THE PRESIDENTIAL COMMISSION on the HUMAN IMMUNODEFICIENCY VIRUS EPIDEMIC

HEARING ON Response to the Pandemic by The United States

April 18, 19 and 20, 1988

August 24, 1988

TO OUR READERS:

The Presidential Commission on the HIV Epidemic held over 45 days of hearings and site visits in preparation for our final report to the President submitted on June 27, 1988. On behalf of the Commission, we hope you will find the contents of this document as helpful in your endeavors as we found it valuable in ours. We wish to thank the hundreds of witnesses and special friends of the Commission who helped us successfully complete these hearings. Many people generously devoted their volunteer time in these efforts, particularly in setting up our site visits, and we want to fully acknowledge their work.

The staff of the Presidential Commission worked around the clock, seven days a week to prepare and coordinate the hearings and finally to edit the transcripts, all the while keeping up with our demanding schedule as well as their other work. In that regard, for this Hearing on the HIV Pandemic, we would like to acknowledge the special work of Nancy Wolicki and Adrienne Allison, in putting together the hearing, and Nancy Wolicki, in editing the transcript so it is readable.

For the really devoted reader, further background information on these hearings is available in the Commission files, as well as the briefing books given to all Commissioners before each hearing. These can be obtained from the National Archives and Records Administration, Washington, D.C. 20408.

One last note--We were only able to print these hearings due to the gracious and tremendous courtesies extended by Secretary Bowen's Executive Office, especially Dolores Klopfer and her staff, Reginald Andrews, Sandra Eubanks and Phyllis Noble.

Sincerely,

Polly L. Gault
Executive Director

Gloria B. Smith
Administrative Officer

PRESIDENTIAL COMMISSION ON THE HUMAN IMMUNODEFICIENCY VIRUS EPIDEMIC

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PRESIDENTIAL COMMISSION ON THE HUMAN IMMUNODEFICIENCY VIRUS EPIDEMIC

RESPONSE TO THE PANDEMIC BY THE UNITED STATES

This Hearing was held at
THE PAN AMERICAN HEALTH ORGANIZATION
WASHINGTON, D.C.

Monday, April 18, 1988

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I-N-D-E-X

I-N-D-E-X(continued)

THE HIV PANDEMIC

EXECUTIVE DIRECTOR GAULT: Good morning. Ladies and gentlemen, distinguished witnesses, members of the President's Commission. My name is Polly Gault. I am the designated federal official here today. In that capacity, it is my pleasure to declare this meeting opened. If everybody could take their seats. Mr. Chairman.

CHAIRMAN WALSH: Good morning. I want to welcome all of you to what I consider to be probably the most meaningful hearings that this Commission will hold.

Up to now, we have concentrated primarily upon the problems with which we are faced in the United States. Needless to say, these are severe because we do have more cases of AIDS, of HIV positivity, than anyone else in the world. However, we do know that this is a pandemic, that cases have been reported from more than 133 countries and we know, from our own experience, that what seems like a small problem ten years in the past can grow into a massive problem in relatively short order.

We have been privileged at this meeting to have been able to get the participation of leading figures in the fight against AIDS from many countries. I can't mention them all, but I certainly do want to mention Jonathan Mann, whom you will shortly meet and who is charged with the role of Commander in Chief, as it were, of the global war on AIDS.

We have Alain Pompidou, who has joined us from France, who, as the leader of the fight against AIDS in France, has assumed really a leadership role in all of Europe and has done much in a bilateral fashion in also bringing information and weapons against this disease to Africa.

We have many others, over these three days, you will be hearing not only from them, but also from representatives of our own government who are involved in both multilateral and bilateral assistance, from people in the academic arena but who have devoted much of their time to international work. We will be hearing from experts on the African continent and in our own hemisphere.

We look forward to learning a great deal and also to getting guidance on how to fulfill the charge given to us by the president who has asked that, among other recommendations, we recommend a position, a line of activity that the United States should take in the global war against this dread disease.

Before finishing these brief remarks, I want to also express the profound gratitude of the Commission to the Pan American Health Organization for making these facilities available for such a meeting. It not only gives importance to the subject, but also indicates on the part of PAHO the concern

that they have in this international arena for participating in this war, certainly in this hemisphere, and recognition that this is indeed a global fight. Before getting into our specific program, I want to introduce Dr. Bob Knouss, who is here on behalf of Dr. Macedo, to say a few words about PAHO.

DR. KNOUSS: Thank you very much, Dr. Walsh. Distinguished members of the Presidential Commission on the Human Immunodeficiency Virus Epidemic and distinguished guests and scientists and ladies and gentlemen, the Director of Pan American Health Organization, Dr. -- Macedo, who is also the Regional Director for the Americas of the World Health Organization, has asked me personally to convey his greetings and to welcome you all to our headquarters building for this important hearing on the HIV pandemic.

He's also asked me to express his regrets at not being present here personally with you today, but previous commitments have precluded his participation. During the next several days, the many important aspects of the international AIDS epidemic will be covered extensively and it's not my purpose to try to address any of these issues in these few remarks. But I do want, however, to convey to you the fact that the Pan American Health Organization shares with you the same sense of urgency and concern for this epidemic.

Since 1983, we have been providing technical collaboration to our member countries, first, in a limited fashion when the disease began to spread in this region and subsequently, in an intensive way during the last sixteen months since the World Health Organization established the Global Program on AIDS thus providing leadership essential for coordinating the world's effort to combat this invariably deadly disease. Without such leadership, we would not be able to assure ourselves that the resources that are available will be used in the most efficient and effective way possible.

WHO, as you said, is firmly committed to the objectives and strategies of the global program and will act firmly and decisively to implement them through our programs of technical collaboration. In this light, I want to particularly express our appreciation to the United States of America, one of our member countries, not only for your financial support to this world-wide prevention and control effort, but also for the significant contributions that have been made in both the public and private sectors toward advancing our scientific and technical knowledge about this disease, about its spread, about how to treat those who are suffering from its consequences. This hearing is yet another example of this commitment.

For these reasons, we are pleased to welcome you to PAHO and WHO, as this is both, and I know that Dr. Macedo wishes you every success and I want to join him in this wish. Welcome, Dr. Walsh.

CHAIRMAN WALSH: Thank you, Bob.

CHAIRMAN WALSH: If Dr. Mann will join us and, Bob, if you wish to sit at the table with Dr. Mann, please feel free to. I'm going to make my introduction of Dr. Mann very brief because I think the world already knows him for the thankless sacrifice that he has made. I have never seen a man expend as much energy and as much dedication in what seemed like an insurmountable task as has been done by Dr. Mann. It's a privilege to have you here with us, Jonathan, so please go ahead.

DR. MANN: Thank you very much, and thank you very much for this opportunity to speak to you, which I've been personally looking forward to for quite some time.

It's very humbling to us to realize that a decade ago there was a world-wide epidemic of a virus, an epidemic that occurred silently. We had no idea it was occurring, but it reached five continents by 1980. The discovery of AIDS in the United States in 1981 was a historical accident. It could have just as easily been discovered on four other continents at that same time. In fact, it's interesting to realize that, had AIDS been discovered say in Africa where it was also existing in 1981, the disease probably would have been thought of world-wide as a heterosexual disease. It is the historical accident of its discovery in the United States that has led some to consider this disease to be more associated with homosexual rather than heterosexual activity.

In 1982, cases of AIDS were discovered and recognized in Europe, in parts of Latin America, and in Africans in Europe. It was not until late 1983 that cases of AIDS in Africa itself were recognized and it was then obvious and evident that Africa had a major AIDS problem about which you'll be hearing more in detail later this morning.

By early 1985, the discovery of a serological test and its distribution allowed us for the first time to really assess the global scope of this problem because, as you know, the cases of AIDS come years after infection and cases of AIDS themselves do not represent an accurate way to track the pace of a rapidly spreading epidemic.

Now, in 1988, we estimate that there are between five and ten million people in the world infected with HIV. As of April of this year, there were almost 88,000, cases of AIDS officially reported to the World Health Organization from 138 countries

around the world. Of these cases, seventy four percent, almost three quarters, come from forty two countries in the Americas. While the United States represents eighty eight percent of these cases, Brazil, Canada, Mexico and Haiti each report more than five hundred cases of AIDS.

Thirteen percent of the AIDS cases come from forty two countries in Africa. Of the African AIDS cases that are reported, ninety two percent are from eleven countries in central, eastern and southern Africa.

Twelve percent of the AIDS cases in the world reported thus far are from twenty seven countries in Europe. The countries with the largest number of cases are France, the Federal Republic of Germany, Italy and the United Kingdom. Eastern Europe, involving eight countries and the Soviet Union, have thus far reported a total of seventy two AIDS cases.

The remaining one percent of the AIDS cases in the world, amounting to just over eleven hundred, have been reported from twenty six countries in Asia and Oceana. While the majority of those cases are from Australia, New Zealand and Japan and Qatar, cases have also been reported from other countries including India, Thailand, the Philippines, Hong Kong, Malasia, Singapore and China. Because under the best of circumstances, not all AIDS cases are actually reported, we estimate that the actual number of AIDS cases having occurred during the current world-wide epidemic is probably closer to 150,000. We also estimate that, because of the wide spread infection that has already occurred, there will be an additional 150,000 cases of the disease AIDS world-wide during 1988. If we extrapolate a little further into the future, we would estimate that by 1991 there will have been a cumulative total of approximately one million AIDS cases world-wide.

In addition to talking about numbers of cases and infections, we're also very aware of what we call the third epidemic. The first epidemic is the epidemic of HIV infection itself. The second epidemic is the epidemic of AIDS and other associated diseases that follow the epidemic of infection.

The third epidemic, which is just as much a part of the pathology of this disease as the virus itself, is the epidemic of social, cultural, political and economic impact and reaction to the first two epidemics. AIDS has a tremendous impact on social and economic development. Because it affects mainly people between the ages of twenty and forty nine, it touches those that are most productive in social and economic terms.

In terms of infant and childhood mortality, we see already evidence from developing countries that, where five percent or more of pregnant women are infected with HIV, the projected gains

through the child survival initiative in infant and child survival may be tragically cancelled out by the effect of AIDS. Therefore, in some developing countries, we expect to see a decline in life expectancy over the next few years as a result of AIDS.

In addition, we have seen a world-wide epidemic of fear, ignorance and prejudice which threaten, at the international level, the open communication, open travel and open commerce which are at the heart of the modern world. Finally, we've seen how AIDS unveils prejudices that already exist regarding race, sex, national origin, and religion in countries throughout the world.

In order to describe to you the current status of the global fight against AIDS, it's important to realize how far we've come in the last two years. Very briefly, I'd like to describe to you the situation internationally in 1985.

First, in 1985, there were many countries that refused or were reluctant to report about AIDS. They simply hid the fact that they had AIDS. That's as bluntly and as clearly as I can say it. They did this for a variety of reasons. One of the most important reasons was the stigma that was felt to be attached to the idea that you had AIDS in your country because, in many societies in the world, male homosexuality is not accepted. In those societies, even if AIDS cases were unrelated to male homosexuality, in a prevailing international climate where AIDS was equated with homosexuality, for countries to say "We have AIDS" would be for countries to say "We have male homosexuality" which, of course, is true, but nevertheless difficult for many countries to discuss publicly.

This whole situation was exacerbated by various aspects of media coverage which tended to dramatize, to point fingers and to in other ways stigmatize areas of the world affected by AIDS.

Research itself was hampered during this period. Research results were occasionally muzzled and not allowed to be published. There was a tremendous sensitivity which obviously comes from the fact that this virus is transmitted through sex, through blood, through skin piercing practices and that these are areas which are culturally sensitive in every country of the world.

In addition, in 1985 we were all prey to wildly varying estimates of the actual scope of infection. One could read in the newspapers anything from hundreds of thousands to hundreds of millions of people infected, all of which were estimates based on preliminary data, small, unconfirmed reports and occasionally studies done with laboratory techniques that were not in fact acceptable.

In this context, those countries in the developing world that realized they had an AIDS problem looked in many directions trying to get help. I can give you examples where countries would send a letter requesting help on AIDS to every development organization and to, to every development assistance organization in the world. The letter would say "We have an AIDS problem please help". Now, that is a chaotic situation. That is a situation which invites development agencies who are concerned to send missions, to try to discover, to promise help and, in some instances, the same help was promised by multiple countries and multiple development agencies. It was accepted by the recipient countries because they were not sure whether any of those development agencies would actually deliver the goods.

So it was a chaotic situation from the viewpoint of the countries who wished to get help and, from the viewpoint of development agencies. They were ambivalent and understandably, a bit confused. What should their role be in fighting international AIDS? What should be done?

Initially -- in 1985 -- what was mostly done were the easy things. In the international development environment it is easy to buy equipment or supplies and to send it. Indeed, that can be a contribution. But in the field of AIDS, it's more complicated, and one can not simply parachute in some testing equipment and walk away and feel that one has accomplished a great deal. I remember vividly a call from a non-governmental organization in 1986 informing WHO that they were planning to send some laboratory supplies to an African country. The country desperately needed those supplies but the organization involved had not considered the fact that the supplies they were preparing did not fit with the equipment that was already available in the country. They had given no consideration to training. Indeed, when they looked at the actual boxes they were preparing to send, they noted that the supplies were outdated and should no longer be used. That kind of chaos reigned two and a half years ago.

The World Health Organization has a constitutional responsibility to coordinate and direct international health work. This was perhaps best illustrated in most people's minds by the smallpox eradication program. WHO considered it essential that some order be put into this environment because, if order did not become evident and the chaos continued, the actual work that needed to be done would not start effectively.

So, we first created a global strategy in order to develop and provide a conceptual framework for the struggle. The beauty of a conceptual framework is that after it's in place and everybody has read it and agreed to it, it seems obvious. But that's the beauty of it because, in fact, it helps insure that

there is, in fact, consensus and consistency. What I'm about to describe to you briefly as the Global Strategy for the prevention and control of AIDS, I hope will seem to you to be self-evident, but I assure you that world-wide, two years ago, it was not self-evident.

The Global Strategy has on three objectives. First, to prevent HIV infection. Secondly, to take care of all those who are HIV infected, including those who are healthy and including, of course, those who now have AIDS. Third, to unify national and international efforts in fighting this disease.

Those objectives are linked to a set of principles, part of the Global Strategy. First, that public health must be protected. Secondly, that human rights must be respected and discrimination must be prevented, and I will return to that theme. Third, that through epidemiology, because we know how the virus is spread, we know how to stop the spread of the virus even without a vaccine and that stopping the spread will require informed and responsible behavior. Therefore, education is the key to AIDS prevention. It will require a sustained social and political commitment because, as much as we would like this problem to go away quickly, it will not. All countries in the world, we believe, need a strong and comprehensive national AIDS program, a program that is integrated with national health systems linked in a global network.

Finally, we believe that systematic monitoring and evaluation will be needed because, in this problem, we must learn as we go. We must learn as we go how best to control this disease.

Those are the objectives and that is the set of principles. I would be shocked if you found any of that shocking because this is the basis on which every country has been establishing its national AIDS program. These principles help determine the manner in which the objectives of AIDS control are actually carried out in countries, regardless of their cultural context, because we're dealing with cultures as absolutely widely different as India and Qatar or Botswana and Brazil.

Specifically, for example, knowing the routes of HIV spread and knowing that the focus of prevention must be behavior allows us to realize that there are three things that are needed: information and education, health and social services to support the information and education, and a supportive social environment that's based on understanding and tolerance.

Furthermore, because risk behaviors are private and often hidden from society regardless of the culture, all people in society must be educated. One does not know who may be at risk. Yet, because risk is not equally distributed throughout the

entire society, it's important to target our efforts and it's important to involve those who are to be targeted in the design of our efforts.

In addition, because of the importance of health workers in fighting AIDS, health workers at all levels must be well-informed and educated and supported. Finally, because information and education in some cultures is probably more powerful on an individual level than on a mass level, counseling and other forms of personal support have to be assured.

In addition to the information and education I've just mentioned, it's clear that we need health and social services to support long-term behavioral change. We say to ourselves, and countries have said, how realistic is it to expect that a person, for example, who is an IV drug user will no longer be an IV drug user by themselves without external support? How likely is it that a person who is infected with HIV will be able to lead the responsible, constructive life that they may lead without access to support and information over time? We have often asked ourselves this question, if we, as individuals, were infected. We ask people in many cultures to consider this situation of - Who would you turn to when you needed information? It wouldn't be just information once. It would be information for the rest of your life. Information about a variety of issues. We believe that, without the commitment to the health and social services over time for the long run that is needed that the information and education by itself can not be enough. Finally, we believe that a supportive social environment is a necessity, not a luxury.

I will turn again, to the issue of human rights which we believe is fundamental, not an add-on to the entire question of AIDS control. In addition to the question of a global strategy, we have provided throughout the world a structured, systematic approach to the planning and development of national AIDS programs. After designing a blueprint which contains the components of a national AIDS program, we have been providing technical and financial support to countries around the world. I'd briefly describe how that process is actually carried out.

First, a country contacts WHO and requests WHO support. That's an important stepbecause, without the request, there may not be the political commitment to see the work through. Once the initial contact is made, a visit is performed by WHO staff with consultant support to assess the epidemiological state and the resource situation. What is the seriousness of the problem and what is the current activity to fight the it?

We then provide urgent support. We provide urgent support because in every country in which we've worked it's clear that there is something that can be done immediately and that does not

require an extensive planning process in order to implement. As one illustration, in some countries, materials have been prepared for health workers but the resources are lacking to print them and distribute them. So that's the kind of urgent support we can provide without needing to go through an elaborate planning process.

But then we focus quickly on the development of a plan. WHO's role is not to go into a country and tell them what to do or to go into a country and do it. What we do is go to a country and say we would like to support you in the development of your own national AIDS program in conformity with the Global AIDS Strategy and its principles. Countries accept this willingly and we, therefore, stand behind the country and help them develop a comprehensive national plan.

That plan then serves as the instrument to focus assistance from the International Development Assistance Agencies. Rather than receiving a one page letter asking for help, Development Assistance Agencies now receive a document that is a comprehensive national plan. The document is used as the focal point for a donor's meeting where all International Development Agencies meet with the representatives of the country itself and discuss how resources can now be made available to implement the national plan.

As of the 11th of April, as of a week ago, and this has basically occurred since February of '87, 139 countries around the world have requested WHO collaboration. In the last 14 months, since the establishment of the AIDS programme in February, 1987, visits have been completed to 117 countries. Of these, 78 have completed written short term plans to cover a six month to one year period; 22 have completed medium term (3-5 year) plans and eight countries have had donor's meetings and received full financial support for the implementation of their national AIDS program: Uganda, Tanzania, Ruwanda, Ethiopia, Kenya, Zaire, Senegal and Zambia. By this work, the ideas of AIDS prevention and control are being turned into a reality throughout the world.

There is now an orderly process which has replaced the chaos of only two years ago. The National AIDS Plan has become the central document, not only for international funding, but for national planning and for national support. Also, through the document, we're able to insure that all parts of the National AIDS Plan are covered. I'm sure you're well aware in this country, because it's true in every country, that there are easy things to do and there are hard things to do. It's important that not only the easy things be done. It's very tempting when one is wanting to support another country's activity to support something which is visible, tangible and looks good. But there

are many things that aren't so visible, that aren't quite as tangible and which are more complex which must be done if AIDS is to be combated successfully. So, by taking the planning process, we're able to insure that everything is looked at, not just the popular things.

Let me be a little more precise about that to make sure I've made that point. It's a lot easier to build a building in a foreign country through development assistance, call it a blood bank and say you built a blood bank. It's a lot more difficult to train the people who will do the work, to insure that the quality control will be done so that the test results are meaningful, to insure that people go to the blood bank to give blood and to insure that the blood that comes from the bank is safe and to insure that that doesn't just happen this week or during the time of a visit, but it happens over the long term.

These are the serious, genuine, real problems of trying to help any country with its national AIDS plan and therefore, the planning process is critical. Through this process, a level of cooperation among the development agencies that is unprecedented has been assured. Everyone has realized the scarcity of resources and this is not an area in which we want to see any duplication or competition at the national level between development assistance agencies of different countries.

Finally, the cultural context is respected. It is extraordinarily difficulty to deal with sexual practices of one's own society and one's own culture, least of all the sexual practices of another society and of another culture. It would be a tragic mistake if anyone attempted, from any ivory tower or any location, to dictate to countries how the details of such as education of school children should or should not be done. That is a national decision. It must be respected as a national decision, but we must provide the resources and the structure to ensure that a full debate occurs, so that the issue is discussed. Then if the country decides it wants to educate all its tenth graders, we will provide the technical and financial support to help them carry that through. Nor can we write the messages, not only because of the language barriers, but because there are many different ways in which sex is discussed around the world.

In addition to this way of helping countries specifically develop their national AIDS programs, WHO has ensured a commitment to the development of additional information. One of the real dangers in this area is that people go off with small pieces of information, extrapolate to continents and believe they understand the situation. That's just as tragic as people examining and interviewing a few sexually active people and from that basis, drawing conclusions about the sexuality of a society, a country, or even a continent or a region.

Therefore, the commitment to information is critical. WHO supports countries by developing methods to determine the scope of infection, to determine attitudes towards sexual practice and sexual behavior. International comparisons become possible as well as comparisons within the same country over time. This activity is fundamental to AIDS control because, if we are to learn what prevention activities work, we must know what people do and we must know how people do or do not become infected. If we don't have that information, I don't see how we'll be able to judge the effectiveness of all our endeavors.

We're also able to open discussion on sensitive problems by using the mechanisms available to WHO as a multi-lateral organization with 166 member states. WHO is against AIDS but we do not have a particular bias or any specific political ambitions in that process. An example, is our early work with African nations on AIDS. At a time when African governments refused to talk about AIDS and, in general, refused to allow studies of the problem, WHO held the first meeting on AIDS in Africa in Bangui, Central African Republic in October 1985. This was the first discussion of a technical, scientific nature about AIDS in Africa. Then in November of 1986, WHO called a meeting of forty countries in Africa and, for the first time -- a historical turning point -- AIDS was discussed in Africa like any other public health problem. The scientific discussion was open - in front of the press - and with the question being asked, not who to blame, but what to do and how to do it.

Similarly, in the Americas, in September of 1987, the first Pan American Teleconference on AIDS may have been the largest health meeting ever held. Its role in accelerating the commitment to AIDS prevention and control action in the Americas can not be underestimated.

Finally, in Asia and Oceania, meetings have been held; in Kuwait for the countries of the middle east and north Africa; in New Delhi for southeast Asia; and in Sydney, Australia for the western Pacific and Oceana. Through these meetings, we achieve momentum and through these meetings, we bring to each country the obvious need to become involved in the global struggle.

In addition to collecting it is important to share the information. As a multi-lateral neutral organization, we have the capacity to move and share information. Although the sense of stigma has diminished markedly, there is still a sense of difficulty or tension around the full disclosure of all information and this remains a delicate issue. We stand behind the countries and say all the information should be shared.

As part of WHO's coordinating and directing responsibility, we have been mobilizing other institutions and organizations. We have been challenging those organizations and saying you must

become involved in AIDS because AIDS is not "simply a health issue". AIDS is an economic issue. It is a social issue. It's a political issue. It's an educational issue. It's a cultural issue. It's an issue, therefore, which requires that many organizations play a role. This is not a one organization campaign. Smallpox was eradicated by a one organization type of campaign. AIDS can not be eradicated, can not be controlled, by that kind of narrow focus. Therefore, working with governmental organizations, with private organizations, with non-governmental organizations, we have been able to help them overcome their substantial initial reluctance to deal with AIDS. There is not an institution, or an organization that has leapt into AIDS from the beginning. Every organization goes through a certain process. Every country goes through a certain process of coming to terms with AIDS before it begins to grapple constructively with the problems. Initially, there's always a desire to deny or minimize a problem. Then finally, there comes the constructive engagement that's so necessary.

In addition, in the United Nations system, we brought AIDS to the floor of the United Nations General Assembly six months ago today. Six months ago, we spoke and, for the first time on the floor of the U.N. General Assembly, a disease was discussed. The first time in history that a disease was discussed, it was AIDS and the response was overwhelming and supportive. As a result of that response, other major U.N. organizations have mobilized. Organizations such as the United Nations Development Program -- which has a critical role to play in social and economic development in countries throughout the world -- UNICEF, the World Bank, the United Nations Population Fund, the International Labor Office, and other parts of the U.N. system. These organizations are beginning increasingly to play an important role.

Non-governmental organizations, including the International Council of Nurses, Save the Children, AMFAR, the League of Red Cross Red Crescent Societies, the National Council for International Health, The World Council of Churches -- these organizations and many others are all increasingly involved for two very good reasons. First, because AIDS is a real problem. Secondly, because the structure now exists, the strategy now exists within which their activity makes more sense, within which each organization, can understand its own role, its own piece, in this overall picture. I contend that, without a view of the overall picture, you can't understand your part in the picture.

There's a mobilization that has occurred and that mobilization is increasing in its intensity. WHO also facilitates research. AIDS research is now irrevocably international. It can never again be strictly national research and, therefore, in an area like vaccine field trials, WHO will have an important role again as a multi-lateral neutral

organization because vaccine field trials will almost certainly be international. Vaccines will probably be developed in countries where the level of new infection is not sufficient to efficiently test the vaccine. Vaccines developed, in the United States or in western Europe, will almost certainly need to be tested in other parts of the world, such as Africa. The stakes are enormous for all of use in such international testing and trials. They are enormous because, if the trial is done in a way that is either scientifically or ethically not entirely acceptable, the consequences fall upon all of us.

In addition, to be very specific, bilateral arrangements suffer from the threat of perturbations of bilateral relationships. For example, if the United States set up a vaccine field trial bilaterally, with an African country -- what would happen when the rulers change, the president changes, the minister of health changes, or there is a break in diplomatic relations? The history of bilateral relations between various countries in the west and African countries, shows a considerable threat to the integrity of vaccine trials that must go on over a period of years. If the bilateral relationship suffers politically, the science may suffer. Similarly, the science may be held hostage to political relationships. Thus, WHO's involvement in the organization of such field trials could be very helpful in order to protect and stabilize international science again perturbations of a bilateral and political nature.

There's also a need for pro-active exchange of information. It's important that everybody have access to scientific information. Let me give a specific example. There are now a number of studies of the perinatal transmission of HIV taking place in different parts of the world. At a consultation held by WHO on breast feeding, and HIV, it was discovered that preliminary data from one of the important perinatal studies had not been shared with the researchers of another perinatal study. A key factor in perinatal transmission was being discovered in one study and another study wasn't even aware of the preliminary data. The second group of researchers were therefore unable to incorporate the new concept into their own study thereby substantially weakening the study.

So, the need to bring people together effectively - repeatedly - for the exchange of preliminary as well as final information is essential in AIDS. We can not afford to wait until research findings are published or until an international meeting occurs.

Similarly, there's a need for common terminology. As a neutral and international organization, WHO can remove these questions from the specific national setting and place the question in a global context. Therefore, we can bring the leaders of international science together. They can agree and

it doesn't matter at that point whose idea it was. It goes out under a WHO umbrella and therefore can be accepted by all.

The same thing is particularly true in the area of social and behavioral research where the questions are more delicate and difficult than some of the virology questions. In addition, by developing guidelines and by helping to establish the technical basis for national policy formulation, we make international contributions to national AIDS efforts throughout the world. For example, the consultation held by WHO on international travel and AIDS (March 1987 Report of the Consultation on International Travel and HIV Infection, Geneva, 2-3 March 1987, WHO/SPA/GLO/87.1) played a major role in preventing a wave of requests and discussions throughout the world of requirements for tourists to hold certificates of freedom from HIV infection. In late 1986 and early 1987, this issue was being discussed throughout the world. The WHO technical consultation and determined that such measures would be highly ineffective, highly inappropriate, highly expensive and therefore should not at all be recommended.

In that regard, we've had 165 successes and one failure. The only country in the world that currently requires a certificate for a tourist to enter the country is Iraq. Every other country in the world has considered this issue and, at least partially with the help of the WHO expert groups' considerations, has agreed not to impose such an ineffective and inefficient restriction.

WHO had an important consultation on the neuropsychiatric impact of HIV infection (Report of the Consultation on the Neuropsychiatric Aspects of HIV infection, Geneva, 14-17 March 1988, WHO/GPA/DIR/88.1). The meeting has major implication as it focused on the issue: what are the neuropsychiatric effects of HIV infection in people who are otherwise healthy? In other words, healthy HIV-infected people. WHO brought together over forty participants from about fifteen countries. The consultation concluded that: At present, there is no evidence that there are any clinically important neuropsychological effects associated with HIV infection when a person is otherwise healthy. This information was used almost immediately by airline companies which had been considering questions such as screening pilots.

Similarly, a meeting on AIDS in the work place to be held by WHO in collaboration with the International Labor Office in June will establish broad guidelines for the issue of AIDS in the work place world-wide. We've had meetings on AIDS in prisons, on strategies for preventing HIV infection among IV drug users, on counseling, on breastfeeding, on childhood immunization and HIV.

I briefly mention the points about human rights, a global issue which transcends national interests. You might ask why is the World Health Organization, a health organization, so involved and becoming increasingly involved with the human rights aspects of AIDS?

The reason is very simple. The reason is that it is a public health issue. It is a public health issue because where and when the human rights of those who are HIV-infected are violated, when and where discrimination is allowed to occur, the capacity to fight the disease effectively is reduced. Where exclusion and discrimination are applied against people who are HIV-infected, the capacity to effectively educate and support people to deal effectively with the problem is reduced. In that sense, discrimination threatens public health. Discrimination itself becomes dangerous to the public health.

The only major barrier that we have seen in terms of universal acceptance of this idea is that there are many societies and many cultures which find it very difficult to deal with reality. By reality, I mean that where there is prostitution, one says there is prostitution and where there is IV drug use, one says there is IV drug use. That's reality. But there are many cultures which have difficulty admitting those things and talking about those things publicly. In those cultures, in those settings, it is sometimes tempting to look for the easy solution. It is sometimes tempting to look for solutions in which ideas of exclusion and discrimination predominate, but that ignores the fundamental human realities of HIV infection. We sometimes ask the decision makers in those countries to consider what they would do if they were HIV-infected themselves, to consider what they would do if the risk of being known to be infected was loss of job, loss of status in society and perhaps being moved to another place entirely. Most people, when they ask this question honestly of themselves, conclude that they would do everything within their power not to be identified as HIV-infected including, if you carry this line of reasoning further, for example, not using a condom if using a condom raised the suspicion of why are you using a condom. In other words, the very responsible behavior that we are trying to promote can be undermined by a climate of fear and a climate of discrimination.

I'm pleased to tell you that in virtually every country of the world, the principle of respecting human rights has been accepted. In summary, we have together forged and faced a rapidly enlarging and new problem. We have been facing a new global health priority. We have brought an unprecedented global effort into reality. It's unprecedented because it has reached more countries more rapidly than any other health program in history. It is unprecedented because it is based on the concept that we are not looking for a quick fix. We are looking to

develop the capacity to fight this problem over time. It's unprecedented because we are insisting upon and receiving agreement that cooperation is essential and that the issue is how to provide the support to all countries of the world, rather than how to provide special visibility to one donor country.

For example, we've reached an agreement on a new mechanism for the evaluation of national AIDS programs by donor agencies. Rather than each donor agency performing their own annual evaluation of a country's program activity, (a large burden on the country's resources if there are ten such agencies), there has been an agreement among the donor agencies that we will forge together a common evaluation and method system. Everyone will be welcome to participate, in this evaluation but it will only happen once. That's an example of the very practical but creative approach that is allowing us to move as rapidly as we've been able to move.

In a very rapid period of time we have replaced chaos with order. We don't yet know all the answers, but we know that we are in the process of setting up the system and setting up the program that will help us learn what the answers are and then be able to apply them. In 1988, and looking beyond, there are several areas of concern which I'd like to briefly mention. First, the AIDS problem is not going to disappear, but we constantly see the desire of people to believe that it will go away. The denial factor with AIDS is enormous. A piece of data that shows why denial is inappropriate and incorrect comes from Thailand. I was in Thailand recently when the new data on their IV drug use problem was received. In Thailand in 1985 and 1986, zero percent of the IV drug users tested were HIV infected. In 1987, one percent were infected. In the first three months of 1988, sixteen percent of the IV drug users tested in Bangkok are infected. The number of IV drug users is estimated at 100,000 in Bangkok alone. So, contrary to predictions rather than sex and prostitution being the entry point for AIDS and the real point of amplification in Thailand, the infection rate in IV drug users is creating an urgent situation. There is now an urgent problem where two years ago there was probably no problem at all. Therefore, we believe that any form of self-congratulation or any form of statement that the problem is essentially over is premature, to say the least.

Secondly, we believe that chaos is a constant threat. Chaos in the international scene could occur for a number of reasons. It could occur if the resource commitment does not continue to come from the resource rich countries towards the resource poor countries. It could come by a failure to consider the international implications of national efforts. I very much appreciate and applaud the fact that during the next several days you will be asking yourselves with each presentation, with each program, in what way does this activity deal with the

international situation? In what way is it supportive of what needs to occur in the international context?

Finally, chaos can occur if there is a focus on what is easy to do. It's going to be difficult to change behaviors world-wide. We already have evidence that it is being done, but it's going to be difficult and we hope that patience will not run out. We hope that countries will continue to provide the necessary support and commitments that will be required over the long term.

There's a need for medium and long term planning. Unlike smallpox, you cannot go into a country, do whatever is necessary and then walk away and go to the next country. With AIDS, that's impossible. With AIDS, we realize we will to be dealing with AIDS for the rest of our lives and that, therefore, it's important that we look to the medium and long term and not look for the quick fix-for the good reason that quick fixes don't work.

Finally, it is essential to ensure that the fruits of international science be available to people around the world. Will drugs and vaccines be affordable for all those who need such drugs and vaccines or will the fruits of international science be available only to the rich? That's a terribly important problem for us to face as a global society in the future.

Therefore, Mr. Chairman, we live in a world which is threatened by unlimited destructive force and yet, we have seen that the work world-wide against AIDS over the last few years represents a creative spirit, a spirit of harmony, a spirit of bringing people together around an international problem that affects not just the rich countries but the poor, affecting east, west, north and south. We know that a world-wide effort will be required to deal with this world-wide problem. This problem, perhaps more than any other health problem in history, will demonstrate and does demonstrate that the world is one.

On behalf of the World Health Organization, I would like to thank you for your concern with how the United States can support the international effort and I thank you for all the technical, the resource and the moral support that the United States has provided to the World Health Organization and to the entire global effort. Thank you, Mr. Chairman.

CHAIRMAN WALSH: Thank you very much, Dr. Mann. I am sure the rest of the Commissioners join me in a sense of encouragement because certainly you have portrayed to us the image of a leader who is dedicated, who is devoted, who is knowledgeable, who is patient and above all, who will lead us into finding a solution.

We are going to have a question period, which is our custom, for you. My only comment from the United States standpoint is I'm delighted we're a donor agency because I don't think we would qualify for assistance since we don't have a plan.

DR. MANN: Is that a question, Mr. Chairman?

CHAIRMAN WALSH: And we would be in great trouble, I'm afraid. But, at any rate, we hope this Commission will come up with one. I'm going to start our questioning on the left side of the table. Dr. SerVaas?

DR. SerVAAS: Thank you, Dr. Mann. It's certainly an opportunity to have you come to join us here. My question is about Ethiopia. How can we estimate the number of infected, or even the number of deaths, from AIDS? I visited Blackline Hospital in Addis Ababa in December of '84 and the refugee camps outside the city, as well. There were machine guns in the hands of teenagers, it looked like, to keep the emaciated refugees from entering Addis Ababa and the hospital and the city limits. These thin, undernourished people could also be dying from Slim Disease, I thought, but I know of two U.S. health care workers who contracted typhus in Ethiopia at that time. Our CDC told us that they feared an epidemic then of typhus but they couldn't get information from the Ethiopian government about typhus in '84 and '85. Are we now getting into the Ethiopian refugee camps to know if these people are dying from typhus or AIDS as well as starvation and --

Since there is no vaccine for typhus, it seems that WHO would alert medical missionaries to bring doxycycline, the magic bullet to treat it. WHO, at that time, told me simply well, we printed it our literature that Ethiopia has ninety percent of the typhus in the world -- what's left of typhus. In Indiana, our state board of health isn't kept abreast by WHO of the need to take medicines for typhus. Are they told now? Is WHO telling the people who leave to go overseas to work in Africa to take a blood buddy, to avoid using this dangerous Ethiopian blood, if it is dangerous? Does the WHO have lack of funds to notify state board of health officers who do vaccinate our people before they leave to go overseas to alert them of the dangers of working there as missionaries or health workers?

