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COMBATING INFECTIOUS DISEASES

HEARING
BEFORE A
SUBCOMMITTEE OF THE
COMMITTEE ON APPROPRIATIONS
UNITED STATES SENATE
ONE HUNDRED FIFTH CONGRESS
FIRST SESSION
—————
SPECIAL HEARING
—————

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COMBATING INFECTIOUS DISEASES

THURSDAY, MAY 15, 1997

U.S. SENATE,
SUBCOMMITTEE ON FOREIGN OPERATIONS,
EXPORT FINANCING, AND RELATED OPERATIONS,
COMMITTEE ON APPROPRIATIONS,
Washington, DC.

The subcommittee met at 10:41 a.m., in room SD-138, Dirksen Senate Office Building, Hon. Patrick J. Leahy presiding.
Present: Senators McConnell and Leahy.

NONDEPARTMENTAL WITNESSES

STATEMENT OF BARRY R. BLOOM, Ph.D., INVESTIGATOR, HOWARD HUGHES MEDICAL INSTITUTE, AND PROFESSOR OF MICROBIOLOGY AND IMMUNOLOGY, ALBERT EINSTEIN COLLEGE OF MEDICINE

OPENING STATEMENT OF SENATOR PATRICK J. LEAHY

Senator LEAHY. Good morning. This happens with all of us. Senator McConnell has the usual five different hearings and meetings going on at the same time and will join us in a bit.

But I do want to note my appreciation to him as the chairman of this subcommittee for scheduling this hearing. It is good to have you here, Dr. Heymann. You have come all the way here from Geneva, and we appreciate that. The fact that you have done this demonstrates the World Health Organization's recognition of the need to discuss these issues, which have been virtually ignored by the Congress.

I looked back 10 years and found one hearing that looked at the problem of infectious disease from a global perspective. That is pretty alarming when you consider the regularity of devastating epidemics throughout history, the potential threat to the health and economic well-being of millions of Americans and vast numbers of others, tens of millions more, people all over the world.

Senator McConnell has pointed out this is an economic issue, a national security issue, when you consider the threat of biological warfare and terrorism. And it is of course a humanitarian issue, and anybody who has traveled around the world and seen the devastation of some of these epidemics would know that. I have. My staff has. My wife, who is a registered nurse, sees more and more patients with infectious diseases, like tuberculosis, that she did not see 10, 15 years ago.

I also want to welcome the others who are here. Dr. Barry Bloom cochaired the 1997 institute of medicine study entitled "America's

Vital Interest in Global Health,” which was very helpful in preparing for this hearing. Dr. Gordon Douglas, who brings the perspective of the pharmaceutical industry as president of Merck Vaccines, has seen the difficulties facing us especially as more and more diseases become resistant to drugs we have used in the past.

Dr. Nils Daulaire, is from my own State of Vermont, and Dr. Don Sbarbaro. You each have a great deal of experience from your work in public health—you, Dr. Sbarbaro in tuberculosis, most recently at the University of Colorado School of Medicine; and Dr. Daulaire from 20 years in primary health care in West Africa and the Himalayas, now at the Agency for International Development [AID].

Ms. Laurie Garrett could not be here today because she is out of the country, but she is the author of the book “The Coming Plague,” which was also the subject of a recent four-part television series, that has helped spotlight the urgency of this.

You know, I remember as a child when you worried about smallpox. I remember as a child growing up in the small city of Montpelier, VT, when the swimming pool would be closed during polio scares. But we do not think of these things today. We got rid of smallpox, we got rid of polio. We thought we had eliminated all infectious diseases forever. As Laurie Garrett said:

The world was a very optimistic place on September 12, 1978, when the Nations’ representatives signed the Declaration of Alma Ata. By the year 2000 all of humanity was supposed to be immunized against most infectious diseases, basic health care was to be available to every man, woman and child regardless of economic class, race, religion, or place of birth.

But as the world approaches the millennium, it seems from the microbes’ point of view as if the entire planet, occupied by nearly 6 billion mostly impoverished people, is like the city of Rome in 5 B.C. Our tolerance of disease in any place in the world is at our peril and, while the human race battles itself, the advantage moves to the microbes’ court.

They are predators and they will be victorious if we, homo sapiens, do not learn to live in a rational world that affords the microbes few opportunities. Either that or we brace ourselves for the coming plague.

AIDS VIRUS

Mr. Chairman, that plague is already here. By the year 2000, 12 million people will be infected with the AIDS virus in India alone, 40 million people worldwide. Over 100,000 people were infected by HIV by 1980, before AIDS was even discovered, and 3 million people die every year worldwide from tuberculosis, a curable disease, and now a multi-drug-resistant form of TB poses a new, even more serious threat.

Each year there are 250 million new cases of malaria, and 2 million deaths. New drug-resistant forms are being transported around the world.

The ebola virus, if it were to spread beyond isolated areas, think what it could do. We saw recently the panic in this city when somebody sent a few overripe strawberries through the mail. Imagine what would happen if the same amount of anthrax was scattered from the top of the Washington Monument.

Over 2 million people each day cross our national borders. Since 1973 more than 30 new infectious diseases have been identified.

We need the attention of Congress. America’s pharmaceutical companies can make an enormous contribution to global health,

but they face many obstacles. We need to hear from them what can be done. We sometimes think that technology can solve any problem, but it is not that easy.

PREPARED STATEMENT

Mr. Chairman, we have lots of hearings to determine how many battleships to buy, how many aircraft carriers we need, how many wings of aircraft we need for our national security. But there are other threats that cross our borders, and everybody else's borders. Microbes do not worry about how many missiles you have aimed at them. They just go right past them.

Thank you, Mr. Chairman.

[The statement follows:]

PREPARED STATEMENT OF SENATOR PATRICK LEAHY

Mr. Chairman, thank you very much for scheduling this hearing. It deals with issues I have been very concerned about for some time, and I appreciate the interest you have shown.

I want to welcome our witnesses. Dr. Heymann, you get the prize for coming all the way from Geneva, and we appreciate that. Your being here demonstrates the World Health Organization's recognition of the need to discuss these issues, which incidentally have been virtually ignored by the Congress.

I searched back 10 years, and found only one hearing that looked at the problem of infectious diseases from a global perspective, which Senator Kassebaum held two years ago.

That is pretty alarming when you consider the regularity of devastating epidemics throughout history, and the potential threat to the health and economic well-being of millions of Americans and vast numbers of people around the world. As you have pointed out, this is an economic issue, a national security issue when you consider the threat of biological warfare and terrorism, and a humanitarian issue.

I also want to thank our other witnesses for being here. They bring a wealth of expertise, and each has made major contributions in the field of public health.

Dr. Barry Bloom co-chaired the 1997 Institute of Medicine study entitled "America's Vital Interest in Global Health."

Dr. Gordon Douglas brings the perspective of the pharmaceutical industry, as President of Merck Vaccines.

Dr. Nils Daulaire and Dr. John Sbarbaro each have a great deal of experience from their work in the field of public health—Dr. Sbarbaro on tuberculosis, most recently at the University of Colorado School of Medicine, and Dr. Daulaire after 20 years in primary health care in West Africa and the Himalayas, now at the Agency for International Development.

I also want to mention Ms. Laurie Garrett, who because she is out of the country could not be here today. But as the author of the book "The Coming Plague," which was also the subject of a recent four-part public television series, her efforts to focus attention on the urgency and complexity of the threat of infectious diseases deserves special recognition.

Mr. Chairman, some of us are old enough to remember the terrifying days when anyone could wake up infected with smallpox or polio. You can speak from personal experience. Yet just twenty short years ago, with the eradication of smallpox and the discovery of the polio vaccine, people actually thought we were on the verge of eliminating infectious disease forever.

As Laurie Garrett wrote: "The world was a very optimistic place on September 12, 1978, when the nations' representatives signed the Declaration of Alma Ata. By the year 2000 all of humanity was supposed to be immunized against most infectious diseases, basic health care was to be available to every man, woman, and child regardless of their economic class, race, religion, or place of birth.

But as the world approaches the millennium, it seems, from the microbes' point of view, as if the entire planet, occupied by nearly 6 billion mostly impoverished people, is like the city of Rome in 5 B.C. Our tolerance of disease in any place in the world is at our peril. While the human race battles itself * * * the advantage moves to the microbes' court. They are our predators and they will be victorious if we, Homo sapiens, do not learn to live in a rational world that affords the microbes few opportunities. It's either that or we brace ourselves for the coming plague."

Mr. Chairman, in many respects, that plague is already here.

—By the year 2000, twelve million people will be infected with the AIDS virus in India alone, and there will be forty million cases worldwide. Over 100,000 people were infected with HIV by 1980, before AIDS was even discovered.

—Each year, 3 million people die worldwide from tuberculosis, a curable disease, and multidrug-resistant forms of TB pose a new, even more serious threat. After years of decline, TB re-emerged as a major public health problem in this country just a few years ago.

—Each year, there are some 250 million new cases of malaria, and 2 million deaths. New drug resistant forms are being transported around the world.

—The ebola virus, were it to spread beyond isolated rural parts of Africa, could cause a similar catastrophe as the AIDS virus.

—And we saw recently the panic caused by a few ripe strawberries sent through the mail in Washington, DC. One can only imagine what might result if the same amount of anthrax was scattered from the top of the Washington Monument.

The cost of stopping these microbial threats at our borders is no longer a realistic option. To quote from the 1997 Institute of Medicine study:

“The movement of 2 million people each day across national borders and the growth of international commerce are inevitably associated with health risks * * *. Poverty and violence impose major burdens on health, burdens that are shared by people in developing countries and in the inner cities of the industrial world alike. Due to the ease of rapid international travel, emerging and drug-resistant infectious diseases in one country represent a threat to the health and economies of all countries.”

Since 1973, more than 30 new infectious diseases have been identified, and numerous known diseases have re-emerged as serious public health threats. Our failure to maintain and strengthen our ability to control the spread of these diseases has recently received attention, thanks in part to Laurie Garrett’s book and films like “Outbreak.” Last June, President Clinton announced a national policy to address the threat of emerging infectious diseases through improved domestic and international surveillance, prevention, and response measures.

Other government-funded studies over the past several years have also warned of the dangers, and made numerous recommendations. However, as so often happens, many of those recommendations were ignored.

Frankly, I am amazed that this topic has not received greater attention in the Congress. The Government has a responsibility to protect its citizens. America’s pharmaceutical companies could make an enormous contribution to global health, but they face many obstacles. We know what needs to be done, yet we continue to treat one of the most serious threats we face with the same kind of naive optimism as we did 20 years ago.

Perhaps it is because microbes are invisible to the naked eye, and we assume that technology can defeat any disease, that we have not done more about it. I hope our witnesses will explain why things have not turned out as was predicted back in 1978, what dangers infectious diseases pose today, and what this subcommittee should do about it.

Thank you.

OPENING STATEMENT OF SENATOR MITCH MC CONNELL

Senator McCONNELL [presiding]. Thank you, Senator Leahy.

The reason for our hearing today really is Senator Leahy’s interest on this subject, and he is to be commended for suggesting it and deserves the credit for this public discussion today. Having been a victim of polio as a child, I have a personal interest in this area. I believe we are finally close to eliminating polio from the face of the Earth, in part due to a dedicated effort by international health organizations, bilateral aid programs, and active involvement of nongovernment organizations and community activists.

But polio should not be the only targeted disease. We need to see the same kind of effort concentrated on tuberculosis, malaria, diphtheria, to name just a few. Senator Leahy has already mentioned this. From my perspective, there are several reasons to focus our attention and resources on the problem of infectious disease.

First, it is consistent with our humanitarian traditions. Right now one person dies every 15 seconds from malaria. Of those deaths, 85 percent are children under 5 years old. We need to add malaria, measles, and polio to the short list of fatal diseases, including smallpox, which we have essentially erased from the Earth.

This is not just an issue of saving children. The spread of infectious diseases directly affects both our personal safety as well as our economic and national security. We need an effective surveillance system to assure our blood supply is not contaminated by emerging deadly microbes. At this point we can screen out well-known bacteria or viruses, but I am not confident we have the national or international mechanisms in place to protect us from emerging deadly agents.

We need to coordinate prevention, diagnosis, and treatment programs for TB, which by some estimates is harbored by more than 2 billion people worldwide, the majority of whom are in Mexico, China, and Russia.

Last year we provided emergency assistance to combat the diphtheria epidemics in Russia and Ukraine. While I think this aid was helpful, it was a stopgap measure, not a part of a comprehensive strategy for the NIS.

