heart was in the right place on this issue. But yesterday Bernie Sanders offered an amendment to the State Department authorization bill that would have put our heart and our policy in the same place, but it was overwhelmingly defeated 307 to 117.

The Bible does not let us get away with mere good intentions. It requires good law, good policy, and money for implementation. The Bible has a different way and a more objective standard. It says, "Where your treasury is, there will your heart be also," Matthew 6:21.

If Congress is serious about addressing these problems, we have the power to do so. We can either be politically correct and side with pharmaceutical companies, or be morally correct and side with the millions of afflicted people in South Africa, Kenya, Zimbabwe, and beyond sub-Saharan Africa. The choice is ours.

Again, thank you, Mr. Chairman, for this opportunity to address the subcommittee. I look forward to working with Members on these critical issues.

Mr. MICA. Thank you, and without objection, your entire statement will be made part of the record.

[The prepared statement of Hon. Jesse Jackson, Jr., follows:]

JESSE L. JACKSON, JR.
2D DISTRICT, ILLINOIS

COMMITTEE ON APPROPRIATIONS

SUBCOMMITTEES
LABOR-HEALTH AND
HUMAN SERVICES-EDUCATION

FOREIGN OPERATIONS, EXPORT FINANCING
AND RELATED PROGRAMS

Congress of the United States
House of Representatives
Washington, DC 20515–1302

STATEMENT BY CONGRESSMAN JESSE L. JACKSON, JR.
COMMITTEE ON GOVERNMENT REFORM
SUBCOMMITTEE ON CRIMINAL JUSTICE, DRUG POLICY AND HUMAN RESOURCES
HEARING ON
THE U.S. ROLE IN COMBATING THE GLOBAL HIV/AIDS EPIDEMIC
Thursday, JULY 22, 1999
11:30 A.M.

Thank you, Mr. Chairman, for this opportunity to address the Subcommittee during today's hearing on the United States role in combating the global HIV/AIDS epidemic, and policies and programs that are being pursued internationally.

As you are surely aware, HIV and AIDS are rampaging throughout sub-Saharan Africa. While sub-Saharan nations comprise only 10% of the world's population, they are bearing the tragic burden of 70% of the world's new AIDS cases. The World Health Organization reports that of the 14 million people who have died of AIDS to date, 12 million have come from this region. In the hardest-hit countries -- Botswana, Namibia, South Africa, Zimbabwe, and Swaziland -- infection rates in the 15-49 age group are an astonishing 25%. In tourist areas such as Victoria Falls in Zimbabwe, the rates are even higher -- 40%.

Please allow me to share additional key findings from the Report on the Presidential Mission on Children Orphaned by AIDS in sub-Saharan Africa, released by the White House on Monday:

* Deaths resulting from AIDS in sub-Saharan Africa will soon surpass the 20 million people in Europe who died in the plague of 1347.

* Over the next decade, AIDS will kill more people in sub-Saharan Africa than the total number of casualties in all wars of the 20th century.

* Each day, 5,500 in the region die of AIDS-related causes. By 2005, the daily death toll will reach 13,000.

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* There are nearly 600,000 new infections each year among African babies. Nine of every 10 infants infected with HIV at birth or through breast feeding live in sub-Saharan Africa.

* In nine sub-Saharan countries, from one-fifth to one-third of children will lose one or both parents to AIDS this year.

* In Lusaka, Zambia, 100,000 children are estimated to be living on the streets, most of them orphaned by AIDS. By next year, 1 million children in Zambia, or one out of three, will have lost one or both parents.

* In large part as a result of AIDS, infant mortality will double and child mortality will triple over the next decade in many areas of sub-Saharan Africa.

* AIDS has reduced life expectancy in Zambia to 37 years from 56. In the next few years, AIDS will reduce life expectancy in South Africa by one-third, to 40 years from 60.

* Over the next 20 years, AIDS is estimated to reduce by one-fourth the economies of sub-Saharan Africa.

* In Malawi and Zambia, 30% of teachers are HIV positive. In Zambia, 1,500 teachers died of AIDS-related causes in 1998.

* By 2005, AIDS deaths in Asia will mirror those in Africa. Asia will account for one out of every four infections worldwide by the end of the year. In India, rates of infection are expected to double every 14 months.

Finally, one in seven South Africans has HIV/AIDS, one in seven Kenyans, and one in four people in Zimbabwe. U.S. Surgeon General David Satcher has likened the HIV/AIDS epidemic in Africa to the plague which decimated Europe in the 14th century.

Existing treatments which enable many people with HIV/AIDS in the United States and elsewhere to survive are unavailable to all but a few people in Africa. Life-saving HIV/AIDS drug cocktails cost about $12,000 a year in many African countries -- far out the reach of all but a small handful of the growing African population of people with HIV/AIDS.

There is a crying need to make life-saving drugs more affordable and available, and quickly. South Africa is seeking to lower prices through use of compulsory licensing and parallel imports policies. Both of these measures are consistent with South Africa's obligations under the World Trade Organization's Agreement on Trade-Related Intellectual Property (TRIPS).

Compulsory licensing would permit generic production of on-patent drugs, with reasonable royalties paid to the patent owner. Market competition as a result of compulsory licensing would likely lower pharmaceutical prices by 75 percent or more. Parallel imports would enable the government to shop on the world market for low-priced pharmaceuticals.

Other countries are watching South Africa. And if the South African policies result in lower drug prices and help alleviate the AIDS epidemic, other African countries are likely to follow with similar life-saving measures.

Unfortunately, the Office of the U.S. Trade Representatives, and the U.S. government, have pressured the South Africans to abandon its legal attempts to employ compulsory licensing and parallel imports. They have been more responsive to the narrow commercial interests of the pharmaceutical industry than to the public health and humanitarian interest in treating people with HIV/AIDS in Africa.

A State Department report explains how "U.S. Government agencies have been engaged in a full court press with South African officials from the Departments of Trade and Industry, Foreign Affairs, and Health," to pressure South Africa to change the provisions of its Medicines Act that give the government the authority to pursue compulsory licensing and parallel import policies.

The United States has withheld certain trade benefits (under the GSP program) from South Africa, and threatened trade sanctions (by putting South Africa on the Special 301 Watch List) as punishment for South Africa refusing to repeal the provisions of its Medicines Act that offend the multinational drug companies.

Section 4(a)(3) of the African Growth and Opportunity Act would make the problem worse. It would condition the modest benefits

offered by the Act on several criteria, including whether a country is enforcing "appropriate policies relating to protection of intellectual property rights." This will give the USTR and other agencies additional leverage to use against South African and other African policies designed to make HIV/AIDS and other essential medicines more accessible -- even if these measures are TRIPS-legal.

The Congress continues to send mixed messages regarding the global HIV/AIDS epidemic. Last week Congress passed by voice vote an amendment which expresses the "Sense of Congress" that "addressing the HIV/AIDS crisis should be a central component of America's foreign policy with respect to sub-Saharan Africa; expresses the sense of Congress that significant progress needs to be made in preventing and treating HIV/AIDS before we can expect to sustain a mutually beneficial trade relationship with sub-Saharan African countries." However, the Rules committee defeated a substantive-binding amendment I offered which
would have resolved this problem and put an end to the misguided U.S. policy of bullying South Africa. It would prevent USTR or other agencies from interfering with African countries' efforts to make HIV/AIDS and other medicines affordable to the sick, so long as their intellectual property rules comply with the TRIPS.

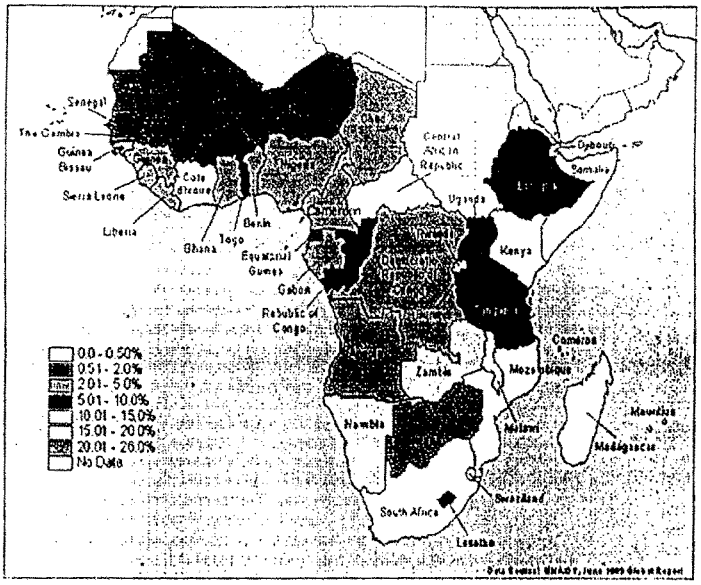
Last week, with the AGOA amendment on HIV/AIDS, the House said its heart was in the right place on this issue. But just yesterday, Rep. Bernie Sanders offered an amendment to the State Department Authorization bill that would have put our heart and the policy in the same place -- but it was overwhelmingly defeated 307-117.

The Bible does not let us get away with mere good intentions. It requires good law, good policy and money for implementation. The Bible has a different and more objective standard. It says, "Where your treasure is, there will your heart be also." (Matthew 6:21)

If Congress is serious about addressing these problems, we have the power to do so. We can either be politically correct, and side with the pharmaceutical companies or be morally correct and side with the millions of afflicted people in South Africa, Kenya, Zimbabwe and beyond in sub-Saharan Africa. The choice is ours.

Again, I thank you Mr. Chairman for this opportunity to address the Subcommittee and I look forward to working with the members of this Subcommittee on this critical issue.

Since the beginning of the AIDS epidemic, 83% of AIDS deaths occurred in sub-Saharan Africa



Adult HIV/AIDS Rates in Sub-Saharan Africa

- **Over 20 million adults living with HIV/AIDS as of end 1997**

http://www.worldbank.org/html/afr/bnails/aidspg1.htm

February 23, 1999

Dear Colleague:

There are approximately 750 million people in sub-Saharan Africa -- almost 500 million more people than live in the United States. The African Growth and Opportunity Act (H.R. 434 - AGOA) is too narrow in its scope to effectively address the size of Africa's problems and the needs of the continent. HIV and AIDS are rampant throughout sub-Saharan Africa. While sub-Saharan African nations comprise only 10% of the world's population, the World Health Organization (WHO) reports that in 1998, they accounted for 70% of the world's new AIDS cases. In the hardest hit countries -- Botswana, Namibia, Swaziland and Zimbabwe -- approximately 1/4 of the population aged 15-49 is currently living with HIV or AIDS.

Any legislation aimed at improving well-being and opportunity in sub-Saharan Africa must address the dire need to contain the AIDS epidemic. AGOA completely ignores the AIDS crisis. The HOPE for Africa Act, on the other hand, takes serious aim at ameliorating the AIDS epidemic through a combination of aid, debt relief and policies specifically designed to increase the availability of pharmaceuticals to HIV positive individuals and AIDS patients in sub-Saharan Africa.

The repercussions of the AIDS crisis have been felt in all corners of African society. 95% of the world's children whose parents or primary care-givers have died of AIDS live in Africa, where social safety nets are under-developed or often non-existent. Women have been afflicted disproportionately largely due to gender-based impediments, including seeking and receiving treatment. The crisis has imposed painful costs on the fledgling African business sector as well. UNAIDS reports that in Botswana, companies estimate that AIDS-related expenses will soar from under one percent of compensation costs now to five percent in six years' time.

-OVER-

It is a long-acknowledged truth that political and economic stability are essential for African growth and opportunity. Yet AIDS is a major destabilizing force. The U.S. Bureau of the Census estimates that the average life expectancy in Malawi will drop to 29.5 years, the lowest in the world. The Southern Africa AIDS Dissemination Service (SAFAIDS) says that although the rate of impact on GDP has so far been small, AIDS will probably reduce the rate of economic growth by as much as 25% over the next 20 years. Studies show that in Tanzania alone, the estimated labor force will shrink by 20% by the year 2010. Indeed, with 1/4 of the population in some areas of sub-Saharan Africa infected with HIV, it is estimated that three times as many teachers will need to be trained than are now currently employed in order to maintain current levels of staffing.

Sadly, this is just the beginning. According to the WHO, 4 million sub-Saharan Africans, 500,000 of them children, contracted HIV in 1998. This has led some to describe the AIDS crisis as the equivalent of a "holocaust" being visited upon sub-Saharan Africa each year.

The wealthiest of nations would be financially overwhelmed by the prospect of dealing with an AIDS crisis of this magnitude. For sub-Saharan African nations, many with per capita incomes of less than $500 per year and crushing debt service payments monopolizing their budgets, the likelihood that they could provide adequate treatment to the exploding number of AIDS patients is bleak. Without international cooperation in providing AIDS education, prevention and treatment (and ensuring that life-extending medicines are available to HIV patients), future generations in sub-Saharan Africa will face short, often agonizing lives. Unlike the AGOA, whose eligibility requirements could prove counterproductive to increasing government funding for AIDS prevention and treatment, the HOPE for Africa Act makes it easier for African nations to address the AIDS crisis and initiates a cooperative U.S. role in advancing the effort:

The AIDS Crisis:

The African Growth and Opportunity Act (H.R. 434) ignores the AIDS crisis by:

- failing to even mention the word AIDS, much less allocate and U.S. aid funding to combat the AIDS epidemic
- not specifying any funding levels for U.S. aid programs to Africa more generally
- requiring that the president certify that countries are "controlling government consumption" if those countries wish to be eligible for the narrow trade benefits offered by the bill. Historically, "controlling government consumption" has meant slashing social service expenditures, particularly in the area of health care. For example, under IMF structural adjustment programs Zimbabwe slashed its healthcare budget by 24%. The result: a 40% increase in maternal deaths during childbirth.

HOPE for Africa addresses the AIDS crisis by:

- replenishing and targeting assistance from the Development Fund for Africa for AIDS education and treatment programs.
- canceling bilateral debt and requiring the U.S. to advocate for full multilateral debt cancellation, thus freeing up precious government funds to address the AIDS crisis
- making it U.S. policy to assist sub-Saharan African countries in efforts to make needed pharmaceuticals and medical technologies widely available.
- prohibiting the use of U.S. funds to undermine African intellectual property and competition policies that are designed to increase the availability of medications.
- encouraging African nations benefitting from debt relief guaranteed under the bill to set aside 20% of savings for health and education

Without proposals to address the AIDS epidemic in sub-Saharan Africa, African Growth and Opportunity Act cannot live up to its name. We urge you to support a sound strategy for tackling the AIDS epidemic in Africa, the HOPE for Africa Act of 1999. If you would like to become a co-sponsor of this bill or you have any questions, please contact George Seymore in Congressman Jackson's office at 5-0773.

Sincerely,

Jesse L. Jackson, Jr. Cynthia McKinney James Clyburn

SUPPORT H.R. 772

Johannesburg, 30 November 1998

en français
en Español

AIDS in Africa

Africa continues to dwarf the rest of the world on the AIDS balance sheet. According to UNAIDS and WHO estimates, 7 out of 10 people newly infected with HIV in 1998 live in sub-Saharan Africa; among children under 15, the proportion is 9 out of 10. Of all AIDS deaths since the epidemic started, 83% have been in the region. At least 95% of all AIDS orphans have been African.* Yet only one-tenth of the world's population lives in Africa south of the Sahara.

The sheer number of Africans affected by the epidemic is overwhelming. Since the start of the epidemic, an estimated 34 million people living in sub-Saharan Africa have been infected with HIV. Some 11.5 million of those people have already died, a quarter of them children. In the course of 1998, AIDS will have been responsible for an estimated two million funerals in Africa.

By the end of 1998, there will be an estimated 21.5 million men and women living with HIV in Africa, plus another 1 million children. Some 4 million of these people will have contracted the infection in 1998 alone.

Hot-spots of **infection**

No country in Africa has escaped the virus, and yet some are far worse affected than others. The bulk of new infections continue to be concentrated in East Africa and especially in the southern part of the continent.

The southern African region in fact holds the majority of the world's hard-hit countries:

- In Botswana, Namibia, Swaziland and Zimbabwe, current estimates show that over one person in five between the ages of 15 and 49 is living with HIV or AIDS.

- Zimbabwe is especially hard-hit. There are 25 surveillance sites in the country where blood taken from pregnant women is tested anonymously as a way of tracking HIV infection. The most recent data, from 1997, show that HIV prevalence remained below 10% in just two of these sites. In the remaining 23 sites, between a fifth and half of all pregnant women were found to be infected with HIV. At least a third are likely to pass the infection on to their baby.

- South Africa trailed behind some of its neighbours in HIV infection levels at the start of the 1990s. Unfortunately, it is catching up fast. This year, just over 50% of all new infections in southern Africa occurred in this one country.

- In South Africa, as in Malawi, Mozambique, Rwanda and Zambia, between one in seven and one in nine adults live with HIV infection.

- In Central African Republic, Côte d'Ivoire, Djibouti and Kenya, at least one in ten adults are HIV-infected.

(Source: Department of Health, South Africa)

In general, West Africa is less affected by HIV than southern or East Africa. Some countries in central Africa have also seen HIV remain relatively stable, while in neighbouring countries rates have continued to climb.

Early and sustained prevention efforts can be credited with these lower rates in some places- Senegal provides a good example. But elsewhere, where far less has been done to encourage safer sex, the reasons for the relative stability remain obscure. Research is under way to explain differences between epidemics in various countries. Factors that may play a role include patterns of sexual networking, levels of condom use with different partners, and promptness in diagnosing and curing other sexually transmitted diseases (which if left untreated can magnify the risk of HIV transmission through sex as much as 20-fold).

Young people in **danger**

In the worst-affected countries, young people are especially at risk. In sub-Saharan Africa, as in many countries in the industrialized world and elsewhere, people embark on their sexual lives when they are in their teens-often in their early or mid-teens. In Kenya, for example, one study of nearly 10 000 schoolgirls between the ages of 12 and 24 reported that on average, girls lose their virginity when they are between 14 and 15 years old. And yet to date, there is no reproductive health education in schools that would prepare girls to avoid early sex or to adopt safer sexual practices.

The Population Reference Bureau estimates that every year babies are born to 14% of young women aged 15-19 in sub-Saharan Africa, compared with 6% of young women in other less developed countries and just 3% in the industrialized world. Many of these births are outside of marriage. A recent study in Namibia showed that close to 40% of births were to unmarried women. Single motherhood was not associated with ignorance or marginalization-over a third of single mothers were educated to secondary level or beyond, compared with just over a quarter of married mothers.

High levels of teen pregnancy, and pregnancy outside of marriage, do tell us two things: young people are very sexually active, and few of them use condoms. If young people are having unprotected sex with several partners, or if their single partner has ever had other partners, they are exposed not just to pregnancy but to infection with sexually transmitted diseases, including the one that can kill them: HIV.

Recent HIV surveillance data show how early this exposure can occur and how devastating its consequences can be. In Rwanda, over 4% of both boys and girls aged 12-14 in one community study already tested positive for HIV. In South Africa, the number of pregnant girls under 15 tested for HIV in 1997 was relatively small, but a distressing 9.5% of them were found to be infected with the virus. Among the far greater number of pregnant South Africans tested in their late

teens, nearly 13% were HIV-positive.

Often, girls become infected at younger ages than boys. A recent community-based study in one area of Kenya showed that 22% of 15-19-year-old girls in the general population were already infected with HIV, compared with just 4% of boys of the same age. In a Zambian study of young city-dwellers in the same age group, HIV infection was reported in 12.3% of the girls and 4.5% of the boys. In the next-higher age bracket, 20-24 years, a study in Ethiopia found that 35.4% of young women were infected-three times higher than the 10.7% rate among the men.

This age gap at infection indicates that young girls are getting infected through sex with older men. Many girls may choose such relationships because they come with gifts, money or other favours attached. But some will simply have been powerless to resist. In Kenya, one young woman in four said she lost her virginity because she had been forced to. In the Democratic Republic of Congo, the proportion was close to a third. Unwilling sex with an infected partner carries a high risk of HIV infection for girls. When the vagina is dry or when force is used, abrasions and cuts are more likely and the virus can more easily find its way into the bloodstream. What's more, condom use is unlikely in such situations.

(Source: Taha et al. AIDS 1998 12:197-203)

As infection rises in the general population, so does the likelihood of encountering an infected partner (especially an older partner) early in one's sexual career. Over time, then, new infections become increasingly concentrated in the youngest age groups. In a recent study in Malawi, HIV prevalence had built up to high levels in older age groups, but the bulk of new infections were occurring in younger women.

People continue to be at risk for HIV throughout their sexually active lives, and all should benefit from services and information that allow them to reduce their risk of infection. However, efforts to promote safer behaviour are especially crucial for young people, who in mature epidemics are those at greatest risk. Prevention efforts also seem to have a greater chance of success among younger people than among people whose sexual habits are well ingrained. For example, following active condom promotion and education campaigns in school and among youth groups, dramatic declines have been recorded in infection rates among teenagers in Uganda and Tanzania.

HIV and AIDS -making themselves felt

HIV can spread silently for many years before the infection develops into symptomatic AIDS and becomes a cause of recurring illness and, finally, death. During 1998 Africa held 5 500 funerals a day for people dying of AIDS, but the death rate is set to increase. Countries where the epidemic is rather recent, such as South Africa, are still far from feeling the major impact of AIDS, despite already high levels of HIV in the general population. But South Africans can anticipate the likely impact by looking at countries where the epidemic has been longer established-Uganda in East Africa, Zambia and Zimbabwe in southern Africa. Millions of adults are dying young or in early middle age. They leave behind children grieving and struggling to survive without a parent's care. Many of those dying have surviving partners who are themselves infected and in need of care. Their families have to find money to pay for their funerals, and their employers-schools, factories, hospitals-have to train other staff to replace them at the workplace.

Children on the brink

Africa is experiencing a growing tide of children living in AIDS-affected households or attempting to survive after the death of their mother, or both parents, to AIDS. Often, the extended family- itself decimated by AIDS-can or will no longer cope. But institutions are not the answer either, not to a problem of this scale. Solutions have to be found in the community.

In Zimbabwe, people are rising to the challenge. Many village heads have designated land to be cultivated by all villagers to feed orphans and families of those suffering from debilitating illness, usually AIDS-related. In some areas, church groups have begun orphan-visiting programmes. Women are trained to identify the neediest orphan households in their area; they

then visit them on a regular basis, providing all-important guidance and emotional support and helping with basic necessities. Because these programmes work from within the community they are affordable, costing an average of just 68 US cents per child per month-a small price to pay for a service that will help keep orphans woven into the fabric of society. Fostering initiatives have also begun on commercial farms.

The challenge to business

Since many economies in the region are in flux, it is hard to determine exactly what the impact of HIV is on national economies as a whole. However it is clear that businesses are already beginning to suffer. In Zimbabwe, for instance, life insurance premiums quadrupled in just two years because of AIDS deaths. Some companies report a doubling of their health bills. In Botswana, companies estimate that AIDS-related costs will soar from under one percent of the wage bill now to five percent in six years' time, because of the rapid rise in infection in the last few years. In Zambia, one large company reported in 1995 that its costs from AIDS illness and death exceeded its total profits for the year. There is a similar report from a large Tanzanian company.

Prevention programmes for workers have been shown to cut costs as well as infections in Africa. While costs vary significantly between countries, it is estimated that a worker with AIDS costs a business in southern Africa around US$ 200 a year in lost productivity, treatment, benefits and replacement training. The costs for senior and skilled staff will be far higher. And yet a study in Tanzania has demonstrated that treatment of other sexually transmitted diseases costing as little as US$ 2.11 per case can cut the number of people getting HIV by over 40%. New HIV infections in Zimbabwean factories with worker-driven prevention campaigns were a third lower than in factories without such campaigns. The campaigns cost US$ 6.00 per worker-less, in other words, than a single set of protective overalls.

Caring for orphans on Zimbabwe's commercial farms

Some 2 million people-a fifth of the nation's population-live on Zimbabwe's commercial farms. Many are immigrants or the children of immigrants, and many more are Zimbabweans who have moved there from their native villages. Because the majority no longer have any regular contact with their extended families back home, this leaves children with no one to take them in if their parents should die-an increasingly frequent occurrence. A survey at the beginning of 1996 estimated 2.1 orphans per farm. Now a new registration system shows that numbers have climbed to around 10 orphans per farm. The average age of these children is 10.

That is the downside. The upside is that many farm owners are increasingly concerned about the welfare of farm workers and their families, and are supporting initiatives to care for these orphans on their farms. Most of these initiatives centre on finding other farm families to foster abandoned children and orphans. This is more difficult than it sounds, since many people believe orphaned children will bring bad luck.

"After two months my husband wanted me to turn the children away," recounted Monica Kamombe, who, with limited support from the farmer who employs her, provides a home for four orphaned brothers. "Everyone in the village came knocking at the door to say if we kept these unlucky children the ngozi, the bad spirits, would get us". She persisted and now others in the village have followed her example.

The country will need many, many more caring foster parents like Mrs Kamombe. In two years' time, because of AIDS the country will be burying some 350 people a day, and by the year 2005 the government estimates there will be over 900 000 children under 15 struggling to survive without a mother.

A hard-to-break silence

For all the palpable effects of AIDS, a silence born of shame and blame continues to shroud the epidemic in many of even the hardest-hit countries.

A recent study of voluntary counselling and testing offered to pregnant women in developing countries found that in many places with extremely high HIV prevalence, women refused testing or did not return for their test results. This was the case even when interventions that might help them give birth to a healthy baby were being offered to those who tested HIV-positive. In Côte d'Ivoire, for instance, fewer than half of more than 13 000 pregnant women in two study sites accepted to be tested and then came back for their results. More worrying still, in a majority of sites it was the HIV-positive women who were less likely to return. This correlation was seen in South Africa's Soweto, too, where almost all pregnant women in the study agreed to be tested, four-fifths overall came back for their test results, but only half of those who were HIV-positive sought out their results. These systematic differences suggest that women who may be aware that they have been exposed to infection, or who have taken risks, shrink from learning their HIV status.

There is evidence that the fear and denial provoked by AIDS extends even to people working in the health sector. One study in southern Africa sought to record the number of needlestick injuries in primary health care clinics. Researchers found almost none-an unlikely scenario in overworked clinics with poor facilities. Senior staff then explained that, under clinic policy, anyone who reported a needlestick injury had to undergo HIV testing to measure the danger of sero-conversion through exposure to infected needles. Nurses did not report needlestick injuries because they did not want to be tested.

Silence can continue to reign even when people with HIV are ill and dying. Because AIDS is just the name for a cluster of diseases that immunodeficient people develop, patients and their carers can choose to view the illness as just tuberculosis, or diarrhoea, or pneumonia. An example from southern Africa is telling. In one study of home-based care schemes, fewer than 1 in 10 people who were caring for an HIV-infected patient at home acknowledged that their relative was suffering from AIDS. Patients themselves were only slightly more likely to acknowledge their status.

"For too long we have closed our eyes as a nation, hoping the truth was not so real," South African Deputy President Thabo Mbeki told South Africans in October. "At times we did not know that we were burying people who had died from AIDS. At other times we knew, but chose to remain silent."

With this major speech, South Africa's leadership joined those who have spoken out loudly and clearly about AIDS,

have sought to demystify it, and have encouraged discussion about safe sex everywhere from the classroom to the boardroom. It is in such countries-of which Uganda is probably the best known example in the developing world-that most progress has been made not just in putting a brake on new infections but in ensuring the wellbeing of those people who are already living with the virus.

Act before it is too late

In Madagascar, an island of 16 million people, HIV is just beginning to raise its head. Surveillance among pregnant women shows exceptionally low levels of infection-perhaps 1 in 5000 (as compared with 1 in 4 in some countries in sub-Saharan Africa, off whose south-eastern coast Madagascar lies). Even among sex workers and patients with other sexually transmitted infections, HIV rates are negligible. An island nation with no need for HIV prevention programmes? Far from it. Madagascar may have been protected by its relative isolation from an early onslaught of HIV, but the high levels of risk in the population are sending alarm bells ringing. The time to act is now.

According to behavioural surveys, sex starts young (at around 15 for the majority of women) and premarital pregnancy is common. Some 14% of pregnant women in a recent survey reported casual partners, and over 9 out of 10 never used condoms in those encounters. Most patients at STD clinics were married, but 16% reported regular extramarital partners and another 14% reported casual partners. Fewer than 10% consistently use condoms in any of these relationships.

STD microbes are already finding plenty of scope for spread. Some 10% of pregnant woman tested positive for syphilis in the most recent round of surveillance-an unusually high rate. Around 15% of STD clinic patients had syphilis. Among sex workers syphilis prevalence ranged up to 28%-not surprising, considering that 35% of sex workers say they never use condoms with any type of clients, and nearly two-thirds never use them with regular partners. Only 14% report using condoms with all of their sex work clients. The potential scope for both STD and HIV spread is alarming.

The government and nongovernmental partners are responding actively. For example, special reproductive health services for 10 to 24-year-olds have been set up in youth centres around the country. The aim is to use these special youth-friendly clinics to spread the word about HIV and to instil a norm of safe behaviour quickly, before the virus can take hold.

For more information, please contact Anne Winter, UNAIDS, Geneva, mobile (+41 79) 213.4312, Richard Delate, UNAIDS, Johannesburg, (+27 12) 338 5294, mobile (+27 82) 902 0256, Lisa Jacobs, UNAIDS, Geneva, (+41 22) 791.3387 or Karen O'Malley, UNAIDS, New York, (+1 212) 899.5575. You may also visit the UNAIDS Home Page on the Internet for more information about the programme (http://www.unaids.org).

JAMA
The Journal of the American Medical Association

Medical News & Perspectives - April 28, 1999
From the Surgeon General

The Global HIV/AIDS Epidemic

An enormous human tragedy is unfolding in many less-developed countries because of the spread of HIV/AIDS. Of the 33.4 million HIV-infected people around the world, there are an estimated 22.5 million in sub-Saharan Africa, 6.7 million in South and Southeast Asia, 1.4 million in Latin America, and 665,000 in the United States. Globally, more than 14 million people have died of the disease, including 2.5 million last year.

In many southern African countries, HIV/AIDS has become an unprecedented emergency, with 20% to 26% of people between the ages of 15 and 49 infected. In Botswana, Kenya, Malawi, Mozambique, Namibia, Rwanda, South Africa, Zambia, and Zimbabwe, HIV/AIDS will reduce life expectancy from 64 to 47 years by 2015. The progress of decades of work immunizing children, controlling diseases, and improving nutrition is being negated by HIV/AIDS.

Conditions in many parts of the world promote rapid spread of the HIV/AIDS epidemic. For example, India, with a population approaching 1 billion, has estimated that 3 million to 5 million of its people are infected, and the number of new infections will double every 14 months.

Social and political issues surrounding sex, injecting drug use, and blood transfusion in many countries have created special circumstances in which the disease has been able to spread unchecked. Some less-developed countries also bear a burden of political and economic instability that makes prevention even more difficult. It was only a few years ago that epidemiologists offered projections of disease prevalence for sub-Saharan Africa that were met with disbelief. If the present warnings go unheeded, South Asia, Southeast Asia, and, perhaps, China will follow the disastrous course of sub-Saharan Africa.

More than a decade of experience has taught us how to control HIV/AIDS—we know what works. Many developed countries have successfully checked the spread of the epidemic. While development of therapy and a vaccine continue, prevention must be emphasized. The basic elements of prevention include education, behavior change, voluntary testing and counseling, prevention of perinatal transmission, and political commitment. Each country must find the mix of methods appropriate to its particular conditions.

Education about HIV/AIDS is necessary but alone does not change the behavior of populations. Promotion of voluntary testing and counseling must complement education. Testing and counseling break the deadly silence around HIV/AIDS and empower individuals to make informed

decisions and change behaviors. Breaking the silence also will begin to diffuse the stigma surrounding the disease. We have seen success with behavioral change in Uganda and Thailand, the only two less-developed countries with extensive capacity for voluntary testing and counseling.

It is known that perinatal transmission of HIV can be reduced by more than 50% by using antiretroviral therapy; however, problems with access to these drugs limit their use in some countries. Transmission of HIV through breast-feeding and poor survival of orphans make the avoidance of disease via treatment for perinatal transmission more complex. We continue to work with international organizations, other governments, and pharmaceutical companies to lower costs and expand access to antiretroviral drugs. Current treatment for perinatal transmission (as well as use of antiretrovirals in general) in less-developed countries is also limited by the fact that very few people have been tested for HIV infection.

Treatment of other sexually transmitted diseases (STDs) is important to control the spread of HIV. One of the reasons HIV has spread so rapidly in Africa is that so many STDs go untreated. Untreated STDs break down natural barriers that prevent transmission. Access to even basic treatment for STDs remains a problem for many less-developed countries.

Perhaps most important in the global battle against HIV/AIDS is political commitment. Leaders at the national, provincial, and local levels of government must speak out about HIV/AIDS and encourage businesses and nongovernmental organizations to commit to work against the disease. I was encouraged by US Vice President Al Gore and Deputy President Thabo Mbeki of South Africa, who put the HIV/AIDS threat at the top of the international agenda at the recent meeting of the United States-South Africa Joint Commission. They set an important example for leaders in developed and less-developed countries.

American medicine and public health have an important role to play in the global battle against HIV/AIDS by supporting international organizations such as the Joint United Nations Program on HIV/AIDS, the World Health Organization, and the World Bank.

HIV/AIDS can be likened to the plague that decimated the population of Europe in the 14th century. While the modern epidemic affects people of all age groups, those of working age are at highest risk, posing potentially dire economic, social, and political consequences for the global community. Unfortunately, the world continues to devote greater attention and resources to traditional national security issues such as wars, postponing notice of an epidemic that, if left to spread unchecked, will kill more people than any of the terrible conflagrations that have so marked this century.

—David Satcher, MD
Surgeon General of the United States and Assistant Secretary, Department of Health and Human Services

(*JAMA*. 1999;281:1479)

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07/19/99- Updated 02:08 AM ET

White House to unveil AIDS strategy

By Susan Page and Steve Sternberg, USA TODAY

WASHINGTON - Calling the AIDS epidemic in sub-Saharan Africa "a plague of biblical proportions," the White House on Monday will propose spending an additional $100 million next year for prevention and treatment and will urge the rest of the world to do more to join the battle.

Vice President Gore will unveil a new White House report on AIDS in Africa, and Hillary Rodham Clinton will convene a meeting next month of officials from the World Bank, the United Nations, foundations and corporations to fortify and coordinate efforts to stem the epidemic.

By the end of the year, the White House also promises to host a religious leaders' meeting, and the National Security Council will help sponsor a summit of African leaders.

"AIDS is not only causing unfathomable human suffering; it is jeopardizing economic growth, political stability and civil society in many sub-Saharan African nations," the White House report concludes. In the past decade, 12 million people in sub-Saharan Africa have died of the disease, which is expected to deprive 40 million children of one or both parents in the next decade.

Within a few years, the 30-page report warns, the epidemic will spread in force to India, Southeast Asia and the former Soviet republics.

Poll on AIDS

▶ Most Americans don't believe global AIDS crisis is coming under control.

Sure, that is false **30%**
Probably false **37%**
Probably true **20%**
Sure it's true **2%**
Don't know **11%**

▶ A majority support increasing U.S. assistance to fight AIDS in Africa.

Very fav. to increased aid **23%**

Somewhat favorable **31%**
Neutral **15%**
Somewhat unfavorable **14%**
Very unfavorable **15%**
Not sure **2%**

▶ African-Americans are more than twice as likely as all voters to be very favorable to increased U.S. assistance.

African-American voters **54%**
All voters **23%**

Poll by Peter D. Hart Associates, commissioned by Children's Research and Education Institute. Phone survey of 1,411 respondents in March. Margin of error: +/-3 percentage points.

The White House report was prepared by Sandra Thurman, director of the Office of National AIDS Policy, who conducted two fact-finding tours to the region this year.

AIDS activists welcomed the announcement. "The most important thing is that the U.S. has to show leadership in combating this disease everywhere in the world," said Cornelius Baker, president of the National Association of People with AIDS. But, he added, " This is a very small down payment."

South African Archbishop Desmond Tutu is to join Gore at Monday's announcement, as will Olivia Nantongo, a 20-year-old Ugandan woman who lost her mother and other family members to the disease.

This year, the U.S. government is spending $125 million on HIV prevention and AIDS care worldwide, with $74 million of it devoted to Africa. Of the additional $100 million, $48 million would go to prevention, $23 million to care of AIDS patients, $10 million to care of AIDS orphans and $19 million to help governments deal with the epidemic.

Congress must approve the new funding, 70% of which is earmarked for Africa and 30% for Asia and the former Soviet republics.

The report emphasizes the need to mobilize other countries and international organizations. "I hope that the developed world joins together to help our African neighbors," said Sen. Orrin Hatch, R-Utah, who has been active on the issue.

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USA TODAY Washington

07/18/99- Updated 10:28 PM ET

U.S. takes aim at Africa AIDS crisis

By Steve Sternberg, USA TODAY

WASHINGTON - President Clinton hardly mentioned AIDS in Africa during his 12-day, six-nation tour of the troubled continent this spring to promote economic development.

Likewise, the Clinton-backed Africa Growth and Opportunity Act, which passed Congress last week, didn't address the continent's leading killer.

Vice President Gore's planned announcement Monday - that the White House will double funding for global AIDS prevention and treatment to $200 million next year - represents an increased administration commitment. Almost two-thirds of that funding will be spent in sub-Saharan Africa, administration officials say.

"We have to look for ways to do more; otherwise the continent will be consumed by AIDS," Clinton told USA TODAY last month, after he instructed officials throughout government to find money for the initiative.

Daniel Zingale, director of the lobbying group AIDS Action, hailed the new initiative as "terrific."

"This means that the U.S. recognizes that AIDS threatens to bring down entire nations in Africa and is responding," Zingale said Sunday.

White House officials say that Clinton and Gore long have been aware of AIDS' killing spree in sub-Saharan Africa, the epicenter of an epidemic that afflicts at least 33 million people worldwide.

Clinton said he decided to act after receiving updates on fact-finding missions to the region by Sandra Thurman, director of the White House Office of National AIDS Policy. Her reports from those trips offer a glimpse of countries ravaged by the epidemic. Since 1981,

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AIDS has killed 11.5 million Africans, 83% of the world's AIDS death toll. Another 22.5 million Africans are infected with the AIDS virus, and 16,000 more people become infected each year.

As the deaths add up, so will the population of orphans, experts say. Over the next 10 years, nearly 40 million children - a population equivalent to all of the U.S. children east of the Mississippi River - will lose one or both parents.

"Turning a blind eye to this crisis is no different than turning a blind eye to Kosovo or turning a blind eye to (World War II) Germany, and the numbers in this crisis are worse than anything we've seen in those horror shows put together," Thurman says.

Yet for two decades, the world and even the afflicted nations have done little to curb the epidemic. Just three months ago, Peter McDermott, a UNICEF official in Zambia, railed at what he regards as the global "conspiracy of silence" shrouding AIDS in sub-Saharan Africa.

"If the same numbers of people dying daily were to occur in a so-called humanitarian emergency, we would be fully mobilized with planes, supplies, media attention, etc.," he wrote recently in a memo to his superiors. "Yet there seems to be no passion, no anger, no outcry."

Ambassador Stephen Lewis, UNICEF's director, says the agency's stance has begun to change. "The commitment to do something about HIV/AIDS is accelerating by the day," he says. "Where the pandemic is worst, east and southern Africa, it is our absolute highest priority."

Even AIDS activists in the USA, who for years have pressed the government to focus first on the crisis at home, have turned their attention to the epidemic abroad. In April, AIDS Action dispatched dozens of activists to the Capitol to lobby for funds to fight the global epidemic.

- Peter Piot, director of UNAIDS, the United Nation's AIDS program, says the Clinton administration's initiative could prompt other donor countries to step up their global AIDS efforts. "The U.S. is a major trendsetter in the world," he said last week in an interview. The White House initiative is one of several under way in the United States and abroad. Among the others:
- The Rev. Leon Sullivan, organizer of the African-African American Summit held in May in Accra, Ghana, announced at the meeting that he is launching a 10-year program to help countries curb their AIDS epidemics and selecting two countries as test cases.
- On March 3, then-South African President Nelson Mandela, who had been largely silent on AIDS, appealed for a major campaign to curb the spread of the killer disease. He said AIDS is "eroding the fabric of our society and jeopardizing the reconstruction and development of our country." Mandela's successor, Thabo Mbeki, has added that the disease is likely to curb the nation's economic growth significantly.

- Former representative Ron Dellums, D-Calif., in April

proposed launching a $400 million "AIDS Marshall Plan" to provide money for basic medical care, though not expensive new drugs. The government and a consortium of drug companies each would provide half of the funding. Rep. Barbara Lee, D-Calif., soon plans to submit legislation that, if passed, would finance Dellum's Marshall Plan.

- Bristol Myers Squibb announced May 6 that the company will contribute $100 million to fight HIV in five sub-Saharan nations.
- In May, a Johns Hopkins University researcher based in Zambia, Paul Zeitz, and colleagues from Harvard proposed that Zambia be relieved of a portion of the interest owed for loans from the World Bank and International Monetary Fund, provided that the savings is spent on AIDS programs.

One month later, the wealthy members of the G 7 group of governments voted to support an effort to reduce interest rates for "heavily indebted poor countries." The G7 is made up of the United States, Germany, Japan, France, Britain, Italy and Canada.

The initiative is designed to free up funds for health, child survival and AIDS prevention.

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In South Africa, doctors, courts fight brutal AIDS 'cure'

May 19, 1999
Web posted at: 1:17 p.m. EDT (1717 GMT)

From Johannesburg Bureau Chief Charlayne Hunter-Gault

The Durban countryside holds a dark myth of a terrible "cure" for AIDS

DURBAN, South Africa (CNN) -- South Africa's northeastern province of Kwazulu-Natal is blessed with a lush landscape -- and cursed with the country's highest AIDS rate.

RELATED VIDEO
CNN's Charlayne Hunter-Gault reports on a province in South Africa with the highest incidence of AIDS.
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The fight against AIDS

The rolling hills and fertile valleys in the province of 8.5 million have spawned a myth of a terrible folk "cure" -- a story that says having sex with a virgin will rid sufferers of the disease. The widespread belief has left parents, children, doctors and the courts struggling with a wave of rapes, frequently of young girls.

Skhumbuza Mthembu, a 15-year-old peer counselor at a village primary school in Mpophomeni, says he has heard of the so-called cure from local men and boys. And he often hears firsthand about the results.

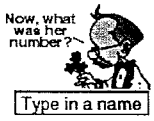
Those who have been victims tell horror stories about being raped by a teacher, or a brother, an uncle or even a father. They tell of being assaulted in restrooms, in the forest or the bush, or in bed while they were sleeping.

More and more stories like this are being told by younger and younger children across this province and elsewhere. But many, many more stories are not being told until it's too late.

Dr. Gillian Key treats sexually abused children at the Addington Children's Hospital in Durban, the harbor port of Kwazulu-Natal.

"Unless you see the children within an hour or one or two days, you're unlikely to find anything," Key said. "It's a pitiful thing."

Some of the children receive good



Some of the children receive good news -- that they test negative for HIV. For another family, the news wasn't good.

One such child Key treated was raped when she was 2: She tested HIV-positive and now is developing full-blown AIDS.

"It's hard every day," said her mother, who asked that her family remain anonymous our of fear that her daughter would be stigmatized. "It's hard not knowing that one day she might not grow up."

In Durban, authorities have set up a special court to deal with child abuse cases. It's difficult to establish which rapes are connected to the cure myth, but prosecutors and other say the abuse of younger children since it began circulating has "skyrocketed."

Victims can testify on videotape so they don't have to face their abusers

Court officials try to ease the process for young victims who must testify. They provide separate rooms for them to testify on videotape so they don't have to face their abusers. But the fact that there are so many of them, coupled with their increasingly younger ages, makes it difficult to obtain convictions.

"The youngest we can put a child on the stand is three years and if we look for an actual trial date, it will be something like six months away," said Durban prosecutor Val Melis. "You can't count on a child to remember details like that that far down the line."

Meanwhile, back in Mpophomeni, teen counselor Mtembu holds another session to help youngsters cope with the trauma of rape -- and to teach them ways they can protect themselves.

But when asked what about that, one young girl answered: "We just have to cry loudly and hope someone will hear us."

RELATED STORIES:

Chat transcript: AIDS and other scares at CDC
May 11, 1999
Cash-strapped S. African government cuts AIDS drug programs
May 6, 1999
Report: AIDS slashes African life expectancies
March 18, 1999
U.S., South Africa plan to improve trade, fight crime
February 18, 1999
Study: One-week treatment can cut mother-to-child HIV transmission
February 2, 1999

RELATED SITES:

National Center for HIV/AIDS Prevention
The Joint United Nations Programme on AIDS
Centers for Disease Control and Prevention
- •Division of HIV/AIDS Prevention (DHAP)
- •World AIDS Day
- •DHAP - (Basic Statistics) - HIV/AIDS Surveillance Reports

AIDS Daily Summary

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Committee on Rules

U.S. House of Representatives

106th Congress

Summary of Amendments Made in Order Under the Rule to H.R. 434, Africa Growth and Opportunity Act

Jackson-Lee #12 Encourages and recognizes the need for U.S. and African small business opportunities and investment in sub-Saharan Africa. **(10 minutes)**

Jackson (IL) #29 Requires that Overseas Private Investment Corporation Infrastructure Funds provided in the bill be targeted for the following purposes: basic health services, potable water, sanitation, schools, rural electrification and accessible transportation; requires that 70% of trade financing and investment insurance provided by OPIC be allocated to small, women and minority-owned businesses with at least 60% African ownership and 40% U.S. ownership and that 50% of funds for energy projects be used for renewable and/or alternative energy development; creates Administration Advisory Boards to oversee these funds and also Ex-Im Bank financing targeted to sub-Sahara Africa. **(10 minutes)**

- **Jackson-Lee #14** Expresses the sense of the Congress that U.S. business should be encouraged to assist sub-Saharan Africa with the HIV/AIDS problem and consider the establishment of a HIV/AIDS Response Fund to coordinate assistance efforts. **(10 minutes)**

- **Olver/Foley/Pelosi #9** Expresses the sense of Congress that addressing the HIV/AIDS crisis should be a central component of America's foreign policy with respect to sub-Saharan Africa; expresses the sense of Congress that significant progress needs to be made in preventing and treating HIV/AIDS before we can expect to sustain a mutually beneficial trade relationship with sub-Saharan African countries; expresses the sense of Congress that the HIV/AIDS crisis in Africa is a global threat that merits further attention in detailed legislation. **(10 minutes)**

*** Summaries derived from information submitted by the amendment sponsors.**

AMENDMENT TO H.R. 434, AS REPORTED

OFFERED BY MS. JACKSON-LEE OF TEXAS

(Page & line nos. refer to H.R. 2489, as introduced on July 13, 1999)

Page 38, after line 7, insert the following (and redesignate subsequent sections accordingly):

SEC. 18. ASSISTANCE FROM UNITED STATES PRIVATE SECTOR TO PREVENT AND REDUCE HIV/AIDS IN SUB-SAHARAN AFRICA.

It is the sense of the Congress that United States businesses should be encouraged to provide assistance to sub-Saharan African countries to prevent and reduce the incidence of HIV/AIDS in sub-Saharan Africa. In providing such assistance, United States businesses should be encouraged to consider the establishment of an HIV/AIDS Response Fund in order to provide for coordination among such businesses in the collection and distribution of the assistance to sub-Saharan African countries.

AMENDMENT TO H.R. 434, AS REPORTED

OFFERED BY MR. OLVER OF MASSACHUSETTS, MR. FOLEY OF FLORIDA, MS. PELOSI OF CALIFORNIA, MR. HORN OF CALIFORNIA, MR. LEWIS OF GEORGIA, MS. JACKSON-LEE OF TEXAS, MR. HOUGHTON OF NEW YORK, AND MRS. KELLY OF NEW YORK

(Page & line nos. refer to H.R. 2489, as introduced on July 13, 1999)

Page 38, after line 7, insert the following (and redesignate the subsequent sections accordingly):

SEC. 18. SENSE OF THE CONGRESS RELATING TO HIV/AIDS CRISIS IN SUB-SAHARAN AFRICA.

(a) FINDINGS.—The Congress finds the following:

(1) Sustained economic development in sub-Saharan Africa depends in large measure upon successful trade with and foreign assistance to the countries of sub-Saharan Africa.

(2) The HIV/AIDS crisis has reached epidemic proportions in sub-Saharan Africa, where more than 21,000,000 men, women, and children are infected with HIV.