DR. MANN: Thanks very much for your question. It opens up a number of important issues. One is that it's important for me to explain to you that the World Health Organization, by working with governments, provides information to national governments. Since I used to work as health officer in New Mexico, I know that in the United States that information was provided through the U.S. Public Health Service and usually particularly through the Centers for Disease Control to me and I would then apply that to

people who were traveling to different parts of the world. In the United States WHO doesn't generally reach to the state level. It reaches the federal government level, which is where I would feel that it would be most important to get guidance for U.S. nationals planning to travel.

In terms of Ethiopia specifically, there are advantages and disadvantages to being a multi-lateral organization. One of the advantages is that we have sent missions to look at AIDS and to begin to help governments working on AIDS. The countries have included Ethiopia, Libya, Iran, Albania, and countries that are closed to various bilateral missions. In Ethiopia specifically, we have gone quite far in helping the Ethiopian government develop their national AIDS plan. We have placed a WHO staff member in Ethiopia to help work on that problem. Can we solve all the Ethiopian problems? Absolutely not. Can we help them deal effectively with AIDS? We think so. Will it work? I don't know. Is it worth a try? Absolutely. I can't give you the clear, final, ironclad answer I'd like to be able to give to your question.

I don't know how many people are infected in Ethiopia. I know that the level of infection has been increasing over the last few years. Ethiopia is a very complex situation. We will continue to help Ethiopia fight its AIDS problem and I hope that a year from now I could give you a lot more information about the facts about AIDS in Ethiopia. Right now, we have the beginnings of a program. I hope in a year we'll have a lot more to say.

DR. SerVAAS: I guess my concern is that even knowing when the World Health Organization knew that ninety percent of our typhus was in Ethiopia that people like myself and a nurse from the Washington, D.C. area who, had gotten all the shots she needed to go there ended up in Hadassa Hospital being treated for resniovirus when indeed she became comatose with typhus and untreated typhus is fatal. There is a magic bullet for it but yet somehow the information isn't filtering from the WHO to Indiana and to Washington, D.C. health people who give the vaccines and send people overseas. There's no vaccine for typhus but there's a good prevention. Now, that's what I'm wondering. They said it was because we couldn't get information from their government, but certainly the WHO did know. You said it goes to national organizations and then it's our fault that it isn't getting out to the state boards of health and the local people who send our health workers overseas.

DR. MANN: If I may say, regarding AIDS, because that is my area of expertise, we are making the point world-wide that AIDS is a world-wide problem and no matter where you go, no matter where you go in the world, you've got to be aware that AIDS likely exists in the country you're going to. There are no safe

zones in the world for AIDS. That's another way of dealing with the general problem of information is to tell people you should behave when you travel to country X exactly the way you should behave when you're in your own country and that way you'll avoid becoming infected. In terms of AIDS, that's the way we approach the overall question of informing people about international travel.

DR. SerVAAS: Then should we be telling our missionaries to bring blood buddies, no to use the local blood supply if they are in an automobile accident? Are we doing that? Are we letting our missionaries and health workers know that?

DR. MANN: I can't answer what is being done in the United States regarding the education information to missionaries and others who travel abroad. I know that from WHO's viewpoint, we're doing a great deal to make those blood supplies safe in terms of HIV infection, which is one issue. We're also doing a lot to try to educate the traveler about the appropriate and inappropriate things. For example, preventing the need for blood transfusion in the first place. Most blood transfusions in developing countries occur as a result of accidents and most of those are automobile accidents. Many of those are preventible. There's a whole line of thinking that has to go into the question before you get to that final question of should you have a "blood buddy" or not. Those are all very complex issues. I'd be happy to give the Commission the text of our current policies and our current statements on these questions.

CHAIRMAN WALSH: Dr. Primm, please?

DR. PRIMM: Dr. Mann, you spoke about the neuropsychiatric effects during HIV infection. Would you elaborate on that a bit more because we get constant reports and, of course, we know that there are many neuropsychiatric effects in people who have been diagnosed to have full blown AIDS. Even during infection, we talk about dementia and dementia is an indicator or marker for diagnosis of AIDS now with the expanded CDC criteria for that diagnosis.

The other question is in Thailand, I was rather shocked by the increasing numbers, from zero in '85 in terms of seroprevalence among IV drug users to sixteen percent now in 1988. To my knowledge, Thailand does have methadone maintenance treatment programs and indeed have employed all kinds of intervention methods to thwart this seroprevalence increase. Have they used the syringe needle exchange in Thailand or are they prepared to do that at this point? You and I have discussed this about other problems. If you'd comment on those two issues.

DR. MANN: Thank you very much, Dr. Primm. In terms of the neuropsychiatric aspects, perhaps I could just quote to you the brief conclusion of the consultation and then I will be delighted to provide to the Commission a copy of the consensus statement that came from the meeting and, as soon as it is available, I expect within a couple of weeks, the final report of the meeting as well.

The consultation occurred in March and it involved forty eight participants from seventeen countries including experts in clinical psychology, epidemiology, ethics, health economics, law, neurology, occupational health, psychiatry, public health. The consultation reported, "At present, there is no evidence for an increase of clinically significant neurological or neuropsychological abnormalities in CDC Group II or Group III HIV I seropositive individuals as compared to HIV I seronegative controls. A parenthesis here, the Group II and Group III refers to people who are asymptomatic or who have persistent generalized lymphadenopathy. Therefore, there is no justification for HIV-I serological screening as a strategy for detecting such functional impairments in asymptomatic persons."

Going back now to a text which we've prepared for another purpose, "The most important outcome of the deliberations is that governments, employers and the public can be assured that the weight of currently available scientific evidence indicates that otherwise healthy HIV infected individuals are no more likely to be functionally impaired than uninfected persons." We will be following this issue very carefully. We don't know what ultimately will emerge from a continued study of HIV-infected but asymptomatic people. The studies are underway and we have a commitment to following through.

In terms of Thailand, we're very concerned. This is an explosion of infection in a group of IV drug users. In the city of Bangkok, approximately 42,000 people a year come for treatment of IV drug use. The general policy applied in Bangkok is to use methadone for detoxification but not for maintenance. They are in the process of reconsidering that policy. In addition, WHO is providing experts on IV drug use as consultants to the Thai government to assist them to reassess their strategies and try to determine what they should do. They are facing an urgent problem. There is evidence of needle sharing and the increase of infection is quite concerning. As IV drug use always does, it links together other segments of the community. It links together issues of perinatal transmission. It links together issues of heterosexual transmission. Therefore, it is not just, as you well know, an IV drug use problem. It's a problem for the whole society.

There is no needle exchange at the present time in Bangkok. They will be reassessing the use of needle exchange programs in the context of the urgent situation they now face.

DR. PRIMM: I wanted to also personally commend you for such a wonderful and complete presentation today. I think it's one of the best we have ever heard and I just commend you highly for that.

CHAIRMAN WALSH: Dr. Lee?

DR. LEE: My questions have to do with incidence and prevalence, Dr. Mann, but they are so multi-faceted that I think I'll defer my questions for now and hope that by the end of today I'll be smarter. I'll have a chance at you tonight.

CHAIRMAN WALSH: Let's start on the end. Dr. Lilly.

DR. LILLY: A question for information. It's my understanding that the United States has not paid its assessed contribution to WHO and the AIDS program?

DR. MANN: On the one hand, the United States through the USAID, has been one of the first and one of the most important contributors to the Global AIDS Program of WHO. Their support - technical, financial and moral has been critical to our success.

On the other hand it is a fact that the United States government is in arrears regarding its assessed contribution for the regular budget of the World Health Organization. This does create a problem for the AIDS program insofar as we are funded by sixteen countries who give extra resources beyond their normal contribution to WHO in order to fund the AIDS activity. Of those, the U.S. is the largest single contributor now to our program of AIDS.

However, we require administrative support services from an organization whose budget is not fully funded. It is true, sir, that the assessed contribution is not fully paid at present. To AIDS directly through USAID, the United States has been very supportive and very generous.

DR. LILLY: Just one other question. Is the WHO in any way involved at present in drug development for the treatment of AIDS?

DR. MANN: We're involved in several areas around the issue of drug development and we expect to be much more involved in the future in several others. Briefly, for example, we just held a technical meeting to examine the question of animal models, an important issue around drug evaluation strategies.

In addition, within six to nine months WHO will be able to play an important coordinating role in international studies of drugs. In the same way, we will play an important role regarding vaccines by providing an international forum and an international umbrella, if you will, for the conduct of certain studies. This will always and only be done at the express request of the governments involved. If a government does not want WHO to be involved, we will not be. We are not a supranational organization but it is of great importance to us all that field trials carried out internationally be done in accordance with the highest scientific and ethical standards. The issue is not that any one government or company or institution does not understand those scientific standards, but sometimes appearance is just as important as reality. If anyone, anywhere, has the feeling that international science is using people as guinea pigs, then we would all be the losers. It's in that interest as well that WHO sees its role.

DR. LILLY: The guinea pig concept is one that bothers me a great deal. I think it's something that has to be taken in consideration there. Another is that while vaccines very often turn out to be relatively cheap, drugs nowadays do not. There is essentially no drug that is currently under development, either for AIDS or for any other disease, that has any chance of being even faintly as cheap as aspirin. For example, AZT is something that's being used pretty widely in this country now. It's my understanding that there's no underdeveloped country that can afford AZT for anybody.

DR. MANN: Yes, sir, that's essentially true. AZT is purchased and used for certain members of different societies. In other words, people have different financial capacity in developing countries. But it's certainly true that, at present, there is no affordable drug that could be used widely in the developing world. In addition, I have to add that the use of AZT implies an infrastructure which includes the capacity to monitor various clinical indicators such as hematologic status and these facilities are not always present in developing countries. We don't yet have the drug that we need. The question will clearly be, once we have it, can we, the world, afford it?

I think there's an issue of fundamental equity at stake here and I think it's a question we're going to have to face. How do we make a drug that works and that can be used, for example, to prevent the development of AIDS in HIV infected people? How can we bring that drug to the people around the world who need it? That seems to me to be a fundamental question that we need to be asking ourselves. At the moment, we're not much further than asking, but we are asking the question.

DR. LILLY: One last question. The United States is indeed an extremely wealthy nation. We are doing an awful lot but we're not doing it terribly efficiently at present. Many of the countries that you deal with are not in the same ball park at all with respect to economic situation. How can an extremely poor country put together a program that has any chance to be effective in preventing AIDS, in coping with the problem of existing AIDS?

DR. MANN: I really appreciate your asking that question because it's something that, of course, concerns us a good deal. When you really look at what will be effective against AIDS, it's not always as expensive as it might look in some ways. It depends on what kind of an AIDS problem you have. When you have an IV drug use AIDS problem, you've got, by definition, an expensive problem on your hands. But, let's say that the basic problem is like the problem in India today or in China or in the Philippines. It's a problem of prevention. It's a problem of education. It's a problem of social commitment and social mobilization. Now, those are things in which no society necessarily has an edge over another and where resources, money, doesn't necessarily make all the difference. You do need a certain amount of resource to conduct any activity, but I think that we'll be seeing, over the next few years, true leadership, in AIDS prevention coming from areas of the world that are resource poor. They will be mobilizing the resources that they already have, in the context of their culture and their society in order to achieve the changes that are needed. After all, that's what is required for a prevention.

No, they will not have large research programs. No, they may not develop new drugs. That's excluded for most of the world's population. They don't have the resources. Again, where IV drug use is a problem, you have a particular issue that is going to require a great deal of resources and time and commitment. So, in many of the countries where the problem is just beginning, they will be able to do a lot with very little. In countries where the problem is well under way but not overwhelming, I think we'll be impressed to see how much can be done with a relatively small amount of money. But some of these countries, sir, have no money at all really and therefore, it is going to require international support through the international networks, through the World Bank, through the bilateral assistance agencies, through WHO. We will be required. We will have to keep people in some of these countries to help them for an indefinite period of time.

But that's not an insurmountable amount of money. We're not talking, for that particular country, of hundreds of millions of dollars. We're probably talking about several million dollars a year. That's a budget that I think the world can afford.

CHAIRMAN WALSH: Dr. Crenshaw.

DR. CRENSHAW: I have particularly appreciated your writing about phases which societies go through from denial, minimization and constructive engagement. I think individuals do that, too, but countries are confronting this problem relatively inadequately still, and I think you would agree in many cases.

You mentioned that the estimate of cases by 1991 worldwide of AIDS was a million. Could you give that estimate for that same date for HIV positive?

DR. MANN: No, but I wish I could. The reason I can't is that for the number of AIDS cases, the die is cast. That is to say, unless we discover and use and deploy a drug that could prevent the development of AIDS in HIV-infected people. Otherwise, for the people already HIV-infected, the die is cast. Now, the risk of developing AIDS is a finite risk and that we can do nothing to prevent. But we have absolutely everything to say and do about that other figure. In other words, that's where we can act.

DR. CRENSHAW: That's where my question is going exactly. What I would add is could you, from the point of view of describing for us the power and the potential of prevention -- if you can't do it with HIV positives with the cases of AIDS -- a worse case scenario and a best case scenario of five years after 1991 and five years again after that, 2001, giving what would happen if we didn't improve and what we have the potential to do by contrast? Best case and worst case.

DR. MANN: I can give you half an answer and maybe three quarters of an answer. The best case is that the number of infected people could essentially stabilize in the five to ten million range. That's a best case, but that's a case, we have to remember, that implies an ongoing number of AIDS cases and burden of illness that would continue beyond 1991.

The worst case I would put this way. We would guess -- it's a guess -- that there are several hundred million people in the world whose behavior puts them potentially at risk of infection with HIV. Now, that is a guess. The studies aren't available yet that would allow us to be any more precise. In other words our best guess is that there are several hundred million people who either practice self injecting behaviors or who have sexual practices and a life style that would allow them to be HIV-infected. The whole question becomes how common is infection where they live and what's the likelihood that they have contact with an infected person? I'm not saying that there could be several hundred million people infected in five years. Fortunately, I think that is not possible.

But, in terms of the ultimate potential of this epidemic -- realizing that if every infected person, infected two other people over the course of their lifetime, they would increase the epidemic -in that context, we see the potential. From what has been observed in IV drug using populations in Edinburgh, in New York City, in Milan and now in Bangkok, in female prostitutes in Nairobi, in male homosexuals in San Francisco and in parts of Europe, we can say that HIV has the potential to create an explosive epidemic in a population if the behaviors that spread the virus are sufficiently intense. All we can do is say that the potential for the involvement eventually of hundreds of millions of people over a long period of time exists. That's the best I can do in trying to estimate that answer.

DR. CRENSHAW: Thank you. And then you made some comments about central nervous system involvement in asymptomatics. Could you make some similar elaboration on comments of HIV infection in the clinical stages and the impact of AIDS dementia and fine motor coordination problems on pilots, etc., the concerns that were raised?

DR. MANN: We basically have divided the issue into otherwise asymptomatic people, CDC Group II and III, and people who have ARC or AIDS. It's clear the people who already have the disease AIDS will not be functioning, or are unlikely to function, in a variety of particular occupational settings. The problem of dementia in the people with AIDS is indeed a major problem and it's a problem that's going to stress and strain the health care capacity of a country like the United States enormously. People have calculated the needs there will be for psychiatric support and for surgeons to do brain biopsies to determine etiology and so forth over the next five years. I've seen the estimates. They're rather staggering in terms of the current neurologic and psychiatric capacity in the United States and what might be needed in five years to deal with an increasing burden of AIDS dementia and neurological problems. The WHO consultation concluded that the current weight of evidence suggests that people who are otherwise asymptomatic, do not have any increase in functional abnormality compared with uninfected people. Once you are speaking of people with the disease AIDS or with ARC, in functional terms one is dealing with a different situation. There, clearly, AIDS dementia and other neurological problems can play a very major role and will be a major challenge to countries like the United States.

DR. LILLY: Do you have additional recommendations on how to cope with that or does the World Health Organization? For the sake of time, could you provide us with that document you mentioned about the projections within the United States of the burden to our psychiatric care system cost estimates? Do you have some suggestions, just general common sense?

DR. MANN: Yes. Again, in the interest of time, if you agree, I'll be happy to provide those to you in writing. They're part of the report of the meeting that was held. Regarding the projections for the psychiatric and neurologic resources needed in the next few years, I will convey your request to the author of that who is an American and ask if he could possibly provide that to you because it's not my data.

DR. LILLY: Thank you.

CHAIRMAN WALSH: Ms. Gebbie?

MRS. GEBBIE: Two questions, at least a portion of which, I think, is answerable in writing later on. I think it would be very helpful for us to have a picture of exactly what resources you have available to you. It at times sounds like you must have a staff of five thousand with all kinds of support. I know that's not true, but it's also bigger than just you. So some outline of the staff directly assigned to your program, how they're deployed and perhaps what you're able to draw on a short term or interim basis from the member countries would help with our perspective.

The question I'd like to have answered here may be one that's awkward and difficult to answer but is very important to us, given our charge. From your perspective, outside the United States, what are the three things that this country should do in the next year that would be most critical to your efforts world-wide. I include in that either things we can do that are contributions directly to your effort or things we could do in total in our AIDS policy that would be a help to you in carrying out your mission.

DR. MANN: Thank you very much. In terms of the first question, we will be happy to provide you with that information. Eighteen months ago, it was me and a secretary. We now have over a hundred people working in the program. I would particularly like to highlight the tremendous work that's been done here in the Americas by the group based at PAHO under Dr. Ron St. John, who you'll be hearing later, who exemplify what's true of everyone working in this field which is to say we're understaffed, overstressed, overworked, but we're doing a pretty good job, all things considered. When you look back at the distance we've all come in just the last year or two, it gives us some strength to proceed, not that more work isn't needed.

Three areas that come immediately to mind. A commitment by the American research community to be fully supportive of international research activities, to link, as much as possible, American research with international research. A commitment to the protection of human rights and to positions of anti-discrimination regarding how people who are HIV-infected are

handled. The whole world looks at the United States. The whole world watches and listens to your debates and your discussions. For you to take the position that the protection of the human right of people who are infected, which in no way diminishes their responsibility to behave responsibly, the commitment to anti-discrimination would be a beacon of light around the world.

The third thing would be ongoing and continued financial, political and moral support for the world-wide effort. The world can't do it without you. We need you to continue to play the strong role that you have played in the beginnings of world-wide AIDS control and to see that carried through.

So, a commitment to research being international and functioning in the international context with international cooperation, commitment to human rights in AIDS, and a commitment to ongoing support. These would give people confidence that, from the United States they see the ingredients for leadership that will help lead the way for the future.

MRS. GEBBIE: Thank you. I would appreciate, with regard to your first and third points, again as a followup in writing, if you could elaborate a little more on how those might be carried out or what you see as the gaps today that need to be filled. I think that would be very helpful to us. Thank you.

DR. MANN: Of course.

CHAIRMAN WALSH: Dr. Mann, I want to thank you for being as attentive in the replies to your questions as you have been. I just want to make a very short comment. I shan't use the prerogative of any questions to you at this time.

First of all, in regard to the United States' obligations to the World Health Organization, I think it should be clarified that the withholding of certain payments was a legislative action taken by the Congress and was taken in the context of all United Nations agencies with particular concern over the one agency which has since, I think, clarified or rectified its problems. Unfortunately, the World Health Organization was caught in the concept of all of the affected agencies and there has been general admission by the Congress in particular that of all of the U.N. agencies that the World Health Organization has probably been the most efficiently run, has squeezed out virtually all of the fat and, as a result of that, a substantial payment to the World Health Organization was made this year. I believe $68 million was given. Again, by law, they could only give eighty percent of the assessment because that's part of what the Congress has on the books. There's nothing you can do about it. I personally am optimistic, however, that there is considerable movement on the part of the administration and the state department to move the rest of the funding so that I hope the

arrears problem will be settled. I don't think we should leave that unclear for those who are paying attention to these hearings.

I think the second aspect of it is that we're all concerned about the cost of drugs and pharmaceutical development. I think these problems have a way of getting solved but I don't like to see it inhibit the research that's being done. If you try to solve them before the research is completed, you'll do away with the research. The normal way in which this has been done in the past is that, vaccines, medications and the like are sold in the developing world at a much lower rate than they are sold in our own country and in western Europe. In fact, we pay, to some extent, for the traffic that goes, in many instances, to the Third World. I think out of fairness we can cite what is being done in river blindness. This was a drug developed by an American corporation that was used, actually in veterinary medicine. Incidentally it was discovered that it was a potential cure for river blindness which affects some forty million people in the world. This was donated by the company to the World Health Organization for distribution in the Third World. So, I don't think we need to spare too much, too early. I think you also Dr. Mann, who, in his own way, is a persistent and would be an even more persistent adversary of anyone profiteering on pharmaceuticals in the war against AIDS. I don't think this is something that this Commission has to be concerned with at this time.

Thank you very much, Dr. Mann.

CHAIRMAN WALSH: If the next panel would proceed to the table, the next session is on the Pandemic in Africa: Description, Responses and Implications. We have a half a dozen people making presentations. As I think all of you know, we gave Dr. Mann a considerable amount of time because he had a great deal to say and gave us an overview of where we stand. Therefore, I would ask that this panel try to keep to the schedule, to allow use more time for questions and we would welcome any additional statements, or remarks that you would like to give to us to be presented in writing should you feel that your views have not been fully presented.

The first representative of this panel will be Dr. Thomas C. Quinn, Associate Professor of the School of Medicine of Johns Hopkins University and a Senior Investigator at the Laboratory of Immunoregulation of the National Institutes of Health. Dr. Quinn.

DR. QUINN: Thank you, Mr. Chairman. Members of the Commission, as indicated by Dr. Mann, within a relatively brief period of time, AIDS has become a global pandemic with over 85,000 cases officially reported to the World Health Organization

from one hundred and thirty seven countries. Since many other cases remain unrecognized and unreported, it is estimated that over 150,000 cases of AIDS have probably occurred world-wide with an additional 500,000 individuals with AIDS-related conditions and an estimated five to ten million individuals infected with the etiologic agent of AIDS, the human immunodeficiency virus.

Unfortunately, the vast majority of both asymptomatic and symptomatic infected individuals reside in developing countries where the economic and social impact of this disease will have its greatest impact. Because of limited financial resources in these countries, the challenge to control this epidemic will be greatest within those areas where traditional efforts to control other infectious diseases with vaccines and other measures have always waned behind more technologically advanced countries.

Five minutes is not enough time to sufficiently review the current status of HIV infection in Africa, a problem which has already claimed thousands of lives and where an estimated three to five million people are already infected with this potentially fatal virus.

Consequently, I've provided the Commission with several recent reports which review in detail the present status of HIV infection and AIDS within some African countries and I would now like to review the salient points of these papers with specific attention on the distinctive epidemiologic features of HIV infection in Africa.

With your permission, I would like to show a few slides while I present these remarks. If I could have the first slide, please.

Presently thirty nine of forty four African countries have reported over 10,943 cases of AIDS to the World Health Organization. However, it is generally accepted that thousands of additional cases remain unrecognized and unreported due to inadequate resources for comprehensive surveillance. Nevertheless, the impact of HIV infection can be readily acknowledged by the extremely high seroprevalance rates of HIV in selective populations throughout central Africa and neighboring countries.

HIV infections range from five to fifteen percent among healthy blood donors, two to eight percent among women attending prenatal clinics, fifteen to twenty five percent among men attending sexually transmitted disease clinics and twenty seven to ninety percent among female prostitutes. In one city in central Africa where surveillance rates have been in place for at least three years, it is estimated that AIDS cases now two hundred cases per hundred thousand population as of the end of 1987. Even with these disturbing numbers, it is probable that

these are minimal estimates, since the data reflect only recognized and reported cases of AIDS in several hospitals within that city.

Both AIDS surveillance and HIV serologic data can be utilized to reflect some of the basic epidemiologic trends of AIDS in Africa. As in developed countries, AIDS in Africa primarily affect young and middle aged persons. However, in contrast to the United States, AIDS cases in Africa are equally distributed among both men and women with a sex ratio of approximately 1 to 1.3. The sex and age distribution of HIV infection in Africa as shown on this slide reflects patterns seen with other sexually transmitted diseases in which the incidence and morbidity rates are higher among younger women and slightly older men. The seroprevalence status strongly suggests that HIV infection is predominantly common in sexually active age groups and that it is predominantly transmitted sexually since there is insufficient evidence at the present time throughout Africa for IV drug abuse and bisexuality to explain this distribution of cases.

Longitudinal studies on HIV seroprevalence demonstrate the annual incidence rates of HIV infection among selected populations in Africa. Among female prostitutes in Nairobi, Kenya, the rate of infection rose from four percent to eighty percent over a six year period. Among men attending a sexually transmitted disease clinic, the rate rose from one percent to eighteen percent during that same time period. Similarly, among the general population such as pregnant women attending a prenatal clinic, the rate rose from less than one percent to three percent in Nairobi and from two percent to eight percent in Kinshasa, Zaire.

Rapidly increasing incidence rates in urban areas are compared to the relatively stable rates in some rural areas as recently documented in a remote village study in Zaire which strongly suggests that rapid urbanization associated with both economic and social changes have played a major role in the rapid spread of HIV infection among certain populations.

Regardless of geographic region, HIV does appear to be transmitted through three major routes: sexual, parenteral and perinatal. There are important regional variations which exist within each of these transmission categories. In contrast to North America and Europe, where the predominant sexual mode of transmission has been seen among homosexual men, heterosexual transmission is far more common in central Africa. Numerous studies have identified the following risk factors associated with heterosexual transmission of HIV in Africa and, to a limited extent, in the United States: the number of sexual partners, sex with a prostitute; and being a prostitute or being a sexual partner of an infected individual. Whereas anal receptive

intercourse is a prominent sexual behavior associated with HIV infection among homosexuals in the U.S., this behavior does not appear to play any specific role in HIV transmission in Africa.

Co-factors such as sexually transmitted diseases which induce genital ulcerations are significantly associated with HIV seropositivity. In nearly every study performed among individuals attending STD clinics in Africa, HIV infection has been independently associated with the presence of history of genital ulcerations. In one recent study, the rate of seroconversion following sexual contact with an HIV infected woman was eight percent for men with a recent history or clinical evidence of genital ulceration.

With HIV seroprevalence rates of two to eight percent among pregnant women in some central African areas, increased evidence of perinatal transmission is being documented as shown on this slide. Perinatal transmission of HIV may occur in utero, through transplacental passage of HIV natally at the time of delivery or postnatally possibly through breastfeeding or other routes. Efficiency and the risk factors associated with perinatal transmission remain unknown and prospective studies are currently underway in several African countries. Preliminary data from Kinshasa, Zaire and Nairobi, Kenya suggest that approximately forty to fifty percent of children born to HIV antibody positive mothers may be infected perinatally. In one study, nearly a quarter of the children born to HIV seropositive mothers have died by twelve months of age compared to only three percent in a control group of children born to HIV seronegative mothers. It is thus apparent that HIV infection is an important cause of premature birth and perinatal death in Africa and that transmission from mother to infant appears to be strongly correlated with clinical stage and immunologic competence of the mother.

The importance of blood transfusions in HIV transmission in Africa is exemplified by the six to eighteen percent seroprevalence rates documented among blood donors in Uganda, Rwanda, Zambia and Zaire. The impact of this mode of HIV transmission is substantial. For example, as shown on this slide, approximately 8,900 blood transfusions were given to children with malaria at one hospital in Kinshasa, Zaire in 1986. Since the HIV seropositivity rate among blood donors is shown to be six percent, one can estimate that 561 seropositive blood donations were given the children with malaria in this hospital setting alone. With assistance from international health agencies, HIV screening by the development of a rapid blood test has been utilized to prevent further transmission with HIV positive blood.

Unfortunately, and this is where the tragedy continues to persist, many other areas of Africa still do not have the resources or assistance from other countries to implement such basic preventative measures for HIV infection.

Exposure to unsterilized needles used for medicinal purposes or rituals may also contribute to HIV transmission, but that contribution in accelerating the HIV epidemic in this region has been difficult to quantify. Additional studies are warranted to delineate the attributable risk of HIV infection following exposure to blood-contaminated needles and syringes. In review of studies on household transmission and other epidemiologic studies that have been performed in this area, it is evident that there is no evidence for casual contact transmission or transmission by insect vectors.

Finally, the AIDS situation in Africa has been compounded by the appearance of another epidemic, HIV-II infection occurring in the countries of west Africa. Identified in 1986, this related human retrovirus appears to be associated with similar clinical features ranging from asymptomatic infection to AIDS similar to that described for HIV I, the predominant strain in the United States. Seroprevalence rates for HIV II among residents of western Africa, as shown on this slide, range from two percent to a high of twenty five percent among female prostitutes. Transmission patterns of HIV II appear to be essentially identical to that described for HIV I. Recent studies have identified evidence of HIV II infection, not only in Africa, but now also, to a limited extent, in the Caribbean, Europe and, more recently, a case in the United States. Intensive studies are urgently needed to examine the natural history of this related retrovirus and to determine its pathogenic role in causing AIDS, not only in west Africa, but throughout the world.

In summary, it is evident that HIV infection and AIDS have become a major health problem in Africa. In some urban hospitals, such as in Kinshasa, Zaire, approximately thirty five percent of hospitalized adults and twenty percent of hospitalized children are known to be infected with HIV. With limited financial resources in many of these areas, the efforts to control this virus will require an unprecedented coordinated international effort involving all countries.

The challenge to control HIV infection is great for all countries, but perhaps it's even greater for Africa where a greater proportion of the population may already be infected and where the general social, political and economic context of modern Africa may limit the effectiveness of some control programs.

An intensive effort by the international health agencies, scientific experts, politicians and the world population at large will be required to combat this disease. This concludes my formal remarks and I want to thank the Commission for the opportunity to present before you.

EXECUTIVE DIRECTOR GAULT: Because of the logistical situation here, I think that the next two witnesses, as I understand it, also have slides that they would like to show. I think that the Commissioners should go into the audience so that they can see the slides and not have to look backwards. Dr. Quinn, if you could provide us for the record with hard copies of your slides because I don't see them here in the testimony as yet.

DR. QUINN: I'd be glad to.

EXECUTIVE DIRECTOR GAULT: If you all don't mind the rudeness of maybe the Commissioners going to the back, it would be easier for them then to understand your presentation. I don't think that the last three witnesses have slides, do they? You do have some slides. Okay. So Dr. Lamptey has some slides, also.

CHAIRMAN WALSH: We'll do the questioning of the whole panel at the same time. Dr. Bongaarts, who is the Senior Associate for the Center for Policy Studies at the Population Council in New York, will be our next witness.

DR. BONGAARTS: Mr. Chairman, the AIDS epidemic in Africa has raised a number of important demographic questions. In the brief time available, I will deal with only one of those and that is the issue of the potential impact of the epidemic on the population growth rate. Some observers fear or claim that we will see reductions in the size of populations in some African populations. My analysis suggests that this will not happen.

Before explaining how I've reached that conclusion, I'd like to show you what is expected to happen in the absence of the epidemic. In the first slide, I've shown population projections from the United Nations for the period 1980 to the year 2025 for three major regions: the developed world, the developing world and for Africa. As you can see, the developed world essentially has reached stability and will go very little further. In contrast, the developing world as a whole will approximately double over the period considered here, so we'll see rapid growth in this part of the world.

Within the developing world, however, there's a great deal of heterogeneity. Continents such as Latin America and Asia will grow slower than average while Africa will grow at a much faster rate. In fact, Africa, at present, is by far the fastest growing region in the world; it is expected to grow from less

than 500 million individuals in 1980 to 1.6 billion people in the year 2025.

The reason for bringing this to your attention is that the more rapid a population grows, the more difficult it is for an epidemic, even a very large one such as AIDS, to stop its growth.

The question before us then is whether this population growth curve which is projected in the absence of AIDS will be marginally affected by the epidemic or whether it in effect will decline, as some people believe. Answering this question requires a complicated analysis because a large number of behavioral, epidemiological and demographic variables are involved. I've turned to the computer and developed a computer model to attempt to answer this question.

The next slide presents the HIV prevalence curves estimated in a projection of a severe epidemic such as we're seeing now in central Africa. It's a projection for a twenty five year period from about 1975 to the year 2000. Since the model keeps track separately of different behavior groups, I have prevalence projections for prostitutes and the male partners of prostitutes, each group reaching very high prevalence levels. But I want to draw your attention to the bottom curve. This is the seroprevalence for all adults.

There are two points I would like to make. The first one is the shape of the curve. Initially, seroprevalence grows exponentially, then linearly and eventually it starts levels off. I believe that this shape of the prevalence curve will be seen in all countries in Africa, indeed everywhere in the world. We've already seen it in the United States and there is evidence in one city in Africa where perhaps seroprevalence is beginning to level off as well.

The only question is at what level this will take place and the timing. These factors will differ greatly from country to country. The second point I'd like to make about this curve is that this is an attempt to simulate the future course of a severe epidemic. Assuming that this epidemic started in 1975, at the moment 1987 would be at the mid point in the projection interval and, according to the computer projection, have a prevalence of about ten percent which is roughly what we see in the hardest hit countries in Africa. So, the first part of this curve is approximately corresponding to that type of an epidemic.

If the rest of the projection is correct, then we can expect a leveling off by the year 2000 at a prevalence level of around twenty to twenty five percent of all adults in countries

such as Uganda. I should emphasize that this is for the country as a whole. For the urban areas, we'll see much higher prevalence rates while the rural areas will be below that.

The final slide shows the effects of this epidemic on the population growth rate again for the twenty five year period from 1975 to the year 2000. At the beginning of the epidemic, the growth rate is approximately three percent, which is typical for central Africa. Over time, the population growth rate declines very substantially to below two percent. However, the growth rate is still very much positive so there will be continued growth, even in the presence of this severe epidemic.

The cause of this decline in the growth rate is a rise in the death rate as shown on this slide. I've plotted here both the birth rate and the death rate. The growth rate equals the difference between them, so the five percent birth rate minus the two percent death rate gives us the three percent growth rate that we saw initially. Over time, the death rate will rise substantially and reach about 2.6 percent, but this rise in the death rate is not sufficient to close the gap between the death rate and the birth rate and therefore, the growth rate will remain positive.

My conclusion then, from this brief analysis, is that we'll see very large increases in death rates in central Africa, possibly doubling in some countries, but this will be insufficient to reduce population growths to negative rates. We'll see continued rapid population growth in these countries.

Two final points. The first one is that the simulation I've shown here is for the most severe case, as seem in some Central African countries. The remainder of Africa will probably be less affected. It's unclear at the moment how much less severe this will be because the epidemic will vary in size from country to country and the timing of the epidemic will vary greatly.

The second point I'd like to make is that, as I already said, these projections are made for countries as a whole. In urban areas, seroprevalence will rise to much higher levels. Some observers have wondered whether we could possibly see a reduction in the population growth rate in the urban areas. The answer again is no because, even if the death rate triples or possibly even quadruples in the urban areas, the population growth rates of the urban areas are so much higher than country averages so that it has a strong offsetting effect, making it very difficult to end up with a reduced size of the urban population in Africa. Thank you very much.

CHAIRMAN WALSH: Thank you. Next we have Dr. Mead Over from the World Bank. I think it is particularly significant that Jonathan Mann has been working together with the World Bank

and with UNDP and other agencies to coordinate as well as he can the joint efforts. Thank you, Dr. Over.

DR. OVER: Thank you, Mr. Chairman. The previous two speakers, Dr. Quinn and Dr. Bongaarts, have described to you the number of cases that we think there might be in Africa and other developing countries and how that number of cases might evolve over time.

I'm here today to talk about the economic impact of the HIV virus on developing countries and I'm going to be talking primarily in terms of the economic impact per case. One could compute the total aggregate impact of the epidemic on individual countries if one were to know the kinds of numerical answers that have just been described and then multiply those numbers times the cost per case.

As the Chairman has just mentioned, this work has been supported by the WHO and the World Bank jointly. I will talk today from a paper that's been made available to you and which has been authored jointly by myself, two authors from the Global Program on AIDS headed by Dr. Mann, and the National AIDS Program Coordinators from the two cooperating countries which were Tanzania and Zaire.

In these preliminary estimates we have not been able to address all types of possible economic impact. In particular, the effect that AIDS might have on the external demand either for a country's hotel and tourism services or for its workers has been omitted from the analysis. Also, it is too early to predict how much countries will spend on prevention of HIV infection using the national AIDS programs that we've heard described this morning by Dr. Mann.

Furthermore, the possibility that large numbers of deaths from AIDS in some countries might have an effect on the average cost per death has not yet been addressed. The focus here is on two categories of cost, the direct cost and the indirect cost. By the direct cost of HIV infection, we mean the cost of health care for ARC and AIDS patients. The indirect cost is the value of the lost years of healthy life caused by the disease. I believe you've already heard the estimates for the direct and indirect cost of AIDS in the United States that have been prepared by Ann Scitovsky and other researchers here in this country.