These epidemics have a human face, but economic cost. Just as one example, 1995 estimates of health care and lost production in tropical Africa from malaria run nearly \$2 billion, a staggering toll for a destitute continent.

Finally, while some may still be indifferent to the human or economic interests at stake, there is no question that improving surveillance, control, and treatment of these diseases have real national security implications. A few weeks ago 100 people were quarantined for 8 hours in northwest Washington in response to an anthrax scare. Pat mentioned that. While it turned out to be a sadistic hoax, the drill was a live demonstration of the problems we may face in the future.

In spite of a global convention banning the production, distribution, or acquisition of biological weapons, 10 countries are suspected of having just such programs. Iraq has acknowledged manufacturing 25,000 liters of an anthrax bacterium, which is sufficient to kill the Earth's population three times over.

I certainly hope we get a better sense today of the commercial and government research programs which may be developing vital antidotes, antibiotics, and vaccines to this threat.

Our panel of experts represents a unique spectrum of expertise on the extent of the threat and medical and organizational responses. I understand that Dr. Heymann, who represents the World Health Organization, is not permitted to formally testify, so we will accommodate his agency rules by allowing him to brief us.

I will be leaving for a meeting around 11:30 a.m. Senator Leahy is going to conduct the hearing and finish it up. Now we would like to lead off with Dr. Bloom.

SUMMARY STATEMENT OF BARRY BLOOM

Dr. BLOOM. Thank you, Mr. Chairman, Senator Leahy. It is a great privilege to be here to talk about infectious diseases in this committee. I would like to use my testimony to address three ques-

tions to set the background for the discussion of my colleagues that I hope will follow. The first is: Are infectious diseases really important? Second: What do we have to offer to address them and the problems of health of developing countries? And the third is: What do we have to gain by it? What is our self-interest?

If one looks at the question of any disease and its importance, perhaps the best place to look is a comparison of the global burden of disease, which I have illustrated here.

The bar graphs indicate how many people die of what kinds of diseases. It makes two simple points. The largest cause of death in the world is not heart disease, cancer, or injuries; it is communicable diseases. And the second point is the deaths are not equitably distributed between the industrialized and the developing world, but fall predominantly on people who live in the developing countries.

If one looks then at the burden of infectious diseases in developing countries and looks in fact at the total burden of disease, of the eight major causes of death and disability in developing countries, six of them—respiratory, diarrheal, perinatal, tuberculosis, measles, and malaria—are the largest burdens of disease. And if one asks what is the impact of infectious diseases on the future generation of developing countries, one finds that 70 percent of the causes of death of children under the age of 5 are caused by infectious diseases. So the burden of ongoing infectious diseases is enormous and it is the major health burden in developing countries.

You have read a lot of media, I am certain, about emerging infections. The question is is this a major problem or is this an epidemic of the media? I would simply show you that, if one looks through history, this is a constant and grim battle between microorganisms and the human hosts for survival.

These are epidemics that wiped out vast numbers of people in Europe that have been recorded in history from the Black Death to 40,000 deaths in Italy to malaria. This is a continuing evolutionary struggle, not a transient epidemic of the press.

The second major concern in the area of emerging infections is drug resistance. Unless there are health infrastructures to properly use the drugs, we already know resistance is developing to pneumonia, malaria, TB, HIV, and all of those resistant organisms threaten the armamentarium at home and our ability to address these problems.

The final concern that was mentioned in the introductory remarks is biological terrorism. I could make up a scenario. I think it is just easier to show a historical scenario, not intentionally introduced, but could be done by genetic engineering or by natural evolution. In September 1918 there was a single case at Fort Devens, MA; 5 days later there were almost 7,000 cases; 10 days later there were 12,000 cases; 25 percent of the civilian population in the United States was infected and in fact 40 million people died from that outbreak. That is not able to be precluded on scientific grounds.

Numbers reflect one aspect. This is a child with cerebral malaria. This is the kind of malaria that kills children, over 1 million kids each year. That child was too late for medical help and succumbed.

And 200 million people, as you know, over 1 million kids, and resistance is dramatically rising.

The first resistance was detected in 1910. It took 60 years or 50 years for the resistance to chloroquine. We now have resistance in 4 years in Asia to the only drug available, and it is my understanding, Senators, that there is not a single major pharmaceutical company in the world developing drugs against this disease.

AIDS, as you know, affects a vast number of people and is the most serious new threat to the health of people in developing countries. The numbers are staggering. The two that I would reflect are that 3 million kids have this disease and have died, and there are at least 9 million children that have lost at least one parent or are orphaned by this disease, so that the long-term social as well as health consequences, particularly in developing countries, are enormous.

This is a disease that affects equal numbers of women and men in the developing countries, and also children.

And the impact already is that the life expectancy in five sub-Saharan countries is declining, the first time we have ever seen a decline in recent years due to a health epidemic.

I am not sure we can get past that.

OK, great.

Finally, there is the problem of tuberculosis. It is the largest cause of death in the world from any infectious diseases. It is responsible for 18 percent of adult premature mortality that could be prevented, and it is emerging as resistant to drugs and requires major attention.

Senator LEAHY. Let me just note Dr. Bloom, that my wife is a nurse at nearby hospital. She said, in the last 5 years there has been a steady increase in TB patients. And of course, that means increased precautions they have to take with special rooms and care and everything else.

She said that, talking with some of the other nurses of her age, they have gone for 20 years almost never seeing a tuberculosis patient.

Dr. BLOOM. That is right.

Senator LEAHY. And now they are just a very common thing.

Dr. BLOOM. And it is sad when it is drug-resistant and we have no tools to deal with it, so it has to be dealt with. I am pleased to say the numbers in the United States for the first time have begun to decline.

What I have said is to argue that infectious diseases are a major burden in the world and the major burden in the developing countries. What do we have to offer? I would argue with a single bit of evidence: this is what we have best to offer. These are data from the World Bank and they compare per capita income and life expectancy, and they show two things:

If you are very, very poor, a very small increase in per capita income, on the left side of that chart, gives you a very significant increase in life expectancy. Any interventions that help self-reliance of the poorest will lead to an increase in life expectancy.

But what we have uniquely to offer in addition is seen on the right side of the chart. If you lived in 1900, no matter how much money you had, you could not buy 25 years of life that we have

available to us for the same income in 1990. And since these are income-adjusted figures, what it says is that difference, 25 years of life, has to be derived from, in the broadest sense, public health and medical knowledge. What we have to offer is a unique expertise in medical knowledge that buys life.

The Board of International Health then asked the third question in its report, "America's Vital Interest in Global Health": What is in it for the United States? There were four reasons that we believe it is within the national interest.

One is, as you well know, a great humanitarian tradition in this country. And I will not deal with it now, but we could discuss it later. Many polls indicate the American people are very supportive of foreign aid if it goes to the neediest, if it is to increase self-reliance, and if it is to get the job done that we are trying to get done.

On the other hand, we are concerned, as I am sure you are, that foreign aid in this country and globally has declined for 6 years and that this may not be a sufficient justification. So there are three other arguments we have tried to educe.

One is to protect our people.

Some 25 million travelers travel each year; 2 million go across borders; 148 million are refugees; 10 countries each have 70,000 refugees each on a permanent basis from foreign countries and 70 million people work across national borders. There are infectious diseases. There is urban crowding, and there is the transport of health hazards, including toxins.

There are three reasons, then, to protect the American people. I will only mention two. One is the need for surveillance that you will hear about later, to identify what the threats are in infection. But the one that I think is the least understood is value for money.

We tested whopping cough vaccine, not in the United States but in Scandinavia, because we could get value for money. They have more cases that we could evaluate. We studied cancer in China because they have more esophageal cancer than we have here and we get value for money. That is not foreign aid. That is common sense.

I will argue in my professional judgment the most important thing in AIDS that the NIH and Government have recognized is the need for a vaccine. I believe for ethical reasons we cannot test any vaccine for AIDS for efficacy in the United States. We will need to test it in countries that have the highest disease rates, that cannot afford the drugs that are available. That is in our vital interest.

Second, prevention is the name of infectious diseases and prevention not only helps people, it saves money. We save a vast amount of money not having to vaccinate against smallpox. We will do the same for polio. Measles is on the agenda. We save money as we vaccinate our kids here. For every dollar we put in, we gain in spared health costs \$21 to \$29. This makes a lot of sense.

The second—the third argument that the Board on International Health educed is that the global health economy is \$1.6 trillion. That is 8 percent of the world's economic product. We are the leader in development of science and new products. We are not the leader, however, in sales and exports to developing countries. The Europeans have 75 percent of that market, and there are major legislative, congressional and economic constraints to allowing

American industry to compete effectively abroad. And I should also add, there are 2 billion people in developing countries that have no expertise—no access to the drugs that are available to people in this country.

Finally, the last is that we have an opportunity to increase U.S. global influence in the world. We have the greatest amount of science and technology. It should be based on that. That is our comparative advantage. It should be put into educating people to help upgrade infrastructures in health abroad. It should be put into organizing and coordinating the many agencies that have statutory responsibility in the Federal Government, but, in an uncoordinated way without that leadership, are unable to deliver that leadership.

PREPARED STATEMENT

If we want to influence the global health community, such as the World Health Organization, through the United Nations system, we really ought to pay our dues so that we can be taken seriously as a leader in that regard.

I have tried to argue simply three points: infectious diseases are important, enormously important globally; the United States has unique strengths and capability to make a contribution; and we have much to gain.

Thank you very much for your attention.
[The statement follows:]

PREPARED STATEMENT OF BARRY R. BLOOM, PH.D.

I am Dr. Barry R. Bloom, an Investigator at the Howard Hughes Medical Institute and Professor of Microbiology and Immunology at the Albert Einstein College of Medicine in New York. At the present time I serve as Co-Chair of the Board on International Health of the Institute of Medicine of the National Academy of Sciences, and as Chairman of the Vaccines Advisory Committee to UNAIDS. I am most grateful for the opportunity to make a presentation on the importance of global infectious diseases and international health to this committee. My testimony will seek to address two questions relevant to these hearings: What is the global context for the major infectious disease challenges which my colleagues will discuss here today? and, Why is it in America's vital interest to engage in global health activities?

THE GLOBAL BURDEN OF INFECTIOUS DISEASES

To evaluate the importance of any particular health problem, it is useful to consider the global burden of mortality and disease. The major cause of death in the world is not cardiovascular disease, cancer or injuries, but infectious disease. [1] If one combines the burden of premature mortality together with long-term disability, a useful metric can be derived for measuring the burden of disease and disability, known as disability adjusted life years or DALYS [2].

TABLE 1.—*The global burden of disease, DALYS*

	<i>Billions</i>
Established market economies plus former Socialist economies	0.161
Developing countries	1.220
Global total, 1990	1.381

Note.—Disability adjusted life years lost (DALYS) equals premature mortality plus long-term disability.

Using either metric, it becomes immediately apparent that the global burdens of mortality or disease are not equitably distributed. The vast burden of premature mortality and disability falls disproportionately upon people in developing countries. If one focuses directly on the health problems of the developing countries themselves, almost 50 percent of the burden of disease and disability is accounted for

by communicable perinatal and maternal mortality, all of which are ultimately caused by infectious diseases.

TABLE 2.—*Burden of disease developing countries, 1990*

	<i>Percent DALYS¹</i>
Communicable, perinatal	48.7
Cardiovascular	8.2
Neoplastic	4.0
Injuries	15.2

¹ Disability adjusted life years lost.

Of the eight leading causes of death and disability in developing countries, six are directly or indirectly caused by infectious diseases, lower respiratory infectious, diarrhoeal diseases, perinatal conditions, tuberculosis, measles, and malaria. HIV infection is the disease most rapidly increasing in developing countries.

Of the eight leading causes of death and disability in developing countries, six are directly or indirectly caused by infectious diseases, lower respiratory infectious, diarrhoeal diseases, perinatal conditions, tuberculosis, measles, and malaria. HIV infection is the disease most rapidly increasing in developing countries.

TABLE 3.—*Global burden of disease and disability ranking causes in developing countries, 1990 [2]*

- | | |
|----------------------------------|----------------------------|
| (1) Lower Respiratory Infections | (5) Tuberculosis |
| (2) Diarrhoeal Diseases | (6) Measles |
| (3) Perinatal Conditions | (7) Malaria |
| (4) Unipolar Depression | (8) Ischemic Heart Disease |

If one considers only the burden of mortality on the future generation of developing countries, children under five years of age, infectious diseases represent the cause of 70 percent of deaths. Thus, for the 85 percent of the world's population living in developing countries, infectious diseases remain a major burden and priority; yet the scientific and technical means for addressing these problems lie in the hands and expertise of the 15 percent of the world's population living in the industrialized world.