(3) 83 percent of the estimated 11,700,000 deaths from HIV/AIDS worldwide have been in sub-Saharan Africa.

(4) The HIV/AIDS crisis in sub-Saharan Africa is weakening the structure of families and societies.

(5)(A) The HIV/AIDS crisis threatens the future of the workforce in sub-Saharan Africa.

(B) Studies show that HIV/AIDS in sub-Saharan Africa most severely affects individuals between the ages of 15 and 49—the age group that provides the most support for the economies of sub-Saharan African countries.

(6) Clear evidence demonstrates that HIV/AIDS is destructive to the economies of sub-Saharan African countries.

(7) Sustained economic development is critical to creating the public and private sector resources in sub-Saharan Africa necessary to fight the HIV/AIDS epidemic.

(b) SENSE OF THE CONGRESS.—It is the sense of the Congress that—

(1) addressing the HIV/AIDS crisis in sub-Saharan Africa should be a central component of United States foreign policy with respect to sub-Saharan Africa;

(2) significant progress needs to be made in preventing and treating HIV/AIDS in sub-Saharan Africa in order to sustain a mutually beneficial trade

relationship between the United States and sub-Saharan African countries; and

(3) the HIV/AIDS crisis in sub-Saharan Africa is a global threat that merits further attention through greatly expanded public, private, and joint public-private efforts, and through appropriate United States legislation.

AMENDMENT TO H.R. 2415

OFFERED BY MR. SANDERS OF VERMONT

Page 35, after line 9, insert the following (and conform the table of contents accordingly):

SEC. 211. PROHIBITION ON INTERFERENCE WITH INTELLECTUAL PROPERTY LAW RELATING TO PHARMACEUTICALS OF CERTAIN FOREIGN COUNTRIES.

No employee of the Department of State shall take any action to deter or to otherwise interfere with any intellectual property law or policy of any country in Africa or Asia (including Israel) that is designed to make pharmaceuticals more affordable if such law or policy, as the case may be, complies with the Agreement on Trade-Related Aspects of Intellectual Property Rights referred to in section 101(d)(15) of the Uruguay Round Agreements Act (19 U.S.C. 3511(d)(15)).

STATE DEPARTMENT AUTHORIZATION BILL

FINAL VOTE RESULTS FOR ROLL CALL 322

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

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

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

--- AYES 117 ---

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

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

--- NOES 307 ---

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

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

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

--- NOT VOTING 9 ---

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

Selected Provisions in the WTO/TRIPS agreement
(From introduction and Articles 1, 6, 7, 8, 27, 28, 29, 30, 31, 39, 41, 44, 65, 66, 67, 70)

(The entire agreement is on the web at:
http://www.wto.org/wto/intellec/intellec.htm)

AGREEMENT ON TRADE-RELATED ASPECTS OF
INTELLECTUAL PROPERTY RIGHTS

Members,

Desiring to reduce distortions and impediments to international trade, and taking into account the need to promote effective and adequate protection of intellectual property rights, and to ensure that measures and procedures to enforce intellectual property rights do not themselves become barriers to legitimate trade;

Recognizing, to this end, the need for new rules and disciplines concerning:

(a) the applicability of the basic principles of GATT 1994 and of relevant international intellectual property agreements or conventions;

(b) the provision of adequate standards and principles concerning the availability, scope and use of trade-related intellectual property rights;

(c) the provision of effective and appropriate means for the enforcement of trade-related intellectual property rights, taking into account differences in national legal systems;

[points omitted]

Recognizing the underlying public policy objectives of national systems for the protection of intellectual property, including developmental and technological objectives;

Recognizing also the special needs of the least-developed country Members in respect of maximum flexibility in the domestic implementation of laws and regulations in order to enable them to create a sound and viable technological base;

[point omitted]

Hereby agree as follows:

GENERAL PROVISIONS AND BASIC PRINCIPLES

Article 1
Nature and Scope of Obligations

1. Members shall give effect to the provisions of this Agreement. Members may, but shall not be obliged to, implement in their law more extensive protection than is required by this Agreement, provided that such protection does not contravene the provisions of this Agreement. Members shall be free to determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice.

[2 and 3 omitted]

Article 6
Exhaustion

For the purposes of dispute settlement under this Agreement, subject to the provisions of Articles 3 and 4 nothing in this Agreement shall be used to address the issue of the exhaustion of intellectual property rights.

Article 7
Objectives

The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.

Article 8
Principles

1. Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement.

2. Appropriate measures, provided that they are consistent with the provisions of this Agreement, may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology.

SECTION 5: PATENTS

Article 27
Patentable Subject Matter

1. Subject to the provisions of paragraphs 2 and 3, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application.See footnote 5 Subject to paragraph 4 of Article 65, paragraph 8 of Article 70 and paragraph 3 of this Article, patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.

[Footnote: 5. For the purposes of this Article, the terms "inventive step" and "capable of industrial application" may be deemed by a Member to be synonymous with the terms "non-obvious" and "useful" respectively.]

2. Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect ordre public or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law.

3. Members may also exclude from patentability:

(a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals;

(b) plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective sui generis system or by any combination thereof. The provisions of this subparagraph shall be reviewed four years after the date of entry into force of the WTO Agreement.

Article 28
Rights Conferred

1. A patent shall confer on its owner the following exclusive rights:

(a) where the subject matter of a patent is a product, to prevent third parties not having the owner's consent from the acts of: making, using, offering for sale, selling, or importing (See footnote 6) for these purposes that product;

[Footnote: 6 This right, like all other rights conferred under this Agreement in respect of the use, sale, importation or other distribution of goods, is subject to the provisions of Article 6.]

(b) where the subject matter of a patent is a process, to prevent third parties not having the owner's consent from the act of using the process, and from the acts of: using, offering for sale, selling, or importing for these purposes at least the product obtained directly by that process.

2. Patent owners shall also have the right to assign, or transfer by succession, the patent and to conclude licensing contracts.

Article 29
Conditions on Patent Applicants

1. Members shall require that an applicant for a patent shall disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art and may require the applicant to indicate the best mode for carrying out the invention known to the inventor at the filing date or, where priority is claimed, at the priority date of the application.

2. Members may require an applicant for a patent to provide information concerning the applicant's corresponding foreign applications and grants.

Article 30
Exceptions to Rights Conferred

Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.

Article 31
Other Use Without Authorization of the Right Holder

Where the law of a Member allows for other use (See footnote

7) of the subject matter of a patent without the authorization of the right holder, including use by the government or third parties authorized by the government, the following provisions shall be respected:

[Footnote: 7"Other use" refers to use other than that allowed under Article 30.]

(a) authorization of such use shall be considered on its individual merits;

(b) such use may only be permitted if, prior to such use, the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time. This requirement may be waived by a Member in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use. In situations of national emergency or other circumstances of extreme urgency, the right holder shall, nevertheless, be notified as soon as reasonably practicable. In the case of public non-commercial use, where the government or contractor, without making a patent search, knows or has demonstrable grounds to know that a valid patent is or will be used by or for the government, the right holder shall be informed promptly;

(c) the scope and duration of such use shall be limited to the purpose for which it was authorized, and in the case of semi-conductor technology shall only be for public non-commercial use or to remedy a practice determined after judicial or administrative process to be anti-competitive;

(d) such use shall be non-exclusive;

(e) such use shall be non-assignable, except with that part of the enterprise or goodwill which enjoys such use;

(f) any such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use;

(g) authorization for such use shall be liable, subject to adequate protection of the legitimate interests of the persons so authorized, to be terminated if and when the circumstances which led to it cease to exist and are unlikely to recur. The competent authority shall have the authority to review, upon motivated request, the continued existence of these circumstances;

(h) the right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization;

(i) the legal validity of any decision relating to the authorization of such use shall be subject to judicial review or other independent review by a distinct higher authority in that Member;

(j) any decision relating to the remuneration provided in respect of such use shall be subject to judicial review or other independent review by a distinct higher authority in that Member;

(k) Members are not obliged to apply the conditions set forth in subparagraphs (b) and (f) where such use is permitted to remedy a practice determined after judicial or administrative process to be anti-competitive. The need to correct anti-competitive practices may be taken into account in determining the amount of remuneration in such cases. Competent authorities shall have the authority to refuse termination of authorization if and when the conditions which led to such authorization are likely to recur;

(l) where such use is authorized to permit the exploitation of a patent ("the second patent") which cannot be exploited without infringing another patent ("the first patent"), the following additional conditions shall apply:

(i) the invention claimed in the second patent shall involve an important technical advance of considerable economic significance in relation to the invention claimed in the first patent;

(ii) the owner of the first patent shall be entitled to a cross-licence on reasonable terms to use the invention claimed in the second patent; and

(iii) the use authorized in respect of the first patent shall be non-assignable except with the assignment of the second patent.

SECTION 7: PROTECTION OF UNDISCLOSED INFORMATION

Article 39

1. In the course of ensuring effective protection against unfair competition as provided in Article 10bis of the Paris Convention (1967), Members shall protect undisclosed information in accordance with paragraph 2 and data submitted to governments or governmental agencies in accordance with paragraph 3.

2. Natural and legal persons shall have the possibility of preventing information lawfully within their control from being disclosed to, acquired by, or used by others without their consent in a manner contrary to honest commercial practices (See footnote 10) so long as such information:

[Footnote: 10. For the purpose of this provision, "a manner contrary to honest commercial practices" shall mean at least practices such as breach of contract, breach of confidence and inducement to breach, and includes the acquisition of undisclosed information by third parties who knew, or were grossly negligent in failing to know, that such practices were involved in the acquisition.]

(a) is secret in the sense that it is not, as a body or in the precise configuration and assembly of its components, generally known among or readily accessible to persons within the circles that normally deal with the kind of information in question;

(b) has commercial value because it is secret; and

(c) has been subject to reasonable steps under the circumstances, by the person lawfully in control of the information, to keep it secret.

3. Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use. In addition, Members shall protect such data against disclosure, except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use.

SECTION 1: GENERAL OBLIGATIONS

Article 41

1. Members shall ensure that enforcement procedures as specified in this Part are available under their law so as to permit effective action against any act of infringement of intellectual property rights covered by this Agreement, including expeditious remedies to prevent infringements and remedies which constitute a deterrent to further infringements. These procedures shall be applied in such a manner as to avoid the creation of barriers to legitimate trade and to provide for safeguards against their abuse.

2. Procedures concerning the enforcement of intellectual property rights shall be fair and equitable. They shall not be unnecessarily complicated or costly, or entail unreasonable time-limits or unwarranted delays.

3. Decisions on the merits of a case shall preferably be in writing and reasoned. They shall be made available at least to the parties to the proceeding without undue delay. Decisions on the merits of a case shall be based only on evidence in respect of which parties were offered the opportunity to be heard.

4. Parties to a proceeding shall have an opportunity for review by a judicial authority of final administrative decisions and, subject to jurisdictional provisions in a Member's law concerning the importance of a case, of at least the legal aspects of initial judicial decisions on the merits of a case. However, there shall be no obligation to provide an opportunity for review of acquittals in criminal cases.

5. It is understood that this Part does not create any obligation to put in place a judicial system for the enforcement of intellectual property rights distinct from that for the enforcement of law in general, nor does it affect the capacity of Members to enforce their law in general. Nothing in this Part creates any obligation with respect to the distribution of resources as between enforcement of intellectual property rights and the enforcement of law in general.

Article 44
Injunctions

1. The judicial authorities shall have the authority to order a party to desist from an infringement, inter alia to prevent the entry into the channels of commerce in their jurisdiction of imported goods that involve the infringement of an intellectual property right, immediately after customs clearance of such goods. Members are not obliged to accord such authority in respect of protected subject matter acquired or ordered by a person prior to knowing or having reasonable grounds to know that dealing in such subject matter would entail the infringement of an intellectual property right.

2. Notwithstanding the other provisions of this Part and provided that the provisions of Part II specifically addressing use by governments, or by third parties authorized by a government, without the authorization of the right holder are complied with, Members may limit the remedies available against such use to payment of remuneration in accordance with subparagraph (h) of Article 31. In other cases, the remedies under this Part shall apply or, where these remedies are inconsistent with a Member's law, declaratory judgments and adequate compensation shall be available.

PART VI

TRANSITIONAL ARRANGEMENTS

Article 65
Transitional Arrangements

1. Subject to the provisions of paragraphs 2, 3 and 4, no Member shall be obliged to apply the provisions of this Agreement before the expiry of a general period of one year following the date of entry into force of the WTO Agreement.

2. A developing country Member is entitled to delay for a further period of four years the date of application, as defined in paragraph 1, of the provisions of this Agreement other than Articles 3, 4 and 5.

3. Any other Member which is in the process of transformation from a centrally-planned into a market, free-enterprise economy and which is undertaking structural reform of its intellectual property system and facing special problems in the preparation and implementation of intellectual property laws and regulations, may also benefit from a period of delay as foreseen in paragraph 2.

4. To the extent that a developing country Member is obliged by this Agreement to extend product patent protection to areas of technology not so protectable in its territory on the general date of application of this Agreement for that Member, as defined in paragraph 2, it may delay the application of the provisions on product patents of Section 5 of Part II to such areas of technology for an additional period of five years.

5. A Member availing itself of a transitional period under paragraphs 1, 2, 3 or 4 shall ensure that any changes in its laws, regulations and practice made during that period do not result in a lesser degree of consistency with the provisions of this Agreement.

Article 66
Least-Developed Country Members

1. In view of the special needs and requirements of least-developed country Members, their economic, financial and administrative constraints, and their need for flexibility to create a viable technological base, such Members shall not be required to apply the provisions of this Agreement, other than Articles 3, 4 and 5, for a period of 10 years from the date of application as defined under paragraph 1 of Article 65. The Council for TRIPS shall, upon duly motivated request by a least-developed country Member, accord extensions of this period.

2. Developed country Members shall provide incentives to enterprises and institutions in their territories for the purpose of promoting and encouraging technology transfer to least-developed country Members in order to enable them to create a sound and viable technological base.

Article 67
Technical Cooperation

In order to facilitate the implementation of this Agreement, developed country Members shall provide, on request and on mutually agreed terms and conditions, technical and financial cooperation in favour of developing and least-developed country Members. Such cooperation shall include assistance in the preparation of laws and regulations on the protection and

enforcement of intellectual property rights as well as on the prevention of their abuse, and shall include support regarding the establishment or reinforcement of domestic offices and agencies relevant to these matters, including the training of personnel.

Article 70
Protection of Existing Subject Matter

1. This Agreement does not give rise to obligations in respect of acts which occurred before the date of application of the Agreement for the Member in question.

2. Except as otherwise provided for in this Agreement, this Agreement gives rise to obligations in respect of all subject matter existing at the date of application of this Agreement for the Member in question, and which is protected in that Member on the said date, or which meets or comes subsequently to meet the criteria for protection under the terms of this Agreement. In respect of this paragraph and paragraphs 3 and 4, copyright obligations with respect to existing works shall be solely determined under Article 18 of the Berne Convention (1971), and obligations with respect to the rights of producers of phonograms and performers in existing phonograms shall be determined solely under Article 18 of the Berne Convention (1971) as made applicable under paragraph 6 of Article 14 of this Agreement.

3. There shall be no obligation to restore protection to subject matter which on the date of application of this Agreement for the Member in question has fallen into the public domain.

4. In respect of any acts in respect of specific objects embodying protected subject matter which become infringing under the terms of legislation in conformity with this Agreement, and which were commenced, or in respect of which a significant investment was made, before the date of acceptance of the WTO Agreement by that Member, any Member may provide for a limitation of the remedies available to the right holder as to the continued performance of such acts after the date of application of this Agreement for that Member. In such cases the Member shall, however, at least provide for the payment of equitable remuneration.

5. A Member is not obliged to apply the provisions of Article 11 and of paragraph 4 of Article 14 with respect to originals or copies purchased prior to the date of application of this Agreement for that Member.

6. Members shall not be required to apply Article 31, or the requirement in paragraph 1 of Article 27 that patent rights shall be enjoyable without discrimination as to the field of technology, to use without the authorization of the right holder where authorization for such use was granted by the government before the date this Agreement became known.

7. In the case of intellectual property rights for which protection is conditional upon registration, applications for protection which are pending on the date of application of this Agreement for the Member in question shall be permitted to be amended to claim any enhanced protection provided under the provisions of this Agreement. Such amendments shall not include new matter.

8. Where a Member does not make available as of the date of entry into force of the WTO Agreement patent protection for pharmaceutical and agricultural chemical products commensurate with its obligations under Article 27, that Member shall:

(a) notwithstanding the provisions of Part VI, provide as from the date of entry into force of the WTO Agreement a means by which applications for patents for such inventions can be filed;

(b) apply to these applications, as of the date of application of this Agreement, the criteria for patentability as laid down in this Agreement as if those criteria were being applied on the date of filing in that Member or, where priority is available and claimed, the priority date of the application; and

(c) provide patent protection in accordance with this Agreement as from the grant of the patent and for the remainder of the patent term, counted from the filing date in accordance with Article 33 of this Agreement, for those of these applications that meet the criteria for protection referred to in subparagraph (b).

9. Where a product is the subject of a patent application in a Member in accordance with paragraph 8(a), exclusive marketing rights shall be granted, notwithstanding the provisions of Part VI, for a period of five years after obtaining marketing approval in that Member or until a product patent is granted or rejected in that Member, whichever period is shorter, provided that, subsequent to the entry into force of the WTO Agreement, a patent application has been filed and a patent granted for that product in another Member and marketing approval obtained in such other Member.

Mr. MICA. I am now pleased to recognize another individual who has been active on this issue, Marion Berry from Arkansas. Welcome, and you are recognized, sir.

STATEMENT OF HON. MARION BERRY, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF ARKANSAS

Mr. BERRY. Thank you, Mr. Chairman. I applaud your efforts for holding this hearing today concerning the HIV/AIDS epidemic.

As you have already heard, over 14 million people have died of this disease. In many sub-Saharan Africa 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 a day.

The United States Surgeon General, David Satcher, recently wrote for the Journal of the American Medical Association, comparing AIDS to the plague, as you have already heard, that decimated the population of Europe in the 14th century.

I also agree with Surgeon General Satcher's comment that perhaps the most important element in the battle against HIV/AIDS is political commitment. Leaders at the national, provincial, and local government level must speak out about HIV/AIDS and encourage businesses and nongovernment organizations to commit to work against this disease.

I worked as a pharmacist and now serve as cochairman of the House Prescription Drug Task Force that I founded, along with Jim Turner and Tom Allen. I am familiar with the issues involving costs and availability of prescription drugs in our country, and I believe that these same issues are critical to improving health care and access to prescription drugs in developing nations. I am optimistic that 1 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 funding new cures and provide access to the technology for those who need it.

Developing a cure for AIDS would be a monumental breakthrough, but even that would not solve all the problems we face. Modern treatments for AIDS have cut in half the number of patients dying from the disease in the United States. 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 living in tropical countries of the world, die of preventable, curable diseases as die of AIDS.

I welcome the administration's proposal to increase the United States investment in fighting HIV/AIDS in Africa by $100 million. The new funding would go primarily to prevention, providing child care for children whose parents have AIDS, and offering counseling and support for those with AIDS. I am sure that the help will be appreciated, but noticeably, it will not help one more patient get lifesaving 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 reasonable prices. 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 played by the rules of the international trade agreements. Over 3 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. In 1997, the per capita income of South Africa was estimated to be $6,200 annually. Prescription drugs are not currently an option for many patients in South Africa, where they often cost more than they do in the United States.

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 drugmakers in their country. 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 describing the United States Government's efforts to stop South Africa from enacting the legislation. 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 the intellectual property rights. Instead, it is a part of the copyright and patent system, which enables the interests 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. In fact, French law authorizes compulsory licensing when medicines are available to the public in insufficient quantities or qualities, or at abnormally high prices.

Only 3 months ago, the House 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 that we are promoting what is in everyone's best interests.

Thank you, Mr. Chairman.

Mr. MICA. I thank the gentleman for his statement.

[The prepared statement of Hon. Marion Berry follows:]

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.

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. Doctors Without Borders, a group that will be testifying later today, has conducted substantial research concerning this topic.

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.

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.

Mr. MICA. I am pleased to recognize the last member of the panel, who talks from very firsthand experience about this terrible disease, Chatinka Nkhoma. She is a Malawi citizen.

Welcome, and you are recognized, ma'am.

STATEMENT OF CHATINKA C. NKHOMA, MALAWI CITIZEN

Ms. NKHOMA. Thank you, Mr. Chairman.

Mr. Chairman and members of the committee, ladies and gentlemen, I am here today to represent the millions of people that you have just heard of that are being infected with HIV/AIDS and have no way out; millions of Africans who are dying and will continue to die if nothing is done immediately.

I am their voice here to cry for help. We need access to the proper treatment of AIDS. I am a 37-year-old African woman, a single woman living with AIDS. I come from Malawi, a very poor country in Africa, actually the second poorest country in the whole world, although I think last week they say we are No. 4, but I still think we are the poorest.

Malawi has an estimated population of 11 million. Twenty percent, as we heard, is infected with the AIDS virus and is dying from it. I now call myself living with AIDS, but just a couple of months ago I was dying of AIDS. I do not think anybody in this House can even begin to imagine what it is like to live in an environment like that.

These figures, the 20 percent, also include, Mr. Chairman, my brother Michael and his wife, who died last year, leaving a 2-month-old baby who had to be fed by a wet nurse; my sister, who died in 1994. She was a widow. She left four children. I have lost three brothers-in-law. I have lost 10 cousins. My mother, who right now she should be enjoying the fruits of her labor, is burying her children.

I have lost so many friends and neighbors and work colleagues; so many relations. Many professional people, entertainers, and local media people, even politicians; everybody is dying. We are either dying from the disease or the effects of it.

Saving the children and not the mothers is even worse, because children are left vulnerable to abuse. I am supposed to have been dead right now, but I can testify that I am here because of the mercy of Christ. I am not here because I was treated for opportunistic diseases. I had a lot of antibiotics and many other stuff that tried to cure the infections that I had. But, Mr. Chairman, if I had not been one of the fortunate people, one of the people who had God's blessing to be able to access these drugs, I simply would not have been here.

Mr. Chairman, we need these drugs to enable us to survive this catastrophe. We need these drugs. We need the full and complete AIDS treatment for the millions of people dying. That need cannot be adequately emphasized in any way. A program that can test and treat millions of us who are infected will also stop the virus from spreading further. Right now that is the only available vaccine.

As we heard early on, Mr. Chairman, you say there has been a significant reduction in the AIDS infection rate in America. That started by the drugs. There have been so many statistics that have been thrown around today Mr. Chairman. Whatever the source

they came from, and whoever presented them, they are alarming, and this trend will not change.

There are many arguments about what other things we do not have. That is true, we do not have many things, but we cannot be condemned to death because we are poor. There are some people that have actually said we Africans are used to death and destruction. We are not; we are only human people living in fear every day, every minute. We do not talk about AIDS because it provokes that fear.

Some people react violently. We have heard about people being killed. That is the only means of self-defense some people find. It is unacceptable to discriminate against anybody, but who are we to judge? If you cannot get to something, you cannot see and touch, then people just use all sorts of ways to self-defend themselves. Maybe by killing your neighbor you think you are going to save yourself.

I know today there will probably be a lot more arguments as to why we should not get the drugs; arguments that they are too costly and they are too dangerous to give to Africans; that it is better for us to die because we do not have high-tech hospitals; that we are not intelligent enough to administer them properly, that we do not need them now. I do not know when we will need them; that we only need aspirins and antibiotics now; that we are going to create a virus that will be resistant to all the newer drugs and probably have wasted scientists' time in their research.

Mr. Chairman, we want to be alive to bring up our children. Whatever it takes to make us live, it must be done. We are also human. I know we are very poor humans, but not by choice. We do not want to die. At this stage in medical advances, it should not be accepted for anybody to be left to die because of the cost factors.

At the end of my studies here, I want to go back home. I want to return to my family. I can only do this if we have access to drugs in my country, because I do not want to die. At the same time, I want to go home and be with my family, so I am begging you to at least give us access to these drugs, whatever way. The pledges that have been made, $100 million, or everything else, but not drugs, this is not right. We should have—the pledges should include everything. If I do not have clothes on my shoulders, you cannot say you are not going to give me food. That is the only way it is going to make a difference.

I know it is not easy to keep up with the treatment regimens. Regardless of where you come from or how rich you are, they are hard. But I know one thing for sure: Where this is a will, there is a way. Africans have contributed to AIDS research. As we speak now, we have institutions that are researching AIDS in Africa, and most of the drugs that have been used now have been researched on people in Africa. We have been used as guinea pigs in trials for these drugs. I think we deserve the drugs, if not for anything else, maybe just because we are humans. We should not be expendable. We should not be punished for being poor.

More prevention, education, and better hospitals will not save the situation. We need that and the drugs. I believe I was able to learn foreign languages, several of them, I have learned foreign technologies, and I believe it would not be true if you say that we

cannot learn how to follow medical procedures that will save our own lives. We can learn how to do that, and by shear will we will make it. I know people who will and do travel 10 miles every day to get an injection if the doctor tells them to do that, by foot.

These days we are no longer mourning our dead, Mr. Chairman, we are just burying them. We do not have the time, the resources, or the tears. The old are burying the young. This is not a good thing for Africans, for we believe that young people do not make good ancestors. They have not gathered enough wisdom and experience for this job of being an ancestor.

Following proper burial customs ensures that the dead lay at rest and do not return to haunt us and bring bad omens upon the community, which is exactly what is happening.

Mr. Chairman, in closing, I just want to say, we have three types of brothers and sisters, Mr. Chairman, in my country. We have the breast brothers and sisters, those that you share the same breast. We have blood line brothers and sisters. Then we have brothers who are people who have been there for us. I am sure you can be our brothers and sisters. You have been there for us for many times, and we need your help this time.

Mr. Chairman, we don't want to die. At the same time, we have what we also called Wantu. I believe in Yiddish, we call it mensch, and in English it is probably humanity. It talks about humanness, gentleness, and hospitality, putting yourself out on behalf of others, being vulnerable. It recognizes that my humanity is bound in yours. We can only be humans together. Bishop Desmond Tutu is better than anyone at doing this.

Mr. Chairman, AIDS is affecting everything, every aspect of our lives. It is leaving no stone unturned. It is cultural, socioeconomic, a productivity degradation. Mr. Chairman, unless it is in one's interest to see us Africans perish, immediate action needs to be taken. Give us this gift of life!

The Greeks said that the last demon that came out of Pandora's box, called hope, was the most dangerous demon, because it looked like an angel. Giving us anything else other than the complete treatment is giving us this demon. Thank you very much, Mr. Chairman, ladies and gentlemen.

Mr. MICA. Thank you for your testimony.

[The prepared statement of Ms. Nkhoma follows:]

WRITTEN STATEMENT ON THE

CONGRESSIONAL HEARING ON HIV/AIDS IN AFRICA

JULY 22, 1999

By Chatinkha C. Nkhoma, (37 year old HIV+ single mother from Malawi, Africa)

The first time I came to America was in 1991after completing a one and half year study of the German language in Bonn, Germany. I came here to chase the Malawian woman's dream combined with the American dream. That is to get a higher education and gain financial independence and security. I proceeded to enroll at Montgomery College, paying for my tuition doing odd manual jobs. I completed the first semester as an A student. I applied and received a scholarship from my government, which enabled me to enter a four-year college at George Washington University in the Fall of 1992. After my graduation with a BA in International Affairs from the George Washington University in 1995, I headed straight back to Malawi, Africa with overflowing enthusiasm and full of anticipation of the good times to come. I was assigned to the Foreign Affairs ministry and rose fast from being a regional desk officer to the post of deputy director.

As a woman in male dominated community, this was not an easy feat. I had to overcome many barriers and obstacles, traditional, socioeconomic and gender, which affected my life both positively and negatively. I achieved success the hard way, not having to pay with sexual favors. (a common trend in my country). Thus I did not gain popularity, but respect.

I was on my path, I was aspiring to become an Ambassador for my country and whatever the future held for me, maybe UN Secretary General. All these dreams had a time frame. But my world came tumbling down when I experience a near death battle with PCP pneumonia resulting in being diagnosed with AIDS. No, this news did not come as a surprise to me, even after the fact that I had tried my best to avoid infection by doing the right things. It did not come as a surprise because AIDS and death were now fully integrated in the everyday life of my surroundings. AIDS had been circulating around me and was drawing closer. I had bargained with God every day to spare me, I promised him I would be good. But as members of my own family began to die, the trap felt tighter. I knew my turn was near. And as sure as the sun will shine, it came, and with it my dreams died.

They died, but God had other plans for me. I got a little better and travel to America to pursue a Masters degree study. It was then that I discovered that I wouldn't have to die as soon as I had thought. There were these new drugs which, I learnt, would allow me to live longer. The advances in the treatment of AIDS had gone beyond only AZT. These treatments, that meant that nobody, needed to have to die right away. It meant that hope would be restored for people dying from AIDS. Since that discovery, I have been unable to think of anything else except to see these new wonder drugs are available for poor people dying with AIDS. Unfortunately, the cost of these drugs turned my dream turn into a nightmare.

Now however, my dream is still to become an ambassador, but a different type of ambassador. Advocate for the voiceless million who desperately need these drugs. I

am here to represent the crying Mother Africa, her children have suffered long enough. History is my witness. Every time I take these drugs, I cannot help, but feel guilty, knowing that my brothers, sisters, mothers, fathers, daughters, sons, uncles, aunts, our children, tomorrow's leaders and they are all dying, slowly and painfully because they are too poor to afford them. It is now not about my survival, but the survival of millions of people sentenced to death and their only crime is that of being poor. A friend here once asked me what I was going to do if I went back home without these drugs. I told her make the question 'What I would want on my tombstone'?

Everyday messages from home are of some one I know, dying of AIDS related illness. My neighbors, work colleagues, friends, local entertainers, politician, many members of the cabinet and parliament are dying. Everybody is dying. Personally, I have lost my brother Mike, my sister Eleanor, three brother-in-laws, cousins, aunts and uncles, all dying in the span of less than 6 years. This is too much for my mother. She has now developed High Blood pressure problem, something that we have never had in our family history. She laments that she never imaged she would be burying her children, but her children and grandchildren burying her. A women with very minimal education (grade 3), raised 9 of her own children and 7 from other relations on her own as a farmer (my father died in 1978), to levels of college. It was now her time to be enjoying the fruits of her labor. But no, at the age of 72 she is busy caring for her sick and dying children. This breaks my heart more than my infection. Her survival depends on us, she is too old to continue with this. I have to go back and look after her, but I cannot without the medication. Please help me to go back and spent my last years, not days, with my son and family. It hurts too much thinking about what my child's future would be like without me, it is every mother's nightmare.

Please allow us to have access to the treatment drug so we can raise our children a little longer and not leave them as orphans. This is the cry of every poor mother infected with the disease. If you can save the new born, you must save the mother, because it is only the mothers that gives total commitment to the healthy development of her baby (even if that baby is 60 years old). Orphanages can only do so much. Traditionally, when a mother dies, her children are raised by her relatives, but the intensity of which the AIDS epidemic has increased deaths of mothers combined with the frail economies, makes this practice difficult to maintain.

We Africans believe in what we call Umunthu, in Yiddish it is called Mensch and I think in English it is called Humanity. We cannot explain exactly what it is means. But it speaks of about humanness, gentleness, and hospitality, putting yourself out on the behalf of others, being vulnerable. It recognizes that my humanity is bound in yours, for we can only be humans together.

The effects of the AIDS epidemic in Malawi, like all other poor nations is worse than you can even begin to imagine. It has affected the cultures, economies, development, family structures. It has increase poverty, crimes and other social ills. Orphaned children are turned into domestic and sex slaves, prostitution is on the rise in an environment not conducive to this life style. The hospitals are unable to cope with the large increase of patients, the morgues are operating 24 hours, and the cemeteries are filling up fast. People are left hopeless, desperate and in total fear. Fear has created the violent discrimination of those who are publicly known to be infected. People are

being assaulted or even killed. Not because those killing are savages or brutish, (although these are inexcusable act, we must not be too quick to judge since we are not in their shoes) but because that is the only way they can get back at this silent and vicious killer called Aids. It is their only means of self-defense. The only way they can express desperation, fear, and anger, like cornered animals, naturally reacting to danger in very brutal way, it is survival instinct. Babies born with or without the virus, without the protection of the mother, have no chance in this environment. They are bound to be abused in many ways if they fall in the wrong hands. We all know this to be true. There is a sense of total social and cultural degradation everywhere. People move around in a state of numbness, like zombies, too afraid to be scared.

The irony is that in recent years, we were being told that we were over populated and this was causing deforestation. Well the population problem is surely being solved, it is decreasing rapidly and but with it, so is forestation as well. Wood is used for coffins, cooking at funerals and several other custom rituals. There is a kind of domino effect, every aspect of life is being affected with this epidemic. Standards of living and life expectancy are being lowered. I know this sounds eerie. These effects are not generally noticeable to the international communities, e.g. diplomats, UN, NGO and other Representatives, because they do not live with the people but under some type of secured premises. Those working in the medical field can be witnesses to deteriorating conditions in hospital, but still not to the social conditions. They don't come to funerals.

We are no longer mourning our dead because of lack of time and resources. We are just burying them. Funeral ceremonies are very important and sacred to my people. Much effort is invested in ensuring that the spirit of the dead rest in peace and do not return to haunt us. Traditionally, we expected those dying to be our grandparents, people who have matured and gained enough wisdom to became our ancestors in the spirit world. But AIDS is killing the younger productive generations. It is believed that people do not naturally die young, but only through witchcraft and sorcery. Young people do not make good ancestors and linger around bringing bad omens on the communities. No wonder AIDS is linked to this phenomenal and those associated with it are victimized. False accusations of witchcraft are thrown around, retributions and revenges on innocent victims are happening more often now.

The circle is vicious and the craziness is gaining momentum with such alarming speed. Unless something is done and done now, we are heading towards a catastrophe the whole world has never seen. This millenium will end on such a tragic note it may be impossible to recover from it. Especially with the known fact that something can be done, but those that have the means to stop these human sufferings do not feel responsible or obliged to lend a hand because those suffering are poor. History already has enough to judge us on regarding the unkindness already heaped on the people of color. The whole millenium is filled with our suffering, from systems of slavery, colonialism, neocolonism, imperialism, apartheid, segregation, discriminations. These practices have made us to be in a tangled system of dependence. That is why we are now unable to find our own solution to this catastrophe, because it is an economic solution and the dependence system ensured that we remain poor and in subordination. So we are now back on your door, begging to you save us. Our survival is once again depended on your generosity. You know, "Nobless Oblige". This is the ultimate and

final blow, and unless it is in somebody's interest to destroy us, then immediate action need to be taken. This is not natural, there no Darwinism here, it is not a natural selection of survival of the fittest. NO. This is pure evil and only Satan is involved.

Let history this time records some unity in times of need. We are asking for immediate and unconditional assistance. Stop these feeble and weak excuses being thrown around. One of your great anthropologists, Turnbill, wrote that when there is trouble in the forest, the Effies, who he called the pigmies of Africa, dig up huge horns that they make from hollowed out trees and old metal pipes. They blow them and blow them to wake up the earth. For they know that the earth is good, that it loves us and that the only reason the earth could possibly allow the world to hurt us, is not out of cruelty, but because she is asleep. And the Effies hope that the sound of the huge horns will wake her up. Let us all call mother earth together, for she is sleeping now and her children are hurting.

It is unfair and hurtful to speak of us as irresponsible and too illiterate to be able to understand how to use medicines and keep track of complicated regimens. We who have never had these drugs are not the cause of multidrug resistant HIV yet. To say we should be condemned to death is practicing politics of genocide. There are even those who say our health care workers are not smart enough. They are smart enough to know that there is no point for them to learning the intricacies of combinatorial antiviral therapy when there are no drugs to use and when they are overworked trying to make the dying suffer less. We have learnt your languages, technologies and even your culture. Is it really possible that we would be unable to learn how to take medication that can save our lives? I don't think so.

A recent television news item argued that it was better to allow Africans to die for fear of resistant strains of virus. May I point out that there is never a valid humane argument which allows for the death of over 40 million people, it should not be allowed, It is our human responsibilities to save each other and not allow unnecessary deaths. We should be here talking about how to save these poor people. Not arguing on why it should be done. If lives can be saved, it is humanity to do so, regardless of the costs. In my country we say, money does not make people, but people make people. People are people because there are other people. The differences in shades of our skins are there because there are there. It is neither a bad or good thing, it is just their, not to prove anything at all and should not be used to value the worth ones life.

Prevention campaign efforts have so far proved to be a failure, because they targeted morality more than mortality. Emphasis is more on the 'wages of sin' syndrome so people naturally prefer to hide their positive status or not get tested at all. This leads to continual unchecked spread of the virus. It also triggers discriminations. Prevention messages have negatively portrayed women as the major culprit. Women are victimized, some by having all the family property taken away by a deceased husbands relatives and leaving her and her children homeless.

With drugs available as part of the prevention programs, more people will want to get tested so that they are put on medication. Discrimination of those of us infected will reduce. When are receiving care we will feel more obliged to control further spreading of the virus and help in outreach peer-education to rest of the populations. On the other

the hand, condemning us to death, is not helping the situation. Those condemned cannot feel any obligation to get involved in the fight against this deadly virus, both knowingly and unknowingly. So it is very important that care for those infected is included with any assistance offered with foreign aid program to effectively control this tragic epidemic. Only together and when greed is removed, can we succeed in eventually combating this virus.

I know how hard people here try to stay alive and be compliant, that is why the infection rate has since reduced to 50% with treatment of these new drugs. This can also happened with us, because, I can assure you of one thing, where there is will there is a way. Condemning millions of people because of unfounded fears is not the answer. There is no proof that we will not be able to adhere to drug requirements. We have adhered to many complex treatment regiments that have since successfully eradicated or brought under control chronic diseases. These prophets of doom are only driven by greed, blind murderous greed. There is no factual evidence to their claim and it is better to try and fail any rescue efforts than never to try at all. The will for a human being to live supersedes science. Let us not underestimate this fact. Africans can walk over a 10 miles distance everyday to get a treatment if that is a requirement. It is no secret that we are in need of many other things. But that is not a valid reason to allow millions of people to die because they are poor.

I want to go home. But to go home is to go to my suffering death. And to stay here and be silent is to suffer inside knowing how many millions of my people are sick with an illness your government has found ways to treat. Let Africa have rights and tools to try and save its people. Allow us to access to these live saving drugs. This is the only way we can be able to survive. That is not asking for too much. It is not fair to punish Africa without a crime. That is what is happening now.

We all know that Africans have contributed in the AIDS research. Some people lost their lives being used as guinea pigs researching the current AIDS treatments. Countries such as Uganda, Kenya, Tanzania, Zimbabwe, Zambia and Malawi have AIDS research projects still underway' being run by U.S.A. institutions such as John Hopkins. It seems like these AIDS research projects are not meant for Africans benefit. Why else would it be such a big deal to allow us to use them?

Over 13 million Africans have already died, over 20 million are dying and over 20 percent will be joining the category every year without these life saving medicines, for in matters of life and death everyone must have a right to their share of the necessities of life. These medicines are necessities for life for those of us who are HIV positive.

A program which tests and treats will also stop the virus from spreading any further and this is the only vaccine available. It works, and we need to use it now. If we do not come together then we will be watching the greatest killing of any event in history unfold, at the same time we know exactly how to stop it. This would be unforgivable. Do not let it be said that the only thing that told the difference between those who would live and those who would die during the days of the great plague was the color of a person's skin. Let us put lives before profits, it can be done and must be done.

Every day that we waste in arguing over who should live and should die, according to

the United Nations Secretary General, 5,000 more Africans die of AIDS. This human carnage can be stop. We need to stop this insanity.

In the end, it cannot be in the interests of your companies to be responsible, along with your government, for the deaths of millions of people, and that is what the world will come to decide if this war against poor countries continues.

When the drugs are available, we the children of Africa wherever we are, in America, Caribbean, Europe, Asia and Africa, will celebrate by singing and playing our drums and horns so loud you will hear us in this house. Mother Africa will begin to wipe away her tears, smiling, because Mother Earth will be waking up to stop her children from hurting everywhere. She will wake up and stop the CHOAS. Let the last couple of months of this horrible millenium be a positive beginning of the next millennium.

This is the cry of the voiceless. The dying millions

Mr. MICA. I also thank the Members who testified.

I will just ask a couple of quick questions. You gave some compelling testimony, Ms. Nkhoma. You did say, as I recall, in your testimony that some people walk 10 miles a day to go and get an injection. That indicates that there is some treatment available.

What percentage of the people in your country, and again, one of the poorest of the countries, are able to get treatment?

Ms. NKHOMA. Mr. Chairman, in my country—it is different in all the countries, but I have been in all the neighborhoods, and if you may allow me, Mr. Chairman, in South Africa they have an infrastructure. Their medical facilities are very up-to-date. They have really high standards. So an excuse that they cannot have the medications because they do not have up-to-date facilities will not really hold any water in this.

But in my country we have a lot of facilities, available now, which are able to treat opportunistic diseases. We have a lot of missionary hospitals which have spread all over Africa, the Catholic missionaries, and we have other denomination missionary hospitals which are in every little space and community in Africa.

These hospitals are being funded by the donors outside Africa, and they are well-equipped, so they are able to administer, and to make sure that people will be able to follow the regimen. Like I say, in the end, it is up to the person. It does not matter where you are.

Mr. MICA. My question really was referring to what percentage of the people. How many that are afflicted with AIDS are able to get treatment? Is it 10 percent, 20 percent, could you estimate? It sounds like there is a regimented treatment available. But obviously you are here for treatment, you are not there, where many people left behind.

We are interested in seeing what kind of unserved population there is, since you have one of the poorest countries. Could you provide us with some estimate?

Ms. NKHOMA. Mr. Chairman, in my country I think there is nobody who will be able to get the medication, considering the fact that it is not a one-time medication, but every month for the rest of the time you are alive. So I can truly and honestly say here that I do not believe there is anybody in my country who would be able to take this medication at this moment. There are people who are attempting to take part of it. That is probably 0.001 percent of the population.

Mr. MICA. That was my question. You came here. Did you come here as a student, and you were able to get treatment in the United States? Did you pay for that, or is that provided?

Ms. NKHOMA. Mr. Chairman, I came here because I had a scholarship to come and get my master's degree. I didn't even know the medication was available. All I knew is that there was AZT. At the time I was going back to my country. AZT cost too much even at that time for anybody. So I didn't even know that things had gone as far as they have. It was after I came here and talked to some people about my condition, because I was still not very well, and they took me to the clinic.

Mr. MICA. Thank you.

Mr. Jackson, thank you for persisting in your interest in this, and Mr. Berry and others. I have many Members of Congress contact me and express their concern. I had some people contact me who did not want to conduct a hearing on this. I know it makes people uncomfortable, both in Congress and in the administration, with the pharmaceutical companies and the whole range.

But having been here, I have family on both sides of the aisle, and I do not think it is our job to ignore problems of this proportion and sweep them under the table. I think it is our job to hear them.

I have had requests from the minority and majority, I think they should be treated equally, and particularly for something of such significance. So I want to personally thank you, and also thank Members for persisting in this hearing. I have had the cooperation of our ranking member, and we did see some action from the administration this week, $100 million. As you say, it may be a drop in the bucket, but at least we are focusing some attention and resources.

We need an examination of our policy, which is critical, and this is not really a question but a comment. I thank both of you for your involvement.

I yield to our ranking member for questions.

Mrs. MINK. Thank you very much, Mr. Chairman.

Certainly, Ms. Nkhoma, the description that you have given the committee and the country about the conditions in your country and the lack of adequate treatment and drugs that are available in this country is certainly a pathetic comment on this Nation's humanity.

I think the question that I really wanted to ask is to our colleague Mr. Jackson, who has been pursuing this issue for a long time. Knowing the way this place works and how it works, and how slowly it takes hold of some of these very, very important issues, is there one particular thing that you feel we could do at the moment to break loose this barrier in this area, the policy of the United States in sharing its medical technology and expertise in alleviating the conditions of suffering and disease in Africa that are connected with HIV and AIDS?

Mr. JACKSON. Madam ranking member, I plan to offer next week a piece of legislation that will make drugs, or pharmaceuticals, much more available to the people of sub-Saharan Africa, and I certainly hope that it will be a bipartisan piece of legislation, and those Members of Congress who have expressed interest in this great issue, that they will manifest that great interest by becoming cosponsors of this bill so that we can make these needed improvements in our relationships with many of these countries more substantive; not just a humanitarian gift by the administration that is a discretionary gift by administrations, albeit Democrat or Republican, but make it the will of the American people in the form of a law that if, in fact, we have access to new technologies, new drugs, new pharmaceuticals, that we find ways to make them more available to more people.

Much of the AIDS research, as Ms. Nkhoma has indicated, has been tested on Africans. That is clearly, according to that map, the center of the AIDS crisis globally. But the results of that research are not making it back to Africa in the form of drugs and pharma-

ceuticals. They are being produced in our hospitals, in our labs, in our research, with our taxpayer dollars. And it is my personal desire, and I certainly would suggest it is the personal desire of the people that I represent, that their taxpayer dollars be used in such a way, since they are going toward AIDS research. I do sit on the Labor-Health-Human Services Committee, and I do have a sense of what the NIH is doing; the end result of that research should benefit people who have the disease.

It is troubling. I think that Members of Congress are going to have to wrestle with this, when the Office of the United States Trade Representative and the United States Government continue to pressure South Africans to abandon legal attempts to employ compulsory licensing and parallel imports.

A State Department report, with which we are all too familiar with now, explains how the United States Government agencies have been engaged in a full court press with South African officials from the Departments of Trade and Industry to pressure South Africa to change provisions of the Medicines Act that give the government the authority to pursue compulsory licensing and parallel import policies.

Why is South Africa so important? It is the largest sub-Saharan economy. Most other nations will take their cues based upon how our government relates to sub-Saharan Africa.

The United States has also threatened to withhold trade benefits under the GSP program from South Africa and threatened trade sanctions. Even in the report, for example, in July 1998, Assistant United States Trade Representative for African Affairs Rosa Whittaker met with the South African Charge d'Affaires in Washington to stress once again the United States Government's concern about pharmaceutical patent protection and parallel importation in South Africa.

She also repeated the United States Government's position that South Africa's request for preferential treatments would be held in abeyance pending adequate research on intellectual property rights protection. Unless we change this statutorily, this will be our Trade Representative's policy. And we cannot on the one hand be supportive of humanitarian concerns, which are purely discretionary, and abdicate our responsibilities as representatives to make it the U.S. Government's policy to address this crisis and keep it from spreading.

I thank the gentlewoman.

Mrs. MINK. A followup question. The point that you made, that Ms. Nkhoma also made reference to, the fact that Africa is basically the target location in this world for the testing of these drugs, is it possible in our legislation, or maybe not in this legislation but in other legislative efforts, that we could require that in situations where a disease such as this reaches a pandemic proportion, that the pharmaceutical companies that are testing drugs and exploring the efficacies or lack thereof of the drug treatments, in large part protected and funded by the United States, not be permitted unless they make suitable arrangements for the distribution of the drugs they have tested, and which have been proven efficacious; could we not establish such a policy or requirement in our support and sanc-

tions of these trials in these countries with reference to this type of epidemic?

Mr. JACKSON. I believe, Representative Mink, that it is possible to accomplish this legislatively. But I would go one step further to suggest that the World Trade Organization already allows for the creation or the availability of these drugs when the crisis reaches epidemic proportions.

Why the United States Government is pursuing sub-Saharan countries in many instances inconsistent with internationally established understandings with respect to availability in the event of epidemics is quite troubling.

But you touched upon something else that I think is critically important. Several of our colleagues today mentioned this idea of triple therapy against HIV viruses. Even Ms. Nkhoma indicated that to question Africans' intelligence about their ability to follow regular regimens, though complicated, was somewhat—this triple therapy, these drugs are expensive and very hard to take, but there are drugs to treat illnesses that kill people with AIDS that are cheaper and easier to take. A year's supply of these drugs is about $70 per year. Most are one pill of four drugs, once a day.

The point is, the kinds of combinations of therapies that some men and women have access to are very difficult to administer and supervise in the developing world's conditions, but these treatments, in many activists' views, 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 kill most people with AIDS. In this regard, I am specifically talking about pneumonia, fungal tuberculosis infections, dehydration due to diarrhea; these are diseases that people subsequently die from who are infected in this area. So it is not just the AIDS drugs which are being produced, which are not making it in South Africa, but many sub-Saharan Africans are dying from many other diseases that are complications of having HIV/AIDS.