Estimates of the direct cost of AIDS per patient in the United States range from 28,000 to more than 50,000 dollars while those for the indirect cost total approximately $200,000 per patient. If these results are expressed in terms of the cost per HIV infected person rather than in terms of the cost per AIDS case and if the costs are discounted back to the time of the HIV

infection, which is that critical point in the history of the disease that Dr. Mann was describing this morning, then in the United States the present value of the direct treatment-related costs would range from 10,000 to 18,000 dollars per infected person and the indirect costs would equal about $73,000 per infected person.

What are the comparable numbers for the developing countries? This figure (Figure 4) displays our upper and lower estimates for direct and indirect costs per case of HIV infection in Tanzania and Zaire, the two countries which have been cooperating with our study. The estimates for direct cost per AIDS case vary between $100 and $1500, however, when expressed as the direct cost per HIV infected person, rather than per AIDS case, the range of these estimates drops to between $37 and $560. The direct costs appear on this graph as the black portions of the bars.

You can see also that the indirect costs per HIV infected person ranges from $900 to more than $5,000 in these two countries. The direct cost is clearly dominated entirely by the much larger indirect costs.

Now let's look more closely at each of these two types of costs. First, consider the direct cost. The estimates for direct cost are calculated by estimating the typical cost of treating each opportunistic illness in these developing countries and then averaging these by weighing each illness according to the estimated probability that it will strike an average AIDS case again in these countries.

The direct cost estimate varies from individual to individual and from country to country depending on both the socioeconomic characteristics of the particular patient and on the medical and institutional characteristics of the health care options faced by that patient. These differences are visible in Figure 1. It displays the direct cost per case on the vertical axis of this chart, measured again in 1985 dollars, and on the horizontal axis we've displayed the 1985 GNP per capita of Zaire and Tanzania, where this work was performed, and of three other countries. The range in GNP per capita is from $170 for Zaire up to about $1700 for the United States.

You can see that the direct cost per case in Zaire and Tanzania and in the other countries are related closely to the GNP per capita. This is a very important finding. It's perhaps not a surprising finding because we already know that health care expenditures in general are closely related to GNP per capita. Whether one looks across European countries, across developed countries or whether one looks across all countries in the world, as GNP changes, health expenditures change. This, we have found, is also the case for AIDS.

Now consider indirect cost which we defined as the value of the healthy life years lost due to the disease. First, we estimate the total number of healthy years of life lost and discount them to the date of infection. We've done this calculation, not only for HIV infection which is represented by the bar on the far left of the diagram, but also for thirteen other diseases which are prominent causes of death and morbidity in developing countries, especially in Africa. (See Figure 2)

The height of the bar represents the discounted number of healthy life years lost per case of this disease. It also represents the number of healthy life years that could be saved by prevention of one case of each of these diseases. Notice that HIV infection ranks about fifth on this diagram. It is dominated by some other diseases whose principal victims are infants, but it exceeds many other diseases which are known to be serious health problems in Africa including malaria, for example. The next step is to take these years of life that are lost due to a case of each of these diseases and weight them by the productivity of each of the years of life. We assign a weight of one to the years between age fifteen and age fifty, a year zero to the ages between zero and five and intermediate rates to other age ranges. In this diagram, the hatched bars are a reflection of the previous chart you just saw, the unweighted healthy life years lost per case of each disease. (See Figure 3). The solid bars represent the effect of weighing. Naturally, because some of the healthy life years lost have been multiplied by numbers smaller than one, the effect of this productivity weighing is to reduce the number of years lost from a case of each disease.

A major impact of this procedure, of course, has been to greatly shrink the measured impact of the childhood diseases relative to the adult diseases. Diseases like tetanus, birth injury and sickle cell anemia are greatly reduced in their net impact when the lost years of life in childhood are omitted from the calculation.

The final step in calculating the indirect cost per case is to attach a dollar amount to each productive healthy life year. Low and high estimates of these values account for the differences between low and high estimates of the values in the first diagram that I showed you. (Figure 4).

Again let me point out that these indirect costs exceed greatly in magnitude the direct costs, just as they do in the United States and by approximately the same factor of proportionality - between five and fifteen.

How large will be the total burden of HIV infection on a developing country? Again, as I said at the beginning, the true calculation of that amount is impossible right now because we still do not have the final results of the quantitative seroprevalence estimates that are being performed by epidemiologists in these countries with the cooperation of WHO and other international agencies. However, we can make some hypothetical guesses. These hypothetical guesses will not apply to either Tanzania or Zaire because we have no data that's sufficiently complete for those countries to be able to make such estimates.

But suppose that we have a country with a per capita income of about $200, which is typical for this region of Africa, and suppose that it has a population of about ten million people, which is a nice round number, larger than some countries, smaller than others in that area. Suppose that twenty percent of this population lives in the urban area. Suppose, in addition, that the average annual income of rural adults and urban adults are about $250 and about $600 respectively. Finally, suppose that the seroprevalence rate among rural adults is about one percent and suppose that the seroprevalence rate among urban adults is about six percent. Those figures are consistent with the information we have on several severely affected countries. Then the total number of HIV-infected adults in these two groups would be 80,000 in the rural area and 120,000 respectively. If approximately fifteen percent of these seropositives were infected in the previous year, then about 12,000 rural and about 18,000 urban adults would have been infected during the previous year.

What was the economic impact of those 30,000 people who were infected in the last year? The results recorded here suggest that the present value of the total direct cost of the health care for these newly infected individuals over the future course of their disease would be approximately between $150,000 and $1.5 million while the total indirect cost would be about $3 million for the rural adults who were infected and approximately $11 million for the urban adults. Thus the total costs for this African country would range between $14 and $15 million.

As a percentage of GNP, this would represent about three quarters of one percent. However, it might represent as much as fifteen percent of total health expenditures in such a country.

Thank you, Mr. Chairman and ladies and gentlemen.

CHAIRMAN WALSH: Our next presentation will come from Dr. Peter Lamptey, who is the Director of AIDSTECH and Family Health International at the Research Triangle Park in Durham.

DR. LAMPTEY: Thank you, Mr. Chairman. I'm grateful and privileged to be asked to testify to this Commission. I would like to address the needs of the low prevalence countries, especially those in Africa. As an African public physician, I'm also grateful for the leadership the U.S. government has shown by its support of the WHO Global Program on AIDS and other United States agencies for international development assistance programs such as the AIDSTECH and AIDSCOM projects.

Africa is the least developed of the developing world. It has the worst health status and has the least financial and human technical resources. It is also the area that is worst hit by the AIDS pandemic. Of the over forty countries that have reported AIDS cases in Africa, about only a quarter may be described as high prevalence. Most of the publicity, some of it adverse, has been focused on these countries. WHO and other agencies have also concentrated their efforts on these high prevalence countries. There's no doubt that countries with relatively high prevalence of the disease must act now to stop the transmission of AIDS.

There are equally compelling reasons why the low prevalence countries must intervene just as quickly and forcefully. My primary recommendation therefore -- low prevalence countries deserve -- as much as the high prevalence countries. Even where the rural prevalence is low, especially in West Africa where I come from, some groups, such as commercial sex workers, have high prevalence rates. AIDS can be compared, in this country, to a forest fire. The fire has started in multiple places in a small way and right now it is probably easier to control and extinguish these fires by individuals using fire extinguishers. If we allow the fire to grow to a raging inferno, it will be more difficult, more costly both in terms of lives and money, to try and control such an infection.

In some ways, AIDS in this country is a public health opportunity. A small investment now in prevention will provide substantial gains in slowing the spread of AIDS, especially in countries who already have overstretched health resources.

AIDS is an international disaster. Lack of funding, politics and ideology should not prevent assistance in AIDS control. Low prevalence countries present an opportunity for a better understanding of AIDS. Some of the gaps in our knowledge, whether it's the epidemiology of the disease, the politics or the cultural and social aspects, can be better studied in the low prevalence countries than in the countries that have high prevalence.

I would also like to make a special appeal to the U.S. government to continue support for the global prevention of AIDS. The current level of funding is inadequate. Here is the

rationale for this continued support. One, knowledge gained in the epidemiology and control efforts in Africa will be useful for control efforts in the U.S.

Second, the economies of developing countries can not afford the cost of an AIDS program. In countries where the per capita health budget for the year is less than a dollar, the additional burden of an AIDS control program obviously can not be afforded.

Three, AIDS is a global problem that is spread in part by international travel. The virus recognizes no frontiers. Lastly, for humanitarian reasons. The AIDS problem will only get worse and we need the assistance of countries such as the U.S. to continue providing such support. However, we must not divert resources from other areas such as child survival programs. A lot of progress has already been made in reducing morbidity and mortality, especially in children. Diversion of resources from these programs will only make the general health situation worse.

In conclusion, I'd like to make a special appeal to the U.S. media. The media has helped raise awareness of the AIDS problem and contributed immensely to the support that is being provided by western countries.

At the same time, the media has also created much damage and added to the AIDS problem by irresponsible reporting, misinformation and sensationalism. These reports have contributed partially to the delay of many African countries in responding to the AIDS problem. Help us fight the global problem of AIDS together by more responsible reporting. Thank you.

CHAIRMAN WALSH: Thank you very much, Dr. Lamptey. Our next speaker is Samuel Adeniyi-Jones who is with the National Institute of Child Health Development and whose national origin is Nigeria, so we again have another first hand view of Africa.

DR. ADENIYI-JONES Thank you, Mr. Chairman and members of the panel. I want to make it clear that I'm not speaking for the NIH because I think this is something that needs to be clarified. My involvement with AIDS is a personal one and arose from a personal desire on my part to help my colleagues in Africa deal with the problem. There are two reasons.

One is that about two years ago when it became clear that there was an epidemic raging in Africa, the political situation immediately arose with the public health situation. I was very worried that we would get into a situation where we would be busy fighting the political situation and lose the battle of the public health situation, which is actually what happened at the very beginning. So I thought that I could play an important part in maintaining the focus on the public health situation.

Secondly, I thought I was also in a unique position, being a scientist at the National Institute of Health. It seemed clear to me that what was needed was international cooperation and that I was in a unique position to bridge the gap for this sort of international cooperation. I had colleagues here whom I had a very good relationship with and I had colleagues in Nigeria. That is why I embarked on this personal odyssey. Much to my surprise, these things are much more easily said than done.

I have traveled to Africa several times in an attempt to talk to health officials. I have been supported to a large part by organizations here, the Africa Bureau of USAID was very

instrumental to my early programs. Through some of the agencies that it supported, they have paid me as a consultant for some of these trips.

I've also been a consultant for the World Bank, especially in its attempt to help the Ugandan government deal with its health problem in general and the AIDS problem in particular. I think I have a sort of unique perspective because I have no allegiance to any group or anybody and I have floated back and forth.

What has become clear, and I think it's clear to everybody, there are two major problems. One is that in some parts of Africa, you have a raging epidemic. In the other parts, you have the beginning of an epidemic. Dr. Lamptey has rightly stated that both areas need equal attention for the reasons which he has stated so I won't go into that.

The question we would ask ourselves is with the epidemic raging in those parts of Africa, Uganda, Zaire, Tanzania, do we have a program that would help control it? If you listen to Jonathan Mann, you would think yes, we do have a program. But, from the point of view of the African health officials who are dealing with the program every single day, we don't have a program. There are a few reasons for this.

One is that there are about four or five aspects of the control program. One is sero- surveillance, and laboratory diagnostic ability. Take a country like Uganda. This has been well-established by the WHO and I think the WHO is best equipped to deal with this sort of problem and coordinate it world-wide. But we know that this is not the aspect of the program to control the epidemic. This is just the assessment part. Of course, for the beginning of the program it is important to assess and to follow the program, to monitor where that program is effective. It's also very essential.

But the control parts of a program are quite different. They require massive education programs. They require somehow dealing with the fact that patients have to be managed. A lot of people are aware of the opinion that since we don't have the facilities to manage these patients, they are not managed. But in fact, they are in hospitals and anybody who has been to any of these countries will tell you that in some hospitals you have thirty percent of the AIDS patients in the adult medical wards, for example.

The blood bank. The numbers Tom Quinn gave, I think it's an under estimate for places like Uganda. The estimates are between fifteen, twenty and up to twenty five percent of blood donors. This part is important because it's one of the few parts of the AIDS program that we can actually do something about and eliminate. There have been arguments put forward by some of the WHO officials within Uganda that it wouldn't make a dent in the system. But, if you talk to the doctors, there are no doctors in any of the hospitals in Uganda, who do not want to stop this means of transmission. They claim the patients come to them for treatment and you have to do some basic minor surgery and you have to do a blood transfusion and you give the patient one chance out of four or five of getting a fatal disease. That, to them, is a colossal disaster and I share their view.

It is one area where we can do something. Unfortunately, the WHO program, as it stands today, and it is a WHO program, we are told that they are a national AIDS program and, to some extent, they are. But they're really programs that have been developed by the WHO and in collaboration with these countries, but many of the countries have had to just go along with it. This is exactly what they have told me. One is that if they don't go along with it totally, then it's difficult to get money from the WHO to deal with the problem.

These are the areas that have to be dealt with. The programs as they stand today are very heavy into these initial assessments of epidemiology, which I said is okay. But the other areas are not. I think probably the problem, and I went into it in detail here, is that contrary to what we're told, in fact the WHO is trying to control the programs within these countries. If it stayed with coordinating the programs, especially this assessment part of the programs that I mentioned, then we'll be in a better position because there's a lot of resistance, which is not voiced to the WHO, within these countries about having to accept these programs that have been brought to them.

Secondly, I don't think that the WHO is equipped to deal with the massive education program that is required. Actually, it requires very aggressive and massive education. I don't think it's equipped to deal with the medical clinical problem.

A lot of African officials are now thinking, in fact, that the more important part of medical program management is in fact not the medication but counseling. They are now crying out for some sort of counseling. Counseling does many things. First of all, it helps the patients themselves. It helps the families. It helps the communities.

Secondly, it's also an important part of an AIDS prevention program, especially when the counseling is extended beyond just the patients and their immediate families and is taken, in fact, to the community to people who are HIV positive. When the people are educated then, I think they will have less tendency to actually spread the disease.

The blood bank issue. The blood bank issue is not a simple one of blood bank testing. This is where I also disagree with Jonathan Mann. That you actually need a lot of money. In our assessment of the Ugandan program, I'll give you a simple example. You can not just take a testing kit to a hospital and say we want to do HIV testing for blood banks. You'll find that there's no electricity. You'll find that the refrigerators are not working. So, it requires some sort of more comprehensive approach. It requires infrastructure development and that's where the money is needed. I was very happy with the assessment made by the World Bank in Uganda. We're not dealing with an AIDS issue. We're dealing with a health issue. It requires a comprehensive health plan. They don't have the infrastructure to maintain any program. That is why some of the WHO officials are correct. You put in too much money and it doesn't have anywhere to go. But, if some of that money is actually channeled to development of infrastructure, then I think we're starting the business because, without it, I don't think we'll get anywhere.

That's why I think we should look seriously at those two aspects of the program, assessment and control. So what can be done for control? I think there are many agencies, like education, UNICEF, USAID, that have had a lot of experience with developing health education programs in these countries. The health education units of these countries are the least developed. That's where virtually no money goes. So it will require development of those health education programs so that they can do not only AIDS education, but they can do general health education within which will be an aggressive AIDS education program.

In reviewing the program in Uganda, it became clear that this sort of health education program has to be controlled by the Ministry and not by any external agency so that part of the Ministry has to be developed and it has to give it the direction, the spirited will, the sort of emotional drive that is required to do this program because otherwise it won't work.

The blood bank issue should be broader and that is why the Ministry of Health also should control the program because it would require development. It would require developing a network within different hospitals of blood banks and it would require actually developing the blood banks because what we're talking about is delivering safe blood to patients who require it when they require it. The safety of the blood is not just HIV safety, that is just one of the things, but I think it's part of the larger picture.

The other important question is the one: what do we do with patients? There are lots and lots of patients in this hospital. I think it has the potential to paralyze the health care delivery systems in this hospital with twenty, thirty patients within a ward where you have about eighty patients. First of all, the other patients know who the AIDS patients are and they're afraid. I remember a case in Uganda, a young boy of fifteen refusing to go to a ward because he said he saw AIDS patients being treated there. So there has to be an aggressive policy towards what are we going to do with all these patients that are going to come up in these countries? The health care delivery system is paralyzed and I'm sure the economic system will be paralyzed.

The time given me is very short but I hope I have somehow tried to convey what is needed in order to actually deal with the problems, especially in those areas where the epidemic is raging. What is needed, of course, in the areas where the epidemic is not raging is the same massive, aggressive education system which should be instituted now, not later. If we don't do it now for the reasons Dr. Lamptey just stated, we'll be in the same position that these other countries were. If you look at some of the graphs that they've drawn, you will find that the countries that don't have a serious epidemic now are virtually in the same position that Uganda and Zaire were about five years ago. Since we don't have a program that can stop AIDS, in five years we'll be exactly in the same position.

What can the United States do? I do not agree with Jonathan Mann that they have money. To be very honest, when I hear the officials saying they have money or too much money like the official said in Uganda, I think that they're doing a disservice to a lot of these African nations because what is required requires a lot of resources, especially to develop the sort of infrastructure that I'm talking about.

What I'm hoping is that the United States can give the sort of leadership it has been able to give in some of these other areas in AIDS control especially in Africa. A lot of money is now being poured into AIDS control within the United States. I think the real test for the United States is whether it can broaden its approach to a more international approach to dealing

with the global problem and divert the necessary resources needed to this program.

I want to make a final point which I don't think has come out here. The WHO has insisted that all funds go to the WHO. Some of us have insisted that it will not work. First of all, some of these countries have had very good relationships with the USA through UNICEF and some of these other organizations where they've established good relations and can develop programs, especially in the field of education. We've been fighting for the last year and a half to have, and I think its important to have multilateral relations to the umbrella of the World Health Organization and that is working and it's nice, but I think it's equally important that bilateral relations should be allowed to occur.

I'm glad to see that the USAID has already come to that conclusion, so I understand. I stand to be corrected. I hope many of the other organizations will come to the same conclusion because if they don't, we are in trouble. We need both multilateral relations and bilateral relations. Thank you.

CHAIRMAN WALSH: Thank you very much, Doctor. Our next presentation will come from Dr. Peter Perine who is the Director of Tropical Public Health Medicine at the Uniformed Services University of Health Science in Bethesda. Go ahead, Doctor.

DR. PERINE: Thank you very much, Mr. Chairman. I'm speaking today with respect to a special situation of AIDS as it affects one African country and that country is Zambia. I want to first preface my remarks by saying that this represents the work of several very remarkable, extremely professional and highly dedicated Zambian physicians and health care workers. They're facing a Herculean task, to say the least.

The first evidence of the presence of the Human Immunodeficiency Virus in Zambia was in 1982 and it was a presentation of patients with an atypical, aggressive form of Kaposi's sarcoma that were being evaluated at the University Teaching Hospital in Lusaka, which is the tertiary care referral center for the country of Zambia. Over the next five years, the numbers of AIDS cases has increased to a reported 754 with eighty deaths which have disproportionately been members of the professions and the educated. During this time, the number of Zambians infected with HIV has also increased dramatically.

Medical care in Zambia is provided by the government to all its citizens through seventy one hospitals in 845 urban and rural health centers. It is organized as a primary health care system extending to the level of the village health worker with a referral mechanism up the pyramid from the district level to health centers to Provincial hospitals and, as I said, at the

national level to the University Teaching Hospital in Lusaka. The total number of hospital beds in the country is 15,348. There are an additional 6,320 beds available in its health centers. Medical care for its 7.5 million people is therefore provided by approximately 800 physicians, 6300 nurses, 1350 clinical medical officers, and 500 health assistants. That works out to be approximately one physician for 100,000 population and one health care worker for 10,000 people.

The HIV epidemic in Zambia is seriously taxing its health care facilities. HIV-related disease currently accounts for about ten percent of all general hospital admissions and up to thirty percent of admissions to general medical wards. The immediate problems this presents include a disproportionate allocation of both diagnostic and therapeutic resources to AIDS patients, repeated hospital admissions and treatment with medications that are often in very short supply or nonexistent.

At the University Teaching Hospital, HIV cases currently comprise 17 percent of all medical ward admissions and 42 percent of these patients have active pulmonic or disseminated tuberculosis. Tuberculosis is often the first manifestation of HIV but diagnosis is difficult because chest x-rays may appear normal or atypical. Although most patients respond to antituberculosis therapy, expensive multiple drug regimens are required and they're required for the remainder of the patient's life time. Hospital stays are also prolonged. HIV infected adults with active pulmonic tuberculosis are also sources of exposure for young children sharing their households unless the patients with tuberculosis are rendered noninfectious by tuberculous chemotherapy.

With respect to pregnancy and congenital transmission, our first study examined a large number of antenatal women that made it to the labor wards of the University Teaching Hospital in 1985. 10.8 percent were confirmed seropositive and approximately half their children appeared to be congenitally infected on followup at one year. Significant risk factors for HIV infection were the number of both life time sexual partners and the number of episodes of sexually transmitted disease the mother had. Most of the HIV infected mothers were asymptomatic and had term pregnancies with no increase in miscarriage or abortion when compared with age and parity-matched HIV negative pregnant women. Of the 400 HIV seronegative mothers followed postpartum for twelve months, only six or 1.5 percent converted to seropositivity.

Infants born of HIV infected mothers do not differ in birth weight or rate of neurological or social development from other children. Those infected with HIV, however, usually become symptomatic within the first year of life. They rapidly lose weight from a combination of chronic diarrhea, cough and fever

requiring frequent and often prolonged hospitalization. We have interestingly observed six sets of twins born to infected mothers. Two of those twins were identical sets. In each instance, one infant was infected and one infant was not infected.

Virtually all Zambian infants are breast fed for the first one or two years of their lives and most receive BCG, measles, polio and DPT vaccinations during the first year. An ongoing study shows no evidence that these attenuated vaccines, that is BCG, polio and measles, act as opportunistic pathogens in HIV infected children. We believe the measles vaccine also provides solid protection against measles since no child immunized has

developed measles whereas several non-immunized HIV infected children, aged eight to fifteen months, have been admitted to the hospital with severe measles.

With respect to heterosexual transmission, there were approximately 8,000 men and women evaluated at the Sexually Transmitted Disease Clinic at the University Teaching Hospital since September, 1985. Approximately sixty percent of men were seropositive for HIV-1. This is a referred population. Many of these patients came to that clinic because their clinician or health worker suspected they may have AIDS. The corresponding figure for women attending the clinic was approximately fifty percent seroprevalence of HIV-1. The only sexual practice acknowledged by both men and women, with few exceptions, is heterosexual intercourse. Homosexuality and bisexuality are denied by almost everyone except for, interestingly, the twenty to thirty percent of male prison inmates. The infrequency of rectal gonorrhea and of syphilis in STD clinics tends to substantiate the rarity of anal intercourse in non-incarcerated adults.

With respect to non-venereal transmission, there is a potential for non-venereal transmission in Zambia from both rural and urban settings because there is a widespread, almost universal, problem with the presence of malaria. The households of patients who have been diagnosed as having AIDS or ARC have been evaluated extensively and we find no instance where a child under the age of five years was HIV infected and whose mother was not also infected.

We also looked at a large population of school children living in a rural part of Zambia where malaria is constant throughout the year. We had about 3300 children who were tested for HIV and only sixteen of the boys, which is one percent of the boys, and about one percent of the girls were seropositive. In this population, almost all of them had malaria, either by blood film examination or by test of antibody against one of the malaria antigens. None of the children we found to be

seropositive had any clinical manifestations of AIDS or ARC, although about half had splenomegaly which we attributed to the presence of malaria. Very few of these children had received blood transfusions, but several had acknowledged sexual exposure. We don't have any identified risk factor for HIV infections in four of these children.

We've also looked at the households in this population of approximately 100,000 in northeastern Zambia and found that forty of about 300 households have one or more members infected by HIV; approximately 1,000 people were tested. What was interesting in this study is that there was a very highly significant clustering of cases. In this population where there were about 100 seropositives, about sixty percent of these seropositive individuals belonged to one of seventeen households. The adults were infected, both men and women, and usually children under the age of five were likely to be found infected.

Significantly there was no child between the age of six and thirteen that was infected. We think this represents one of two things. These children had not been exposed to the virus, despite they're very clearly being exposed to vectors on a daily basis. They're also traditionally scarified on the skin for decorative and traditional healing reasons on a very frequent basis. In fact, one evidence of that is that we found, much to our surprise, a dramatically high prevalence of hepatitis B virus in this population. So we think all this evidence points out that there is very little non-sexual, non-perinatal transmission of HIV taking place in this population.

Admittedly, with this high prevalence of virus, approximating ten to fifteen percent in the adults, there are a large number of children who have been infected by being given transfusions for malaria, since it is likely that at least one in six or seven blood donors who will be infected with HIV.

Although it's premature to draw conclusions about the modes of transmission in our study in the rural parts of Zambia, our data indicate that heterosexual intercourse and congenital and perinatal transmission are the principal modes. Despite frequent exposure to unsterilized instruments such as razor blades for scarification, there is little evidence that this practice transmits HIV.

Finally, with respect to prevention and control, Zambia has been rather progressive in developing a counseling service for all patients who are found to be seropositive. This is true throughout the country. They're told to bring their sexual partners in for testing. Many of these patients are being followed in cohort studies. They're encouraged to use condoms to lessen heterosexual transmission. The usage rate of condoms in Zambia over the past year has increased five fold.

Infected women are informed about the risks of congenital transmission and the potential adverse effects of pregnancy on themselves and their fetus. However, because children are so cherished in Zambia, most women continue to become pregnant in hopes that their child will be free from infection.

There has been a major emphasis put on educational programs, particularly focused on pre-adolescent, pre-pubescent children, that's been endorsed and widely publicized by President Kuwanda of Zambia, as the current chairman of the Organization of African Unity, who has indeed a personal and a rather tragic experience with this disease. His oldest son died of AIDS, which

he has acknowledged and has used in talking to groups of people to tell them about the human side and the dimensions of this problem in Africa.

In summary, HIV is epidemic in Zambia among both urban and rural populations. Transmission is predominately by heterosexual intercourse and during pregnancy. Hospitals can not now or soon will not be able to treat the large number of HIV patients requiring care. The health care system faces critical shortages in personnel, supplies and equipment and its facilities are rapidly deteriorating because of a lack of maintenance forcing families to assume a greater responsibility for patient care at home.

Available epidemiologic data suggests that the slope of the HIV epidemic in Zambia is falling, but the number of projected AIDS cases among those already infected by the HIV may produce catastrophic socioeconomic consequences for Zambia in the next decade. Thank you very much.

CHAIRMAN WALSH: Thank you very much. We'll start the questioning in a moment. Just a brief comment.

Dr. Jones, I think you'll be very happy to know that we're spending most of tomorrow on potentials of bilateral assistance, so a lot of your questions may be answered tomorrow. In fairness to WHO, I think that Dr. Mann was not indicating that he was against bilateral assistance or wanted all the funding to come to WHO. Rather he indicated that there is a proper time for that assistance when it would be most productive. What he was trying to get at was some type of coordinating process so that the bilateral assistance could be given efficiently. Maybe he was so subtle in this expression that you may not have heard it. But I think he was pretty clear on that, that he was encouraging bilateral assistance.

DR. ADENIYI-JONES I wasn't referring to what he said. I was referring to what is going on.

CHAIRMAN WALSH: Oh, yes, I understand. I was just bringing out the fact that I think if he believes in that, believe me, I know Dr. Mann, it will be stimulated if he believes in it. I'm not going to question your statement but I know that he believes in bilateral assistance. It's just the timing of when it should be given. Dr. Colleen Conway-Welch.

DR. CONWAY-WELCH Dr. Jones, you mentioned counseling as one of the most efficient ways to address the problem. Do you have models of counseling? Do you use family members? The shortness of health care professionals obviously means counseling needs to be extended into the general population with resources other than health care workers. How are you addressing that?

DR. ADENIYI-JONES I'm not addressing it in any detail because it just came up. I was actually impressed when it was brought up by officials in Uganda. When I went to Kenya, it was brought up immediately that they're realizing now that they're burdened with all these patients and some sort of counseling is needed. One way it would help is to keep patients out of the hospital. Like he was saying, they have to be treated outside within the community.

I think what we're advocating is to be able to get some money so that we start developing programs for counseling. They have started having education for counselors in Uganda which is the first thing to do. That has to be massive education for counselors to integrate the counselor, education and functioning into the health education system at all levels right up to the community level. So I'm talking in broad terms because I don't have a program but it came up and we have started discussing the best way to approach it. The first thing to do is to train counselors.

COMMISSIONER CONWAY-WELSH: Thank you.

CHAIRMAN WALSH: Dr. Lilly?

DR. LILLY: I have just one quick question. One figure that was quoted this morning which I've heard quoted before, or roughly the same thing, that the male to female ratio in many parts of Africa is 1 to 1.3. This is, nevertheless, not a one to one ratio. I'm wondering what this implies. I assume that the risk for a woman to be HIV positive is somewhat detectably larger than it is for a man. What does this mean for transmission?

DR. QUINN: Since I presented those figures, I'll respond to that question. It does appear that there are more women than men infected with the virus in some areas of Africa where studies

have been done. Some of these studies have involved female prostitute populations and that may alter that data to some degree. If one looks at AIDS statistics and people with AIDS in the hospital, you still come away with this finding of slightly more women than men, but it's fairly close to one to one. It may be that male to female transmission may be slightly more efficient. It may also reflect social cultural factors that may be more common in Africa than in other areas of the world. These issues need to be addressed and I don't believe that sufficient studies have been conducted to answer that satisfactorily.

CHAIRMAN WALSH: Dr. Crenshaw?

DR. CRENSHAW: Dr. Perine, following up on that same issue, in your transcript backup material here, you make a very strong statement that from your studies it appears that female to male and male to female transmission is equally efficient. Could you elaborate on that because the common perception is again what we hear and what many in the United States believe, that men have some kind of sex-linked immunity and the only reason it's different in Africa is because of "co-factors". Would you bring us up to date?

DR. PERINE: I made a general statement and I didn't intend to say that the numbers of men infected in Zambia and the numbers of women are proportional.

DR. CRENSHAW: I was referring to your spouse article.

DR. PERINE: When we looked at households of infected patients where either the index case was a man or a woman, we were surprised to find that in fact there were more spouses of infected women who were infected as compared to fewer spouses of infected men. I think part of the problem is that we now recognize that the infectivity of a partner may change with the duration of disease. This isn't clearly an accurate measurement of that. What is, I think, happening, if you look at the broad number of cases, in Zambia and elsewhere in Africa, the proportionate number of cases indicate that the efficiency of transmission is approximately the same for man to woman and from woman to man.

DR. CRENSHAW: Did I understand you correctly that, of the couples that you studied, there were more males infected, would you repeat that one more time so I'm clear?

DR. PERINE: If the wife was infected, approximately sixty nine percent of their male spouses were infected. If we looked at the infected man and look at his wife, we found that a lower percentage of the wives were infected of infected men than the converse.

CHAIRMAN WALSH: Ms. Gebbie?

MRS. GEBBIE: I have a question that I'll direct to both Dr. Bongaarts and Dr. Over with a request for some comment now and then some written followup. In both of your cases, it would be very helpful to me to see your methodologies in more detail to really make sure I understood the points you were making. My particular question, with regard to Dr. Bongaarts, is the fact that you seem to be using total death rates rather than age specific death rates. At least to a casual observer, if the age specific death rate in those groups that are potential child bearers shoots up dramatically, then, not in the short time frame you illustrate but in the much longer time frame, I would expect a more dramatic effect. So it may be you've accounted for that and a more detailed look will help.

Dr. Over, with regard to yours, I'm used to looking at productive years of life lost statistics in the United States which discount years of life from sixty. Your totals seem to come out with productive life lost below the age of eighteen and then you discounted childhood years of life lost which I don't always see. I'd appreciate some better understanding of the rationale for the choices you made which appear different.

DR. BONGAARTS: Thank you.

To answer your question about the age specificity of the death rate, the model is fully age specific. In fact, I calculate death rates for each single age. So, if one has a twenty five year projection, I would have to present twenty five times eighty numbers which is too many. For the purpose of my presentation, I have only summarized results with the overall death rate. I'll be happy to provide you with the details of the model. I do have a document that describes this.

MRS. GEBBIE: Thank you.

DR. OVER: Because not everyone agrees on exactly how lost healthy life years should be valued, I did the calculation in the steps that you saw, in several steps.

For many purposes, the first calculation I made would be sufficient. For example, some decision makers may not care to weight children's years of life differently than adult years, and for those decision makers the first estimates I gave are healthy life years lost, discounted, but without any discounting for low productivity of the childhood years would be the best.

However, if we want to move farther and try to think about what the economic impact of the disease is on a country, we do need to try to estimate that

impact. And, in order to do so, we need to differentiate between productive years and unproductive ones, or less productive ones, and that was the basis for the weighing that I performed. Is that responsive?

MRS. GEBBIE: That's helpful. I'd like to see a more detailed discussion of your methodology.

DR. OVER: Certainly.

MRS. GEBBIE: Thank you.

CHAIRMAN WALSH: Dr. SerVaas?

DR. SerVAAS: My question is to Dr. Perine. Are there sufficient AIDS tests available in Zambia to know which children should receive vaccines and which should not? Is that a problem?

DR. PERINE: Thank you for the question. No, it's not a problem. The vaccines are given starting at the first day of life. That's when they receive BCG vaccine.

The children are immunized beginning at the third, fourth and fifth month of life against polio and DPT, and receive measles at eight months of age. And, you cannot test the infant for antibody to the AIDS virus, because during this whole period of time they are likely to have passively transferred antibody from their mothers. So that, the testing procedure, including even antigen tests for HIV, don't seem to be very efficient in determining whether or not the infant is infected.

DR. SerVAAS: Then, do you go ahead and vaccinate the children of HIV positive mothers?

DR. PERINE: Yes.

DR. SerVAAS: For measles, for everything.

DR. PERINE: Well, children who ultimately prove to be HIV infected, they are vaccinated, that's correct.

DR. SerVAAS: And, is that a complication then?

DR. PERINE: It hasn't appeared to be, and, indeed, it appears to also provide protection for the child.

CHAIRMAN WALSH: Dr. Primm?

DR. PRIMM: I had a considerable concern when Dr. Jones spoke, and I did not hear the kind of concern that he expressed, from any other member of the panel. And, that bothered me,

because with most of our panels I've been able to glean a concurrence or some similarities in what they expressed. And, I was very shocked by that.

Dr. Perine presented statistics, of course, on Zambia, that were startling to me, that certainly would question the ability of the infrastructure to support the onslaught of whatever this disease entity is going to bring to that nation.

Then Dr. Quinn did likewise, and I'm concerned that I don't hear an orchestration of the problems of the infrastructure in these countries that cannot handle the situation at the present time, even if the WHO was in there, and a refusal on the part of these countries to do something because it's coming from an outside source and it's not from inside itself. In other words, it would be much more successful if the countries themselves, the Ministers of Health, as he expressed, may receive some of these dollars, and much more effective if we did something about the infrastructure of these nations, particularly a health infrastructure, if we plan for them to handle this problem, or if we intend to help them. Any panel member could respond to that.

DR. PERINE: I'd like to respond to your question. I should have pointed out very clearly, these are studies done by Zambians. Our input has been very minimal. They've been given money through a variety of sources, and they've utilized the money, they've designed the studies, they've done the work. This is Zambians doing the work; it's virtually no one else, or people working in Zambia that are not nationals but under contract to the government.

So that, the Zambian Ministry of Health is the person or the group of people who have decided what their priorities are and how they'll approach these problems, and I can't, again, say enough about their professionalism and the way they've gone about this.

They were one of the first countries, I might add, that, perhaps, were a little bit reticent to take international aid or assistance, because they felt that they had within themselves the resources to do something about it.

Now that they know some of the dimensions of their problem, they are clearly in a more receptive phase to further develop the research they've initiated. And, there's no question that they need all the help they can get, financial and otherwise, to begin to cope with the burden of illness that HIV is presenting to them now, and God only knows how they'll cope in the future.

I might add also, and this is something that no one has said about Africa, that the people, the family unit in Africa is a remarkable supportive network. It's something we could learn a lot from. Patients are never abandoned. They are taken care of. Children are never abandoned. There are no orphanages in Zambia, for example.

There is a coping mechanism in Africa that is remarkable, and I wish there were some parts of it we could integrate into our own health care system. They will cope, I have no doubt about that, and they will suffer, but I think they will ultimately persevere.

CHAIRMAN WALSH: Dr. Quinn?

DR. QUINN: I'd also like to respond. There is no question that the situation of AIDS and HIV infection in Africa is paramount to being a very serious medical problem that affects all Africans, as it does to all Americans and other people throughout the world.

Since 1983, we've been working in close collaboration with the Ministry of Health in Zaire, the Ministry of Health of Uganda, the Ministry of Health in Kenya, and the Ministry of Health in Tanzania to try to assess the problem, and then to implement preventive measures.