The atomic physicist, Leo Szilard, once defined an optimist as, "one who believes the future is uncertain." In addition to the major infectious diseases that have burdened humanity for centuries, the media and public have become aware of new and emerging infectious diseases. To address any concerns that the emerging infectious disease are a recent invention, or an epidemic of the press, let me remind you that the grim evolutionary battle between the pathogens and their human hosts for survival has endured from historic times, and that emerging infections are not a phenomenon only of recent years.

TABLE 4.—*Emerging infectious diseases—a historical perspective*

<i>Epidemic</i>	<i>Year</i>
Leprosy	644
Smallpox (Rhazes)	900
Black Death (plague)	1348
The great pox (syphilis)	1495
The red sickness (scarlet fever)	1510
Jail fever (typhus)	1546
Malaria	1557
Smallpox	1567

These are but a few of the terrible epidemics of Europe that have been recorded, that establish the continuing threat of new and emerging infections entering the human population. Among the newest and most serious threats are microbes developing resistance to antimicrobial drugs, often due to their inappropriate use. The drug resistant organisms are increasingly causing pneumonia, meningitis, malaria, tuberculosis, sexually transmitted diseases, particularly gonorrhoea, and HIV.

THE IMPORTANCE OF THREE MAJOR INFECTIOUS DISEASES OF DEVELOPING COUNTRIES

Of the infectious diseases that are particular burdens for developing countries, I would like to focus attention on three. Malaria is a major parasitic disease transmitted by mosquitoes that infects over 200 million people each year in Africa, Asia and Latin America. It affects citizens of the United States largely through its importa-

tion with travelers and is a major threat the military stationed in tropical countries. Malaria kills a million children each year, and resistance to drugs is rapidly rising. Resistance to quinine developed in 1910, resistance to chloroquine was reported in 1967 and four years after the introduction of mephloquine, the newest antimalarial drug, resistance has developed particularly in Asia. On the Thai-Cambodian border, over 60 percent of malaria is resistant to all the anti-malarial drugs. Because malaria is a disease primarily of developing countries, there are virtually no new drugs in the pipeline, and it is my understanding that not a single major pharmaceutical company worldwide is engaged in developing new drugs for this disease.

AIDS is the recently emergent virus infection that is devastating the poorest countries in the world, and will continue to do so for the foreseeable future. UNAIDS estimates that there are 22.6 million people infected with HIV and 6.4 million have already died of AIDS, including 3 million children. Almost 100 million children have lost a mother or are orphaned from AIDS. It is a tragic fact that 90 percent of HIV-infected people live in developing countries that cannot afford the new and expensive drugs that cost perhaps \$15,000 per year. UNAIDS estimates that 40 million people will have died from AIDS by the end of this decade. In United States, where the Centers for Disease Control (CDC) has excellent surveillance figures, HIV is the most rapidly rising and now leading cause of death of men aged 25–44, and the picture in developing countries is that women share 46 percent of the burden of HIV. The devastation of this disease in sub-Saharan Africa is reflected by the fact that life expectancy in sub-Saharan countries which had been steadily rising from the mid-1970's has started to decline and will continue to decline because of the impact which this disease is having on its young and most productive people.

The third disease is tuberculosis, which remains the largest cause of death in the world from any single infectious disease. There are over 7 million new cases each year of tuberculosis, 2 million deaths annually. In Africa, it is the most common cause of death in people whose immune system is weakened by HIV infection, and the attributable cause of death of over 30 percent of AIDS patients there. Particularly ominous, as we learned recently in New York, is the emergence of multidrug resistance. We have learned that unless drug treatment is properly supervised, tuberculosis rapidly becomes resistant to the only effective drugs available. The lesson was learned originally in Tanzania and replicated in New York, and showed that directly observed treatment (DOTS) both prevents emergence of resistance and leads to cures in over 85 percent of tuberculosis patients rendering them non-infectious within a month. For malaria and AIDS afflicting people in developing countries, for which drugs are either not available or prohibitively expensive, and for tuberculosis where treatment is long, the long-term hope is for development of preventive vaccines.

FOUR MAJOR WHO EXTRA BUDGETARY PROGRAMS THAT CAN MAKE A DIFFERENCE

For each of these diseases I would suggest that extra budgetary programs at the World Health Organization, specifically the Tropical Disease Research (TDR) Program, Global Program for Tuberculosis (GTB), and the new Programme on Emerging Infections, and the UNAIDS Programme that unifies efforts of all the UN Agencies, have the potential to make an enormous difference, and would urge you to give them consideration for increased financial support. Over 30 years, I have served all but one of these programs. As Chairman of the Scientific and Technical Advisory Committee to the Tropical Disease Research Program I was responsible for reporting to the donor group and the co-sponsors, the United Nations Development Program (UNDP) and The World Bank, on the scientific progress and integrity of that program. In my judgment, and in the words of the representative from the British Overseas Development Agency, "there is no program in foreign assistance that receives a higher level of technical expertise or more stringent review". In terms of capacity building, the WHO TDR program has trained more scientists working in biomedical research in developing countries than any other program, and over 90 percent of those trained have returned to their countries. TDR has developed new packages, such as a Fever Package that can be administered within households, or the Sick Child Package, that integrates treatment of children with fever that will prevent deaths from severe malaria, pneumonia and meningitis, and a package for removing the burden of helminths (worms) that afflict school children and retards their growth and academic performance, but they do not have the resources even to test them on a sufficient scale in developing countries.

I would like to emphasize the work that the new United Nations Program on HIV/AIDS (UNAIDS) is helping to address the greatest infectious disease challenge in this era. UNAIDS was established in 1996 to bring together the efforts of six UN

agencies and The World Bank in a common effort to address the international response to HIV/AIDS, including the United Nations Children's Fund (UNICEF), United Nations Development Program (UNDP), United Nations Population Fund (UNFP), United Nations Education, Scientific and Cultural Organization (UNESCO) and the World Health Organization (WHO). Although only two years old, UNAIDS has made a significant impact in disease prevention, policy development and public-private sector partnerships. There is encouraging evidence that well defined prevention efforts can lead to substantial progress in reducing HIV transmission. Declines in HIV prevalence in military recruits in Thailand and among pregnant women in Uganda indicates that with a well designed and organized program can achieve significant progress in reducing HIV infection and transmission. UNAIDS work in Vietnam, Ukraine and Pakistan has encouraged these governments to undertake large scale AIDS prevention programs, and UNAIDS has helped national partners to plan and carry-out programs to improve blood supply safety and institute medical care for curable sexually transmitted diseases. Because of increased awareness generated by UNAIDS efforts, some major companies in the private sector are working to protect and educate their work forces, especially in emerging markets. Shell Oil for example is assisting the Botswana national HIV/AIDS educational program, Levi Strauss is working on a major AIDS education program for supplying communities in Southeast Asia.

The Global Program on Tuberculosis at WHO has introduced directly observed therapy (DOTS) into China, Bangladesh and several countries in Latin America with dramatic results. Reported cure rates have been over 85 percent, and transmitting the design and operation of such programs is strengthening the healthcare infrastructures in those countries in a sustainable way. Without such carefully designed programs drug resistance will increase. Because of the cost-effectiveness of prevention through immunization, the GTB has a major need for increased resources in strengthening the longer term effort to develop and test vaccines that can prevent infection or disease.

Finally, vaccines represent the most cost-effective known medical intervention to prevent disease and death. In the United States, we save \$32 million every 20 days by not having to vaccinate against smallpox [3]. For every dollar invested in measles, mumps and rubella, \$2 dollars is saved in direct and indirect medical costs. For diphtheria, whooping cough and tetanus, that savings is \$29 dollars for each dollar expended. We know from the Global Programme on Vaccines deriving from the Expanded Program for Immunization at WHO/UNICEF, that vaccines can be delivered to children in virtually every corner of the world. In 1975 fewer than 15 percent of the world's children received their childhood vaccines. In 1996 83 percent of the world's children have received childhood immunizations, resulting in the saving of at least 4.6 million lives. Thanks to partnership of WHO, UNICEF and the Pan American Health Organization with Rotary International in effecting polio vaccination in Latin America, the most astonishing result is that there have been no cases of paralytic poliomyelitis reported in the entire Western Hemisphere in the past four years. The next target is the global elimination of polio and initiating a comparable attack on measles.

WHY SHOULD THE UNITED STATES TAKE A MORE ACTIVE ROLE IN GLOBAL HEALTH?

The Board on International health of the Institute of Medicine of the National Academy of Sciences has, over the past year and a half, examined the role of United States in international health [3]. It recommended strongly that it was in America's vital interests to engage more actively in global health activities. In this context, global health is defined as "health problems, issues and concerns that transcend national boundaries and may best be addressed by cooperative actions". The Board presented four sets of arguments to support its recommendation: (i) To fulfill a genuine humanitarian tradition; (ii) to protect our people; (iii) to enhance our economy; and (iv) to advance our international interests. A number of recent polls, [4] [5] have indicated that there is greater than generally perceived public support for international health and overseas humanitarian assistance provided, that it goes to those most in need, and accomplishes what it is intended to do. Those same polls reveal, on the other hand, widespread misperceptions among the public that the United States is spending a great deal more on foreign aid than is the case. For example, the majority of respondents believed the federal government was spending more on foreign aid (1 percent of the budget) than on Medicaid (13 percent of the budget). When informed of the true circumstance, most favored spending more in foreign assistance than is the current state. In fact, of the 20 OEDC countries, the United States ranks last in percentage of gross domestic product expended on foreign aid, and fourth in the absolute dollar amount [6]. In the global context, support for for-

eign assistance has declined for the past several years, declining from about \$83 million to about \$71 million from 1993 to 1993 [1]. Of total foreign aid funds, only about 10 percent is spent on health. The Board on International Health report argues that with the enormously rapid globalization of trade and commerce, there is a globalization of risks [3] [7]. Currently, there are 23 million international travelers each year; 2 million people move across national boundaries each month. There are 45 million refugees who are dislocated from their countries or homes, and 70 countries have more than 70,000 refugees. Over 120 million people live outside their country of birth, and 70 million people work legally or illegally in other countries. The impact of this new circumstance is increasing health risks of transfer of infectious agents for both human and animal diseases, increased risk of epidemics and outbreaks because of urbanization and crowding, increased risks through transport and traffic in toxic substances, including drugs, pesticides, pollutants and tobacco. And there is the risk of biological and chemical terrorism.

In fulfilling the government's responsibility to protect our people, the Board believed that the U.S. must be more active in supporting a global network for infectious disease surveillance, and in protecting against existing and emergent infectious diseases in humans and in animals. Perhaps one example of the actual historical impact of the influenza epidemic of 1918 will serve to indicate the potential threat we face from evolutionary or terrorist induced emergence of infectious disease.

TABLE 5.—*The dynamics of a global epidemic: Influenza, 1919*

Camp Devens, MA:	<i>Cases</i>
September 12	1
September 18	6,674
September 23 (727 deaths)	12,604

NOTE.—In the United States: 25 percent of the civilian population infected in 2 years. The fatality rate was 4,000/100,000.

Globally: In 6 months there were 40,000,000 deaths. (In contrast, in the 4 years of World War I, there were 15 million deaths).

This can clearly best be done by supporting the WHO Emerging Infections Program and enabling it to develop a useful global surveillance system for early warning of new and drug resistant infectious pathogens.

In the interest of protecting our people, another reason must be considered for the United States to be actively engaged in international health activity. Because of unique opportunities abroad for gaining medical knowledge or testing new interventions, for example for testing vaccines against pertussis in Scandinavia, or against malaria in Africa or AIDS in Thailand, the United States can obtain greater value-for-money by trials abroad where the incidence rates of disease are greater and the time required to obtain a statistically significant endpoint are greater. In perhaps the most pressing case, AIDS, most experts in the field agree that, at a time when we do not yet know how effective the new and expensive drugs will be against HIV in this country, or whether resistance will emerge to them, it is essential to develop vaccines, even with significantly lower protective efficacy than we are accustomed to in measles or polio vaccines, to combat HIV and AIDS. It is my professional judgment that, because of the ethical need to offer any individuals in this country who show evidence of HIV in the blood the opportunity for combined drug therapy, it is no longer possible to carry out meaningful clinical trials to determine the efficacy trials of candidate HIV vaccines in the United States. Hence we are all dependent for such knowledge enhancing the health and scientific infrastructure in disease endemic countries.