Mr. MICA. Ms. Schakowsky.

Ms. SCHAKOWSKY. Thank you, Mr. Chairman.

I want to say a particular thank you to Ms. Nkhoma. We are all overwhelmed by the numbers and the breadth and extent of this crisis. But hearing the name of your brother, I can barely say it myself, somehow puts a different perspective on it, and your cousins, your sisters, and you.

I think it is so important for us to understand that these are not faceless people, and in a real sense, as you made clear in your testimony, but these are our brothers and sisters for whom we do have an obligation.

So in that regard, I was interested to know, when you go home, which I know it is your hope to go home, should nothing else happen, that is, no circumstances change, what happens to you? What are the circumstances in your country? What will you be facing?

Ms. NKHOMA. Thank you very much. I am normally asked that question all the time, and I normally tell people what I want on my tombstone. If I go home, I die. There is no any other way out

of it. If I go home and I don't take the drugs, unless probably by taking them for the past 5 months I have developed like an immunity within myself, but I would die.

Ms. SCHAKOWSKY. So they are not accessible, they are too expensive? What exactly are you facing?

Ms. NKHOMA. Just recently, I think as early as the end of last year, the Glaxco-Welcome representative came and saw some people. This I heard after I came here and went back home in November. That is when I was talking about the drugs here, and some people said, yes, we had representatives from these companies who are encouraging people to take double therapy, like two drugs.

From my being here, I have discovered that it is actually more dangerous to even take only the two drugs. One, you are wasting your money; and two, it is not really going to help that much.

But the drugs now, to answer your question, I do not say they are available, because nobody can get to them, but they are there, we hear, in the pharmacies, but nobody can afford them. So we just look at them and die.

I just wanted to make the point, which is an irony stemming out of this that the few people that attempt to buy these drugs, spend everything that they have, maybe sell a house, maybe sell a car, and then say it is a father, is still going to die after he finishes his source of money. That means he is going to leave his wife and children with absolutely nothing. It has domino effects.

Ms. SCHAKOWSKY. You referred to Africans being used as guinea pigs. I presume during a certain period of time that those individuals who are being used to test the drugs are being given those drugs, and then what happens? When the test is over, do they just say, good-bye, thanks a lot, and you are gone?

Ms. NKHOMA. In all the tests, currently, until somebody blows the whistle to the international community on what is happening, nobody will ever get to know about it. I have talked to the Minister of Health a little bit, and I know what has happened, and what has been happening.

In Zimbabwe, currently AZT was being tested on mother-to-child transmission. Some mothers were given placebos, and the others were given AZT. After the trial, the researchers packed their bags and came here. Neither did they attempt to continue treating the mother, nor continue with maybe the other people who were given placebos. I know of nobody who has actually been given this treatment who continued. I think I would have heard about it.

Ms. SCHAKOWSKY. What is remarkable to me about that testimony is that I well remember when it was announced in the U.S. press that it was discovered how effective the use of AZT was in preventing the birth of HIV-infected infants. So we all celebrated the results of that experimentation. But as you point out, it appears that no one in Africa has subsequently benefited from it.

I have a number of other questions, but my time is up. Thank you.

Mr. MICA. I thank the gentlewoman.

I now recognize the gentleman from Maryland, Mr. Cummings.

Mr. CUMMINGS. Thank you Mr. Chairman.

I want to thank you, Mr. Jackson, for what you are doing, and I certainly will join you in doing everything I can to address this major, major problem.

And to Ms. Nkhoma, thank you also. I think it is quite accurate, I think so often what happens here on the Hill is that sometimes we divide policy from real people, and I think when we are able to put the faces on the policy, it does make a difference.

I want to go to you, Mr. Jackson, and just ask you a few questions.

One of the things that we hear over and over again in this country is how do drug companies get their investments back? We constantly hear them talking about the research that they have done. As a matter of fact, I have heard some folks at certain pharmaceutical companies say that even if they came up with a cure for AIDS today, we might see a substantial delay in it actually hitting the street.

One of the things they complain about is that they want their money back for research. I am sure the same kinds of arguments are made with regard to Africa and developing countries. What is your answer to that?

Mr. JACKSON. Congressman Cummings, the present United States policy, that which we are articulating before the subcommittee today, is to threaten sub-Saharan nations who support compulsory licensing and parallel imports, that is, on the open market, assuming free trading relationships, that they might be able to shop around, produce, or find cheaper drugs to get them directly to their people.

Any self-respecting government, including our own, under these circumstances would find such a policy to be fair.

I personally believe medicine is a human right. I think if someone finds a cure to cancer, it is not something they can keep in their basement and just hide. At some point in time we have to make a decision as a government that we have enough people with cancer that we need to make that cure available, to get them some resources, to protect some of their legal patent rights, to compensate them accordingly; it is not a secret that you get to hide.

Medicine and its production is not purely for the availability of profit. When we look at an epidemic of the magnitude of the AIDS crisis, for which all of our charts are clearly available, we have some obligation as a superpower, as one who has been economically endowed by God to make certain judgments about our Nation's commitment to the human family, that we are not going to allow millions of people to be decimated, not because they do not need drugs, but because we simply recognize that they cannot afford those drugs.

We have an obligation, on the question of their investment, to find creative ways to protect their patents, to protect their intellectual property rights, but at the same time not threaten with trading embargoes or various provisions in our trading law, manipulated in various ways, to keep sub-Saharan Africans from finding on the open market or producing more generic drugs at cheaper costs, so they might create stability in their own countries.

If the infection rate in many of these countries continues, and their governments are in a position where they cannot even fight

to get lifesaving drugs for their people, inevitably it is going to create a level of government instability in those countries which is going to affect our normalized trading relationships. Those governments will not be stable going into the future economically if, in fact, there are various revolutions based on who gets access to medicine simply because they can afford it and those who cannot. We have some obligations, Mr. Cummings.

Mr. CUMMINGS. One of the things that I could not help but think about as you were talking was when the Kosovo issue came up, this country responded quite rapidly and with quite a bit of money and dealt with that issue. When I look at what is happening here, when we have millions of people dying, it is interesting to look at those two situations and how we are dealing with them.

Finally, let me say this. When we talk about putting a face on this problem, Mr. Chairman, when I visited Zambia, I was on my way, and I was about to leave the last day, and I had met a young girl named Sakia, and I think you will appreciate this, Mr. Jackson; a little 10-year-old who was an orphan. As I was about to leave, I had done several speeches about AIDS, this little girl, Sakia, who I had met earlier that week, came up and said—pulled me on the coat, and says, are you leaving? I said, yes, I am leaving. She said, are you going to come back? Are you going to help our people? Because, you know, my mommy and my daddy are dead, and all my relatives are dead. And I said, yes, I am going to come back. I am going to figure out a way to help you. We have to help you, and we have got to help your people. And she says, well, when are you going to come back? I said, I am going to come back soon. She said, when you come back, she said, will you look for me? And I said, sure. And I said, I will write you. She said, but if you can't find me, will you look for me in heaven?

And I will never forget that, never ever forget that, because she saw her life sort of just disappearing, as she had seen so many other people's lives disappearing.

Mr. MICA. Thank you.

Mr. Lantos.

Mr. LANTOS. No, thank you.

Mr. MICA. You have both been most patient. We thank you. Your coming forward today has helped provide us with reasons that we should go forward, from your own personal experience. Hopefully it will help make a difference as Congress decides its policy here, so we particularly thank you for participating today, and also my colleague Mr. Jackson and my colleague Mr. Berry.

We will excuse this panel and thank you both again.

I would like to introduce and welcome our second panel.

The first participant witness is Ms. Sandra Thurman, Director of the Office of National AIDS Policy of the White House; then Mr. Joseph Papovich, Assistant U.S. Trade Representative under Services, Investment and Intellectual Property of the United States Trade Representative's Office. Then we have Dr. John Killen, the Director of the Division of AIDS in the National Institute of Allergy and Infectious Diseases in the National Institutes of Health. Then we have Dr. Timothy Dondero, the Chief of International Activities Branch, the Division of HIV/AIDS Prevention, with the Centers for Disease Control and Prevention.

I would like to welcome all of our panelists. Again, this is an investigations and oversight subcommittee of Congress. If you would not mind, I would like to swear you in, if you would please stand.

[Witnesses sworn.]

Mr. MICA. The witnesses answered in the affirmative.

Again, welcome to our subcommittee. We appreciate your providing testimony.

As I said previously, if you have lengthy statements, we are going to run the clock because we have another full panel after you. If you have lengthy statements, we will make them part of the record, or additional documentation, by unanimous consent.

First, I would like to recognize Ms. Sandra Thurman, the Director of the Office of National AIDS Policy for the White House. Welcome, and you are recognized.

STATEMENTS OF SANDRA THURMAN, DIRECTOR, OFFICE OF NATIONAL AIDS POLICY, THE WHITE HOUSE; JOSEPH PAPOVICH, ASSISTANT U.S. TRADE REPRESENTATIVE, SERVICES, INVESTMENT & INTELLECTUAL PROPERTY, U.S. TRADE REPRESENTATIVE; JOHN KILLEN, DIRECTOR, DIVISION OF AIDS, NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES, NATIONAL INSTITUTES OF HEALTH; AND TIMOTHY DONDERO, CHIEF OF THE INTERNATIONAL ACTIVITIES BRANCH, DIVISION OF HIV/AIDS PREVENTION, CENTERS FOR DISEASE CONTROL AND PREVENTION

Ms. THURMAN. Thank you, Mr. Chairman. I knew I should not have released my report before I came to this committee, because most of you have already heard some of the statistics out of it.

I just want you to know how pleased I am to be with you here today. Your interest in addressing this crisis is very much appreciated, and your help is very much needed.

My colleagues from the NIH and the CDC will again lay out for you a very vivid picture of the depth of this tragedy and describe for you some of the work that their agencies are doing to address the many challenges before us. You have heard the statistics, but you have also heard that these are not just numbers, but very real people and real lives.

I would like to take this time to talk with you a little bit about the human dimension of AIDS. AIDS truly is a plague of Biblical proportions. While many of us have witnessed firsthand the devastation, 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, and yet the AIDS pandemic rages on.

In a host of different ways and from a variety of different vantage points, it is children who are caught in the cross-fire of this relentless epidemic. In Africa, an entire generation is in jeopardy.

In many sub-Saharan 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 their parents to AIDS, 40 million. That is the equivalent of every child in the United States living east of the Mississippi.

AIDS is wiping out decades of hard work and steady progress in improving the lives and health of families throughout the developing world. For millions and millions of those families, and in some cases entire nations, AIDS is the engine of destruction that is pushing us toward the brink of disaster. Not only do precious lives hang in the balance, but so, too, do the economic viability and the political stability of their homelands. As the chairman has said, AIDS is a trade and investment issue, not just a health issue. Both in terms of exports and natural resources, Africa is a critical partner to the United States. 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, and in many instances companies are having to hire two people for every single skilled job they have, assuming one will die of AIDS.

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 that the HIV prevalence in the seven armies engaged in the Congo is somewhere between 50 and 80 percent of all military personnel.

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

Yet my message here today to you 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 great hope. Amidst this terrible crisis, there is great opportunity. The opportunity is for us, working together, to empower women to protect children, and to support families and communities throughout Africa and throughout the world in our shared struggle against AIDS.

The United States has been a leader in the struggle. The administration has taken an active role in sounding the alarm on the AIDS crisis in Africa, and in marshalling support for 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 percent of those funds have been used to address the epidemic in sub-Saharan Africa. Overall, nearly half of all the development assistance devoted to HIV care and prevention in the developing world has come from the United States.

The United States has also been the leading supporter of the United Nations Joint Program on AIDS, or UNAIDS, contributing more than 25 percent of their budget. It is a strong record of engagement of which we can be proud, but unfortunately, it has not kept pace with this terrible epidemic. We have done much, but much more remains to be done by the United States and by the world's other developed nations.

In that spirit, on World AIDS Day in 1998, the President directed me to lead a fact-finding mission to sub-Saharan Africa and to make recommendations for an enhanced United States battle in our global fight against AIDS. I was pleased to lead that mission during the Easter recess, accompanied by Members and staff from

both parties and both Chambers to witness firsthand the tragedies and triumphs of AIDS in Africa.

In response to that trip, as we all have heard, the President and the Vice President agreed we need to do more. This week the administration announced a broad initiative to invest $100 million in the fiscal year 2000 budget toward this effort. This initiative provides a series of steps to increase U.S. 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 G–8 partners and other partners to increase their efforts as well. This initiative is the largest increase in the U.S. Government's investment in the global battle against AIDS, and it begins to reflect the magnitude of this rapidly escalating epidemic.

Our commitment to seek an additional $100 million in fiscal year 2000 will help to support four key efforts: $48 million will be used for prevention, $23 million will be used to support community and home-based care, $10 million will go to take care of children who have been orphaned as a result of AIDS, and $19 million will be used to strengthen the infrastructure and to build the capacity that we need to provide care to people who are infected throughout the African world.

We hope this initiative will receive the broad-based bipartisan support that it deserves. I greatly appreciate the favorable comments of the members of this committee about this initiative. AIDS is not a Democratic or Republican issue, it is a devastating human tragedy that cries out for all of us to help. I look forward to working with all of you.

On Monday, Bishop Tutu mentioned an African proverb which says, "When one steps on a thorn and it goes into the toe, the whole body bends down to pull it out." We ask for your help in doing that, in addressing this crisis of AIDS.

Thank you very much.

Mr. MICA. Thank you.

[The prepared statement of Ms. Thurman follows:]

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 this continent 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 sub-Saharan Africa, 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 has wiped 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 the Congo range at 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.

Mr. MICA. We would like to recognize now Mr. Joseph Papovich, the Assistant U.S. Trade Representative with the USTR's Office.

Thank you. Welcome, you are recognized.

Mr. PAPOVICH. Thank you, Mr. Chairman. Thank you very much for inviting us to testify at today's hearing. This hearing focuses on a topic that is of crucial importance to the health and future of millions of people in Africa and elsewhere, the role of our policy in ensuring access to effective medicines for AIDS and other illnesses.

The administration, together with our partners in Africa and around the globe, has developed a policy intended to ensure access to current medicines to treat AIDS while preventing the incentives that will speed the development of effective medicines that in the future have the potential to occur and prevent disease.

In the so-called Uruguay Round negotiations that established the World Trade Organization, a top priority for the United States, as a leading exporter of creative and innovative products, was to secure adequate and effective protections for all forms of intellectual property, including patent protection for American pharmaceuticals.

In this we have succeeded. All WTO members, over varying transition periods, committed to this, through the Agreement on Trade-Related Aspects of Intellectual Property Rights.

Another important component of the trade policy is the so-called Special 301. Under those provisions of the Trade Act of 1974, Congress directed USTR annually to identify foreign countries that deny adequate and effective protection of intellectual property rights and to issue a public report to this effect at the end of each April. In the report, countries are placed on lists, ranging from most egregious, where trade sanctions may ultimately be involved if significant problems are not resolved, to a priority watch list or to a watch list, where we monitor the situation and urge improvements in protection.

Congress amended Special 301 in the Uruguay Round Agreements Act to clarify that a country can be found to deny adequate and effective intellectual property protection, and thus placed on one of these lists, even if the country is otherwise in compliance with its obligations under the TRIPS agreement.

Each year USTR, in consultation with other agencies, examines the level of intellectual property protection afforded by our trading partners. We analyze legislation, enforcement activity, and market trends to arrive at our determination. We draw on the reporting from our embassies and consulates overseas, but we also receive input from industry associations, individuals, and even foreign governments.

In some instances we agree with the recommendations of those outside of the government; in others we do not. For example, during this year's Special 301 review, there were recommendations to designate South Africa as a Priority Foreign Country, which could have resulted in trade sanctions. We chose not to do so, however, because we did not agree with their assessment of the magnitude of the problem and because we had already developed a framework to resolve our differences, which we are confident will work.

The objective of intellectual property protection is focused on ensuring incentives for research and development, so that new drugs

can be developed and commercialized. Nevertheless, the application of our intellectual property policy is sufficiently flexible to respond to legitimate health care crises.

The administration's approach to patent protection is to ensure that the necessary incentives are provided to promote rapid innovation of new drug therapies, and to ensure the protection of medicines which now exist. Patent protection is essential to encourage rapid development of new and more efficient drugs to treat AIDS and other illnesses, and for the commercialization of these drugs. To effectively remove patent protection for such treatments could ultimately lead to a delay in the discovery, production, and distribution of medicines which could go beyond treatment, prevention, and cure.

Our goals in the area of patent policy for pharmaceuticals are complemented by the administration's efforts to address the HIV/AIDS crisis around the world, including Africa, which my colleagues are describing. We are also seeking to help developing countries create the public health infrastructure that will allow AIDS treatments to be utilized effectively.

Finally, let me say a few words about the case of South Africa, in which the committee has expressed some particular interest. We acknowledge the serious health care crisis in South Africa. Moreover, we appreciate that the Government of South Africa has taken measures to improve access to quality health care for all its people. This is a goal we and the entire administration fully endorse and support.

We believe this goal can be achieved while promoting adequate and effective patent protection for pharmaceutical products. Our goal is to chart a course that assists in improving access to affordable medicines, while not freezing the financial incentives that fuel continued research and production of new products. With the shared commitment to improve health care and provide intellectual property protection, we are continuing our efforts with South Africans to find common ground.

That said, we have been working with South Africa to try to ensure that its new Medicines Act can achieve its intended goal while being applied in a TRIPS-consistent manner. We believe both of these goals are achievable, and we are working with South Africa to ensure that the Medicines Act will be TRIPS-consistent. Indeed, we have been fully engaged in trying to clarify these matters with South Africa, with the goal of ensuring that the South African Government has the full ability to address AIDS and other health issues in a manner consistent with its WTO obligations.

In August of last year, the administration proposed a framework for resolution of our differences concerning South Africa's Medicines Act. The intent of the proposal was to bring together a group of experts, including all relevant decisionmakers, to reach our mutual goal of bringing better health care to the people of South Africa while assuring effective and adequate protection of intellectual property.

Although neither government-to-government nor industry-to-government discussions have resulted in a resolution of the differences that exist, we are encouraging continued dialog to find a solution

that ensures that the health concerns of South Africa can be addressed in a TRIPS-consistent manner.

The TRIPS agreement has specific rules that govern compulsory licensing expressed in Article 31, which allow for their use under certain conditions. We realize that AIDS is a special case which may require special measures. Thus, while we do not believe that compromising intellectual property rights is the solution to the greater problem, contrary to our general approach, we raised no objection to compulsory licensing or parallel importing of pharmaceuticals on the part of South Africa, as long as it is done in a way that complies with TRIPS.

Of course, we are committed to working with South Africa to ensure the safety and efficacy of pharmaceutical imports; this is the policy of the administration.

[The prepared statement of Mr. Papovich follows:]

TESTIMONY ON THE PROTECTION OF US INTELLECTUAL PROPERTY ABROAD, PARTICULARLY WITH RESPECT TO COMBATING THE GLOBAL HIV/AIDS EPIDEMIC

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

July 22, 1999

Mr. Chairman:

Thank you very much for inviting us to testify at today's hearing.

This hearing focuses on a topic that is of crucial importance to the health and future of millions of people in Africa and elsewhere: the role of our policy in ensuring access to effective medicines for AIDS and other illnesses. The Administration, together with our partners in Africa and around the globe, has developed a policy which ensures access to current medicines to treat AIDS, while providing the incentives that will speed the development of effective medicines that in the future have the potential to cure or prevent the disease.

THE "TRIPS" AGREEMENT AND "SPECIAL 301"

In the so-called Uruguay Round negotiations that established the World Trade Organization, a top priority for the United States, as the world's leading exporter of creative and innovative products, was to secure adequate and effective protection for all forms of intellectual property, including patent protection for American pharmaceuticals worldwide. In this we succeeded: all WTO members, over varying transition periods, committed to this, through the Agreement on Trade-Related Aspects of Intellectual Property Rights (or "TRIPS"). Over time, the result will benefit both producers and users as, in the case of pharmaceuticals, companies in the U.S. and overseas are given greater incentives to research and produce new medicines to continue the fight against disease.

An important component of USTR's policy is the so-called "Special 301." Under the Special 301 provisions of the Trade Act of 1974, Congress directed USTR annually to identify foreign countries that deny adequate and effective protection of intellectual property rights and to issue a public report to this effect at end of each April. In the report, countries are placed on lists, ranging from most egregious, where trade sanctions may ultimately be involved if significant problems are not resolved, to a priority watch list or to a watch list, where we monitor the situation and urge improvements in protection. Congress amended Special 301 in the Uruguay Round Agreements Act to clarify that a country can be found to deny adequate and effective intellectual property protection--and thus placed on one of these lists--even if it is in compliance with its obligations under the TRIPS Agreement.

Each year USTR, in consultation with other agencies, examines the level of intellectual property protection afforded by our trading partners. We analyze legislation, enforcement

activity, and market trends to arrive at our determination. We draw on the reporting from our embassies and consulates overseas, but we also receive input from industry associations, individuals, and even foreign governments.

In some instances, we agree with the recommendations of those outside of the government; in others we do not. For example, during this year's Special 301 review, there were recommendations to designate South Africa as a "Priority Foreign Country," which could have resulted in trade sanctions. We chose not to do so, however, because we did not agree with their assessment of the magnitude of the problem and because we had already developed a framework to resolve our differences, which we are confident will work.

PATENT POLICY

The objective of intellectual property protection is focused on ensuring incentives for research and development, so that drugs can be developed. Nevertheless, the application of our intellectual property policy is sufficiently flexible to react to legitimate health care crises.

Until the recent development of protease inhibitors and other highly sophisticated medicines, many considered AIDS to be invariably fatal. While I lack the expertise to speak about the specifics of these new medicines, their development has given new hope to many millions of people living with HIV.

The Administration's approach to patent protection is to ensure that the necessary incentives are provided to promote rapid innovation of new drug therapies and to ensure the protection of the medicines which now exist. Patent protection is essential to encourage rapid development of new and more effective drugs to treat AIDS and to the commercialization of those drugs. Together with government investment in research, private sector incentives for research and development are critical to develop new treatments for AIDS as well as other diseases. To effectively remove patent protection for such treatments would ultimately be to delay the discovery, production and distribution of medicines which could go beyond treatment to prevention and cure.

Our goals in the area of patent policy for pharmaceuticals are complemented by the Administration's efforts to address the HIV/AIDS crisis around the world, including in Africa. Our efforts in this regard are varied and extensive. As my colleagues have testified, we are active on a variety of fronts to combat this disease. Most recently, on Monday of this week, the Vice President announced a new $100 million initiative to help fight AIDS in Africa.

We are also seeking to help developing countries create the public health infrastructure that will allow AIDS treatments to be utilized effectively. This includes not only adequate investment in prevention efforts, clinics and medical equipment, but continuous monitoring of treatments to ensure that no contamination occurs and that medicines are administered at the time and with the appropriate dosage. Without such infrastructure, there is significant risk that pharmaceuticals, including antibiotics and HIV drugs, may not be administered to patients correctly. This poses dangers not only to individual patients but the wider community, as

without proper administration bacteria and viruses will mutate, creating powerful new forms of drug-resistant organisms.

THE SOUTH AFRICAN CASE

And this brings me to the specific case of South Africa.

We acknowledge the serious health care crisis in Africa, including in South Africa. Moreover, we appreciate that the government of South Africa has undertaken to improve access to quality health care for all its people. This is a goal we and the entire Administration fully endorse and support. We believe that this goal can be achieved while promoting adequate and effective patent protection for pharmaceutical products. Our goal is to chart a course that assists in improving access to affordable medicines, while not freezing the financial incentives that fuel continued research and production of new drugs. With a shared commitment to improve health care and provide intellectual property protection we are continuing our efforts to find common ground.

That said, we have been working with South Africa to try to ensure that its new Medicines Act can achieve its intended goal, while being applied in a TRIPS-consistent manner. We believe that both of these goals are achievable, and we are working with South Africa to ensure that the Medicines Act will be TRIPS-consistent.

Indeed, we have been fully engaged in trying to clarify these matters with South Africa, with the goal of ensuring that the South African government has the full ability to address AIDS and other health issues in a manner consistent with its WTO obligations.

In August of last year, the Administration proposed a framework for resolution of our differences concerning South Africa's Medicines Act. The intent of the proposal was to bring together an experts group including all relevant decision makers – trade, health, and intellectual property – to reach our mutual goal of bringing better healthcare to the people of South Africa while assuring effective and adequate protection of intellectual property. Although neither government-to-government nor industry-to-government discussions have resulted in a resolutions of the differences that exist, we are encouraging continued dialogue to find a solution that ensures that the health concerns of South Africa can be addressed in a TRIPS-consistent manner–both of which are achievable.

The TRIPS Agreement has specific rules that govern compulsory licensing, which are expressed in Article 31. The Agreement establishes specific conditions that a WTO member must follow if it authorizes use of a patent without the patent owner's consent. For example, a WTO member may grant a license to a party without the patent owner's consent, but only on a case-by-case basis, normally only after the proposed user of the patent has been unable to obtain a license on a voluntary basis on reasonable commercial terms. The latter requirement may be waived in a "national emergency," but other conditions apply. The South African Medicines Act does not provide for any of these conditions and no regulations have been issued that would ensure that the TRIPS Agreement's requirement would be met.

We realize that AIDS is a special case which may require special measures. Thus, while we do not believe that compromising intellectual property rights is the solution to the greater problem, contrary to our general approach, we raise no objection to compulsory licensing or parallel importing of pharmaceuticals on the part of South Africa, as long as it is done in a way that complies with TRIPS. Of course, we are also committed to working with South Africa to ensure the safety and efficacy of pharmaceutical imports. This is the policy of the Administration.

Mr. MICA. We now recognize Dr. John Killen, who is the Director of the Division of AIDS for the National Institutes of Health's National Institute of Allergy and Infectious Diseases.

Dr. KILLEN. Thank you, Mr. Chairman. I am pleased to have the opportunity to discuss with you recent developments related to the human immunodeficiency epidemic. As we have heard already today, HIV is a looming tragedy, a global catastrophe to public health and a threat to political stability. Overcoming it will require a sustained commitment by public and private sector partners working together in research and prevention.

Our remarks today will focus on progress in and challenges to biomedical research relevant to the control of the epidemic.

AIDS diagnoses and deaths have dropped significantly in the United States in the past 2 years. The same is true in other developed countries. Several factors are responsible, as we have heard, especially through the increased use of potent, albeit expensive combinations of anti-HIV drugs. Unfortunately, many HIV-infected individuals have not responded adequately to the medications, cannot tolerate their side effects, or develop viral resistance to the current drugs, even in this country where we have virtually everything going for us.

In this context, the development of new and better therapies remains a priority. Research is focusing on new strategies, including drugs that prevent the virus from entering a cell, and approaches to boosting an infected person's immune response. A number of new agents are in various stages of preclinical and clinical testing. We have also heard at length today how use of antiretroviral drugs is simply not currently feasible in developing countries, where per capita health care spending may be only a few dollars per year. Therefore, the identification of effective, low-cost tools for preventing infection and disease caused by HIV is absolutely crucial to slowing the epidemic.

I will highlight two examples of relevant NIH-supported research in this important endeavor.

In early 1994, an NIH-funded clinical trial showed that passage of HIV from an infected mother to her infant could be reduced by as much as two-thirds when an intensive regimen of AZT is given to a mother and her newborn baby. Unfortunately, costs and formidable logistical barriers prohibit the widespread application of this proven regimen in most of the developing world. To surmount these obstructions, a globally coordinated effort was launched to identify simpler, less costly alternatives.

Several recently reported studies have shown that shorter regimens of AZT can also be beneficial, reducing transmission by as much as 50 percent, but the same logistical and cost factors have precluded widespread implementation of these drug regimens.

Last week, scientists from Uganda, Johns Hopkins University, and the NIAID reported exciting results of an NIH-supported study carried out in Uganda which demonstrated that just two doses of the antiretroviral drug nevirapine, when administered to the mother at the onset of labor and one to the baby shortly after birth, reduced the instance of maternal-to-infant transmission of AIDS—reduced by nearly 50 percent when compared to a similar brief course of AZT.

This study could have profound implications for the epidemic of HIV in children worldwide because nevirapine is extremely inexpensive and easy to administer. In fact, the regimen costs approximately $4, and is 70 times cheaper than the previously studied regimens of the shorter course of AZT.

The development of a safe and effective vaccine for HIV remains the Holy Grail of AIDS prevention research. To hasten HIV vaccine discovery, many public and private agencies, including the NIH, have dramatically increased the resources devoted to HIV vaccine research.

At the NIH we've created new programs to foster innovative research on HIV vaccines and to expedite their development in clinical testing. In addition, the Dale and Betty Bumpers Vaccine Research Center has been established on the NIH campus in Bethesda. Since 1998, we have enrolled more than 3,000 healthy volunteers into 52 clinical trials involving 27 possible HIV vaccines.

The results with the combination vaccine approach have been especially encouraging. The vaccine appears safe and has invoked several types of immune responses that may have an important role to play in protection from HIV-associated disease. Additional phase 2 trials will open later this year in Brazil, Haiti, Trinidad, and Tobago.

A very important milestone in AIDS vaccine research was the initiation this spring of the first AIDS vaccine study in Africa. This NIH-supported clinical trial, which is being conducted in Uganda, is designed to help determine whether it will be possible to design universal vaccines that work against more than one strain of HIV.

Training and infrastructure are essential underpinnings of a robust biomedical enterprise, and part of NIH's commitment to international AIDS research involves the Fogarty International Center's initiative to build HIV training and research capacity in developing countries. This vitally important effort has expanded research capabilities in a number of countries and facilitated many NIH international AIDS research initiatives.

Two years ago, President Clinton set a national goal of developing a useful HIV vaccine within 10 years. We are well positioned in our attempt to meet this goal with an extraordinarily strong program of 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 the subcommittee.

Mr. MICA. Thank you.

[The prepared statement of Dr. Killen follows:]

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.

Mr. MICA. I would like to now recognize Dr. Timothy Dondero, who is the Chief of International Activities Branch, Centers for Disease Control and Prevention.

You are recognized, sir. Welcome.

Dr. DONDERO. Thank you, Mr. Chairman, and members of the subcommittee.

The HIV epidemic continues to be a major challenge with over 33.4 million people estimated to be infected worldwide. Many horrifying statistics have already been cited in this hearing. For the sake of time, I will not repeat those, but refer you to my written testimony.

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. I would like to draw your attention to the graph over on the right. It shows the extremes to which the HIV epidemic has reached the populations of the developing world.

These data are the percent of child-bearing women infected within countries. The lower group, the large, long bars, are in Africa, predominantly east and southern Africa. What you see is the massive penetration of HIV into the general population, especially in countries in eastern and southern Africa. Reports from four southern African countries, Botswana, Namibia, Botswana, and Zimbabwe indicate from a fifth to a quarter of their entire adult population age 15 to 49 are now infected with HIV, and in Botswana over 40 percent of the child-bearing women in cities are now infected.

Countries in other parts of the world, including Thailand, Cambodia, and India, have also been heavily impacted, although not on a proportional basis yet anywhere near the impact in southern and eastern Africa.

Global trends in HIV/AIDS indicate that women are at greater risk than men from heterosexual transmission. Women then can 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 infection through breastfeeding.

It is also important to note the interaction between HIV and other diseases, specifically tuberculosis and sexually transmitted diseases. Worldwide, 8 million cases of TB and 3 million deaths occur each year. Ninety-five percent of these occur in countries with low per capita income. Tuberculosis kills more adolescents and adults in the world than any other single infectious disease, although part of this is, in fact, due to AIDS. The HIV epidemic has significantly increased the TB epidemic.

People who have latent or inactive TB 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. Increased TB in AIDS patients enhances the potential for the spread of drug-resistant TB organisms, both locally and globally.

Also linked to the HIV are sexually transmitted diseases. STDs cause a two to fivefold increased risk for HIV transmission. STDs facilitate HIV transmission by increasing shedding of the virus,

and also they enhance the susceptibility to HIV through increased likelihood of penetration of the virus into the body. STD treatment is part of prevention of HIV.

But there are actually some glimmers of hope. Several countries have shown improvements, including Uganda, Tanzania, Cote d'Ivoire, Senegal, and Thailand.

As a quick example, in the country of Uganda, over the past 4 to 5 years there has been significant and encouraging reductions in 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. Behavioral studies have shown a 2-or-more-year increase in the age of first sexual intercourse for youths, a 9 percent reduction in casual sex, and a 30 to 40 percent increase in condom use.

An important element of Uganda's AIDS control is a very intensive HIV counseling and testing program fiscally supported by USAID with CDC technical expertise. This has provided HIV testing and counseling to upwards of one-half million people since 1990 through the AIDS Information Center, a nongovernment organization.

Very important has been the strong political leadership in the country as well, with the President and First Lady of Uganda themselves frequently addressing HIV-related issues, making these acceptable for public discussion.

Because the epidemic in much of the world is expanding, the most critical public health approach is prevention, for a number of the reasons which have been discussed here. For the sake of time, I will not present again the arguments of concern about treatment as opposed to prevention.

The CDC's role, in brief, has been focused in international efforts offering assistance to countries with great public health needs who seek assistance conducting collaborative research and training on prevention interventions and serving as partners in global initiatives.

Although our geographic focus is limited, we assist in the application of U.S. scientific advances within other countries, such as rapid HIV testing, prevention of mother-to-child transmission, refinement and installation of HIV diagnostics and research techniques, and a variety of other things described in my testimony.

The CDC has a strong existing international field station structure in Cote d'Ivoire, Uganda, Kenya, Thailand, and Asia, as well as a long history of providing technical assistance. We also have resident advisors knowledgable in HIV in a number of countries.

I appear not to have time to go through some of the key elements of prevention. I would note that in the President's recently submitted budget amendment, under this initiative, the CDC would 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.

I will not describe the other elements key in my verbal testimony for prevention. I would just note in conclusion that while there are a few countries we can point to demonstrating improvement in the HIV/AIDS epidemic, continued leadership within the countries and

international expertise and resources 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 this opportunity.

Mr. MICA. Thank you, Dr. Dondero. Would you like us to make that entire statement part of the record, so it is complete?

Dr. DONDERO. Yes, sir.

Mr. MICA. Without objection, so ordered.

[The prepared statement of Dr. Dondero follows:]

TESTIMONY OF

TIMOTHY DONDERO, M.D.

CHIEF

INTERNATIONAL ACTIVITIES BRANCH

DIVISION OF HIV/AIDS PREVENTION

NATIONAL CENTER FOR HIV, STD, AND TB PREVENTION

CENTERS FOR DISEASE CONTROL AND PREVENTION

BEFORE THE

U.S. HOUSE OF REPRESENTATIVES

COMMITTEE ON GOVERNMENT REFORM

SUBCOMMITTEE ON CRIMINAL JUSTICE,

DRUG POLICY, AND HUMAN RESOURCES

JULY 22, 1999

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

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

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

The HIV/AIDS epidemic continues to 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.

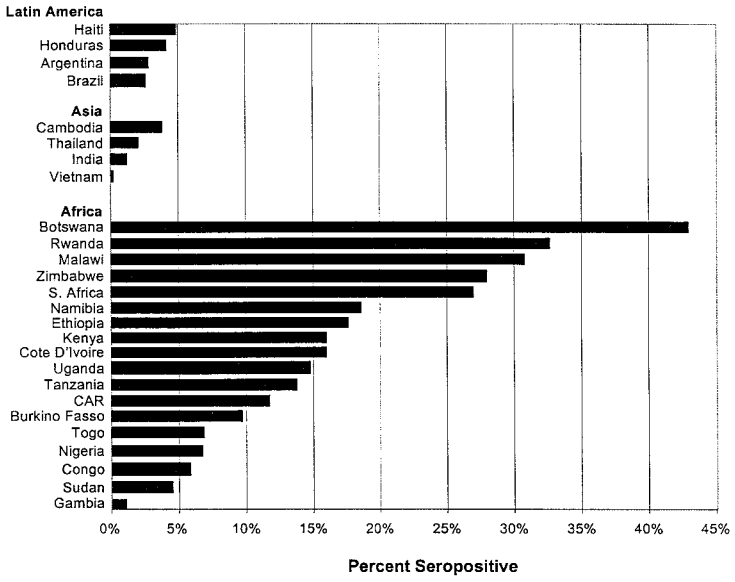
Currently it is estimated that there are 22 million adults and 1 million children living with HIV infection in sub-Saharan Africa and over six million infected persons in Asia. By comparison, the U.S. has in the range of three quarters of a million persons living with HIV infection. An estimated four 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, 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, 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, and WHO on both a long-term and a short basis, enhancing the capacity of the UN agencies committed to combating the epidemic through. 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.

Mr. MICA. Unfortunately, we have a series of votes coming up. I am going to ask just a couple of quick questions.

I see the chart here, Ms. Thurman, about how the money is being expended. The bulk of it is for prevention, which is recommended by Congressman Berry and others, and we heard Ms. Nkhoma talk about people who are infected now. I do not see any money for treatment now. There is no money for treatment?

Ms. THURMAN. No, sir, there is money for treatment in the home-based and community care piece. There will be some money provided for medicines for opportunistic infections.

Mr. MICA. This says $23 million to deliver counseling, support, and basic medical care.

Ms. THURMAN. Those medicines are included in the basic medical care.

Mr. MICA. That, again, is a concern.

Also my second part of this quick question to Mr. Papovich is that getting low-cost drugs available is a problem. It appears that it has not been our trade policy to encourage that actually. We have worked against that, as far as our policy in South Africa, which Mr. Jackson said should be the focus of our attention, because it sort of sets the pattern.

I will tell you what, I am not going to ask you to respond now. That is my quick question. I am going to submit to each of you questions in writing.

I yield to the gentlewoman from Hawaii.

Mrs. MINK. Thank you. I have a whole host of questions, too.

While I appreciate the importance of prevention and education, I think the course of these hearings is really to investigate the issue of treatment and to what extent the U.S. policies have related to this issue.

Ms. Thurman, could we have a 10-year listing of the efforts on treatment by the U.S. Government to African countries, and exactly, over the total budget, what percentage went to the treatment component?

Ms. THURMAN. Yes.

Mrs. MINK. And then to Mr. Papovich, on the intellectual property question, you said that it was important to create public health infrastructure in order to provide the AIDS treatment. My question is if we are going to spend efforts in improving the infrastructure, how does that go along with access to the drugs themselves? Is that part of the policy inference when you talk about infrastructure?

Also, the question of the WHO, if you recognize AIDS in Africa as a national emergency, is this going to allow you to distribute the drugs without the patent owner's consent? Because that is the basic question that we are investigating.

And to Dr. Killen, when you talked about these new discoveries that have been made by NIAID and the Health Ministry with respect to less expensive drugs, are we talking about less expensive drugs that can be distributed without patent applications and barriers? I think that really is the question. Those are the questions I have.

Mr. MICA. We will get those in detail.

I yield briefly to my colleague.

Ms. SCHAKOWSKY. I have one sentence because we have to go vote.

I wanted to ask Mr. Papovich if you would provide us with the language that would be TRIPS-compliant and not subject any country to any Special 301 designation and still allow for compulsory licensing and parallel importing. It seems as if in these negotiations we clearly have something in mind, and I, for one, would certainly like to know what that language is and would appreciate getting that.

Mr. MICA. Thank you. We will have additional questions. I apologize, but we are going to have three votes, and it is going to be 45 minutes to an hour. We will recess this hearing until quarter of the next hour. We will excuse you, and we will have the next panel at that time. We will have a break for lunch. But you will have additional questions submitted.

[Recess.]

Mr. MICA. I would like to call this subcommittee meeting back to order.

And our next order of business is to hear from our third panel of witnesses. Our third panel of witnesses I will introduce. Dr. Allen Herman, dean of public health of the Medical University of Southern Africa. We have Mr. James Love, director of Consumer Project on Technology; Dr. Peter Lurie, medical director of the Public Citizen's Health Research Group; Mr. Eric Sawyer, executive director of the HIV Human Rights Project, also associated, I guess, with ACT UP in New York; and Dr. John Siegfried, senior medical officer of the Pharmaceutical Research and Manufacturers of America.

I would like to welcome all of our panelists. As I've said in the past, this is an investigations and oversight subcommittee. If you would stand, please, and be sworn in.

[Witnesses sworn.]

Mr. MICA. The witnesses all indicated—answered in the affirmative.

I would like to welcome each of you. We're going to run our little timer here. If you have a lengthy statement, we would like you to summarize it, and we will put the entire statement in. If you have additional information and/or data, we will also include that as part of the record. And we will run the timer on that; then we will have an opportunity for questions.

First, I will recognize Dr. Allen Herman, with the Medical University of Southern Africa.

STATEMENTS OF ALLEN HERMAN, DEAN OF PUBLIC HEALTH, MEDICAL UNIVERSITY OF SOUTHERN AFRICA; JAMES LOVE, DIRECTOR, CONSUMER PROJECT ON TECHNOLOGY; PETER LURIE, MEDICAL DIRECTOR, PUBLIC CITIZEN'S HEALTH RESEARCH GROUP; ERIC SAWYER, EXECUTIVE DIRECTOR OF HIV HUMAN RIGHTS PROJECT, ACT UP, NEW YORK; AND JOHN SIEGFRIED, SENIOR MEDICAL OFFICER, PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA

Dr. HERMAN. Good afternoon, Chairman Mica and distinguished members of the committee. It's a privilege for me to testify before you on the subject of such fundamental importance to the people

of Africa. The pandemic of HIV/AIDS has been adequately described to all of us this morning. And there is a tendency sometimes in this description that one is left slightly stunned by the magnitude of the problem.

So what I would like to talk to you about today are some specific incidences where this epidemic has particular influence on the society in South Africa, and then to talk a little bit about what we are doing at the National School of Public Health, which is associated with the Medical University of Southern Africa.

By way of introduction, I am the dean of South Africa's National School of Public Health. This is a school that was one of the new schools that was formed by President Mandela's Cabinet in 1997, and I was asked by my old classmate, then Minister of Health, Nkosazana Dlamini Zuma, to be the first dean.

The School of Public Health has a particular interest in the issue of AIDS, and for us, we have become convinced that we have to spend most of our time dealing with this epidemic in a very practical fashion. Unfortunately, HIV/AIDS has a grave effect on the middle class and on the leadership of countries in Africa. In fact, in Africa, AIDS has truly been a disease with no class distinction. This reality could and will lead to the destruction of invaluable human resources needed to continue the development in African countries.

Let me give you an example, a stark one. If I chair a faculty meeting, it is probably highly likely that a member of my faculty will be dead in a few years from HIV/AIDS. To replace a faculty member is an expensive proposition. You have to train a person up to a doctor level so that they can teach and do research in the country. If I go to my students, and my students are the largest number of public health students in South Africa at the moment, at least a quarter of them will die from AIDS in the next few years.

So for us it's a fairly real problem that both the people who are attempting to do something about the epidemic and the communities in which we work are very stretched by this epidemic.

President Mandela said in his February 1997 address to the World Economic Forum that the pandemic is a threat that puts in the balance the future of nations. AIDS kills those of whom society relies to grow the crops, work in the mines and the factories, run the schools and the hospitals and govern countries. It creates new pockets of poverty where parents and breadwinners die, and children leave school earlier to support the remaining children.

The problem of access to adequate health care for individuals infected and affected by HIV/AIDS is a very complex one. There are a number of barriers to adequate health care for individuals like this. These include the costs of providing supportive health and social services essential for safe use and compliance, the setting up and/or strengthening of treatment units, laboratory facilities, drug delivery systems and the training of health care professionals, and the cost of drugs.

An interesting example; I had a conversation last week on my way back to the United States with the Minister of Health, the Secretary of Health for the province of Gauteng. Gauteng means a place of gold, and it's the province where Johannesburg is, and the Minister of Health for that province, Dr. Gwen Ramakgopa, is a

2nd-year student in the School of Public Health; she called me up to talk about the problem that she had, a budgetary problem.

The health budget for that province is 5.6 million rand, which is around a billion—around $1 billion, and she has a 300-million rand shortfall. And as we're talking about this, she indicated that HIV/AIDS was the biggest problem in two of her largest hospitals. One is the Chris Hani Baragwanath Hospital, south of Johannesburg in the township of Soweto, and the other is the Johannesburg General Hospital. And both of these hospitals had accumulated a 300-million rand deficit, about a $60 million deficit.

As I was speaking to Dr. Ramakgopa, she said to me that it was not a problem of access to drugs that she was dealing with, but it was a problem of a broken-down health care system that needed fixing. So part of our work in the next few months with the Department of Health for the province of Gauteng, we will be bringing consultants from the National School of Public Health to the Ministry of Health to help them sort through the management problems that they have.

At a smaller level, one of my other students who runs a small hospital in the eastern province that both President Mandela and President Mbeki come from, have a budget of about 5 million rand a month, and that's just about under $1 million a month, and about 10 percent of the patients who come into the hospital die. They leave the hospital through the way—by way of the morgue. Most of these patients are dying from HIV/AIDS.

The problem that we face is that most of these patients are young, and the students asked the question as to how he could best use his resources which he thought were relatively ample to deal with the problem of managing the health care of a specific district in the eastern province. Those are the kinds of problems that students bring to us in our university.

I would like to talk a little bit about what we think are adequate or appropriate approaches to the pandemic. I see my time is up. So I will go through this fairly quickly. First, there's a need to train health professionals in public health skills of screening and surveillance; that is what we are doing at the moment. We're training about 150 people every year to the level of a master's degree in public health.

There's a need to train health professionals to treat patients with HIV/AIDS. There's a need to develop infrastructure, which is laboratory support for this epidemic. And there's a need to deal with the cost of resources.

I will conclude by just making a very short story about this issue. My older brother, who works in one of the most devastated communities, works in a hospice that cares for babies dying of AIDS, and he tells me that it takes about 5 hospital visits before the baby dies of AIDS. He lives in a very poor community, and this is what he spends most of his free time doing as a volunteer in a hospice that cares for babies dying of AIDS.

And he tells me that part of his free time he spends working in a hospice caring for adolescents dying of AIDS. His request to me as the dean of the National School of Public Health, is not to deal with the cost of drug issues, but his request to me has always been quite specific: How do you prevent young people in South Africa

from getting the disease in the first place? He sees this as the real devastation in the country, and not the issue of costs. He does not underplay the issue of costs, but he sees this as the more critical problem.

Thank you very much.

Mr. MICA. Thank you for your testimony.

[The prepared statement of Dr. Herman follows:]

Testimony of
Dr. Allen A. Herman
Dean
National School of Public Health
Medical University of Southern Africa
To the
Committee on Government Reform
Subcommittee on Criminal Justice, Drug Policy, and Human Resources
On the Unites States' role in combating the global HIV/AIDS epidemic

Good morning Chairman Mica and distinguished Members of the Committee. It is a privilege for me to testify before you on a subject of fundamental importance to the people of Africa. The pandemic of HIV/AIDS is the critical problem facing the global community and threatens to surpass all the problems of the African continent. In my role as the Dean of South Africa's National School of Public Health I have been confronted by the simple truth that we have to focus most of our attention on the pandemic.

Introduction

HIV/AIDS has wreaked havoc on Africa. In Sub-Saharan Africa, more than 20 Million people are living with HIV/AIDS. In South Africa over 360,000 people have died from the disease. The UNAIDS program has estimated that nearly 3 million South Africans are currently infected with HIV (7% of a population of 43 million), with 1,500 new infections each day. Of these, half are women ages 15-49. Among pregnant women 16 percent are HIV-positive. There are more than 180,000 living children who had been orphaned by the disease and another 80,000 children infected with HIV. The impact that the epidemic has on the health care system can be illustrated by the fact that almost 40% of the requests for HIV testing at the Virology laboratory of the Academic Hospital at the Medical University of Southern Africa are positive for the virus that causes AIDS. Some estimates predict that more than 25% of the working age population in South Africa will be infected with HIV by the year 2010. These data are based on sentinel studies and intermittent surveillance programs. We in South Africa are not sure how many of our citizens are infected with the human immunodeficiency virus. We do not know how many individuals die from HIV/AIDS. We do know that HIV/AIDS has greatly reduced the life span of the people of Southern Africa.

Unfortunately, HIV/AIDS has had a grave effect on the middle class and the leadership in many countries. In Africa, AIDS has truly been a disease with no class distinction. This reality could and will lead to the destruction of valuable human resources needed to continue the development in African countries. The economic base, being developed today, may crumble if the path of AIDS is not stopped. President Nelson Mandela said in his February 1997 address to the World Economic Forum that the pandemic "is a threat that puts in the balance the future of nations...AIDS kills those on whom society relies to grow the crops, work in the mines and factories, run the schools and hospitals and govern countries...It creates new pockets of poverty when parents and breadwinners die and children leave school earlier to support the remaining children."