The first and easiest, which Dr. Jones has already alluded to, is implementation of blood bank screening programs, by bringing in types of programs that introduce rapid screening tests for HIV. But, it can't stop there.

Any program that's to be successful on controlling HIV in Africa has to rely on the health infrastructure of that particular country. It has to be strengthened.

A very classic example, not just for Africa but for the United States as well, is heterosexual transmission of HIV appears to be related to genital ulcers and other sexually transmitted diseases among heterosexuals. A control program that would be successful in controlling those genital ulcers, gonorrhea and syphilis and herpes and chancroid, would have an indirect effect on helping control HIV among those heterosexuals.

So, in our efforts to try to assist to control AIDS worldwide, within Africa and in this country, I think we have to broaden our perspectives, to not just AIDS, but the entire health infrastructure within each country. That's a massive effort, but it's one that we must do, and it will have secondary benefits.

The major benefit would obviously be helping to control AIDS, which is killing thousands of people. The secondary benefit, would be to provide health to millions of people. Thank you.

CHAIRMAN WALSH: Thank you. Dr. Lamptey?

DR. LAMPTEY: Yes. I'd like to comment. And, part of what Dr. Jones has said is very true in terms of the absence or inadequacy of infrastructure, and I'd like to illustrate one or two examples.

One is the blood banking area. There are a lot of countries in Africa where blood banks only exist in the urban areas, or some of the bigger towns. And, the moment you go beyond that, blood is almost sometimes transfused as soon as the patient is bled.

In the absence of a blood bank, it becomes extremely difficult to try and screen adequately blood in these circumstances. Therefore, one of the best things to do is to either develop a blood bank or improve the system.

Dr. Jones was mentioning the absence of some of the equipment that you need in a laboratory, it could be a refrigerator or it could be other commodities that they need for the optimal functioning of the laboratory. Improving the infrastructure is therefore essential if we are to improve services.

One other problem that we found in some of these countries is lack of expertise in managing AIDS programs. What has happened is that, a lot of physicians, such as microbiologists have been put in charge of AIDS prevention programs, people who have no expertise at all in handling a public health situation or managing large health programs. Adequate training in health care management for these program managers is essential for the successful implementation of AIDS programs.

We need to fill the gaps in our knowledge in terms of epidemiology of AIDS and knowledge of sexual behavior. We have already started trying to change sexual behavior when we least understand it. Technical assistance is needed to study and understand the AIDS problem in developing countries.

The needs of developing countries are both fiscal and technical - we need funds to improve the infrastructure of the health system, to provide equipment and commodities as well as technical assistance to define the problem and manage the intervention programs.

CHAIRMAN WALSH: Dr. Lee?

DR. LEE: One of the most important parts of our charge is to tell the President what's going to happen, incidence and prevalence continues to bother me, because the statistics contradict each other. And, basically, this question will get back to Dr. Bongaarts.

Now, if we look at some of the material that has been presented by Dr. Mann and most of the rest of you, we're saying that at least 10 percent of the blood donors in most of these countries; around 2 to 18 percent of pregnant women, about 6 to 18 percent of the blood donors in various other countries, 10 to 15 percent of all the adults in Zambia, et cetera, et cetera.

Now, if we start looking at this and adding up the figures, we were told by Dr. Mann that we've got 10 million overall HIV infected in the world today. But, if we have 1.5 to 2 million in this country, and if 10 percent of Kenya is infected, that's at least 2 million. That's two countries, and we're up to 4 million. It seems to me that our exposure here could be a great deal larger than we are giving it credit for.

We add to that the fact that if 10 percent of the women that are delivering are positive, half of those babies will die. It seems to me we've got to have an effect on population here somewhere, according to the figures that you've given us. Can you comment on that?

DR. BONGAARTS: Well, there are two parts to your question. Let me start with the seroprevalence picture. You are quite right, and several of the speakers have already indicated, there are very high levels of seroprevalence in urban areas of Central and East Africa, 10, 15, perhaps 20 percent in some parts.

It is also important to remember that the majority of Africans 80 percent or so, live in rural areas, and they, by and large, are much less severely affected. I think there is probably no rural area in which seroprevalence is over 10 percent, and most of them are far below that.

Secondly, large parts of Africa, North Africa or West Africa, are much less severely affected by this epidemic than Central Africa. The two largest populations in Africa, Nigeria and Egypt, probably have a prevalence of less than 2 percent, maybe only 1 percent.

DR. LEE: Nigeria, 2 percent?

DR. BONGAARTS: Well, there's a recent publication that suggests 1 percent, .9 percent for Nigeria, a national sample. Also very interesting is the low prevalence among prostitutes. If an epidemic started in Nigeria, one would expect to see seroprevalence rise first among prostitutes. The prostitutes seroprevalence in Nigeria was estimated at less than 2 percent.

What I'm getting at is, that we're going to see a great deal of variation in the sizes of epidemics in African countries. It's possible that large parts of rural areas will never have a serious epidemic. The reason for this is that, some parts of Africa will not have what's called a self-sustaining epidemic. One can introduce HIV, and a number of individuals, perhaps a substantial number, will get infected and will eventually move on to AIDS, but they will not have a self-sustaining epidemic like we have among homosexuals and IV drug users in this country, or as we have in the urban areas.

Now, how it all will develop is very unclear. At the moment, the highest numbers are observed in urban areas in Central Africa and in no rural area is seroprevalence over 10 percent.

Now, to the second part of your question, namely, the demographic impact, a graph that I didn't show to you is one that estimates what level of prevalence would be required to stop population growth. In my simulation, it's approximately 50 percent, that 50 percent of the adults would have to be seropositive before a population growth rate turns negative and population size is reduced. That is the average.

Since the younger adults, between, say, 20 and 40, have a higher seroprevalence than older ones, the prevalence among the young would have to be 60-70 percent. It seems very implausible that will happen, but I cannot rule it out. Theoretically, it's possible, but it seems very unlikely. And, as I demonstrated, the computer model suggests that this will not happen.

DR. LEE: Could I deduce from this then that in Africa, just as in this country, this disease remains compartmentalized?

DR. BONGAARTS: No, I don't think that will happen. What will happen, is that we'll get epidemics of very different sizes in different countries.

We have the first and largest epidemics in some Central African countries. It will undoubtedly spread to many other countries, and we'll see increases in seroprevalence just about everywhere in Africa and, perhaps, in the rest of the world.

The question is, what level of prevalence will we end up with 10, 15 years from now? I think it is safe to say that the rest of Africa will be below the 15 to 20 percent levels now observed in some urban areas, of Central Africa.

DR. LEE: Any other comments on that?

DR. PERINE: Yes. I want to remind you that the prevalence, about half of all Africa in this population are children under the age of 15, and they are not sexually active, and from our studies they are not infected, except if they are infected at birth or they are unlikely to survive beyond the age of five.

So that, you have to halve those prevalence figures and apply them only to the sexually active population, somewhere between the ages of 15 and 35 or 40. Beyond that, most people seem to be at very low risk.

DR. LEE: I just have -- go ahead, do you want to --

DR. BONGAARTS: Perhaps, I should add one point that I didn't make clear in my presentation, and, that is, that projections I have made so far, all assume no behavioral change. That is, the behavior that's analyzed in this epidemic will continue as in the past.

I have no doubt that education campaigns will have an impact, and they are crucial at this point in time to stop whatever epidemic is coming and building momentum.

I believe that we already may be seeing the impact in one country, in one city, Kinshasa, of such an epidemic. The data are perhaps not conclusive, but they suggest a leveling off of seroprevalence in Kinshasa. We'll need a few more years worth of data before we can think this is definite, but there have been strong education campaigns in Kinshasa, and it appears to have done some good.

CHAIRMAN WALSH: I have only one brief question, and, that is, should we be concentrating, therefore, more effort on the education and training of infrastructure if we're ever to win this battle? It just seems to me that from what I have heard, all that we may wish to be done cannot be done in Africa, without a greater base of infrastructure. Is that an overstatement?

DR. ADENIYI-JONES No. I think you are absolutely correct. In the first place, that's the only thing that will control it, the education type of program.

I was part of a group that went to assess the situation in Uganda, the overall situation, and it was quite clear that if you really want to do something, if you really want to effectively do something, you have to develop those aspects of the infrastructure that will --

CHAIRMAN WALSH: Because, this will help everything, not just AIDS.

DR. ADENIYI-JONES And, it will help them.

CHAIRMAN WALSH: Any other comments on that? There is general agreement on that, that more attention has to be paid to training of infrastructure.

All right. Thank you very much. It's been a most interesting panel, and I think we've all learned a lot. I think you raised, perhaps, more questions than gave us answers, but that's what we're here for.

And, we thank you very, very much.

THE PANDEMIC IN THE AMERICAS:

DESCRIPTION, RESPONSES AND IMPLICATIONS

CHAIRMAN WALSH: The next panel will bring us back to this hemisphere, where we are going to learn something about the pandemic in the Americas.

Now, our first presentation on this panel will be from Dr. Alastair J. Clayton, who is the Director General of the Federal Centre for AIDS in Ottawa, Canada.

Dr. Clayton?

DR. CLAYTON: Thank you, Mr. Chairman.

I think, if I may, I'll stand here and talk briefly.

As you, perhaps, know, I have to leave about 1:00 o'clock.

CHAIRMAN WALSH: Yes.

DR. CLAYTON: -- so thank you for allowing me to go first.

CHAIRMAN WALSH: With your permission, if any of the panel has questions, may they ask you before you leave?

DR. CLAYTON: Thank you, sir.

CHAIRMAN WALSH: Thank you.

DR. CLAYTON: I'd like then, very briefly, just to talk to you about the Canadian situation, ladies and gentlemen. I think the first thing to recognize is that while Canada is somewhat north of the United States, and most of you have heard of us, you don't know very much about us. I don't suggest that's the case of this distinguished panel, but it is often the case.

But, one thing which is important is that Canada has 1/10 the population of the United States, 25 million distinct from 250 million. And, that, of course, influences our statistics dramatically.

The latest figures that we have, the material I sent to you some month or so ago, have changed, and we have as of today, some 1,700 cases in our country, of whom 900 or so have died. The major difference between the U.S. and Canada is in the lack of cases in intravenous drug users. We only have 11, which is about .7 percent of the total, whereas, in the U.S. 17 or more percent are intravenous drug users. I think there are reasons to explain this, but I don't think I have time to go into this at the moment.

The other major difference is, perhaps, children. We have, again, less incidence in children, and most of those are children of Haitian mothers, because there is a large Haitian community in Montreal, which is predominantly French speaking.

Our National AIDS Program has developed over the past seven or eight years, as has been the case in the United States. Originally, we started off activities in the Laboratory Centre for Disease Control, which is the Canadian equivalent of the Centers for Disease Control in Atlanta.

And, as time moved along, and as the matter became more serious and more, albeit, limited resources were added to us, so did our activities become more comprehensive. Last year, we created a Federal Centre for AIDS, which is now in the process of being staffed with some 57 people, we have a limited budget at the moment, but have requested the Canadian Government for enhanced resources and funding, on which we have not yet had a response.

The centre is designed to coordinate all governmental activities we don't have an NIH, or a number of organizations such as exist in the U.S. So, again, because of that 10 to 1 population differential, there is more concentration in our activities. And so, our centre does virtually all of the things that many of the central agencies in the U.S. are doing; this includes the promotion of public education, liaison and promotion

of clinical trials, and development of new vaccines, liaison with the manufacturers and the clinical investigators as well as the regulatory agency.

Also we are involved in the coordination of preventive social health activities, stimulation of epidemiological studies, for example, a survey of health care workers who are exposed to HIV infection. We've had nearly 200 people recruited into the survey and nobody has seroconverted. This is encouraging.

Another epidemiological study involves multiply sexually active women. We now have about 1,500 women recruited from 6 cities across the country. There have been very few women who have seroconverted.

We are responsible for maintaining, establishing and improving surveillance within the country. The Centre conducts most of the international liaison with WHO and other agencies involved with AIDS control.

Also, within the center, we provide the National Reference Service for Canadian laboratories. This involves the more complex and definitive diagnostic testing, production of reagents, quality control, culturing the virus and so forth.

We have an active international component in the laboratory, acting as one of the WHO Reference and Collaborating Centers. One of the major issues that we've had to deal with at the moment, Mr. Chairman, is the matter of testing of immigrants and others. We have a great deal of political pressure on our government to institute testing for immigrants. This, of course, has been conditioned very much by what has happened in the United States.

The U.S. government recently produced a paper which discusses the success of the "mechanism" of testing immigrants. One can accept that this can be a successfully prosecuted program, but how effective has it been? The information from the U.S. has not to this time indicated to us that this has been an effective program.

As Dr. Mann said earlier on, we know that testing of large groups of relatively low risk people will not control the spread of this disease. The political pressures of screening immigrants are very high, but we are maintaining the existing Canadian government policy, which is that testing should be done only under conditions of informed consent with pre and post-test counseling, in place.

How long we'll be able to resist these pressures, I don't know. I hope we can continue with the present policy because and I think this is probably the pattern developing in the U.S., once you test one group of people, then it's kind of "domino effect". Next, is testing of prisoners, which is already happening in your country, then people going into hospital, people who are going to get married and so forth. We are trying to forestall this type of "chain reaction."

Our National Advisory Committee has produced a very extensive document, which may have been given to you. It discusses ever category of testing, whether it should be mandatory or compulsory, distinct from voluntary. The Committee has come out firmly on the side of non-mandatory testing. So, we're very curious, as I think is the rest of the world, to see what's going to happen in this country.

I would like to make a recommendation to you, but it's probably not my business to do so.

Let me, therefore, just summarize or finalize, by talking a little on our international activities. The Canadian

International Development Association, has provided $4 million this year and $4 million last year to WHO/GPA. This makes us the fourth highest contributor to WHO/GPA.

We have undertaken, with the Panamerican Health Organization and our laboratory, a number of activities. These involve training specifically a course to be held in August, providing technology training for 50 scientists. One of the more interesting things we're doing is providing reference services for the Haitian Red Cross specifically, they have asked us to undertake their Western Blot tests.

Finally, Mr. Chairman, let me express to you that the Fifth International Conference on AIDS will be held in Montreal next year, next June. This is the fifth in the series of Conferences, previously held in Atlanta, Paris, Washington, and Stockholm this year. Thank you.

CHAIRMAN WALSH: Thank you. I wonder if you are willing, may we ask you some questions, so that you can leave, and we'll save the rest for the others?

I think I'll start myself now, since we have a short table. And, that is, in using the term "immigration," are you using permanent immigration or are you using tourists as well, because we see in our papers from time to time that because of the high incidence of AIDS in the United States that you are getting political pressure on that, and that's one question?

DR. CLAYTON: I think that's a very good question, sir. I'd like to respond to it. As far as we are concerned, we are talking about immigrants only. We have about 100,000 immigrants who come to Canada each year. Now, those are legal immigrants. We've, obviously, a number of illegal immigrants, as you do. Also, there are a number of resident aliens, as you call them who, of course, are part of that same picture. But, we are talking about legal immigrants only.

I should say, to put this into context, that while we have 100,000 legal immigrants a year coming into Canada, we have 68 million border crossings. I think the risk of acquiring infection by a Canadian tourist to San Francisco or New York City is probably more significant than detecting an infection in an immigrant coming from Czechoslovakia or Iceland.

CHAIRMAN WALSH: Right. Well, I wondered, because I know that in our own work in the foundation which I run, we are now required in most of the countries in which we work to have HIV testing done if our teachers are going to stay more than three months. And, that seems to be a pattern that is developing, and I wondered about that. But, as I say, with the extensive exchange between our borders, the pressure has got to be unbelievable.

DR. CLAYTON: It is quite difficult, and in some cases you are sending people up to Montreal and Toronto to be tested before you are letting them back in again.

CHAIRMAN WALSH: That's right.

DR. CLAYTON: This doesn't make it very easy for us either.

CHAIRMAN WALSH: This is right. Okay. Dr. Lilly, would you like to ask a question?

DR. LILLY: I was interested in your analogy of sort of the domino effect in testing, but, in particular, you seemed to be on the verge of making a recommendation with respect to that, and then you seemed to decide better of it. I was wondering if I could convince you to give us your recommendation.

DR. CLAYTON: Well, it's a little difficult, Dr. Lilly. It's probably not my business to do so. Canada, like the U.S., has provincial or state autonomy in health care delivery, and so, if we are considering testing for people who are going to get married or going to the hospital, that becomes a state or provincial responsibility. If we are talking about prisoners or people coming in from abroad then, that's a federal responsibility.

I was going to make a recommendation, but instead I would suggest that, perhaps, an illustration of what can happen with respect to testing of certain groups, and what this can lead to would be worthwhile deliberating upon in your reports. It is the "domino effect" that's so important, and I'm concerned that we'll eventually end up testing so many subgroups of people with very low yield, and with so much expense involved. Particularly, when you consider the number of false positives. For each single positive test, there must be a follow-up regimen of repeat and confirmed testing, and that costs money. And, I think one has to recognize that the expense of testing to low-risk groups is going to involve an expenditure which would be better directed in other directions.

DR. LILLY: I couldn't agree more. To me, the cost effectiveness of testing groups like that is simply non-existent. The other question I wanted to ask you is, why do you have so few AIDS cases among intravenous drug users in Canada?

DR. CLAYTON: It might be because it hasn't happened yet. In other words, the virus hasn't penetrated into the drug using society. I don't think that's quite the case, because normally we've been about two years behind the U.S. in virtually all of our epidemiological patterns, except for this one.

Certainly we have shooting galleries, but we don't have them to the same extent. We don't have the problem and the numbers that you have in New York City, for example. Most of our drug users, are in our three major cities of Toronto, Vancouver and Montreal, which are relatively small. But, I realize that doesn't explain it either.

And, we've performed some serological surveys in methadone clinics and detox centers, and we don't have more than about a 4 percent seroconversion rate in those groups. So, the infection is present, but still contained, and extensive transmission hasn't happened yet. But, why this delay? I don't know.

CHAIRMAN WALSH: Do you have a question?

MRS. GEBBIE: One quick question.

One of the major areas we've talked a lot about is the care of those ill with AIDS or with symptomatic HIV disease of all kinds. And, in many parts of this country it has been a wrenching problem to provide that care. It's revealed flaws in our system.

People comparing this country to Canada frequently point out that you appear to lack some of those problems because you have a more organized and comprehensive system of illness treatment care than we have. You didn't really say much of anything about that. Are you finding the illness treatment care of these patients to be a problem? If so, could you just briefly comment on that?

DR. CLAYTON: We do not have a problem yet. I think that's likely because with a relatively few number of cases, 700 or so who are still alive, This hasn't had a big impact upon our health care system.

I think at any given time, there are about 200,000 occupied acute care beds in Canada, and so, another 700 has little impact as yet on the system. The other thing is, that we have a Universal Health care System, which you do not have. So, health care is accessible to everybody, including the indigent, which many of the patients or people with AIDS especially become.

CHAIRMAN WALSH: All right. If there are no other questions, we appreciate very much your coming down and talking to us, and we're sorry that we're going to miss you the rest of the day.

DR. CLAYTON: Thank you, sir. It's been a pleasure.

CHAIRMAN WALSH: Bye, bye. Thank you.

CHAIRMAN WALSH: All right. Dr. St. John is our next witness, and he is the Coordinator of Health Situation and Trend Assessment Programs at PAHO, and every time I call over here to find anything out about AIDS, they tell me I've got to talk to him. So, you must be their authority.

DR. ST. JOHN: Thank you, Dr. Walsh.

Mr. Chairman, distinguished members of the Commission, very briefly this morning I'd like to do three things. First of all, paint a brief backdrop of the health situation in the Americas; second, review the AIDS situation; and third, talk to you a little bit about the regional response to the AIDS situation.

Just very briefly, the Region of the Americas is composed of 46 countries and territories in different stages of development, including two of the most developed countries in the world, the United States and Canada.

Only one or two, perhaps, three of the countries in the Americas can be counted among the poorest countries in the world. Most nations are further along in the developmental spectrum, and

some may be classified as in transition between developing and developed nations.

In spite of its geographic diversity and extension, the Region of the Americas has some unique, unifying characteristics. Of the 655 million people of the Americas, 61 percent live in Latin America, 260 million in Latin countries share one language, Spanish, as their official language, and share a common 450-year old cultural and historical Spanish-American heritage.

This influence reaches the southern borders of four states of the United States, some of its larger metropolitan areas and the Commonwealth of Puerto Rico. Portuguese is spoken by 140 million people in Brazil, the largest county in Latin America, which borders on all but two of the countries in South America.

Besides the United States and most of Canada, English is spoken by 6.5 million people distributed in 18 countries and territories in the Caribbean Basin. A small proportion of the total population of the Americas speaks other languages, principally, French, Creole, Dutch and a host of American languages.

The important point is that 99 percent of the population can communicate with each other in just two languages, a romance language, Portuguese or Spanish, which are quite well understood between the two, or in English. The overall health status of the population in the Americas is also marked by geographical diversity resulting in an epidemiological mosaic of health problems.

The peoples in Latin America are still affected by a multitude of infectious diseases, including malaria, dengue, Chage's Disease, diarrheal disease and multiple respiratory infections which contribute to high morbidity and mortality in certain population groups.

At the same time, the population is aging rapidly, and most countries have surpassed WHO's global life expectancy goals set for health for all by the year 2000. A consequence has been the appearance of chronic diseases as major public health problems.

Finally, massive urbanization has been occurring during the last 20 years, bringing with it social and environmental stresses, including severe atmospheric pollution, chemical contamination of the environment, urban violence and general breakdown changes of traditional family structure and social mores.

The AIDS epidemic is superimposed on this disease health profile. Given the ongoing economic crisis throughout Latin America and the Caribbean, it is now clear that most economies are not generating enough income to meet current health needs. Over 700,00 children die each year in the Americas from preventable illnesses or conditions.

PAHO estimates that approximately 130 million people do not have regular access to routine health care, and cannot be reached at the present time by the current moderately well-developed health infrastructure. By the year 2000, 175 million more people will be added to the total population. Health care services will have to reach more than double the number of people which they cannot reach now.

AIDS is one more economic burden added to the problems of this Region. It is important to understand that the AIDS epidemic in the Americas takes place within this rather unique social, cultural and economic context.

I'd like to show you a few slides that will illustrate the epidemiology of AIDS. May I have the first slide, please? The Panamerican Health Organization initiated region-wide AIDS surveillance in 1983. Only officially reported cases of full-blown AIDS have been tabulated.

Surveillance of HIV infection has not been carried out in a systematic fashion as yet. As in all other regions of the world, the number of AIDS cases grossly underestimates the magnitude of the problem. PAHO estimates that between 2 and 2.5 million persons are infected in this region, and that approximately 500,000 to 750,000 are located in Latin America and the Caribbean.

This slide reveals that the Andean group of countries, composed of Bolivia, Colombia, Ecuador, Peru and Venezuela, have contributed a total of 334 accumulated cases as of February 16th. The Southern Cone countries, composed of Argentina, Chile, Paraguay and Uruguay, have contributed 206, while Brazil has reported a total of 2,458 cases.

This slide reveals that the Central American countries and Panama have reported a total of 191 cases, while Mexico, at the time of this slide, had reached 779. The Mexican total, I know, has surpassed 1,000 by now.

In this slide, the non-Latin Caribbean countries have reported a total of 753 cases scattered among many different countries. Some countries should be noted: Bahamas, with 176 cases; Trinidad and Tobago with 227 cases.

North America, composed of Bermuda, Canada and the U.S.A. has contributed a total of 54,633 cases, with the greatest majority, of course, coming from the United States. Thus, since the beginning of surveillance in 1983, a total of 60,867 cases and 33,209 deaths have been reported. The overall case fatality rate is approximately 50 percent.

To give you some idea of trend, this slide compares data from 1986 and '87, and reveals the percentage increase in the number of reported cases. Although reported cases from North America increased by just 13 percent, several other subregions reported dramatic increases, such as: 207 percent from the Southern Cone; 118 percent from the Central American Isthmus; 139 percent from the Latin Caribbean countries.

Five countries, the United States, Canada, Brazil, Haiti, Mexico, contribute approximately 97 percent of all the cases in the region. With the exception of Montserrat and the British Virgin Islands, evidence of the spread of the AIDS virus is found in all the countries and territories of the Americas.

Today the world has tracked this epidemic by monitoring the total number of accumulated cases since 1981 when the epidemic began. The total number of cases by country is not particularly useful for making comparisons between countries because the total does not consider the size of the population which gives rise to the AIDS cases. Calculating the ratio of reported cases for a given calendar year to the median population estimates for that year provides a better method for comparison. In this slide, we have taken the number of cases reported for the year 1987 and divided by the mid-year population estimates to give us cases per million population. This slide reveals that the Caribbean Region, with 52.6 cases per million population, is second only to the North America Subregion, which has 66.6 cases per million population. Yet, even these averages obscure significant differences between the countries.

These are the same calculations by individual country, with more than ten reported cases per calendar year. In this slide, you can see that there were 7.5 cases per million population in Brazil, and Brazil is near the bottom of this list, compared to places like the Bahamas, French Guiana and Bermuda, where the ratios were in the range of 240-400 AIDS cases per million population.

Indeed, the United States has moved down this list as the epidemic has spread throughout other countries, and the vast majority of countries in the first ten are Caribbean countries.

Initially, AIDS cases in Latin America were reported among male homosexuals and bisexuals with a history of travel outside Latin America and the Caribbean, mostly to the United

States. The first cases, many of which had already been diagnosed in Europe and North America, were found in Mexico, Colombia, Argentina, Brazil and other Latin American countries from 1982 to 1985.

This pattern of predominant male sexual transmission continues in North America and most countries in the southern part of South America, as well as in the Andean countries. But, an important difference between the countries in Latin America and North America is the proportion of bisexual males, which ranges from 15 to 25 percent of all AIDS cases. Many of them are married or have stable female partners.

Seroprevalence studies to detect the presence of HIV antibodies in some groups of homosexual and bisexual men, most of them volunteers, have disclosed rates shown in this slide. They range from 8.3 percent in the Dominican Republic, to 37.5 percent in Brazil.

Although this contrasts with the very high risk, usually above 70 percent, of HIV infection among some homosexual groups in some areas of the United States, the data may only indicate a later introduction and dissemination of HIV infection among homosexual men in Latin America and Caribbean countries.

Thus, HIV prevalence rates in some prospective studies have gone from below 5 percent to the present rates of 10 to 20 percent in studies conducted in countries such as Argentina and Uruguay.

The proportion of cases in which heterosexual transmission of HIV is implicated is still below 10 percent of all cases in most countries in Latin America. However, in the Caribbean and parts of Central America, significant numbers of AIDS cases and HIV infections in women are being detected.

During 1987, 24 cases of AIDS were diagnosed in Jamaica, but ten of them were women. In 1984, in the Dominican Republic, none of the cases were women; today, up to 40 percent of the cases diagnosed are in women.

The prevalence of HIV infection in sexually transmitted disease clinic patients has not been systematically evaluated outside of the United States and Canada. Studies in female prostitutes have shown HIV infection rates from 0 in some studies in Mexico and Argentina, to a high of 49 percent in one limited study of prostitutes in Haiti.

In some countries, between 5 and 10 percent of all cases of AIDS are presumed to be secondary to blood transfusions, mostly in Costa Rica, Brazil and Jamaica.

HIV antibody prevalence among blood donors is highly variable, as shown in this slide, ranging from 0 percent in 4,000 donors in Argentina, 0.1 percent in 1,400 samples in Barbados, to as high as 1.5 percent in the Dominican Republic, and 7.3 percent among some paid blood donors in high-risk areas of Mexico City.

The contribution of contaminated needles and syringes to the transmission of the AIDS virus among IV drug abusers appears to be less significant in Latin America than in the United States. Less than 1 percent of AIDS cases are believed to be associated with IV drug abuse in Latin America, as opposed to 17 percent in the United States. May I have the lights, please?

The cases associated with perinatal transmission in Latin America and the Caribbean are still few. For example, less than one fifth of cases in infants and children have been associated with perinatal transmission in Brazil. In Mexico, 16 percent of cases are current infants of infected mothers. However, limited studies in Haiti have found prevalences of HIV infection of 3 to 8 percent in pregnant women.

The majority of cases in children have thus far been associated with transfusion of blood and blood products, and, in rare cases, with sexual abuse and child prostitution. In contrast, more than 75 percent of pediatric cases in the United States can be traced to a parent with HIV infection or engaged in one of the high-risk behaviors, principally, IV drug abuse.

What has been the regional response to this epidemiological situation? The Regional Offices of WHO are fully participating components of the Global Program on AIDS. For example, the Panamerican Health Organization, which is WHO's Regional Office for the Americas, executes the Regional Program on AIDS in the Americas. The PAHO/WHO program has mobilized a total of $5.1 million since early 1987 from WHO's non-regular funding sources for AIDS prevention and control activities in this Region.

In countries where there has already been epidemiological and political recognition of the HIV problem, the PAHO/WHO Regional Program on AIDS provides technical assistance and financial support for the formulation and execution of national programs. This work will be strengthened and broadened to assist other member states already engaged in confronting the HIV epidemic. ./

By June, 1988, all countries and territories in the Americas will have initiated National AIDS Prevention and Control Programs. We hope the United States will join as well.

An additional $5 million has been obtained for AIDS research in Latin America and the Caribbean for a special contract between PAHO and the U.S. National Institutes of Health, National Institute of Allergy and Infectious Diseases. This contract emphasizes perinatal and heterosexual transmission research, as well as studies of the interaction of AIDS infection with other endemic diseases.

PAHO has been very active in promoting AIDS education throughout the Region. As Dr. Mann mentioned, PAHO organized the first Panamerican Teleconference on AIDS, which was broadcast to over 650 sites in all major countries and territories in the Western Hemisphere.

For the first time in the history of PAHO and WHO, approximately 45,000 rank and file health workers participated in a PAHO/WHO technical scientific meeting by means of this teleconference. PAHO is currently organizing and seeking funding for the Second Panamerican AIDS Teleconference, which will take place in Sao Paulo, Brazil, September 6th, 7th and 8th of this year. With WHO's assistance, PAHO has established two AIDS Information/Education Exchange Centers to act as resources in support of national educational strategies, and we hope to establish three more.

In this Region, the AIDS problem has been approached in a manner which will permit the accomplishment of as much as possible, as quickly as possible. Certain protocols and certain procedures have been bypassed and eliminated. Given the urgency of the HIV pandemic, PAHO believes that countries cannot follow traditional "business as usual" approaches. PAHO and WHO have made a commitment to its Member Countries in this Region and they in turn are now committing themselves to confronting this unprecedented epidemic. Thank you very much.

CHAIRMAN WALSH: Our next witness will be Dr. Jaime Sepulveda, from Mexico. He is the Director General of Epidemiology at the Ministry of Health. Doctor?

DR. SEPULVEDA: Thank you. Mr. Chairman, distinguished members of the Presidential Commission. I shall divide my presentation in two parts. First, referring to the magnitude of the AIDS problem in Mexico, and second, referring to the social and public organized response to the problem.

The first case of AIDS in Mexico was diagnosed in 1983 in a foreigner, who had onset of symptoms two years earlier. That means, our epidemic is a young one, relatively. Since then, 1,233 cases have been reported to the Ministry of Health. The incidence rate is exponential, with a doubling time of 7.5 months from 1985 to the present. That means, the velocity of growth is twice as large as in the U.S.A. almost.

Estimates of the number of AIDS cases indicate that more than 20,000 new cases will occur in 1991 solely, with more than 35,000 accumulated cases by that year. While the first cases reported were associated with foreign contacts, since 1985 the spread can be attributed to endogenous transmission. Each of Mexico's 32 States has reported at least two cases; most, slightly over 50 percent of the cases, are concentrated in the three largest metropolitan areas: Mexico City (37 percent), Guadalajara (14 percent), and Monterrey (6 percent). Young adults between 25 and 44 years of age account for 70 percent of the cases. Of the 47 cases in children, ten are associated to perinatal transmission. This proportion of pediatric cases is three times the rate found in the United States. Eighty two cases have occurred in women; thus, the male to female ratio is 14:1, essentially, similar as in this country. The risk groups include homosexual and bisexual males (80 percent); heterosexuals, (7 percent); recipients of blood transfusions (7 percent); hemophiliacs (3 percent); children through perinatal transmission (1 percent); homosexuals who are also drug abusers (1 percent); and, IV drug users only (0.4 percent). The proportion of transfusion associated cases doubles that of the United States.

The trends observed have shown the largest growth in cases associated with heterosexual and perinatal transmission. At the present moment, AIDS cases are occurring in people from every socio-economical stratum and are beginning to appear in rural areas. The growth rate in women has increased significantly in recent months.

Serological surveys conducted across this country in different sub-population groups have yielded the following results: homo and bisexual males with a prevalence between 1 and 33 percent, according to the geographical area; seroprevalence in male prostitutes ranges between 2 and 16 percent; female prostitutes show a low prevalence of 1 percent; hemophiliacs, between 28 and 67 percent; prisoners, between 0.5 and 1 percent; military recruits, 0.5 percent. Paid blood donors, when they existed, had a high prevalence of 7 percent before the ban of blood commerce, which occurred in Mexico last year, while voluntary donors had only 0.1 percent.

The response. The Ministry of Health designed a National Committee for the Prevention of AIDS (CONASIDA) that started working in February, 1986, responsible for the elaboration of national policies and programs. Epidemiological surveillance in Mexico is now based, by Federal Law, in mandatory notification of AIDS cases and HIV infected people. Sixty five screening labs have been implemented, including a National Reference Laboratory for confirmation of positive results and supervision of laboratory performance. Our national blood supply

is now considered to be safe, due to mandatory screening of this tissue, since 1986. As mentioned above, following the discovery of such high seroprevalence rates among paid blood donors, a law was passed by Congress banning this trade.

There is a central, confidential registry of cases which serves as data base for this monthly epidemiological bulletin, published since early 1987. All seroepidemiological surveys have been designed and conducted by CONASIDA, and I'm sort of proud to announce that the first strictly representative survey on a national scale will be completed very soon in Mexico with over 80,000 sera collected and tested, and results will be presented in Stockholm this coming June.

Surveys of knowledge, attitudes and practices about AIDS have been undertaken in five different population sub-groups in six large cities. The results show an increasing knowledge about condoms as a preventive measure for AIDS. However, few people incorporate knowledge into practice.

The educational campaign has been directed to groups with high risk practices, health practices, and the general public. Materials produced include flyers, posters, audiovisuals, radio and television spots, one of which I hope I will be able to present here soon. A National Information Center was created in Mexico City, with others following in several States. The main services provided by these centers are free confidential testing, counselling, and a hotline that attends several hundred calls a day.

A mass-media campaign for the prevention of HIV transmission, with the participation of greater sectors of the society, including actors, and that's the TV spot that I want to present to you if that is technically feasible, and other well-known personalities, was recently launched.

Finally, a Regional Documentation Center was created, with support from WHO and PAHO, to concentrate, organize and disseminate information regarding AIDS to serve Mexico and other Spanish-speaking countries.

I want to gratefully acknowledge economic support for our program from WHO, PAHO, USAID, the Population Council, NIH, and above all, the Mexican Government. I wonder if we can technically present this spot now. Otherwise, I will leave it as part of my testimony. It seems like the latter will have to occur.

CHAIRMAN WALSH: Well, why don't we, while they are waiting, have they got it? Oh, good. All right. If they've got it, we'll show it.

DR. SEPULVEDA: This is a very famous and popular actress, number one in popularity in Mexico, and she's going to give this contribution.

(Whereupon, TV spot shown.)

DR. SEPULVEDA: Could we have the lights back?

CHAIRMAN WALSH: We'll be able to look at it at another time, okay, because we'd like to see it. I've seen a lot of them from different countries, and many of the countries are well ahead of us in this type of education, and it's important that we learn from them.

CHAIRMAN WALSH: Our next speaker is Dr. Jean Pape, from the Department of International Medicine, Cornell University Medical School in New York.Dr. Pape?

DR. PAPE: Thank you. Mr. Chairman, distinguished members of the Commission, as a native Haitian, and a staff member of Cornell University Medical College, I've been working in my home country for the past eight years. So, I hope to give you first-hand information on what goes on there. I am also a member of the National Commission on AIDS, and if the Commission has not done as much as it should have, I'd be very happy to tell you why.

If I could have the first slide, please. (Table 1). The first case of AIDS was diagnosed in Haiti in June of 1979. From June of 1979 to 1981, less than about one case a month was diagnosed at the Cornell Medical Clinic in Port-Au-Prince. I must tell you that this clinic, supported by NIH funds, sees about 80 percent of all the AIDS cases diagnosed in Haiti, with a staff of four physicians, including myself, we care for over 6,000 infected patients, AIDS patients, and their spouses and children.