The third set of reasons the Board on International Health adduced to support increased engagement in global health was its importance to enhancing our economy. The global health market itself represents \$1.7 trillion, that is the equivalent of 8 percent of the entire world economic output. The global pharmaceutical and medical device markets represented in 1992 over \$220 billion in drugs and \$71 billion in devices [8]. Of that, \$44 billion was sold in developing countries. Despite the fact the U.S. creates more new patents for new drugs and devices, the European Union had 73 percent of drug exports in developing countries in 1992. Clearly there are economic and regulatory barriers to allowing American pharmaceutical and vaccine and medical device industries to gain access to emerging and developing markets, and more importantly, preventing the people of developing countries to obtain access to lifesaving drugs at a price that can be afforded. There are currently 2 billion people who do not have access to essential drugs. Social and economic studies by WHO-TDR and others in Africa have indicated that mothers of children with ma-

laria spend up to 30 percent of their annual disposable income for treatments of their child's illness, yet fewer than half of the treatments purchased would be expected, on medical grounds, to provide any benefit whatsoever. There are major economic constraints that need to be addressed.

Finally, the Board believes that U.S. engagement in global health provides an important opportunity to advance the United States global interests. The United States is by any standard the world's leader in science and technology, and produces more knowledge, publications, and new medical interventions than any other country in the world. We need to provide more resources to train the leadership in health in developing countries, to enable the development of health infrastructures to make a significant contribution to improving the quality of lives of people in developing countries, and that will take continued commitment and support. Despite our scientific and technical expertise, multiple agencies within the government have statutory responsibilities for aspects of international health, and there is no coherent strategy or obvious focus leadership within the United States government. The Board on International Health recommended an inter-government agency task force, given the limited and scarce resources available for global health, to coordinate and focus the activities of each of the agencies in a more coordinated and effective fashion. In addition, because the problems in global health are likely to be more technically and scientifically demanding, and because of the strengths of the National Institutes of Health and the Centers for Disease Control within DHHS, the Board recommended further that authorization and support be provided to DHHS for new initiatives in global health and coordination between academic institutions, industry, NGO's and international organizations such as WHO. In this context, the Board recommended undertaking a significant effort to establish global surveillance for infectious diseases. Finally, the Board argued that it is very difficult for the U.S. to exert the global leadership in health that it could, or even to be taken seriously as a leader in global health within international organizations, if the United States was hundreds of millions of dollars in arrears in its treaty-obligations to the World Health Organization and the United Nations system in general. Because of our leadership in medical science and technology, the United States has an important opportunity to influence the international community, international organizations and developing and industrialized countries alike to address the health problems of those most in need. Greater U.S. engagement would serve both the global health needs, and our own our enlightened self-interest. As the poet John Donne long ago wrote,

"No man is an island, entire of itself.
Every man is a piece of the continent, a part of the maine * * *
Any man's death diminishes me,
Because I am involved in Mankind."

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**STATEMENT OF DAVID HEYMANN, M.D., DIRECTOR, DIVISION OF
EMERGING AND OTHER COMMUNICABLE DISEASES SURVEIL-
LANCE AND CONTROL, WORLD HEALTH ORGANIZATION**

Senator McCONNELL. Dr. Heymann.

Dr. HEYMANN. Thank you, Mr. Chairman and Senator Leahy. WHO appreciates the opportunity to provide information to the committee on the critical importance of strengthening international cooperation and participation in the surveillance and control of communicable diseases.

In my written statement I have laid out the details of the global framework for surveillance and control of communicable diseases. WHO, at the request of its 191 member countries, is putting this framework in place. Many partners are involved in this effort—countries, international organizations, business and industry, national nongovernmental organizations, scientific laboratories, research institutions, universities, and the monitoring group of the Biological Warfare Convention.

Page 2 of my written statement outlines four major areas which are top priority for worldwide attention. They are: strong national infectious diseases surveillance and control; global monitoring and alert systems with electronic access to the WHO information highways on infectious diseases; and international preparedness.

This first chart shows you that in 1996, just a 12-month period, 27 infectious diseases outbreaks have added to the heavy burden of underlying diseases, such as malaria, diarrhea, respiratory disease, and AIDS. Some of these diseases create ominous associations, such as TB, which is facilitated by HIV. Others suggest that infectious agents can effectively jump the species barrier from animal to man, such as is the case of BSE, or mad cow disease, in the United Kingdom.

Over one-half million cases of dengue, a viral disease carried by mosquitoes, have been reported from Latin America during the past 2 years. During 1996, a tourist to Latin America returned to Tennessee with yellow fever. There have been an average of 954 imported cases of malaria each year, some of which have taken up residence in U.S. mosquito populations and been transmitted to persons who have never traveled internationally.

This next chart shows you the distribution of malaria in the United States 50 years ago. Malaria was eradicated from the United States in the 1950's and 1960's, but mosquitoes that can carry malaria and mosquitoes that can also carry dengue and yellow fever remain. They move north to the great metropolitan areas in the summer.

Strong surveillance and control of dengue, yellow fever, and malaria in developing countries where they are occurring will lead to prevention and containment where they occur.

The next chart shows you cholera, which is on the increase throughout the world, but as you can see in the green bars, mostly in Latin America. Over 1.4 million cases of cholera have been reported from Latin America since 1991. Up to 10 percent of those who develop cholera died in some areas.

Cholera costs countries in human suffering and death, in patient care, in lost economic output, and in trade sanctions. Peru just \$770 million in 1991 because of bans of its seafood exports because cholera had been imported to the country.

Cholera could have posed a real threat to the United States if unsuspecting authorities had not been alerted by information from

WHO and if WHO through its Baja regional office had not worked intensively with Latin American countries to stop the spread.

The next chart reminds us that international travel spreads infectious diseases. It also spreads microorganisms that have developed resistance to antibiotics. Strains of the bacteria that cause common pneumonia resist both old and new antibiotics. In the early 1990's, during a period of weeks multiresistant streptococcus pneumoniae, shown on this chart, spread from Spain throughout the world. Man, like the mosquito, is a vector of infectious diseases.

Antibiotic resistance spreads rapidly. Death occurs when antibiotics no longer work effectively and costs for treating patients increase.

WHO works with developing countries to ensure that antibiotic resistance is tracked, that prescribing practices are correct, and that resistant organisms are contained at their source.

This chart shows you the new WHO network of laboratories for monitoring antibiotic resistance, which helps countries develop effective treatment policies. Last year eight developing countries in Asia and in Africa were brought into the system, with support from Japan, the United States Pharmaceutical Research and Manufacturers Association, which supported activities in Africa, and CDC.

The network must be expanded to other developing countries in Africa and Latin America, to both human and veterinary laboratories, and linked electronically to industrialized country networks.

This chart shows you the WHO network for monitoring influenza. Laboratories are located throughout the world. Each year information from this network is provided to the pharmaceutical industry for development of vaccines which prevent influenza the following year in our aging populations. This network must be expanded, especially in southern China, where new influenza viruses frequently jump the gap between animals and humans and cause epidemics such as Dr. Bloom described in 1918, when at least 20 million people were killed from influenza.

This chart shows the WHO laboratory network for monitoring and alert of bacterial, viral, and veterinary diseases. These are strong national laboratories that collaborate with WHO and use WHO norms to ensure early detection of infectious diseases in those countries and regions. Information from these laboratories is used nationally and provided directly to WHO. The network must be expanded to more developing countries, especially in Africa and Latin America, and linked electronically.

PREPARED STATEMENT

Finally, I would just like to go back to the first chart again, to remind you that infectious diseases occur throughout the world. They are increasing because of weakened public health infrastructure and are linked to behavior, deforestation, climate change, and social upheaval. It is in the interest of the world community to strengthen WHO's programs to strengthen national capacity to detect and control infectious diseases so that we can ensure their containment where they are occurring. And it is in the interest of the world community to expand WHO's existing infectious diseases monitoring networks and electronic information systems.

United States support could make the decisive difference in how rapidly and how well the job is done.

Thank you very much.

Senator McCONNELL. Thank you Dr. Heymann.

[The statement follows:]

PREPARED STATEMENT OF DAVID L. HEYMANN, M.D.

Mission: To strengthen national and international capacity in the surveillance and control of communicable (infectious) diseases, including those that represent new, emerging and re-emerging public health problems.

THE CHANGING PICTURE OF INFECTIOUS DISEASES: THE PROBLEM

Few public health concerns today carry as much sense of urgency and importance as emerging and re-emerging communicable (infectious) diseases. Many factors contribute to these diseases, including population growth, migration, urbanization and poverty compounded by inadequate or deteriorating public health infrastructures for disease control. Changes in human behaviour and alteration in land use, agricultural practices, climate and environmental conditions contribute to increased exposure to and spread of infectious disease agents. Humans, through world travel and trade unprecedented in history, have themselves become a principal vector of infectious diseases, transporting them easily from one country to another within periods less than 24 hours. Fresh concerns have arisen about the ability of infectious agents of animal origin to cross the species barrier from animal to man. Not least, resistance of microorganisms to the drugs used to combat them and resistance of vectors to pesticides used to control them have profound implications for our ability to deal effectively with infectious diseases. Resistance threatens the very base of infectious disease control. Furthermore, infectious diseases can have many sources, from natural human or animal occurrences due to the changing world environment just described to potentially intentional release of pathogens with the objective of harming human health or the health of animals and plants on which humans depend.

The urgency and importance for public health of emerging and re-emerging infectious diseases create an urgent need to monitor the situation nationally and globally and to respond in a rapid and effective manner. Effective monitoring and response can only be ensured by international collaboration and the solidarity of many different partners ranging from countries and international organizations to non-governmental organizations, business and industry, government and private public health and laboratory systems, and universities.

GLOBAL FRAMEWORK FOR COMMUNICABLE DISEASE CONTROL: THE RESPONSE

The World Health Organization is uniquely capable of putting in place a truly global framework for communicable disease surveillance and control activities because of its universal membership of 191 Member States. As the Specialized Agency of the United Nations system with responsibility for the direction and coordination of international health work, its Member States have requested WHO to coordinate intensified efforts to improve global surveillance and control, especially for the newly emerging, re-emerging and other communicable diseases.

WHO has identified many partners with the same vision, and its strategy is to work with these partners within a cooperative global framework to reshape and strengthen national and international networks for infectious disease surveillance and control. Laboratory-based surveillance, international communication networks, national surveillance systems and a strong national and international public health infrastructure form the basis of this strategy. Areas of concentration are:

- Global monitoring and alert systems to bring together laboratories and disease surveillance systems from all countries to share information through electronic and printed media;
- Global information systems to ensure that information collected through global monitoring and alert can be rapidly and widely disseminated;
- Strong national surveillance and control to detect and decrease or eliminate infectious diseases; and
- International preparedness to provide strong, coordinated and engaged response at the international level to provide the environment necessary for countries to improve their surveillance and control capacities.

GLOBAL MONITORING AND ALERT SYSTEMS

Five global monitoring and alert systems are being strengthened by WHO:

The International Health Regulations (IHR) are the only international public health legislation which requires mandatory reporting of infectious diseases. Currently the IHR cover cholera, plague and yellow fever, though countries often refuse to report these diseases because of the resulting negative impacts on trade and tourism. Under the direction of the World Health Assembly, and in order that the IHR may serve as a working global alert system, WHO is revising them to make them more effective and comprehensive. Through electronic links with quarantine officers in the 191 WHO member countries the system will become proactive, providing immediate reports of disease and syndrome outbreaks of international importance and permitting timely provision of recommendations on what measures should and should not be taken in response.

WHO Collaborating Centers on communicable and zoonotic diseases already comprise more than 200 institutions worldwide—mainly human and veterinary microbiological laboratories. These laboratories are centers of excellence which provide reference services for verifying the diagnosis of bacterial, viral and zoonotic diseases and/or training or epidemiological services for WHO Member States. Linking all Centers electronically will ensure regular exchange of information on infectious diseases and permit timely identification of problems and needs so that the necessary training, supplies and/or reagents may be provided. Information from this system is regularly used to update the WHO World Wide Web site at <http://www.who.ch>. Current efforts are underway to widen the geographic coverage of the network of WHO Collaborating Centers to include more developing country laboratories. Additional military laboratories are also being solicited to join the WHO networks.