The pressure on health care costs is perhaps a single most important economic manifestation of the burden on society of HIV/AIDS. The Gauteng Department of Health reports that more than 50% of hospital beds in medical wards are occupied by HIV/AIDS patients and those with opportunistic infections. Treatment costs to industry are increasing. For instance, the electrical utility company, ESKOM with 37,000 workers is expected to spend R400 million per year from the year 2005 on the 18 to 25% of the workers who are infected with the HIV. Similarly ISCOR, South Africa's largest iron and steel company, is expected to spend R600 million over 7 years. These health care costs are not effective since most of the resources are spent at the end of life.

The United Nations AIDS programs (UNAIDS) and The World Bank have spent time and energy gathering information and setting up programs to encourage AIDS prevention and education. The scientific, medical and pharmaceutical sectors have focused energy and resources on developing effective treatments for people who are living with HIV/AIDS, design studies for development of a vaccine to prevent HIV infection, and efforts toward the ultimate goal of a cure for AIDS. These two approaches to the epidemic have been seen as alternative interventions. We believe that effective treatment within a context of sound public health practices is the only appropriate approach to the epidemic. We cannot rely on primary prevention and education to reduce the current mortality and morbidity burdens of HIV/AIDS. HIV/AIDS is having a profound effect on the health care system of South Africa. Most secondary and tertiary level public hospitals focus much of their resources on the medical management of patients with HIV/AIDS. Often the treatment provided is palliative and terminal. For children living and dying with AIDS, between five and eight painful and expensive admissions to the hospital usually precedes their death (usually by eight months). Within the current public health care setting where antiretroviral drugs are not available, inpatient bed costs for patients with AIDS have been estimated to be as high as 82%. These high costs reflect intensive care.

Access to adequate treatment for HIV/AIDS is a complex problem in Southern Africa. There are a number of barriers to the management of HIV/AIDS. These include: the cost of providing supportive health and social services essential for safe use and compliance, the setting up and/or strengthening of treatment units, laboratory facilities, drug delivery systems and the training of healthcare professionals, and the cost of drugs.

The health care system in South Africa is undergoing fundamental transformation and the province with the largest health budget (R5.6 billion) – Gauteng (both Johannesburg and Pretoria are in this province) - had a shortfall of almost R300 million for the 1999 / 2000 budget cycle. Much of the budget shortfall came from two academic health centers the Chris Hani Baragwanath Hospital and the Johannesburg General Hospital. The Minister of Health for Gauteng, Dr. Gwen Ramakgopa, who is also a second year Master of Public Health student at the National School of Public Health requested the support of the National School in two specific areas: the management of the health care system of the province, and the management of the HIV/AIDS epidemic in the province. During a lengthy conversation with me last Friday, Dr. Ramakgopa indicated that her fundamental concern was not the cost of drugs, but the lack of coherent and well-managed programs

within a very large and very complex health care system.

Opportunistic Infections:

The Medical University of Southern Africa has an AIDS Clinic with approximately 5,000 patients. None of these patients receives any antiretroviral therapy from the hospital. If one assumes that each patient has at least one opportunistic infection per year; then we probably spend a minimum of R35 million per year on the management of these infections. The clinic is headed by a part-time attending physician with an interest in, but no formal training in, the management of HIV/AIDS. The clinic operates once a week and is staffed by a small number of physicians and nurses. We have some indication of the impact of tuberculosis and oral thrush for the patients within our academic health care center.

South Africa has been in the throes of a tuberculosis epidemic since the middle 1960s. This is reflected in the fact that 25% (1630 patients) of the 6544 patients tested for tuberculosis during 1998 at our academic health center were positive for *mycobacterium tuberculosis*. It is entirely likely that 50% of these patients have tuberculosis in association with their HIV infection. The remainder may be part of the ongoing epidemic. The tuberculosis and HIV/AIDS epidemics form an explosive disease mixture for a beleaguered health care system. The tuberculosis epidemic is clearly illustrated in the following figure.

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In addition to the epidemic, South Africa has an increasing problem with resistant strains of tuberculosis. The problems of managing the tuberculosis epidemic in South Africa are independent of the cost of drugs. The average costs for anti-tuberculosis therapy is shown in the following table:

Drugs Combinations	**Public Sector Costs**	**Private Sector Costs**
Isoniazid+Rifampicin+Pyrazinamide 80mg+120mg+250mg five times per week for 8 weeks	R88.74	R165.66
+Ethambutol	+R12.89	+R77.61
Isoniazid+Rifampicin 100 mg+150 mg five time per week for 16 weeks	R171.84	R387.04

The fundamental problem is the inadequate and incomplete treatment of tuberculosis and the lack of a comprehensive public health strategy that includes early screening, adequate disease surveillance among populations at increased risk for disease, and the prevention of the spread of tuberculosis. There is a critical need to train health professionals and

create the health care infrastructure to manage the tuberculosis epidemic. South Africa has a poor system of public health management of tuberculosis.

Oral Thrush – In our dental hospitals we isolated yeasts from 34% of 1230 dental patients who were HIV positive. The dental clinic for HIV+ patients is managed by a small team of interested individuals with no specific training in the care of patients with HIV/AIDS.

Approaches to the Pandemic

1. There is a need to train health professionals in the public health skills of screening and surveillance, primary prevention of HIV transmission by means of health education, and secondary prevention of morbidity due to opportunistic infections by health promotion and early treatment.
2. There is a need to train health professionals who care for patients with HIV/AIDS if good clinical practice. This would reduce health care costs.
3. There is a need to train health professionals to better manage the health care system. Currently the level of skills to manage small and large hospitals is almost non-existent. Two examples will illustrate the severity of the problem:
    a. In the Eastern Cape, a small community hospital with a monthly budget of R5 million has a patient mortality rate of 10%. The bulk of the patients who come to this hospital are young. The hospital manager has no idea what the causes of death are and is uncertain how the resources are spent within the hospital. It is unclear to the staff of this small rural hospital what changes in management practices will influence health outcomes.
    b. The National School of Public Health has been admitting students for only two years. During the first year 170 individuals applied for 50 student slots. During the second year this number increased to almost 300. More than 80% of the applicants want to study Health Systems Management and Health Policy. We have estimated that more than 2,000 health managers require high-level training.
4. Development of infrastructure: Laboratory support for the adequate treatment of HIV/AIDS is non-existent in many large tertiary level and academic health centers. With the absence of good laboratory services, it is more likely that resistant strains will develop making the treatment of HIV/AIDS and the co-morbid conditions such as tuberculosis more difficult.
5. Cost of resources: It will be critical for cost-effective methods of treatment to be identified. We cannot simply import treatment regimens from other countries. It will become increasingly important for Southern Africa to identify effective and efficient mechanisms to cope with the epidemic.

It is my hope that you will agree that with me that the cost of drugs, whilst important is a small part of the battle against the HIV/AIDS epidemic in Southern Africa.

Mr. Chairman, thank you for allowing me to testify this morning.

Mr. MICA. I would like to now recognize James Love, the director of the Consumer Project on Technology.

Mr. LOVE. Thank you. My name is Jamie Love. I work in Washington, DC, for a consumer group. I've been working on disputes involving intellectual property and health care since 1991, when I was asked by a subcommittee of the Government Reform Committee to take a look at a contract between Bristol-Myers Squibb and the National Institutes of Health on the development of tax law, the government-funded invention.

I have subsequently not only done a lot of work in the United States on issues relating to the research and development and patent issues, but I've done a lot of work internationally with governments, with public health groups, and with international organizations in different parts of the world. I will be attending meetings in Pakistan next week about trade policy and patent policy and health care. And I've been working a lot in the last couple of years about issues relating to access to AIDS drugs.

My testimony has been submitted really in two different parts. One is a prepared statement, and the other one is marked additional materials. The additional materials have five appendixes that contain certain documents or information I may refer to. I'm not going to read my statement, but I would like to highlight a few points.

First of all, the issue about whether or not you can do things like compulsory licensing or parallel imports is something that people involved in U.S. trade policy have held out as some complicated area or some controversial areas as though there's some mystery about whether or not these countries, like Thailand or South Africa, or places like that, have to find some magic formula to be able to accomplish things like this.

In fact, the legal issues, at least from a point of view of international law, are really not complicated. In the case of parallel imports, for the benefit of the committee, which is if you, for example, go to Canada and buy Claritin for $61 instead of $218 in the United States, and import it back here; that would be called a parallel import.

That's clearly permitted under the international agreements, under the WTO agreements. There's an Article 6 that says whatever a country does—whatever it does in that area is up to the country; that there's nothing in the WTO agreement that would ever stop a country from doing it. And, in fact, England does it; the Netherlands, the Danes do it. This happens in areas outside of pharmaceuticals as well.

We don't have trade sanctions against England about it. We don't have trade sanctions against Germany about it. We don't have trade sanctions against Denmark or the Netherlands. We do have trade pressures against South Africa on this. We do have trade pressures against Thailand on this. We have a lot of trade pressures on poor countries on compulsory—rather on parallel imports; it's legal, everybody knows it's legal, and the basis of U.S. policy is what they call TRIPS plus, which is to take what's in the WTO agreement as a starting opening statement, and then see what you can get up on top of that.

So when Mr. Papovich from USTR gets up before this committee and says USTR, after 2 years of negotiations with the Health Ministry and the government and the President of the country are trying to figure out whether or not South Africa has our permission to pass a law in their own Parliament to do parallel imports, if we're grandiose enough to permit them to actually do that, we're still trying to figure it out, whether it's legal or not. I would represent that that's not a truthful statement about the nature of the dispute; that everybody from the Vice President, to the Trade Representative, to the Department of State, to the Patent and the Trademark Office, and throughout the government understands as we do, as the LPO does, as the WTO does, as every expert in the field knows that parallel imports are not barred by trade agreements, and your own legislative counsel in Congress will tell you it is not even barred under U.S. patent laws.

It's not a question of patent rights of the United States. So on the area of parallel imports, it's crystal clear that the governments have the right to do it, and the only thing that is stopping South Africa, other than the litigation by drug companies under their own laws, just like big corporations sue the United States Government under our laws, and we try to pass like the Telecom Act, it always has to do with the domestic litigation, but politically it's pressure from the United States. And it's not just been in South Africa, it's been in many, many countries.

No. 2, compulsory licensing. Does the WTO permit compulsory licensing? Of course, it does. And how do we know that? Well, because the U.S. Government wrote most of the provisions about compulsory licensing, and we wrote them because we have compulsory licensing under the Clean Air Act. And we have compulsory licensing of patents for nuclear power. And we have compulsory licensing for public health purposes under the Bayh-Dole Act. And we have compulsory licensing in the United States for government use under eminent domain statutes. If the government wants to use patents in the United States, it can deputize Lockheed or General Motors or any private corporation to use any patent that it wants or any copyright that it wants and just do it.

And all you can do as the patent owner is seek compensation from the government. You can't even get an injunction against the U.S. Government if they want to use your patent. That is the law in the United States of America. And we can also do it on antitrust laws. There's 5 separate laws, ways that we do compulsory licensing in the United States of America. The government does it a fair amount.

Now, the Government in South Africa through the Public Health Service would like to do compulsory licensing, because they know they can bring the prices down of many different drugs, in some cases 90, 95 percent. It's a difference of life or death in a wide range of areas.

If we oppose it, it's not based on legal grounds, it's based upon policy. It's our decision, it's our public policy decision, not to let them do it.

Does that mean my time is up, the red thing there?

Mr. MICA. If you can try to wind up.

Mr. LOVE. I will, I apologize.

Now, there's another issue that I think people recently have been trying to call attention to, and that is the U.S. Government pays for a lot of research on the pharmaceutical drugs. The U.S. Government developed on its own ddI and ddC, a couple of AIDS drugs. There's a d4T, which is an important one that was invented at Yale. The U.S. Government has grants that—there are patents on 3TC, which is another important AIDS drug; Norvir, which is the first protease inhibitor, which was developed by Abbott Laboratories in a government grant.

All of these cases, and there are many more, the U.S. Government has patent rights that they have alienated and they cannot alienate by government regulations and statutes. And the law in the United States says the following on these interventions: It says that the U.S. Government has a right to practice and have practiced the invention on behalf of the United States and on behalf of any foreign government or international organization pursuant to any existing or future treaty or agreement with the United States.

What does that mean in practical terms? It means we could, by the stroke of a pen, without an appropriation, without a law, just by doing it, give the World Health Organization the permission to use patents on inventions, paid for by the taxpayers and use that to get medicine out to people who are sick and who are dying.

Our decision not to do it is a deliberate thing, it's a policy. It's our policy that the World Health Organization cannot use our patents. Why do we do it? We do it to protect the domestic drug industry. We don't do it to protect patients.

The World Health Organization wants this authority. They've asked for this authority. There's discussions about this. We've asked, and many groups have asked, the United States to do this. You can help if you could encourage the administration to enter into a memorandum with the World Health Organization to permit these intellectual property rights be used.

I've exceeded my time. The rest of my statement is, I think, here, and I would be happy to answer questions or respond to written questions later. Thank you.

Mr. MICA. Without objection, what we will do is make your entire statement part of the record.

[The prepared statement of Mr. Love follows:]

Statement of James Love
Director
Consumer Project on Technology

Before the

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

on

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

July 22, 1999

1. Introduction

My name is James Love. I am the Director of the Consumer Project on Technology (CPT). I have been involved in a number of disputes involving health care, intellectual property and trade policy, beginning in 1994. Extensive information about these disputes is on the internet at http://www.cptech.org/ip/health.

Today's hearing marks the first time the US Congress has invited the public health community to comment on US government policies on foreign trade and the protection of the public health. This inquiry is important for everyone, but particularly for the majority of the world's population that is too poor to afford access to essential medicines.

The topic for the hearing is the US government's role in "combating the global HIV/AIDS epidemic." I will address a negative role that the US government has undertaken -- preventing poor countries from using policies like compulsory licensing and parallel imports to obtain less expensive essential medicines, with a particular emphasis on the current trade dispute with South Africa. I will also discuss proposals that the US government permit the World Health Organization (WHO) to use US government rights in patents invented with taxpayer funds.

2. Millions of People will die without access to essential medicines

It is a horrific fact that in several Southern African countries 20 to 25 percent of the young adults are already infected with HIV/AIDS. The US Surgeon General recently estimated the current number of infected persons in Sub Saharan Africa at more than 22 million. These people will die without access to essential medicines. Indeed, these people are dying now because they do not have access to essential drugs. An estimated 1,400 persons per week in Zambia. 2,400 persons per week in Zimbabwe.

The infection rates in South Africa are stunning. At the University of Durban-Westville in the Kawzula-Natal, South Africa, 25 percent of the student body recently tested positive for HIV. An estimated 45 percent of the South African military is HIV positive. A quarter to a fifth of the pregnant women in South Africa are testing positive for HIV/AIDS.

There are also 6.7 million infected persons in South and Southern Asia, and 1.4 million infected persons in Latin America.

3. Poor countries cannot afford high drug prices

The ability of any country to treat HIV/AIDS patients is related to the level of the country's income and the rate of infection. Table 1 provides data on the amount of national income for each person living with HIV/AIDS, as measured by 1997 Gross Domestic Product (GDP). This is a useful measure of a country's ability to pay for HIV/AIDS drugs.

In 1997, Japan had an income of more than $616 million for every person living with HIV/AIDS. For the UK, France and the US, the figure were $51 million, $12 million and $9.6 million. These countries can afford to pay even very high prices for medicines needed to treat HIV/AIDS.

The countries in Group 2 are much poorer, and have much higher infection rates. Thailand has GDP of $197 thousand per infected person, about 2 percent of the US income per infected person. South Africa has $45 thousand in national income per infected person, or less than one half of one per cent of US income per infected person. Zambia has $5 thousand in national income per infected person. Zambia could not afford a typical multidrug therapy for its population, even if it spent its entire national income on HIV/AIDS drugs.

Table 1
National Income per person living with HIV/AIDS

Group 1	
Japan	$ 616,210,735
UK	$ 51,459,520
France	$ 12,659,100
USA	$ 9,553,702
Group 2	
Thailand	$ 197,319
India	$ 93,065
South Africa	$ 44,515
Botswana	$ 26,684
Uganda	$ 7,077
Zambia	$ 5,019
Mozambique	$ 2,294

Drug companies are quick to point out that drug prices are not the only barrier for HIV/AIDS patients. Certain treatment regimes require significant medical infrastructure, including laboratory tests and access to trained medical personal. However, other treatment regimes may be more appropriate, even with very modest medical services. In any event, HIV/AIDS patients will die without access to drugs. Indeed, most of the 30 million HIV/AIDS patients in poor countries will die, precisely because they cannot afford drugs or health care services.

4. US Trade Policy

In the face of this human tragedy, the US government is carrying out a global battle to keep drug prices high. The US government has organized a cross agency team that is largely directed by the global pharmaceutical industry to monitor and influence legislation in virtually every country on earth. The scope of this campaign is enormous. The US government insists on having the opportunity to review and comment on regulations or legislation involving the pharmaceutical industry by any foreign government. As part of this campaign, the US government actively opposes the use of compulsory licensing and parallel imports, two important mechanisms that countries use to obtain less expensive drugs. The US government also opposes a number of other policies that would broaden the public's access to essential medicines.

When the World Trade Organization (WTO) was created, member countries approved an agreement on Trade Related Aspects of International Property, known as TRIPS. The TRIPS accord sets out minimum international standards for patents, copyrights and trademarks. The TRIPS accord has specific provisions on both compulsory licenses and parallel imports.

Compulsory licensing is when the government permits a third party to manufacture a product without the permission of a patent owner. This is permitted in the TRIPS agreement, as long as a country abides by the "safeguards" in Article 31 of the TRIPS. One safeguard is Article 31(h), which requires adequate compensation to patent owners, typically as a royalty of sales revenue. Compulsory licensing, combined with good procurement practices, can reduce prices of some drugs by 30 to 95 percent.

Most governments already have some authority to issue compulsory licensing of patents, and the US government is no exception. Indeed, the US government can issue compulsory licensing under the Clean Air Act (42 USC 7608), for nuclear power (42 USC 2183), for public health purposes under the Bayh-Dole Act (35 USC 203), for government use (28 USC 1498) and as a remedy for anticompetitive practices under US antitrust laws.

Parallel importing of medicines occurs when someone other than the authorized distributor is permitted to import a product, usually because of differences in national prices. For example, identical versions of Claritin sell for $61 in Canada and $218 in the US. Drugs prices vary significantly across markets, depending upon local market conditions, often without regarding to country incomes[1]. Parallel importing is permitted under Article 6 of the TRIPS, under the principle of the "exhaustion of rights," also referred to as the "first sale" doctrine. Parallel imports of pharmaceutical drugs are common in several European countries[2].

5. The Dispute over the South Africa Medicines Act

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[1]For example, some drugs are cheaper in Canada than in Indonesia, or cheaper in the US than in South Africa.

[2]In the United States, there are legislative efforts in the House (HR 1885) and Senate (S 1191) to permit the parallel importation of drugs so long as the drug is manufactured in by the patent owner in an FDA approved plant.

The current dispute over the South African Medicines Act provides a useful and important illustration of US government policy. In 1997 the South African Government (SAG) proposed sweeping changes in its Medicines Act that were designed to curb unethical marketing practices of pharmaceutical companies, promote the practice of prescribing drugs by generic names, and legalize parallel imports of pharmaceuticals.

The South Africa government correctly perceived that it could economize on drug purchases if it purchased drugs in more competitive national markets. The large pharmaceutical companies opposed parallel imports, preferring a world where companies charge different prices in each national market.

In an effort to convince the South African government that parallel imports were a bad idea, the drug companies made a number of sweeping, vague and misleading assertions that parallel imports violate patent rights. Ironically, when the South African government couldn't find anything in its patent laws that appeared to address this issue, it decided to add language, as insurance, that stated: "notwithstanding anything to the contrary contained in the Patents Act" the Minister of Health can "prescribe conditions for the supply of more affordable medicines." These provisions were included in Section 15C of the South African Medicines Act. The legislation thus came to authorize both parallel imports and compulsory licensing.

As South Africa began to more fully appreciate the desperate circumstances of its AIDS patients, support for compulsory licensing began grow in that country.

The drug companies turned to the United States government, a usually dependable ally on these issues, for help. The US government launched what is now a two year effort to seek the repeal or modification of Section 15C of the South African Medicines Act.

Pressuring South Africa on behalf of the drug companies has been a decidedly bipartisan undertaking. The Administration lobbying efforts were coordinated by Vice President Gore, as US Chair of the US/South Africa Binational Commission (BNC). Special task forces were organized on the South Africa issue, and the Vice President frequently raised the patent issues directly with South Africa officials, including (now) President Thabo Mbeki. There was also pressure from both parties in Congress to put push on South Africa on these issues.

I am including as Appendix B, a 13 page time-line of key events in the South Africa dispute. Some of these events were reported in a February 5, 1999 US Department of State to Congress, and others are based upon FOIA requests to various federal agencies and our own research.

The Vice President's office has recently suggested that Al Gore was a moderating voice in the Administration's dealings with South Africa, and when compared to some administration officials, this may be true. However it is inaccurate to portray the Vice President as an innocent bystander who has been unfairly tared by this controversy, or to suggest there were no earlier efforts to address these issues.

I personally have been involved in efforts to change US policy on the South Africa trade dispute since 1997, and much of this effort has been directed at the Vice President's office. On July 29, 1997, about two years ago, Ralph Nader, Robert Weisman and I wrote the Vice President to object to pressures being put on South Africa over parallel imports, the promotion of generic drug prescriptions and the marketing approval of a generic form of Taxol (Paclitaxel), an unpatented US government funded cancer invention sold in the US by Bristol-Myers Squibb. We said:

> The United States has a stake in sound public health policies, not only in the United States, but throughout the world. The widespread availability of pharmaceuticals and other health care inventions will be increasingly important as the United States seeks to combat infectious diseases and promote development and economic growth. The international rules for intellectual property in the health care sector are extremely important, and will bind policy makers in the United States and elsewhere. These rules are simply too important to be left up to the imagination of the pharmaceutical and biotechnology industry. A balanced dialogue must include stakeholders who represent consumers and public health officials.

We asked for meeting with US officials who were working on the South Africa dispute. No one from the Vice President's office or any other federal agency ever responded to our letter.

In October 6, 1997, CPT provided detailed comments on the South African Medicines Act to the South African Portfolio Committee on Health. These comments, which were highly critical of the US government's position in the trade dispute, were also distributed to US trade officials. Then on a periodic basis, we had interactions with various Administration staff on this dispute, including discussions with persons from State, Commerce, USPTO, US FDA, USTR, DHHS and the Vice President's own staff.

In early 1998, the World Health Assembly (WHA) nearly exploded over a controversial "Revised Drug Strategy" resolution, that called on counties to make public health considerations paramount in trade disputes. South Africa became the most important supporter of the resolution, and the US government was initially the most important and bitter opponent. The US government eventually supported the resolution, but remained bitter at South Africa for its role in pushing for wording that was opposed by US drug companies.

On February 18, 1999, the US Department of State held a briefing on the global HIV crisis, but refused to permit any discussion about US trade pressures on South Africa or Thailand on compulsory licensing of AIDS drugs.

On March 26, 1999, more than sixty non-government organizations and dozens of governments and international organizations met in Geneva for a meeting on compulsory licensing and access to AIDS and other essential medicines. The US government's role in pressuring South Africa, Thailand and other countries on behalf of the drug companies was addressed often during the meetings, and reported widely in the European press.

On April 8, 1998, Ralph Nader and I again wrote the Vice President on the subject of the South Africa dispute, pointing out that every request for consultation by the public health community had been rebuffed. We once again asked for a reversal of US policy, and we complained bitterly about the Administration's frequent public assertions that the South African initiatives were not permitted under the WTO TRIPS accord, while the US refused to bring its concerns to the WTO under the WTO dispute resolution framework. Three weeks later the Administration announced yet another round of trade pressures on South Africa.

On April 30, 1999 USTR announced a special "out-of-cycle review" of South Africa's intellectual property policies, that would be completed in September 1999. (one of three announced out-of-cycle reviews that involved pharmaceutical drugs). In addition to the earlier US government complaints about compulsory licensing, parallel imports and the regulatory approval of Taxol, the US government identified this "barrier to trade:"

> During the past year, South African representatives have led a faction of nations in the World Health Organization (WHO) in calling for a reduction in the level of protection provided for pharmaceuticals in TRIPS.

By elevating the act of speaking up at the World Health Assembly to a barrier to trade, USTR was sending a signal to every developing country that it would punish even the expression of dissent on US trade polices. The South African Minister of Health subsequently removed herself from a WHO Ministers discussion of policies to fight the global AIDS battle, an action welcomed by US officials.

The April 30, 1999 USTR action electrified the public health community. On May 14, 1999, a public letter to the Vice President was circulated, and now contains hundreds of signatures from public health groups around the world. The letter said "It is shocking that the US government is adopting such an aggressive trade policy on behalf of US pharmaceutical companies, when all of sub-Saharan Africa is confronted with a public health crisis of historical dimensions."

On June 7, a subcommittee of the Presidential Advisory Commission on HIV/AIDS held a public meeting in Washington, DC on US trade policy and compulsory licensing and parallel imports. No Administration official would accept an invitation to explain US policy.

During this period, public health groups began to add a new issue to the debate. Under US technology transfer laws, the US government retains broad "public use" rights on government funded inventions, including many important AIDS drugs, such as ddI, d4T, 3TC or Ritonavir, as well as other essential medicines. The relevant statutes and regulations are 35 USC 202 (c)(4) and 37 CFR 404.7. According to these provisions, the US government retains the rights to:

> practice and have practiced the invention on behalf of the United States and on behalf of any foreign government or international organization pursuant to any existing or future treaty or agreement with the United States.

Public health groups have asked the Vice President and other Administration officials to support efforts to give the World Health Organization the right to practice these inventions in poor countries. The US government so far has declined to do so.

It is important to recognize that US policy toward South Africa is in fact, consistent with hundreds of US government actions over several years. I am attaching as appendices comments from various USTR reports on pharmaceutical policies the US government opposes in Thailand, Israel and New Zealand. In Thailand the US government was opposed to compulsory licensing, parallel imports, prices controls, and government attempts to collect economic information about drug prices and development costs. These were all considered barriers to trade. In Israel, the US government opposed parallel imports, compulsory licensing and the Israel adoption of a so called "bolar" provision, modeled after US law, to permit speeder introduction of generic drugs following patent expiration. In New Zealand, the US government declared that New Zealand's "use of reference pricing, the practice of doing trade-off deals between classes of drugs . . . can negatively affect a company's revenue return on its intellectual property." In the New Zealand case, USTR is claiming that using competition to negotiate good prices is a barrier to US trade.

On June 16, 1999, the entire political environment changed when a small band of AIDS activist interrupted the Vice President's announcement that he was running for President. After the AIDS activists disrupted several campaign events, and this was reported in the news, the Vice President began to send some signals that US policy might change. The most important such signal

was Vice President Gore's June 25, 1999 Letter to James E. Clyburn, the Chair of the Congressional Black Caucus, where the Vice President said:

> I want you to know from the start that I support South Africa's efforts to enhance health care for its people – including efforts to engage in compulsory licensing and parallel importing of pharmaceuticals -- so long as they are done in a way consistent with international agreements.

This letter was seen by CPT as a remarkable and welcome turn around on this issue. However, our enthusiasm was tempered by uncertainly over the phrase "so long as they are done in a way consistent with international agreements." On its face, the statement was fine, because no one was objecting to the WTO/TRIPS Article 31 safeguards for compulsory licensing, and parallel imports are freely permitted under the TRIPS. The problem was the longstanding practice of US government trade officials to make up far fetched and tenuous theories why the South African Act might violate the TRIPS. The US government was never willing to test these theories before a WTO tribunal, because it would lose. CPT then wrote the James Clyburn on June 29, 1999, asking that the Vice President clarify his June 25, 1999 statement, and tell us what it really means. What does the Vice President think the TRIPS accord actually says about parallel imports or compulsory licensing? Is this a trick to fool the AIDS activists and the Black Caucus, or is this a change in policy?

6. A note on Research and Development Incentives

Providing incentives for research and development is important. However, many measures that broaden access to drugs do not have a quantitatively significant negative impact on R&D incentives. For example, by some reports, Africa is about 1.4 percent of the global market for pharmaceuticals. As Professor Richard Laing points out, for most drugs, and in particular for high priced drugs, Africa just isn't a material consideration for R&D efforts.

And, for high priced drugs with no significant domestic sales, compulsory licensing is just as likely to increase company revenues, in that market. What companies are concerned about is the embarrassment of seeing a drug like Fluconazole selling for $23.50 in Italy but only $.95 in India. What drug companies say is that they are concerned that cheap prices for drugs in Thailand might undermine the willingness of governments or insurance companies to pay high prices in the US or European market. It is in this sense, a public relations issue. But how many millions should literally die of this embarrassment?

Moreover, there are a large number of important drugs that were developed with substantial taxpayer subsidies, including many current AIDS drugs. It makes little economic sense to make these drugs artificially expensive, after the public has already paid for much of the development costs.

Compulsory licensing is ultimately a compromise on the issue of R&D. Patents are recognized and patent owners are paid, giving rise to incentives for R&D. But the amount of the incentive is limited by the government, in order to ensure that the public health needs are met. This is a sound policy, and extremely important, given the rising death toll in Africa and elsewhere for AIDS.

Testimony of James Love

Additional Materials

Appendix A	Statements by the WTO, WHO, WIPO and USTR on compulsory licensing
Appendix B	Timeline of Disputes over Compulsory Licensing and Parallel Importation in South Africa
Appendix C	USTR Reports on Thailand Pharmaceutical Policies,
Appendix D	USTR Reports on Israel Pharmaceutical Polices
Appendix E	USTR Reports on New Zealand Pharmaceutical Policies

Appendix A

WTO, USTR, WHO, and WIPO comment on compulsory licensing

1. **Adrian Otten, WTO**

The [TRIPS] Agreement also allows Members to authorize use by third parties (compulsory licenses) or for public non-commercial purposes (government use) without the authorization of the patent owner. Unlike what was sought by some countries in negotiations, the grounds of which this can be done are not limited by the Agreement, but the Agreement contains a number of conditions that have to be met in order to safeguard the legitimate interests of the patent owner.

Adrian Otten, Director Intellectual Property Division. World Trade Organization. Presentation to the World Health Organization (WHO)'s ad hoc working group on the Revised Drug Strategy, Geneva, October 13, 1998.

2. **Michael Kantor, USTR**

We have been balanced in our approach to the protection of pharmaceutical products. The relevant provisions of the TRIPS Agreement reflects this problem: TRIPS specifically sets out a considerable number of conditions under which compulsory licensing may be utilized for use by those countries wishing to impose limits on intellectual property protection within its own borders. TRIPS contains no transition period phasing-out the use of these compulsory licensing provisions, they may be relied upon for the indefinite future.

Michael Kantor, then the United States Trade Representative, February 1, 1996 letter to Alfred B. Engelberg (member of USTR's IFAC-3).

3. **World Health Organization**

Thus Member States are not limited in regard to the grounds on which they may decide to grant a license without the authorization of the patent holder. They are in practice only limited in regard to the procedure and conditions to be followed. . .

Compulsory licenses are the easiest and the most effective way to increase the supply of products, by acting directly on marketing conditions or by deterring patent holders from taking measures that would arbitrarily reduce supply or artificially or excessively increase prices. . .

According to Article 8 of the [TRIPS] Agreement, Member States may adopt the necessary measures to protect public health and nutrition (provided these measures are consistent with the provisions of the TRIPS agreement). There are many instances of regulations that envisage compulsory licenses for reasons of public health. In practice, if a new pharmaceutical product introduced into the market were to constitute an important innovation or play an essential role in health policy, such as a vaccine against AIDS or malaria, the national law may provide for the granting of a compulsory license, under the conditions of Article 31.

German Velasquez and Pascale Boulet, "Globalization and access to drugs: Implications of the WTO/TRIPS Agreement." WHO/DAP/98.9 Revised

4. Richard Wilder, WIPO

The right to exclude others from using a patented invention may be subject to limitations in some countries, including by the right of the government to use the invention or by the grant of compulsory licenses. . . A patent system, to function properly, should be balanced. On the one hand, the patentee must be granted effective protection for his or her invention to induce further research and encourage the disclosure of inventions to the public. On the other hand, national law may take cognizance of the constraints that may be imposed on the grant and exercise of the patent right.

Richard Wilder, World Intellectual Property Organization, presentation to the World Health Organization (WHO)'s ad hoc working group on the Revised Drug Strategy, Geneva, October 13, 1998.

5. The Paris Convention for the Protection of Industrial Property of March 20, 1883.

Each country of the Union shall have the right to take legislative measures providing for the grant of compulsory licenses to prevent the abuses which might result from the exercise of the exclusive rights conferred by the patent, for example, failure to work.

Article 5(A)(2).

APPENDIX B

Timeline of Disputes over Compulsory Licensing
and Parallel Importation in South Africa

version 1.02
July 14, 1999

1994. The US/South Africa Binational Commission (BNC) is formed, co-chaired by Vice President Al Gore and Deputy President Thabo .M. Mbeki.

March 1, 1995, BNC holds first meeting in Washington, DC.

April 7, 1997. Andrew Stoller of USTR writes letter to UN Ambassador from South Africa Selebi concerning the questions of the U.S. about implementation of TRIPS. Questions touch on such topics as compulsory licensing.

May 13, 1997. PhRMA's Harvey Bale writes letter to Deputy USTR Jeffrey Lang discussing objections to proposed amendments to the South African Medicines and Related Substances Control Act.

May 20, 1997, Aldridge Cooper, a Vice-President of Johnson & Johnson and Chairman of the U.S.-South African Business Council, writes Secretary of Commerce William Daley about the proposed changes in the South African Medicines Act.

June 2, 1997. Representatives of Bristol-Myers Squibb, Merck, Johnson & Johnson, Eli Lilly, and American Home Products meet with the South African Ambassador to the U.S. Franklin Sonn, to discuss the proposed Medicines and Related Substance Control Amendment Bill and the issue of registration of a generic version of Taxol (Paciltaxel).

June 3, 1997. Aldridge B. Cooper, a Vice-President of Johnson & Johnson and Chairman of the U.S.-South Africa Business Council, again writes US Secretary of Commerce William Daley to claim that the proposed amendments to the South Africa Medicines Act will have "grave consequences for not only the US pharmaceutical industry, but all US direct investment in South Africa." Cooper notes that the US government has set up "an inter-agency task force has been established under the direction of the Department of Commerce, involving the Office of the US Trade Representative, the State Department and the Department of Health and Human Services," and that a recent Congressional delegation raised the SA Medicines Act amendments in a recent trip to Africa. He asks that this be a subject of the July 1997 BNC meetings.

June 1997. The US Embassy in Pretoria, echoing testimony by US pharmaceutical companies operating in South Africa, presents US government views at a parliamentary hearing on the proposed amendments to the Medicines Act.

Since mid-1997. According to the US Department of State, US Ambassador to South Africa James Joseph makes frequent public statements and multiple private demarches to high-ranking South African officials against the legalization of parallel imports.

July 24, 1997. US Representatives Menendz, Royce, Payne, Chabot, Rothman, Pallone, Davis and Andrews write letters to Deputy President Mbeki and Vice President Gore expressing concern about intellectual property of pharmaceuticals in South Africa. The letter addresses the pharmaceutical industry concerns over parallel imports and proposed requirements that drugs prescribed by public health doctors be identified by generic names, which the industry claims violates trademark rights under the WTO/TRIPS accord on intellectual property.

July 29, 1997. Ralph Nader, James Love and Robert Weissman write Vice President Gore, asking for a meeting with US government officials to discuss dispute with South Africa's pharmaceutical policies. The letter focuses

on parallel imports, generic drug substitution and registration of generic versions of Taxol. "We see no grounds for U.S. government intervention on behalf of the international pharmaceutical companies. Indeed, the U.S. should be supportive of the South African government's thoughtful initiatives, and use the opportunity to assert that U.S. foreign economic policy with respect to pharmaceuticals will subordinate commercial concerns to broader public health interests," they wrote. Vice President Gore was also urged to expand USTR's IFAC-3 advisory committee on intellectual property to include consumer interests.

July 29, 1997. During U.S.-South African Binational Commission meeting, Secretary of Commerce William Daley voiced opposition to the proposed amendments to South African Trade and Industry (DTI) Minister Alec Erwin.

July 29, 1997. PhRMA meets with Minister Zuma and others from South Africa in Washington, DC to discuss intellectual property of pharmaceuticals. The US government pushed for the meeting. The South African Ministry of Health wanted to invite intellectual property and trade experts but PhRMA objected. The meeting was chaired by Franklin A. Sonn, the Ambassador of the Republic of South Africa, and attended by Alan Holmer, the President of PhRMA, Tom Bombelles (PhRMA), Cathie Bennett (Pfizer), Dr. Khalil (Merck), Mitchell Cybulski (SKB), Brian Healy (Merck), Minister Zuma (SA MOH), Dr. Olive Shisana (SA MOH), Dr. Ian Roberts (SA MOH), Gregg Burton-Durham (SA DTI). and others. Dr. Zuma tells PhRMA that parallel importing will only be done for selected drugs, when it benefits patients, and that "it is unacceptable for South Africa to pay higher prices than Australia." PhRMA attacks parallel import authority as well as South African plans to promote use of prescribing drugs by generic name.

August 19, 1997. The Pharmaceutical Manufacturers Association of South Africa (PMA) distributes a document entitled "South African Pharmaceutical Prices: A Six-Country Comparison," to argue that prices for pharmaceuticals are competitive in South Africa.

September 17-19, 1997. The PMA South Africa submits comments and a position paper on the Medicines and Related Substances Control Amendment Bill to Portfolio Committee on Health.

October 4, 1997. Ambassador James Joseph writes letter to Dr. Abe Nkomo of the Portfolio Committee on Health describing U.S. objections to section 15(c) of the Medicines Bill. Ambassador Joseph says "my Government opposes the notion of parallel imports of patented products anywhere in the world. We argued for a prohibition of such parallel imports in the TRIPS Agreement. They are illegal in the United States, both as an infringement of patent rights and, because in the case of medicines, our Food and Drug Administration (FDA) believes it cannot adequately monitor quality."

October 6, 1997. James Love, on behalf of the Consumer Project on Technology, presents comments, via fax, to the Portfolio Committee on Health Parliament, Cape Town, on the Medicines and Related Substances Control Amendment Bill and South African Reform of Pharmaceutical Policies. The CPT comments reviewed the legality of parallel imports under the WTO/TRIPS Agreement (legal under Article 6), and in recent cases in Japan and the European Union. CPT also presented evidence from the UK on parallel import savings on HIV drugs, and discussed the Taxol issue.

October 10, 1997. MSD South Africa (Merck) writes a position paper expressing concern about Section 15C of the SA Medicines Act.

October 14, 1997. Dr. Elizabeth Ominde-Ogaja, the Director of the National Quality Control Laboratory in Kenya, writes the Peter Foib (sp?), the Director of the South African Medicines Control Council, to express opposition to parallel importation, which Kenya has outlawed.

October 24, 1997. Simon Barber, writing in the Johannesburg Business Day, reports that Senator Jesse Helms may hold up ratification of the new U.S./SA Tax Convention, in retaliation for South Africa having "abrogated" the patent rights of US drug companies by permitting parallel imports. Barber reports that Helms' is acting on behalf of Glaxo, the British drug company that sells AZT and other drugs, with offices in North Carolina.

October 27, 1997. The Department of Trade and Industry (DTI) of South Africa responds to U.S.-South Africa Business Council concerns over article 15(c). Emily B. Solman, the Managing Director of the SA Business Council, contacts USTR, US Department of Commerce, US PTO, US Department of State and the US National Security Council the next day.

November 19, 1997. David Miller of the Corporate Council on Africa writes to the Southern African Development Community, Secretary Shalala, USTR Barshefsky, Senators Helms and Ashscroft, Representatives Gilman and Royce, and others, to express opposition to the South African Medicines Act amendments.

November 25, 1997 - Ambassador Erwan Fouere, the Head of the European Commission delegation in South Africa, writes letter to Dr. Olive Shisana, the Director General for the South African Department of Health, advising South Africa that "The European Commission has received complaints from the European Pharmaceutical Industry that the South African bill Section 15C, to amend the Medicines and Related Substance Control Act from 1965 (MRSC) appears to be in violation of the TRIPS Agreement and in particular Article 27 (non discrimination) and 28 (rights conferred by the patent)." No mention is made of the extensive use of parallel imports within the European Union, or of Articles 6 or 31 of the TRIPS.

December 12, 1997. President Mandela signs into law amendments to the South African Medicines Act, including Section 15C.

January 8, 1998. Dr. Nathaniel Murdock of the U.S. National Medical Association (NMA) writes a number of letters expressing opposition to the SA Medicines Act.

January 21, 1998 - The U.S. National Black Nurses Association writes to President Mandella expressing concern that the South African government might "inadvertently encourage the production of drugs that are not authentic," and urges changes in the South African Medicines Act.

January 23, 1998 - The National Black Caucus of State Legislators sends letters, signed by Lois DeBerry, the Speaker Pro Tem of the Tennessee House of Representatives and Roscoe Dixon of the Tennessee State Senate, to Minister of Health Zuma and President Mandella. The letters ask for a new amendment to the SA Medicines Act to prohibit parallel importation of patented products.

January 27, 1998. The Executive Board of the World Health Assembly recommends the adoption of EB101.r24, the Revised Drug Strategy. The resolution asks member countries to "ensure that public health rather than commercial interests have primacy in pharmaceutical and health policies and to review their options under the Agreement on Trade Related Aspects of Intellectual Property Rights to safeguard access to essential drugs." The resolution, which was introduced by Dr. Timothy Stamps, the Minister of Health for Zimbabwe, is attacked by the international pharmaceutical industry and governments in the US and the EU.

February 2, 1998 - 47 members of U.S. Congress write letter to USTR Charlene Barshefsky urging her to take actions against the recently passed amendments to the SA Medicines Act.

February 11, 1998. The US Department of State tells USTR that the New York Times is researching an article on the South African trade dispute. Steven Fox from USTR tells Jay Ziegler in South Africa to use the following statement "We are very concerned about the implications of these amendments. We have conveyed our concerns to the Government of South Africa in strong terms and are consulting closely with affected U.S. companies about appropriate action." The NYT story runs on March 29, 1998.

February 11, 1998. Anthony Carroll from The Services Group (TSG, located in Arlington Virgina), send a fax to USTR's Rosa Whitaker, with suggestions for talking points on parallel imports.

February 13, 1998. USTR's Joe Papovich attends interagency meeting chaired by Leon Fuerth of Vice President Gore's office to discuss addressing the Medicines Bill at the upcoming South African BNC meeting.

February 19, 1998. Tom Bombelles of PhRMA sends USTR's Rosa Whitaker talking points and articles on parallel importation.

February 23, 1998 - Pharmaceutical Research and Manufacturers of America (PhRMA) asks USTR to designate South Africa as a Priority Foreign country under the Special 301 Review. PhRMA says that "South Africa has become a `test case' for those who oppose the U.S. government's long-standing commitment to improve the terms of protection for all forms of American intellectual property, including pharmaceutical patents."

February 23, 1998. Bristol-Myers Squibb (through Collier, Shannon, Rill & Scott and the Gorlin Group) presents comments to Joseph Papovich at USTR, asking that South Africa be "designated a priority foreign country" under Special 301. The compliant focuses on the decision of South Africa to permit registration of a generic from of Paclitaxel (BMS brand name Taxol).

March 9, 1998. The US Supreme Court upholds the legality of parallel imports of certain copyrighted goods in Quality King Distributors, Inc. v. L'Anza Research International.

March 10, 1998. Tom Bombelles of PhRMA writes USTR's Steven Fox, thanking him for "meet with our PhRMA group today, and attaching notes from the July 29, 1997 meeting between PhRMA and Minister Zuma and her staff.

March 11, 1998. The U.S. South African IP Working Group holds a teleconference. One issue discussed was the March 9, 1998 US Supreme Court decision that upheld U.S. parallel imports for certain copyrighted goods.

March 17, 1998. USTR Barshefsky responds to Congressman Menendez and 46 other members of congress stating that "This issue is a centerpiece of our annual `Special 301' review of countries' intellectual property practices. Our concerns about the Medicines Act were the central focus of a bilateral IPR teleconference we conducted March 11. We will raise the issue again during the President's visit to South Africa. USTR and other agencies with both trade and health policy responsibilities will continue to press the South African Government in all possible fora as long as possible."

March 19, 1998 - USTR's Rosa Whitaker, Liz Artky and Stephen Fox meet with Congressman Menendez to discuss the SA Medicines Act.

March 20, 1998. USTR's Stephen Fox discusses with Jim Carouso in the US embassy in Pretoria a March 23 meeting with the European Union, asking the EU to push Minister Zuma on the SA Medicines Act.

March 23, 1998 - Sir Leon Brittan, VP of the European Commission, writes to VP Mbeki describing his concern with Section 15(c) of South African Medicines and Related Substances Control Act, saying the Act "would negatively affect the interests of the European pharmaceutical industry." Brittan does not knowledge that parallel imports of pharmaceuticals are common within the European Union.

March 25, 1998. The Government of South Africa send a report entitled "Trade Policy Review" to the World Trade Organization, stating that "IPR protection in South Africa is consistent with the WTO Agreement on Trade Related Intellectual Property Rights (TRIPS)."

March 26, 1998. President Clinton addresses South African Parliament.

March 26, 1998 - Secretary of Commerce Daley met with South African Health Minister Zuma. According to the US State Department, Daley emphasized the USG resolve to ensure South Africa would not use 15(c) to undermine pharmaceutical patent rights or allow parallel imports. Minister Zuma tells Daley the South African laws do not violate any international agreements.

March 27, 1998. In a radio broadcast in South Africa, Tom Bombelles of PhRMA says the dispute over the South African Medicines Act is "the single most important economic or trade issue." The report says that

Bombelles "alleges that South Africa is being used by India and Argentina as a test run to see how world wide agreements could be broken relating to the protection of intellectual property rights." Samir Khalil from Merck is also quoted.

March 29, 1998. The New York times publishes "South Africa's Bitter Pill for World's Drug Makers," by Donald G. McNeil, Jr. The NY Times article reports that South Africa pays prices that are sometimes eight or nine times as high as other countries for common drugs.

Spring 1998 - Assistant U.S. Trade Representative for Africa Rosa Whitaker raises U.S. government concerns with both the Minister of Health and Minister of Trade and Industry in South Africa.

April 9, 1998 - Congressmen Menendez and Royce write to Secretary of State Albright asking to use Special 301 against South Africa.

April 14, 1998. Peter Collins, Steve Fox and Claude Burcky send a memorandum to Ambassador Richard Fisher, with talking points about why South Africa needs to be cited in Special 301. Among them: "Our Special 301 decisions will have no credibility with our industry or with the South Africans if we do not name South Africa in this year's announcement." And, "This law is a mistake. and identifying South Africa in the Special 301 announcement is a gentle reminder." Attached is a 4 page memo, "U.S. Support for South Africa's Health Care Goals," which claimed that prices in South Africa now "represent some of the lowest prices in the world," and "parallel importation . . . does not work. . . Parallel importation often is only a way for middlemen to make more money."

April 21-23, 1998. In Geneva, USTR's Rosa Whitaker submits "questions from the United States" to the WTO Trade Policy Review of South Africa, Botswana, Lesotho, Namibia, and Swaziland. The US questions on South Africa focus on South Africa's approval of generic versions of Taxol (As a possible TRIPS Article 39.3 violation), and Section 15C of the SA Medicines Act.

May 1, 1998. USTR puts South Africa on the Special 301 Watch list. The USTR announcement focuses on the SA Medicines Act, including the authorization of parallel imports and empowering the Minister of Health to "abrogate paten rights," as well as the registration of a generic form of Taxol. and insufficient enforcement of copyright laws.

May 7-8, 1998. Seven public health and consumer groups from around the world (including CPT, HAI and Consumers International) hold a conference in Washington, DC on the issue of health care, intellectual property rights and international trade agreements. The USTR and the US FDA refuse to participate. The Department of State, the NIH and other federal agencies do participate.

May 11, 1998. The World Health Assembly (WHA) begins meetings in Geneva. An executive board resolution on the WHA "Revised Drug Strategy" draws heated opposition from the US, the EU and Japan. In negotiations on the resolution, Dr. Olive Shisana from the SA MOH is the lead negotiator for the African countries. The US government threatens diplomatic pressure remove Dr. Shisana from the negotiations. The EU DGI does not permit Finland and other Nordic EU members to support the resolution. Italy and the US move to defer action on the resolution.