From 1982 to 1983, you can see already a dramatic increase to about four cases a month, and for the last four years, an eight-fold increase to 30 cases a month.

Now, one of the most significant changes that has occurred is the change in residence in patients with AIDS. (Table 2). You can still see that the capital city of Port-Au-Prince has about 70 percent of all the cases diagnosed from 1984 to 1987. However, in the last three years, there has been a three-fold increase in the number of cases diagnosed outside Port-Au-Prince, from 11 percent to 30 percent.

However, the most significant change that has occurred is a change in the sexual pattern of transmission. (Table 3). I'd like to focus your attention on 1983. Remember that the

first case was diagnosed in 1979. In 1983, 50 percent of all the AIDS cases were in homo and bisexuals. Actually, if you were to do these factors according to sex, 65 percent of all the male AIDS cases would have been in that category. 23 percent of cases had received a blood transfusion in the previous five years. Intravenous drug abusers are few: about 1 percent.

The second point I'd like to focus your attention on is that already in 1983, 26 percent of cases had either documented heterosexual transmission or highly suspected heterosexual transmission.

Now, from 1983 to the present, we've seen a change of transmission patterns from those that are seen in the U.S. to those that resemble what is found in Central Africa. Indeed, you can see a rapid drop in the number of the percentage of patients with homo or bisexual behaviors, from 50 percent in 1983, 27 percent in 1984, to 1 percent in 1987.

On the other hand, you can see a marked increase in the percent of patients with either documented heterosexual transmission from 5 percent to 15 percent, or highly suspected heterosexual transmission from 21 percent to 73 percent.

Now, if one were to look at what had happened in Haiti, one could have predicted what is happening now in many other Caribbean countries. Look at Trinidad, for example. (Table 4). The first case was diagnosed in 1983, and for the first two years of the epidemic, 1983 and 1984, all cases were essentially in homo and bisexual men. From 1985 on, there is a rapid shift in sexual transmission pattern of the HIV infection. You can see that the homo or bisexual group has decreased to 40 percent in 1987. On the other hand, patients with documented heterosexual transmission have increased from 10 percent to 36 percent, and those with probable heterosexual transmission from 2 to 22 percent, to the point that in 1987 heterosexual transmission is really the major pattern of transmission of this disease in that country.

As to be expected in Haiti, there has been doubling in the number of women with the infection. (Table 5). Indeed, from 1979 to 1982, 15 percent of all cases were in women, 27 percent

in 1983-1985, and 30 percent in 1986-1987. So, we are not quite yet in the same situation as Central Africa, but I think we are getting there.

Similarly, in Trinidad and Tobago, in 1983 and 1984 all the 27 cases diagnosed were in males, essentially, male homo or bisexuals, and in the two years that followed, 1985 to 1987, 15 percent of all the cases occurred in women. (Table 6). In summary, (Table 7) HIV infection and disease are of recent onset

in the Caribbean. Homo and bisexuality is no longer the major risk factor for acquiring AIDS. Within a five-year period, heterosexual transmission has become the major mode of HIV spread. These findings have serious implications for countries where other modes of transmission are still predominant. Thank you.

DR. LEE: Nice to see you again. We'll wait for the rest of the Commissioners to get up here. We can start with the questions. Dr. Crenshaw?

DR. CRENSHAW: Dr. Pape, one of the things that I thought was really compelling about your slides and your conclusion is that you documented rather rapid progression into the heterosexual community. But, interestingly, by contrast to what people believe here, that it's mediated entirely through drug abuse. The drug mediated heterosexual transmission seemed relatively small. Am I interpreting your data correctly?

DR. PAPE: That's quite correct. Actually, except for Bermuda, all countries in the Caribbeans have a very low incidence of drug abuse as being a risk factor for acquiring AIDS. For both Haiti and Trinidad and Tobago, it's about 1 percent of our patients who are intravenous drug abusers. So, actually, the disease has shifted rapidly, but it is not due to this group.

DR. CRENSHAW: Dr. Sepulveda, I wanted to compliment you very, very emphatically on what you described having done in Mexico, particularly, your seroprevalence study, which I think you are to be commended for. And, I also want to say that given the additional handicaps of a primarily Catholic society to have gotten as far as you have in as brief a time. It really puts us to shame in some ways here in the United States.

I just wanted to thank you. I didn't have any specific questions, unless you'd like to comment on some of the things, perhaps, the obstacles and the solutions to how you managed to make this degree of progress. I'm not meaning to suggest your problem is solved. I know it's not.

DR. SEPULVEDA: Thank you very much for your nice comments. Perhaps, I should only say that indeed the Mexican society, is a conservative one, and we are facing problems in our public health campaign, particularly, relating to the advocacy of condoms as a preventive barrier, a mechanical barrier for preventing sexually transmitted diseases, such as AIDS. But, I think slowly but steadily we'll get along.

DR. CRENSHAW: And then, my last question, which any or all of you might wish to answer, is that I heard from most of you that the pictures you are seeing are very limited by our focus on the disease AIDS, and gives us, if you'll excuse my interpretation of your words, backward look of, perhaps, five to ten years when we are dealing with AIDS cases. And, this is the common theme that we hear from many, many of our witnesses.

On the other hand, from many of those same witnesses, we hear an enormous amount of reluctance to testing or moving beyond AIDS to get a more accurate picture, perhaps, because of the political issues and pressures. Could you comment on how we can get out of this dilemma, learn more about a current picture in various countries, in spite of the problems and obstacles in the way?

And, if I may simplify it by saying, hypothetically, I know the finances are a big issue, but if we could, for a moment, hypothetically eliminate the cost factors, which I know isn't practical. What would you do if it weren't for the money? What would you like to see done?

DR. PAPE: Well, I must tell you that because of time I did not go into seroprevalence studies, but we have tested over 30,000 healthy people throughout the country, and the seroprevalence rate is between 0 and 10 percent for healthy adults in Port-Au-Prince.

It varies according to age, obviously. It is higher in the sexually active age group. According to socio-economic status, from 2 percent for higher socio-economic groups, to 13 percent in the lower socio-economic groups.

It also varies according to sexual activity. Dr. St. John mentioned 49 percent in our prostitutes, repeated studies in 1987 and 1988 showed 69 percent seropositivity in our prostitutes. So, this is increasing tremendously in this population group.

It also varies according to state of illness. Patients with tuberculosis, for instance, in hospitals have had a seropositivity rate of 40 percent to the point that we believe

that we do not really need an AIDS hospital in Haiti, because the sanitoria that care for TB patients are already, whether they want it or not, AIDS hospitals.

For the rural areas, the situation is much different, and seroprevalence rates are much lower, and it varies from 1 to 3 percent.

DR. CRENSHAW: Thank you.

CHAIRMAN WALSH: Yes?

DR. ST. JOHN: I'd like to also respond, and it's always a delight for an epidemiologist to be told that resources are no constraint. There are lots of things we'd like to do if resources were no constraint.

You might be interested to know that there is one country in this Region that has opted for massive screening as one of the cornerstones for their AIDS program, and that is Cuba. Cuba has screened over 1.6 million of its total 10 million population. They have screened -- they have effectively screened, in the last two to two and a half years, 25 percent of their sexually active population, for mixed reasons, which are too long to go into here. We are not sure how much the cost has been.

There are two aspects of massive screening that I think are important to try to separate. One is the need for epidemiological information. For epidemiologists, anonymous screening of large segments of the population has a lot of appeal.

There is another perspective, though, and that has to do with what you are going to do with the information once you get it? If you are capable of screening a large mass of a population, what are you going to do with all those people that you might find to be truly positive or falsely positive?

In Cuba, for a variety of reasons, including the extent of their health care delivery system, they are taking -- they have taken measures, they have activities planned for all the ones that have been detected positive, and it adds to 174 people. If we were to test 230 million people in this country, we'd have quite a few more, and what would we do with them, and how much would it cost?

Thus, when you move out the of purely epidemiological realm into the cost benefit realm, and you throw in a few economists to argue with you, it looks like, and I think WHO feels this way as well, I do, that on the whole the balance is against massive screening at the present time.

MRS. GEBBIE: We started to hear a little bit of an answer to this, but I'd like some more discussion. While this Hemisphere may be more developed than some of what we heard about from Africa this morning, certainly I hear continually about problems with the basic structure of providing health services in many of the countries that we're discussing in this panel now.

What is the potential impact of AIDS on that basic provision of services to all citizens? What are the things that are being struggled with in various countries, either as examples or comprehensively, what needs to be done in that regard? I address it to any of you.

DR. ST. JOHN: The potential impact throughout the Americas, especially Latin America and the Caribbean, is also large. The economic consequences of 500,000 to 750,000 infected persons, and we know, as Dr. Mann said, the stage is set for what will happen there.

In Rio de Janeiro right now, it costs between to $200.00 to $300.00 a day to take care of an AIDS patient, and the average stay is between 12 and 30 days. So, it could conceivably cost a patient at the maximum about $9,000.00 for each hospital stay.

A secretary's salary in Rio is $200.00 a month. There is no way that that's going to be able to be met by the system as it is currently constructed. Large wrenching changes would have to take place to accommodate the foreseen burden of AIDS.

I'd like to stress also that unlike the United States situation, the endemic diseases that are prevalent in other populations are different. In Brazil, and in many countries in Latin America, tuberculosis is a common disease of children, so that large proportions of the population are infected with tuberculosis, held in check by their immune systems.

When you take that away, we find that, for example, in Brazil about 17 percent of all the new cases of AIDS present as tuberculosis. Well, that means you have a patient that now can transmit two infectious diseases at the same time, AIDS and tuberculosis. Hence, we think the impact on the really significant progress made in tuberculosis control in Latin America is really threatened by the AIDS situation.

So, the impacts are multiple. How far, how extensive they will be will depend on what course the epidemic takes and what we can do about it.

DR. SEPULVEDA: I agree completely with Dr. Ron St. John. I want to say that even though economists say there is no such a thing as new monies, it helps in part in Mexico.

So far, we have been able to get additional funding on top of that originally assigned to the Ministry of Health, dedicated to the combat against AIDS, but I do not know how far we'll be able to sustain that.

MRS. GEBBIE: My other question is, really, the same one I asked Dr. Mann this morning. From the point of view of the Americas, what are the two or three things that this country should do, either internally as a model, or as catching up with the other countries in the Americas, about AIDS that we should get on and do right now?

DR. ST. JOHN: I'd give a regional perspective, and then I would ask Jaime to please give, and Jean, could give a national perspective.

There is no question that the United States often sets the tone and is the model. Unfortunately, in this Region at least, we've had to say to countries time after time, don't look at the United States model as a whole. There are individual cities, there are individual states that have developed active AIDS programs, and we frequently cite San Francisco, parts of the Miami program, parts of the New York City program as models for Latin American colleagues to look at and be aware of.

But, in developing their own National AIDS Programs, we are often in a position of saying, no, don't look to the United States for that model. You've got to strike out on your own, or you've got to follow the WHO guidelines, but you are going to have to develop your model because there is, in my opinion, a lack of leadership in the AIDS situation in this country.

MRS. GEBBIE: So, straightening that out, in your view, would be one of the most important things we could do. Thank you.

DR. SEPULVEDA: Well, I really hesitate to give recommendations to other countries. But, if that is the case, and if you insist, I think most of the good things that need to be done are being done in this country.

To me, the most efficient of all preventive measures, in terms of cost benefit, is making the blood supply safe, and that was done long ago in this country. So, that's the easiest to achieve of all control measures.

I would like to see more research done, and as I see the research agenda in this country, I do not see enough research done in social issues and in sexual behavior, and I think that is a must. If we are contending with a sexually transmitted disease, a lot more sexual research needs to be done. hat's one comment.

DR. PAPE: I certainly agree with what was said here. I think Haiti confronts a particular problem in view of the fact that you really have to understand that this country has been traumatized by a number of things. The first thing that has traumatized my country is the fact that the scientific world said that Haiti was the origin of AIDS. We all know that this is not correct, but this is not something that you can easily change. It's still in the mind of people, it is still in the mind of health officials.

I've been a non-salaried health advisor to the Minister of Health, and I can tell you at many points in time they were very unhappy to report about AIDS cases, essentially, because they felt that this was going to damage the country. They said, well, other countries are not reporting about this.

The second thing, obviously, that has hurt us a lot, as you know, is the tragic political situation we've lived in the past two years. And, certainly, this had made the effort of the National Commission very difficult.

However, there are some things that have been accomplished. I think that the blood supply is now safe, and the reason why it's safe, it is only because there is a limited amount of blood donors. But, it is still safe, so that's one important thing.

What I think that can be done mostly for us is really this type of research that was just talked about, and also, some kind of more generalized support for the National Commission.

As an example, we are kind of limited in what we can do. For instance, we tell people they should use condoms, but with the USAID aid that has been cut, as you know, there are no condoms to be found in the country. So, everybody is striving for condoms but they are no where to be found. So, how can we have an ad on TV asking people to use condoms if they cannot find it.

So, you see, it's a very complex problem that will be resolved somenow when the generalized political situation is improved. **MRS. GEBBIE:** Thank you.

CHAIRMAN WALSH: Dr. SerVaas?

DR. SerVAAS: I'm interested in what you have to say about tuberculosis in Brazil and in Haiti, and could you, from Mexico, tell us about how serious is the tuberculosis problem there with AIDS?

DR. SEPULVEDA: I will be happy to do so. Tuberculosis has been an endemic problem in Mexico for many years. Now, AIDS is revealing, in some age groups, in urban areas, an increased rate in TB, and we are finding that many of those TB cases in young adults are associated with HIV infection.

And, that's one of the most common opportunistic infections found in patients, TB.

DR. SerVAAS: Are drugs very effective with AIDS patients, the traditional drugs for tuberculosis? Do they keep it in check, or is it hard to control with --

DR. SEPULVEDA: It is possible to get over an acute case of pulmonary TB, but it is, of course, much harder in the long run to keep that person alive.

DR. ST. JOHN: If I could just add a comment there, Dr. Walsh. I think that anybody with AIDS who comes down with acute pulmonary tuberculosis has got to look at life-long maintenance tuberculosis therapy. You don't cure TB unless you have some help from the immune system.

DR. SEPULVEDA: That's right.

DR. SerVAAS: Now, in Haiti, you use your sanitaria for those patients?

DR. PAPE: Well, we use a number of facilities. I must tell you that 50 percent of all the AIDS cases that we see have associated tuberculosis.

In addition, 18 percent of people who are HIV infected, but who do not have any other infection, also have tuberculosis.

We have been able to control tuberculosis somehow in those patients with the drugs, but we have a tremendous burden of putting on isoniazid prophylaxis all HIV infected individuals which is a very large sector of our population.

CHAIRMAN WALSH: Dr. Primm?

DR. PRIMM: Dr. Pape, we see a number of young Haitian males in New York who are positive for the virus, or who have full-blown AIDS, or one episode or two of opportunistic infection, and they completely deny homosexuality. They might

say that they might have had an experience, and that experience is generally for survival rather than for the homosexual act itself.

And, many Haitians do, indeed, deny that homosexuality exists among their population. I'm wondering about the interpretation of homosexual behavior when someone does it primarily for survival. In other words, $10.00 for a sexual act in Haiti is quite common, both for men and women, and yet, these people are heterosexual in terms of their orientation.

Is that now still going on, and what is the incidence and prevalence of homosexuality in Haiti now as you see it? I noticed that you made no mention of what's happening in terms of sexually transmitted diseases among that population. I'd like to hear you comment on that.

The same with you, Dr. Sepulveda, in terms of Mexico.

DR. PAPE: Thank you for this question.

As you probably know, homosexuality is taboo in Haiti, and when I got back there in 1980, I barely knew anybody who would say that they were homosexual.

And, the reason is simple. Our patients are primarily bisexual. When you ask them what is their sexual preference, they say it is for women, and one of the reasons why our women got infected so early, we believe, is because actually those bisexual men had many more contact with women and many more contact with prostitutes than they actually did with men. And, those are what we call commercial homosexuals, who do it for the money, and very often their wife does not know anything about this.

Now, in those people, we have found there is a very significant percentage of sexually transmitted diseases, namely, gonorrhea and syphilis. But, I must say to answer the last point, is that percent of people who presently have AIDS and who are bisexual have dropped tremendously.

DR. PRIMM: Well, has HIV infection, and, of course, AIDS in Haiti caused a lessening of the kind of behavior that we saw among the "beach boys" that led to what might have been the spread into the heterosexual population.

DR. PAPE: Yes, I think that's quite correct.

DR. PRIMM: It has had an effect.

DR. PAPE: Yes.

DR. PRIMM: Significant?

DR. PAPE: I think so.

DR. SEPULVEDA: Well, you are asking about incidence and prevalence of homosexuality, and I don't think myself or any person can give you a good estimate of that in any country. But, estimates vary from 5 to 15 percent of young adults, male young adults.

What is a matter of concern to us is that there are, particularly at the border, at the Rio Grande border, an increasing number of male prostitutes. We see a lot of Americans coming down and asking for male prostitution, and we are seeing prevalence rates in male prostitutes are much, much higher than in female prostitutes. In some places, they are as high as 15 percent.

So, that is a matter of concern. I think it has to do more with prostitution than with homosexuality prevalence.

DR. PRIMM: I just remarked knowing that none of your data really reflected very much homosexual/bisexual contribution to the numbers that you presented. And, I know that it exists.

Thank you very much.

CHAIRMAN WALSH: Dr. Lee?

DR. LEE: Dr. St. John, tell us what are the Cuban results? Do you know what their incidence was in their 1.6 million people?

DR. ST. JOHN: Yes. They've detected a total 174 seropositive persons as of February. That includes asymptomatic persons, people with ARC and people with AIDS. They have 27 cases of AIDS among those 174 people detected.

DR. LEE: 174 out of 1.6 million?

DR. ST. JOHN: Yes.

DR. LEE: I'm interested, in going back to some of the population questions from the African panel, Dr. Bongaarts gave us some very interesting curves and projections.

Now, in Dr. Mann's paper he talked about the pattern one and pattern two, the U.S. versus the African.

Now, Dr. Pape shows us that we have some countries that are going pattern two, that we're pattern one. In my conversations with some of the African panel, they thought this would not happen.

What do you think? Is pattern one a weigh station on the way to pattern two, or are they going to remain separate?

DR. ST. JOHN: Well, in the Americas, fairly rapidly the same kind of epidemiological mosaic applied to AIDS. It is not a pure situation.

In North America, the pattern continues to be dominated by homosexual/bisexual transmission and IV drug abuse.

In the far south of South America, in Argentina, Chile, Uruguay, it remains a homosexual/bisexual male pattern.

But, throughout the Caribbean and now in parts of Central America, we've seen the same rapid shift that Dr. Pape has described in Haiti, and Trinidad and Tobago is occurring in a variety of countries. So that, for the Caribbean as a whole, the male/female ratio is less than 6 to 1.

And, in some countries in Central America, it is 2 to 1, and that's been a very rapid change over the last two to three years.

I think that in some societies, for a host of reasons, we are going to see the disease spread in that way, into the heterosexual community.

DR. LEE: Dr. Bongaarts showed us a curve of leveling off in Africa at 25 percent, do you have any ideas of where it might level off in this hemisphere?

DR. ST. JOHN: No, I don't. It will level off. Not everybody is susceptible, but it will level off at different places in different countries for a whole host of variables, many of which we don't understand.

We have avoided, up to now, making projections, official projections for individual countries or for the region as a whole.

In this region, because we don't think we know the mathematical model that we could correctly apply, it is not right to take the 50 to 100 multiplier effect used in this country and apply it to other societies and cultures.

And, most mathematical models that have been developed and published so far still do not have the basic information on the critical variables, and people are still guessing at the critical variables, and so, we have avoided creating an alarmist environment, which often happens when you make unfounded projections. I don't know where it will level off.

DR. LEE: You don't know where it will level off, but I take it from this panel that you all think that pattern one is a weigh station on the way to pattern two, and it will happen in this country, in this hemisphere?

DR. ST. JOHN: In this hemisphere, yes, it already is happening.

DR. SEPULVEDA: I will just add that, for instance, in the very short span of one year, from March, 1987 to March, 1988, the proportion of cases associated with homosexual men changed from 72 percent to 57 percent. That's a very dramatic change in such a short span. While, the heterosexual transmission changed from 22.5 percent one year ago to 7.4 percent nowadays. So, there is definitely a trend towards heterosexual transmission.

DR. LEE: Bill, can I just ask him one more? Do you have any idea why we haven't seen it yet in this country?

DR. PAPE: Well, there may be a number of reasons. The first one is why we are seeing it in the Caribbean. The first one is that we are dealing mostly, as Dr. St. John mentioned earlier, primarily with a bisexual population, many more bisexuals than strictly homosexuals.

The second point will have to do with the fact that prostitution is legal in a number of countries in those areas. And, the third part is that free sex and polygamy is also acceptable in many areas in the Caribbean Islands.

So, I think that those reasons may explain partly why we are seeing more cases in the heterosexual population. In addition, we have the fact that the blood system has not been safe, particularly for women, since they were the one to get the blood transfusions during obstetrical procedures. But, on the other hand, you have a major problem here in this country with IV drug abuse, which we do not have.

DR. ST. JOHN: When I talked to my colleagues at CDC, I asked them that same question, and that's when I hear the smell of burning rubber, their brains. I don't know that anyone really knows why it hasn't happened. There are many, many things you could speculate about, you know, based on everything from the magnitude of the problem of poverty in different societies, the level of education, sexual behaviors, there is just a host of

variables that we don't understand really. I've wondered it myself.

DR. LEE: Thank you very much.

CHAIRMAN WALSH: Do you have a question, Dr. Lilly?

DR. LILLY: A small question. Is there a correlation between the level of repression of open homosexuality within a country, and the tendency for AIDS to become a heterosexual disease in that country.

DR. ST. JOHN: It's clear to us that there are in Latin American societies, which tend to be more conservative, tremendous pressures on a males to conform to a heterosexual life style.

And, I think many men who might in a different society openly declare themselves as homosexual and pursue a homosexual life style, that many of these men do marry under tremendous social pressure and they do have children, and then their behavior falls in a wide range, either as predominantly homosexual with heterosexual intercourse with their wife for purposes of procreation only, to the opposite, which is mostly heterosexual behavior with an occasional homosexual encounter.

What is clear is that the bisexual male bridge is much, much broader than it is in this country. As I mentioned in my testimony, 20 to 25 percent of the male gay associated AIDS is bisexual, and that is a major avenue for introduction, and probably an even better avenue in terms of magnitude than IV drug abuse for introducing the disease into the heterosexual community.

If you then add to that social conditions, such as in lower socio-economic classes where a free union marriage is more common than a formal marriage, and for economic reasons these unions tend to come and go. And so, there isn't maybe a lot of promiscuity at one time, but there is serial polygamy, if you will, going on. I mean there are many factors that would help to foster heterosexual spread of AIDS.

DR. SEPULVEDA: I agree with that. The proportion of the AIDS cases associated with bisexuality in Mexico has remained rather constant, 20 to 25 percent over time.

We just completed a study, of those people attending the National Information Center, one third who were infected with HIV were married. So, bisexuality is a much more common practice than pure homosexuality in Mexico.

CHAIRMAN WALSH: All right. Thank you very, very much.

We'll take a break, and we will reconvene at 2:15. We are almost back on schedule.

(Whereupon, the hearing was recessed at 1:42 p.m., to reconvene at 2:15 p.m., this same day.)

A-F-T-E-R-N-O-O-N S-E-S-S-I-O-N

CHAIRMAN WALSH: I think that we could agree that we had a most interesting and informative morning, and I know, speaking for the Commissioners, that we learned a great deal and have got ample food for thought.

I believe, too, that this afternoon will provide us with an equally interesting program.

RESPONSE TO THE PANDEMIC: FRANCE

CHAIRMAN WALSH: I have a special privilege really in introducing our first speaker, whom I have come to know over the past couple of years as a very good friend, as a man who is a problem solver and a leader, and who does things just naturally well. Alain Pompidou is the Technical Counselor for Health at the Ministry of Health and the Family in France, and I have participated with him in not only many meetings but also in many other matters.

We touched just a little bit, for example, on bilateral assistance this morning, and I was very impressed when I was last in Paris to find how the government of France was already well to the forefront of attempting to help many countries in the Third World, while at the same time devoting attention to solving the problems of AIDS in their own country, and actually providing leadership for a good part of Western Europe.

We all used to refer to Alain Pompidou in France as "Mr. SIDA," which is really a compliment, and I know that I'm looking forward to hearing what you have to say and want you to share your thoughts with all of us. Thank you.

PROFESSOR POMPIDOU: Thank you, Mr. Chairman. Mr. Chairman, distinguished members of the Commission, I must say that it's a real pleasure and a great honor for me to testify in front of the Presidential Commission for AIDS of the United States. I hope that I will be helpful, and I am worthy to answer as far as my responsibilities can allow me to all your questions.

We have now, in France, 3,073 cases, and in a few weeks we'll have 3,500 cases accumulated since '81. That means we have about 2,500 AIDS patients already in care in the hospitals, which breaks down to 55 per million inhabitants. France is, therefore, the most severely affected by this new viral infection among European countries.

The predictions are announcing 10,000 to 15,000 AIDS cases at the end of '89; but, it is necessary to underline that during the next four to five years, the tremendous increase of AIDS cases will mask the decrease in the progression of contamination which is already being observed.

This decrease is observed actually among the homosexual community as has been observed on the West Coast of the United States, and also, the contamination through heterosexual contact is now stabilized in France, as is proven by the stabilization of contamination of at-risk pregnant women in France, and the stabilization of transmission through heterosexual contact.

Nevertheless, the fact that AIDS is a real challenge for the public health in France, engaged the French government and especially Prime Minister, Mr. Jacques Chirac, and Michele Barzach, Minister of Health and Family to settle a coordination structure and a strong national program on AIDS as early as January of '87. The coordinating organization represents two major components.

First, a National Committee of Reflection, whose function is to advise the Minister of the important decisions to be taken in the fight against AIDS. Its members include scientists, specialists in ethics, education, communication and leisures as well as representatives of insurance companies and the clergy.

On the other hand, reporting directly to the Minister of Health, the National Coordinator is responsible for the following:

- Ensuring the complimentarity of the work carried out by the different Ministries with administerial responsibility;

- Coordinating international research and cooperation;

- Establishing ties with private associations and organizations, like NGO's, foundations and industrial groups;

The aim of the French National AIDS Program is based upon two main assertions.

First, public health must be protected. Second, patients and human beings must be respected. And, it seems to be a kind of autonomy between these two aspects, an exclusivity between these two aspects. But, the assessment of these two major principles could not seem realistic regarding its application to an infectious disease.

Nevertheless, this challenge is made possible by two reasons. The first, and the more important one, is that AIDS is an avoidable disease. AIDS is not plague, AIDS is not cholera, AIDS is avoidable. And also, a cure is not impossible to find.

These two points induce the major components of the AIDS program for France. Prevention, including information, education and screening; research and care facilities; and, international cooperation.

Prevention and research are the only means we have today to limit the progression of this avoidable but deadly new viral disease.

The National Prevention Campaign is composed of two large measures. A National Information Program based upon sensitization of the whole population using all media, videos and leaflets. A program of educators formation (for face to face information). And, the priority for AIDS will be the formation of an outlet for information, so that you have a dialogue basis information system.

Besides these two large measures, we have set up two immediate measures. One is the authorization of advertising of condoms and organization of quality control. We have observed last November that 15 to 20 percent of the condoms were not viable, and we have organized the control of quality for the condom all over the country.

And, I must say that it was easy to do that since we were not producing these materials. Second control measure is the syringes sale in drug stores without prescription or identity control.

The aim of these measures is to avoid contamination by sexual contacts and contaminated blood from IV drug users. This does not modify the determination of the French government to struggle and to fight against IV drug users, but it is absolutely necessary after this intoxication not to have contamination by this virus by those people who are addicted and intoxicated.

The third measure, besides the first two large measures, the two immediate measures, is that no mandatory screening was organized in France. Of course, mandatory testing is only performed for blood donors and organs, blood for tissue donors or cell donors.

Why do we have no mandatory systematic screening? For four different reasons: the first one is that it would have a poor efficiency in areas which are limitedly involved by the infection, and we know in France, because of the mandatory declaration of AIDS cases, that 84 percent of the cases are located in five provinces among 20 in France. That means, essentially, Paris, and around Paris, and the south of France.

The second reason is the false security because contamination can occur right after a screening test. The

third reason is that a mandatory systematic screening would be an incitation to clandestinity for high-risk groups. And, we saw that already for the testing for syphilis.

And, the last reason is that this measure would not be an incitation to responsibility. The evaluation of this set of measures is now the following, within one year - - Condom sales have increased by 38 to 40 percent;

And, we know now from a new study, which has been polled in the Paris area, that 12 percent of the 900 people who we asked the question, which are sexually active people, use condoms, and that is within the past six months. So, it's a new phenomenon, and we went from 5 percent to 12 percent using condoms actually in the Parisian area.

- The second evaluation is that the syringe sales have increased by three times in the more exposed quarters of the largest towns.

- The access to voluntary testing independently from testing for blood donors was multiplied by three. In '86, we have realized 800,000 voluntary tests, in '87, 2,400,000 voluntary tests.

And, what is interesting also in terms of the epidemiological data is that in Normandy, for instance, there was an exponential increase in the demand for voluntary testing, but there was a very low increase in seropositive patients.

- The fourth measure is large access to HIV screening.

100 centers for free and anonymous screening are now set up, as of the 18 of April, we have 100 centers, free and anonymous,

working all over the country, one for each department, and sometimes two in large towns, two or three in large towns.

In these centers, prescriptions and positive results are given only by physicians. And, the person tested does not have to give his identity and has nothing to pay.

More than that, we have 300 counselors in hospitals all over the country, who are able to take care of seropositive people, people who want to know about their seropositivity.

All physicians, of course, are allowed to prescribe screening tests, which is reimbursed by the Social Security system, and the positive ELISA test is systematically controlled by Western Blot, and two ELISA tests are systematically performed in the laboratory before control by Western Blot.

The confidentiality of the testing is guaranteed by an absolute respect of the medical secret. When to propose the HIV testing? During key periods of life, and Mr. Barzach has written a letter to the doctors all over the country, which is being received now by all the physicians, which says that the tests must be proposed but not prescribed. The differentiation is that if it is proposed it can be avoided, it can be refused. If it is refused, the physician has the opportunity to sensitize a person who has refused, and to bring this person to acceptance, but this person can still refuse it.

And, this must be proposed during key periods of life, during prenuptial examination, during hospitalization for patients in such departments as surgery, gynecology and explorations. And, the testing must be proposed, as I said, and all the results given to informed individuals.

It must be proposed during prenatal examination, but not systematically. Testing must be proposed if any doubt regarding contamination based upon questioning of the patient exists.

Also, couples desiring to procreate must be proposed to be tested as well if there is any doubt regarding contamination. And, France is more faithful in a targeted and correctly prescribed testing program, than in the blindly systematic mandatory screening.

Following the recommendation of WHO and European Council, systematic screening of foreigners has been refused by all health and foreign office ministers of European communities.

And, an information campaign of international travelers will begin within the next week, within the next few weeks, with information leaflets, which are the same message as WHO has

proposed. This program is based upon sensitization and responsibility. It will support public health in the respect of patients and of human personality.

The prescription of HIV testing is something, the consequence of which cannot be neglected. If the seropositivity is not accepted by the tested person and by the population as well, the responsibility will not occur leading to quarantines.

We must not speak anymore about groups at risk, but we must speak about at-risk behavior, because everybody, whatever is his own strengths, whatever is his own capacity to resist, may be confronted by at-risk behavior, during which he must protect himself. After testing, the only way to determine changes in behavior from individuals and population is to organize medical care, and research developments without forgetting the global aspect of the pandemic.

Now, we speak about research and care facilities. Care facilities are organized mostly within 22 pilot centers, 6 in Paris, 14 all around the country, and 2 in Antilles and Guyana. In these centers, patients are not quarantined but spread out in all the different departments regarding their own symptomatology. Out patients are monitored in day care units and laboratory facilities are increased in immunology and in virology units.

The pilot center is the main point of a network including the regional hospitals. The pilot centers are themselves coordinated with the other pilot centers all around the country in order to evaluate, first, the costs, and also to allow multicentric technical and theoretical studies.

Research is under the responsibility of the Minister for Research and Universities. A specific program has been set up for basic and clinical research, for treatment and vaccines, as well as for the screening tests.

More than 50 different teams are working specifically on AIDS, on socio-economical aspects as well as on laboratory research, and 100 clinical departments are involved in hospitals. In terms of international cooperation, it is a necessity to take care of the global aspect of AIDS. As you know, a special settlement has been signed between the Pasteur Institute and NIH for research. A French-American Foundation has been created, part of the money of which will help to promote the struggle in the Third World.

An evaluation of the impact of the French National Campaign will be held in collaboration with the United States of America, and especially with Project Hope. An agreement has

been set up between France and Germany, as well as Great Britain, for AIDS research.

France participated in the European Community Program on AIDS, and is strongly supporting the WHO's Global Program on AIDS. Yet again, as regards the fight against AIDS, we have tried to plan for the future and to act. I would briefly remind you of the measures which have been adopted.

1. Mandatory declaration of confirmed AIDS cases.

2. The launching of an information and sensitization campaign aimed at the medical and auxiliary medical professions and at the public as a whole.

3. The setting up of the 22 HIV centers for care with improved means as regards personnel and equipment.

4. The National Reference Laboratory for HIV detection reagents.

5. The authorization to market AZT, which, while not curative, has proven to be efficient in the treatment of AIDS.

6. The authorization to advertise condoms and the authorization, valid for one year, to sell syringes.

7. Organization of wide access to voluntary testing, especially in 100 free and anonymous testing centers.

And finally, a large-scale training and information program for social workers which has been started.

A total of more than 200 million U.S. dollars will be spent in '88 on AIDS research, prevention and care.

In France, we have the firm intention of respecting a certain number of fundamental principles.

Firstly, the desire to protect public health while respecting the dignity of the patient and, in more general terms, human beings. That is, for us, an invisible principle and the honor of civilized societies which requires that they guarantee it under all circumstances.

Secondly, that AIDS is a disease and not some nightmare from the Dark Ages or a product of the subconscious. As with any disease, it must be fought by strictly respecting medical deontology and by protecting the link between the patient and his doctor. Thirdly, that AIDS must on no account be used as a political ploy. The fight against AIDS will demand both time and continuity. To overcome it, we must act. A coherent overall

strategy is needed, but not sterile conflicts. Fourthly, the absolute necessity to foresee, to plan for and to make reasoned choices.

We must also begin now to plan for the material and medical means which will be required to cope with the increase of the number of infected people in the years to come. Our fifth principle concerns the deliberate choice made by the French authorities to inform people without creating a panic reaction, to make them aware without being patronizing and especially to encourage the individual to assume responsibility for his own actions.

The results already obtained, such as the modifications in the behavior of homosexuals and the increase of the use of condoms, clearly demonstrates that the road taken, though not the most spectacular, has been effective. This French program is balanced, taking account not only of prevention, health care and research, but also of socio-economical and cultural aspects.

Confronting AIDS and at-risk behaviors is necessary to remember that to be informed does not mean knowing, that to know does not mean deciding, and that to decide does not mean to act.

Approaching such a problem, it is necessary to be fast but not to hurry up too much in order to avoid irreversible or inadequate decisions. It is necessary to take account of all of the consequences of the decisions before they are adopted.

And to conclude, as said recently, Jonathan Mann, Director of the Global Program on AIDS, "Confronting AIDS necessitates to be stronger than fear and moreover to fear quarantine or discrimination," in order that each country could find the proper way to live with AIDS. Thank you.

CHAIRMAN WALSH: Thank you very much, Professor Pompidou. We will start out questioning at this time on the right with Dr. Conway-Welch.

DR. CONWAY-WELCH Thank you, Dr. Walsh. Mr. Pompidou, in describing your voluntary testing measures, could you speak for a moment on whether or not your country requires people to sign a document saying that they have been counseled? In our country, in some places, for medical/legal protection, patients, while they can be confidentially and anonymously tested, have to sign a piece of paper saying that they have received counseling.

Now, some sign Mickey Mouse, or Donald Duck, or Santa Claus to the piece of paper, but it's one of the vagaries that we are encountering in my State of Tennessee, and I wondered if any

of the regions in your country had that legal problem. The other question I wondered if you could talk about a bit would be contact tracing, or need to know by the spouse or significant other of the person who is identified as carrying the virus.

PROFESSOR POMPIDOU: Thank you very much. The first thing is that the person who wants to be tested does not have to sign a paper. There is different cases. If a person is going to the free and anonymous center, he has a number, and there is another question between this number and the results which will be given from the blood sample. And, we know from these centers how many have been tested, how many people are positive, but we don't know the name of these people.