Antimicrobial Resistance Monitoring Networks are an expanding group of medical and veterinary laboratory centers which perform antibiotic sensitivity testing on bacteria which cause diseases ranging from gonorrhoea and other sexually transmitted diseases to tuberculosis. The national data are used for antimicrobial policy formulation and feed electronically into the WHO regional and global networks for monitoring of drug resistance and into geographical displays on the World Wide Web site. Expansion of these networks in developing countries is currently underway.

WHO Rumour/Disease Outbreak List contains unconfirmed rumours of communicable and zoonotic disease outbreaks worldwide, which are received from various sources outside of WHO. This “rumour” list is distributed electronically to key public health policy makers in each country and to UN agency and NGO collaborators to consider relevant policy implications prior to actual confirmed reporting of those diseases by countries. Once confirmation is received, it is published on the WHO World Wide Web site.

Other Active Global Surveillance Systems which collect information for action include the influenza network, which collects information from more than 130 participating laboratories worldwide that is used to make a decision on influenza vaccine composition for the following year, and the HIV/AIDS network, which provides information from more than 90 sentinel sites that is used to monitor the AIDS situation worldwide. The influenza network is the first of these active systems to go online with direct electronic data entry by participants, and with global access via the WHO World Wide Web site for queries to the database and for the generation of comparative charts and maps. WHO is in the process of building other global disease databases similar to this influenza prototype.

To strengthen sites participating in these five systems and to expand them to those developing countries which are not yet incorporated WHO and its partners will need to provide intensive training and some basic laboratory equipment and supplies.

GLOBAL INFORMATION ACCESS

Developments in electronic communications in recent years have enhanced national public health surveillance systems and enabled revolutionary progress in surveillance that crosses national boundaries. WHO is paving the way in international surveillance by using communication networks to facilitate rapid collection and analysis of data using standardized case definitions, transmission of information for the prevention of communicable diseases, and promotion of effective public health practice.

WHO provides a focal point for global data and information exchange. It is working to ensure the timely worldwide dissemination of information obtained from its monitoring and alert systems and other information relevant to infectious diseases through the Weekly Epidemiological Record, WHO publications, the Internet's

World Wide Web, and other media available to the program. WHO is focused above all on the value of the information being delivered—its quality, accuracy, relevance and reliability. Electronic communications can make that information available at any time and place.

The participants of the WHO monitoring and alert systems have been targeted by WHO as priority sites for electronic linkages. Electronic linkages under the WHO Global Information Access project are being developed within the framework of a joint WHO/UNAIDS/World Bank project which will also link other sites for information exchange. These other sites include the WHO country representatives, the country/regional representatives of the UNAIDS program, and the World Bank's projects in health.

To provide electronic linkage for the developing country sites, computer software and in some instances hardware, along with connectivity to the Internet, are required.

STRONG NATIONAL SURVEILLANCE AND CONTROL

Strong national surveillance systems are at the heart of national infectious disease control programs. Relevant, accurate and timely information permits action that decreases or eliminates infectious diseases, can avert a local or national outbreak, and at the same time prevent a crisis at the international level. Strong surveillance and control systems in countries help to identify areas of high risk for infectious disease, guide immunization and other prevention strategies, and detect and control the re-emergence of infectious diseases. To strengthen the national infrastructure in order to recognize, report and respond to infectious diseases, WHO provides technical guidance using international consensus policies on surveillance and control strategies, facilitates activities of governments and non-governmental organizations to train epidemiologists and public health specialists, provides minimal support for supplies and equipment, and advocates for government support of these efforts.

To strengthen national infectious disease surveillance and control, WHO and its partners will need to supply routine national, regional and interregional training of trainers and provision of minimal supporting infrastructure.

INTERNATIONAL PREPAREDNESS

International preparedness requires a concerted effort to ensure that various resources and necessities for communicable disease surveillance and control are available and adequately operationalized. This includes ensuring that vaccines, drugs and other supplies necessary to prevent or treat infectious diseases are available in sufficient quantity at the international level. It also requires that expert advice is available when and where needed, and that operational research continues to identify and operationalize the most efficient and cost-effective disease surveillance and control strategies. At times, international preparedness also involves provision of WHO staff and international partners to work with national health authorities at the time of epidemics and immediately afterwards in control activities and in developing plans to prevent future occurrences.

To ensure international preparedness, normative activities such as support for priority operational research and development of international consensus strategies for surveillance and control, laboratory norms and diagnosis must be continued by WHO. In addition, through continued dialogue and meetings with representatives of the pharmaceutical and other medical supply industries, issues concerning availability of drugs, vaccines, and diagnostic tests must be addressed.

A ROLE FOR THE UNITED STATES OF AMERICA

If the world is to respond effectively to emerging and re-emerging infectious diseases we must do so locally, nationally and internationally. Whether we are dealing with the complexities of establishing national surveillance and effective disease control, or are in the front lines of a response to an outbreak, we need good laboratory facilities and technicians, people well trained in epidemiology and disease control, and solid and reliable communication networks. We must rebuild the infrastructure of public health, and continue to support it internationally.

Despite gains made in recent decades, many national surveillance and control programs are still fragile. The world will continue to battle against infectious diseases for years to come and the costs of inaction are high. The challenge will be to find the balance of resources that will preserve and build on what has been accomplished by WHO and its Member countries and partners. The global framework for surveillance and control of infectious diseases which WHO is putting in place will ensure

cost-effective and non-duplicative investment in developing countries in order to rebuild and strengthen capacity to detect and control infectious diseases. The United States has been one of WHO's important partners in infectious diseases surveillance and control, including the global eradication of smallpox in the 1970s and polio eradication in the 1990s. To tackle the newest challenges in infectious disease surveillance and control successfully, WHO and the developing countries will need the United States to continue its support to form even stronger links in its partnership with WHO. The report of the National Science and Technology Council Committee on International Science, Engineering, and Technology (CISET) Working Group on Emerging and Re-emerging Infectious Diseases has documented why it is in the vital interest of the United States to contribute to WHO's activities to strengthen disease detection and containment in developing countries. Such an investment will further decrease the risk of the international spread of infectious diseases and antimicrobial resistance and the associated costs for every nation.

FORTY-EIGHTH WORLD HEALTH ASSEMBLY—AGENDA ITEM 19—MAY 12, 1995

COMMUNICABLE DISEASES PREVENTION AND CONTROL: NEW, EMERGING, AND RE-EMERGING INFECTIOUS DISEASES

The Forty-eighth World Health Assembly, having considered the report of the Director-General on new, emerging, and re-emerging infectious diseases;¹

Recalling resolutions WHA39.27 on rational use of drugs, WHA44.8 and WHA46.36 on tuberculosis, WHA45.35 on human immunodeficiency virus, WHA46.31 on dengue prevention and control, WHA46.32 on malaria, and WHA46.6 on emergency and humanitarian relief;

Aware that with the increasing global population many are forced to live under conditions of overcrowding, inadequate housing, and poor hygiene; that more frequent international travel leads to rapid global exchange of human pathogens; that changes in health technology and food production, as well as its distribution (including international trade) and handling, create new opportunities for human pathogens; that human behavioural changes expose large segments of the global population to diseases not previously experienced; that expanding areas of human habitation expose thousands of people to enzootic pathogens previously unknown as causes of human disease; and that microbes continue to evolve and adapt to their environment, leading to the appearance of new pathogens;

Aware also of the continued threat of well-known diseases such as influenza and meningococcal infections, and of tuberculosis, cholera and plague, once thought to be conquered, and the growing danger of diseases transmitted by vectors no longer controlled, such as dengue haemorrhagic fever and yellow fever;

Concerned at the lack of coordinated global surveillance to monitor, report and respond to new, emerging, and re-emerging infectious diseases, by the general absence of the diagnostic capabilities necessary to identify accurately pathogenic microorganisms and the insufficient numbers of trained health care professionals to investigate these infectious diseases;

Alarmed by the increasing frequency of antimicrobial resistance in bacterial pathogens, which can make some diseases such as tuberculosis virtually untreatable with currently available antibiotics,

1. URGES Member States:

- (1) to strengthen national and local programmes of active surveillance for infectious diseases, ensuring that efforts are directed to early detection of outbreaks and prompt identification of new, emerging and re-emerging infectious diseases;
- (2) to improve routine diagnostic capabilities for common microbial pathogens so that outbreaks due to infectious diseases may be more easily identified and accurately diagnosed;
- (3) to enhance, and to participate actively in, communications between national and international services involved in disease detection, early notification, surveillance, control and response;
- (4) to encourage routine testing of antimicrobial sensitivity, and to foster practices for rational prescription, availability and administration of antimicrobial agents in order to limit the development of resistance in microbial pathogens;
- (5) to increase the number of staff skilled in both epidemiological and laboratory investigations of infectious diseases and promotion in such specialization;
- (6) to foster more applied research in areas such as the development of sensitive, specific and inexpensive diagnostics, the setting of standards for basic

¹ Document A48/15.

- public health procedures, and the establishment of fundamental disease prevention strategies;
- (7) to control outbreaks and promote accurate and timely reporting of cases at national and international levels;
2. Urges other specialized agencies and organizations of the United Nations system, bilateral development agencies, nongovernmental organizations and other groups concerned to increase their cooperation in the recognition, prevention and control of new, emerging and re-emerging infectious diseases both through continued support for general social and health development and through specific support to national and international programmes to recognize and respond to new, emerging, and re-emerging infectious diseases;
3. Requests the Director-General:
- (1) to establish, in consultation with Member States, strategies to improve recognition and response to new, emerging and re-emerging infectious diseases in a manner sustainable by all countries and prompt dissemination of relevant information among all Member States;
 - (2) to draw up plans for improved national and international surveillance of infectious diseases and their causative agents, including accurate laboratory diagnosis and prompt dissemination of case definition, surveillance information, and to coordinate their implementation among interested Member States, agencies and other groups;
 - (3) to increase WHO's capacity, within available resources, for directing and strengthening applied research for the prevention and control of these diseases, and to ensure that reference facilities remain available for safely characterizing new or unusual pathogens;
 - (4) to establish strategies enabling rapid national and international responses to investigate and to combat infectious disease outbreaks and epidemics including identifying available sources of diagnostic, preventive and therapeutic products meeting relevant international standards. Such strategies should involve active cooperation and coordination among pertinent organizational programmes and activities including those of the Global Programme for Vaccines, the Action Programme on Essential Drugs, and the Division of Drug Management and Policy;
 - (5) to coordinate WHO's initiative on new, emerging and re-emerging infectious diseases in cooperation with other specialized agencies and organizations of the United Nations system, bilateral development agencies, nongovernmental organizations, Member States, and other groups concerned;
 - (6) to improve programme monitoring and evaluation at national, regional and global levels;
 - (7) to keep the Executive Board and the Health Assembly informed of progress in the implementation of this resolution.

**STATEMENT OF NILS DAULAIRE, M.D., CHIEF HEALTH POLICY ADVISOR, U.S. AGENCY FOR INTERNATIONAL DEVELOPMENT
ACCOMPANIED BY DENIS CARROLL, M.D., AID**

INFECTIOUS DISEASES

Senator McCONNELL. Would you help me with the pronunciation of your name?

Dr. DAULAIRE. Doctor "DeLare."

Dr. HEYMANN. "DeLare." Dr. Daulaire, you are up.

Dr. DAULAIRE. Thank you. I appreciate the opportunity, Senator McConnell and Senator Leahy. This is an exciting day for those of us who have devoted our professional careers to addressing the issues of infectious diseases.

From my own personal training as a family physician and subsequently as a public health specialist, I learned that the best way to ensure good health is not simply to treat the symptoms of illness, but to systematically address the underlying causes. Today we call this wellness, and prevention is at its core.

We all recognize infectious diseases as a very serious problem, causing 17 million deaths per year and hundreds of millions of new infections. We can respond by chasing endlessly after the symp-

toms of this disease—outbreaks of ebola in Africa, of plague in Asia, of dengue fever in Latin America, diphtheria in the former Soviet Union—or we can help the international community in surveillance and response, as my colleague Dr. Heymann has just been describing, but focus ourselves on prevention, on addressing the root causes for the spread of infectious diseases.

It is my professional judgment that the latter approach is the best investment we can make in global health and a vital role for the United States. Therefore, the Agency for International Development's approach consists of four closely linked elements. I will describe them briefly.