June 30, 1998 - White House announces that four items, for which South Africa had requested preferential tariff treatment under the Generalized System of Preferences (GSP) program will be held in abeyance pending adequate progress on intellectual property rights protection in South Africa. The South African press refers to the withheld GSP tariff reductions as "hostages."

June 1998. According to the US Department of State, US Embassy official travel to Midrand, South Africa to speak at "Pharmecon SA '98" pharmaceutical industry conference about strong US negative views on Article 15(c).

July 1998. French President Chirac raises France's concerns about Article 15(c) in state visit to South Africa. Swiss and German presidents also raised issue privately with Deputy President Mbeki.

July 1998. Assistant USTR Rosa Whitaker met with the South African Charge d'Affaires in Washington to stress US concerns about pharmaceutical patent protection and parallel importation in South Africa.

August 1998. During U.S.-South Africa Binational Commission meetings in Washington, Vice President Gore made the issue of pharmaceutical intellectual property rights protection a central focus of his discussions with Deputy President Mbeki.

September 1998. Commerce Secretary Daley, in trip to South Africa, made pharmaceutical patent protection a key item in discussions with South African Trade and Industry Minister Alec Erwin.

September 1998 . Discussions between Assistant USTR for Services, Investment, and Intellectual Property Joseph Papovich and the Deputy President Mbeki's legal advisor takes place. The South African government asks the US government to intervene with the US pharmaceutical industry to suspend or terminate its pending legal challenge to Article 15(c).

October 1998. The US Embassy dispatches an economic officer to Cape Town to monitor committee and full chamber debates on the South African Medicines Act. He "forcefully advocates" the US position and advised parliamentarians that new law should not include provisions that jeopardize patent rights.

October 12-16, 1998. In Geneva, the World Health Organization hosts a meeting of the "Ad Hoc Working Group" to discuss the WHA's Revised Drug Strategy. 59 countries participate in often bitter discussions. South Africa is the leading country in favor of a strong public health statement, and the US is the leading country representing the industry point of view. The Ad Hoc Working Group approves a resolution that asks countries to "ensure that public health interests are paramount in pharmaceutical and health policies," "to explore and review their options under relevant international agreements, including trade agreements, to safeguard access to essential drugs," and the WHO is asked to become involved in trade disputes involving pharmaceutical health policies. According to Nordic countries, the US seeks to water down the resolution, but after support for the US position collapses among the participants, the U.S. drops opposition and announces it will support the resolution. The US
and PhRMA offer nearly the opposite interpretation of events. Public health groups endorse the new resolution.

October 21, 1998. HR 4328 passes, and becomes PL 105-277. This omnibus appropriations law contains a provision inserted by Rep. Rodney Frelinghuysen (R-NJ) that cuts off aid to the government of South Africa, pending a Department of State report outlining its efforts to "negotiate the repeal, suspension, or termination of section 15(c) of South Africa's Medicines and Related Substances Control Amendment Act No. 90 of 1997."

November 1998. A new medicines bill is passed in South Africa with provisions identical to Article 15(c).

November 1998. The U.S. State Department's Economic Minister Counselor in Pretoria meets with South African Department of Foreign Affairs officials to discuss resolution of the pharmaceutical patent controversy.

December 4, 1998. Joe Papovich, the Assistant USTR for Services, Investment, and Intellectual Property, sends a letter to Deputy President Mbeki's legal advisor Mojanku Gambi noting the USG's interest in Health Minister Zuma's discussions with pharmaceutical industry executives.

December 1998 - Secretary Daley meets with Mbeki and Erwin. The Department of State says that pharmaceutical patent protection was the most important topic discussed.

January 26, 1999. The WHA Executive Board meets in Geneva, and approves the Revised Drug Strategy resolution that was proposed by the Ad Hoc Working Group in October, 1998. Dr. Desmond Johns from South Africa presents comments to WHA Executive Board that specifically mention parallel importing and compulsory

licensing.

January 1999. The State Department's Economics Minister Counselor in Pretoria raises pharmaceutical patent protection issue with Deputy President Mbeki's economic advisor.

February 5, 1999. The US Department of State sends a report to the US Congress, entitled, "US Government efforts to negotiate the repeal, termination or withdrawal of Article 15(c) of the South African Medicines and Related Substances Act of 1965." According to the report:

> All relevant agencies of the U.S. Government the Department of State together with the Department of Commerce, its U.S. Patent and Trademark Office (USPTO), the Office of the United States Trade Representative (USTR), the National Security Council (NSC) and the Office of the Vice President (OVP) - have been engaged in an assiduous, concerted campaign to persuade the Government of South Africa (SAG) to withdraw or modify the provisions of Article 15(c) that we believe are inconsistent with South Africa s obligations and commitments under the WTO Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS)
>
> . . .
>
> Since the passage of the offending amendments in December 1997, U.S. Government agencies have been engaged in a full court press with South African officials from the Departments of Trade and Industry, Foreign Affairs, and Health, to convince the South African Government to withdraw or amend the offending provisions of the law, or at the very least, to ensure that the law is implemented in a manner fully consistent with South Africa s TRIPS obligations.

February 16, 1999. PhRMA's 301 submission to US government asks that South Africa be listed as a Priority Foreign Country under Special 301. PhRMA's complaint focuses on parallel imports, compulsory licensing and "data exclusivity" (the Taxol issue). A new element in the 1999 submission is PhRMA's attacks on South African government's public statements at the World Health Assembly, including a bitter attack on the South African governments statements during the negotiations on the Revised Drug Strategy. PhRMA added:

> "From the recent remarks and actions, the apparent intent of the Government of South Africa is to not only defend its diminishment of the effectiveness of patent protection in South Africa, but to urge other countries to similarly weaken patent protection for pharmaceutical products. Such a posture is plainly antagonistic to the concept of effective patent protection for pharmaceuticals,and is likely to give rise to a substantial diminishment of the effectiveness in protection not only in South Africa but elsewhere."

February 17, 1999. The US Department of State briefs the pharmaceutical industry on international HIV/AIDS policy, and on international efforts to promote compulsory licensing of HIV/AIDS drugs.

February 18, 1999. The US Department of State briefs non- government public health groups on international HIV/AIDS policy, but refuses to permit discussion of trade disputes involving compulsory licensing, parallel imports or other intellectual property issues. Ralph Nader and James Love write Secretary Madeleine Albright, "strongly objecting" to the decision to forbid discussion on IP issues, and asking for a second NGO briefing focusing on the IP/trade issues.

February 23, 1999. Representative Jess Jackson, Jr. introduces HR 772, the HOPE for Africa bill, which includes Section 601, which would cut off funding to any department or agency that sought "through negotiation or otherwise, the revocation or revisions of any sub-Saharan African intellectual property or competition law or policy that is designed to promote access to pharmaceuticals or other medical technologies," as long as the laws comply with TRIPS.

February 1999. USTR officials and Mbeki's advisors meet.

February 1999. Vice President Gore meets with Mbeki, and again raises US concerns regarding South Africa Medicines Act. Leon Fuerth, the Vice President's National Security Advisor is among those attending the meeting. The Vice President's staff later gives different versions of the discussions. Following the Vice President's talks with Mbeki, the US PTO speaks out against the use of compulsory licensing in a meeting in Geneva,South Africa is placed on the USTR watch list for intellectual property violations, scheduled for an out-of-cycle review focusing on the Medicines Act, and criticized by the US government for its intention to use compulsory licensing and parallel imports, for speaking out at the World Health Assembly and for approval of generic versions of Taxol, an unpatented drug that was invented by the US government.

March 25-27, 1999. CPT, MSF and HAI sponsor meetings in Geneva on compulsory licensing of essential medical technologies. Lois Boland, representing the US Patent and Trademark Office (US PTO), acknowledges that the USG position on compulsory licensing is not reflected in the TRIPS.

> The fact that [the USG] view is not reflected in the TRIPs agreement, in the multilateral context, is fully acknowledged. In our bilateral discussions, we continue to regard the TRIPs agreement as an agreement that establishes minimum standards for protection and, in certain situations, we may, and often do, ask for commitments that go beyond those found in the TRIPs agreement.

The South African government attends the meetings, but in deference to pressures from the US, does not participate on panel discussions.

April 8, 1999. Ralph Nader and James Love write Vice President Gore asking for a reversal of US policy on South African Medicines Act and parallel import and compulsory licensing.

April 11, 1999. Lisa Richwine from Rueters writes the first major U.S. wire story about the South Africa/Thailand trade dispute over access to HIV/AIDS drugs.

April 21, 1999. Several hundred demonstrators march in downtown Washington, DC in support of Jessie Jackson's H.O.P.E for Africa legislation, in support on compulsory licensing for HIV/AIDS and other essential medicines.

April 28, 1999. Merrill Goozner writes a page one story in the Chicago Tribune, "Third World Battles for AIDS Drugs." This is the first major US newspaper story on this issue. The President reads the story on Air Force One.

April 30, 1999. USTR announces that South Africa is placed on the "watch list" in its Special 301 Review, and schedules an "out-of-cycle" review for South Africa to conclude in September 1999. According to USTR, South Africa's "barriers to trade" are parallel imports, compulsory licensing, registration of generic forms of Taxol, and speaking out at the World Health Assembly. "During the past year, South African representatives have led a faction of nations in the World Health Organization (WHO) in calling for a reduction in the level of protection provided for pharmaceuticals in TRIPS. "

May 12, 1999. CPT and Act Up meet with the Department of Health and Human Services (DHHS) to discuss trade disputes involving intellectual property rights and health care, to ask DHHS to moderate US trade polices in order to improve access to drugs. DHHS is also asked to give the World Health Organization and foreign governments to right to use US government use rights in patents obtained with federally funding.

May 24, 1999. In Geneva, the World Health Assembly approves the Revised Drug Strategy.

June 7, 1999. The International Issues subcommittee of the Presidential Advisory Council on HIV/AIDS (PACHA) holds a public debate on compulsory licensing and parallel imports. The Clinton/Gore Administration declines a request to explain US policy. CPT asks that PACHA recommend that the US end trade pressures on compulsory licensing and parallel imports, and that the US government enter into an agreement with the WHO

giving the WHO the right to use federal "public use" rights for pharmaceutical patents based upon government funded research.

June 16, 1999. HIV/AIDS activists begin campaign to disrupt Vice President Gore's campaign to draw attention to US trade sanctions against South Africa and Thailand.

June 22, 1999. CPT, Public Citizen and HIV/AIDS activists meet with Sandra Thurman, Director of White House Office of National AIDS Policy, Thomas Rosshirt, Vice President Gore's foreign policy spokesman and others to discuss compulsory licensing and parallel imports.

June 24, 1999. The US Supreme Court rules that State governments cannot be sued for patent infringement. (Florida Prepaid Postsecondary Education Expense Board V. College Savings Bank et al.)

June 24, 1999. Rep. James Clyburn of Congressional Black Caucus writes a letter to VP Gore with concerns over trade sanctions against South Africa

June 25, 1999. Vice President Gore writes James Clyburn of the Congressional Black Caucus, saying "I want you to know from the start that I support South Africa's efforts to enhance health care for its people including efforts to engage in compulsory licensing and parallel importing of pharmaceuticals -- so long as they are done in a way consistent with international agreements."

June 26, 1999. CPT writes James Clyburn asking the Black Caucus to seek clarification from the Vice President on his interpretation of international law concerning parallel imports and compulsory licensing

Appendix C

USTR NTE Reports on Thailand Pharmaceutical Policies

The following are portions of USTR's 1995, 1996, 1997, 1998 and 1999 commentary on Thailand policies toward pharmaceuticals, as reported in USTR's annual National Trade Estimate (NTE) reports. Each year's entry is somewhat repetitive from the previous year, but illustrates the nature and progress of USTR efforts to reshape national legislation in Thailand on pharmaceuticals. For example, in 1997 USTR reported:

> The Thai legislature is expected in 1997 to consider a bill abolishing the Pharmaceutical Review Board. This measure would advance objectives of American manufacturers.

And in 1999, USTR reported:

> Thailand's Patent Law was amended by the Thai Parliament in October 1998 and the amended provisions will enter into effect in 1999. Pursuant to the U.S.-Thai IPR Action Plan, the amended law abolished the Pharmaceutical Review Board. According to initial observations, businesses in Thailand are generally pleased with the amendments. However, they foresee problems rising from new provisions regarding compulsory licensing authorizing the Director General of the Department of Intellectual Property to override a patent and issue a compulsory license if the patent is deemed as not being locally "worked" or if the price is deemed unreasonably high.

It is interesting that USTR's report goes far beyond patent protection to express opposition to policies such as price controls or even the collection of economic data (permitted under the WTO/TRIPS), as well as the US insistence on high regulatory barriers to the introduction of generic drugs. For example, on numerous occasions, USTR complains that in Thailand, "the market exclusivity period is only 5-6 years." What USTR doesn't say is that regulatory exclusivity (the period before generic drugs can use bioequivalency to register drugs) is 5 years under the US Hatch/Waxman Act, and that USTR is asking Thailand to adopt the longer market exclusivity period now used by the European Union (6 to 10 years).

Jamie Love <love@cptech.org>
May 16, 1999

Here is the text from the past five years of USTR NTE annual reports on Thailand:

1995

In January 1991, the Pharmaceutical Manufacturers Association filed a petition under Section 301 for relief from Thailand's failure to provide patent protection for pharmaceuticals. In March 1992, the USTR determined that Thailand's acts, policies and practices related to patent protection were unreasonable and burden or restrict U.S. Commerce. These acts, policies and practices were the subject of consultations between the United States and Thailand.

In September 1992, Thai legislation became effective that extended patent protection to pharmaceuticals and agricultural machinery and increased the patent protection term to 20 years. However, the law did not provide protection for existing products patented in other countries that had not yet been marketed in Thailand ("pipeline protection") and it contained extremely broad authority to issue compulsory licenses in cases where patented goods are not yet produced in Thailand. Additionally, this legislation created a pharmaceutical patent review board with unique and extraordinarily broad authority to require sensitive cost and pricing information. These provisions are a significant disincentive to obtain product patent protection for pharmaceuticals in Thailand and seriously reduce the benefits of the patent protection provided in the 1992 law.

In 1993 the Thai government established administrative measures to provide a degree of market exclusivity for

pharmaceutical products not eligible for protection under the 1992 law, to narrow the scope of compulsory licensing provisions and to restrict the authority of the pharmaceutical patent board. These administrative measures, however, are not fully consistent with the growing international consensus on protecting pharmaceutical products. For example, the market exclusivity period is only 5-6 years. [CPT Note: market exclusivity is 5 years under US Hatch/Waxman act, but as much as 10 years in the Europe Union. USTR seeks the EU rather than the US period]. Thailand is still in the process of developing a a new, fully-TRIPs consistent patent law, which is crucial to resolving important issues in the patent area.

1996

Following a complaint by the Pharmaceutical Manufacturers Association, the Administration determined in March 1992 that Thailand's acts, policies and practices relating to patent protection were unreasonable and restricted U.S. commerce. In September 1992, Thai legislation extended protection to pharmaceuticals and agricultural machinery and increased the patent protection term to 20 years. However, the law did not provide protection for products patented in other countries that had not yet been marketed in Thailand ("pipeline protection"), and it contained extremely broad authority to issue compulsory licenses in cases where patented goods are not yet produced in Thailand. The legislation also created a pharmaceutical patent review board with unique and extraordinary powers to require sensitive cost and pricing information. These provisions are a significant disincentive to obtain product patent protection for pharmaceuticals in Thailand and seriously reduce the benefits of the patent protection provided in the 1992 law.

In 1993, the RTG established administrative measures to provide a degree of market exclusivity for pharmaceutical products not eligible for protection under the 1992 law, narrow the scope of compulsory licensing provisions, and restrict the authority of the pharmaceutical patent board. These measures, however, are not fully consistent with the growing international consensus on protecting pharmaceutical products. For example, the market exclusivity period is only five to six years [CPT Note: market exclusivity is 5 years under US Hatch/Waxman act, but as much as 10 years in the Europe Union. USTR seeks the EU rather than the US period]. Thailand is still in the process of developing a new patent law that is meant to comply with the WTO Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPs); parliament will consider such legislation in 1996. The Pharmaceutical Research and Manufacturers of America estimates that in 1994 its members lost $70 million in sales due to deficiencies in patent protection in Thailand.

1997

In September 1992, Thai legislation extended protection to pharmaceuticals and agricultural chemicals and increased patent protection to 20 years. In 1993, following complaints from private industry about inadequacies in the law, the Thai Government established administrative measures to provide a degree of market exclusivity for pharmaceutical products not eligible for protection under the 1992 law ("pipeline protection"), narrowed the scope of compulsory licensing provisions, and restricted the authority of the Patent Review Board. These measures, however, are not fully consistent with the growing international consensus on protecting pharmaceutical products.

Thailand is still in the process of amending its patent law to comply with the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs). The Thai legislature is expected in 1997 to consider a bill abolishing the Pharmaceutical Review Board. This measure would advance objectives of American manufacturers. Industry representatives report that in 1994, approximately $70 million in sales was lost due to deficiencies in patent protection in Thailand. Estimates of losses during 1995 and 1996 due to inadequate patent protection in Thailand are not available.

1998

In September 1992, Thai legislation extended protection to pharmaceuticals and agricultural machinery and increased patent protection to 20 years. In 1993, following complaints from private industry about inadequacies in the law, Thailand established administrative measures to provide a degree of market exclusivity for

pharmaceutical products not eligible for protection under the 1992 law ("pipeline protection"), narrowed the scope of compulsory licensing provisions, and restricted the authority of the pharmaceutical patent review board. These measures, however, are not fully consistent with the growing international consensus on protecting pharmaceutical products. For example, the market exclusivity period is only five to six years. [CPT Note: market exclusivity is 5 years under US Hatch/Waxman act, but as much as 10 years in the Europe Union. USTR seeks the EU rather than the US period]

Although the Thai Government recognizes importation as "working the patent," this policy position is not uniformly understood by Thai officials. The Thai Government has long promised to amend its patent law to comply with the WTO Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS), including the abolition of the Pharmaceutical Review Board. Due to domestic opposition and frequent changes of government, it has failed to do so. The Thai Government also refuses to exercise discretionary power to amend pending patent applications under the 1979 law. Such action would provide enhanced protection under the 1992 patent law and would permit coverage of the pharmaceutical product, as well as the production process.

1999

Thailand's Patent Law was amended by the Thai Parliament in October 1998 and the amended provisions will enter into effect in 1999. Pursuant to the U.S.-Thai IPR Action Plan, the amended law abolished the Pharmaceutical Review Board. According to initial observations, businesses in Thailand are generally pleased with the amendments. However, they foresee problems rising from new provisions regarding compulsory licensing authorizing the Director General of the Department of Intellectual Property to override a patent and issue a compulsory license if the patent is deemed as not being locally "worked" or if the price is deemed unreasonably high.

In September 1992, Thai legislation extended protection to pharmaceuticals and agricultural machinery, and increased patent protection to 20 years. In 1993, following complaints from private industry about inadequacies in the law, the Thai Government established administrative measures to provide a degree of market exclusivity for pharmaceutical products not eligible for protection under the 1992 law ("pipeline protection"), narrowed the scope of compulsory licensing provisions, and restricted the authority of the Pharmaceutical Review Board. These measures, however, are not fully consistent with the growing international consensus on protecting pharmaceutical products. The market exclusivity period, for example, is a maximum of just six years [CPT Note: market exclusivity is 5 years under US Hatch/Waxman act, but as much as 10 years in the Europe Union. USTR seeks the EU rather than the US period]. The Thai Government has refused to exercise discretionary authority to amend pending patent applications under the 1979 law. Such action would provide enhanced protection under the 1992 patent law amendments and would protect not only pharmaceutical products, but also the production process.

Sources:

National Trade Estimate Reports
http://www.ustr.gov/reports/nte/1999/contents.html
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Appendix D

USTR Reports about Israel Pharmaceutical Polices

1999 NTE Report

Current Israeli patent law contains overly broad licensing provisions concerning compulsory issuance for dependent and non-working patents. A draft revision of Israel's patent law, now under review, is expected to upgrade patent protection and eliminate compulsory licensing. . . .

Despite U.S. objections, the Government of Israel enacted in 1998 an amendment to the patent law which allows non-patent holders to manufacture patented pharmaceutical products prior to the expiration of patent rights in order to submit data to foreign and Israeli health authorities to gain marketing approval. In addition, in 1998, the Israeli Government introduced legislation to permit the unauthorized parallel importation of pharmaceutical, patented or otherwise, into Israel and to sanction unfair use of test data. In February 1999, despite strenuous U.S. objections, the Knesset approved the legislation.

1998 NTE Report

Current Israeli patent law contains overly broad licensing provisions concerning compulsory issuance for dependent and non-working patents. A draft revision of Israel's patent law, now under review, would upgrade patent protection and eliminate compulsory licensing. In addition, revised laws are under consideration for the protection of industrial designs, trademarks, and integrated circuits.

In February 1998, the Israeli Knesset passed a separate amendment to the patent law which will allow non-patent holders to manufacture limited quantities of patented pharmaceutical products prior to the expiration of patent rights in order to submit data to foreign and Israeli health authorities to gain marketing approval. The amendment will also extend patent terms for pharmaceutical products. The U.S. unsuccessfully objected to the amendment and urged that Israel model its law on the comparable provisions of U.S. law.

Appendix E

USTR Reports about New Zealand and Pharmaceutical Drug Policies

USTR's 1999 NTE Report

Access for Pharmaceuticals -Pharmaceutical Management Agency (PHARMAC)

PHARMAC was established in 1993 as a limited liability company to manage the purchasing or funding of pharmaceuticals for the Health Funding Authority (HFA). The HFA is responsible for purchasing health services and supplies for all New Zealanders. PHARMAC administers the National Pharmaceutical Schedule on HFA's behalf. The Schedule lists medicines subsidized by the government and the reimbursement paid for each pharmaceutical. The schedule also specifies conditions for prescription of a product listed for reimbursement. At its creation, PHARMAC was exempted from New Zealand's normal competition laws, an exemption upheld in a 1997 High Court ruling in an umbrella court case brought against PHARMAC by New Zealand's Researched Medicines Industry (RMI) association. While New Zealand does not per se restrict the sale of non-subsidized pharmaceuticals in NewZealand, private medical insurance companies will not cover unsubsidized medicines. Thus, PHARMAC effectively controls what prescription medicines will be sold in New Zealand and, to alarge extent, at what price they will be sold.

Pharmaceutical suppliers complain that it is difficult to list new chemical entities and line extensions on PHARMAC's schedule. In general, PHARMAC will not apply a subsidy to a new medicine unless it is offered at a price lower than currently available subsidized medicines in the same therapeutic class or unless the producer is willing to lower its price on another medicine already subsidized in another class. Pharmaceuticals can also be delisted if a competing product is selected to serve the market as the result of a tender or if a cheaper alternative becomes available and the manufacturer of the original product refuses to discount its price to that of the lower-priced alternative. PHARMAC's use of reference pricing, the practice of doing trade- off deals between classes of drugs, and tendering practices can negatively affect a company's revenue return on its intellectual property. The United States and New Zealand governments have begun a dialogue with the aim of allèviating impediments to market access from PHARMAC's practices.

Mr. MICA. And now we will recognize Dr. Peter Lurie, who is with the Public Citizen's Health Research Group.

Dr. LURIE. Good afternoon. My name is Peter Lurie, a person born in South Africa who has done clinical work both in South Africa and elsewhere in the developing world. I've also done quite a bit of international AIDS research both inside South Africa and elsewhere in Africa, Asia and South America.

What I want to do in my time is to address two arguments that Dr. Siegfried is likely to raise in opposition to the arguments in favor of compulsory licensing and parallel imports, and they are: one, the argument of drug resistance made rather forcefully and inaccurately on the Peter Jennings clip that you showed; second, the argument that somehow compulsory licensing or parallel imports will reduce pharmaceutical profits to the point that they indeed will dry up.

Let me talk about viral resistance first. Tom Bombelles, who is with the Pharmaceutical Research and Manufacturers Association, said—actually it might have been on that program—"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."

Now, we agree that resistance is an important issue and something to be avoided if at all possible. Before I even address that, though, I want to make two points about compulsory licensing and parallel imports. The first is that compulsory licensing and parallel imports do not require any country to do them. It is simply an opportunity that countries can choose to exercise or not. But if you prevent compulsory licensing and parallel imports in blanket fashion, what you do is you rob the countries of their ability to choose for themselves. We should not be making these arguments in paternalistic fashion and preventing governments in choosing for themselves how they wish to spend their money.

Second, the viral resistance argument is actually being made against the totality of compulsory licensing and parallel imports, but many of the drugs that would be affected by this are not only not AIDS drugs, but they're not even for infectious diseases. Now we have this resistant-strain argument being used in ways that might prevent access to drugs for cancer or for heart disease.

Now let's talk about HIV resistance directly. What the pharmaceutical industry seems to be arguing is the following: 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 or compliant to anti-HIV therapy and, therefore, develops a resistant HIV strain is worse off than if that same person had not been treated at all.

There's no scientific evidence for this assertion at all. First, many patients who take anti-HIV drugs do not develop resistance even if they're noncompliant. Of course, the more compliant they are, the better. Second, even for those who might develop resistance, the change in the viral genetic material that results in resistance is different than the part of the genome which is important for aggressiveness. And most of the time, mutant microorganisms reproduce less efficiently than nonmutants.

A Review in the Journal of the American Medical Association—we made this point in another article cited in my testimony—made the point that HIV strains that are resistant to drugs are probably more difficult to transmit to other people. So, if anything, the scientific evidence, which is not strong, suggests that the resistant strains are less aggressive and more difficult to transmit than those that are not resistant. So the argument is not based on any science whatsoever.

Really, the decision of whether or not to treat a patient should be something that is between a patient and their doctor. But to oppose compulsory licensing and parallel imports is a blunt instrument. Physicians and patients can no longer make that case-by-case assessment, and instead people will be denied drugs simply on the basis of where they happen to live.

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's condescending to lump them together in order to justify withholding effective treatments from them. There are enormous differences both between developing countries and within them, and that needs to be taken into account.

Again, the countries should be allowed to choose for themselves. The solution to the problem of lack of drug adherence to often complex AIDS regimes is not to withhold drugs from people. The solution is, as Dr. Herman said, to improve the infrastructure, and all this needs to be done together.

Could anyone imagine turning to a developing country and saying to them, "You might develop resistant strains of malaria and tuberculosis, and consequently you shouldn't treat those patients and just let those diseases remain untreated?" That's the argument that is being made here.

Lack of adherence to HIV drugs is a problem in the United States as well. Will we, therefore, apply the same logic to populations in this country? Are we going to identify specific risk groups or socio-economic sectors of this country and say, "Sorry, you are not likely to be adherent, you cannot have these drugs?" The lack of health care infrastructure is critical. It needs to be built up; to use the lack of infrastructure as an excuse to not address the pricing mechanism seems to be completely inappropriate.

One of the reasons that the infrastructure in HIV is as bad as it is is because there's no particular reason to test people when you're not going to be able to provide them treatment at the end. So to have treatment available will provide the incentive for people to improve the infrastructure.

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

I'm just going to briefly address what we call the R&D scare card, the argument made by the pharmaceutical industry that research will dry up in the event that compulsory licensing and parallel imports—legal mechanisms, as Mr. Love pointed out—are implemented. This seems to argue that patients in developing countries would be better off right now without drugs while we wait pa-

tiently until later drugs are developed, which may or may not be available after all.

And similarly, the history of international drug development teaches us that waiting for the new, equally effective, but less expensive regimens is not something that really has shown a lot of benefit over the years. Furthermore, pharmaceutical R&D expenditures have actually doubled between 1990 when Congress imposed some price restraints on Medicaid drugs, and 1995; we heard the R&D scare card brought out in full force in 1990.

The pharmaceutical industry is uniquely profitable; the most profitable industry in this country, whether measured by sales, by assets or by equity, and since 1989, pharmaceutical companies' return on equity has been at least 1.7 times the median of all other U.S. industries.

Given these extraordinary profits and the failure of the drug industry to make critical medications available for developing country patients, we urge you to call the R&D scare card bluff.

In conclusion, neither the viral resistance nor the R&D scare card arguments provide support for closing these legal trade measures. As it happens, the sub-Saharan Africa market represents a scant 1.4 percent of the global pharmaceutical market. An explanation for the pharmaceutical companies' opposition to compulsory licensing and parallel import is to be found elsewhere: in their desire to not have their irrational pricing practices exposed—we have drugs available in Europe at often 50 percent lower than they are here—and to maintain their high profit margins.

We suggest that providing potentially lifesaving drugs to residents of developing countries should have a higher priority. Thank you.

Mr. MICA. Thank you for your testimony.

[The prepared statement of Dr. Lurie follows:]

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 21, 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 for even non-infectious diseases such as heart disease and cancer. Drugs like simvastatin, to lower cholesterol, and ranitidine, for ulcers, could be dramatically 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 develops a resistant HIV strain due to partial adherence to anti-HIV therapy 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 do not develop antiviral resistance. Resistance to zidovudine, the first anti-HIV drug to be approved, has been estimated at 0% to 10% in Europe and North America.[4] Even for those who develop resistance, there is no reason to believe that the mutations necessary to confer resistance will be associated with those that confer greater aggressiveness, as these are separate genetic phenomena. A recent review points out that in the absence of therapy, "wild-type [primarily non-resistant] strains may have a replication advantage [over resistant strains] that dominates over time."[5] There is also some evidence that HIV strains resistant to zidovudine are more difficult to transmit.[6]

●The decision to prescribe or not prescribe effective medication is 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."[7] 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[8] and patients would instead be denied drug simply on the basis of their residence.

●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. Such interventions have had substantial success with tuberculosis in developing countries,[9] including with HIV-infected populations.[10] Has anyone suggested leaving tuberculosis or malaria patients untreated to prevent the development of resistance?

●One should not write off the entire developing world with a broad-brush stroke. 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.[11] Other countries, such as Brazil, provide complex anti-HIV drug regimens to their HIV-positive populations.

●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.

●Adherence 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.[12] Should we therefore apply the same logic to some US populations? 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 US? If so, is the pharmaceutical industry really arguing that Africans should remain untreated so that Americans can live longer?

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 countries 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."[13] This seems to argue that patients in developing countries should wait patiently without existing drugs 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.[14] R&D represented a median of 11.4% of sales for the top 10 pharmaceutical companies (ranked by revenue) in 1998.[15] 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.[16] Since 1989, pharmaceutical company return on equity has been at least 1.7 times the median of all U.S. industries.[17]

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. The explanation for the pharmaceutical companies' opposition 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 take 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. Yerly S, et al. Prevalence of transmission of zidovudine-resistant viruses in Switzerland. Schweiz Med Wochenschr 1996;126:1845-88.

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

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

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

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

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. 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.

12. 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.

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

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

15. Based on 1998 Annual Reports.

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

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

Mr. MICA. And now I would like to recognize Mr. Eric Sawyer, executive director of the Human Rights Project. Welcome, and you're recognized, sir.

Mr. SAWYER. Thank you, Mr. Chairman, members of the committee and ladies and gentlemen. My name is Eric Sawyer. I'm the director of the HIV/AIDS Human Rights Project. I'm also one of the founders of ACT UP NY, an activist group that was formed in 1987 to focus attention on the lack of governmental action with respect to AIDS and to advocate for access to medical treatment for AIDS and related opportunistic infections.

I also cofounded a housing group that houses more than 2,000 people with AIDS and have organized AIDS conferences in more than eight countries, three of them in the developing world. I'm also a person that has been living with AIDS for nearly 20 years, thanks to my privileged access to a sophisticated and expensive regime known as salvage therapy. This regime includes daily doses of five antiretroviral drugs. They include two protease inhibitors. These drugs cost me $30,000 a year. But at present, my viral load is undetectable. My T-cell count has risen to the highest level it has been in a decade.

I'm more well today than I've been in 10 years, and I'm happy to be alive and to be here today, but I'm also extremely sad because I represent less than 2 percent of those with AIDS for whom HIV has almost become a manageable disease. There are nearly 40 million men, women and children with HIV in the world today, and 98 percent of them have no access to these drugs.

For 98 percent of those 40 million people, this disease remains, and there's no other term for it, a death sentence. It certainly was a death sentence for one of my heros, Auxcillia Chimusoro. Auxcillia was a brilliant woman from Zimbabwe, full of life and energy. She had just found out she had HIV when I met her in 1992, after 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 by opening her home to others. Her bravery was rewarded with a firebombing and with her children being beaten in school. Auxcillia responded by starting a sewing project to give AIDS widows in her village an alternative to exchanges for sex, income, and food. Then she went on to start a project to care for AIDS orphans.

To have access to health care, Auxcillia traveled overnight on three different buses to reach a doctor who could treat her. Even though Auxcillia developed her HIV infection 10 years after I became symptomatic, she's dead today, and I'm alive. And that's wrong.

Auxcillia deserves to be alive and here with us 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, there would be millions more like Auxcillia who will die before their time. Make no mistake about it, we're witnessing a global crisis of unprecedented proportions. It will leave a fossile-like imprint on human civilization for decades to come.

This very committee hearing, in my opinion, is of historic importance, and I urge you to listen to the testimony of everyone you hear today with courage and compassion, but especially with a sense of urgency.

During the few minutes that I have left, I'm going to zero in on pricing issues for a few drugs to treat AIDS-related opportunistic infections. My point is this: The kinds of combination therapies that I have privilege to access are far beyond the resources of most men and women in the developing world. They are somewhat difficult to administer and to supervise in those countries, but a lot of these drugs are one tablespoon twice a day.

Combination therapies, in my view, are not the most important drugs that we should be talking about, they're a second-line priority. The first-line priority for extending the lives of people living with HIV in the developing world should be access to very inexpensive drugs that exist to treat and prevent the development of opportunistic infections that kill most people with AIDS.

I'm especially troubled that the pharmaceutical industry focuses all of this attention on these overpriced cash cows that they like to point out are difficult to use. It would be far more important and a far more immediate benefit to people with AIDS if they could have access to these inexpensive, easy-to-use treatments that prevent the opportunistic infections that kill people with AIDS.

A few brief examples. Most people with AIDS die of preventable illnesses like tuberculosis, pneumonia, fungal infection, or dehydration due to diarrhea. Prior to the advent of these triple therapies, significant reductions in deaths for people with AIDS were achieved here in this country by providing access, first, to these inexpensive easy-to-manage drugs for opportunistic infections.

What are the actual costs of these drugs I'm talking about? TB prophylaxis, to prevent the development of TB, in a World Health Organization program costs less than $15 a year per person. PCB prophylaxis in HHS programs here in the United States, the most expensive drug market, costs $24 a year. NTZ, a wide-spectrum antiparasitic drug to treat diarrhea, and some of the older antifungal drugs cost far less than that $15 for those Uganda TB treatments.

For under $70 a year in U.S.-based costs, most of the related opportunistic infections that kill people with AIDS can be prevented, delaying the deaths of those people for several years, perhaps long enough for them to raise their children. Generic production of these drugs and bulk buying by organizations like the World Health Organization could further reduce those prices.

Planned Parenthood-type programs in the developing world have brought the cost of birth control pills down to 50 cents per month in some developing worlds. These drugs are affordable. In other words, a partial remedy to the global AIDS crisis in the form of prolonging the lives of millions of people while we search for a vaccine, while we search for a cure, goes unused, and the importance of implementing trade policies such as compulsory licensing and parallel importing is that these policies can actually drive prices down on these expensive drugs by introducing generic equivalents.

At the same time that we gear up our efforts to dramatically expand access to the drugs to treat opportunistic infections, we must

start to investigate policies like parallel importing and compulsory licensing or get the drug companies to introduce two-tier pricing systems to reduce the price of these expensive combination therapies so that they're affordable. Such efforts are already underway in India, proof that it can and it must happen. In India, generic AZT costs $34 for a month's supply. The same drug, the same quantities, are sold at $250 a month by Glaxco-Welcome in India.

For too long, in my view, the U.S. Government has allowed the commercial interests of the pharmaceutical industry to drive trade policy and, frankly, to avoid meaningful debate on what our public policy should be with respect to global health issues like AIDS. What is our responsibility as Americans? Now that we live in a global village, do we really understand what it means to live or far too often to die in a global village? What should our response be? Should it be $100 million like Vice President Gore recently announced?

This is a welcome initiative, but it's a drop in the vast ocean of suffering created by AIDS and other infectious diseases, and it amounts to only $3 for each of the world's 34 million AIDS cases. What I believe is required is a comprehensive and compassionate policy that is driven by an informed vision of our responsibility as Americans to a global society.

It's time for us to realize that the public health of South Africa is also the public health of the United States, and it's time to act accordingly. It's time to challenge greed. It's time to promote debate. It's time to recognize that public health is never about them, it's about us.

The lesson that we can learn from AIDS, and I do believe that there is a lesson, is that we must respond as one.

In conclusion, I would like this committee to consider the following: Please call for congressional hearings on the real costs of drug development, to identify who actually pays for the research and development of the critical medicines. I believe that in many cases you will find out it's the U.S. taxpayers. Call for hearings on drug pricing practices, and then really work to pass fair pricing legislation. Pass legislation that will make it illegal for the U.S. Government to use trade sanctions to bully the developing world to deny its people access to affordable essential medicines.

Things like compulsory licensing are legal trade practices. Then ask the President to license all U.S. taxpayer-funded medicines to organizations like the World Health Organization. Jamie mentioned at least five drugs that we know that the U.S. Government either holds the patent on, developed or significantly funded the drugs, and therefore, retains ownership rights to. The U.S. Government can issue additional licenses by themselves and allow them to be sold at whatever price they set.

Please also ask the world banking community to write off the developing countries debt and allow Africans to spend their money on health, not on interest payments to banks. My mentor and hero, Jonathan Mann, the architect of the World Health Organization's Global Program on AIDS, and his wife, Mary Lou, were tragically killed last September on a crash on the way to Geneva, but he left behind a global AIDS village and indeed, for all of us, the vision of the inextricable link between health and human rights.

I would like to end my remarks with a statement that Jonathan made at last year's international AIDS conference in Geneva. Jonathan said, "our responsibility is historic, for when the history of AIDS and the global response to it is written, our most precious contribution may well be that at a time of plague we did not flee, we did not hide, and we did not separate ourselves; in this spirit may we all not separate ourselves, but, instead, work together to provide every man, woman and child with one of their most fundamental rights, health." Thank you.

Mr. MICA. Thank you for your testimony.

[The prepared statement of Mr. Sawyer follows:]

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!

Mr. MICA. And we will now hear from Dr. John Siegfried who is with the Pharmaceutical Research and Manufacturers of America. Welcome, sir, and you're recognized.

Dr. SIEGFRIED. 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 led the way in the research 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. 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 lead 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 and knowledge into HIV/AIDS medicines to help patients.

Drug discovery and development in the United States usually takes 12 to 15 years from the test tube to the pharmacy. The development of 15 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, and Dr. Killen who was with us this morning, 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 lifesaving 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 United States 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 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 effective and cost-effective health care for AIDS

patients. The new products not only help many patients, but can also reduce the needs for other medicines to treat diseases associated with AIDS and the need for treatment 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 response to the HIV/AIDS challenge in developing nations must take into consideration all of 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 priority.

The principal role of the research-based U.S. pharmaceutical industry in confronting HIV/AIDS worldwide is to continue what it does best, to marshal the expertise and capacity and applied biomedical research and drug development to discover new and more effective treatments. In cooperation and collaboration with scientists and 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 way to prevent HIV/AIDS.

Investors and 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 1 in 5- to 10,000 compounds tested ever reaches the marketplace. Additionally, of marketed products, on average only one in three generates revenue that meets or exceeds the average R&D cost.

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 keystones of and essential to this research effort. The research-based U.S. pharmaceutical industry has contacts with governments and health agencies around the world, and therefore, is well positioned to provide input in the area of intelligent 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 just several brief examples. Bristol-Myers Squibb is spending $100 million over 5 years in five southern African countries to fund extensive AIDS research trials, improve training for more than 200 physicians, and help nongovernmental organizations bolster community AIDS prevention and treatment programs. The company has also developed a pediatric AIDS program in Mexico, and is donating drugs to cover all untreated cases of pediatric

AIDS in the country, and providing physician training and community outreach.

The Merck Co. Foundation is underwriting the Enhancing Care Initiative, an initiative coordinated by the Harvard AIDS Institute. The Enhancing Care Initiative will address the issue of HIV-AIDS in the developing world by bringing together the most important expertise within specific developing countries including representatives of the HIV community. Glaxco-Welcome is providing deeply discounted prices for AZT, in cooperation with UNAIDS, and in addition, the company is sponsoring a program called Positive Action, whose activities are devoted to initiatives and organizations in developing countries.

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

In conclusion, Mr. Chairman, 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 worldwide 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 Coats, 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 earlier this afternoon 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 the disease.

Thank you, sir.

Mr. MICA. Thank you for your testimony.

[The prepared statement of Dr. Siegfried follows:]

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 this morning 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, consultant to the Pharmaceutical Research and Manufacturers of America (PhRMA) and a PhRMA employee during the period ___ to ____. I also am a practicing physician with a specialty in treating HIV/AIDS patients at the Whitman Walker Clinic in Washington, DC. PhRMA is the scientific and professional organization representing the American research-based pharmaceutical industry globally. Defined by their commitment to innovative research and development, PhRMA members 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 HIV/AIDS, the contribution made by the industry in the United States is nothing short of remarkable. The first AIDS cases were identified in 1981, and the HIV virus identified in 1983. The first HIV/AIDS

treatment was approved in 1987; since then 54 medicines have been approved, and an additional 113 are in development.

The results in the United States, and in many other developed countries are noteworthy, largely due to new medicines (protease inhibitors) discovered and developed by the industry and used in combination with other medicines. 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 are returning to work and leading more productive lives. Often demand for much more expensive secondary and tertiary health care services has declined as a result, providing the most cost effective health care for HIV/AIDS patients.

The foundation on which this progress rests is investment in innovative research and development. And it is in the area of research and development that we identify the role of the pharmaceutical industry. It is the industry's role in this crisis to lead the way in finding sustainable long-term solutions that will marshal the expertise and resources of all stakeholders to improve the health of those infected with HIV/AIDS, and to help establish balanced approaches to education, prevention, and treatment of HIV/AIDS. Effective responses to the HIV/AIDS challenge must take into consideration all the relevant factors such as available therapies and their applicability for developing countries, medical infrastructure, available resources, disease

awareness and prevention initiatives, and national commitment and leadership to make HIV/AIDS a public health priority.

The principal role of the research-based U.S. pharmaceutical industry in confronting HIV/AIDS in the developing world is to continue to marshal the expertise and capacity in applied biomedical research and drug development to discover new and more effective treatments. Along with scientists in the government and academia, some pharmaceutical companies are also seeking to discover and develop an effective HIV vaccine, which 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 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. This plows over 20% of all domestic sales revenues back into research and development - - the highest proportion of any industry with which we are familiar.

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

Here are just a couple 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.

- At the Twelfth World AIDS Conference in 1998, Merck & Co., Inc., announced a $3 million grant from the Merck Company Foundation to underwrite the Enhancing Care Initiative, 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 world countries.

- 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 other stakeholders--including the HIV community, governments, and international organizations.

Conclusion

Broadening access to modern health care, including pharmaceuticals, in developing countries is a complex challenge, with significant barriers to be overcome. In particular the HIV/AIDS pandemic creates special challenges. Many countries lack the broad public health infrastructure, necessary to support the use of complex regimens of anti-HIV treatments. This includes the relative cost of drugs used to treat and alleviate the symptoms of HIV/AIDS. Public health experts, such as Dr. Thomas Coates, of the University of San Francisco have been quoted as saying that delivery of AIDS drugs without the necessary infrastructure is a "recipe for disaster." As you heard from Dr. Herman today, it is not feasible or desirable to "simply import treatment regimens from other countries into South Africa. The same is true for many other health conditions. Partnerships involving industry, international organizations, patient and medical groups, are vital to finding workable solutions that will help patients with HIV/AIDS lead better lives and prevent others from contracting AIDS.

Mr. MICA. I thank all of the witnesses for their testimony.

I have a couple of questions. I will start out with Dr. Herman.

Dr. Herman, you cited one of the Ministers of Health, Dr. Ramakgopa.

Dr. HERMAN. That is close enough.

Mr. MICA. I am not very good at the pronunciation. But your testimony said that the doctor indicated that her fundamental concern was not the cost of drugs, but the lack of a coherent and well-managed program. Is that really the problem there?

Dr. HERMAN. South Africa is just 5 years post-apartheid. Most of the health care system is still in a state that can best be described as confused.

Mr. MICA. Is it a public or socialized health care delivery system?

Dr. HERMAN. This is only the publicly funded health care system.

Mr. MICA. Do they have a private system, also?

Dr. HERMAN. There is a larger private health care system in South Africa.

Mr. MICA. Has this been converted, and you are saying that is part of the problem, not the cost of drugs?

Dr. HERMAN. We have a very complicated health care system where both sides are in crisis. In the private side we have a health inflation rate that is twice that of the national inflation rate, so the private sector has problems in costing for drugs, et cetera.

Mr. MICA. What percentage of the population has access to——

Dr. HERMAN. Private insurance?

Mr. MICA. We will just say to AIDS treatment.

Dr. HERMAN. Twenty percent of the population actually have some kind of insurance. The insurance companies now, which number 170 such companies in a country of 14 million people with 40 different fund managers that keep on changing things, those people are starting to get access to drugs, but the remaining people do not.

Mr. MICA. So there is a large percentage of the population in South Africa that does not have access to drugs for treatment; is that correct?

Dr. HERMAN. They do not have access to antiretrovirals, but they do have access to drugs for opportunistic infections.

Mr. MICA. And you are saying that cost is not a factor there?

Dr. HERMAN. Not at the moment. The problem is the system is not working very well for many different diseases.

Mr. MICA. Mr. Love, you were critical of our trade policies, and seemed to single out South Africa for specific treatment, unfair treatment.

Can you elaborate on what you were saying? You said that other countries, and I think you named some of them, that, in fact, we turn our backs or have a different policy than we do for South Africa on this particular issue.

Mr. LOVE. The U.S. Government has had, for the last decade or so, a policy of advancing positions that are favorable. The drug companies are like an exporter. They look at it like a domestic business. They want to help them out, so they want to back them up.

So, on the particular issue of parallel imports, which is an important part of the dispute with South Africa, it is a fact that many European countries do parallel imports as a matter of course. In

fact, the European Commission actually encourages parallel imports within the European community. They think it makes the markets more efficient.

I was pointing out this hypocrisy between the fact that we do not complain about the fact that it is an established practice in Europe, the colonial powers of South Africa, yet we have spent a couple of years of government officials' time trying to pick apart the efforts of the South African Government to do something that is modeled after European practices.

That said, if the United States had its way, they probably would try and persuade the European countries not to do it. It is just that they do not think they would succeed in Europe, so the United States is most active where it thinks it has the most leverage, which has to be with small, non-European, and poor countries.

I have an example in my testimony about pressures on Israel, Thailand, and New Zealand, to give you an example of different countries we apply pressure to. South Africa is not the only country where there is pressure.

The South Africa dispute has become quite important because the South Africans have been uniquely defiant of the Americans. They have not really backed down. That is why they have become such a big test case. The sense is that if the South Africans succeed in doing what they want, then other countries will follow suit. So it has become of interest to people throughout the world.

Mr. MICA. Thank you.

Mr. Sawyer, your participation in Act Up is rather historic. Has Act Up testified before Congress before? I know you have participated in hearings.

Mr. SAWYER. I don't think we have ever been invited.

Mr. MICA. We are pleased that you accepted our invitation.

Mr. SAWYER. I am pleased to be here.

Mr. MICA. I must say that you have made a big difference, because people did not want to broach this subject. I was shocked today at the difficulty in trying to get the hearing together, and that is some 12 years later than you started. But we do appreciate what you have contributed. Sometimes in our societal system, the only way you can bring attention is by acting up; watch me sometime.

I find you have to get people's attention, and you have done that very well and probably have saved a lot of lives, so we appreciate what you have done, and also your willingness to come forth and provide constructive testimony.

One of the dilemmas that we have is we do not want to—and you are sitting next to the pharmaceutical manufacturer's representative—is we do not want to stop those folks from doing what they do so well. Every time government gets involved in something, they have a tendency to mess it up. One of the great things about our system is the private sector has worked so well, and often with a profit incentive, and we don't want to discourage that. There is nothing like a profit that seems to motivate folks. But there is also the public good, so we have to balance that.