The second thing is that, what we plan to do, and what is done in some hospitals, but not yet a proposal from the Minister of Health, is that if somebody refused to be tested, he has to fill out a form and sign why, and to say that he refused to be tested. But, no, that is not a directive of the Ministry, that is practiced by some hospitals or clinics. But, I mean, it's not necessary.

But, what is absolutely necessary, is that nobody should be tested without knowing it, and nobody should be tested without being given the results of the test. But, of course, there is no way to say that somebody has been tested, and because he can show that, and say I've been tested, I'm negative, he can be contaminated a few hours later. That's the first point.

In terms of tracing partners, is that your question? In terms of tracing partners, I must tell you two things. The first thing, I was in Japan three works ago, and I was impressed by the proposal from the Liberal Party, which said, approximately, the doctor should not say anything about seropositivity to the family, to the employers and to the people all around this person, but, to the police, which is very interesting. This, though, has not been voted yet. That's the first thing.

The second thing is that a physician in France has the obligation to find the contact after syphilis contamination. Prenuptial tests, syphilis tests, VD tests, and that is done regularly.

But, when somebody has been contaminated by syphilis and goes to the physician, the physician has to, this is a law, has to find the contact and to treat the contact. And, this is not anymore used since 30 years, and that is complex and unsuccessful. And, that is one of the reasons why we decided not to try to find contact, because this would not work. This doesn't work for syphilis, this would not work more for HIV infection.

DR. CONWAY-WELCH May I ask one quick question? What would your rationale be for not requiring mandatory testing for patients going into surgery?

PROFESSOR POMPIDOU: Because we have tested 20,000 pregnant women, and the rate to refuse for testing is less than 1 percent. So, we think that on the first approach, it's much more necessary to have 99 percent of the people, of the women tested in case of surgery, to accept the test.

DR. CONWAY-WELCH As voluntary.

PROFESSOR POMPIDOU: And, if they accept the test, they will accept the training, and they will accept, perhaps, they will more accept to change their behavior than others.

DR. CONWAY-WELCH Thank you.

CHAIRMAN WALSH: Dr. Lilly?

DR. LILLY: Just a couple more details on the question of mandatory testing. We have mandatory testing in this country in some areas, including in the field of immigration and in federal prisons and in some state prisons, and I'm just wondering why you do not have those in France.

PROFESSOR POMPIDOU: Yes. For immigration, we have no testing -- no mandatory testing.

DR. LILLY: Yes.

PROFESSOR POMPIDOU: That is true if there is no symptoms. If there is presence of symptoms, the program is different, because at that time testing is proposed.

DR. LILLY: Yes.

PROFESSOR POMPIDOU: But, even if somebody is seropositive and knows he's seropositive, he will not be rejected from coming into the country, but he will have special educational program which are now set up in universities, for instance.

So, we have not quarantined, of course, and we have not put out people from other countries which are seropositive. That's the first point. Of course, for international travelers there is no testing, but information. And then, what I must tell you, which is very important, is that at the European level there are more than 10,000 educators, among which 92 percent are from European origin, so there are only eight percent from

foreign countries all over Europe. In terms of prisons, there was a commission which was in charge, and I was working as a professor as a coordinator.

So, the recommendation was at three levels. The first level is that, 90 percent of the people found seropositive in prison were seropositive before arriving in prison, and so were not contaminated in prison, the first point.

And now there is three levels. First, any prisoner can ask for testing on a voluntary basis, and this will be done, you know, there are rapid turnovers in prison of prisoners, but within three months this will be done.

The second thing is that if somebody is seropositive, presents symptoms, it will be mandatory, not in the hospital, but there will be blood -- some persons will go to the private centers to be tested.

If a prisoner is ill, as soon as the prison infirmary can take care of him, he will stay at the infirmary. The point is to have not too much movement of the prisoner from the hospital to the prison.

But, when he has some opportunistic infection, for instance, he will be brought to the hospital. If he is close to dying, I mean, some months to die, there will be opportunity to ask presidential grace, presidential pardon if the person is a prisoner asking, because some of the prisoners prefer to die in the prison and not to have problem outside of the prison. So, these are the three points, and there is special settlement between Ministry of Justice and Ministry of Health to take care of these patients in prison.

DR. LILLY: One further question. I think I understood you to say that in France you have legalized the buying and possession of needles and syringes, is that true, and has it resulted in an increase in intravenous drug use?

PROFESSOR POMPIDOU: What we know is that, first, this was done for one year, and this will be renewed next May, but the evaluation we have is an increase in the consumption of syringes in the registers of large towns. In the registers of towns less than 100,000 inhabitants, the drug users were put out by the people in the drug store. But, in drug store where --

DR. LILLY: I'm sorry, I didn't understand. What happens?

PROFESSOR POMPIDOU: In towns less than 100,000 inhabitants --

DR. LILLY: Yes.

PROFESSOR POMPIDOU: -- when an IV drug user is asking to buy syringe --

DR. LILLY: Yes.

PROFESSOR POMPIDOU: -- the pharmacist, doesn't want to sell the syringes. In large towns, and in the districts more exposed to the large towns, the pharmacists sell the syringes, and there is a three-time increase in the sale of syringes.

We'll have more data next May, but to my knowledge there is no increase in drug abuse in France, and also, people who want to be detoxified will go to the detoxification system. Less and less are contaminated.

DR. LILLY: Thank you.

CHAIRMAN WALSH: Dr. Crenshaw?

DR. CRENSHAW: You were mentioning the policies on contact notification, and indicating that basically you didn't feel that was effective or working. What is the law in France pertaining to someone who is married? Is the husband or wife, the spouse, informed if their partner is infected, and, in particular, what if the patient doesn't wish to have the partner notified, how do you handle that?

PROFESSOR POMPIDOU: Okay. In France, the medical secret is absolute, and the only person who can authorize the doctor not to be bound by the medical secret is the patient himself. So, the program is inappropriate when the man or the woman is contaminated.

So, the law is that the medical secret should be kept and the physician should not turn to the person who is not contaminated that the other one is contaminated. And, this can go to court if the doctor says that.

Nevertheless, we think that it is the role of the doctor to sensitize the contaminated person, or to allow the doctor or physician to tell to the others, or to the sexual partner, or to sensitize the contaminated person to tell the sexual partner himself.

And, we always say that one part of the role of the physician, besides diagnosis and treatment, is to sensitize and care for the person, and to sensitize the person and to reassure the anxious person. So, I think this is the role of the physician, and it's a problem of case by case treatment.

DR. CRENSHAW: Thank you. Also here in the United States, in some of our states, a physician is forbidden to tell another physician that they are both treating a patient who is infected without that patient's written consent. So, in some cases, all the records go to another treating physician without the blood tests. Is there a parallel in France, or is it handled differently?

PROFESSOR POMPIDOU: No. In France, as I told you, the medical secret is absolute, but all the physicians can share the medical secret. And, for instance, the physician for the insurance company can share this medical secret, but we have to ask what we call the Order of the Physicians, the Order of the Doctor, this is a special committee, you know, which is a national committee, who is looking at the behavior of all the doctors.

And so, Order of the Physicians has to remember the physician of the insurance company, that it can share any kind of diagnosis only with the patients or with other physicians, but not with the company, of course.

DR. CRENSHAW: Thank you.

CHAIRMAN WALSH: Ms Gebbie?

MRS. GEBBIE: I thought I heard you indicate that all of the counseling in your counseling sites was done by physicians. If so, that's quite different from our pattern here, in which a variety of trained counselors are used, depending on the site. Would you clarify that for me?

PROFESSOR POMPIDOU: Thank you. We have different levels of counseling. The more frequent counseling is when somebody asks the physician to be tested, and when you go back to the physician, and the physician counsels regarding positive test results.

So, there are two attitudes. The physician must say the diagnosis, but if the physician is not strong enough, is not aware enough how to present the diagnosis of seropositivity, he can say, he can ask the patient or the person to go to see another physician who is trained to do that. That's the first point.

The second point is that it is a free and anonymous center, and if the result is negative, a non-physician, a medical worker, or a worker, will speak about the problem, and with concern because if somebody came to the center it is perhaps because he is at risk or he has a chance to be contaminated. So, there will be a discussion between a worker and this person.

If the diagnosis is seropositivity, so there is a doctor who will take the time, at least half an hour, to explain everything, and he will ask this patient to go and consult, get a specialized consultation of the hospital, because, as you know, during the first announcement of the diagnosis the patient is there but is not listening to anything. So, you have to be twice or three times trained about that.

And, the last aspect of counseling, we are association, like for San Francisco, it's an association, we're private and available association, which can do counseling for people who want to have more information about AIDS and about contamination and prevention and so on.

So, we have these three different counselings, the doctor, the physician, the family physician, the doctor in the center, free and anonymous, and workers, and we have now information, 2,000 workers for this kind of counseling for spreading out all facts. And, the last is the association, and many of us, we can get counseling about information.

MRS. GEBBIE: Thank you very much.

CHAIRMAN WALSH: Dr. Lee?

DR. LEE: Monsieur Pompidou what happens, first of all, if the doctor does tell the consort? Is the doctor liable for criminal prosecution?

PROFESSOR POMPIDOU: Is the doctor what?

DR. LEE: If the doctor notifies the sexual contact, is he criminally liable?

PROFESSOR POMPIDOU: Yes. You mean, if the doctor notifies the sexual contact administration or to an enterprise?

DR. LEE: No, if X is positive --

PROFESSOR POMPIDOU: Yes.

DR. LEE: and the doctor tells X's wife, is the doctor criminally liable for a crime in your country?

PROFESSOR POMPIDOU: It will not go to the courts, but he will be erased from the list of doctors by the National Order of the Doctors.

DR. LEE: Is that correct?

PROFESSOR POMPIDOU: That's absolutely true. The Physician Order is very powerful. Every physician has to be

inscribed in the Physician Order, and if a doctor, without authorization of the patient, tells the spouse, tells the mistress, or tells somebody else that this person is seropositive, he will be erased from the Order of the Doctors, and he will not be allowed to practice anymore.

DR. LEE: Now, let me pose a question, a theoretical question. The definition of assault would be abuse upon the body of someone else. Now, isn't this assault, I mean, in this country the lawyers are starting to think of this in terms of a charge of aggravated assault.

PROFESSOR POMPIDOU: Yes.

DR. LEE: Now, in France, why is this not assault?

PROFESSOR POMPIDOU: You mean, if somebody is contaminating somebody else knowing it?

DR. LEE: Yes.

PROFESSOR POMPIDOU: So, there is different aspect of the thing. The first aspect is that it could be considered as voluntary murder knowing it, and this has to be treated by the courts.

Actually, the problem is that we decided not to have a new law about that, but that a person which has been inserted, whether or not it is contaminated, and, of course, if this person has been contaminated, this person can appeal to the court. And, the legislation now could be giving death, willing to give death, but also we have old legislation which has been used for toxemia, which has been used ten years ago which is based upon poisoning, and perhaps, the lawyers are thinking about that now.

And, that's a more appropriate law to advocate the poisoning law, because first you have to prove the poisoning, and second, you have to be sure that the person was not willing to be poisoned.

DR. LEE: That's very French, to put it in terms of poisoning.

So, currently, it's not a criminal offense. Currently it is not --

PROFESSOR POMPIDOU: Well, poisoning is a criminal offense.

DR. LEE: So it is, if you knowingly transmit the virus, it is a criminal offense in France.

PROFESSOR POMPIDOU: You have to prove it first. If you prove that, there is no jurisprudence now. Nobody has appeared before the court because they have contaminated, so I cannot tell you what will be the jurisprudence.

I give you some feelings, it's not quite nice, really, it's feelings, and it is close to giving deaths by wanting to give it, or to poisoning, but that's all I can tell you. And, all that will be taken into account only if there is a proof that there was intent to contaminate, and there is contamination.

As you know, all sexual acts are not contaminating, but only one is contaminating. Among hemophiliac, after six years of regular sex for life without protection, only 40 persons are contaminated.

So, it's not because one person had sex, one person seropositive, have sex with a person seronegative, that this person would be contaminated. And if this person goes to court and this person is not contaminated, there is no proof. There is only proof that there was sex, but no contamination.

DR. LEE: Thank you.

DR. PRIMM: Mr. Pompidou, you have a number of narcotic addicts in your country, and, apparently, the modality of treatment of narcotic addicts of methadone maintenance is not employed on a large scale in France. What are you doing to take care of those people who need and desire treatment who are toxicomania in France?

PROFESSOR POMPIDOU: So, for those people, we have a system which is an administerial commission which has been created four years ago, which has a special project, and we are about 15 different places all around France where these people can be cared, not cured, but cared, in terms of drug abuse.

And, there is also a physician taking care of this patient when these people are willing to be cared. And now, there is discussion between the Minister of Justice and the Minister of Health on how to organize a kind of mandatory care --

DR. PRIMM: Yes, Japonica Junction.

PROFESSOR POMPIDOU: And, also, among the 2,000 as workers who are being trained for outlets for information. We have are workers involved in the prevention and care of drug addicts.

So, we are now reinforcing, what has been taken from this administerial commission against toxicomania. $1 million

Franc has been given to reinforce the system of care for IV drug users.

And also, we are setting up for prostitutes and for IV drug users information -- specific information system with social workers going to meet these people and to provide them with special information, giving them the address of the center where they can go, and giving them also the address of the association where they can meet and where they can be sensitized to detoxification.

DR. PRIMM: Community drug treatment centers are in France?

PROFESSOR POMPIDOU: The evaluation is, we don't have exact numbers, but the evaluation is about 150,000 drug addicts in France.

DR. PRIMM: And, you have treatment for 150,000 in place with those 20 some places that you have designated, and these are --

PROFESSOR POMPIDOU: No. We have association, we can speak with half of these people. As you know, half of these people don't want to have any contact with this association or with others. But, we have enough associations for half of these people, and we have about 30,000 places in detoxification centers.

DR. PRIMM: You had mentioned also that you had a year's trial program with your needle and syringe exchange through the pharmacist, and that that year will be up this May.

PROFESSOR POMPIDOU: Yes.

DR. PRIMM: One of the Commissioners had asked a question, what was the result of that one-year's trial? Do you have an increase drug abuse, or intravenous drug use, among those persons? You said in towns over 100,000 people, for example, the druggists continued to sell needles and syringes to them, but in towns of under 100,000 people, they were sent away from the drug stores or the pharmacies. What happens to those people who are sent away? Do they go into treatment, or do they just languish in the street?

PROFESSOR POMPIDOU: One year is not enough to build a successful program. So, these people who have been put out of the drug store, can go to the hospital, and can also buy syringes from the hospital. These people also can have syringes from other people, but what will be more difficult to break is the ritual of exchanging and passing around the syringes from one to the others. That is the first thing to do. And, we plan

now to have a program on how to bleach the syringes, but I think it is much better to buy new syringes. They are not expensive.

DR. PRIMM: What is the seroprevalence rate among your IV drug users? Apparently, you test IV drug users when they come into the prison system. What has been the prevalence of HIV infectivity among that group?

PROFESSOR POMPIDOU: That depends upon the area, but I can tell you that in Marseilles, for instance, where there are very many users, 80 percent of the drug users are contaminated.

DR. PRIMM: 8?

PROFESSOR POMPIDOU: 80 percent are contaminated. And, the rate is between 40 and 80 percent contamination among IV drug users.

DR. PRIMM: Thank you.

CHAIRMAN WALSH: Dr. SerVaas?

DR. SerVAAS: Mr. Pompidou, about counseling, how is pre-test and post-test counseling done at the blood banks in Paris? Before and after screening for AIDS, some of our states have laws requiring pre and post-test counseling for all persons tested for AIDS, but simultaneously permit no post-test counseling for those who test negative, and let's the blood banks contact their AIDS antibody positive persons by letter, by mail.

Do you have laws against letting blood banks notify positives by letter, and are blood banks permitted not to counsel their negatives at all in France? And then, I'd like to know about your TB problem in France, is that also growing among your AIDS patients?

I have a question on page 4 of your report here, where you say, "Couples desiring to procreate must be proposed to be tested if any doubt regarding contamination." What if they propose not to accept and say, no. What do you do then? Is that something that you make -- I didn't see anything or hear you say that you have any pre-marriage license testing in France.

PROFESSOR POMPIDOU: We have no mandatory pre-marriage, but this will be proposed to all couples who are going to be married.

DR. SerVAAS: How do you propose that?

PROFESSOR POMPIDOU: When the couple is waiting to be married, the physician must propose them to be tested and explain to them why, because they are beginning a new life, because they will be about to procreate and to raise a family, and so the physician explains to them that it is in their own interest to be tested altogether, male and the female. That is proposed.

But, if the couple doesn't accept the test, there is no law which authorizes the physician to do it. But, he has his own persuasion system. I mean, the pressure is not as strong as during Mussolini time. But, of course, he may have discretion, and he may have confidence between the physician and the patient.

DR. SerVAAS: Do they always see a physician when they get a marriage license? In our country, we just go to a clerk. In France, they go to a physician?

PROFESSOR POMPIDOU: Yes. They go to a physician, because we are doing mandatory testing for syphilis, so they must go to the physician.

DR. SerVAAS: And then, the physician must propose an AIDS test.

PROFESSOR POMPIDOU: Yes. The physician must prescribe syphilis test and propose the HIV test.

DR. SerVAAS: What percent of the couples go along with the AIDS test in France?

PROFESSOR POMPIDOU: Oh, I mean, this is a new measure, so I cannot tell you. This is just being done now. So, after one year I can tell you, but now I cannot.

DR. SerVAAS: TV?

PROFESSOR POMPIDOU: So, about TV, we have spots on TV, you know, one saying that AIDS will not go through me, to show responsibility, and then a few months later, AIDS will not go through us, and this was a couple, and the wife, the young lady was showing a condom to the young man. But, this TV spot was well accepted.

DR. SerVAAS: Then the blood banks. What about the blood banks and counseling?

PROFESSOR POMPIDOU: For the blood banks, we have not done the testing of blood, but everybody who is giving blood has to fill a form, and if there is any doubt about at-risk comportment, the blood is discarded even if it is negative.

DR. SerVAAS: How do you notify the person who tests positive at the blood bank? How are the blood banks going to handle that?

PROFESSOR POMPIDOU: Yes. When somebody is positive, he has concern not only that the blood bank should be the first contact, but that it will be sent to one of the 300 counselors, because it is necessary that these people see not exactly specialists, because it is not a specialization, because it should be the role of any physician, but to see physicians who are all over in charge and trained, and are accustomed to take care of seropositive people.

DR. SerVAAS: Thank you.

PROFESSOR POMPIDOU: You are welcome.

CHAIRMAN WALSH: Alain, as always, you have been most stimulating, and I think that all of the Commissioners welcomed your candor and your exchange.

Out of courtesy for our long-standing friendship, I will defer my questions, and also in the interest of time, because I know you and I will be seeing one another again.

And, I can't thank you enough for making the effort to come to our country to share your experiences with us, and to share your suggestions with us. And, we look forward to being in touch with you in the future. Thank you very much.

PROFESSOR POMPIDOU: Thank you very much.

THE PANDEMIC IN ASIA

CHAIRMAN WALSH: Our next speaker is Captain Michael Kilpatrick, Medical Corps, United States Navy, who is the Research Area Manager for Infectious Diseases at the Naval Medical Research Development Command in Bethesda. And, he is going to discuss the Pandemic in Asia. Captain, go ahead.

CAPTAIN KILPATRICK: Thank you, Mr. Chairman, distinguished members of the Commission. It is certainly my pleasure to be here today as a spokesman for the pandemic of HIV in Asia. I say "spokesman" because my normal function is to serve as a receiver, collector, organizer, interpreter, and then transmitter of medical data on infectious diseases so that appropriate medical policy treatment can be established within the Navy.

Today, the focus is HIV, and the prevalence and incidence of HIV in specific countries, as we've heard earlier

today several times, is an extremely sensitive area, both politically, socially and economically. I would like to present to you an overview of the HIV prevalence and incidence data in Asia, limited though it is, along with further limitations in the accuracy, completeness and interpretability of these data. As is true of HIV data from all parts of the world, we only see small parts of the population being sampled, and in general the sampling or evaluation is done at a single point in time. The disease with which we are concerned today, HIV, is not static in the world. Terms are still being clarified, testing is variable, fear continues to be a main adversary. Regional coordination and cooperation is essential and must be developed. Education remains our sole weapon.

The data in my report represent the dedication and scientific excellence of hundreds of medical personnel in Asia and around the world. The technology transfer, the laboratory training, political awareness and honesty have really produced this information database. The focus and future direction of these efforts will be determined in large part by the conclusions of this, the Presidential Commission on the Human Immunodeficiency Virus Epidemic, and similar organizations throughout the world.

The World Health Organization has taken a major step forward in deciding to gather, summarize and publish all data on HIV for member governments in the WHO Western Pacific Region, and it's from their Virus Information Exchange Newsletter for Southeast Asia and the Western Pacific that I have drawn the majority of the data in this report.

Other information was obtained from the First International Congress on AIDS in Asia and Other Sexually Transmitted Diseases, which was held in Manila, Philippines in November, 1987. That Congress was truly an open forum for discussion and presentation of data.

As we've heard earlier today, the estimate for the number of cases in the Asia area is 11,000, and I have a breakdown from the Virus Exchange Newsletter showing cases as of November of 1987. These cases totaled only 766 at that time. Australia was the leader with 622, and going down the list, China with 2, French Polynesia with 1, Hong Kong with 4, India with 17, Japan with 50, Korea with 1, Macao and Malaysia with 1 each, New Zealand with 54, Philippines with 10, Singapore with 2 and Tonga with 1. You see the numbers are extremely small in all these areas.

Laboratory confirmation of these cases of AIDS is presumed on my part because it was not present in the information published. For Australia and New Zealand, the data along with this information indicated that the great majority of those who

were positive were male homosexuals or bisexuals. In Japan, the majority of the AIDS cases were in hemophiliacs. Almost all other cases reported, as has been present in so many areas of the world, were said to have been in foreigners who were in the country and became ill, or who were individuals from the country who had acquired their disease outside of the home country and had returned home knowing that they had AIDS.

The next portion of data I'd like to present is the HIV antibody prevalence data for various countries in the Asian area. One should not really attempt to compare these prevalence rates between countries, because there is a wide variability in the population groups which were sampled, and, perhaps, there was even some bias in selecting individuals within the subgroups that were sampled.

It's important to realize that the divisions that were given or made, perhaps, artificially for the HIV seropositive individuals fell into either blood donors, hemophiliacs, homosexuals, bisexuals, female prostitutes and others. Anyone who did not fit into any of those categories, obviously, would have to fall into the others, and individuals who belong to more than one category were not handled in a very clear manner.

I'd like to go through the numbers. Numbers are very hard to try to present, but I'll try to distill it down to the real rates and the limitations on the data. In Australia, there were 17,741 individuals who were seropositive out of 362,000 who were tested, for a prevalence rate of 48 per thousand. However, there was no indication of the test that was done for HIV seropositives, whether this was just an ELISA or whether this was confirmed with Western Blot, and there was no definition of the population which was sampled, whether these were hemophiliacs, male homosexuals or just all comers. That rate of 48 per 1000 is extremely high. The assumption is that this has to be a very high-risk group that was sampled.

In Brunei, only two were positive out of nearly 4,000 that were sampled. In China, where the test was shown to be Western Blot confirmation, only 4 of 6,500 were positive. Again, in those last two, they didn't give a breakdown as to what subgroups of people the positives were in, but they were very small.

In French Polynesia, 29 of some 13,000 were positive, but all 29 positives were from a group of 945 who were described to be individuals at risk. In Guam, there were only 4 out of 543 positive, but again, no definition of the population group that was surveyed.

In Hong Kong, there were 110 of 377,000 that were seropositive, but 50 of those 110 were hemophiliacs, 55 were in

another group, and there were no prostitutes or homosexuals sampled in that group. So, again, the data is skewed, and you cannot compare the prevalence rate in these areas.

In India 120 were positive out of 40,000, for a prevalence rate of 2.9 per thousand. Ninety percent of all those positives were in prostitutes.

DR. LEE: What country was that?

CAPTAIN KILPATRICK: That was India.

DR. LEE: India.

CAPTAIN KILPATRICK: In Japan, there were 298 seropositives. There was no denominator given as to how many were tested, and no definition of the population that was surveyed.

Skipping to New Zealand, there were 256 seropositive, but again, no denominator as to how many were tested or what population they were from. In the Philippines, there were 52 who were seropositive out of 65,000 who were tested. Fourty-seven of the fifty-two were prostitutes, and no hemophiliacs were tested in the country.

In the Republic of Korea, there were 11 positive of some 216,000. Seven of the 11 were prostitutes, three were identified as overseas workers, with no indication as to where they had been working overseas.

Singapore, only 14 of 110,000 were positive, and in Taiwan, 54 of some 77,000 were positive, but the ELISA test was the confirmatory test. The Western Blot was not used. And, of those 54, 17 that were positives were from a group of 775 homosexuals and 31 were from a group of 317 hemophiliacs. None of the some 2,800 prostitutes who were sampled in Taiwan were positive.

I think the essence of what I would like to put across to the Commission is that, until there is a standardization of defining the groups that are sampled, until there is a determination of the standardization of testing that's done, prevalence rates, in and of themselves, cannot be used for comparing one area of the world with another, or even one country in itself from one time to another.

The last data that I'd like to present to the Commission are true incidence data of HIV positivity of prostitutes in the Philippines. In a project that involved the Philippine Ministry of Health and the Navy Medical Research Unit Number Two in Manila, some 3,271 female prostitutes who tested

negative for HIV in 1986 were tested again one year later Seven of this group were found to be positive, which is an annual incidence of 2.1 per 1,000. This is a highly-selective population.

Education must remain as the principal objective in dealing with HIV. The scientific community must continue to become educated on how to perform HIV testing with standardized methods and quality control. Population groups studied should be completely categorized with standard descriptors. Incidence studies must have standardized intervals and must evaluate specific risk factors. Statistical evaluations need to be done in a manner which is universally accepted. And again, the media needs to be educated to understand the complexities inherent in a seemingly simple statement about HIV rates.

The general population needs to be educated that what is currently being measured in HIV studies is the humoral response to the virus; we still don't know the variability of interval between virus exposure or virus infection and the HIV antibody production.

As I've listened through the morning, it's become even more apparent that there are many basic questions that we don't understand on HIV that need to be answered. Prevalence rates certainly do give us a static retrospective picture of this disease. Incidence rates put some motion to that picture but they, too, are not focused in the present but in the near past. It's essential that we have research programs which continue to measure for transmission of this virus. International cooperation is essential, since our world population is so mobile. The HIV epidemic, I am certain, will continue to be a medical, social and political challenge for the years to come.

I would like to state that recommendations from this Commission will have a major impact on the way the world deals with the HIV problem. A recommendation for a standard nomenclature, which is internationally accepted, should be adopted for describing the populations which are surveyed and any testing that is done. We can only compare from one area to another using a standard nomenclature because prevalence and incidence rates are going to be variable depending upon the subgroup that's tested. The denominator group is extremely important.

Some of the currently used groupings that you read in the literature and have heard described here today are intravenous drug users, homosexuals, bisexuals, prostitutes, hemophiliacs, overseas workers, blood donors, people attending STD clinics. We need to work on making more precise what we mean by these terms. Certainly, for example, as we heard discussed earlier today, the definition of a homosexual or a homosexual act

may vary depending upon the cultural overlays that the individual would have when being questioned for data to go along with the test.

When we have workers overseas, we need to know which geographic area they were in, and what were the risk factors while they were in that geographic area. People who belong to more than one risk group need to be precisely defined in the denominator group when we are trying to prepare prevalence and incidence data.

Without this standard internationally accepted population subgroup identification system, no comparison can be made from one region to another, or within any region over a period of time. Another very critical element is the question of the type of testing to be done. The technology is exploding in the world of HIV testing. We are looking for easier to do, more economical tests, and when seropositive tests are reported, it's essential that along with that data go the information on the kind of test that was done, so that comparisons can be made.

If an ELISA is the test for positive HIV results in one country, and another country uses a Western Blot for its HIV confirmatory test, those two data cannot be compared directly. And, it's going to be important that all agencies who assist in worldwide health care should subscribe to standardized testing and reporting.

One additional factor here is the quality control that must be done in all testing, that this should be done in as internationally standardized a manner as possible, so that we can be sure that when we are talking quality control, particularly when we are looking at larger populations to be studied, that we have good quality control and comparable results, regardless of which area of the world the report is coming from. This is all that I have from Asia at this time.

CHAIRMAN WALSH: Thank you. We'll start with you, Cory.

DR. SerVAAS: Captain, do our civilian travelers or military personnel have any problems in Asian countries? And, my other question is, is HTLV-I testing done in Asian countries, where HTLV-I is more prevalent?

CAPTAIN KILPATRICK: The first question, to date there has not been any problem, but I just Friday saw a brief message that the Philippines is going to start requiring HIV results of people entering who are going to be staying longer than three months.

This may continue to be a problem, and part of responding to those kinds of questions is really educating about what HIV tests like this mean. From a military standpoint, people who are HIV positive do not leave the Continental United States, so that this should not be a problem from a military standpoint. I think the State Department is doing a similar kind of program, since both our organizations have people overseas for extended periods of time.

On the other question, the HTLV-I, there is no reporting mechanism for HTLV-I. We know that prevalence rates are much higher in certain areas of Asia, particularly Japan and Okinawa. Testing to date has really been on a research, epidemiological seroprevalence model, and until there are good quality control standardized tests it's very difficult to say that there should be testing done in any larger sort of numbers. The big problem is that the commercially available tests are not all that sensitive or all that specific.

DR. SerVAAS: You mentioned new things coming in testing. Do you have any information on tests that are in the works that we may be expecting soon?

CAPTAIN KILPATRICK: I don't directly. I'm working with the Army Research and Development Command in the Infectious Disease area. They are looking at comparing three or four different kinds of tests, latex agglutination particles for example, that would be cheaper to do. But, it's going to have to be measured against our gold standard of the Western Blot.

These newer tests and newer procedures have to be evaluated against the standard testing. And, that's being done, not only within the military systems, but I'm sure within private industry, trying to develop newer tests.

DR. SerVAAS: Thank you.

CHAIRMAN WALSH: Dr. Lee?

DR. LEE: Can we throw out all your statistics? I can't come to grips with anything you said and think about it and extrapolate it in any way. Would you agree with that?

CAPTAIN KILPATRICK: I think this is a problem that we're dealing with, that these statistics have been gathered by small groups or organizations for example, a university sponsored group going into an area, drawing a sampling of blood, giving limited denominator information, and then reporting their data.

Until we have larger numbers reported through a system such as the World Health Organization is trying to initiate in

the Asian area, in particular, the numbers are really meaningless, because they are apples and oranges and no comparison can be made.

I think when you look at it overall, and you see prevalence rates of 1 or less per 1,000, it means the disease is there, it is not in a major epidemic proportion, but you need to know what the population group being studied is.

DR. LEE: Dr. Roy Widdus is sitting right here listening to this, and I don't envy him. They are trying to make sense on a world basis about what the problem really is. They estimate 10 million cases, but if you look just superficially at your figures they could be off by a factor of 10 easily. Anyway, thank you, sir.

CHAIRMAN WALSH: All right. Dr. Welch?

DR. CONWAY-WELCH I wondered if you could expand on the issue of the prostitutes who are HIV positive in the Philippines, and the ways that we are responding to that problem?

CAPTAIN KILPATRICK: To date, there have been 44 prostitutes who have been identified as positive for HIV in the Philippines. None of these individuals are symptomatic, and the Philippine Ministry of Health has encouraged them to stop professional prostitution and to look at another form of earning money.

DR. CONWAY-WELCH Are we assuming responsibility, though, for the fact that they are HIV positive, given the fact that they are around our military bases?

CAPTAIN KILPATRICK: Okay. The 44 positives are prostitutes and, indeed, have been identified near two large military bases, Air Force and Navy, in the Philippines. There has, to my best knowledge, been no determination of responsibility.

DR. CONWAY-WELCH Is there a dichotomy between the statement that you made about the military not allowing any military personnel going overseas if they are HIV positive, and the fact that there seems to be a direct relationship, geographically at least, between the location of the bases and the infection of the prostitutes. Would that have to do with prior to the institution of this requirement?

CAPTAIN KILPATRICK: Obviously, the military testing began once the epidemic, the disease, was identified as being present. How many military people were overseas who were HIV positive is data that I do not have. But, being able to extrapolate from numbers that are positive and numbers that are

present overseas, that this would be a fairly small number of individuals.

So, we can say today, having identified that there is an infection, HIV, that the military is not in a position to be sending individuals overseas who are positive. As we've heard earlier today, the test is at one point in time, and an individual may have been infected and be seronegative for antibody, and this is one of the problems, one of the limitations of testing.

The fact that we are not seeing much increase in the numbers of HIV positive prostitutes in the Philippines, either around the military bases or in metro Manila, where the major testing continues to be done, means that, again, as I said earlier in the testimony, we are looking back at seropositives today, perhaps being infected as long ago as one or two or several years ago. There is not hard evidence to say when they were infected.

The military standpoint is that we are not, as best as we can do with testing, sending anyone overseas who is seropositive. For those 44 individuals, it is very difficult to know for sure where they acquired the infection, because they, too, are a mobile population.

DR. CONWAY-WELCH You also stated that the State Department was, to the best of your knowledge, not sending anyone overseas who was HIV positive. My understanding, which certainly may be incorrect, was that at least last year that they were trying to identify places that had access to tertiary medical care, so that there were still some places abroad that State Department personnel who were HIV positive could be assigned. To your knowledge, has that policy changed now?

CAPTAIN KILPATRICK: On the State Department, I really can't speak to that. When the policy began, whether they had to modify that, I'm not certain.

DR. CONWAY-WELCH Thank you.

DR. LILLY: I pass.

DR. CRENSHAW: Having been in the Navy myself many years ago, and treated many sailors, at least at that time I prescribed a lot of antibiotics for sexually transmitted diseases, and they were good consumers of prostitutes in local ports. When we think of the Orient, we think of sexual tourism, prostitution, and I have a two-part question relating to sexual tourism.

One is the concern for the military men who followed those who may or may not have infected prostitutes in the Philippines or elsewhere, or military men overseas in the Orient who frequent prostitutes and then bring home HIV infection that's endemic to that prostitution population, regardless of how it got there, to their families stateside.

Are there any studies going on to evaluate the flow of infection from one direction to another, and what are the thoughts? I'm sure there is some concern about it.

CAPTAIN KILPATRICK: Yes. There definitely is concern, and that is why the military is going for the second round of all force testing, as it is called, in that all military people will be tested a second time, with the people who are overseas being the primary focus. They will be tested first.

And, the database will continue to be kept. We'll continue to monitor people who are at risk. Sexually transmitted diseases qualify as putting a person at risk, which will be then followed with a test for HIV.

The limitation, of course, is what is the window between acquiring the virus and being positive on testing, and that's what we're hoping to try to narrow down with the second all force testing, to focus where continued testing needs to be done, and what defines risk, and what are the risk behaviors that need to be modified with education?

DR. CRENSHAW: Are equal rules being applied to officers as well as enlisted personnel? When I was in the Navy, if an enlisted man got an STD, he was grounded, and an officer wasn't. I'm wondering if we have gotten more universal in our --

CAPTAIN KILPATRICK: The problem with the STDs policy is that the action rest with the unit commander as to how to handle that. From the medical standpoint, the policy is, that grounding someone puts the symptoms under cover until the liberty period is over. Medically we are recommending all treatment should be given, and if an individual is infectious then, certainly, they should not be allowed the opportunity to spread that disease, whether it is strep throat or STD.

DR. CRENSHAW: This last question you may not be able to answer, because it pertains to history and I'd really appreciate your trying to refer me to someone if it isn't within your field.

But, it's my understanding from several different areas where I've heard it, that earlier in the 1900s China did one of

the best jobs in the world of eradicating sexually transmitted diseases. This was long before AIDS. Is my impression correct, or do you know?

CAPTAIN KILPATRICK: Yes. I have heard that, that sexually transmitted diseases were eliminated, and the methodology of eliminating them was fairly severe. The people who were found with sexually transmitted diseases were executed, and --

DR. CRENSHAW: Forget I asked.

CAPTAIN KILPATRICK: -- that truly did eliminate sexually transmitted disease.

DR. CRENSHAW: Okay. I don't need to know anymore about that.

CHAIRMAN WALSH: Thank you very much for your testimony. I have no questions. My only comment was, I also served in the Navy, and it's contrary to policy for officers to get VD.

OTHER MULTILATERAL RESPONSES: THE WORLD BANK AND THE UNITED NATIONS DEVELOPMENT PROGRAMME

CHAIRMAN WALSH: Our next section of the program is Other Multilateral Responses. You may recall this morning that Jonathan Mann mentioned the cooperative relationship they are attempting to establish with the World Bank and with the United Nations Development Programme.