First, basic prevention through changing conditions that allow infectious diseases to flourish and spread;

Second, secondary prevention through improving health systems in developing countries so they are themselves able to prevent and control infectious diseases within their borders;

Third, targeted disease-specific prevention and control efforts focused on priority diseases; and

Fourth, response to emergency situations.

That is an intentional ordering.

In terms of basic prevention, the 1992 report of the Institute of Medicine on emerging infections, which was really a seminal work for much of what we do here, cited six underlying factors responsible for the spread of infectious diseases. Most of these factors cited in the Institute of Medicine report are addressed not by health interventions, but by development.

For instance, they talked about crowded megaslums which are the ideal breeding ground for infectious diseases. We address these through programs aimed at poverty reduction and at slowing explosive population growth. They talked about the undernourished, especially children, who have far lower resistance to disease and, therefore, serve as incubators, if you will, and spreaders of infection. We address these through programs aimed at improved nutrition and food security. They talked about polluted waters and unchecked breeding sites for mosquito vectors of disease that are the highways, if you will, of disease transmission. We address these through our environmental programs.

The Institute of Medicine also cited the breakdown of public health measures as a fundamental cause for the spread of infectious diseases. We all recognize that countries must be able to provide their own first line of defense, what Dr. Bloom referred to as self-reliance. Therefore, our focus on the second part of the four-part strategy I talked about, secondary prevention, is aimed at rebuilding and strengthening the fragile health systems of developing countries so they can be run and managed by their own people.

At AID we focus our efforts on the fundamental building blocks of health systems—training, supervision systems, drug supply and logistics, information systems, communications, and budget and finance. These may seem sometimes arcane, but they are the basic blocks that will allow all countries to systematically protect their own people against infectious diseases threats and, thereby, serve as the first line of defense for our own country.

Third, far from neglecting targeted disease-specific prevention and control programs, these have in fact over the past several

years constituted the core of AID's health programs. In fact, in 1996 approximately \$320 million to activities directly addressing infectious diseases of major public health importance. I think that is a fact that is not often recognized, the degree of our investment. And in fact, this is far greater than any other bilateral donor.

These efforts were principally encompassed within two groups of activities, child survival and HIV-AIDS. As you are aware and as has been cited earlier, most of the world's infectious diseases deaths occur among children. Pneumonia and diarrhea lead the list, and we have active and effective programs in these areas.

Malaria kills mostly children. It is estimated about 85 percent of all deaths, as you mentioned yourself, Senator McConnell, from malaria are among children. And this has been increasingly incorporated into our child survival programs.

We are also addressing the threat discussed a few moments ago of antibiotic resistance through these programs, particularly our pneumonia control programs, where timely and appropriate treatment with antibiotics is the key to effective solutions.

I would also mention, Senator McConnell, from your own experience that starting in the early 1980's AID pioneered the efforts in the Western Hemisphere to eradicate polio. In fact, I think we gave the very first grant to Rotary International that got them into this, which I think was probably the very best public health investment we have ever made.

Of course, since the 1980's we have also led the world in programs to address AIDS in the developing world. As we heard, AIDS is one of the truly emerging disease threats of the world.

Finally, while we recognize—and I mentioned the first three factors, the first three activities—we recognize that you do not want to start a health care system by building emergency rooms, we do recognize that you have to have emergency response. And we have been actively involved in a system with response to outbreaks, such as the ebola outbreak in Zaire, where I believe we were the principal funder of the immediate response.

Now, that leaves two important issues that were discussed earlier, malaria and tuberculosis. I have mentioned malaria. We have invested over the years—and I was quite surprised when I saw these figures myself—over \$1 billion in malaria prevention and control. In recent years we focused our efforts on malaria vaccine development, something we call the Africa integrated malaria initiative, and incorporating malaria treatment into an integrated case management of childhood illness, which is at the heart of our child survival program.

Finally, TB. TB remains a major challenge, and we have focused the resources we have on addressing coinfection with TB and AIDS because of the enormous risk that this poses. While an effective approach, technical approach to TB control treatment, directly observed therapy short [DOTS] course, now exists—there continue in fact to be major hurdles to be overcome before this can be widely applied in the developing world, and I would be happy to address those in followup questions.

Without good program management, supply, and supervision, WHO has noted that no TB program is better than a poorly functioning TB program. It encourages the development of multidrug

resistance, and that is what turns a treatable disease into an untreatable deadly disease.

Is USAID doing enough to address infectious diseases in the world? Of course we are not. The needs are many times greater than the resources we have available to them. And yet AID today devotes a greater proportion of our development assistance funds than ever before to health, and we do not think it would be wise to further cut back on our corollary efforts in agriculture, combating poverty and hunger, basic education, environmental protection—all issues that I mentioned earlier as key factors in helping to prevent the spread of infectious diseases.

PREPARED STATEMENT

Over the past decade, as you are well aware, Senator Leahy, our development assistance budget has been cut in approximately 50 percent, a 21-percent decline in the past 2 years alone. If we are going to continue making progress combating infectious diseases and providing a first line of prevention and defense for the American people, it is critical in our opinion that the Congress approve the administration's full budget request for sustainable development for this coming fiscal year.

Thank you.

[The statement follows:]

PREPARED STATEMENT OF NILS DAULAIRE, M.D., M.P.H.

Thank you Mr. Chairman for giving me an opportunity to present to this Committee information on global needs for the control of infectious diseases and on what the U.S. Agency for International Development is doing to address this challenge in the developing world.

KEY HEALTH ISSUES IN DEVELOPMENT

Just two principal health issues in the developing world account for most of the gap between the health of their citizens and ours. Both are of direct importance to the development of their countries and to the continued security of ours. These two issues are the prevention and control of infectious diseases, and the promotion of reproductive health through family planning, safe pregnancy and delivery services, and prevention and control of sexually transmitted infections. Today I will address infectious diseases. But I would remind you of the continued importance of reproductive health, with its direct effect on decreasing the toll of injury and death to women and children, on allowing the poor—especially poor women—the opportunity to break free from the cycle of poverty, and on helping societies to escape from the trap of unsustainable population growth.

The threat posed by infectious diseases to the security and well-being of the global community is very real. Today we understand that national borders are irrelevant to microbes, and that in an interconnected world no disease is more than a day away from our own shores. We have learned that infectious diseases, and the conditions that engender them, must be dealt with at their source.

While public attention has focused on acute outbreaks of exotic viral diseases such as Ebola, age-old bacterial diseases such as plague, and even new categories of "prion" diseases such as Mad Cow Disease (BSE), the larger infectious threats to human health are more commonplace and therefore less publicized. Deaths from outbreaks of the high-visibility diseases that I have mentioned number in the hundreds. Meanwhile, each year 17 million people die around the world as a consequence of more routine infectious diseases, principally vaccine preventable and bacterial diseases. This is where the true threat lies.

USAID has contributed directly to control efforts for the rare and high-visibility outbreaks, but it is the large-scale threats to public health which are at the core of our health programs around the world. Let me stress that this is already a considerable part of USAID's budget—in fiscal year 1996, we estimate that USAID devoted approximately \$320 million dollars to the direct prevention, control and treat-

ment of infectious diseases, making us by a considerable margin the largest bilateral donor for this area.

However, we do not consider a dollar comparison with other donors as the most appropriate yardstick of U.S. efforts, and share the belief that the world's only superpower has good reason to do more.

USAID'S APPROACH TO INFECTIOUS DISEASES

Let me share with this Committee USAID's view of how infectious diseases should be addressed, where we have made our principal investments, and where we have been unable to do as much as we would like.

The simple view of infectious diseases is that you wait for an outbreak, then go in with massive resources to stop it. Yet this is neither good resource management nor good public health—this must be our last resort, rather than our first line of defense. Prevention of disease is far more cost-effective than treatment and emergency response.

In contrast, USAID's approach consists of four elements:

- 1. Basic prevention through changing the conditions that allow infectious diseases to flourish and spread.
- 2. Secondary prevention through improving health systems so they are themselves able to prevent and control infectious diseases.
- 3. Targeted prevention and control through specific focused programs tailored to individual high priority diseases.
- 4. Response to emergency situations.

Let me address each in turn.

Basic prevention through changing the conditions that allow infectious diseases to flourish and spread

The Institute of Medicine's groundbreaking 1992 report on emerging infectious diseases highlighted six underlying factors responsible for the spread of infectious diseases. They were:

Human demographics and behavior; Technology and industry; Economic development and land use; International travel and commerce; Microbial adaptation and change; and Breakdown of public health measures.

Ever-increasing international travel and commerce are the defining reality of today's global economy. They are responsible for much of the economic growth and vitality of virtually all of the world's countries. Yet they are also the principal conduits for the rapid spread of infectious diseases. Similarly, developments in technology and industry can also serve as spurs to the spread of disease. Other agencies are addressing these areas.

USAID's work makes a vital difference in efforts directed at all of the other factors.

We work to stem rapid population growth leading to overcrowded mega-slums, the true breeding grounds that allow diseases to reach a critical mass, through our efforts at family planning.

We work to improve nutrition, and thereby strengthen resistance to the spread of diseases, through our efforts in economic development, agriculture and food security.

We work to provide clean drinking water, reducing the transmission of deadly pathogens, through our efforts in both urban and rural water and sanitation programs.

We work to enhance sustainable agricultural practices and natural resource management, reducing the growth of vectors and disease organisms, through our environmental programs.

And last but by no means least, we work to improve public health measures and decrease the chances of dangerous microbial changes through our support of health systems.

These efforts are the essential aspects of a true long-term prevention strategy. The fact that they have other equally important benefits outside the area of infectious diseases makes them even more valuable as essential elements of our integrated approach to sustainable development.

Secondary prevention through improving health systems so they are themselves able to prevent and control infectious diseases

While it is appealing to think of American doctors coming to the aid of countries around the world, the growing reality of the world is that countries must provide their own first line of defense. They must be able to manage, run and support their own health systems if they are to control infectious diseases. A great deal of USAID's assistance in health over the past several decades has been directed at key

elements of sustainable health systems. This is not only more cost-effective, but is an investment which bears long-lasting results.

We work to develop the capacity of host-country nationals to carry out their own training, supervision, logistics, information systems, communications, and budgetary management.

We assist in reforming health system policies and financing mechanisms to encourage collaboration between public and private sector health providers.

We work to reform national pharmaceutical policies, regulations, training, and provider and client practices to ensure appropriate (and minimize inappropriate) use of antimicrobials and other drugs and to improve the quality of pharmaceuticals that people use.

We assist health systems in applying more effective epidemiologic surveillance systems for detecting and responding to outbreaks, and health information systems for monitoring trends of disease over time and for tracking progress in targeted disease control programs.

We assist in the development of new low-cost preventive, diagnostic, and treatment technologies, and in the use of information and communications technologies to enhance health programs and health education efforts.

Ultimately, we look to leaving successful and workable health systems in place when USAID assistance has come to an end, as we have done in countries as diverse as Thailand and Costa Rica. These systems serve as the true first line of defense against infectious diseases.

Targeted prevention and control through specific focused programs tailored to individual high priority diseases

USAID's health programs also target specific infectious diseases which are the principal contributors to death and illness around the world. Of the 17 million annual infectious disease deaths, the majority are among children, and the large majority of child deaths are caused by infections. Therefore, most of our child survival efforts are specifically targeted against major infectious disease threats. These efforts have already resulted in 3 million fewer deaths per year according to UNICEF. They include:

- Diarrheal disease control, including cholera and dysenteries, all caused by infectious microbes and causing more than 3 million annual deaths and hundreds of millions of infections.
- Prevention and control of pneumonia, the cause of more than 4 million deaths each year.
- Immunizations against the major vaccine preventable diseases of childhood, especially measles, tetanus, diphtheria, and polio—diseases which cause nearly 2 million deaths.
- Prevention, control and treatment of malaria, responsible for over 2 million deaths, more than 90 percent of which are among children primarily in sub-Saharan Africa.
- Efforts within treatment programs, such as against pneumonia, to assure appropriate and full courses of antimicrobial treatment to minimize the likelihood of antibiotic resistance.
- Targeted research in testing new vaccines, technologies and treatments against the major childhood killers.

In addition to our child survival efforts, the other major targeted component of our current infectious disease efforts is directed at the prevention and control of today's most threatening and costly newly emerged infectious disease: HIV/AIDS. For the past decade, USAID has played a leading role in developing the tools needed to combat this epidemic, and in helping countries to apply these tools.