I am not sure if it was you or Dr. Lurie that mentioned that there are instances of buying these licenses or providing additional licenses, and I think that might have been one of your constructive

suggestions. Could you elaborate? I am not that familiar. There are drugs——

Mr. SAWYER. Sure.

Mr. MICA. Then you said—the other part was turning over some of these licenses to international organizations. Can you elaborate as to how that would work and how we would cover the cost, and is there some schedule or some precedent for proceeding?

Mr. SAWYER. Yes, and, Jamie, please feel free to chime in. He sometimes knows the technical trade legalities a little better than I.

But let us take one drug, for example, ddI; developed by the National Institutes of Health. The patent is in the name of Sam Broder and a few other scientists who still work in Bethesda for the National Institutes of Health. So HHS has that patent. HHS auctioned that drug off. Bristol-Myers Squibb has a licensing agreement with HHS to, for 10 years, exclusively market that drug in some countries.

My understanding is that the license is primarily for the United States, Europe, Japan, Australia, the places where they can charge the highest prices for those drugs.

Because the U.S. Government holds the patent, did not give them exclusive worldwide right to that drug, and retained the patent, the U.S. Government can issue additional licenses, especially in countries where Bristol-Myers Squibb was not given exclusive rights.

The World Health Organization, for example, as well as South Africa and Thailand, have expressed interest in being able to produce generic versions of those drugs. If the U.S. Government gave a license and did transfer of technology, they basically could be producing not just generic equivalents, but the exact same drug that Bristol-Myers Squibb produces. The price of that could be negotiated at whatever level was deemed appropriate by the manufacturers and by the U.S. Government.

Bristol-Myers Squibb, for the first 10 years of its license, I believe, pays the U.S. Government 5 percent royalty, 5 percent of sales. My understanding is that the next 10 years they have a right to renew that agreement, and that there also was a fair pricing clause inserted in that contract that stated that Bristol-Myers Squibb needed to price that drug in a way that it was affordable to people who needed access to the drug.

We have asked Donna Shalala's staff, we have asked Sandy Thurman, we have asked people in the Vice President's office, including Tom Roshert, who was here earlier today, to please have the government, and we believe this would be an executive branch function, do a review of that drug to see if indeed Bristol-Myers Squibb is being compliant to that fair pricing clause. I do not believe it is, given that the majority of people cannot gain access to it. I would think that would be reason alone for the U.S. Government to issue additional licenses.

Now, that 10-year exclusivity period is up for review, I believe, at the end of this year. We have also encouraged the U.S. Government not to renew that.

Mr. LOVE. Actually I have a copy of the license here. We can clarify it.

Mr. MICA. That could be an interesting question that we could probably submit to Ms. Thurman. Thank you for your response, maybe we will include that.

I don't want to take up all the time. We have other Members waiting.

The other big point that you made is important, that this is not just an international issue, but also domestic. You are a survivor because you have somehow managed to pony up the $30,000 a year. I could probably name two dozen people, many who work for Congress and others, who I have known personally very well who have since died who either did not have the $30,000 or did not have the drug available. So we have an international and we have a domestic problem. So we need to address that, too.

There are a whole range of questions there that we are unable to get into in this hearing, but we appreciate again your testimony.

I yield now, if I may, to our ranking member, Mrs. Mink.

Mrs. MINK. Thank you.

Mr. Sawyer, the comments you made about this drug that the United States holds the license for, you said it was ddI?

Mr. SAWYER. Correct.

Mrs. MINK. What specifically is that used for?

Mr. SAWYER. It is an antiretroviral drug that prohibits reproduction of the HIV virus, so it slows the progression of HIV to full-blown AIDS, in short it helps control the HIV virus.

Mrs. MINK. Is that used solo, or is that used in combination with other drugs?

Mr. SAWYER. It was first used as monotherapy, but that was not deemed to be effective, due to its short-term effects. It is one of the components of a triple therapy.

Mrs. MINK. What about the other two components?

Mr. SAWYER. There are actually a whole number of additional drugs that can be used in a triple therapy. I mentioned that I take five.

For someone like myself, who has had access to each of these drugs in monotherapy as they have come to market, I have developed a partial resistance to them, so for me, it takes five of these drugs to control my virus. But here is another one, 3TC, that the U.S. Government does not have a patent on. There are about four patents held by some universities, a generic drug company in Canada, some other companies, but this drug was one that was significantly funded by government grants, and again, the patents and the licensing agreement have footnotes that state the U.S. Government retains some ownership rights.

You could use this drug in combination also with this drug, Norvir, a protease inhibitor. It is one of the most expensive classes of drugs. Again, these three triple cocktails help control the HIV virus and stop or slow the progression to full-blown AIDS.

Norvir also was significantly funded. The initial research on this, funded by the U.S. Government, was what helped discover this whole class of drugs. Again, the footnotes in the licensing agreement and patents say because of taxpayer investments in the research of this drug, the U.S. Government retains certain ownership rights.

So if you added these two drugs together with ddI, you would have drugs that the government maintains ownership rights to that could effectively be used at prices the government deems appropriate, in my understanding, so that they could be used on a more cost-effective basis.

Mrs. MINK. This information that you have provided this subcommittee certainly underscores, at least in my way of thinking, a tremendous legal and moral responsibility on the part of the United States to devise a policy that would utilize these proprietary rights which it owns for the benefit of our own citizens here in the United States, as well as internationally.

Mr. SAWYER. And global public health.

Mrs. MINK. We, Mr. Chairman, I think have hit on an issue here that would require us to expand this investigation, call upon the government to explain the lack of extensive use of these drugs that it has in its ownership.

I'm very compelled by an argument made by Mr. Love with reference to the opportunistic illnesses that come together with AIDS. As Mr. Sawyer testified in many cases they are the reasons for death. So if we want to support these individuals, one of the ways to do it is to provide the drugs necessary for tuberculosis, diarrhea, and all these other things that you have explained.

My problem in coping with that rather simple, direct issue is why aren't we doing it? What are the barriers that confront us and prevent us from using the World Health Organization or UNAID or all of our resources, or the full $200 million to make it possible for the accessibility of these very simple drugs, which I assume are no longer in the proprietary control of the pharmaceutical companies?

Mr. SAWYER. That is, many of the reasons, many are controlled by the generic drug companies or they are on the generic market, so there is not a huge profit margin in them. Therefore, the big multinational drug companies are not interested in developing new versions. They have the most extensive distribution networks. The generic drug companies don't have as huge profits and don't have as far-reaching distribution networks, so they have not been able to put them out. Things like structural adjustments prevent many developing countries from allocating sufficient amounts of their own national resources to health care. They are forced to repay loans to the World Bank.

Mrs. MINK. Why couldn't the USAID policy in this area include substantial monetary support so that these particular kinds of drugs can be made more readily available?

Mr. SAWYER. We have actually asked USAID to do that very thing for several years. Their mandate so far that has come down from the State Department, in my understanding, and Paul Delay, who is the head of the USAID Global Program, was here. Is he still here? I guess he is not. We have had these various discussions with him. He has stated that the State Department mandate limits the role of USAID to prevention only. The thinking was that condoms and preventing someone from getting infected was more cost-effective than treating people.

Again, unfortunately, organizations like the World Health Organization, or I'm sorry, the UNAIDS, the primary coordinating body to join in the UNAIDS budget is less than $60 million a year.

Dr. LURIE. I think in addition to the issue of infection treatment is the issue of mother-to-child transmission prevention. That is another area where, for a relatively small amount of money, you can make an enormous difference, not only extending people's lives, but actually saving them.

In that regard, it can be a rather small amount of money that is the difference between access and nonaccess. Despite Dr. Herman's assertion that money is not the issue in South Africa, I have an article that I published in the South African Medical Journal last week, last month, in which we addressed the failure of the South African Government to be willing to invest even approximately $50 per patient in HIV prevention, mother-to-infant.

When asked, Dr. Zuma, then the head health person in South Africa, said, "The drug treatment is not cost-effective because we don't have the money." So I simply do not find believable, even in South Africa, that money is not a problem; there you have the Health Minister making that precise point.

I also would just, in a rather slightly different note, before I miss the opportunity of having the mic, is Dr. Siegfried quoted Dr. Coats on the question of antiviral resistance. I happen to know Dr. Coats. I have written a number of papers with him. Dr. Coats is a psychologist? He is a doctor, but he is not a psychologist. If that is the best the pharmaceutical companies can come up with, that is a rather sad state of affairs.

Mr. MICA. Mr. Lantos.

Mr. LANTOS. Thank you, Mr. Chairman, very much. Let me again commend you for holding this very important hearing. And let me commend all of the witnesses for their very interesting and useful input.

I have a somewhat different approach than what emerged from your dialog with Mr. Sawyer a few minutes ago. I was very much impressed by your testimony, Mr. Sawyer.

We must not trivialize this issue. Tactics of advocates who clearly are speaking on behalf of a minority must not create a backlash on the part of the majority that needs to be persuaded. I think it is always important to realize that we all have roles to play. An advocate has a very clearcut role to play. A one-issue advocate has an even clearer role to play.

But I think you need to know that a whole range of illnesses, from Alzheimer's to diabetes, are coming to us on a regular basis saying, this particular tragic illness is getting a disproportionate share of attention, interest, money, and involvement.

Since I represent, along with my friend, Nancy Pelosi, San Francisco, I am extremely sympathetic and understanding and supportive of all these efforts. But I think it is extremely critical to understand that if we wish to go beyond just feeling good about powerful statements we make, coalitions have to be built. And statements that $100 million additional funding announced by the administration just a short while ago is really a step in the right direction, but palpably insufficient is not very helpful.

We have a range of issues that we in the Congress deal with, ranging from tobacco to cancer to drug abuse to gun violence to alcoholism to hate crimes, every one of which, and 100 others, could gain 10 times the financial support that it is gaining and would still not be sufficient.

So with all due respect, I would suggest that temper tantrums and histrionics are not a good avenue to advance the cause, which is much too serious. The numbers of lives involved are unbelievably weighty, and good will needs to be generated across the board on the part of people who are supportive. Attacking people who are supportive is not a helpful formula.

I would merely make the general observation, having learned a great deal during the course of this hearing, that I think as the issue gains more visibility and support, as I hope that it will, a greater sense of responsibility must be present on the part of its advocates, because the advocates will succeed in proportion to their sense of responsibility and sensitivity to other problems.

This is not the only medical problem the Congress is called upon to deal with. While statements such as yours, Mr. Sawyer, and I truly admired your testimony, which was very moving and I think very impressive, that their health problems in South Africa are our health problems, I don't think you would get many votes for that statement in the House of Representatives. We are a much more parochial body than one which would embrace such a statement.

Therefore, as one who is so strongly supportive of what you are attempting to achieve, my word of caution is merely a very friendly one. Broad coalitions need to be built to begin to move in the direction that all of us would like to move in. The people who are supportive, perhaps not to the extent that any one of us would like to see them being supportive, nevertheless need to be appreciated and recognized for their support. It is very easy to alienate people, while it is very difficult to build coalitions. I think this issue deserves the painful task of building coalitions. I, for one, will be very much a part of that coalition as we move ahead.

Thank you, Mr. Chairman.

Mr. MICA. Thank you.

Let me, if I may, recognize Mr. Cummings, who is a member of our subcommittee, next.

Mr. CUMMINGS. I have no questions, Mr. Chairman.

Mr. MICA. And in seniority, Ms. Norton.

Ms. NORTON. Thank you, Mr. Chairman.

Let me echo the words of my colleagues who have complimented you on bringing this issue forward. It has not received the public attention of this body that it requires, and I have been listening not only because of my concern and the concern of the Congressional Black Caucus, or the plague in Africa that is wiping away the continent, but because so much of the testimony we hear today applies to situations in the United States.

After this hearing, I'm not going to forget it. Fifty percent of the new AIDS cases in this country are black people right here, where all the drugs are supposed to be available. Why do you think this is happening? We are 13 percent of the population.

I want to make sure that there is an understanding that we are truly knitted together, and that we begin to deal with what is a

real epidemic in this country as well. We have to be able to walk and chew gum at the same time.

I want to begin by some questions to Dr. Siegfried.

First, make me understand, Dr. Siegfried, why there would not be uniform treatment across the globe of compulsory licensing and parallel importing. How is it possible to justify differential treatment among countries with respect to these two legal approaches?

Dr. SIEGFRIED. Congresswoman Norton, I appreciate the question. Unfortunately, my involvement with AIDS and AIDS policy has been very limited to treatment issues; I am not an expert at all or a lawyer or involved with parallel imports or in a position to describe that.

Ms. NORTON. I was asking you that question as a physician. Would you see any reason why there should be any difference among the countries of the world in these approaches to providing drugs?

Dr. SIEGFRIED. As a physician, what I would love to see is uniform access to all the AIDS treatments throughout the world, just as I would like to see all hungry children fed and all ill people——

Ms. NORTON. So your answer is you do believe there should be uniform compulsory licensing and parallel importing policies throughout the world, as a physician? I understand you are not a lawyer, I understand you are not a trade expert.

Dr. SIEGFRIED. I am not sure that is what I said, because I don't know the policy terminology. I think as a physician, we ought to have access to the best treatment, not only for everyone in this country, but throughout the world, absolutely.

Ms. NORTON. Dr. Siegfried, let me ask you something that I am sure is right directly in your sphere of knowledge, because it is in your testimony.

You testified that Bristol-Myers Squibb is spending $100 million over 5 years in five southern African countries to fund extensive AIDS research trials. Now, I don't know if you heard Ms. Nkhoma's testimony, but her testimony included a very poignant point and one that is very disturbing to me. Let me see if I can get some sense of it from you.

She says that when these trials are done, and I certainly believe it is important to do trials in developing countries, AZT, for example, has been given to some and placebos, as trials must, given to others. And then she says the companies pick up and leave so that the people who had the placebo have no access to any treatment.

As a physician, would you comment on that practice of the drug companies?

Dr. SIEGFRIED. As a physician and also as somebody who has been involved with the research and development end of drugs, I think the thing that is important to appreciate is that every trial that is done in developing countries, as well as in this country, has individual kinds of protocols, or contracts. In some of those, I am sure what she referred to this morning is, in fact, the case. It is not a uniform practice, and there are trials in which treatment continues.

Ms. NORTON. What is your view of that?

Dr. SIEGFRIED. It becomes, for the pharmaceutical companies, almost a deterrent to do drug trials in developing countries if part

of the contract is that they must then continue treatment, and along with treatment, the laboratory studies, all of the other ancillary services for long periods of time.

Here in this country the way it gets handled, of course, is after the trial is over, there often is a compassionate use program to assist people until the drug comes on the market. If you don't have the infrastructure in countries, it is not possible to do that.

Ms. NORTON. If you did have the infrastructure, if you are using a fairly simple drug, do you think that should be done?

Dr. SIEGFRIED. Absolutely.

Dr. LURIE. Let me try and help out a little here, because the whole matter of use of placebos and the subsequent availability of drugs after clinical trials is one that our group brought to public attention 2 years ago in the context of the mother-to-infant transmission studies, which I think in part was what was referred to.

Actually it is not to provide—we objected to the use of placebos in those studies because there were known effective treatments at that time which the American government-funded researchers elected not to provide.

Ms. NORTON. Let's deal with those where there are effective treatments.

Dr. LURIE. My point is that in those initial trials, there were placebos, despite the availability of effective treatment. In defense of the pharmaceutical industries, the sort of followup studies that were done in developing countries were not funded by the pharmaceutical industry. Actually, the situation is much worse; they were funded by the CDC and the NIH, and a number of other funding agencies around the world.

Ms. NORTON. I don't care who funds them. I am asking an underlying medical ethics question.

Dr. LURIE. I understand.

Ms. NORTON. His testimony talked about Bristol-Myers Squibb's spending $100 million specifically for such trials. I understand this may be happening in all kinds of ways. The government does it even worse. I am trying to find out if you go to a developing country, if it is an ethical practice to have two groups and to leave one group with nothing afterwards, even though they have understood that they are in the placebo group. That is my simple question.

Dr. LURIE. I am trying to not complicate it, but in the case of mother-to-infant transmission, it does not really matter what happens after the trial, in the sense that if you are in the placebo group, you are already more likely to have developed an HIV-infected infant.

Ms. NORTON. Are you suggesting there should not be such trials at all?

Dr. LURIE. With regard to effective treatment that exists, but with regard to this, ethics are clear, but frequently violated. The Council of Organizations in the Medical Sciences, which has written one of the two major ethics documents for the world, states that after a trial is completed, any medication proved effective during the trial should be made "reasonably available" to the population from which the study subjects were drawn.

It is, however, an unfortunately common practice for pharmaceutical companies and government-funded researchers to do the

research and then to do exactly what Dr. Siegfried has sought to justify; to not provide therapy after the trial. We find that completely unacceptable.

Unfortunately, the pharmaceutical industry, to a limited extent, but especially researchers from this country, including those from the NIH and the CDC, have sought to address the problem of the fact that they have been violating these ethical agreements with regard to reasonable availability after the trial, as well as with respect to the requirement to provide best-known therapy to people in developing countries during a trial. They have addressed that problem by trying to rewrite all the ethics rules.

What we have now going on in the world is a coordinated effort involving principally people from the United States, especially U.S. Government researchers, who are trying to rewrite the Declaration of Helsinki, and are trying to rewrite the SIAMS document I just referred to, such that these kinds of practices would be less likely to be criticizable.

Ms. NORTON. Let me just say that I think that those involved in trials are a relatively small group.

Dr. LURIE. Absolutely.

Ms. NORTON. When people volunteer to possibly be somebody who would not, in fact—who is not, in fact, receiving treatment, the least we can do for this small group is to provide continuing treatment.

Dr. LURIE. One would hope that. But in the aftermath of what I call the second generation of studies, the one that included the placebo group in developing countries, what we now have is a new generation, a third generation of studies, including one in Malawi, in which the new, cheaper effective regimens are still being denied people, even today.

I agree with you, though, that the situation in the clinical trial is very easy to complain about because it is conducted by the U.S. Government, for example. But the far greater problem is the lack of commitment of pharmaceutical companies and others who conduct research, human experiments, on the citizens of developing countries and then seek to evade their ethical obligation to provide treatment after the trial.

Ms. NORTON. Dr. Siegfried wanted to respond.

Dr. SIEGFRIED. I think it becomes very difficult to put all trials in developing countries in one basket, or all companies conducting trials, or all government agencies conducting trials. My guess is if these were looked at very carefully, you would find specific differences.

Ms. NORTON. That is why I was looking for a universal principle.

Dr. SIEGFRIED. I am really reluctant to comment on Bristol-Myers Squibb in terms of specific trials in Malawi or wherever, because my understanding as part of this program in which they are doing a number of trials is that they will be providing continuing drugs. But that is an understanding, and I cannot state that for sure.

Ms. NORTON. That is why I looked for the principle.

One last question; you testified that the company has developed, and this is really of interest to me, because even the very important testimony of Mr. Sawyer, if I may say so, Mr. Sawyer, it was

just poignant for me to see you pour those drugs out, because I represent many people right here in the Nation's Capital who cannot get anywhere close to affording those drugs, and these drugs are going to middle-class white people, let us be clear.

And that is why, when somebody tells me about drugs like that in Africa, I am very much more interested, and I know my time is going to be up, in hearing more about what Dr. Herman has to say about a practical approach to dealing with an epidemic.

This is so American, really, and we do it all over the world. We get sick, and even poor people, not people in between; by the way, even poor people can go to the emergency room and go to the doctor. So we have our approach to a Dr. Herman, because we are used to finding medicines. So you have to understand that the way we think about these problems is, there is a cure, get yourself a drug, it will take care of it.

I want to say to you, Dr. Herman, that what you say resonates with me, because AIDS cases in this country are so largely black today that I feel like we have a runaway problem among black Americans. And I am here, and that is why you see me far more interested in getting my government to figure out what to do at the front end of this disease. Because as long as I have to look at a young man telling me that these drugs are available, and some of them are even simpler than others, I know he is not talking about large numbers of people that I happen to represent. I am much more interested when I see the magnitude of the problem throughout Africa.

South Africa may be even better as the only industrialized country in Africa. When I see the magnitude of the problem there, I am interested in trying to keep countries from doing what Uganda has to do, which is to go to triage and say, we have to let some people die, because the only way we can do now is to deal at the back end with drugs. That is hopeless for us.

I am looking for what is practical. You used the word "practical." I'm looking for a practical way to get hold of this problem in a developing country. I must tell you, Doctor, I'm looking for a practical way to get hold of this problem in Anacostia, across the Anacostia River, because the American way is not even helping African Americans in this country. So I cannot imagine that the American way is going to help in your country, though of course I must say that I regard it as immoral not to allow these drugs to be transmitted to South Africa and other countries in perfectly legal ways which may underprice them relative to how they are usually priced.

This is what I want to ask Dr. Siegfried. He testifies and raised my hopes that the company, and this must be Bristol-Myers, 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.

Now, where I want to start—and here I am talking about pragmatism, if I were trying to get hold of AIDS in the developing world, would not be—you all come. I would try to find an entryway to break the back of the epidemic. Bristol-Myers must understand that in Mexico, because it apparently has said every case of pediatric AIDS in Mexico.

I am asking you whether or not there is any company that you would be willing to recommend, if there is one that for any country in Africa, wouild try to get hold of this epidemic? Do you believe that is a challenge that the pharmaceutical companies should take on, given the fact that they have set a precedent right in Mexico, and considering the severity of the epidemic in Africa, that this would be an important thing to repeat in some country, of their choosing, on the continent?

Dr. SIEGFRIED. Congresswoman Norton, I can't speak for any of the companies, obviously. I think it is a wonderful challenge. I do know that the pharmaceutical companies are anxious to be seen as and try very hard to be good citizens and to respond positively, you know, to crises in times of need.

I take it as a challenge I can take back to the organization and that can be really disseminated throughout the industry, but I would be very hopeful, frankly, that if Bristol-Myers Squibb can do this for pediatric AIDS in Mexico, that other companies might be able to step forward for specific countries or populations. I think it is a wonderful challenge.

Ms. NORTON. Dr. Siegfried, I appreciate it. I would appreciate your responding to Chairman Mica, who I am sure would let me know what response you have gotten from the industry.

I realize this is a small step, but I can't—these are children. If we start with babies, and with children, where there has been greater success than adults, it does seem to me that we could work our way up and finally get hold of this epidemic in at least one country.

Thank you very much, Mr. Chairman.

Mr. MICA. If the gentlewoman from the District will compose the letter on behalf of the committee, we will sign it and send it to all of them.

Ms. NORTON. Thank you very much, Mr. Chairman. I will.

Mr. MICA. I would like to recognize now the very patient gentleman from Vermont, Mr. Sanders. You are recognized.

Mr. SANDERS. Thank you very much, Mr. Chairman. And thank you very much for holding this hearing. I consider this issue to be extremely important.

As you may know, Mr. Chairman, yesterday I brought up an amendment with Ms. Schakowsky's help, among others, just to deal with this issue. I was extremely disappointed that we only got 117 votes on it.

Mr. Chairman, as you know, and as we have heard from testimony already, the pharmaceutical industry is arguably the most profitable industry in America. Last year the top 10 companies averaged $2.5 billion in profit each, and earned 26 percent more last year than they did the year before. Also, I think what we should know, and it is important to be frank about this and throw this out on the table, is that the pharmaceutical industry spends more money in lobbying and in campaign contributions than does any other industry. I think 97 out of 100 Members of the U.S. Senate have kindly received money from your PACs, and many Members of the House, have also. I think it would be very naive not to assume that that largesse on the part of the very profitable and

wealthy industry has had some impact on the public policy by the U.S. Congress regarding pharmaceuticals.

Mr. Chairman, I wondered if I might, before we get to Africa, tell you about a trip that I took 2 weeks ago. I didn't go to Africa, but to another foreign country called Canada. I was not dealing with AIDS, but with breast cancer. I took five women from northern Vermont who were battling breast cancer to Montreal, Canada. The reason I went was to help them purchase pharmaceutical drugs that they are using. One of the drugs that all five of these women were using is a drug called Tamoxifen, which, Dr. Siegfried, you are certainly aware of, used pretty commonly for those women who have breast cancer.

Dr. Siegfried, do you happen to know the price differential these women experienced in the drug Tamoxifen in Canada versus the United States?

Dr. SIEGFRIED. No, I don't, sir.

Mr. SANDERS. No idea? The women purchased Tamoxifen for one-tenth, not 10 percent, one-tenth of the price that they paid 50 miles south in the good old United States of America, in the most extreme case. These are women battling breast cancer, and every other drug that they had to purchase was also purchased at significantly lower prices in Canada than in the United States.

I have to say that there is clearly something very wrong, and I think probably all of the panelists have raised this issue, about the pricing mechanisms that exist in the pharmaceutical industry, because I would give you day and night, Dr. Siegfried, to explain to the people of the country why a drug used to battle breast cancer costs one-tenth of the price in Canada than it does in the United States.

Now we are dealing with the issue of South Africa. It seems to me that what we are dealing with is an extraordinary moral issue, that is, is it acceptable for the U.S. Government to unilaterally put pressure on the South African Government and other governments because they are trying to develop and purchase prescription drugs to treat a killer disease?

Is it acceptable for the U.S. Government to work hand in glove with the pharmaceutical industry, which, as you know, is currently suing in the courts in South Africa on this issue, trying to get the South African Government to rescind that law which gives them the right to parallel import and to develop generic drugs?

To me, it is beyond comprehension how—the pharmaceutical industry has the right to do what they will do, and that the U.S. Government would work hand in glove, and I have seen the reports, with the pharmaceutical industries to try to force South Africa and other countries not to generate the cheaper drugs that they need in order to treat people.

I would simply say, picking up on a point, I think, that Mr. Sawyer made, Mr. Chairman, and I hope that you will pursue this issue, because I think you have an enormous moral dilemma, what do you do when you have a product that can save somebody's life from an industry which enjoys record-breaking profits, and then, all over the world, people who are poor are dying because they cannot have access to that product?

Now, all of us know, in fact, that the pharmaceutical industry has done a good job, and we are proud of the work that they have done not only on AIDS, but on many other diseases. But what we also know, whether it is Washington, Burlington, Vermont, or South Africa, is that all of the research and development that you have done does not mean a damned thing if somebody cannot afford that product.

If all of the research and development means that you come up with a treatment that costs $15,000 a year, forget about the people of South Africa, forget about the people in DC, forget about the working families of the State of Vermont, and say that it is going for the wealthiest people in this country. That is what your treatment is for.

Picking up on a point I think Mr. Sawyer made, and as somebody who has also introduced legislation on this, we know that the taxpayers of the country have contributed billions of dollars to the NIH for research they have done, and to research that other universities and colleges all over America have done. They have developed products and given them over to the pharmaceutical industry without any reasonable price clause attached to it.

We have seen case after case where the pharmaceutical industry has said, thank you very much for this government-sponsored research. Now we are going to charge the consumers of the country $10,000 or $15,000 for that treatment, and then you have profits of $2.5 billion each for the top 10 companies.

So what we are dealing with is an extraordinarily difficult issue from an economic, medical, and moral point of view. I think it is not good enough, and I will say, Mr. Chairman, and I know Mr. Gore has been criticized, that yesterday I think we got 19 votes from the Republicans on this issue. We got a lot more votes—we didn't get enough votes from the Democrats, but we got almost half the Democrats, and a very few Republicans stood up on this issue, being prepared to take on the pharmaceutical industry.

But I think we have to take a hard look, because this is so unique. This is not housing, this is not automobiles; this is life and death. What is the proper role of the U.S. Government in terms of dealing with an industry in which we have been very closely related to that issue, putting a lot of funds into that issue, giving up tax breaks to go to Puerto Rico to develop their products; what is the moral and proper role of the U.S. Government in saying to you, we want you to continue to do your research, but we want the results of that research to be spread out and to be positive for working families in this country, for poor people in this country, and for desperate people all over the world?

That is an enormously profound moral issue, and I hope as a Congress we can begin to address that issue.

I wanted to congratulate all of the panelists up there, but I don't know if Dr. Lurie wanted to add 2 cents to what I said.

Dr. LURIE. It is hard to. I think another way of putting it is like this: There is an inevitable tension between the price of the drug and its accessibility. Quite how that curve looks might vary from drug to drug, but as a general matter when price goes down, access will go up.

What we have basically done in this country and elsewhere is taken the position that it is more important to maintain the ability of the pharmaceutical industry to retain these kinds of irrational drug price practices than it is to bring them down to prices like what they have in Canada, and in the rest of Europe; substantially lower than here, even knowing that as long as those prices remain high, people will not get those drugs, and if people will not get those drugs, they will die. Collectively that is the decision we have made. That seems unacceptable to me.

Mr. SANDERS. I would like to ask Dr. Siegfried, and I get disturbed, Doctor, by your telling me you don't know the answers, because that is the purpose of this hearing. If they sent you here as a nice guy and a good physician who does not know the answers, maybe they should have sent somebody else to answer these questions, because that is the issue we are dealing with today.

Can you give me your response, and you indicated that you don't know why the prices of drugs, of Tamoxifen, in the United States, for women who are battling a life-and-death struggle with breast cancer, is 10 times higher in the United States than in Canada. You don't know the answer to that; is that what I hear you say?

Dr. SIEGFRIED. Congressman Sanders, I don't know the answer to that. But I do want to comment, going back to Mr. Mica's earlier observation, the pricing differential is one thing, but also the differential of what the pharmaceutical industry in terms of its research and development in Canada and others parts of the world versus what the United States has accomplished is also significantly different.

I find, interestingly enough, and I may be perceived as the enemy because I represent the pharmaceutical industry, but I have found very little today in the presentations that I personally have much argument with. I have great concern that the goose that laid the golden egg not be killed in the process of trying to provide omelettes for people throughout the world. That is a personal concern.

I really don't envy you or any members of the panel who have to struggle with these issues of how do you do that, how do you keep golden eggs coming out of pharmaceutical research and development, how do you do that in a situation that is going to allow pricing that is universally affordable, much less globally affordable. I don't have an answer to that, I'm sorry.

Mr. SANDERS. Let me just ask my last question, Mr. Chairman. That is actually taking something that came out of your statement. Maybe Mr. Love might want to comment on that.

On page 3 or 4 of your statement, under compulsory licensing, you state that "in terms of pharmaceutical production in times of national emergency, trade agreements may permit the government of a developing country to grant production rights to a local company." You say the question arises as to whether HIV/AIDS epidemic in sub-Saharan Africa is such an emergency. I am reading from your testimony.

Jamie, did you want to respond to that? What we heard yesterday from my opponents on this amendment is that what South Africa is doing is illegal. My response is if it is illegal, take them to the WTO, don't take unilateral action. But I am hearing from Mr.

Mica's own testimony that it is apparently not illegal; that if you have a medical emergency, you can produce generic drugs.

I cannot believe that anyone could tell us with a straight face that what is going on in HIV and AIDS in South Africa is not a medical emergency.

Mr. LOVE. It is true that in the international trade agreements that if there is a declared national emergency, the most liberal rules apply to compulsory licensing, which means that you do not have to try and do any prior negotiation. And the compensation is actually—is whatever is considered adequate under the laws of the national government; that is the part of the international trade agreement for international emergencies.

But it's also true that those same roles apply to government use; that is to say that if a government manufactures through its public health service, even if it was not a national emergency, that those same liberal rules would apply.

And I would go further to say that even if it wasn't for government use, and it wasn't an emergency, you are still permitted to do compulsory licensing, it's just that you have to follow a different set of procedures. And so within the WTO agreement, which we have a book here about the agreement that's published by the World Health Organization, including a chapter on compulsory licensing, you just figure out what rules should apply, depending on what you're trying to do.

Now, you also, Congressman, accurately described this tension between claiming what South Africa is trying to do is illegal under the trade agreement and refusing to bring our dispute before the WTO's own dispute resolution mechanism. The South Africans are begging the United States to take them to the WTO. They're saying, if you think we violated the agreement, take us to the WTO, where at least we can have a decision by a judge. We only have a 2-year-old—2-year nightmare of sort of a Kafkaesque-like thing where we don't even know what we're accused of precisely. You submit briefs, there's a decision, and there's a finding. That's what they want.

What South Africa—the problem the industry has with South Africa is precisely that what they're doing is legal under the agreement. That's actually why it's such an important case. And that's why bilateral is used, because if they were doing something illegal, we would already have a WTO, we bring WT cases against countries all the time.

Mr. SANDERS. Bananas.

Mr. LOVE. Bananas; we bring it against India on pipeline protection. We won that. WTO, we're not afraid to use it. The reason why don't we use it in South Africa is we would lose; we don't have a case.

Mr. SANDERS. That's a good point.

Do you think we have more Republican support in the future for this issue?

Mr. MICA. Mr. Sanders, I think—as we begin hearings, I think the only two hearings on the AIDS question which was brought to my attention was one that Mr. Gilman did in his subcommittee and our subcommittee. This is the first time that ACT UP folks even

had an opportunity to testify. And, again, I think if there's more education——

Mr. SANDERS. I applaud you.

Mr. MICA. This is indeed unfortunate, and I commented to my colleague that, you know, you can have a disaster in Central America where 10,000–15,000 people are killed in a natural disaster, and we rush in with a supplemental appropriation and huge amounts of money, and it gets attention, where you have millions die.

Mr. SANDERS. You're absolutely right.

Mr. MICA. Everyone is asleep at the switch. So it is an education process. Part of that is this hearing process, and, as I said, this is only the second hearing.

Mr. SANDERS. And I thank you very much.

Mr. MICA. I will discuss with the ranking member the followup, and I think you can hold one hearing, and it doesn't mean anything on issues. But followup is important, and we have a whole range of areas. I mean, they've—this panel and the previous panel have given us enough to probably just do many hearings on with those comments. Let me just——

Mr. SANDERS. Let me thank you again. This is an enormously important issue, and you put together excellent panels. And I thank you very much.

Mr. MICA. Let me yield now, and without difficulty, Mr. Sanders, that has not been a fun thing. I got heat from my side, from your side, from pharmaceutical folks, from congressional folks, from administration people. I mean, it is not a popular thing to do for some reason, but it does deserve our attention.

With that, let me yield to the most patient, and she will get the last word on this issue, Ms. Schakowsky from Illinois.

Ms. SCHAKOWSKY. Thank you, Mr. Chairman. And I've really appreciated spending the day on this important issue. And I hope that this hearing will result in some practical moves as the lady from the District has been seeking.

I wanted to followup—that's the advantage of going last, I can comment on everybody—something that Mr. Lantos said, and he was right when he said that we're faced with competition, with these competitive requests all the time, particularly among diseases. And that's in a way the beauty of the recommendations that have come out of this panel is that we're not, in fact, talking about any taxpayer dollars, but rather using approved market and trade mechanisms and things that the United States could do at negligible costs to the taxpayer, other than working out an agreement and signing some papers.

And so what you've presented to us, I think, are solutions that we ought to posthaste explore to make sure that we are delivering these drugs to people around the world at a cost that can be afforded.

And the other thing that Mr. Lantos was talking about were strategies. What are the strategies that we can use that bring people together rather than separate them? And I'm hoping that we cannot pit, for example, prevention against treatment, because I think we all agree how important both are, and treatment we're facing, what, almost 40 million people around the world. This is a

pandemic that currently have it, so clearly we do need to be talking about treatment.

And I appreciate that one of you also talked about rather low-cost solutions, was it—who talked about for $70 a year the three drugs that could save many lives. We're not necessarily talking about $30,000 a year, and that was $70 at the U.S. costs that Mr. Sanders already showed us that is very often the highest in the world. We don't want to have diabetes versus AIDS, you know. Let's figure out ways that we can address both.

And, again, with AIDS we're talking about not using taxpayer dollars. And let's also be concerned about, all of us in the United States, particularly African Americans and Latinos who don't have and/or may not be able to afford access, but I think also as Ms. Nkhoma, was it, said, we also need to treat each other around the world as brothers and sisters. And therefore, I hope we don't make this a Republican versus Democrat issue, so that we can all work together.

There were a couple of questions that I wanted to ask Dr. Siegfried. Again, I am disappointed that these issues of South Africa and trade agreements are not your bailiwick, because that is what we're talking about today. But perhaps you can provide me with this information. I know you haven't come alone; I know there are other people from PhRMA that are with you, and certainly those that can help.

What I'm interested in is knowing what the dollar amount that your members have received in tax credits and research funding from the U.S. Government over the past 10 years. What has been the U.S. investment? When you talk about the $24 billion on research and development, I suspect that a good deal of that are taxpayer dollars as well; but in any case, what is the contribution to developing all drugs, that is, what is the U.S. contribution to R&D in the pharmaceutical industry and specifically in AIDS drugs. I would hope that I could get that information.

Dr. SIEGRIED. The $24 billion, I believe, is really industry money and does not include the public funding that you're speaking of. I don't have the information, and certainly not over a 10-year period of time. I'm not even sure whether that's easily available within the industry or through the government. But if it's information that's important, we can certainly try and get that to the chairman.

Ms. SCHAKOWSKY. I think that it is important for us, when we talk about research and development, that we do have an understanding of the extent to which taxpayers are funding that as well.

Dr. SIEGRIED. I think one of the things that gets a bit confused here is that a lot of the public funding for NIH kinds of research is focused on what we call basic research. The industry picks up on that and does applied research. You sort of have to have the basic understanding of the scientific or pathogenic process before you can go ahead and develop drugs that might attack it. So the two are complementary. And there's a sense in which you can't have one without the other. We went through that a few years ago when NIH was into——

Ms. SCHAKOWSKY. Dr. Siegfried, I'm going to ask your indulgence since my time is running out, if I can just ask my questions and you can answer.

Dr. SIEGRIED. I apologize.

Ms. SCHAKOWSKY. No, that's OK. I'm also interested in—because it relates to the question of parallel importing certainly. If we took the top 10 AIDS drugs and I could get information about the price of those drugs in the United States, Spain, Canada, South Africa and Australia, I would be interested to see, as Representative Sanders has found, these differentials.

You also mentioned that we don't want to kill the goose that laid the golden egg. But it was Dr. Lurie's testimony that I think did put it in some perspective when he said that R&D represented a median of 11.4 percent of sales for the top pharmaceutical companies, and contrast to that with profit, net income representation, 18.6 percent of sales by those same companies in 1998.

And another figure that I think would be useful to know, I would be interested to know how the advertising budgets compare to the R&D budgets as well. And I think that we want to be responsible in making sure we don't kill that golden goose, but we also want to have some sense of how those costs relate to other costs.

Yes, Mr. Sawyer, do you have a response to that?

Mr. SAWYER. I was going to say some of the questions you've asked, I know Jamie Love has data on it, according to the orphan drug tax credits for the development of several of the early AIDS drugs. The point you just made about the amount of money that was invested in research, Dr. Siegfried said 20 percent is what the industry puts in. Dr. Lurie—actually analysis showed that it was 11 percent.

I looked at Abbott Drugs' annual report. Abbott Drugs on sales of $12.8 billion, their own annual report listed their research and development budget at 9.8 percent of sales, because they invested less than $1.2 billion out of that almost $13 billion in sales into research and development. Their marketing budget was more than $2.6 billion. So more than 20 percent went to advertising. Less than 10 percent went to research and development. That's just one company.

But Jamie, I think, has data on early AIDS drugs.

Dr. LURIE. I'm glad you're asking these questions, because historically it's been very difficult to get any kind of handle on what is going on in the pharmaceutical companies' accounting practices. Aside from the fact that there are millions and millions of dollars in handouts to the pharmaceutical industry that come courtesy of U.S. taxpayers, these estimates of R&D are themselves most likely distorted to the best that we can tell. Much of the R is not, in fact, R, but rather D. And much of the D is not D, but is probably marketing.

And even the R that is done is primarily spent not on these breakthrough drugs, but much of the brainwork comes from the NIH and other places, or universities funded by the American Government, but instead is expended in the service of developing copycat drugs which provide little advantage over existing drugs rather than truly breakthrough ones, and then the process is that you just mount a massive advertising campaign, and you make your money that way.

The money—that's where most of the work is being done in simple copycat drugs, and much less is—it's hard to tell, they don't

give you numbers, but we suspect that limited amounts are actually true significant breakthroughs.

Ms. SCHAKOWSKY. I wanted to ask if there are documents on hand that are responsive to this, I wonder if they could become part of the record of this—is that possible, Mr. Chairman?

Mr. MICA. We can certainly—anything you would like to request, we would make a part of the record. We're going to ask questions to the previous panel. We will leave the record open for at least 3 weeks here so that we can get some responses, and we can submit questions. If you would like to do that, we would be glad to pass them on.

Ms. SCHAKOWSKY. If Mr. Love could make—I know my time is up, but if you could answer.

Mr. LOVE. One thing that the committee could be very helpful on is that there are these controversies about what it costs to develop a drug. I think we heard today 500 million, 1 out of 10, that sounds like $5 billion a drug now. So every week it seems to be going up faster than Internet stock.

One thing that the committee could do is the U.S. Government for some set of drugs has actually done all the clinical work, and if you were to ask Donna Shalala's office to provide you with data on what—for those drugs that it's actually taken all the way through approval, how much it costs for those drugs, we would leave the area of the Wizard of Oz behind the curtain and start dealing with real data, and it might be interesting.

We've asked for that data, but I think, as the chairman of the committee, you're probably a much more important guy than we are; so it would be helpful if you would ask for that information, and maybe they would give it to you.

The other thing is that there's an orphan tax credit which covers one-half of the cost of clinical trials that are done under the Orphan Drug Act, which includes all AIDS drugs, a few cancer drugs, and drugs for the severe illnesses. It's another independent audited source of information which would be a nice addition to the record; that is to say, for the drugs that are covered in that category, which includes all AIDS drugs plus other things, like how much do the companies report on their tax returns they actually spent on the clinical trials. Then you would also again go beyond the public relations world to the world of actual data.

And if you were to take those two numbers and put them in the record, it would be maybe a helpful nice trend to actually look at the evidence.

Ms. SCHAKOWSKY. Thank you.

Mr. MICA. Well, thank you.

Did anyone have any additional final questions?

Well, we haven't gotten all the answers today, but we've certainly raised a lot of questions. We've gotten some answers.

I want to thank each of you for participating in this hearing. I still have some questions that I will submit to some of the members of this panel and the previous panel.

Dr. Siegfried, you didn't bring up the problem of liability. I'm a real big advocate of reform of product liability. And I've been told in the immunization area where you can buy an immunization shot for $10, that $6 or $7 of it goes now to product liability, and that,

you know, $1 or $2 goes into actually the manufacturer, plus we're losing manufacturers of some of these substances. So you need to get some more examples of some of the problems for us, but I think we have found a whole range of areas we can explore.

The question of U.S. rights and the interests and research was an interesting thing that was raised, and we do have some rights, and maybe it should be part of our research grants that we ensure that we have some hook into that on behalf of those that are funding this.

Certainly there's been—there was a great deal of discussion about unfair U.S. trade policy and actually preventing some of the countries from making the products available at reduced costs. And I think some of the suggestions about looking at providing additional licenses might be interesting.

I was in the communications business, and lo and behold a government issued another license after we invested an incredible amount of money. I wasn't too happy, but that's the way the cookie crumbles sometimes, and it created competition, and the consumer benefited. And most importantly, I think we've opened some congressional debate. The important thing is that we have some followup.

Our subcommittee has jurisdiction over international trade issues, over HHS, and a number of other agencies. There have been questions here about State—and maybe we can get Mr. Lantos and Mr. Gilman to followup on those issues. And then if the committee panel members have others, I think Agriculture was also mentioned, we don't have jurisdiction there—we can ask some of the other subcommittees to look at these, some of these problem areas.

I think the interest, of course, is to see that we can get treatment, research, and development to everyone; not only in our country, but across the globe, as expeditiously as possible, especially when you're faced with a crisis of this magnitude that sort of has been glossed over to date.

But again, in closing, I want to thank all of you for your participation. I'm sure you didn't anticipate being here through almost the dinner hour with us, but we do appreciate your testimony and your contribution to our subcommittee.

Ms. Schakowsky asked unanimous consent that a statement by Congressman Jim McDermott be submitted for the record.

[The prepared statement of Hon. Jim McDermott follows:]

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

Mr. MICA. She also asks unanimous consent that a statement by Donna Christenson be submitted for the record, and further that a statement from Doctors without Borders be submitted to the record. Without objection, so ordered.

[The prepared statements of Mrs. Christenson and Doctors without Borders follow:]

DONNA M. CHRISTIAN-CHRISTENSEN
DELEGATE, VIRGIN ISLANDS

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MEMBER, SUBCOMMITTEE ON NATIONAL PARKS AND PUBLIC LANDS
MEMBER, SUBCOMMITTEE ON WATER AND POWER

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Statement of
the Hon. Donna M. Christian-Christensen
re Hearing on the U.S. role in combating the global HIV/AIDS epidemic
before the Criminal Justice, Drug Policy, and Human Resources Subcommittee
July 22, 1999

I want to begin by thanking you, Chairman Mica, for allowing me to make this brief statement. I also want to commend you and Ranking Member Patsy Mink for holding this very important and timely hearing today.

It is a sad fact, Mr. Chairman, that the HIV/AIDS virus has perhaps gone beyond the epidemic realm around the world -- if such a thing is possible. As an illustration of this fact, the New York Times recently confirmed that AIDS has now become the leading killer in Africa, only 18 years after the first infection was recognized. As the richest nation and sole reaming supper power in the world, the United States must take a leadership role in fighting to eradicate this horrible disease. It is true that we have done a lot, particularly through our efforts in our foreign aid budget and our support of international organizations such as the World bank and UNAIDS and others. But we can and must do more, if there are to be any meaningful success in stopping this scourge.

But while this hearing today is very timely -- it is a good thing for us to examine possible new approaches needed to combat this dreaded disease -- this isn't the time to start casting stones or assigning blame. And I hope that this is not what will result from this hearing today.

As Chair of the Congressional Black Caucus' Health Braintrust, I have been at the forefront of the CBC's efforts to address the problems of AIDS/HIV domestically because, as you know, the African-American community have also been severely impacted by this disease. While we have had some success, particularly through the appropriation of $156 million dollars last year – we still have much to do.

At the same time, the CBC is also very concerned about the impact of this disease around the world. In this regard, I want to acknowledge the efforts of my colleague Jesse Jackson, Jr., who is among the witnesses you will hear from today. Congressman Jackson and others have been steadfast in their fight to have more done to address this problem globally.

I also want to applaud Vice President Gore for his efforts on this issue and for the role he played in getting the Administration to unveil a new $100 million initiative to combat HIV/AIDS in Africa. This new initiative, as you know, will double the existing efforts to prevent and treat AIDS in Africa.

Finally, I want to implore the members of the Subcommittee and all of my colleagues in the House to work with our friends in the pharmaceutical industry to address the challenges to affordable HIV drugs and other treatments getting to the people that need them the most.

Thank you again Mr. Chairman for allowing me to make this statement. I look forward to working with you and the members of your subcommittee in implementing the recommendations that will come from this hearing.

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Honorable John L. Mica
Chairman of the Subcommittee on Criminal Justice, Drug Policy and Human Resources
of the Committee on Government Reform
House of Representatives
B373 Rayburn House Office Building
Washington, DC 20515

New York, July 19, 1999

Mr. Chairman,

Thank you, Chairman for convening a hearing before the subcommittee this Wednesday July 22, 1999 to discuss the US role in combating the global HIV/AIDS epidemic. This hearing has renewed our hope that efforts by Congress and the Administration will take further action on behalf of the millions worldwide affected by this epidemic.

The reality of the AIDS pandemic in Africa and Asia can be overwhelming. The staggering numbers lead some people to believe that no action—in the absence of an effective vaccine—could possibly make a dent in the suffering.

At Doctors Without Borders/Médecins Sans Frontières (MSF), our medical volunteers, with many Americans among them, and our local staff work with one patient at a time. We know that access to effective treatments can and does make a difference. The sad reality is that even in communities where there is sufficient health care infrastructure to administer life-saving therapies, people are dying of treatable infections because of the high prices of these treatments.

In the United States, AIDS care has been transformed with the availability of effective anti-HIV and anti-opportunistic infection treatments. At Doctors Without Borders, we believe that it is possible to share some of these advances with people in developing countries. What if penicillin had been patented—would we have let high prices keep it beyond the reach of entire countries? If the Salk vaccine had received an ironclad patent would we have allowed prices to prevent access?

Times have changed and we clearly understand the need to have patent protection as an incentive to drive investment dollars into research. But we also believe there are ways in which we can humanize the current global pharmaecutical market without changing the existing global trade rules.