So, we are privileged to have representatives of both of those organizations with us. We have Ann Hamilton, who is the Director of Population and Human Resources Department, World Bank, and I see we have a reprise from Dr. Mead Over, who is here with her, and you are welcome back. And, we also have Timothy Rothermel, the Director of the Division for Global and Interregional Programmes, of the United Nations Development Programme, and he is accompanied by Alan Doss, who is the Resident Representative in Zaire. So, Ms. Hamilton, you are up first.

MS. HAMILTON: Thank you very much, Mr. Chairman. First, let me say a few words about what the World Bank is. It was established in 1945. It's more formally known as the International Bank for Reconstruction and Development, or the IBRD. It is owned by its member governments, of which there are now 151, with voting power linked through their capital subscriptions to their relative economic strength. The Bank obtains its funds by borrowing in the capital markets of Europe,

Japan, the United States and the Middle East. These funds are then loaned to the governments of developing member countries which request them, and which present acceptable proposals for the use of the borrowed funds. In our fiscal year 1987, which ended last June, the IBRD committed loans totaling $14.2 billion to finance development projects in 78 member countries. IBRD loans have a maturity of 15 to 20 years, including a grace period of three to five years, and an interest rate which is currently 7.72 percent.

The Bank Group also has a "soft loan" window, called the International Development Association (IDA). IDA is financed by contributions from the wealthier countries, including the United States, and lends to the world's poorest countries. The cutoff point is countries with a per capita income below $790.00 a year. It is administered by the same staff as the IBRD and the same criteria are used in project selection. In fiscal year 1987, some $3.5 billion were loaned on IDA terms, These terms are very generous. They provide for a ten-year grace period, a 30-year maturity, and a service charge of 0.75 percent a year.

Most African countries, including those most affected by AIDS, qualify for IDA terms. Some of the countries in Latin America that are most affected by AIDS borrow from the World Bank at IBRD rates.

Turning now to our lending activities, the Bank has come increasingly to recognize that good health is itself both a fundamental ingredient and a fundamental goal of the development process. Investments in reducing the rate of population growth, in improving nutritional status, and in reducing morbidity and mortality across the board make a direct contribution to the well-being of a population. Furthermore, it's apparent that the prevention or cure of many diseases can release a country's productive potential for the development process.

World Bank lending for the population, health and nutrition (PHN) sectors has grown rapidly since it began which was recently as 1980. Annual lending has more than doubled from about $100 million a year in the early years of the decade to about $220 million a year in the last three-year period, and our projections for the next three-year period suggest that annual lending will triple by the last years of the decade, to a total of about $750 million a year. In the African countries south of the Sahara Desert, which include the countries most affected by AIDS, annual PHN lending has increased threefold since the early years of the decade and will rise again threefold by the end of the decade.

A similar growth has taken place in PHN lending as a share of World Bank lending. From a very low level at the beginning of the decade, it doubled during recent years to 1.4

percent of our total lending, and is projected to more than double again, attaining over 3 percent in the next few years. In Africa, PHN lending is already 3 percent of the total and is projected to rise to almost 5 percent by the end of the decade.

Because the World Bank's goal is overall development, most of our projects in the health sector are broad, aimed at reinforcing a country's efforts to combat a wide range of its disease problems. The World Bank has emphasized strengthening of the national capability to extend basic preventive and curative services to the general population of developing countries. At the same time, in order to help promote the sustainability of these investments, and reminiscent of some of what was said this morning, the Bank places considerable emphasis on the strengthening of the national institutions, which plan, manage, and finance the health care systems.

Against this background of the Bank's mandate and its activities in the health sector as a whole, I would like to describe the place of AIDS control activities in our projects. The role of World Bank-financed projects in the struggle against AIDS is conditioned by three facts. First, our terms, even IDA terms, are more costly than the grant financing which is currently available from many other donors to finance AIDS control programs. Second, the typical World Bank loan in the PHN sectors is large, ranging from an average of $15 million in Africa, to $35 million in Latin America, and about $55 million in Asia. Third, because we appraise in depth and reach agreement with the borrowing country government on virtually all aspects of a project, including its economic, its financial, its technical, its managerial and its institutional aspects, the preparation and negotiation of a World Bank project is time-consuming. It normally requires 12 to 24 months. Taken together, these facts suggest that World Bank projects are better at addressing medium and long-term issues raised by the struggle, against AIDS than at mounting a fast emergency attack on the program.

Countries which cannot obtain enough grant financing to cover the entire cost of their AIDS control programs are the most likely to request Bank Group financing for this purpose. But, in these countries, as well as in those where AIDS programs are fully funded by grants, World Bank projects are designed to strengthen the total national health care system, within which AIDS programs must function. Our continuing focus on management and finance of the entire health system will support the AIDS prevention programs while simultaneously protecting important programs targeted at other diseases or population groups.

AIDS components in broader health projects are currently under discussion in about 20 countries. In most of these countries, these discussions are in their preliminary stages. However, projects in two seriously affected countries,

Burundi and Brazil, have recently been approved. In Burundi, the breakdown of financing between the AIDS component and the other major components is telling. The AIDS component represents about 12 percent of the cost of the Bank-funded project, most of which is devoted to maternal and child health and health education, and about 42 percent of the total cost of Burundi's AIDS control program. In the much larger Brazil project, a $9.3 million AIDS component is 4 percent of the cost of the project and 8.5 percent of the cost of Brazil's AIDS program.

Finally, I'd like to conclude by stressing that the World Bank strongly supports WHO's leadership role in the global struggle against AIDS, which Dr. Mann so eloquently described this morning. Since the inception of WHO's program, the Bank staff have cooperated actively to ensure the coordination of Bank-financed operations with GPA-supported national AIDS plans. The Bank has also supported GPA directly, by participating in its analysis of the economic and demographic impact of AIDS, which Dr. Over described this morning.

I'm hopeful that our budgetary situation, which is currently under active discussion within the Bank, will permit us to continue and expand our collaborative efforts with WHO. Whatever our budgetary situation, however, we in the Bank who are associated with the health sector remain committed to vigorous collaboration with GPA, with UNDP, and with other donors, including prominently the U.S. Agency for International Development, in assisting the less developed countries in their struggle against this new threat to their prospects for development. Thank you very much.

CHAIRMAN WALSH: Thank you. Mr. Rothermel?

MR. ROTHERMEL: Thank you very much, Mr. Chairman, and I thank you and the members of the Commission for giving my colleague, Alan Doss, the United Nations Development Programme Resident Representative in Zaire, and me the opportunity to appear before you today.

Working as we do in an international development institution, your attention to the international aspects of AIDS in developing countries is especially welcomed.

Since the United Nations Development Programme, or UNDP, may not be a well-known institution to all members of the Commission, I'll briefly describe what we do. As the world's largest voluntarily funded international grant technical cooperation organization, now with a budget of over $1 billion annually, UNDP operates in all developing countries and territories. It has 112 field offices, headed by Resident Representatives.

In the countries we serve, UNDP has the responsibility of providing interdisciplinary assistance to governments in planning and helping to achieve their overall development priorities.

The implications of the global spread of AIDS have been outlined by several other speakers today. It is clear that AIDS is a social, economic and political issue, just as much as a medical and scientific one. Its consequences already have become a special concern for virtually all developing and developed countries, and with the likelihood of five to ten-fold increases in the number of AIDS cases in some countries within five years, there are serious development implications.

We face the sobering prospect that in some of the poorest developing countries, based on present HIV infection levels, the death rate from AIDS among young or middle-aged adults could equal or exceed the number of deaths from all other causes by the early 1990s. And, excluding the increasing number of children who will succumb to AIDS, the deaths of these men and women will generally be in the 20 to 40-year old age group, thus depriving countries already desperately lacking in human resources of their most productive citizens. In all likelihood, this group will include many of those who have the most to contribute to their country's development.

Added to this is the yet undetermined but obviously enormous future cost of health care for governments, which already face severe health constraints. These costs will include not only the provision of direct care to AIDS victims, but the related costs of counseling, blood screening, medical supplies and training. Taken together, these costs can be expected to exceed by far current health expenditures in many countries, resulting in an enormous drain of financial resources.

Finally, and on top of the diversion of human and financial resources due to AIDS, the poorest in the world will face indirect economic costs through lost years of production. The result for developing countries can be a declining GNP, the need to rethink development priorities, and the deferral or elimination of vitally needed development programs.

The United Nations system has, in my judgment, responded remarkably quickly with WHO leadership to meet the challenge presented by AIDS, especially in developing countries. The U.N. system is working together with bilateral and other development organizations, including, particularly, the United States Agency for International Development, to achieve two overriding objectives for AIDS prevention and control.

They are, first, the development and implementation of strong national AIDS prevention and control programs, since the responsibility for national AIDS programs rests with governments. The second objective is international leadership, coordination and cooperation. The WHO Global Programme on AIDS is the lead directing and coordinating organization in combatting AIDS.

In other parts of the United Nations system, international organizations in their respective fields of competence are complementing WHO's leadership role. UNICEF is bringing its expertise to bear on the tragedy of AIDS in mothers and children, and is undertaking several programs of health education for AIDS, four of which are already underway in Africa.

The U.N. Population Fund is involved with the interaction between AIDS and family planning programs. And, UNESCO is assisting in the design of AIDS education in formal and non-formal educational systems.

Ms. Hamilton has just spoken about the important work carried out by the World Bank. Less than three weeks ago, the Director General of the World Health Organization and the Administrator of UNDP formally announced a unique joint agreement called the WHO-UNDP Alliance to Combat AIDS. Under this agreement, UNDP's Resident Representatives, in the 112 field offices I mentioned earlier, will bring together UNDP's experience in multi-sectoral, socio-economic development, with the health policy technical and scientific expertise of WHO to support governments of developing countries in initiating, implementing, monitoring and evaluating national AIDS prevention and control plans.

UNDP will also be involved in seeking to ensure that all inputs from the United Nations system are coordinated, and that these AIDS plans are integrated into countries' overall national development priorities. In developing countries, UNDP and WHO officials have already begun to operate within this new relationship with positive results, which Mr. Doss will be describing.

I should add that UNDP at the country level is also providing financing for a variety of AIDS-related activities, amounting to several million dollars, covering education and training activities, blood screening equipment and other forms of technical assistance within the primary health care context.

At the international level, the UNDP Governing Council, two months ago, approved a global program entitled, the Global Blood Safety Initiative. The intent of this endeavor is to set

urgently in motion the steps required to make blood supplies safe throughout the world in order to stem the spread of AIDS and other diseases.

Specifically, UNDP is providing seed money, $700,000.00 in this case, to establish a consortium of organizations beginning with the World Health Organization, the Red Cross and Red Crescent Societies, the International Society of Blood Transfusion and UNDP, to be joined next month by an expanded number of national and international organizations.

Working together with governments, this consortium will seek to ensure that blood supply systems are fully sustainable, and that comprehensive safe blood banks and transfusion mechanisms are in place in every country.

If successful, in a few years the spread of diseases through this mode of transmission, such as hepatitis-B and malaria, as well as HIV, can be substantially reduced. The Administrator of UNDP, Mr. William H. Draper, III, clearly, and at an early stage, charged all of my colleagues to put our financial, intellectual and managerial resources at the disposal of developing countries in combatting AIDS. We firmly intend to spare no effort to meet this challenge, and we welcome this Commission's recommendations in this task. Thank you very much, Mr. Chairman.

CHAIRMAN WALSH: Thank you very much. I personally can't tell you, with sufficient eloquence, how delighted I am to find your institutions really becoming involved in health.

For 30 years, we have felt at Project Hope that economic development depended upon the health of the people. And, if AIDS has highlighted this, and I know WHO shared the same views during its lifetime, but if AIDs has highlighted the necessity for the economic institutions to be able to persuade their boards to take a greater interest in health, AIDS has already done some good with all the tragedy it has brought. And, I'm just so delighted, I just can't tell you. So, we'll start with questions again --

DR. CONWAY-WELCH Mr. Doss --

CHAIRMAN WALSH: Oh, is Mr. Doss going to speak? Oh, I'm sorry. I didn't know that.

MR. DOSS: I shall be brief, Mr. Chairman.

CHAIRMAN WALSH: No. Oh, go ahead. Go ahead.

MR. DOSS: I'll try to stick to --

CHAIRMAN WALSH: I just thought you were sitting like he was.

MR. DOSS: I'm the sunny-sided partner from the field. Thank you Mr. Chairman, members of the Commission.

The U.N. Development Programme (UNDP), and the World Health Organization have already joined forces in Zaire to support the government's national campaign against AIDS, and I thought, perhaps, I could say a few words on how this is working, as it might be of interest to the Commission members.

As the United Nations technical agency responsible for health matters, WHO, obviously, has already played a leading role in devising the national strategy for the prevention of AIDS in Zaire. The implementation of this strategy calls for substantial resources, about $15 million over five years, which may be a conservative estimate.

Zaire, obviously, cannot raise all these funds from its own budget in the present economic situation. External assistance is, therefore, vital to the success of this campaign.

To mobilize these resources, the Zairian government organized a donor conference in February, 1988. Eighteen bilateral and multilateral donors attended the conference, including ourselves, of course, WHO, the World Bank and USAID. WHO provided technical support to the meeting, and called on UNDP for guidance about financing mechanisms, and, particularly, donor coordination.

In consultation with the Zaire Ministry of Health and its AIDS Coordination Office, WHO and UNDP developed an approach designed to secure maximum national and international support for the AIDS campaign. Let me say a few words now about the main elements of this approach, if I may. First and foremost, we stressed the need to strengthen national coordination, national coordination to ensure proper management of the AIDS campaign, and we suggest that this could be done in the first instance in two ways.

Firstly, by asking the Ministry of Planning to co-chair the donor conference with the Ministry of Health. The Planning Ministry in Zaire is designated, within the Zairian government for external aid coordination, as well as for the preparation and monitoring of the public investment program.

National financing for the campaign, especially for recurrent costs -- I think that's very important to stress that -- recurrent costs have to be properly planned and budgeted, and the Ministry of Planning is an important and vital ally in that process. The second point we stressed was to upgrade the status

of the National Committee for AIDS Prevention from a departmental, i.e., a Ministry of Health Committee, to an interdepartmental one, placing it under the authority of the President or the Prime Minister's Office. This will help to ensure, we believe, that the campaign gets full national support and access to all relevant information and research results.

The second main element in our approach was to find a suitable donor financing mechanism. Various alternatives were looked at, taking into account the experience with similar fund raising ventures for other multi-donor programs.

Administratively speaking, the simplest method was simply to have created a kind of a trust fund, put all the money into that pool and manage it collectively. But, for various reason we recognized that most donors clearly preferred to keep their contributions under their own direct control.

In the circumstances, we concluded that a consultive approach was the best alternative. Essentially, this lets the donors keep their contributions under their own direct control and management, but they agree to direct them towards common goals.

To make a consortium viable, however, it is vital for the participants to agree on joint program objectives, agree also to exchange information, and accept some common criteria for the evaluation of the program. This can only be done with good communication, and good communication in two ways. So, we recommended that a permanent government donor mechanism coordination and monitoring committee be established as a means of ensuring this cohesion. This proposal, happily, was accepted by the conference.

What are the next steps? A strategy is not a plan of operation. While donors are certainly willing to finance the Zaire AIDS campaign, the first year's funding is already subscribed. We have indications that the full program will be committed. Nevertheless, they still want a detailed action plan that sets out program priorities and targets. We want cost breakdowns, and some indication of who does what.

This last point is particularly important, because we know that already they are at least ten donors are willing to contribute to the Zaire campaign. So, a plan of operation is, obviously, indispensable.

We want to prevent, in effect, a dispersion of effort and resources, and avoid creating ten or more different AIDS programs. We also want to make sure that AIDS activities are fully integrated into the existing primary health care network. I think it's vitally important that AIDS support, AIDS programs

not be seen as a diversion of resources from those primary health care networks, because AIDS is but one of many problems that confront African countries such as Zaire. It is an extremely important program, but that doesn't mean to say resources should be diverted from, as I say, the primary health care network, which has been put in place over many years by many of the donors who were present at that meeting.

UNDP, through WHO, would provide technical assistance now to the National AIDS Coordination Office, so that it could complete its plan of operations as soon as possible and provide backup for its implementation. We will also help establish the coordination and monitoring committee that will review the terms of reference for the restructured national committee. We hope to accomplish these tasks by October, 1988.

Mr. Chairman, my five minutes are up. I will conclude, if I may, by saying that it's, obviously, too early to draw any firm conclusions from this very preliminary experience. We are embarked on a venture that will require many years of sustained assistance, and I think, again, it's important to stress that

longer after the AIDS scare is over in the Western Press, the African countries will still have to face up to the costs of this program. So, we'll need follow-up.

We can say, I think at this point, that the UNDP-WHO Alliance is operational, that it is helping to put in place the institutional structure that's a prerequisite to the success, eventual success, of the AIDS campaign in Zaire.

We think that it's a good start, and I must say that we're encouraged, and continue to be encouraged by the openness and cooperation shown by the Zairian authorities, who, after all, must run the program. Thank you.

CHAIRMAN WALSH: Thank you very much. Now, I don't want to make a mistake twice. Now, Mead, you don't have another presentation?

DR. OVER: No.

CHAIRMAN WALSH: Okay, fine. Well then, Dr. Welch, do you want to start?

DR. CONWAY-WELCH The background presentation that you all have made is extremely helpful in seeing the cooperation that's occurring.

I wonder, though, if you might be able to help us identify very specific recommendations that we would make as a

Commission that would facilitate your programs. I'm having a little trouble bringing it down to some very pragmatic, one-sentence concerns that you have, and that you believe that we could be helpful in facilitating. And, that's addressed to anyone. If you could open the report, June 25th, what would you like to see written in it?

MS. HAMILTON: I would find it hard to improve upon Dr. Mann's response of this morning. The United States is, of course, the most important donor to the World Bank, and to its "soft loan" affiliate, IDA. In terms of our parochial interests. In terms of our broader interests, I think Dr. Mann stated extremely well in terms of research cooperation, the human rights aspects and financial support. I really personally don't have any particular claims to make except for such cooperation and support.

DR. CONWAY-WELCH Does anyone else have any suggestions?

MR. ROTHERMEL: I'd like to join Ann in recalling what Dr. Mann said this morning. I think we have two points that we're relating to the recommendations. It would be important to

include as one the importance attached to a national AIDS plan, and not a plan in country X, with donor Y, and with donor A, B and C. But, truly in a national AIDS plan.

The other point is one that Mr. Doss just made, and, that is, it will be a long-term proposition, and it's not just because AIDS happens to be in the news today, but even when it's not in the news I suspect these problems will still be there.

DR. CONWAY-WELCH Thank you. Are there any other comments? Mr. Doss, did you have --

MR. DOSS: If I might add one, simply a recommendation. I would say that each country should have its national plan produced by its own people, and that part of that component should be some sort of mechanism for coordination between the donors and the government authorities.

It would show that, with the very limited resources we have, we don't disperse our efforts, and that we commit ourselves over a lengthy period of time. Thank you.

DR. CONWAY-WELCH Thank you.

MRS. GEBBIE: We heard this morning some comments about the effectiveness of the programs being performed under the auspices of organizations such as your's, and the World Health

Organization. The allegation that while those were good programs, and would probably do something about this epidemic, they were often not the programs that those countries would have written for themselves. This was by one speaker particularly, that they were bullied into taking what the World Health Organization wanted done, and that they felt that even if it didn't match what they wanted, they had to take it because it was the condition of the money.

I think it would be very helpful to hear from any of you the extent to which you are aware of feelings such as that, whether they are founded in reality or not, feelings such as that in the countries which you are assisting, and what kinds of things that might be done to improve upon that situation if, in fact, it is being felt.

MR. DOSS: I was simply going to say, that comment could be heard in any kind of aid program. It would apply to Agriculture --

MRS. GEBBIE: I am not surprised about that, but I think we need to hear some more discussion of it.

MR. DOSS: It is a constant preoccupation, but many programs are perceived by recipients as donor imposed, priorities are imposed by the donors. This is why I stressed earlier the importance of not seeing AIDS totally outside of the context of the primary health care system, because otherwise there is that reaction that AIDS has affected America and Europe, therefore, Africa must act. So, I think one has to counter that by insisting that this is part of a package of assistance for primary health care, that we're not excluding malaria control, we're not excluding schistosomiasis, onchocerciasis or diarrheal diseases. But, it is part of an integrated program, and that the AIDS program, in fact, can help those other programs, as my colleague from the World Bank mentioned earlier.

To avoid this perception of donor imposition, I think the only solution, as in the other case, is a dialogue, is give and take on both sides, and it does take time.

I can say in the case of Zaire, I haven't, in the AIDS program, interestingly enough, run into that reaction in such an overt fashion. There has been quite an open dialogue, and I think it's because WHO, from the start, consulted, talked to them. But, it is important. That programs, they feel responsible for these programs from the very start, that these are not donor imposed programs, but they have a say, that they do really run these programs. Thank you.

CHAIRMAN WALSH: Ms. Hamilton?

MS. HAMILTON: I would like to emphasize something that Mr. Doss said. I think that the solution to this problem, and the only solution to the problem when you've got an outsider/insider distinction, is time, time for discussion.

It's much easier, we find, in countries where we have a continuing relationship in the health sector. Then discussion of any component, an AIDS component, or a malaria component, or anything else, fits nicely into established relationships and into an increasingly shared view of the problems and the solutions.

We learn from the countries and the countries learn from us. It's a very mutual process. So, yes, it is a problem at the beginning, but it gets to be less and less of a problem as time goes on and the dialogue continues.

CHAIRMAN WALSH: I could even add to that from my own experience, and even going back to the days of Point 4 and so on, when we were just starting aid. It was tradition for a countries' health ministers to say, well, what are you giving for this year. And, whatever you are giving for, we need it, and we'll abide by any rules you have because we are so desperate in our need, which emphasizes what you have said. When the AIDS program opens up,any assistance program opens up, it's the long-term relationship that develops from it that makes it work.

And, I think anyone who has been in development, either on the granting or receiving side, knows that. I mean, you are sensitive to that, and they watch it. They do watch it.

DR. OVER: I have a comment.

CHAIRMAN WALSH: Mead?

DR. OVER: Could I just add more comment here? I think it's important to remember that AIDS is new, and because it is new it enters a situation where interest groups have been established, both in the donor agencies and in the developing countries.

All of a sudden, a new niche must be created. In the creation of this niche some people will be hurt by a reallocation of priorities. Some people who will be helped. In the donor agencies, in the donor governments, and in all the affected countries of the world it will take a while for that process to work its way through.

Dr. Mann refers to this three-stage procedure of denial, minimization and finally of constructive work with the problem. And, I think we're talking about that process while we are discussing this topic.

CHAIRMAN WALSH: Go ahead.

MRS. GEBBIE: Well, a somewhat related question. We heard a little bit from Dr. Mann, this morning about the attempts to coordinate evaluation of these programs to avoid being burdensome.

What we didn't hear was the composition, perhaps, of the evaluation team. We often encounter, those of us who grant money within this country even, to ethnically diverse communities allegations of bias in evaluation, because the team that comes in may not include an adequate representation of the ethnic group being served. And so, we've had in more recent years to learn a great deal about inclusion of served populations on evaluation teams in order to avoid bias.

To what extent is that an issue in evaluating programs such as you support, and if it is an issue or it's becoming an issue, to what extent are you able to deal with it, and how?

MS. HAMILTON: Again, I'll take a quick stab.

That's valuable advice, and I think we should bear it in mind and learn from that kind of experience in all of our activities. In the case of evaluation of AIDS in particular, it's an unusual type of issue because we are all so much on a learning curve. It's not a grading episode. It's not a judgmental process. We must make a special effort to see what we can learn from different applications in different countries.

But, in my experience, the problem it doesn't come up so much in AIDS -- specific matters, where we are all wide open to learning whatever we can learn about what works, and don't blame anybody for what doesn't work. That's part of the learning process. But, it certainly is valuable advice for almost everything else.

CHAIRMAN WALSH: Anything else, Commissioner Gebbie?

MRS. GEBBIE: No.

CHAIRMAN WALSH: Okay, next?

DR. PRIMM: Yes. I had a question concerning also Dr. Jones' testimony earlier. Mr. Over, you were on that panel with Dr. Jones, if you recall. And, what I think Ms. Gebbie was trying to get at was the infrastructure of these nations that you are helping, with your, "soft loan" window, what are you doing to construct that infrastructure so that they can take whatever help that they get and use it effectively? Because, the way I got it this morning, from Dr. Jones, is that even the malaria, and the

sickle-cell anemia that oft times accompanies it, is not handled properly. They don't have the wherewithal even to do that.

Injection equipment is used over and over again, because they don't have the means for sterilization. He said that oft times there is no electricity. What are we doing to do something about the infrastructure of these nations so that they can accept what the World Health Organization brings, what you bring from your "soft loan" window to them to rebuild that, so that their health system can have a structure that can be built upon?

MS. HAMILTON: We're doing everything we know how. But, of course it is an extremely slow, time-consuming and difficult process. In the case of World Bank loans, almost every single loan we make in this sector involves institution building. Under the heading of institution building, we include technical assistance in how to do these things, equipping offices, providing vehicles to get around to the field stations, of training of staff and training of trainers to train the future staff. But these contributions are only drops in a bucket. It is slow. It is time-consuming. It is really the building of human capital.

As Mr. Doss pointed out there is also, an overwhelming need for recurrent cost financing. Once you build the building, or buy the vehicles, you then need the resources to put fuel in the cars, to turn the electricity on.

We also, of course, in the World Bank, finance a lot of infrastructure loans for, power, road, water supply and similar investment, but there are difficult trade offs. We do what we can, but it is slow and difficult!

DR. PRIMM: Well, it has been said to me that in Uganda and other countries, that there is really no infrastructure period, and that if you go in there to do anything it's so very difficult.

And, I have seen some results of some of the World Health Organization's work in Uganda at the London summit conference, where I thought that they had produced some excellent prevention and education materials. And, I was rather shocked when I heard that they had really nothing to do anything with there, and so disorganized that what will result from them being hit by this epidemic is going to be catastrophic, and that if we thought the Ethiopian famine was a serious occasion in Africa, that was a picnic compared to what's going to happen in countries like Uganda.

So, I'm concerned, and I'm happy that you all sort of allay some of my concern, which means that Dr. Jones' testimony

this morning, I'm to assume that it was probably erroneous. Is that the conclusion?

MS. HAMILTON: No, I wouldn't say that he was wrong.

DR. PRIMM: What should I assume? What should we take away from here? He was adamant.

CHAIRMAN WALSH: Mr. Doss, do you want to take that?

MR. DOSS: Yes. I would like not to allay Dr. Primm's fears. In fact, the truth is that, of course, the infrastructure is deteriorating in all of these countries in Central Africa. With the impact of the present economic situation, we'll be hard pressed to stay where we are.

We are running to stand still, and we're really running backwards. So, international assistance has to not only do AIDS, but it has to do the things that will make AIDS programs feasible. We have to somehow prevent this deterioration.

Even to do that will require a lot of resources, and I don't think we can be too optimistic. I think we really are, as they say in French, -- try to save what you can. I'm sorry to be so pessimistic, but I think you have to be realistic also about what we can do in the next few years.

DR. PRIMM: But, I think that is somewhat the attitude toward Africa, and that's my concern, and not that that's a bad one. I mean, you do the best you can with what you've got, I understand that. But, I see that attitude as being pervasive, and that we don't really do everything that we can. I think we could do a hell of a lot more.

I've been told by African physicians, both infectious disease physicians and pathologists from Zaire especially, that unless they got disposable needles and syringes, and unless they got just a simple ELISA test, and the Western Blot to test their blood supply, that the problems would be devastating to the population, and that we could, in the United States, just supply that. That would be enough for them. I've heard that, directly from them.

MR. DOSS: I wouldn't wish to get into a debate on this, but I think it's not enough, frankly. Supply the doctors, if you will, with their supplies, but if they don't get paid properly, if they don't have gas for their cars, what are they going to do with them?

DR. PRIMM: Exactly.

MR. DOSS: This is what I'm saying, that the AIDS programs in Africa are very important. It's a vital program, but you can't divorce it, as Dr. Hamilton was saying, you can't divorce it from the overall deterioration of the health infrastructure in these countries.

DR. PRIMM: So, what we need then is a social earthquake in those nations to bring about a change that will affect this problem, so that we can have a more positive outcome, and that's what I gleaned from what you have said today.

MS. HAMILTON: If I may say so, Dr. Primm, you've described the situation in Uganda very well. And in a very real sense AIDS is the social earthquake. It's another one of those cases that Dr. Walsh described, where there are some positive benefits from this scourge. The collapse of the Ugandan health infrastructure has been apparent to observers for a long time. It is the overlay of the AIDS epidemic there that has finally gotten enough attention paid to the problem that we are, in effect, now discussing an AIDS project that involves no investment in AIDS in Uganda. But in a sense, it is the ultimate AIDS project, because it will begin to rebuild the health infrastructure of the country.

DR. PRIMM: Thank you very much.

CHAIRMAN WALSH: Dr. Lee?

DR. LEE: Part of our success with our interim report was that we tried to put a price tag on a lot of the things that we did. Whether we were right or wrong remains to be seen. We probably underestimated everything.

But, let me be educated by you bankers on a few facts before I get to my final point. First of all, what really is the mandate of the World Bank and who gave it to the World Bank?

MS. HAMILTON: The mandate was given at the Bretton Woods Conference in 1945, by a group of finance ministers. It started out post-war essentially, as the "R"-reconstruction-in its name implied. Post-war reconstruction was the important part, development was secondary.

DR. LEE: And, what did the Bretton Woods Conference charge you with?

MS. HAMILTON: To finance, through loans, for projects, essentially, the reconstruction of Europe and the development of other countries.

DR. LEE: So, the UNDP and the World Bank have very parallel purposes, is that correct?

MR. ROTHERMEL: In a sense, yes and no. Yes, we're both interested in development. The UNDP is a creation of the United Nations General Assembly, rather than the Bretton Woods organizations. And, secondly, we are in the grant business rather than lending.

DR. LEE: You are in the grant business.

MR. ROTHERMEL: Yes, sir.

DR. LEE: Well, that brings me into my second question. The World Bank has lent some money to Burundi, $2 million for health care for mothers. In the history of the World Bank, what percentage of those loans are paid back?

MS. HAMILTON: So far, virtually all.

DR. LEE: No kidding.

MS. HAMILTON: Yes. Now, I'm sorry to say, that magnificent record is beginning to fray a little bit around the edges with the debt crisis that is affecting so many countries. But, up until now, the Bank really has been an effective preferred creditor, even when a country defaulted on other loans, it paid back the World Bank because of its influence --

DR. LEE: Prestige, yes.

MS. HAMILTON: -- in the international donor community.

DR. LEE: Could I just ask one other question to get my facts straight? How does USAID relate to the World Bank? You have, again, very parallel purposes, don't you?

MS. HAMILTON: Yes.

DR. LEE: It's just funded a little differently.

MS. HAMILTON: It does involve different funding as a bilateral agency. Virtually all developed countries have their own bilateral aid agencies.

DR. LEE: Now, another thing that you said surprised me very, very much. I thought the funds that the World Bank used were donated by the various countries, but you said most of the funds are borrowed.

MS. HAMILTON: Yes.

DR. LEE: Now, you are borrowing these funds from whom?

MS. HAMILTON: Capital markets. We issue bonds in capital markets.

DR. LEE: All the capital markets.

MS. HAMILTON: Yes.

DR. LEE: And, you are paying more than 7.73 percent for those funds, aren't you?

MS. HAMILTON: Yes.

DR. LEE: So, you just keep rolling over the difference.

MS. HAMILTON: We have a large paid-in capital base, dating from 1945. That goes a long way to reduce the average cost of our funds. At the beginning, we got a large injection of paid-in capital at zero cost.

DR. LEE: I see.

MS. HAMILTON: So that, if you average that together with what we are borrowing at 7 and 8 percent, you --

DR. LEE: All right, but you are running down, aren't you?

MS. HAMILTON: That will happen, yes.

DR. LEE: It is not happening now.

MS. HAMILTON: The interest rate goes both up and down. It's fixed every six months. It is .5 percent above --

DR. LEE: But, I mean, your capital.

MS. HAMILTON: No, the interest rate that we charge covers the full cost of our capital plus our operating cost.

DR. LEE: I know your interest rate varies, but have you been able to maintain your capital?

MS. HAMILTON: Yes. Secretary Baker is testifying regularly before the Congress and he is seeking a capital increase now, a general capital increase. We have had two or three capital increases in the life of the institution.

DR. LEE: Okay. Now, in USAID and the UNDP and the World Bank, in the final analysis, what percentage of your money comes directly from the United States taxpayer? Can that be sorted out?

MS. HAMILTON: Well, USAID's all does.

DR. LEE: All.

MS. HAMILTON: Yes, by definition.

DR. LEE: And, UNDP, we'll let Mr. Rothermel --

MR. ROTHERMEL: About 10 percent of our income is from the United States government.

DR. LEE: And, the other 90 percent?

MR. ROTHERMEL: Yes. It comes principally from other industrialized countries, although, almost all developing countries make some token contribution.

DR. LEE: So, Nancy Kassebaum can't get at you. I mean, it seems like it is a very fair distribution.

MR. ROTHERMEL: On a per capita basis, it is very small, indeed, the contribution from the United States, in comparison to, say, the Scandinavian countries.

DR. LEE: Well, that's very fair. Now, how about the World Bank? In the final analysis, what is -- can you come up with it?

MS. HAMILTON: IDA constitutes about 25 percent of our total lending. Of that 25 percent, the U.S. contributes about 25 percent. We borrows the rest, the IBRD funds are borrowed in the world capital markets.

DR. LEE: So, we can say your organizations really are doing God's work here, and not depending on the United States taxpayer for a hell of a lot of it. Okay. That's what I --

MS. HAMILTON: That's true.

DR. LEE: Thank you very much.

CHAIRMAN WALSH: Well, again, I thank this panel. You were stimulating and informative, and I think also, again, from my own standpoint, the increased importance and emphasis that you are placing upon health warms my heart very much.

And, secondly, I think the realistic point of view that you have taken on infrastructure, and I think that Dr. Primm's concerns as he expressed them were, perhaps, maybe he was a little bit misled by the intensity of Dr. Jones' testimony, because I think to me it was apparent, and I think you should be encouraged, Benny, that each of these institutions, and the World Health Organization, have placed absolutely, to my mind, predominant emphasis on the necessity for developing infrastructure, and also for remembering that AIDS is only one problem.

And, I have heard at many international meetings the concerns of the Third World countries, which you both expressed so well, that they hope AIDS and the interest in AIDS does not submerge the rest of their health care systems to the exclusion of everything else.

And, I know that the World Health Organization is not letting that happen, despite the fact that they have the responsibility with AIDS, and I am so delighted to hear each of you speak along the same line, because that's the only answer in the long run, because we hope that AIDS will come and AIDS will go, but the problems are going to stay unless we build that infrastructure. And, I'm just delighted to hear your views on that.

Thank you all very much, and we look forward to seeing you all and hearing from you again. Please, don't hesitate to write us any suggestions or ideas, because we have a charge to recommend policy to the President, and we depend on those of you who are involved in this to give us guidance and input so that we give him good advice. So, thank you very much.

MR. ROTHERMEL: Thank you.

MR. DOSS: Thank you.

THE FOOD AND DRUG ADMINISTRATION:

RESPONSE TO THE PANDEMIC

CHAIRMAN WALSH: Our next speaker is an old friend, and has appeared before this Commission before. Frank Young, the Commissioner of the Food and Drug Administration, today is appearing with a few friends, in his role, however, as a member of the Executive Board of the World Health Organization. So, if any of the Commissioners want to talk to him about treatment INDs and so on, please, reserve that for a later time. If anyone wants to discuss with him the price of pharmaceuticals, or the

cost of research, please defer that to another time, because we already had that show in New York, Frank.

So, I hope that you will stress your role as a member of the Executive Board of WHO, and how you feel this international war on AIDS is going. Thank you very much for taking the time to be with us again.

DR. YOUNG: Thank you very much. I'll introduce the individuals that are with me. On my far right is Dr. Paul Parkman, who coordinates FDA's activities in AIDS, and also since Biologics was recently named as an international center, I've asked him to come along. On my immediate right, is Dr. Stuart Nightingale, who runs the Office of International Health for us, and I thought that it would be helpful in the case if there were international questions there. My Deputy, John Norris, has been also active in the international activities that we have been involved in, so I brought John.

I've learned that no good FDA Commissioner goes anywhere without his general counsel, so Mr. Scarlett is there, and finally, Paul Carpenter, because we have studied the international evaluation of drugs and how the United States evaluation fits into that I've asked Paul Carpenter, who has done these studies, to be available as a resource person, because I'd like to describe how the approval and evaluation of drugs internationally are important.