USAID also actively supports applied research on a range of infectious disease issues. These include:

- Development of more effective, safe, and less expensive vaccines, and strengthened systems for their delivery.
- Strengthening systems for early case detection; diagnostics and treatment protocols that are more effective, easy-to-use, and less expensive; behavioral research and change in key aspects of disease risk and in how families seek and access appropriate care.

Response to emergency situations

As I noted earlier, USAID was a major contributor to the emergency response to the Ebola outbreak in Zaire and played a smaller role in responding to the plague panic in India; we have played a similar role over the years in numerous emergencies around the world. However, we strongly believe that responding to emergencies should be our last recourse, not our first, and we worry that essential pre-

vention and control efforts may inadvertently be undermined by a diversion of resources to whatever has most recently appeared on CNN.

ISSUES RELATING TO MALARIA AND TUBERCULOSIS

As I have described, USAID's efforts in addressing infectious diseases over the span of several decades have been and continue to be considerable. This is not to argue that they have always been sufficient. As resources for development assistance have declined, so has our ability to mount major efforts targeted at specific infectious diseases.

I would like to highlight two important infectious disease threats which pose particular challenges to the world community: malaria and tuberculosis. Malaria kills more than 2 million people each year, principally children. Tuberculosis is responsible for more than 3 million deaths, the majority of whom are adults in their working years.

Malaria

Over the decades, USAID has devoted substantial resources to malaria control—more than \$1 billion since the 1950's. In recent years, with the considerable success of these efforts in countries of Latin America and Asia which were the principal focus of our efforts, we have moved to a more targeted approach.

Currently, we focus our malaria efforts around our child survival activities. We recognize that malaria, particularly in Africa, is a major killer of children. Indeed, approximately a third of all deaths of children under age five in Africa are related to malaria. To maximize our investment, we have focused on a few key areas.

- USAID's Malaria Vaccine Development Program (MVDP) is now focused on finding a vaccine that is effective for children in high endemic areas. We have partnered closely with the National Institutes of Health (NIH) and the Walter Reed Institute of Research (WRAIR) to maintain a substantial U.S. effort in all of the necessary stages of malaria vaccine development, and coordinate well with WHO, EU and other donors. This enables us to translate current knowledge into experimental vaccines which can be tested in humans. In fiscal year 1996, initial safety studies of a new USAID initiated experimental malaria vaccine were conducted in cooperation with other USG Agencies, and a second experimental vaccine is scheduled for testing this year.
- Last year, USAID established the Africa Integrated Malaria Initiative (AIMI) to apply the technologies now known for combating malaria. AIMI promotes a comprehensive "package" of approaches, including the first large scale, sustainable impregnated mosquito net program in Africa.
- Extensive malaria control activities take place under other USAID programs. We are the lead bilateral donor and have played an important technical leadership role in WHO's initiative for the Integrated Management of Childhood Illness (IMCI), which sets clear clinical standards for treating malaria and its complications. Our support for the development of new technologies has produced two promising diagnostic tests that health workers in the field can use to rapidly confirm malaria parasite infection in a cost-effective manner. USAID continues to train national malaria program managers, in Africa especially, in information systems and operations research.

More needs to be done, however, in terms of investments in vaccine development and testing, in efforts directed at controlling the mosquito vectors of malaria, in developing innovative new approaches in malaria prevention and in assuring that these approaches are both practical and sustainable.

Tuberculosis

TB is today reemerging as a leading infectious scourge of mankind after years of decline. USAID's principal efforts, outside childhood BCG immunization (which provides modest protection against new TB infection), have been in support of programs aimed at developing a rational approach to managing TB among people with HIV infection. Since the chance of rekindling an active case of TB rises by a factor of ten as a result of the immunosuppression that comes with HIV, we believe this is a critical area for action.

While the global need for stronger efforts directed at TB is obvious, practical solutions in the reality of most developing countries are less apparent. WHO has recommended that widescale TB control efforts not be initiated in the absence of confirmable and strong program management and oversight. The principal risk of a widespread poorly run program is the high likelihood that multi-drug resistance will develop, transforming TB into an untreatable deadly disease.

It has been our experience that health service delivery systems in developing countries are generally not well prepared to attack TB systematically and on the

scale which is required. TB experts have recognized that treatment and control of TB is among the most labor-intensive of health interventions; current protocol calls for direct health provider contact with each TB patient several times a week during the entire eight months of short course therapy.

We have found that in most of the developing world where TB is most prevalent we have had to start more or less at the foundation of building a health care delivery system before it would be appropriate or effective to launch an effective program for a nation-wide treatment of this health problem. In fact, a considerable portion of USAID's health budget, over \$27 million each year, is aimed directly at health systems development and strengthening. Without this, efforts at TB control would be futile.

While we do not "count" this health systems funding as TB-related because it has effects on the control of virtually all major public health problems, our successes in establishing improved public health systems mean that the more closely targeted TB efforts of others have a far better chance of succeeding. USAID's involvement has made an important difference.

It is clear that the resource needs of a truly global effort to address TB are enormous, in all likelihood dwarfing today's AIDS control efforts. This is unquestionably the biggest unmet need among infectious diseases today. Nonetheless, I would argue that in terms of resource prioritization, our continued emphasis on health systems development and other important and more easily addressed infectious diseases is appropriate. The former because TB control efforts will only work once operational health service delivery systems, well-managed and well-supplied, are in place. And the latter because we have proven, cost-effective technologies ready for delivery to save lives.

CONCLUSION

Is USAID doing enough to address infectious diseases around the world? Of course not—the needs are many times greater than the resources we have available to apply to them. Yet USAID devotes a greater proportion of our Development Assistance funds than ever before to health, and we do not think it would be wise to further cut back our efforts in agriculture, combating poverty and hunger, basic education, environmental protection—all, as I have mentioned, key factors in helping to prevent the spread of infectious diseases. We would urge this Committee not to cut these critical budgets below the President's request level.

We continue our efforts to meet this challenge, recognizing the greater need before us, and working to make the most efficient use of the resources the Congress has made available to us to improve both human health and the human condition in the countries of the developing world. These efforts are broader than USAID or any single agency. In June 1996, President Clinton released a policy directive that recognizes emerging infectious diseases as both a domestic and an international threat. The policy directive calls for improved international cooperation, training, surveillance, research and public awareness of these diseases. The President's directive grew out of an initiative of the National Science and Technology Committee on International Science, Engineering, and Technology, which created the report, *Infectious Disease—A Global Health Threat*. USAID has been a key participant in the Ciset initiative, and USAID's programs of prevention and cooperation are an integral part of the President's strategy to protect the health of U.S. citizens and the global community.

In giving top priority to prevention, and in helping countries to develop their own capacities to prevent and control infectious diseases, USAID continues to play an essential role in this effort, consistent with the requirements of sustainable development and the long-term interests of the American people.

STATEMENT OF GORDON DOUGLAS, M.D., PRESIDENT, MERCK VACCINES, MERCK & CO.

Senator LEAHY [presiding]. Dr. Douglas.

Dr. DOUGLAS. Senator, it is a pleasure for me to be here and have an opportunity to address this question, which is very important to me personally as well as to the company I represent, which is Merck. I am the president of the Vaccine Division at Merck & Co., Inc., and I am by background a medical doctor and a specialist in infectious diseases.

We believe that an increased effort—and I emphasize, increased—on the part of the United States to understand and con-

trol infectious diseases in developing countries is both vital to our national interest and it constitutes good public health policy as well. I think you should recognize it as not only support through the various agencies that you support, but with good policies you can enlist the help of the medical schools and universities in the United States, private industry, certain scientific and philanthropic foundations as well.

What I would like to address in my comments is what you can do to help us, and there are really two things you can do. First, you can support adequate medical infrastructure in the poorest countries in the world so that drugs and vaccines can be used—and I will come back to that in a little bit more detail—and second, create a business climate so that U.S. vaccine and drug companies can operate effectively.

I want to do this with a story from our experience with Mectizan, which has been a very successful program in public health, because we can learn something about what is possible and what are the limitations and barriers to being successful. In the 1970's we developed a drug which we refer to as Mectizan, and we developed it in a program where we were looking for remedies for parasitic diseases in large farm animals, such as horses.

It turned out that this drug was unique and was the most effective antiparasitic drug that had ever been developed to that time. And it was noticed that it was effective against a parasite in horses which closely resembled a parasite which infected humans and caused a disease which is known as river blindness, or onchocerciasis. People inside the company and outside the company persuaded the company to develop it for that use, that is for river blindness, and we began our first human trials in Senegal and realized that this disease afflicted about 20 million people in the poorest countries in the world, in the remotest regions of the world, and with either very primitive or absent health care systems.

It became obvious there was no international market for this drug and that the proper solution was to donate it for use in river blindness, and so that Merck did this. Our biggest concern immediately when we got into the issue was the lack of medical infrastructure in the countries where persons were affected with river blindness.

Now, you have to remember that this is a very, very simple regimen. One pill taken once a year is sufficient to cure this disease. It is a remarkable drug. However, in the countries which we were dealing with there was no mechanism of assuring that that could be done. One has to make a diagnosis in a patient, make sure that that is the right patient to treat. You have to persuade the patient that the drug is safe. They are not used to modern medicines. You have to get the drug to the patient. You have to make sure when patients line up that you are not treating the same person over and over again because they do not know the difference. You have to maintain records therefore. You have to assure treatment of all the patients with the disease.

These are major issues that have to be solved, and you need at least a basic medical infrastructure in place for that to happen. And finally, you have to secure funding for the distribution of the drug.

We first had to convince people at the tropical research program at the WHO that this was important. Previously they had emphasized a program of spraying for black flies. The black flies transmit this parasite from person to person. And that program faced all the problems with spraying for mosquitoes for malaria, for example, and it was doomed to failure. Our drug worked against the microfilaria, which was the organism which actually caused the disease.

The solution we came up with was to set up a Mectizan expert committee, which established criteria and reviewed applications from countries and regions from people who wanted to use the drug. And we put in charge of this Bill Fagey, the former head of the CDC, who is now the executive director of the Carter Center. With the cooperation of the Carter Center, the Mectizan expert committee, plus the donation of the drug, we have had a very, very successful program, and I am pleased to report that about 20 million people are currently under treatment and have been getting treatment repeatedly on an annual basis with this drug.

The point is that having the drug is not enough. Access to health care or at least an adequate health care infrastructure is essential for administration of either a vaccine, because remember this is a vaccine-like drug in that it requires a single medical intervention once a year in a person, those appropriate services have to be available. You have to have full cooperation with the government at all levels in the donor country.

Senator LEAHY. That is once a year as long as the person is in the area where they are at risk?

Dr. DOUGLAS. Presumably, yes.

And it is essential that this cooperative atmosphere was in place and the infrastructure was in place and the assurance the drug could be given.

Now, if you magnify this problem just a little bit and think about the example about tuberculosis that has just been described here and will be described some more, remember that in tuberculosis it is several drugs given several times a week over an extended period of time. It is a much more difficult problem.

And if you take it one step further, in the United States today with the advent of the protease inhibitors—and Merck developed one of them, Crixivan—we have changed AIDS into a disease that was life-threatening in all individuals to one that looks today as if it can be chronically medically managed, which is an enormous change. It is a very complex regimen. It is multiple pills, multiple times a day, up to eight pills per day, many given at points of dietary restriction, and making the diagnosis, monitoring therapy, monitoring for side effects, is critical to making this drug successful.

In addition, if it is not done in both tuberculosis and in AIDS, if inadequate therapy is given, it leads to the emergence of resistant strains. And it is going to happen in AIDS just as it has happened in tuberculosis, and that is a threat to people in the developed world, including the United States.

The goal in HIV therapy is to drive down the virus load with the persistent giving of multiple drugs, and if you cannot assure that then drug therapy cannot be given.

Finally, I would like to turn to my last comment, which has to do with the barriers to American vaccine and pharmaceutical companies to participating in the lower economic markets in the world. These are listed in my written—I have listed eight such barriers, such as inadequate protection of intellectual property and parallel trade in patent product medicines, government price controls, et cetera. Those are listed there. I would be happy to discuss those in more detail during the question and answer period.

PREPARED STATEMENT

I would just finally like to conclude by saying that if you can help us in these two areas, that is building up the medical infrastructure in the poorest countries in the world so that our drugs and the vaccines which we invent—what a company like Merck can do best is to discover, develop, produce, and distribute new and innovative medicines that can help solve some of these worldwide infectious diseases problems.

Thank you.