In an effort to support the pharmaceutical industry, the US government has been exacerbating rather than alleviating the pain caused by AIDS in poor countries.

Take the case of Thailand, a country in which Doctors Without Borders works with local Thai staff to care for people with AIDS. The Thai government had a system whereby it produced generic versions of drugs to treat life-threatening diseases. This system depended on the Pharmaceutical Patent Review Board which had the authority to collect economic data, including the production costs of pharmaceuticals.

The US government, claiming that the Review Board violated the rights of the US pharmaceutical industry, threatened Thailand with higher tariffs on imports of wood products and jewelry. This threat was made during the Asian financial crisis when Thailand was starved for export earnings. Thailand capitulated and therefore today only has access to AIDS antiretrovirals at global prices set by global drug companies—prices 90 percent higher than those of generic drugs (with the exception of AZT which is processed locally).

US trade pressure must stop. We must take the moral high ground and acknowledge that life-saving medicines should not be treated as non-essential goods.

Doctors Without Borders believes that the US and other wealthy nations need to state clearly that they are willing to shoulder more of the research and development burden than poor countries. This means that we should be willing to pay the existing high prices while encouraging drug companies to sell or license their products to poor countries at prices that cover manufacturing costs plus a reasonable profit margin.

Our demands are not radical when you consider that safety valves already exist in current global trade law that facilitate this dual pricing strategy. **We ask only that the US government stop trying to prevent poor countries from enacting these legal provisions—such as parallel imports and compulsory licensing.**

The drug industry claims that without high prices in poor countries they will not be able to fund research and development. This argument falls flat when you consider that at current prices a tiny minority of people is currently buying these treatments. IMS, an authority on pharmaceutical marketing, estimates that by the year 2002 Asian countries will account for only seven percent of the worldwide market.

The US government must stop supporting a policy that benefits the pharmaceutical industry at the expense of people with life-threatening diseases. We believe it is possible to strike a more humane balance.

Daniel Berman, Doctors Without Borders/Médecins Sans Frontières

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SPECIAL COMMUNICATION

Access to Essential Drugs in Poor Countries
A Lost Battle?

Bernard Pécoul, MD, MPH
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Drugs offer a simple, cost-effective solution to many health problems, provided they are available, affordable, and properly used. However, effective treatment is lacking in poor countries for many diseases, including African trypanosomiasis, *Shigella* dysentery, leishmaniasis, tuberculosis, and bacterial meningitis. Treatment may be precluded because no effective drug exists, it is too expensive, or it has been withdrawn from the market. Moreover, research and development in tropical diseases have come to a near standstill. This article focuses on the problems of access to quality drugs for the treatment of diseases that predominantly affect the developing world: (1) poor-quality and counterfeit drugs; (2) lack of availability of essential drugs due to fluctuating production or prohibitive cost; (3) need to develop field-based drug research to determine optimum utilization and remotivate research and development for new drugs for the developing world; and (4) potential consequences of recent World Trade Organization agreements on the availability of old and new drugs. These problems are not independent and unrelated but are a result of the fundamental nature of the pharmaceutical market and the way it is regulated.

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THE EFFECTIVENESS OF DRUGS DEpends on a long chain of factors: research and development (R&D) of an appropriate pharmaceutical agent, production, quality control, distribution, inventory control, reliable information for health care professionals and the general public, diagnosis, prescription, financial accessibility, drug dispensing, observance, and pharmacovigilance. At each level, those involved may have conflicting interests, and poor populations are the first to suffer the effects of frail links in this long chain. Today, entire populations lack access to essential quality drugs, and the situation appears to be deteriorating, further marginalizing much of the world's population.

Essential drugs are the foundation for nearly every public health program aimed at reducing morbidity and mortality in the developing world, and pharmaceutical expenditure can account for a high proportion of the total health expenditure of a country. Important health programs that rely on essential drugs include child survival programs, antenatal care, treatment of enteric and respiratory pathogens, and control of tuberculosis and malaria. Other major public health issues exist for which there is no effective pharmaceutical treatment.

This article focuses on 4 main issues associated with the inaccessibility of drugs for populations in greatest need: (1) poor-quality and counterfeit drugs; (2) lack of availability of essential drugs due to fluctuating production or prohibitive cost; (3) need to develop field-based drug research to determine optimum utilization and remotivate R&D programs for new drugs for the developing world; and (4) potential consequences of the recent World Trade Organization (WTO) agreements on the availability of old and new drugs. For all these issues, practical recommendations to improve the situation are proposed.

The lack of access to essential drugs or vaccines because of economic reasons raises new human rights issues in a world that remains divided among wealthy countries, developing countries, and the rest of the world. Yet, financial access to drugs does not necessarily mean correct use. Continuous training for health care professionals, dissemination of reliable pharmacological data, and improvement of the management of drugs are fundamental steps in improving the quality of care in the developing world.

THE PROBLEMS

Examples of problems related to development and access to drugs and the magnitude of the public health problems concerned are given in TABLE 1.

Counterfeit and Substandard Products

Drug products must be produced according to good manufacturing practices.[1] Unfortunately, many developing countries do not have the technical, financial, or human resources required for the application of such standards, and some developed countries may be less strict when the product being manufactured is destined for exportation. Today, the quality of drugs and, therefore, their effectiveness and safety are less and

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Table 1. 1996 Worldwide Accessibility to Drugs or Vaccines for 10 Diseases*

Diseases†	Deaths†	Incidence (I) or Prevalence (P)†	Drugs or Vaccines	Type of Problem
Acute lower respiratory tract infections	3.9	394 (I)	Ceftriaxone sodium (for severe cases in hospital)	Available but limited use, prohibitive price
			Anti-*Haemophilus* vaccine (Hib conjugates *Haemophilus*)	Available but limited use, prohibitive price
			Antipneumococcal vaccine (group A streptococci)	Clinical development (phase 1 trial)
Tuberculosis	3.0	7.4 (I)	Isoniazid, rifampicin, pyrazinamide, ethambutol hydrochloride, streptomycin, thiacetazone	Poor compliance with therapy and outbreaks of drug-resistant strains (isoniazid, rifampicin)
			Sodium aminosalicylate, ethionamide, capreomycin sulfate	Production not secured, toxic effects of drugs
			Rifapentine	Available but limited use
			BCG vaccine	Effectiveness disputed
Diarrhea	2.5	4000 (I)	Ciprofloxacin (shigellosis)	Available but limited use, prohibitive price
			Antirotavirus vaccine	Available but limited use, prohibitive price
			Anticholera vaccine (whole cell B)	Available but limited use
			Anticholera vaccine (103Hgr)	Available but limited use
			Antishigellosis vaccine	Clinical development (phase 2, 3 trials)
Malaria	2.0‡	300-500 (I)	Pyronaridine	Clinical development (phase 3 trial)
			Artemisinin derivatives	Available but production not secured for substandard products
			Coartemether	Clinical development (phase 2, 3 trials)
			Atovaquone-proguanil	Available but limited use
			Antimalaria vaccine (preerythrocytic)	Clinical development (phase 2, 3 trials)
			Antimalaria vaccine (asexual erythrocytic stage)	Clinical development (phase 2 trial)
Preventable diseases (pertussis, measles, diphtheria, polio, tetanus)	1.7	82 (I)	Pertussis whole cell, measles, diphtheria, oral polio, and tetanus vaccines	Substitution of classic formulations by new formulations, prohibitive price (eg, acellular pertussis)
Human immunodeficiency virus	1.5	3.1 (I), 22.6 (P)	Antiretroviral drugs	Available but limited use, prohibitive price
			Anti-HIV vaccines	Clinical development (phase 1, 2 trials)
Hepatitis B	1.2	200 (P)	Hepatitis B recombinant vaccine	Available but limited use
Human African trypanosomiasis	0.15	0.2 (I), 0.3 (P)	Suramin sodium	Production not secured (no commercial interest)
			Pentamidine isethionate	Production not secured (no commercial interest)
			Melarsoprol	Production not secured (no commercial interest)
			Eflornithine hydrochloride	No longer produced (no commercial interest)
Leishmaniasis	0.08	2 (I)	Meglumine antimoniate	Production not secured (no commercial interest)
			Amphotericin B lipid complex	Limited use
			Aminosidine	Old drug (production stopped)
Meningitis	0.04	0.4 (I)	Ceftriaxone sodium	Available but limited use, prohibitive price
			Oily chloramphenicol	Available but production not secured for substandard products
			Antipneumococcal vaccine	Clinical development (phase 2, 3 trials)
			Anti-*Haemophilus* vaccine (Hib)	Available but limited use, prohibitive price
			Meningococcal A-C conjugates vaccine	Clinical development (phase 2 trial)

*For these diseases, there were a total of 16.07 million deaths of 52 million worldwide. One third (17.3 million) were due to infectious diseases (>90% in developing countries).
†Data, in millions, are from the World Health Organization, *World Health Statistics Annual*, 1998.[17]
‡Data indicated in *World Health Statistics Annual* as 1.8/2.2.[17]

less certain, especially for the poorest populations, who are attracted by lower-priced drugs sold outside pharmacies.

Recent years have seen an increase in the prevalence of counterfeit and substandard drugs on the market. Counterfeit drugs are those that mimic authentic drugs; substandard drugs are those produced with little or no attention to good manufacturing practices.

For example, during the meningitis epidemic in Niger in 1995 (41 000 cases reported), Niger authorities organized an extensive vaccination campaign. In March 1995, Niger received a donation of 88 000 Pasteur Mérieux and SmithKline Beecham vaccines from neighboring Nigeria. A Médecins Sans Frontières (MSF) team working with local health authorities noticed that the vaccines from Nigeria had an unusual appearance (eg, difficult reconstitution, black filaments in the solution). Inquiries were made and Pasteur Mérieux laboratories confirmed that the batch numbers and expiration dates did not correspond to their records. The drugs supplied had been substituted with counterfeit drugs. Tests carried out found no traces of active product, confirming they were false. Bottles and labels were copied to perfection.[2,3] Pasteur Mérieux subsequently filed a counterfeit suit. Some of the false vaccines (approximately 28 000) were located by batch number and destroyed. According to estimates, approximately 60 000 persons were inoculated with false vaccines of a total 5 million vaccinated during the campaign. Such a production would have necessitated an industrial-scale manufacturing facility, and it is probable that the 88 000 vaccines identified as false did not account for the entire fraudulent production.

Médecins Sans Frontières teams have encountered similar field examples that lead to the following conclusions: organized illegal circuits seem inclined to manufacture copies with the appearance of known trademark drugs (counterfeit) than comparatively less-expensive generic products, whereas nonorganized illegal circuits (small production) increasingly manufacture drugs that are substandard or inadequate, including generic drugs.

Poor quality may be accidental, with no intention to deceive, but oversights in manufacturing or neglected controls can have tragic consequences. Such was the case in recent decades with acetaminophen syrups that contained, by mistake, a lethal ingredient.[4,5]

Fluctuating Production of Essential Drugs

Drugs necessary for the treatment of certain tropical diseases have begun to disappear from the market because they are commercially unprofitable. Many of these drugs were discovered in the 1950s and 1960s or earlier and are seldom or never used in wealthy countries.

An example is seen in the effort to treat epidemic bacterial meningitis, caused by *Neisseria meningitidis*, which is rampant in sub-Saharan Africa. Efficacy of treatment with chloramphenicol in oily suspension (1 intramuscular injection repeated after 48 hours) for bacterial meningitis is comparable with the traditional treatment with ampicillin (intravenous injections 4 times daily for 10 days).[6] The lower cost of chloramphenicol in oily suspension—only one tenth the cost of ampicillin—and its simple administration make it particularly suitable to the precarious conditions in developing countries.[6] This is particularly important during epidemics. In Nigeria in 1996, for example, more than 100 000 cases of *N meningitidis* infections were reported.[7] However, production and availability of chloramphenicol in oily suspension are no longer guaranteed. Roussel-Uclaf stopped its production in 1995 and transferred its technology to another laboratory, which began production last year. In the meantime, temporary solutions have ensured that a certain (but far from sufficient) amount of chloramphenicol is made available.

The circumstances described herein also apply to other serious illnesses, such as leishmaniasis and its treatment with meglumine antimoniate and African trypanosomiasis and melarsoprol (Table 1). The trypanocidal activity of eflornithine hydrochloride was discovered in 1985.[8] It is the only treatment proven effective in cases in which African trypanosomiasis shows resistance to melarsoprol, and such resistance is becoming more frequent (20% in Omungo, Uganda).[9] This drug was sold at an extremely high price and is now no longer manufactured. Only through a joint effort of the World Health Organization (WHO), nongovernmental organizations involved in fieldwork, cooperative bodies, and pharmaceutical companies could this drug become available and affordable again.

Prohibitive Costs

The prohibitive cost of antiretroviral drugs for treatment of people with acquired immunoeficiency syndrome is well known.[10] There are many other examples of drugs that are simply not affordable, most of which have been recently marketed and therefore are still patent-protected.

Shigella dysenteriae type 1 dysentery is extremely contagious and, without effective treatment, is lethal in 5% to 15% of cases.[11] Since 1979, this disease has been the cause of large epidemics in Africa (for example, in Malawi in 1992 and 1993[12] and in Burundi in 1994[11,13,14]). *Shigella dysenteriae* type 1 bacteria quickly became resistant to traditional treatments. The only effective antibiotic drugs today are fluoroquinolones (eg, ciprofloxacin and norfloxacin). However, treatment with these new drugs is 10 times more expensive than the traditional treatment using nalidixic acid (approximately $20 vs $2).[15] A special agreement was reached between Bayer Laboratories and MSF in 1997 to make available treatments with ciprofloxacin for 50 000 people for a unit price of $2 per treatment. This example shows that it is possible to find a short-term ad hoc solution with the pharmaceutical industry, yet no midterm solution is anticipated.

A recent study of bacterial meningitis caused by *Streptococcus pneumoniae* in children aged 2 months to 3 years demonstrated that use of ceftriaxone sodium could reduce mortality from 66% to 32% compared with treatment with chloramphenicol in oily suspension.[16] Both antibiotics have a sustained action and require very simple protocols (daily intramuscu-

lar injection for a short time) and therefore are equally easy to use in adverse conditions. However, ceftriaxone treatment is 10 times more expensive than chloramphenicol treatment.[16] *Streptococcus pneumoniae* infection is also one of the main causes of severe acute respiratory tract infections—the primary cause of child mortality in Africa.[17] Therefore, ceftriaxone is vital but financially inaccessible to those populations that need it most.

Prohibitive pricing also extends to prevention when new vaccines are not available for the population most at risk. For example, hepatitis B virus and anti-*Haemophilus* vaccines are not accessible because of their steep price. Vaccines for hepatitis B, a disease predominantly found in eastern Asia and sub-Saharan Africa,[18] are approximately 10 times more expensive than other vaccines included in the Expanded Programme on Immunization promoted by UNICEF.[19]

Essential Drugs Not Adapted to Field Conditions

Tuberculosis caused the deaths of 3 million people in 1997, but the current treatment regimen, known as *directly observed therapy—short course* (DOTS), is impractical and compliance is poor: only 23% of the world's population has access to the WHO tuberculosis control strategy.[20] Research to simplify or shorten the DOTS regimen is needed to make the treatment more widely available. Furthermore, the emergence of strains resistant to commonly used antibiotics has potentially devastating worldwide consequences. Current second-line treatments are too expensive, too complex, and too long, and therefore not realistic for field conditions. Priority should be given to simpler treatment guidelines that combine several antibiotics, which may not achieve the same level of efficacy of more complex protocols but are at least more practical for the field. Today, those with multidrug-resistant tuberculosis in countries with limited financial resources are not receiving treatment, which from a medical and humanitarian perspective is completely unacceptable.

Access to drugs for poor populations would be greatly improved by research into new forms of existing drugs (eg, sustained action or rectal formulation) and the development of simpler treatment guidelines (eg, "one-shot" or short treatments). This type of research cannot be developed unless technical and financial resources are made available and, more importantly, unless new efficacy criteria are applied to the treatment being studied.

Insufficient R&D for New Drugs

Increasing drug resistance, adverse effects, and the lack of feasibility of current protocols point to the need for greater R&D into new drugs for diseases found in the developing world. From 1910 to 1970, the pharmaceutical industry's contribution was crucial to the fight against endemic tropical diseases: trypanocides and antiamebic agents in the 1930s (Bayer, Rhône-Poulenc), chloroquine during World War II (Specia, Winthrop), and in the 1960s, the discovery of leading anthelmintics (Janssen). Since then, pharmaceutical companies have adopted a completely different strategy.[21]

Among the 1223 new chemical entities commercialized from 1975 to 1997, 379 (30.9%) are considered therapeutic innovations, but only 13 (1%) are specifically for tropical diseases (TABLE 2). Two of these 13 drugs are actually updated versions of previous products (new formulations of pentamidine and amphotericin B), 2 are the result of military research (halofantrine hydrochloride and mefloquine), 5 come from veterinary research (albendazole, benznidazole, ivermectin, oxamniquine, and praziquantel), and only 4 (0.3%) may be considered direct results of R&D activities of the pharmaceutical industry (artemether, atovaquone, eflornithine, and nifurtimox).[22]

Thus, it appears that pharmaceutical R&D is abandoning tropical diseases. There are 4 main reasons for this shift:

1. Costs and Risks of R&D Relative to the Low Purchasing Power of Developing Countries. A typical R&D program (from initial results to registration) would cost approximately $160 million and take between 8 and 12 years to complete.[23] Moreover, a successful outcome is not guaranteed (as was the case with oltipraz, an antibilharzial agent abandoned during clinical trials).

2. A Shift to More Profitable Production. To cope with large investments and reduce duplicate spending, pharmaceutical companies started an unprecedented cycle of industrial consolidation and mergers at the end of the 1980s (eg, Glaxo and Wellcome, Sandoz and Ciba-Geigy, Roche and Synthex). This consolidation focused on the most profitable segments of the market (infectious diseases, cardiovascular conditions, cancer, dermatology, and neurology), leaving tropical medicine largely out of the equation.

3. Competition and Counterfeiting of Drugs. Some drugs patented in the developed world are being copied in developing countries, where patent rights of pharmaceutical products are not protected. Such production competes, sometimes fiercely, with the innovating laboratory. For example, Bayer Laboratories, the patent holder of praziquantel, was outpriced by Shin Poong, a Korean laboratory that had developed a less-expensive manufacturing process.[24] In addition to copies of drugs resulting from a different notion of intellectual property rights, there are cases of pure and simple piracy (appropriation of the name and appearance of a trademark drug) that are frequent in countries where informal markets play a significant role.[25]

4. Cost of Adhering to Quality Standards. There has been a general trend toward heavier regulations with which companies must comply to obtain approval before marketing a drug product, which raise the costs of clinical development. The necessity of minimizing therapeutic risks leads to reinforcement of various quality standards (good clinical, laboratory, and manufacturing practices).[26] In practice, when clinical development incidentally identifies a promising product (eg, eflornithine for African trypanosomiasis) or a new indication (eg, atovaquone for malaria, ivermectin for onchocerciasis, and albendazole for lymphatic filariasis) for the treatment of tropical diseases, the manufacturer often decides not to market the drug,

knowing it would be too expensive. The company generally decides to either make exceptional arrangements (eg, donations in the cases of albendazole, atovaquone, and ivermectin) or takes negative action (eg, discontinued production of eflornithine).

GLOBALIZATION AND DRUGS: QUESTIONS AND CONCERNS

A discussion of the current landscape in the area of drug availability would not be complete without a consideration of the increasing globalization of the pharmaceutical industry and the potential implications of recent and upcoming world trade agreements.

Drugs: Another Industrial Product?

The General Agreement on Tariffs and Trade (GATT) was signed on April 15, 1994, and was replaced by the WTO agreement, signed in 1997.[27] This agreement ratifies the worldwide implementation of a free-trade economy. Its enforcement with regard to the pharmaceutical sector raises certain concerns. Two types of provision seem particularly important for pharmaceutical companies in developing countries: that which puts an end to protectionist measures and that which defines as mandatory the protection of patents on drugs and their respective manufacturing processes, such as the Trade Related Aspects of Intellectual Property Rights Agreement (TRIPS). This is important because many developing countries do not fully acknowledge patent protection rights for pharmaceuticals.

Newly Invigorated Research?

Directors of pharmaceutical companies in the developed world have stated repeatedly that the reason for not conducting research on tropical diseases is the lack of protection for innovations in some developing countries, which would also explain their limited investments in the countries concerned.[28] The moment the enforcement of patent protection becomes effective (in developing countries, no later than January 1, 2006) tropical disease research should logically start again, funded by Western companies or by manufacturers in developing countries.

However, it is unlikely that Western manufacturers will devote much of their effort to nonsolvent populations, with or without patents. Manufacturing companies in developing countries may actually be motivated to invest more in research for new drugs, but such investments will essentially respond to the need to shift their innovation capacity away from finding ways to copy the patented drugs of developed countries and toward discovering new drugs.[29] All things considered, tropical research may not have a more promising future, even if patents are widely enforced.

Table 2. Tropical Disease Drug Development Output, 1975-1997*

Indication	Product	Year Marketed or Approved	Development Context
Marketing Approval of New Chemical Entities for Treatment of Tropical Diseases			
Malaria	Artemether IM	1997	Chinese academy discovery; public/private collaboration (WHO-TDR/Rhône-Poulenc-Rorer); Rhône-Poulenc-Rorer/Kunmig (China) agreement
	Atovaquone/proguanil	1992/1997	Glaxo-Wellcome antimalarial research; initially orphan product designation and approval for *Pneumocystis carinii* pneumonia associated with human immunodeficiency virus
	Halofantrine hydrochloride	1992	US Department of Defense discovery (WRAIR); public/private collaboration (WHO/WRAIR/SmithKline Beecham); US orphan product designation and approval for acute malaria
	Mefloquine	1987	US Department of Defense discovery (WRAIR); public/private collaboration (WHO/WRAIR/Hoffman LaRoche); US orphan product designation and approval for acute malaria
Human African trypanosomiasis	Eflornithine hydrochloride	1990	Hoechst Marion Roussel; US orphan product designation and approval for human African trypanosomiasis (*Trypanosoma brucei gambiense*)
	Nifurtimox	1984	Veterinary R&D (Bayer)
Schistosomiasis	Oxamniquine	1981	Veterinary R&D (Pfizer)
	Praziquantel	1980	Veterinary R&D (Bayer); public/private collaboration (WHO/Bayer)
Helminthic infections	Albendazole	1987	Veterinary R&D (SmithKline Beecham)
	Benznidazole	1981	Veterinary originally (Roche)
Onchocerciasis	Ivermectin	1989	Veterinary R&D (Merck); public/private collaboration (WHO/Merck)
New Indications for Chemical Entities			
Human African trypanosomiasis	Pentamidine isetionate	1950/1984	Rhône-Poulenc-Rorer; galenic reformulation (mesylate to isetionate); US orphan designation and new approval only for *P carinii* infection
Leishmaniasis	Amphotericin B lipid complex	1962/1996	NeXstar; galenic reformulation of amphotericin B in liposomes; US orphan designation and approval only for treatment of invasive fungal infections

*WHO indicates World Health Organization; TDR, Tropical Disease Research; WRAIR, Walter-Reed Army Institute of Research; and R&D, research and development. Products are listed by international nonproprietary names.

Increasingly Prohibitive Prices?

A study sponsored by US pharmaceutical companies shows that granting drug patents does not tend to increase the price of drugs on the market.[30] This study, however, does not examine the prices of new innovative drugs and declares that, logically, the price of these new drugs should be higher. Naturally, when the manufacturing company is assured that its product cannot be copied, it holds a stronger position to negotiate prices with public health authorities. Moreover, the liberalization of international pharmaceutical trade entails the development of parallel imports between countries where the same drug is sold at different prices. Pharmaceutical companies, which are consequently less inclined to grant significantly lower prices to less developed countries, may instead set unique worldwide prices or delay marketing their drugs in developing countries.[28] In either case, access to drugs is jeopardized.

RECOMMENDATIONS

WHO's Revised Drug Strategy and the essential drugs concept are still key strategies to help improve access to essential drugs and worldwide health. The essential drugs concept is evidence based, is simple, promotes equity, and is rooted in firm public health principles. WHO's assistance to countries and advocacy work to promote the essential drugs concept and support countries in the formulation and implementation of national drug policies has resulted in change for the better. This strategy is a proven success but it needs to be continued and strengthened, and new ways of implementation have to be explored, given the changing context. In this spirit, the following recommendations are made with respect to the 4 main issues that have been developed in this article.

Procurement of Quality Drugs

To improve the quality of existing drugs and their procurement, it is important to develop a permanent "Observatory of Drug Quality," established by WHO in collaboration with organizations involved in the provision of essential drugs (eg, UNICEF, World Bank, the European Union, and nongovernmental organizations), that would oversee the implementation of adequate and effective control procedures. The practical knowledge acquired by international organizations to ensure the quality of generic drugs must be shared with health authorities in developing countries. Invitations to bid, required by big sponsors such as the World Bank, European Union, and the US Agency for International Development, must combine quality criteria and lower costs. Furthermore, procurement of drugs should be centralized at a national level to reinforce the responsibility of governments to make procurement, quality control, stock management, and distribution of essential drugs a priority.

Increased Availability

To provide better access to effective treatments for people in greatest need, several initiatives must be launched now, even if their results will not be realized immediately. In the short-term, practical solutions involving the various partners must be found to maintain the production of essential drugs. By establishing public health priorities, new high-priced drugs must be made available to the poor through solutions similar to those implemented for Expanded Programme on Immunization vaccines, for which the supply is guaranteed by UNICEF. These drugs could be made available by creating centralized purchase funds whereby manufacturers would be guaranteed large sales volumes (financed by existing public and private funds). The funds would also set forth, by consensus, compliance with drug indications. Finally, operational research in the field must be promoted and developed in close collaboration with health care professionals in developing countries. Such research should produce simple, efficient, and low-cost protocols without losing sight of the risk-benefit factor for the poorest countries.

Restart of R&D

In an attempt to offset this costly structural evolution in the pharmaceutical industry, several public and private initiatives have attempted to introduce public health criteria in R&D strategies. The 1975 Special Programme for Research and Training in Tropical Diseases (sponsored by the United Nations Development Programme, World Bank, and WHO) has had outstanding results in strategic research (eg, entomology and pathogenesis) and has bolstered research potential (eg, epidemiology and training). However, strategies for product R&D that were actually launched in 1994 have yet to produce any convincing results.[31] Nevertheless, this program has succeeded in raising awareness and has promoted reflection on potentially effective tools, even if most projects focus exclusively on malaria (eg, Multilateral Initiative on Malaria). The US Orphan Drug Act implemented in 1983 also has produced significant results for rare diseases (157 new drugs were commercialized and 837 new indications were developed from 1983 to 1997), but no real impact has been seen with respect to tropical diseases.[32] We can therefore conclude that while such initiatives may occasionally boost the development of new drugs (eg, derivatives of artemisinine and pyronaridin), they are unable to significantly redirect R&D toward tropical diseases. In the midterm, a legal and fiscal framework must be developed to spur R&D on tropical diseases or related areas, similar to those developed in the United States for orphan drugs used in rare diseases.

Humanizing the WTO Agreements

On the whole, it is regretful that WTO agreements contain no specific provisions that would guarantee both funding for ambitious tropical pharmaceutical research and realistic pricing of potential drugs. However, some developed countries were able to protect vulnerable economic and business sectors (eg, textiles, agriculture, and culture). One can understand why wealthy countries demand that developing countries comply with regulations on unfair competition. It is obvious that to meet pressing public health needs, we need new essential drugs. To develop them, we need

innovative research and industry. To fund new research, industry needs commercially viable results. It is therefore vitally important that the pharmaceutical industry collaborates with organizations like WHO, UNICEF, and the World Bank to identify the challenges and get a clearer view of what they can achieve together in developing sustainable markets for new tropical pharmaceuticals.

It must be remembered that those developing countries that are the main sources of cheap copies of patented drugs[31] are nevertheless relatively poor. Enforcing the WTO regulations will remove a source of affordable copies of innovative quality drugs on which the poorest countries depend. Developing countries, particularly the less advanced, should be encouraged to take advantage of the limited alternatives offered by the WTO agreements. Specifically, they should be able to obtain compulsory licenses whereby national authorities allow local manufacturers to circumvent patent rights (with certain conditions and in return for the payment of royalties to the inventor, as stipulated in article 31 of the WTO agreements).[33] Judiciously enforced, such an alternative seems to be the only recourse to balance the interests of the developing and developed world.

WHO is in a unique position to argue the case for health at an international level. Health-related nongovernmental and consumer organizations certainly have a supportive role to play, but WHO is the only intergovernmental organization with a formal international mandate to protect and advance health internationally. While WHO's authority in this area has suffered in the last decades, part of WHO's strategy should now be to clearly and unambiguously put health first and provide leadership in promoting access to essential drugs.

CONCLUSIONS

Access to essential drugs is a basic human right often denied to people in poor countries. However, it would serve no purpose to demand new public health or human rights in a manner that would suggest that such rights will soon become a reality. The current situation points to the opposite. For a great proportion of the world, health conditions are worsening, and without fundamental change in the pharmaceutical market, perspectives for improvement are not encouraging.

Acknowledgment: As a medical emergency organization present in 80 countries through 400 medical assistance projects, MSF undertakes to speak about the living conditions of those who cannot speak for themselves and to defend their right to vital health care. This article is mainly based on the field experience of MSF and our local partners.

We wish to thank the many field volunteers who, in one way or another, have participated in gathering the information contained in this article. Special thanks to Nathan Ford for reviewing the manuscript.

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Mr. MICA. We will also, without objection, leave the record open for 3 weeks, as I said, for additional statements. And we will be asking questions.

There being no further business to come before the subcommittee, this meeting is adjourned.

[Whereupon, at 5:11 p.m., the subcommittee was adjourned.]

[NOTE.—The report entitled, "Report on the Presidential Mission on Children Orphaned by AIDS in Sub-Saharan Africa: Findings and Plan of Action," may be found in subcommittee files.]

[The prepared statements of Hon. Bernard Sanders and Hon. Henry A. Waxman, and additional information submitted for the hearing record follow:]

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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.

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Thursday, July 22, 1999

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STATEMENT OF CONGRESSMAN HENRY A. WAXMAN
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HEARING ON THE U.S. ROLE IN COMBATTING THE GLOBAL HIV/AIDS EPIDEMIC

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, 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.

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July 20, 1990

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Statement Regarding The U.S. Response To The Global AIDS Crisis
Asia Russell, ACT UP Philadelphia

I submit these remarks as a representative of ACT UP Philadelphia, the AIDS Coalition to Unleash Power, a political organization dedicated to fighting AIDS through non violent direct action, and currently in its 12th year.

The scale of the AIDS crisis in poor nations is unfathomable to a wealthy nation such as ours: in countries in sub-Saharan Africa, the region bearing the greatest burden of the global AIDS crisis, AIDS related mortality has cut life expectancy as much as 25 years. By 2010, life expectancy in South Africa will plummet to 50 years. While in the US we celebrate the emptying of AIDS hospices, Zimbabwe has instituted new policies to keep its morgues open 24 hours a day, in order to accommodate overwhelming demand created by the AIDS related deaths.

United States Government policies have for years ignored the emergent needs of millions of infected people without access to crucial medical care and pharmaceuticals, prioritizing instead prevention efforts that are themselves terrifically underfunded. The United States has shown deliberate indifference to the urgent need for comprehensive treatment and care initiatives for poor nations overwhelmed by the AIDS crisis.

Medication overpricing by the pharmaceutical industry has kept life extending medications from 95% of people in the world with HIV. Less than 1% of AIDS medications are sold in sub-Saharan Africa, although 70% of people in the world with HIV live in that region.

In the case of compulsory licensing and parallel importing of pharmaceuticals, the United States has allowed the profit-driven interests of the drug industry to threaten the efforts of poor nations such as Thailand, South Africa, Brazil, and India to increase access to affordable medications to legal intellectual property policies. This unconscionable effort must stop.

The United States must use its power, wealth and resources to support nations struggling to respond to an overwhelming public health crisis, rather than to lobby on behalf of the pharmaceutical industry, the most profitable industry in the world, and to allow their greed to dictate national policy.

In order to mount an effective response to the global AIDS crisis in the areas of prevention, care, and treatment, the United States must:

Immediately cease bilateral pressure on nations attempting to exercise their rights to issue compulsory licenses or to practice parallel importing of necessary pharmaceuticals;

Allow all nations to create and implement compulsory licensing and parallel importing legislation in order to increase access to life saving medications inaccessible because of price; and

Exercise its power as a retainer of rights, licenses, or patents to essential HIV medications whose research and development was subsidized by taxpayer money, including ddI, d4T, and ritonavir by allowing an international health body to distribute such drugs at or below cost to people with AIDS in the developing world.

A recent study of the combination anti-HIV regimen hydroxyurea, ddI and d4t conducted in South Africa and Botswana illustrated that medical treatment consistent with First World standards of care can be successfully implemented in the Third World. Unfortunately, the study subjects no longer have access to the medications that were keeping them healthy—the investigator's funding ran out. The AIDS activist demands that the United States fund promising AIDS treatment initiatives in the developing world, and reverse domestic policy regarding compulsory licensing and parallel importing that is keeping medications out of the bodies of millions of poor people with AIDS.

QUESTIONS FOR JOSEPH PAPOVICH

1. Can you describe in detail the role of the Office of the U.S. Trade Representative in pressuring or advising South Africa to change its Medicines Act, and why your office asserted pressure? Did your office assist formulating or writing the State Department's report on this topic? Did your office coordinate with the State Department on its communications with South Africa, attempting to pressure them on this issue?

2. We have prepared a chronology of this Administration's efforts to strong-arm South Africa into rescinding its Medicines Act. Do you believe that South Africa's not-yet-implemented, law which attempts to ensure that the millions of infected people in their country can have access to drugs, merits this Administration's intense campaign to get them to rescind it?

3. Can you tell us specifically what treaty obligation or international law that South Africa has violated? Please don't refer to concerns or apparent "inconsistencies" now or in the future. Does the United States engage in parallel imports? Do you have information that South Africa would not negotiate a fair compensation to manufacturers of AIDS drugs should compulsory licensing occur?

4. Does the USTR believe that the South Africa government would violate any international law by permitting parallel imports of pharmaceutical drugs? And, if not, why has the US government been waging a two year war against parallel imports in South Africa?

5. Is it true that the WTO's rules do not allow a country to bring an action against another country for parallel importing?

6. Does the USTR believe the South African government is violating any international agreement by simply having broad legal authority to issue compulsory licenses, so long as its actual practice follows WTO rules regarding procedures? Does the USTR believe it is illegal under the WTO to have a compulsory licensing statute that singles out medicines? If not, why has the US government brought trade pressures against South Africa for considering compulsory licensing of essential medicines?

7. What has been the role the Vice President has played in communicating to South African officials his concerns regarding provisions of the Medicines Act, or regarding parallel imports or compulsory licensing issues? Has the Office of the Vice President been involved in this issue, and does it continue to have a role or support a position on this matter? Did you or your office communicate with the Office of the Vice President or its representatives regarding this hearing? Did officials of that office provide advice for your testimony before this Subcommittee? Explain the nature of any discussions and the advice that was given.

8. What has been the role of the European Union countries during the U.S. - South Africa trade negotiations on intellectual property? With pharmaceutical companies located all over the world, have other governments pursued the interests of their drug companies as actively as the United States (the State Department report indicates that European governments preferred having the US lead the way on this issue)?

ADDITIONAL SUBMISSION FOR THE RECORD FOR MR. PAPOVICH

Submitted during the hearing by Representative Schakowsky (D-IL)

Ms. Schakowsky:

"I wanted to ask Mr. Papovich if you would provide us with the language that would be TRIPS-compliant and not subject any country to any Special 301 designation and still allow for compulsory licensing and parallel importing."

(Please contact the subcommittee for additional context or information, 225-2577.)

House Government Reform
Subcommittee on Criminal, Justice Drug Policy & Human Resources
Questions Submitted for the Record By Representative Schakowsky
July 22, 1999

1. Can you describe in detail the role of the Office of the U.S. Trade Representative in pressuring or advising South Africa to change its Medicines Act, and why your office asserted pressure? Did your office assist formulating or writing the State Department's report on this topic? Did your office coordinate with the State Department on its communications with South Africa, attempting to pressure them on this issue?

Answer 1:

Under the "Special 301" provisions of the Trade Act of 1974, Congress directed the U.S. Trade Representative (USTR) annually to identify foreign countries that deny adequate and effective protection of intellectual property rights and to publish a list of countries so identified on April 30 of each year. The statute also requires USTR to identify as "Priority Foreign Countries" those countries that (1) have the most onerous and egregious acts, policies and practices which have the greatest adverse impact (actual or potential) on the relevant U.S. products; and (2) are not engaged in good faith negotiations or making significant progress in negotiations to address these problems. In identifying countries that deny adequate and effective protection of intellectual property rights, but whose practices do not satisfy the statutory criteria for Priority Foreign Country, USTR has customarily placed countries on a Priority Watch List or a Watch list in order to signal concern, facilitate continued monitoring of the situation and urge improvements in protection.

Congress amended Special 301 in the Uruguay Round Agreements Act to clarify that a country may be found to deny adequate and effective intellectual property protection even if it is in compliance with its obligations under the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).

Each year USTR, in close consultation with other agencies, examines the level of intellectual property protection afforded by our trading partners. We analyze both intellectual property legislation and enforcement activity to arrive at our determination. We draw on the reporting from U.S. embassies and consulates overseas, but we also receive input from industry associations, individuals, and even foreign governments.

USTR has never identified South Africa as a "Priority Foreign Country," despite requests from U.S. industry that we do so. Instead, South Africa has been kept on the "Watch list" (our lowest administrative signal of concern). South Africa was placed on the Watch list in 1998 and retained on that list in 1999 because of our concern that Article 15(c) of the Medicines Act grants the Health Minister broad and unspecified powers to abrogate

patent rights, as well as our concerns about deficiencies in the protection of confidential test data and copyrights. The decision to reject the industry recommendation to identify South Africa as a Priority Foreign Country reflected our recognition of South Africa's decision to suspend implementation of Article 15(c) of the Medicines Act until pending litigation is resolved, and (then Deputy) President Mbeki's commitment to resolve the matter.

Following the normal interagency process, USTR was one of several agencies that reviewed the State Department report on the Medicines Act. Again following standard practice, USTR and other relevant agencies and offices have worked in coordination with the State Department in developing communications with South Africa aimed at finding a solution that ensures that the health concerns of South Africa can be addressed in a TRIPS-consistent manner.

2. We have prepared a chronology of this Administration's efforts to strong-arm South Africa into rescinding its Medicines Act. Do you believe that South Africa's not-yet-implemented law which attempts to ensure that the millions of infected people in their country can have access to drugs, merits this Administration's intense campaign to get them to rescind it?

Answer 2:

We acknowledge the serious AIDS crisis in Africa, including in South Africa. Moreover, we appreciate that the government of South Africa has undertaken to improve access to quality health care for all its people. This is a goal the entire Administration fully endorses and supports.

However, we are concerned that Article 15(c) of the Medicines Act grants the Health Minister broad and ambiguous powers to abrogate patent rights. The WTO TRIPS Agreement establishes specific conditions that a WTO member must follow if it authorizes use of a patent without the patent owner's consent. The South African Medicines Act does not provide for any of these conditions and no regulations have been issued that would ensure compliance with the TRIPS Agreement.

The goal of our on-going dialog with South Africa is to chart a course that assists in improving access to affordable medicines, while not undermining the financial incentives that fuel continued research and production of new medicines or raising concerns about the safety and efficacy of imported drugs. We are seeking a solution that ensures that the health concerns of South Africa can be addressed in a TRIPS-consistent manner. We firmly believe that achieving this goal merits the attention of this Administration.

3. Can you tell us specifically what treaty obligation or international law that South Africa has violated? Please don't refer to concerns or apparent "inconsistencies" now or in the future. Does the United states engage in parallel imports? Do you have information that South Africa would not negotiate a fair compensation to manufacturers of AIDS drugs should compulsory licensing occur?

Answer 3:

As drafted, the South African Medicines Act gives the South African Health Minister the authority to violate the TRIPS Agreement. U.S. law does not permit parallel imports of patented pharmaceutical products. The South African patent law provides authority for granting compulsory licenses, and establishes the requirement to pay compensation to the patent holder. Rather than use the pre-existing authority under the Patent Act to grant compulsory licenses, the South African government passed a separate statute, the Medicines Act, that also would allow compulsory licensing and establishes no such requirements for compensation to the patent holder.

4. Does the USTR believe that the South African government would violate any international law by permitting parallel imports of pharmaceutical drugs? And, if not, why has the U.S. government been waging a two year war against parallel imports in South Africa?

Answer 4:

The TRIPS Agreement contains provisions that grant patent holders certain rights, one of which is the exclusive right to prevent third parties from importing a product without the patent owner's consent. Thus, parallel imports of pharmaceuticals generally are prohibited under the TRIPS Agreement. However, Article 6 of the Agreement states that issues related to the exhaustion of rights, such as parallel imports, are not covered by WTO procedures governing dispute settlement. Furthermore, TRIPS allows countries to make limited exceptions to exclusive rights in certain circumstances.

As a policy matter, this Administration generally does not support policies that allow for the parallel importation of pharmaceuticals because such imports compromise intellectual property rights and raise concerns about the safety and efficacy of imported drugs. We realize, however, that HIV/AIDS is a special case that may require special measures. Thus, while we continue to believe compromising intellectual property rights is not the solution to the greater problem of HIV/AIDS, in this particular case we raise no objection to parallel importing of pharmaceuticals on the part of South Africa, as long as it is done in a way that complies with TRIPS. Of course, we also want to work with South Africa to ensure the safety and efficacy of any pharmaceuticals that are parallel imported.

5. Is it true that the WTO's rules do not allow a country to bring an action against another country for parallel importing?

Answer 5:

Article 6 of the TRIPS Agreement states that issues related to the exhaustion of rights (parallel imports) are not covered by WTO procedures governing dispute settlement. Therefore no country can bring a formal dispute settlement case against another WTO Member involving parallel imports. Nothing in the Agreement, however, prevents countries from expressing concerns about such practices through consultations or taking other WTO-consistent measures to address such concerns.

6. Does the USTR believe the South African government is violating any international agreement by simply having broad legal authority to issue compulsory licenses, so long as its actual practice follows WTO rules regarding procedures? Does the USTR believe it is illegal under the WTO to have a compulsory licensing statute that singles out medicines? If not, why has the US government brought trade pressures against South Africa for considering compulsory licensing of essential medicines?

Answer 6:

We engaged the South Africans because we are concerned that Article 15(c) of the Medicines Act grants the Health Minister broad and ambiguous powers to abrogate patent rights. The United States has consistently asked for clarification from South Africa that it will use the Medicines Act only to engage in compulsory licensing and parallel importation in a manner consistent with the TRIPS Agreement, and not in any other way that would undermine patent rights. The TRIPS Agreement prohibits discrimination in the enjoyment of patent rights by field of technology. The Agreement also establishes specific conditions that a WTO member must follow if it authorizes use of a patent without the patent owner's consent, including specific rules that govern compulsory licensing. The South African Medicines Act does not provide for any of these conditions and no regulations have been issued that would ensure that the TRIPS requirements would be met.

7. What has been the role the Vice President has played in communicating to South African officials his concerns regarding provisions of the Medicines Act, or regarding parallel imports or compulsory licensing issues? Has the Office of the Vice President been involved in this issue and does it continue to have a role or support a position on this matter? Did you or your office communicate with the Office of the Vice President or its representatives regarding this hearing? Did officials of that office provide advice for your testimony before this Subcommittee? Explain the nature of any discussions and advice that was given.

Answer 7:

In August of last year, the Administration proposed a framework for resolution of our differences concerning South Africa's Medicines Act in the context of the U.S. - South Africa Binational Commission chaired by Vice President Gore and (then Deputy) President Mbeki. The Vice President's Office and a number of other relevant agencies work together through this framework in our on-going dialogue with the Government of South Africa on these issues.

The intent of the U.S. proposal was to bring together an experts group including all relevant decision makers – trade, health, and intellectual property – to reach our mutual goal of bringing better healthcare to the people of South Africa while assuring adequate and effective protection of intellectual property. Although neither government-to-government nor industry-to-government discussions have yet resulted in a resolution of the differences that exist, we are encouraging continued dialogue to find a solution that ensures that the health concerns of South Africa can be addressed in a TRIPS-consistent manner.

With respect to the testimony that was provided before this Subcommittee, the Administration's standard process for preparing and clearing testimony was followed. A draft was prepared by the agency that was to testify, in this case USTR, and it was circulated to all relevant agencies, including the Vice President's Office, for clearance.

8. What has been the role of the European Union countries during the U.S.-South Africa trade negotiations on intellectual property? With pharmaceutical companies located all over the world, have other governments pursued the interests of their drug companies as actively as the United States (the State Department report indicates that European governments preferred having the U.S. lead the way on this issue)?

Answer 8:

We understand that certain European governments are actively consulting with the Government of South Africa about the concerns of their pharmaceutical industry with the Medicines Act. As noted in the State Department report, we understand that French President Chirac raised France's concerns during his July 1998 state visit to South Africa, and that the Presidents of Switzerland and Germany also have raised the issue with (then Deputy) President Mbeki.

Supplemental Question: I wanted to ask Mr. Papovich if you would provide us with the language that would be TRIPS-compliant and not subject any country to any Special 301 designation and still allow for compulsory licensing and parallel importing.

Answer:

The question appears to rest on a premise that TRIPS compliance guarantees that a country will not be identified under Special 301. However, as directed by Congress in the Section 301 and Special 301 statutes, USTR considers that "a foreign country may be determined to deny adequate and effective protection of intellectual property rights, notwithstanding the fact that the foreign country may be in compliance with the specific obligations of the [TRIPS Agreement]." 19 U.S.C. §2242(d)(4); *see also* 19 U.S.C. §2411(d)(3)(B). Thus, a country's TRIPS-compliance is an important consideration in the Special 301 process, but not the only one. Special 301 designations are made by the USTR on a country-by-country basis, after a full inter-agency review, and take into account the entire picture of intellectual property protection in that country and any other relevant facts.

With respect to compulsory licensing and parallel importing under TRIPS, the following points that would be relevant to fashioning language are noteworthy: The TRIPS Agreement allows compulsory licensing under certain circumstances. Thus, language that would allow compulsory licensing would need to adhere strictly to the conditions set forth in TRIPS. The TRIPS Agreement provides patent owners with the exclusive right to prevent third parties from importing patented products without the patent owner's consent, but provides that issues concerning the international exhaustion of intellectual property rights are not subject to dispute settlement in the WTO. The TRIPS Agreement allows countries to make limited exceptions to exclusive rights under certain conditions.

QUESTIONS FOR DR. JOHN KILLEN

1. Are enough resources now being devoted to HIV/AIDS research, both to vaccine development and drug treatments? Does NIH have any projections as to when HIV/AIDS vaccines might be available for the public? Does NIH place a greater emphasis on HIV/AIDS vaccine research than drug treatments?

2. If AZT is a superior drug for preventing the transmission of HIV from mother to unborn, but is more costly than other drugs such as nevirapine, is the immediate cost savings for the lower priced drug really cost effective in the long-term, considering the increased infections of children and related costs?

3. Does NIH work collaboratively with drug manufacturers in researching and developing new vaccines and treatments? Does the Government help to fund this research? If so, does NIH continue to include "Reasonable Pricing Clauses" in its "Cooperative Research and Development Agreements" (CRADAs) between NIH and companies? If not, what guarantees exist that companies will make drugs affordable for the drugs that were developed in large part with taxpayer dollars?

4. For what HIV/AIDS treatment drugs does the NIH currently hold patent rights? For these drugs, how has the NIH gone about issuing licenses to pharmaceutical companies? What have been the costs of such licenses? And finally, has any precedent been established for selling HIV/AIDS treatment drug licenses to the World Health Organization?

Responses to Follow-Up Questions from the July 22, 1999, Hearing on Global HIV/AIDS

Question 1: Are enough resources now being devoted to HIV/AIDS research, both to vaccine development and drug treatments? Does NIH have any projections as to when HIV/AIDS vaccines might be available for the public? Does the NIH place a greater emphasis on HIV/AIDS vaccine research than drug treatments?