I think, actually, it's more than symbolic that we are in a hall, in which sitting behind you are a number of flags from the Americas, only one of which is the United States of America. And, if I were to pick any theme that would be important for my testimony, it is the crucial aspect of networking of information as we deal with this. As you focused on the infrastructure in the last testimony, the absolute need for it, I believe it was Dr. Conway-Welch who asked, what are some specific recommendations for the report, some things that you might like to consider in regards to the international question. So, I will, in my five minutes, assume that you've asked me that as well.

If you look at what I would like to say, in addition to introducing my entire testimony, is that there are three themes that I would like to interweave. First, I am particularly pleased to have had the honor and privilege of representing the United States on the Executive Committee of the World Health Organization, and, therefore, on the Program Committee. And, as some of you may know, I was particularly insistent to try to have WHO raise this issue, and I was pleased than in the Program committee it was brought forth, we were able to get it included amongst infectious diseases. Jonathan Mann has done a stellar

job in developing and arguing for this program, and from that time forward I've had the privilege of working with him.

The United States has insisted that this topic be put on the agenda of the World Health Organization, because in almost a 50-year celebration of Orson Welles, War of the Worlds, this, in a sense, is a war of the worlds between an infectious agent and mankind.

In few instances have we had an organism that has been so widespread throughout the world, and which has such a high degree of mortality, and a high potential for disrupting social patterns throughout the world.

The second theme that I would like to weave in is networking in the diagnosis, the prevention and the cure of this disease. Up to this time, a large amount of effort has been expended, as Jonathan Mann rightfully focused, on the prevention of the disease. He has, in his testimony, which I had the opportunity to review, focused on the need to prevent additional people from being infected, but he also recognized that those people that are seen today with the disease were infected a long time ago. And, we cannot abandon them or others along the way.

In my mind, this networking requires a number of things, to try to answer Dr. Conway-Welch's question. The first is the rapid spread of information throughout the world, and if I were to answer your question, Dr. Conway-Welch, and add, what could be done in addition, it would be the development of an electronic bulletin board that would enable us to have rapid access throughout the world. We are very pleased that we have been able to use an electronic bulletin board in FDA and ITT Dialcom, and just one nation to date has recently come on that. We feel that an electronic network that would enable a rapid access amongst nations would gain in a very substantially hastened spread of information.

In addition to that, though there are biannual meetings of the regulatory agencies around the world, and an annual meeting of individuals dealing with AIDS research, there is no dedicated meeting to bringing the nations of the world together, those particular 11 nations which I will cite on Dr. Coppinger's study, that would enable the regulatory agencies of the world to look at this.

Let me give you an idea of what I mean. Dr. Coppinger has studied, for the past 14 years, 11 developed nations, U.K., U.S., Switzerland, France, Germany, et cetera, and looked at how drugs were introduced upon approval of one country into these. The vast majority of these drugs stay within one or two countries.

Interesting, those drugs that are developed in the United States, spread more than any other nation to the 11 nations that we studied.

It is also interesting to note that six and a half months after the time of approval of AZT in the first nation in the world, nine of the 11 nations had approved it, and about one year after that 47 countries around the world. This is an unparalleled penetration. But, resources are involved in the approval of these drugs in the evaluation, and possibly with an electronic bulletin board, and possibly with a way of getting information spread amongst these regulatory agencies there might be more harmonization.

We do not have all of the information on clinical trials done in other nations. That also could be put, obviously, respecting confidentiality, on such an electronic bulletin board.

I am not suggesting at this point in this information network that a particular organization take the responsibility for this. This is very sensitive. There is an organization at WHO under Dr. Dunn, John Dunn, who coordinates the information on regular drugs. I don't know whether this other information should be under the coordination of one of the 11 nations that are involved in drug evaluation, or whether it should be in WHO. But, I think someone should take the lead as a repository of information, and we at least, and I have asked Dr. Nightingale to enlarge what we do on a quarterly basis of reporting to the 11 nations, and to enlarge what we do with our tripartite, Canada, the U.K. and ourselves, where we send things by fax around the world, to do this to the other nations on AIDS.

But, there is a defect in that. We get nothing back necessarily. There is not an organized system that has an efficient loop, so while we can send information out, I think this is something, Dr. Conway-Welch, that could be raised as an additional thing to do.

I would also urge very strongly the focus on infrastructure. This has been something in the building of a national need, both in the countries in Africa and elsewhere, that is absolutely key. Why do I say that? The United States, through its ability to deal with licensure, investigational drugs, including the treatment IND, and the export recently in the Waxman-Hatch bill has capacities to exchange the use of drugs and devices very rapidly. Example, the licensure is the classical way. The second, and very important, is the ability through the investigational new drug, or the investigational new device, to get devices and drugs and diagnostic kits spread throughout the world.

So, you will see in my testimony that 50,000 test kits

were sent under an IND to Zaire. To the best of my knowledge, this is the largest IND that we have ever approved and approved for a single country, but this test has the ability to be done rapidly, and inexpensively, but it has not been evaluated yet within the United States. So, those aspects do exist.

We need to have a better information loop on this infrastructure, though, as to how, when we send materials to other nations, how that gets out. It would be a shame to send 50,000 diagnostic kits out and have them used improperly, not get to the right spot, or give misleading results. One of the concerns that we have in any test kit is the validation of these results to know whether it will work. So, we need to have input back on that.

In the infrastructure area, as another suggestion to the question Dr. Conway-Welch asked me, of course, is the issue of how to get unapproved drugs submitted out to other countries. The Hatch-Waxman law that I cited provided the export to 21 countries in the developed world, thus, excluding all of Africa, South America and most of Asia.

For your consideration would be a number of ways of fixing that. One might be a simple rider on a law that would enable, for AIDS only, the export of unapproved drugs.

For devices, it's relatively easy. The diagnostic tests we made, Mr. Scarlett is looking at this, which is why I have him with me, called Diagnostic Test Devices. If we call them Diagnostic Test Devices, then we are able, through the Investigational Device Exemption, to ship those broadly. We are not sure legally whether we can do that.

But, certainly, save the IND route, we have no way to deal with this in a widespread shipment to developing nations. I would not personally like to advocate a widespread shipment of unapproved drugs throughout the world to developing nations. And, in my testimony before Congress, I urged that there be some way of restricting that. But, in the case of AIDS, I would submit that restriction may not be as sensible.

I would also, since we do hope to be able to conquer this disease some day, if I were asked how this should be designed, I'd put a sunset on it which could be renewable, so that there is not a flooding and exploitation of Third World countries by, as yet, unapproved drugs. I would think, finally, that we have only begun in the United States to fulfill our international mission. I'm delighted that Dr. Windom will be speaking in general tomorrow on the PHS role, but we do stand one flag among many.

Fortunately, I believe that the research intense

companies that are within the United States and other multinationals are going to be the hope for these medicinals that will be forthcoming.

And, thus, the organization and coordination of this research will require the three ingredients that I mentioned: the networking, the harmonization of evaluation and approvals. I did not emphasize as much as I should the concern of how we will develop the trials, that's an important subnote, and I'll save that for questions if you are interested.

And then, finally, the most critical issue of infrastructure, and the way in which we can coordinate the rapid dissemination of information and be sure that when drugs and devices are brought forward to developing nations that they are not squandered by the absence of an infrastructure, both in its evaluation, its distribution and its utilization.

Dr. Walsh, I thank you for the privilege of coming here today, and I'd be delighted to answer any questions that I can, and I hope that the United States will fulfill its commitment in an appropriate role in leadership in this, not only supporting WHO, but also conducting its research and making approved therapies and unapproved therapies appropriately available as rapidly and expeditiously as possible. Thank you.

CHAIRMAN WALSH: Thank you, Frank. Dr. Young, and your staff, we hope that the FDA is still functioning while you are all here.

DR. YOUNG: We know that we are all biodegradable and we have backups.

CHAIRMAN WALSH: Sure. But, we are delighted that you are all here, because there is really nothing more important for us than to be able to pick the brains of those of you who are able to give it to us. So, we're going to start now with you, Cory. It's your turn.

DR. SerVAAS: Well, thank you. I'll ask the question you proposed. How will you develop the trials?

DR. YOUNG: One of the things that we have been working on very extensively is, under Dr. Windom's leadership to determine whether or not there can be some systematic way that we can interface with WHO on populations throughout the world, both domestically and in other countries, that would enable us to get the answers.

One of the critical factors that we have realized now is that the trial has to be conducted in a very disciplined fashion. We have had a little experience in the past, whereby

not following -- and I'm not talking about placebo control or other types of control, but controls with questions in mind, we can sometimes waste time. So, we would like to work either in

collaboration with WHO, which has been making countries available as test sites, a way to function, or develop ways in which we can coordinate them throughout the world.

Now, we have been looking at a number of these, Zimbabwe is one, Zaire is an other. But, I would add one point that I've been encouraged about. I'm detecting an increasing interest in the countries that are looking to sponsor trials to also give the country in which the trial is going on something that country believes is important. It is not fair to intellectually rape and pillage. In that sense, one of the things that I've been pleased with is that as sponsoring countries have been exploring this they've been asking, can we make it possible, to have resources available for things such as blood testing. There is a lot of concern about that. Where are the countries going to get the resources for that?

Impact on infrastructure, I would foresee collaborative experiences where the country that is having its population donated in part for clinical trials, could also receive some help in their priorities. I would focus, their priorities. The one that I see the most that nations have talked to me about is diagnostic testing and screening. There the concern is, as in the United States, how do you know the tests really are valid, and how do you know that it's done right? So, that's the area that I would see added to. The infrastructure is the other point.

DR. SerVAAS: Thank you.

DR. LEE: Dr. Young, a guy who sits with his lawyer that close to him looks like a guilty man to me.

DR. YOUNG: It's a custom.

DR. LEE: It's a custom?

DR. YOUNG: It's a custom. I was told a few things upon coming into FDA, really two. The first one was, "Commissioner, we want you to know that no one in FDA ever got an award for doing something. The only award was given for not doing something." And, the second thing was, "Commissioner, we want you to know that we trust you, we honor your judgment, but you don't go anywhere without your lawyer, because the law is something that is important in the Food, Drug and Cosmetic Act, and it's a big arcane, and you might not understand it." They are right on both counts.

DR. LEE: Well, we're safe. We have no lawyers on this panel here at the moment. What hat are you wearing today? Are you wearing the FDA hat or the WHO hat, or both?

DR. YOUNG: Since I am not cloned, and there is only one copy, I would have to say that I'm here for you with my WHO/international hat, but that's where FDA is involved extensively. Since we have the responsibility for $570 billion worth of commerce in the United States, and bilateral agreements with other nations, I would be here in both the international and the FDA hat, a single hat.

DR. LEE: Now, maybe the gentleman second from the right is the man who is involved with international drug development, what was that again?

DR. YOUNG: Paul Coppinger, on my far left, is the person who did the study on the 11 nations, and the approval rates there. On my immediate right is my associate Commissioner for Health Affairs, who has the International Office.

DR. LEE: Could I get into a thing that bothers us consistently?

DR. YOUNG: Of course.

DR. LEE: And, that is, drug trials and vaccine trials in other countries. I tend to think America is being somewhat arrogant when it takes the position that, if you are not doing it up to our standards, you are making a mistake.

But, on the other hand, how does the World Health Organization approach the ethics of this particular problem? The vaccines are so hot, we have heard, that the companies here, because of the tort process, don't want to get involved. They ship them off to European companies. They transfer the problem outside of the borders of this country, so they do not have the liability that comes with it. But, how do you handle, on a world basis now, the ethics of these various drug and vaccine trials that liability-wise we don't seem to be able to do in this country?

DR. YOUNG: Let me answer your question by answering three points. First, the United States, with its, what is called the NDA Rewrite, the new drug application rewrite of its regulations, fully accepts all foreign data. And, in regards to the human rights, we rely on the Helsinki Agreement that describes, when there are not biosafety committees in other parts of the world as there are in the United States, the basic fundamental human rights and the informed consent that is involved.

Now, we monitor that to be sure that, to the best of my knowledge, the Helsinki Agreements are followed, but we don't have the authority to reach in and deal directly. Now, in regards to the ethical standards of countries, I have been impressed with the novelty and ingenuity of the lawyers in our country in dealing with other countries' citizens that were adversely impacted.

DR. LEE: You mean to say, they're getting -- the cancer is spreading?

DR. YOUNG: You noticed the large number of U.S. lawyers that flew to India?

DR. LEE: Yes, I did.

DR. YOUNG: That's right, I noticed very few flew to Chernobyl.

DR. LEE: Yes.

DR. YOUNG: That might say something in regards to societies. I watched that very carefully, and did not see any New York lawyer go to the Soviet Union to deal with that particular accident. But, I think our ingenuity in legal aspects might see that happen. I'm very serious when I say that I think the tort law, though not directly applicable, could be seen, because the bell tolls around the world on this. I think that there will be very little skulduggery permitted, because the punitive risks are so high.

Now, in regards to the vaccine, though I know I've taken some criticism by allowing FDA to approve testing for safety of two vaccines without an animal model, those tests are going on in the United States. It should also be said for the record that in excess of 50 percent of the clinical trials occur throughout the United States, and the rest, about 50 percent around the world.

One of the problems in our doing clinical trials, in my opinion, is from the time that you and I went to medical school there has been an erosion of the great clinical trial centers in the United States. There are very few centers, and, certainly, very few deans, I can attest, that give tenure for doing clinical trials. And, we have seen an erosion of the capability. I think this and other events to, particularly, biotechnology, will bring back some clinical trials into the United States.

The cost is a factor. I do not think it is merely just a human subject, and since now we can accept foreign data under the Helsinki Agreement, I think we can guarantee human rights.

Now, I've given you a longer answer, but your question was so important that I wanted to cover it.

DR. LEE: Does your staff agree with you, or do they dare disagree with you?

DR. YOUNG: They dare disagree with me on many occasions. Stu, you deal with the institutional biosafety. Can you comment on the Helsinki Agreement?

DR. NIGHTINGALE: I think, indeed, it's true in terms of the ethical criteria that are used worldwide, the Declaration of Helsinki is available. If something is done under an IND in this country, it has to meet the standards to be acceptable to us.

I think, again, Dr. Mann might be able to better address this, but I believe that all studies that WHO is involved in have to be reviewed by their own IRB institution or review board. I think the infrastructure for the ethical issues is there.

DR. YOUNG: Paul, would you like to comment, if you could, on any of the 11 nations? Do they have comparable IRB equivalents to our's that you know of?

DR. COPPINGER: No further information.

DR. LEE: But, as far as you are concerned then, this Commission should not be particularly worried about these ethical problems of testing these materials in other countries?

DR. YOUNG: If you were to relax, I would be worried. I think that we have to focus on the ethical issues, but to the best of my knowledge the systems are in place to address it.

But, I think under no circumstance can we slumber on this, because there should not be, as I said earlier, the experimental raping and pillaging of sub-populations. John, did you want to add something?

MR. NORRIS: Yes. I might just add one more point to that. We're concerned enough about the ethical issues to have had just about five weeks ago Professor William Curran, who is the Frances Lee Glesner, Professor of Law and Medicine from Harvard University, come to FDA and talk to us about ethical issues involved in clinical trials.

It's an issue that we are currently very concerned about and looking at on an ongoing basis to make sure that we're approaching it properly. One last comment also I would add is, we don't want to mislead you at all. We are willing to receive

foreign data, and we're willing to give it its due weight, whatever that might be. In some cases, the foreign data may be perfectly acceptable in every way and helpful, and in other cases it may be not terribly helpful.

DR. YOUNG: I would also add that Dr. Windom, in the task force, has got the authority and is working together with CDC, NIH and FDA to look at ways in which trials will be conducted in other parts of the world, and you might like to also ask him that question tomorrow. But, I've been very pleased that he has been focusing on that issue.

DR. LEE: Thank you.

CHAIRMAN WALSH: Did Colleen leave? We lost our flanker. She had to catch a plane, I'm afraid.

DR. YOUNG: Well, I'm glad I answered what I thought she might ask --

CHAIRMAN WALSH: That's right.

DR. YOUNG: -- listening to the last panel.

CHAIRMAN WALSH: Okay.

Dr. Lilly?

DR. LILLY: She actually left the question with me to ask you.

DR. YOUNG: Wonderful.

DR. LILLY: I'm going to postpone it, because I think it fits a little bit later in some of the questions that I wanted to ask. My first is a very fundamental question. What is the philosophy behind our willingness to export drugs to other countries that we wouldn't use?

DR. YOUNG: There are a number of drugs that are being developed primarily for tropical and infectious diseases, and others that are not applicable in the United States. The best example is one that was given away by Merck, Ivamectin, for river blindness. To the best of my knowledge, we have no river blindness in the United States, other than those people that would come in with that disease. And, for them to go through the evaluation, approval and development for the use of this drug, which was then given away subsequently, would be inappropriate.

Right now, we are working on a malaria vaccine. The malaria vaccine, through biotechnology, and one for schistosomiasis, will, if effective, be very important for parts

of the world, but that's not going to be important for the United States.

And, in view of the laborious task of bringing this through that was thought to be important. Now, the second big bucket on this is the drug that might be requested while it is under development in another nation, and yet to be --

DR. LILLY: Requested by whom?

DR. YOUNG: By the authority, the regulatory authority in the other developed nations. So, the way the bill works is, if a regulatory agency in another nation requests it, we would evaluate that request and determine, based on our information of that drug, whether it is appropriate to ship it elsewhere. So that, it respects the other regulatory agencies and their capability in dealing with it.

MR. NORRIS: I would only add one more point, and, that is, also, as in the case with the IND where we authorized a shipment of some 50,000 tests to Zaire, the question of infrastructure comes up again. What would be helpful, very helpful, and those tests apparently have -- there is an indication that they have been helpful -- because of the lack of infrastructure, tests that would work well in the United States aren't really usable in a country like Zaire. On the other hand, because of the high infrastructure in the United States, the tests that were shipped wouldn't necessarily be very helpful to the United States. So, you have to look at the market, you have to look at the infrastructure that's there, the ability to actually use something and make a difference in that country.

CHAIRMAN WALSH: I think Frank, in Ivamectin, too, I think WHO field tested Ivamectin for about three or four years --

DR. YOUNG: I believe so.

CHAIRMAN WALSH: -- and, did toxicity studies and so on, before the gift was made.

DR. YOUNG: That's right, and it's also been approved for a long time for heartworms for dogs.

CHAIRMAN WALSH: Exactly.

DR. YOUNG: But all the experimental evaluation was there, and clinical trials were done. It was just not sought for approval in the United States.

MRS. GEBBIE: This is a factual question to clarify something before you go on this. You talked about this relationship being dependent on your work with the regulatory

body in other countries. Do all other countries universally have a body to deal with drugs, or are there, in fact, some countries where that question becomes irrelevant, the drugs can just be dumped or marketed?

DR. YOUNG: Yes. That's the way the law was written, so that 21 that were selected are countries that are analogous to the U.S. in their regulatory schemata. They are not the countries which would not have regulatory organizations, and they were specifically chosen by Congress to take those nations that are equivalent to the United States.

That's a very important question. It would be bad if that were not the case. Excuse me, if I could, Mrs. Gebbie, that's why I asked that you might want to consider an exemption in AIDS for other countries that might want to request a drug for treatment that is not yet approved in the United States. Because, as it exists now, we could ship to the 21 and it would be illegal for trans-shipment to go from here to Africa. That's against the law, and thus, we are barred, if we had a drug that was coming down, and under an evaluation, for example, of a treatment IND, though we might subsume it under the IND and have to go through the request of an IND, and the evaluation of the physicians and such which we could use as a loophole, save that, we could not ship a drug just prior to approval in the United States to any of the developing countries, and that's something that I wanted to point out for Dr. Conway-Welch.

CHAIRMAN WALSH: Frank?

DR. LILLY: Yes. Then her question goes on from that. Given the fact that there is a mechanism for exporting AIDS-related drugs to other countries prior to full FDA approval, she wants to know is there a mechanism for the United States to receive similar, not yet approved AIDS drugs for use in our citizens with AIDS?

DR. YOUNG: No. There is not such a mechanism in that way at all. One of the problems that we have in our law is that we must, by our law, state that the drug is not only safe, but also effective. So that, in that case we could ask for it to be sent out, but we couldn't receive it, with a few caveats. At the time that HPA-23, as a crisis arose, we were able to get some of the interaction between the Institute of Pasteur and bring it in as an investigational new drug, and as you know, as soon as it was studied for any significant period of time, it was found out that in that particular country, and in the countries that had studied it before, there was not any toxicity data done, and it was found to be a hepatotoxic drug of a significant magnitude, and thus, there are not too many active studies on HPA-23 today.

As a footnote to her question, probably for better or worse, the United States Congress has made laws that are more stringent than any other part of the world, and thus, we could bring it on investigational new drug, but the drugs that are not approved in the United States would be mis-branded.

We have, though, taken a course that I've advocated, I know I've been criticized in some quarters for it, that individuals who wanted to bring in a drug from another country for their own use, or went to another country and obtained the drug for their own use, would not in any way be influenced by FDA.

However, once it gets commercialized in the country or is sent in a commercialized fashion without approval, then we would deal with the company, not the individuals. So, we've tried to adjust that way. It is not a complete solution, but I've seen so many individuals involved with drugs that have not been completely evaluated, that it's a knife-edge call, and we're stuck with our law at this time.

DR. LILLY: Under what circumstances would you consider research data obtained outside the United States?

DR. YOUNG: In all situations, we would evaluate this data with the same intensity of scrutiny that we do in the U.S., and if it was good data, we would fully accept it, and there have been a few drugs that have been approved on almost completely foreign data.

There were some situations before the NDA Rewrite, where at least one study had to be conducted in the U.S. That is no longer applicable at this time, and I think that's a good change, and I was glad to bring that one on board.

DR. LILLY: Okay. Let's see, I had one more question. Relevant to the question of international standards for evaluating drugs, are there internationally accepted standards? Would it be useful to develop them?

DR. YOUNG: No, there are not. I do not see them being useful at this point, because the cultures are so different. For example, in West Germany, the company is bonded against severe penalties in the information that they have. So that, the company is trusted and then in the event that they did something dishonorable there would be legal sanctions. That is not the culture in the United States.

DR. LILLY: But, if there were a set of international standards that company were bonded to.

DR. YOUNG: The United States, I think, as I see it today would not necessarily want to be bonded to international standards, and I know the E.C. now struggling trying to get international standards by 1992 in pharmaceuticals, and they are having a particularly difficult time.

We see even in the United States at this point, some states looking to unbond themselves on standards, and I think that it would be very hard to hold this at this particular moment. Do you want to add a point, John?

MR. NORRIS: Just along the lines that Dr. Young started off his testimony about, establishing a collaborative network for information sharing with loops in it, so that we get feedback on what is working and what's not working. So, you get the best of both worlds that way. You don't have to establish "international standards" or methods. You get the experience of other countries in this country, and learn from that what really will work. I want to make one other comment while I've got the floor.

DR. LILLY: Well, with that, I wonder could I ask, what are the barriers to getting that information into --

MR. NORRIS: Right now, there is not a successful on-line, real time way of sharing information. We need to use -- and we've begun to use already, electronic media for sharing information. We need to get feedback from other countries. We need the same kinds of information we send them, we need to have sent back to us.

DR. LILLY: And, why don't you get it?

MR. NORRIS: Well, we need to establish that infrastructure, as the term you've used, the network.

DR. YOUNG: Dr. Lilly, I think I can add some points on this that may be helpful. In the case of the three nations, Canada, U.S. and U.K., we have agreement on a tripartite basis, that we have that information.

Part of the problem has been resources in other nations as well. One of the reasons that I raised this as a potential issue is that, one nation does have to take the lead, or WHO has to take the lead, and this is going to cost some degree of funds in dealing with that.

Now, I'm not trying to advocate resource expenditures here, but you're saying that one of the problems that WHO has had in its international drug information system is there has just not been the resources to make it really move internationally as fast as possible.

And, I, for one, am very interested in seeing this information started, and would be even if it were acceptable internationally take the lead in that. But, I do think there is some sensitivities that other nations might be concerned with.

DR. LILLY: This information that you're hoping to get, is this information that you are hoping to be able to plug into your evaluation of a drug?

DR. YOUNG: Yes. These are the kinds of things that I would like to know. I would like to know, just as we put out monthly our list of drugs that are under investigation, I would love to know drugs in other nations that are under investigation.

We don't receive this in a formal fashion. We get some of this, but it is only catch as catch can. I would like to see adverse reactions, specifically, for AIDS drugs, as early as we can. Sweden has an adverse reaction system, but it has fallen, in regards to many, to disrepute. And, actually, at the last Executive Board Committee, they were trying to evaluate and did put a study forward to see whether the adverse reaction reporting system is really meeting its needs. I'd like to see that type of a situation, because we have the case, as I cited, HPA-23 counted as an important drug, only to find out that there had not been any substantial studies that dealt with toxicity.

I'd like to have a network on what animal studies have been done on toxicity, so we would know, and not make the wheel turn around each time. We would to, and Stuart has the responsibility in our organization of communicating with the other nations, but one of the things that I've asked him to do now is to develop a method, if we can't use electronic, what can we do by fax to send information out? But, I think we also ought to have some information coming in, and I would like to see those adverse reports.

Finally, I'd like to see if there were any major concerns on research, any of the compounds that were looked at to be of high interest in other countries. We do get some of this information through NIH and Tony Faucci, as a good network. But, the regulatory agencies, I think other than a research network, need to have a network of what's going on in regards to other countries, so that we can see what is likely to be a good lead as early as possible. I will just recount one of these. When A.L. 721 first came out, it came out from, a European source, it took a while to get the information on what that was based. I mean, what were the definitive studies? How much was known? It's these kinds of things that I would like to have a routine sharing in some way, so that we can electronically get this around the world as fast as we can.

DR. LILLY: Are these difficulties to any extent proprietary? Are the barriers to transmittal of this information in proprietary?

DR. YOUNG: Some of it would be proprietary, and each nation has a different law, but the dominant issue is not proprietary. The dominant issue is an exchange of just what's going on there. You do have to protect proprietary, but the regulators are used to doing that.

MR. NORRIS: It's really organizational and leadership kinds of issues, and dollars kinds of issues. But, we have a primitive information sharing network now established with some WHO member countries to share post-marketing surveillance information that's just coming on line now.

But, the system now can produce information in six months that would have taken a year before, let's say. We need to get that eventually geared up to a system that can give you real-time feedback of drug experience, post-marketing experience, and also pre-marketing experience with drugs. Information from around the world would be helpful in our deliberations, and vice versa.

CHAIRMAN WALSH: Thank you. How about you, Theresa, do you have something?

DR. CRENSHAW: Yes. This seems like another and very good example of how our concern about AIDS has become an impetus to establish systems that will help us in many other diseases and many other health care issues.

One of the questions that I'd like to ask that may be a little naive, is that in relation to exporting drugs not yet approved here, if they get an exclusion and they could go to countries that didn't have our systems, could this not create a black market for drugs? I'm particularly sensitive to that because of being in San Diego and close to the Tiajuana border, and I see what's happening already, where the net effect could be that people with HIV infection in the United States could be paying black market prices for drugs that have gone a very indirect route back to them as their emissaries or others transport them back and forth across the border. And, I know for a fact, and I personally disapprove of this that the border guards kind of wink at the HIV-related medications and allow --

DR. YOUNG: I'm responsible for that one way or another.

DR. CRENSHAW: I know, you answered part of my question a moment ago. But, could you comment on this?

DR. YOUNG: Surely. In regards to the black market concern of drugs, that is a great one. The law says that there cannot be trans-shipment, but you would have to catch the violator to show that trans-shipment has not occurred to the other developing countries.

I think it is a finite problem. The one thing that will help us the most is to get good information out as to how good or how poor a drug would be.

I was encouraged by the information that we cited in your testimony for you, that if the drug is good, like AZT, nine of the 11 countries, developed countries, have approved it in six and a half months, and 47 countries in a year. The biggest thing that we can do in the United States is get out information on drugs that are useful.

The difficulty that I see in the United States, if the Chairman will permit me to take a slight tangent, is the fact that we now are moving to public action on one study. I'll give you two non-AIDS examples. A number of ladies in the United States are using Retin A to take care of wrinkles, and Retin A was done in a study of 30 people in a placebo. I have said on television that no long-term carcinogenicity study or teratogenicity study has ever been done on that drug, and that drug is similar in makeup to Acutane, which we know gives congenital defects.

So, the danger of now using that "willy-nilly" is high. The same is true with aspirin, when you saw with a published study on 44-year old to 84-year old men, that individuals were switching to aspirin, and I had one person say, "Well, I really love my husband so much, if one aspirin is good, couldn't I have him take five?" You know, what risk is that per day?

And so, people are moving on therapies without them being studied, and I worry about that in AIDS, but again, we've got to get information out worldwide, and that's why I'd like to have a network of regulators that can really spread information back and forth on what is the validity of some of the claims in the first studies.

DR. CRENSHAW: If there were bonding of some form in place to neutralize your concern about liability within the United States, would you support or favor making unapproved drugs available in humanitarian studies? I know certain humanitarian studies are already being done, but I mean on a larger basis within the United States itself, or are there problems I haven't thought of associated with that?

DR. YOUNG: I would personally not favor them until we had some shreds of evidence of efficacy, for two reasons. The

first is, people are likely to chase, because of the desperately ill nature of the disease, I can identify with this, I've shared in another audience, I haven't shared before this Commission, but last fall I had a melanoma that was removed. Fortunately, it was a superficial melanoma. It's probability of a seven-year cure, my odds are very good, 96 percent seven-year cure. Do I feel behind my ear where this was located? Yes. Do I worry about it? Yes. Now, what if a person, instead of this prognosis, has something where they've got a good chance of dying?

DR. CRENSHAW: Sure.

DR. YOUNG: By gosh, the temptation to try anything is high. And thus, in that circumstance, I would not like to see personally a deviation away from what the treatment IND has done.

Now, we have not had a large number of drugs come forward yet on the treatment IND. I think that's a moment in time. I think we will have more. And, since the time that I believe I testified with you, we've looked back into the number of INDs, and 61 percent of the 124 INDs that are active now are in phase two, and 6 percent are in phase 3. So, we think we're going to see some substantial treatment INDs. I think we have the mechanism in place that will deal with that.

But, your question is one that's been an age-old one, should anyone that's afflicted with a disease have access to any drug, whether it be approved or not? I think that even if the liability standpoints were taken care of, that there would be such a temptation to use drugs that may be harmful, that some sort of a collation of information might be important. John, did you want to add to that?

MR. NORRIS: I just wanted to add that just a month ago in Kansas City, we held a National Conference on Health Fraud, and the temptation, the pressures to exploit these people are very great, and we've got to be very concerned about them.

Fortunately, so far, the exploitation of the AIDS patient has not been as great as we feared it would be. We've taken a number of steps to help prevent that, but the potential is very great. These people are desperately ill, and the purveyor of health fraud, who successfully purveys billions of dollars worth of fraud each year to cancer victims, and people who are suffering from other ailments, can readily exploit this population if we let them loose.

So, we've got to balance both the right of the individual and the need of the individual to access to anything that has real promise, with the protection of the individual from true exploitation when they are so desperately ill.

DR. CRENSHAW: Well, I think it's a really difficult balance to achieve, and I don't envy you your task. Thank you.

DR. YOUNG: This is a very great burden, there is no question.

CHAIRMAN WALSH: Ms. Gebbie?

MRS. GEBBIE: First, I can't help but remark with regard to your idea about an electronic network, which is an admirable goal. One, I'm a little skeptical about achieving on a worldwide basis in the short term, remembering how long it took the FDA to get onto our nationwide network connecting us to health departments, just an example, and we have a phone system that generally works. It's admirable, but I have some questions.

DR. YOUNG: It's a hard issue, but I'd like to -- I've got to get real-time sharing or fax sharing, or something.

MRS. GEBBIE: The two questions I have are a shift of gears from the drug piece, and things that I think would be nice to receive in writing, partly because of the time. We are already running late and so on.

I think we need to hear a little more about the United States agenda as a member of the Executive Committee of the World Health Organization. We are a nation that tends to run after quick fixes and shiny things, and I am concerned that AIDS can be one of those, and would like some sense of how our agenda, as a voting country, reflects those points about infrastructure that you made at the beginning, either in the form of proposals we have made, are making, or directions we are going, things we are sustaining that build that, because I do see that as critical.

DR. YOUNG: I will supply for you for the record a number of speeches that I have given, one in particular, I believe you have it, an international meeting where I focused on infrastructure.

Second, in regards to the program, at least as long as I'm there on the WHO seat, you can rest assured that I will be very vigorous, both in talking with the Secretariat, in speaking with Dr. Mann, and I believe that he is still --

MRS. GEBBIE: He went into hiding, I think.

DR. YOUNG: -- here. He went into hiding. You can ask him whether or not I have been vigorous on pounding on the international scene there, and demanding, in the best way that I can, that the United States meet its full commitments in regards to AIDS. I think that this cannot be let go.

MRS. GEBBIE: Well, I see it as much easier for us to meet our full commitments on AIDS, but slither off on commitments on that infrastructure more broadly stated, and that's the piece I want some backup on.

DR. YOUNG: Yes. I think that there's a recognition, and I will also have Stuart send you some information that we've been working with in PAHO, to try to develop experimental networks to build infrastructure. And, the one that I'm working on now actually is, we've been asked by the Chinese government, People's Republic of China, to develop their infrastructure in regards to the Food and Drug Administration, and we'll be going over there, I believe, in the fall, this September, and we are working with them on questionnaires. We have also been asked to do this in Pakistan. We have not completed that yet. We are working with Jamaica and Costa Rica in this now, and we'll send you that information.

MRS. GEBBIE: The other area that I'd like some follow-up on is really a version of the question I've asked a couple of witnesses earlier today. We are charged with making recommendations for this country. It is clear from the testimony we've had that what happens in this country has an impact other places.

DR. YOUNG: Obviously.

MRS. GEBBIE: Wearing the hat, your hat as a voting member of the WHO Executive Committee, what are the two or three things that we could recommend this country do that would make your seat on that body more comfortable, more expedient, more useful, easier -- however you would label that? What are the two or three things, from that point of view, that are most critical for us to do?

DR. YOUNG: The first is a prompt and full payment of our assessment. We are accused continuously of abrogating unilaterally treaty agreements. And, I must say that in the two years, the last two years, I have been deeply embarrassed. I would say further that failure to meet our payments has resulted in other nations being successfully able to take the leadership, even though we still pay 20 percent, and other nations pay far less than that, because all of the nations in the world say that the United States has unilaterally abrogated its treaty. What is our defense?

Our defense is that we are already paying 25 percent, that we needed some reforms, and they were appropriate reforms, and I support that. The only problem is, after the reforms came, the money didn't, and that's a difficulty.

The second thing that would be very important, and I think would help me immensely and my successors in that post, is to have some continuity. I guess that I'm one of the few people that have served out the WHO Executive Committee term for the three years that the person sits on it.

Sir John Reed served 17 consecutive years in the Executive Board. The Soviet delegate serves many consecutive years. Most of the nations in the world serve many years consecutively on the Executive Board. The United States reinvents its Executive Board membership about every year and a half, and thus, the person coming over there does not have an institutional history.

I have learned through this that you do need to build up a degree of trust. You have to be consistent. You have to be forthright and honest. In the absence of that, the first year or two that you are at the Executive Board, you are not going to be listened to, and then that changes.

The third area that I would see that's very important for the United States is for the United States to have a stronger network with other nations in a working relationship in its international health. And, in here, the role of the Surgeon General has been very helpful. He has spoken strongly about international health, and in his visibility in AIDS, that's true.

But, the United States, because of the three areas that I mentioned, has not had, in my opinion, the leadership that it should. I believe that personally we've been able to garner some good inter-relationships, but it is likely, following past pattern, that after serving a three-year term, yet again, someone else will start another three-year term, and will serve about a year and a half of it, and the next person will fill the next year and a half. I think you combine that with a lack of payments, and you have an erosion of leadership, and that's an irony for a country as great as this one is.

MRS. GEBBIE: Thank you.

DR. YOUNG: I've tried to be possibly too blunt on that.

MRS. GEBBIE: I don't mind people being blunt.

CHAIRMAN WALSH: We'll take it out of the record, Frank.

DR. YOUNG: I may have to --

MRS. GEBBIE: Leave it in.

DR. YOUNG: -- comment for the record further on that. I was more candid.

CHAIRMAN WALSH: Well, we thank you again for your candor, which you always demonstrate when you testify before us, and I want the Commission to join me in congratulating you for the award you are going to receive tonight for the work that you've done in the "orphan drug" area. It's a well-deserved recognition, and we congratulate you for it. And, with that, you and your team are excused.

DR. YOUNG: Thank you very much.

CHAIRMAN WALSH: 9:00 o'clock tomorrow morning.

(Whereupon, the meeting was adjourned at 5:52 p.m.)