Response: By any criteria, AIDS must be considered the great plague of the 20th century. The disease has already caused more than 11.7 million deaths worldwide since its appearance in the late 1970s. With an estimated 30.6 million current infections, and new infections occurring at the rate of more than 250,000 monthly, the potential magnitude of the HIV/AIDS pandemic is truly profound. In response to this pandemic, the National Institutes of Health (NIH) has developed a comprehensive biomedical and behavioral research program to better understand the basic biology of HIV, develop effective therapies to treat it, and design interventions to prevent transmission. For FY 1999, the U.S. Congress appropriated $1.8 billion to the NIH for the AIDS research program, which will ensure continued progress in these areas.

It is essential to sustain and increase the investment in AIDS research until effective ways are found for preventing and treating this disease on a global scale. There are three critical and related reasons to continue and to expand our AIDS research investment: *need, the multiplier effect, and scientific opportunity.*

Need

While the *overall* death rate due to AIDS has declined in the U.S., HIV incidence rates have not changed. Moreover, new HIV infections and AIDS-related deaths continue to increase dramatically in many subpopulations, particularly women and minorities. Throughout the developing world, including sub-Saharan Africa, the Indian subcontinent, and southeast Asia, the epidemic continues to rage. New epidemics are emerging and rates of HIV and AIDS are increasing in some parts of the world, such as Eastern Europe and China.

In the U.S. (as elsewhere), the epidemic actually consists of many sub-epidemics. AIDS continues to affect those most disenfranchised in our society--the poor, the homeless, and those with addictive or mental disorders. AIDS cases are rising among women, racial/ethnic minorities, heterosexuals, adolescents, drug users, and people over 50 years of age. AIDS remains a leading cause of death among all Americans aged 18 to 45 years old, and **the** leading cause of death among African-American males in that age group.

The U.S. HIV/AIDS epidemic is not isolated. The transmissibility of HIV--between individuals and across borders and populations--is what most defines the global pandemic and makes it imperative that the United States help address prevention and treatment needs worldwide.

Multiplier Effect

The transmissible nature of HIV also makes it radically different from non-transmissible diseases such as heart disease and cancer. Because HIV is an infectious disease, any intervention that

reduces the probability of transmission--breaking a link in the epidemic chain--has an effect that extends far beyond the treated or protected individual to an infinite series of potential infections that are averted. Preventing one infection is therefore preventing the potential for many other infections. The possibility for dramatic reductions in new infections--and ultimate control of the pandemic--exists for HIV/AIDS in a way that will never be possible for noninfectious diseases.

Scientific Opportunities

Investment in HIV/AIDS research to date has yielded a rich lode of knowledge, materials, and methods that have set the stage for a wide variety of new advances and interventions that will benefit HIV-infected individuals, those at risk of infection, and, in fact, individuals who suffer from a wide number of other life-threatening illnesses.

Treatment. Ground breaking AIDS research in basic biology, spearheaded by NIH, has revolutionized drug design that is benefiting the fight not only against AIDS, but against other diseases. This basic research was the foundation for the development of a new class of drugs, known as protease inhibitors, that are extending the length and quality of life for many HIV-infected individuals in this country. But the list of serious problems associated with these new therapies is long. Even with therapy, the virus has not been completely eliminated from the body and may still be transmissible. We do not know how long the benefit of therapy will last or whether immune function of treated individuals can be restored. There are many for whom the new drug regimens have not been effective or for whom the side-effects are not tolerable. Serious complications of therapy are being identified, including metabolic disorders and deforming lipid (fat) deposits. Many patients are unable to adhere to the complicated drug schedules. Drug resistant viral mutants are beginning to emerge, representing a new and dangerous threat to public health. It is an urgent challenge to develop simpler, less toxic, cheaper drug regimens; new generations of antiviral drugs directed against different viral components; therapies to reconstitute immune function in treated patients; and more effective methods to enhance access and adherence to complex therapeutic regimens.

Prevention. Important advances have also been made in diagnosis and prevention of perinatal HIV infection. NIH-funded clinical trials have demonstrated that therapeutic intervention protocols can significantly reduce perinatal transmission. A recent trial of nevaripine in Uganda demonstrated its effectiveness for potential use in developing countries. To reduce transmission further, additional research is necessary, including studies to better understand the timing, mechanisms, and risk factors of perinatal transmission; whether specific strains are more likely to be transmitted; the potential benefit of Caesarean section; and development of newer therapeutic regimens and immunotherapy. The virtual elimination of perinatal transmission in our nation and the world is a goal that must be vigorously pursued.

Heterosexual transmission has been the chief route of HIV infection in most of the world, and accounts for an increasing proportion of new infections in the United States, particularly among women and racial/ethnic minorities. It is critical to develop new interventions that will have the greatest impact on these groups, for example, effective and acceptable female-controlled methods to block transmission of HIV, such as microbicides. We also are in great need of interventions that address the co-occurrence of HIV and other STDs, hepatitis, drug abuse, and

mental illness, and that account for the role of culture, family, and other social factors in the transmission and prevention of these disorders, especially in minority communities. While the AIDS epidemic in the United States has stabilized among white gay men overall, it is increasing among younger men who have sex with men, including men of color. It is crucial to develop interventions to address the specific behavioral and psychosocial risk factors prevalent among communities of young gay men. Drug users and their sex partners are the fastest growing segment of AIDS cases nationwide and in many other countries. High priority must be given to research regarding the phenomenon of addiction itself, as well as the complex interaction of alcohol, drug use, and poor impulse control. Scientifically-based interventions have been demonstrated to alter sexual and drug using behavior and reduce the risk of transmission among a number of population groups. But we are still far from realizing the full potential of such prevention research on a global scale.

Vaccines. The remarkable advances in HIV therapies and behavioral interventions notwithstanding, it is generally believed that true global control of the AIDS pandemic will require a safe and effective vaccine. Development of an AIDS vaccine presents a daunting scientific challenge, much more difficult than the formulation of effective vaccines for acute viral diseases such as measles, poliomyelitis, and smallpox. It is important to acknowledge that even when an effective AIDS vaccine is developed and delivered to people around the world, it will always be imperative to employ it in tandem with other approaches to prevention and treatment, if we are ever to control HIV/AIDS for the long run. NIH has doubled the level of funding for vaccine research over the past five years to a total of $200 million in FY 1999.

Summary

The continuing incursion of HIV infection and AIDS in populations and communities throughout the United States and the world, the uniqueness of HIV/AIDS as an infectious, debilitating disease, and the opportunity that ongoing advances in science affords to more effectively address the pandemic requires an intensive, sustained commitment to HIV/AIDS research now and in the foreseeable future. The NIH AIDS comprehensive research program balances the twin priorities of finding vaccines and other preventive measures for those who are not infected with the need to find more effective, less toxic, cheaper therapies for the millions of people around the world who are already infected.

Question 2: If AZT is a superior drug for preventing the transmission of HIV form mother to unborn, but is more costly than other drugs such as nevirapine, is the immediate cost savings for the lower priced drug really cost effective in the long-term, considering the increased infections of children and related costs?

Response: Unfortunately the cost of drug is only one factor that must be considered in this very complex issue. The long course regimen of zidovudine used in AIDS Clinical Trial Group protocol 076 (ACTG 076) is now the standard of care for HIV-infected pregnant women in the United States and is extremely effective in preventing mother-to-infant transmission of HIV. Two factors prevent its routine use around the world, particularly in developing countries where the epidemic is soaring. First, the ACTG 076 regimen costs approximately 80 times the amount that is spent per person annually for health care in many of these developing countries. Second,

the successful implementation of the 076 regimen requires the existence of and access to prenatal care early in pregnancy and a health care infrastructure, which are simply not available in most of the developing world.

Currently, women in most developing nations have no options regarding the reduction of HIV transmission to their babies. The NIH and the CDC believe that other effective regimens, which are not only cheaper but also simpler and more practical, offer the best hope for developing the most rapid acting therapy to address the epidemic of mother-to-infant HIV transmission. Previous studies had demonstrated significant reductions in transmission with shorter courses of AZT, but logistical and cost factors remain as impediments to its use in most of the developing world.

Nevirapine, as shown in the recently reported results of a study in Uganda, offers a simple, inexpensive alternative that has the potential for widespread use and profound reductions in mother-to-infant transmission of HIV, of a magnitude comparable to shorter courses of AZT

Background information on the nevirapine study is included as Attachments 1, 2, and 3.

Question 3: Does NIH work collaboratively with drug manufacturers in researching and developing new vaccines and treatments? Does the Government help to fund this research? If so, does the NIH continue to include "Reasonable Pricing Clauses" in its "Cooperative Research and Development Agreements" (CRADAs) between NIH and companies? If not, what guarantees exist that companies will make drugs affordable for the drugs that were developed in large part with taxpayer dollars?

Response: The NIH enters into Cooperative Research and Development Agreements (CRADAs) with the private sector to conduct collaborative research, as authorized by the Federal Technology Transfer Act of 1986, 15 U.S.C. § 3710a. Some CRADAs are entered into with drug manufacturers, and some are for the purpose of conducting research which may lead to the development of new vaccines and treatments.

Legislation does not permit the NIH to provide any funding to CRADA collaborators for research or other activities carried out under a CRADA.

Since April 1995, the NIH has not included any clauses related to pricing of the final product, but has undertaken licensing strategies to balance timely development and competition which we believe brings market forces to bear on new products. The following summary of the events that lead first to the use and then to the removal of a pricing-related clause in NIH CRADAs may be helpful.

The Bayh-Dole Act and the Federal Technology Transfer Act of 1986 (FTTA) were enacted by Congress to encourage Federal laboratories to secure intellectual property rights and convey them to commercial entities through licensing. The express intent of the legislation was to improve economic competition and to provide a financial return to the public in the form of royalty payments. There are no pricing considerations or criteria in either of these laws. In 1989, due to a concern related to the pricing of AZT, the NIH Patent Policy Board voted to include a standard clause (the so-called "reasonable pricing" clause) in its exclusive license

agreements and CRADAs as a statement of concern about the pricing of products developed under NIH exclusive licenses.

In 1993, the biotechnology and pharmaceutical industries began to express concern to NIH that the presence of pricing language in NIH exclusive license agreements and CRADAs was a serious impediment to companies' willingness to enter into these agreements. Among other issues, they noted there was no statutory basis for the clause. NIH also heard from its own scientists that the presence of the reasonable pricing clause was hindering their ability to interact effectively with industry scientists, a critical prerequisite to advancing new knowledge. NIH became concerned about the effect that chilly interactions with industry would have on both the NIH biomedical research mission and the goals of the FTTA.

In 1994, NIH held two public meetings to evaluate the effect of and continuing need for a reasonable pricing clause. Among others, NIH heard from patient groups, who testified that although product pricing was of concern to them, concern for pricing should be subservient to the continual search for new discoveries and the development of new products based on those discoveries. Such products will reduce morbidity and mortality and improve the public health. After fully evaluating the facts and testimony presented by numerous public groups, the NIH determined that the clause inhibited the formation of potentially beneficial scientific collaborations without providing an offsetting benefit to the public. In addition, NIH concurred with the view expressed by many who testified that the NIH, as a biomedical research organization, did not have the requisite expertise or legal authority to engage in price controls. In the spring of 1995, the clause was removed from the NIH model Exclusive License Agreement and CRADA.

Although there is no statutory basis for the NIH to mandate that companies having CRADAs will develop inventions into drugs and will sell those drugs at particular prices, the NIH has taken numerous steps since removal of the "reasonable pricing" clause to ensure that its licensing practices encourage competition. Rather than trying to exercise control over the price of the product, NIH has developed licensing strategies that seek to ensure as much market competition as possible, so that pricing and other issues of public access are moderated by market forces. When market competition is not possible or desirable in order to ensure the development of a new product, the NIH can still ensure appropriate access to products through monitoring and enforcement of its exclusive license agreements, which contain provisions by which companies agree to develop technologies within agreed-upon time frames.

NIH has developed and implemented several licensing strategies that balance new product development with appropriate market competition. First, the NIH gives preference to non-exclusive licensing, so more than one company can develop products in competition with one

another. In fiscal year 1998, 94 percent of the commercial development licenses executed by the NIH were non-exclusive.

Second, the NIH gives an exclusive license to a company only for those medical applications (called "fields of use") for which the company can demonstrate that it will achieve benchmarks and milestones toward commercial development. In the case of a CRADA, the exclusive license usually covers only the applications that were within the scope of the research plan of the CRADA. Of the ten exclusive licenses entered into in FY 1998, three (30%) provided only specifically defined fields of use, leaving other applications of the technology available to license to other companies for development. The other seven (70%) of the licenses were for specific fields of use which in effect encompassed all NIH patent rights for a narrowly granted patent; therefore, the patent itself restricted a company's use of a particular technology. None of the exclusive licenses granted a blanket use for all fields of use if there were multiple uses for a particular technology.

Third, all NIH exclusive licenses can be modified (e.g., made non-exclusive so another company can enter the market) or terminated for failure to comply with the terms of the license. One such term is the requirement to keep the licensed technology available to the public. The terms of the license would be used by NIH as one means of addressing an egregious pricing practice if it arose. Since FY 1996, 180 licenses were either modified or terminated, often for failure to comply with various terms of the license agreement. Over 1,000 licenses remain active. No licenses have been terminated due to pricing concerns.

Since the enactment of federal technology transfer laws, there has been legitimate debate about the nature and extent of "return" that the public should expect on the commercialization of taxpayer-supported federal research. A panel, substantially comprised of patient groups and health activists convened by NIH in 1994 to study and make recommendations on the reasonable pricing clause, developed the following hierarchy of returns on the public's investment in biomedical research at NIH: First, NIH should foster scientific discoveries. Second, NIH should ensure rapid transfer of these discoveries to the bedside. Third, NIH should be concerned with accessability of resulting products to patients, and fourth, NIH should obtain royalties. This hierarchy is reflected in the PHS Patent and License Policies which provide the foundation for the NIH technology transfer program.

Question 4: For what HIV/AIDS treatment drugs does the NIH currently hold patent rights? For these drugs, how has the NIH gone about issuing licenses to pharmaceutical companies? What have been the costs of such licenses? And finally, has any precedent been established for licensing HIV/AIDS treatment drug protection to the World Health Organization?

Response:
The following are products which involve an NIH patented technology, are therapeutics for HIV infection or AIDS-related conditions approved by the Food and Drug Administration, and are currently on the market:

HIV Infection:

Videx–a synthetic purine nucleoside analogue also known as didanosine or ddI, which is active against HIV. Videx functions by inhibiting the replication of HIV in humans. This was the second drug approved for such use by FDA.

Hivid–a synthetic purine nucleoside analogue also known as zalcitabine or ddC, which is active against HIV. Hivid functions by inhibiting the replication of HIV in humans. This was the third drug approved for such use by FDA.

AIDS-related Conditions:

Vitravene–a phosphorothioate oligonucleotide that inhibits cytomegalovirus (CMV) infections in the eye. Such infections more commonly occur in immunocompromised patients with resultant damage to the retina. This is the first antisense therapeutic approved for use in humans.

Sporanox Oral Solution–an oral formulation of the anti-fungal agent itraconazole that is used for the treatment of painful and debilitating fungal infections of the esophagus or the mouth, commonly called thrush.

NeuTrexin–an injectable version of trimetrezate glucouronate used to treat Pneumocystic carinii pneumonia (PCP), a lung infection which often occurs in people with poorly functioning immune systems.

These drugs have been licensed through standard NIH licensing procedures and in accordance with public law and regulations.

The costs associated with the development of such licenses constitutes highly sensitive confidential business information that is closely held by companies and protected under the Freedom of Information Act (FOIA). In order to protect the legitimate business interests of the companies that have chosen to work in partnership with us, we prefer not provide any specific information that relates to license financial terms, scope of license, milestones and royalties. We are concerned about the confidentiality of this information and respectfully ask for the opportunity to discuss this matter further should you wish to continue to pursue the information.

The NIH has had a long history of interaction with the World Health Organization (WHO). This includes collaborating on a variety of matters from treatment strategies to being co-inventors of a technology in the field of reproductive medicine. Negotiations are now underway with a commercial entity to license this joint technology. The NIH has had limited discussions with WHO regarding the licensing of NIH inventions to the organization to permit it to develop and distribute a product. WHO staff involved in those discussions have not expressed an interest in obtaining licenses to develop technologies and manufacture products.

QUESTIONS FOR SANDRA THURMAN

1. According to the Washington Post (July 20; page A4), the recent White House announcement of $100 million for prevention and treatment of HIV/AIDS will come from existing funds, including $48 million for a program that provides "education, counseling and blood screening." Can you tell us specifically where this money is coming from, and how it will be used? How much will go directly for drug treatment for people who are HIV positive and how would they be selected?

2. Congressman Berry testified that he "...welcomes the Administration's proposal to increase the U.S. investment in fighting HIV/AIDS in Africa by $100 million...but noticeably it will not help one more patient get life-saving medicines that are now available." What would you recommend to address the needs of over twenty million infected persons who are in need of treatment? Would you support the government's making available to the World Heath Organization the drugs that the US has the patent rights to? Don't you think that relying upon periodic announcements of recommended aid could raise false hopes, and that more comprehensive approaches are required to save significant lives, such as has occurred in the U.S. with effective drug treatment? What else would you recommend to help these countries get affordable treatment?

3. Since you've seen the situation in South Africa first-hand, would you describe it as an emergency? If so, wouldn't you rather see the United States government respond to this crisis as if it *were* an emergency, rather than threatening trade retaliation against a country like South Africa for enacting a law that appears to be in accordance with existing international laws and agreements, and has not even been implemented as yet?

4. Is your office on record as opposing parallel imports or compulsory licensing of AIDS treatment drugs by nations that are experiencing major AIDS epidemics? What is your policy regarding the expansion of HIV/AIDS drug availability in developing nations?

5. Do you support this Administration's "assiduous, concerted campaign to persuade the Government of South Africa" (state department report) to give up on their Medicines Act?

6. Do you think that drug treatments should be withheld from the millions now suffering due to fears that new strains of HIV/AIDS might develop? If so, should this policy apply to the U.S.? Why or why not?

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

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

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

In brief, our investment breakdown is as follows:

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

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

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

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

The Administration believes that aspects of a comprehensive HIV/AIDS strategy include encouraging the Congress to enact the $100 million in new global AIDS spending for

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

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

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

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

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

Of course, any effort to expand HIV/AIDS drug availability must include a broad-based effort to expand and improve the health care delivery system in nations where as many

as 95% of the people have no access to care and treatment of any kind. This issue is beyond matters of trade law or the price of pharmaceuticals; it demands a dramatic and unprecedented worldwide commitment to the cause - the kind of commitment that can be generated in part by keen and continuing attention by Members of Congress.

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

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

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

QUESTIONS FOR DR. JOHN SIEGFRIED

1. How do drug companies determine drug prices internationally? Why do drug prices vary so dramatically between countries, even neighboring countries? Is this a product only of market forces?

2. You cite the dramatic impact that new drugs have had in prolonging lives in this country. Why isn't this desirable internationally? Why shouldn't the drug companies do everything possible to repeat this success abroad, including negotiating lower costs while making reasonable profits? By saving lives, wouldn't they be ensuring a large market for their products, over long periods of time

3. Isn't it true that some developing countries may lack expansive drug delivery systems because affordable drug treatments are not now available? If you provide the drugs, isn't it more likely that delivery infrastructures will develop?

4. In your testimony, you call for partnerships involving drug companies, international organizations, and medical and patient groups. I think that those with AIDS represent a large group internationally -- more than 34 million. What type of partnership do you recommend for those with immediate treatment needs?

5. A recent AIDS Action report cites the 15 largest pharmaceutical companies as spending $68 billion on marketing, advertising and administration, and $24 billion on research and development. If pharmaceutical companies focused less resources on marketing and advertising, would that provide more funds for research and development and greater drug availability?

6. In your testimony you mention that "54 medicines have been approved for HIV/AIDS and associated conditions." How many of these medicines are readily available in the developing countries that need them most?

Mara Guarducci
Director
Federal Affairs

PhRMA

April 19, 1999

Chairman John L. Mica
Committee on Government Reform
Subcommittee on Criminal Justice,
Drug Policy and Human Resources
B-373 Rayburn House Office Building
Washington, DC 20515

Attention Mason Alinger:

Enclosed please find answers to the follow-up questions for Dr. Siegfried on the July 22 hearing on global HIV/AIDS and the U.S. role in combating it.

If you need additional information, please do not hesitate to call.

Sincerely,

Mara Guarducci

Pharmaceutical Research and Manufacturers of America
1100 Fifteenth Street, NW, Washington, DC 20005 • Tel: 202-835-3485 • FAX: 202-835-3488 • E-Mail: mguarduc@phrma.org

SUBCOMMITTEE ON CRIMINAL JUSTICE, DRUG POLICY AND HUMAN RESOURCES

RESPONSE TO CONGRESSIONAL QUESTIONS FOR DR. JOHN SIEGRIED ON GLOBAL HIV/AIDS

SUBMITTED BY THE PHARMACUETICAL RESEARCH AND MANUFACTURERS OF AMERICA

August 19, 1999

1. How do drug companies determine drug prices internationally? Why do drug prices vary so dramatically between countries, even neighboring countries? Is this a product only of market forces?

Response:
The prices of drugs in any given country are the result of a complex mix of supply and demand factors, rather than being determined by drug companies alone. Countries, even neighboring countries, differ in important ways that may affect prices of all commodities, but particularly drugs, including living standards, income levels, differences in medical practice, disease and prescribing patterns, and consumer preferences, among others. These demand-side factors are part of the "market forces" that have an impact on drug prices. Another part of the equation is supply-side factors, including the costs of production, transportation and distribution, the length of time and cost required for obtaining drug marketing approval, as well as taxes, import tariffs, and other business expenses.

However, it would be incorrect to assume that drug prices are determined by market forces alone in most countries. In fact, most countries employ a variety of government-imposed reimbursement, price, volume, or profit controls that have a significant impact on the price of pharmaceutical products. As a result, it would be difficult to characterize the difference in drug prices across countries as being due solely to market forces.

While there are legitimate reasons for prices to differ across countries, such as income levels and morbidity and drug consumption patterns, differences are also often due to government interventions that distort market forces. Such efforts limit the industry's ability to generate returns for its investors, negatively impact investment decisions, generate costly government bureaucracies, distort competition, and most importantly, endanger the industry's ability to fund R&D to continue discovering and developing innovative products.

2. **You cite the dramatic impact that new drugs have had in prolonging lives in this country. Why isn't this desirable internationally? Why shouldn't the drug companies do everything possible to repeat this success abroad, including negotiating lower costs while making reasonable profits? By saving lives, wouldn't they be ensuring a large market for their products, over long periods of time?**

Response:
As a result of the pharmaceutical industry's tremendous investment in HIV/AIDS therapy, proper and careful use of drug treatment has had dramatic impacts, not just in the United States, but in many other countries around the world, including developing countries where the governments have made a commitment to investing in public health and HIV/AIDS treatment specifically. Of course it is desirable that every country around the world implement sound public health policies, including adequate resources, to decrease the mortality and morbidity caused by HIV.

What is crucial to understanding how to repeat the successes in dealing with HIV/AIDS is the realization that no single entity, be it national government, individual health ministry, international organization, or pharmaceutical company, is responsible for or able to deliver the success referred to in your question. Therefore, the issue is not that "drug companies" in and of themselves should do everything possible to repeat this success abroad, because "drug companies" are not solely responsible for this success. Rather, as stated repeatedly by UNAIDS, "experience shows that the challenges of access to AIDS-related drugs can best be met when the government enters in partnerships with other sectors. . . . At the same time, strategic partnerships are necessary at international level. UNAIDS is currently working with its Cosponsors and *several multinational pharmaceutical companies to improve access to drugs for persons living with HIV*." (Source: Access to drugs. UNAIDS Technical Update, October 1998, page 2. Emphasis added.)

Clearly, the "drug companies" are working to repeat the success the United States and other countries have demonstrated is possible in the face of the deadly scourge of HIV/AIDS.

3. **Isn't it true that some developing countries may lack expansive drug delivery systems because affordable drug treatments are not now available? If you provide the drugs, isn't it more likely that delivery infrastructures will develop?**

Response: It is true that the drug delivery systems in a number of developing countries are deficient. Again, as stated by UNAIDS, the obstacles to access to drug therapy are many, and include affordability, legal, infrastructural, distribution and cultural factors as serious impediments to drug delivery (UNAIDS, op. cit.) For example, no system can be effective without trained medical personnel. We do not believe it is likely that the availability of pharmaceutical products would significantly increase the availability of

trained medical personnel or the patient support services that are needed to effectively administer long-term HIV/AIDS care, including that based on pharmaceutical administration. For example, in the United States there is one physician per 420 members of the population, and the average for OECD/high economies is also 420. In Malawi, there is one physician for every 45,740 members of the population, and the average for low-income economies is one physician for every 6,760 members of the population. (Source: Investing in Health, World Development Report 1993, the World Bank, Table 28, page 292. Data are 1990 figures.) It is difficult to understand how providing drugs, even free of charge, will increase the number of physicians per capita.

Experience with major pharmaceutical donation programs, such as the Merck Mectizan® to eliminate onchocerciasis (river blindness) and SmithKline Beecham's recent partnership with WHO to eliminate lymphatic filariasis (elaphantiasis) by donating several billion doses of albendazole, are instructive. In both cases, the respective companies are donating the medicines free of charge, thus eliminating any affordability obstacle. Massive global efforts involving numerous partners, including national governments, WHO, private voluntary organizations, donor organizations, etc., are still required to design and administer effective eradication programs. Just making the drugs available in and of themselves did not necessarily spur the creation of adequate infrastructure and treatment protocols to eliminate either disease. Most importantly, the announcement of the donation programs did not create the political will at the national level to eradicate either disease. The commitment to disease eradication had to be created at the international level, driven by multisectoral partnerships. And, as noted above, it is this model of multisectoral partnership that the industry is already engaged in with UNAIDS. Finally, the onchocerciasis and lymphatic filariasis examples are also instructive because in both cases the treatment protocol consists of providing each patient with only one dose, and only once every 12 months. As effective HIV/AIDS treatment is vastly more complicated, the solutions to effectively treating HIV/AIDS in poor countries with inadequate public health systems are just as if not more complex.

4. **In your testimony, you call for partnerships involving drug companies, international organizations, and medical and patient groups. I think that those with AIDS represent a large group internationally – more than 34 million. What type of partnership do you recommend for those with immediate treatment needs?**

Response:
A first step to establishing effective partnerships to address immediate treatment needs must be the explicit recognition by national governments that HIV/AIDS treatment is indeed a public health priority. UNAIDS has identified the establishment of political will as a principal challenge to delivering HIV/AIDS treatment: "[I]n some countries, health-care infrastructure (chiefly the physical infrastructure of health-care facilities, both public and private) is too sparse to ensure adequate usage of drugs *even if these drugs were to be imported at no cost*. It will be a challenge in each country to objectively assess and prioritize the possible medical and public health interventions in the existing infrastructure

(as well as to assess country's needs), and to decide where it should be strengthened or expanded." (UNAIDS, op. cit., p. 8. Emphasis in original.)

Once the political commitment to HIV/AIDS treatment is established, there would seem to be many types of partnerships. This is precisely the focus of the UNAIDS pilot projects in a number of developing countries. As noted in the PhRMA testimony, Brazil provides an example of private/public partnership that addressed the need to provide immediate treatment to people living with HIV/AIDS. A pharmaceutical company worked with the Brazilian medical community to run clinical trials of a new antiretroviral drug. The company trained medical staff, expanded clinical facilities, and supervised treatment. As a result, many HIV/AIDS patients were successfully treated and demand for secondary and tertiary medical care decreased, with concomitant reduction in health care spending. With the transfer of information technology from the clinical trials, the Brazilian medical establishment was far better equipped to organize itself to deliver effective and appropriate HIV/AIDS treatment. (Source: U.S. International Response to HIV/AIDS, Department of State, January 1999, pp. 51-52.)

5. A recent AIDS Action report cites the 15 largest pharmaceutical companies as spending $68 billion on marketing, advertising and administration, and $24 billion on research and development. If pharmaceutical companies focused less resources on marketing and advertising, would that provide more funds for research and development and greater drug availability?

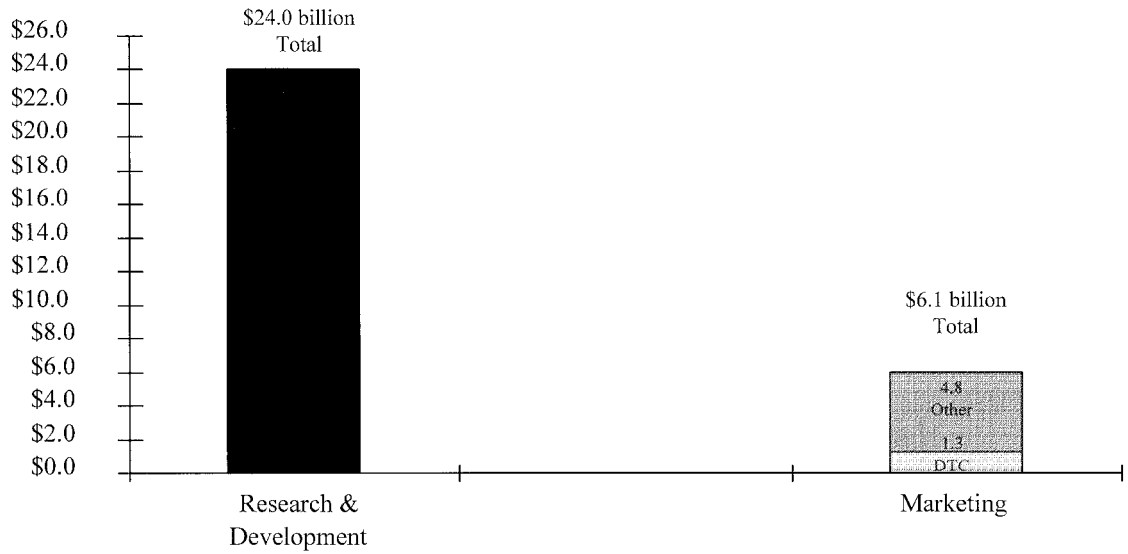
Response:
We are unfamiliar with the source of the $68 billion figure, but on its face it appears quite absurd. PhRMA survey, and data from IMS Health, Inc., indicate that American research-based pharmaceutical companies spent about $6.1 billion on marketing in 1998 (see, attached chart). This represents slightly more than 6 percent of sales revenue, compared to almost 21 percent of sales revenue invested in R&D.

On the issue of marketing generally, it is important to understand that unlike in other areas of commerce, efforts to market pharmaceutical products necessarily have a large educational component. Those marketing the products must often furnish a large number of health care providers with detailed information about the benefits of the products, when they should be used, and how they should be used. The amount of information necessary is more for newer products, especially those that treat newer diseases such as HIV/AIDS or rare diseases. Without this information, health care providers will not be able to use new products or may use them improperly. Pharmaceutical marketing is thus critical to the optimum use of pharmaceutical therapy, and as such is not a drain on R&D investment but rather is an investment in physician and patient knowledge.

6. In your testimony you mention that "54 medicines have been approved for HIV/AIDS and associated conditions." How many of these medicines are readily available in the developing countries that need them most?

Response:
We have not conducted any surveys on the availability of these medicines on a country-by-country basis. Consequently, we do not have comprehensive facts and figures on the global registration of these medicines. As we have emphasized, however, we note that the availability of HIV/AIDS therapies in a given country depends greatly on the political will to ensure that public health services and HIV/AIDS care is available to the population. The answer to the question of how many AIDS medicines are readily available to patients depends on how readily available the government and public health authorities have decided to make HIV/AIDS care, including but not limited to pharmaceuticals.

IN 1999, THE RESEARCH-BASED PHARMACEUTICAL INDUSTRY WILL SPEND THREE TIMES AS MUCH ON R&D AS ON MARKETING



Source: IMS Health and PhRMA, 1999

Note: Results expressed as a percent of sales. Marketing and sales data tabulated by IMS Health. R&D data from 1999 PhRMA Industry Profile.

QUESTIONS FOR DR. PETER LURIE

1. Do you feel that it is futile to attempt to treat large numbers of infected persons in developing countries due to insufficient medical professionals and infrastructures? Is this a reason for not expanding drug treatment to those nations?

2. Do you feel that drug companies and the United States benefit from vaccine and drug treatment research conducted in developing countries? Do we conduct this research fairly and reward participants appropriately?

3. What are some of the major problems that you see in expanding the availability of drug treatment in developing nations? How can these problems be overcome?

Public Citizen

Buyers Up • Congress Watch • Critical Mass • Global Trade Watch • Health Research Group • Litigation Group
Joan Claybrook, President

August 20, 1999

Representative John L. Mica
Chairman
Subcommittee on Criminal Justice,
Drug Policy, and Human Resources
Committee on Government Reform
B-373 Rayburn House Office Building
Washington, DC 20515-6143
Fax: (202) 225-1154

Dear Representative Mica:

Thank you for the opportunity to testify before your committee on the global HIV/AIDS epidemic on July 22 of this year. That hearing was one of the first occasions on which the U.S. Congress afforded the international dimensions of the epidemic significant attention.

In this letter, I respond to the three follow-up questions you mailed to me on July 28, 1999.

1. *Do you feel that it is futile to attempt to treat large numbers of infected persons in developing countries due to insufficient medical professionals and infrastructures? Is this a reason for not expanding drug treatment to those nations?*

Any consideration of the gravity of the AIDS epidemic must begin with the recognition that over 95% of current HIV infections are believed to be in the developing world. To in effect write off the developing world as somehow not appropriate for benefiting from the recent advances in anti-HIV therapy is to resign ourselves to having almost no global impact in treating this now-treatable disease.

In addition, there are important differences between developing countries in both their abilities and their desires to make anti-HIV drugs available. Argentina, Brazil, Colombia and Mexico have all begun to make anti-HIV drugs available to their populations. Other even poorer countries such as Botswana, Cote d'Ivoire, Senegal, Uganda, Zambia and Zimbabwe have focused on providing anti-HIV drugs to HIV-positive women to prevent transmission to their infants. Clearly, these countries believe that they have infrastructures adequate to support the administration of these drugs. Rather than using the grossly inadequate infrastructures of many developing countries to justify not providing needed therapies, we should be greatly increasing our investment both in the

infrastructural needs of the countries, which would have beneficial effects throughout the health system, and in paying for the drugs themselves.

But even if funding were not to be increased, the U.S. government could act today to increase access to these critical medications without spending a penny. Compulsory licensing and parallel imports, discussed extensively at your hearing, represent a no-cost method for the U.S. government to expand access to much-needed medications in developing countries. Instead, we have seen a sustained effort by the Clinton administration to put pressure on developing countries to not implement compulsory licensing or parallel importing mechanisms, even though these are perfectly legal under World Trade Organization rules. In so doing, the administration has placed the profit motives of multinational drug companies over the public health needs of desperately ill patients in developing countries.

The real point is that developing countries should be allowed to decide for themselves how much emphasis they wish to place on providing access to anti-HIV treatment drugs (as opposed to HIV prevention, drugs for other diseases or infrastructure improvements, for example). But for the world's economic superpower to force developing countries to abandon perfectly legal strategies, lest they lose access to U.S. markets, is to deny developing countries that choice.

2. *Do you feel that drug companies and the United States benefit from vaccine and drug treatment research conducted in developing countries? Do we conduct this research fairly and reward participants appropriately?*

There is every indication that drug companies plan to expand their drug testing into developing countries. We are extremely concerned that ethical standards for conducting clinical trials that are accepted in the U.S. will not be honored when this research is conducted abroad.

Three ethical issues are of particular concern. First, will drug companies and other sponsors of clinical trials ensure that adequate informed consent has been obtained from study participants? Study after study in developing countries has documented just how inadequate informed consent often is.

Second, will drug companies or funding institutions feel obligated to provide known effective therapy in clinical trials? The evidence from recent mother-to-infant HIV transmission studies conducted or funded by the U.S. government suggests that they often do not. Thousands of HIV-positive pregnant women received placebos when effective preventive therapy existed. Pharmaceutical companies will probably not prove more likely to provide these treatments.

Third, will drug companies and other sponsors feel obligated to provide the study drug, if it is proven effective, to local populations? Researchers' track record in this area is also extremely poor. The Council for International Organizations of Medical Sciences' ethics guidelines require that any treatment proved effective "be made reasonably available to

inhabitants of the underdeveloped community in which the research was carried out." But this precept is frequently violated, leading to cries of exploitation from developing countries as the knowledge generated by the research is used in industrialized countries and local residents fail to benefit.

The current situation with regard to the ethical conduct of clinical trials is likely to worsen. A coordinated campaign involving researchers both within the U.S. government and in the academic sector is now underway. The campaign is attempting to rewrite the major documents governing the ethical conduct of research so that informed consent requirements are relaxed and the obligation to provide known effective treatment is weakened for poor people, both domestically and abroad. A letter we published in the British medical journal The Lancet describing these proposed changes is attached, as is our article describing the perinatal HIV transmission trials.

3. *What are some of the major problems that you see in expanding the availability of drug treatment in developing nations? How can these problems be overcome?*

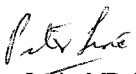
The pharmaceutical industry has raised two issues that they believe weigh against providing drug treatment: the potential development of strains of HIV resistant to existing drugs and the lack of health care infrastructure to actually administer the drugs. The former was the focus of my testimony before your Subcommittee, so I will not reiterate my comments in detail here. But there is no scientific basis for believing that patients will be worse off for receiving these drugs, even if drug-resistant strains emerge, compared to receiving no treatment at all. If anything, the scientific evidence is that drug-resistant strains are likely to be less aggressive than non-resistant strains.

The lack of infrastructure in many developing countries is certainly a massive public health problem. But the solution to this problem is to improve infrastructure, not to deny potentially life-saving drugs. One reason the infrastructure for HIV counseling and testing in many developing countries is so weak is that there is no incentive to improve it. In the absence of drugs to treat those diagnosed as HIV-positive, there are only limited reasons to expand HIV testing.

The real question before the Congress is what the U.S. government can do about a situation in which those most in need go without critical drugs. First, U.S. government spending on international health remains minuscule and needs to be greatly augmented. Second, the U.S. government should not simply hand over the patents for drugs it has played a major role in developing to drug companies without exacting agreements on pricing. Third, the Clinton administration's pressure on governments seeking to employ legal mechanisms such as compulsory licensing and parallel importing to expand drug access must end. Again, some countries do have the infrastructure to provide anti-HIV drugs, particularly in the setting of mother-to-infant transmission, but the policies promoted by the administration in effect summarily group all developing countries in a single category and then deny them a legal mechanism for promoting access to medications.

Thank you once again for the opportunity to share this information with you. If I can be of any further assistance, please do not hesitate to contact me.

Yours sincerely,



Peter Lurie, MD, MPH
Medical Researcher

QUESTIONS FOR DR. TIMOTHY DONDERO

1. The current number of infected Africans is staggering, and continues to increase. This trend is occurring in other developing countries around the world as well. Does CDC have any projections as to how this epidemic compares to other past or present international health threats? Isn't this epidemic truly unique and deadly -- and resulting in unprecedented death and destruction from a world health perspective?

2. Is it likely that new strains of HIV/AIDS can and will develop among untreated populations, due to the vast numbers of carriers around the world? Would wider drug treatment in developing nations significantly increase the risks of new strains of HIV/AIDS? Does CDC support a policy of not making HIV/AIDS drug treatments more available in developing nations?

3. Are the recently publicized problems with CDC dedicating its limited resources to programs or purposes other than those intended by the Congress (i.e., funding other activities than chronic fatigue research), also problems in the HIV/AIDS research? Is there disagreement within CDC regarding the funding levels of HIV/AIDS vaccine and drug treatment research?

Responses to Supplemental Questions from the Subcommittee on Criminal Justice, Drug Policy, and Human Resources - from hearing on July 22, 1999

1. **Question: The current number of infected Africans is staggering, and continues to increase. This trend is occurring in other developing countries around the world as well. Does CDC have any projections as to how this epidemic compares to other past or present international health threats? Isn't this epidemic truly unique and deadly–and resulting in unprecedented death and destruction from a world health perspective?**

Answer: CDC does not make formal projections of the HIV/AIDS epidemic internationally, that being the work of the Joint United Nations Programme on HIV/AIDS (UNAIDS). However, a rough epidemiologic comparison with other great epidemics of history suggests that the HIV/AIDS pandemic truly is unique and deadly. The only other great epidemics that come to mind are the bubonic plagues (*Yersinia pestis*) that struck Europe in the late middle ages, where as many as a third of the urban population died of plague; and the influenza epidemic of 1918-1919 where as many as 6 million died through the world, over half a million in the U.S. But while the plague and the "flu" epidemics were terrible, they were relatively short lived (since the disease had a short duration the survivors were immune, and the infections died out for lack of susceptible hosts).

By contrast, the HIV/AIDS epidemic continues to kill. Virtually everyone infected in developing countries eventually dies of the infection, and in some parts of the world the epidemic continues to intensify years after its beginning. The HIV/AIDS epidemic also differs from these other epidemics in that HIV is preventable, and the biologic and epidemiologic aspects of this epidemic are well understood.

2. **Is it likely that new strains of HIV/AIDS can and will develop among untreated populations, due to the vast numbers of carriers around the world? Would wider drug treatment in developing nations significantly increase the risks of new strains of HIV/AIDS? Does CDC support a policy of not making HIV/AIDS drug treatments more available in developing nations?**

Answer: The virus, HIV, mutates easily, and a number of strains have already evolved within human populations. Indeed there are two different viral types (type 1 being the principal one around the world), each with multiple subtypes. Thus far, the subtype differences have been of public health importance principally in terms of requiring that antibody tests and other reagents be modified so as to detect all the infections, and the different subtypes may make vaccine development more difficult. Resistance to anti-retroviral drugs is currently the more important change occurring, and this appears to be a natural consequence of treatment with anti-retroviral drugs. Development of resistance occurs most quickly when only a single drug is used, somewhat less fast when two drugs are used simultaneously, and more slowly when triple drug therapy is used. Resistance also occurs more frequently if the treatment regimens are not strictly

followed and doses are missed. Wider drug use in developing countries will inevitably increase resistance (resistance has already been found in Uganda after only a few months of anti-retroviral use). The development of resistance is intensified if only single or two-drug therapy is practiced (the typical therapy available in developing countries) or where treatment is intermittent, as happens when the patient's financial resources are limited.

CDC does not have a policy on the practice of making HIV/AIDS drug treatment available in developing countries. CDC does, however, support the concept of adequate treatment and care for all AIDS infected individuals. Sadly, for reasons of cost and lack of infrastructure, this concept in not reality in most parts of the developing world. We do, however, have some very effective tools in our collective arsenal. CDC considers prevention a higher priority to combating the epidemic than anti-retroviral drug therapy. One area where the use of therapies has proved effective in developing countries is the use of short-course regimens in pregnant women to prevent mother-to-infant transmission. For HIV-infected people in developing countries, prevention and treatment of opportunistic infections, especially tuberculosis, is a more cost-effective and realistic means of treatment than is anti-retroviral therapy. It would also have the added benefit of combating the TB epidemic (which is worsening because of HIV.) Currently, in most places, screening HIV infected persons for TB and treatment is infrequent. In addition to the huge expense of triple-drug therapy, the medical infrastructure necessary for evaluating, maintaining, and monitoring patients on these drugs is frequently not available in the most heavily affected developing countries.

3. **Are the recently publicized problems with CDC dedicating its limited resources to programs or purposes other than those intended by the Congress (i.e., funding other activities than chronic fatigue research), also problems in the HIV/AIDS research? Is there disagreement within CDC regarding the funding levels of HIV AIDS vaccine and drug treatment research?**

Answer: Each year Congress provides guidance and, often, very specific direction on the HIV/AIDS appropriation to CDC. This, together with the President's budget, provides the basis on which new and existing programs are implemented. CDC strives to assure these programs are consistent with the letter and intent of Congress and the President.

I am not aware of any major disagreement within CDC on the direction and scope of HIV/AIDS research. On an ongoing basis CDC conducts internal reviews of it's research portfolio and periodically supports an external review of its programs and directions. Although consensus is not always achieved on the recommendations, general agreement is the norm.

CDC does not have a major role in vaccine or drug development. Although some vaccine-related basic research activities are conducted at CDC, most of CDC's vaccine-related efforts are directed toward the latter stages of vaccine development, including phase III efficacy field evaluation of candidate vaccines, post-licensure evaluation (phase IV demonstration projects) and program implementation. Once a safe and effective vaccine is licensed and available, CDC's role includes: the development and evaluation of strategies for vaccine use; the surveillance of infection/disease and vaccine-related adverse events; epidemic investigations; and the provision of technical assistance to states, international agencies and developing countries.

CDC's role in HIV therapies is not in development but in their appropriate use in preventing secondary infection and in preventing mother-to-child transmission. The determination of the appropriate funding levels for vaccine or drug development is not CDC's area of expertise.

QUESTIONS FOR DR. ALLEN HERMAN

1. In your testimony, you indicate numerous approaches to the HIV / AIDS epidemic. You include the needs for health professionals, infrastructures and resources. But isn't the availability of drug treatments the most essential resource, one that could lead to improvements in the others? Isn't the existing treatment of tuberculosis and other AIDS related ailments of those infected but not receiving HIV / AIDS treatment also resource intensive? Is it cost-effective to let millions die who are in the most productive phase of their lives?

2. How successful are the educational and counseling programs that are being financed by the United States? Are condom products and use instructions really working for most of the people in Africa? What educational efforts are working, and what evidence supports this success?

3. In your final recommended approach to combat the African HIV/AIDS epidemic, you indicate the following in discussing the cost of resources: "It will be critical for cost-effective methods of treatment to be identified. We cannot simply import treatment regimes from other countries. It will become increasingly important for Southern Africa to identify effective and efficient mechanisms to cope with the epidemic." How is this approach and need inconsistent with South Africa's Medicines Act, which was passed to do that?

QUESTIONS FOR JAMES LOVE

1. Are you aware of any provisions of South Africa's Medicine's Act that violate international laws or treaties? In fact, has South Africa attempted to conform to these laws and treaty provisions?

2. Do you know how drug company investments in public relations and marketing compare to their investments in research and developments?

3. Are you aware of examples where the United States engages in parallel importing? What about compulsory licensing? Explain.

QUESTIONS FOR ERIC SAWYER

1. What types of activities do you engage in to bring attention to your cause? Do you feel that these activities in gaining public attention to your cause are effective? Explain.

2. Do you feel that Americans with HIV / AIDS are feeling more desperate about the conditions and spread of the disease in the U.S. or internationally? Explain.

3. Do you feel that the global HIV / AIDS epidemic is receiving sufficient attention and resources by this administration? What would you recommend?

ADULTS AND CHILDREN ESTIMATED
TO BE LIVING WITH HIV/AIDS AS OF END 1998

TOTAL: 33.4 MILLION

Source: UN AIDS epidemic update, December 1998

U.S. TACTICS WITH SOUTH AFRICA

U.S. Warns South Africa Regarding Efforts for Affordable Drugs, *but South Africa has not engaged in parallel imports nor suspended intellectual propoerty rights, nor been found to violate any treaty*

MID-1997: U.S. Ambassador to South Africa demarches against parallel imports

JULY 1997: **Commerce Sec. Daley voices opposition** to South Africa's Medicines Act

DEC 1997: U.S. agencies begins ***"full court press with South African officials"***

EARLY 1998: State Department advises Embassy to publicly oppose Medicines Act

EARLY 1998: U.S. approaches EU members to pressure the South African Government

SPRING 1998: U.S. Trade Rep for Africa raises US concerns during trip to South Africa

APRIL 1998: USTR places South Africa on a ***Special 301 "Watch List"***

JUNE 1998: White House withholds preferential tariff treatment of certain SA exports

MAR 1998: Sec. Daley meets with Health Minister Zuma to ***"underline US resolve"***

JUNE 1998: U.S. official voices U.S. opposition at a pharmaceutical industry conference

JULY 1998: U.S.T.R. for Africa meets again with SA officials to stress opposition

SEPT 1998: Sec. Daley *stresses* pharmaceutical patent protection to SA trade officials

AUG 1998: **VP Gore meets with Deputy President Mbeki** to discuss pharmaceutical patents

AUG 1998: **USTR selected to lead** the U.S. negotiation efforts with South Africa

SEPT 1998: **U.S. officials refuse SA's request to intervene** in pharmaceutical legal challenge

OCT 1998: State Department dispatches economic officer in SA to advocate U.S. policy

DEC 1998: USTR sends letter to SA Dep. Pres. Mbeki, offering tax benefits for change in law

DEC 1998: Sec. Daley repeats that **pharmaceutical patents was key issue** in SA discussions

JAN 1999: US officials reiterate ramifications of proposed suspension of aid to South Africa

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