[The statement follows:]

PREPARED STATEMENT OF R. GORDON DOUGLAS

Good morning Mr. Chairman and members of the Committee. My name is Dr. Gordon Douglas.

I am a medical doctor and a specialist in infectious diseases and President of Merck Vaccines.

Merck believes that an increased effort on the part of the United States to understand and control infectious diseases in developing countries is both vital to our national interest and constitutes good public health policy.

The discovery of penicillin more than 60 years ago instilled Americans with a level of confidence in our battle against infectious diseases that no longer applies. It is all too apparent today that resistant bacteria, antiviral-resistant viruses, and “new” infections resulting from ecological changes threaten our society. Indeed, infectious diseases are an increasing cause of death in the United States.

This nation’s renewed war against infectious diseases should not fall on the shoulders of our government alone. Private industry, medical schools and other academic institutions, and scientific and philanthropic foundations can and do have a role to play. Nor should we view this as a problem exclusive to the U.S. On an international level, we should build on the solid base of experience provided through the ongoing work of the World Health Organization (WHO), the World Bank and United Nations’ Children Fund (UNICEF).

BARRIERS TO CONTROLLING INFECTIOUS DISEASES IN DEVELOPING COUNTRIES

Solutions to controlling infectious diseases include more than just direct spending by various government agencies. Providing access to comprehensive health services in developing nations presents a unique set of challenges including, poor nutrition and sanitation, lack of trained medical staff, minimal medical facilities (particularly in rural areas), lack of disease awareness, poor or non-existent medical record-keeping capability or capacity. We need a comprehensive public policy that addresses issues ranging from research initiatives to health-care delivery infrastructure, and whose implementation depends on strategic partnership efforts between government and other segments in society. A recent loan condition adopted by the World Bank is a good example of such policy. For a nation to secure World Bank resources, it must demonstrate compliance with the WHO’s Expanded Program of Immunization.

Mr. Chairman, Merck’s own involvement with infectious diseases over the last century illustrates the range of contributions that you should anticipate from the private sector as a result of our long-range commitment to better health worldwide.

First is our commitment to—and success in—the discovery and distribution of vaccines as a preventive weapon against infectious diseases. Measles, mumps, rubella, hepatitis, Haemophilus influenza type B, varicella (or chickenpox)—all can be prevented through immunization with Merck vaccines.

In our pipeline we are developing preventions against rotavirus, a potentially deadly disease for children in developing nations, and against otitis media.

Second, with our research in antibiotics, we've made major contributions in the treatment of infectious diseases. Streptomycin—which Merck discovered and developed in collaboration with scientists at Rutgers University in the 1940's—was one of the first important drugs for the treatment of tuberculosis and is still used in many parts of the world today.

LESSONS FROM THE MECTIZAN STORY

Our experience with the donation of our drug, mectizan, to prevent onchocerciasis, or river blindness, offers several key lessons for policies and programs designed to deal with infectious diseases in developing countries. River blindness is a disease that affects approximately 20 million people, mostly in sub-Saharan Africa.

During the 1970's, Merck researchers pursued the development of a new, powerful anti-parasitic compound that proved effective in the prevention of parasites in horses. While testing the drug on animals, our researchers noticed that it was effective against a parasite that resembled the one that causes river blindness.

An infectious disease doctor working in Africa who had seen, first-hand, the ravages of river blindness, championed further investigation of the potential human applications for Merck's animal drug.

Human clinical trials were begun in Senegal. But even as we proceeded with our research, it became very clear that the need for mectizan was limited to a narrow band of countries and that the communities in need of the drug are among the very poorest in the world, in the most remote areas, with only the most primitive of healthcare services available. Far from anticipating an international market, Merck recognized that the target population probably could not afford to pay for the drug at any price and decided to donate the drug.

Our biggest concern with donating mectizan was the lack of a medical infrastructure and a commitment at every level of government to get the drug to the people. Absent these, a donation was valueless. Even though mectizan involves only minimal medical care—just one pill, once a year—there was no possibility that Merck alone could establish a delivery and monitoring system that would assure the drug was used successfully. The product is relatively easy to handle, store and transport. Yet the significant challenges to delivering it and getting it administered—establishing a system of identifying potential patients, persuading them the drug was safe to take, getting the patients to the drug or the drug to the patients, maintaining records of the drug's administration and securing a source of funding to cover distribution—cannot be overstated.

Ironically, one of the major challenges involved convincing experts at the WHO's Tropical Disease Research program to make distribution of mectizan a priority. Their focus had been on eradicating the blackflies that carry the disease and killing the adult worms that cause it, whereas mectizan was particularly effective against the microfilariae, or larvae.

The solution was to create an independent committee of experts in tropical medicine—The Mectizan Expert Committee (MEC)—to establish criteria for mectizan treatment programs, and to review applications for free supplies of the medicine. This procedure allowed the orderly development of guidelines for distribution, the monitoring of any adverse reactions, and record keeping. The MEC was headed by Dr. William Foege, executive director of the Carter Center—the institution created by President Jimmy Carter to promote third-world development.

Having drugs for infectious disease is not enough, as the mectizan experience demonstrates. Access to adequate health care infrastructure and appropriate medical services, having the full cooperation, participation and commitment of all levels of government, including the activities of international agencies in the areas where river blindness occurs, has been critical to the successful use of mectizan—a drug that is relatively easy to distribute and monitor. These challenges pale in comparison to those we face in successfully tackling TB and HIV/AIDS.

Despite availability of several effective anti-TB drugs, millions of people suffer from TB worldwide. Failure to use these therapies appropriately has led to the widespread emergence of TB strains that are resistant to existing antibiotics. Furthermore, the HIV/AIDS pandemic has provided a fertile breeding ground for the spread of multi-drug resistant TB.

You are probably aware of the remarkable progress that is being made toward turning HIV infection into a chronic, manageable disease with the advent of combination drug anti-HIV therapy and the growing use of a new class of compounds, the HIV protease inhibitors. But these new drugs are extremely complicated to take.

Merck developed one of these new HIV protease inhibitors, Crixvan, after a ten-year intensive research effort. Thousands of people with HIV now are coming forward for treatment, challenging the capacity of the HIV drug budgets in the public and private sectors in the U.S. and Europe. The bigger challenge is how such therapies can be used in developing nations, which bear the burden of over 90 percent of all HIV infections worldwide.

Clearly, the challenges of HIV/AIDS treatment in these nations are magnified many times over by the requirements of a complex drug regimen—multiple doses of multiple drugs that must be taken every day, most with dietary restrictions. For example, many patients are taking eight or more different drugs every day. In addition, these patients must undergo stringent monitoring that requires regular laboratory tests. This, in turn, requires the clinical laboratory capacity to perform and evaluate these tests.

A major goal in the use of these new HIV therapies is to drive down and keep the virus at undetectable levels, but this must be done in a manner to prevent the emergence of an AIDS virus that is resistant to treatment with the new therapies. Patients must adhere to a strict schedule, for instance Crixvan must be taken every eight hours on an empty stomach or with a low-fat meal. They must have continued, uninterrupted access to therapy and must have overall comprehensive AIDS care, that is, access to drugs to treat the opportunistic infections (such as TB), and access to sophisticated laboratory tests to monitor the response to therapy. Unfortunately, relatively few places outside of the OECD countries can offer a critical mass of HIV care to benefit the patient and protect the public health from the development of drug-resistant HIV.

BARRIERS TO INTERNATIONAL PARTICIPATION

Merck annually dedicates thousands of research hours and millions of dollars toward the discovery, development and production of new vaccines and medicines targeting the prevention and treatment of infectious diseases. And we welcome the opportunity to work with this Committee, and others, to formulate public policies that will provide true benefits.

But we face some significant barriers, Mr. Chairman, barriers which are shared by other U.S. pharmaceutical and vaccine companies that want to supply developing countries. These barriers include, but are not limited to:

- Inadequate protection of intellectual property—specifically, that countries are failing to meet the Trade Related Intellectual Property Sections (TRIPS) of the GATT agreement designed to protect our patent's confidential data and trade secrets, and even to accept that TRIPS should remain in force.
- Parallel trade in patent-protected medicine also serves to undermine our property rights—property rights that fuel research and development for tomorrow's medicines. Parallel importing arises when different prices are set by governments among price-controlled markets. A wholesaler purchases drugs in a market with a low price and then resells the product in markets with a higher price, pocketing the profits.
- Government price and profit controls that limit research incentives and the revenues needed to invest in high-risk development programs.
- Black market sales that often divert products from those who need them most.
- The lack of quality assurance and the willingness to compromise on quality to achieve cost savings.
- Inadequate resources for countries to acquire effective therapies and newer vaccines which necessarily cost more than older vaccines.
- Epidemiology gaps, by which I mean inadequate data to assess the occurrence or incidence of an infectious disease in a given country.
- And finally, as explained more fully above, the lack of health system infrastructures that can support rigorous treatment regimens.

An environment enabling U.S. drug and vaccine companies to operate effectively is needed to ensure delivery of the best quality, most effective products. For the poorest countries, however, even this is not enough. These countries need more resources to carry out even minimal care programs and thus the involvement of agencies such as the WHO, the World Bank and UNICEF. Clearly vaccines, which may require only one interaction with a patient, offer much greater hope for these parts of the world than do complex treatment regimens.

Mr. Chairman, without question the issues surrounding global infectious disease warrant this Committee's attention. They are serious issues—they are growing issues—and they represent a clear threat to the United States. By promoting an environment in which U.S. industry can operate most effectively overseas, and ensur-

ing adequate funding for key international agencies, Congress maximizes America's ability to contain this threat.

I thank you for the opportunity to share these thoughts with you today and I look forward to your questions.

STRENGTHENING INFRASTRUCTURE

Senator LEAHY. Believe me, Dr. Douglas, you have a lot of people in this room on both sides of this dais who would like to see how best to strengthen that infrastructure. A lot of it comes down just to one thing, money. That is also why I made the comment I did earlier, that the nations of the world can spend hundreds of billions, even trillions, of dollars a year on defense. A lot of it may well be justified. But we have got to realize that this is part of our national security and the amounts of money that we are talking about are so infinitesimal compared to what we spend on armaments and standing armies, navies, and air forces.

You have millions, tens of millions, hundreds of millions of people traveling every day around the world, crossing borders. That is the guided missiles coming in, the viruses that travel with them.

And there is the humanitarian aspect. You mentioned river blindness. I was born blind in one eye and I know how frustrating that has been to me throughout my life. But I do not have to work at a job where I need both eyes.

When I hear about river blindness I instinctively shudder. I think of somebody who has lost both eyes in a place where they are not a U.S. Senator with a staff and everything available to them, but somebody who has got to go out and grow their crops, make their living off their land, sometimes the most difficult things. And to think that it can be easily prevented.

And river blindness is not, I would assume, going to affect us here in the United States. But if we live in the wealthiest nation history has ever known, 5 percent of the world's population using 25 percent of the world's resources, then something ought to tell us we have a moral responsibility, a very great moral responsibility to help those people.

STATEMENT OF JOHN SBARBARO, M.D., PROFESSOR OF MEDICINE AND PREVENTIVE MEDICINE, SCHOOL OF MEDICINE, UNIVERSITY OF COLORADO HEALTH SCIENCES CENTER

Senator LEAHY. Dr. Sbarbaro.

Dr. SBARBARO. Senator, you just kind of summarized everything I was going to say and I will make this very comfortable for you.

Senator LEAHY. Go ahead and say it anyway.

Dr. SBARBARO. It was really insightful.

I was asked to come up with a disease that kind of exemplified what all my colleagues, the points that they have made. The obvious answer is tuberculosis. I was thinking how best to do this, so to make it personal for everybody in this room I would kind of like you to assume that I have pulmonary active tuberculosis. And it is a bacteria, and unfortunately it is one of those bacteria that can stay alive outside the human body and it is spread basically through the air.

If you all take a deep breath. The group behind me has just breathed in one bacteria, OK. That is going to grow in their body over the next 6 to 8 weeks, spread throughout their body, and then

1 out of 20 sitting in the room right now will progress on to active pulmonary tuberculosis and share their disease with somebody else.

Now, the other ones, the 19 out of 20, are going to put that bacteria into a dormant state, but it is going to stay alive in their body. And another one, 1 out of 10, is going to develop the disease in the rest of their life and then they are going to share that with somebody else.

So if you will all just take a deep breath now. OK, got it?

Senator LEAHY. They have been holding their breath ever since you coughed. I am waiting for them to start passing out back there.

Dr. SBARBARO. This is why your wife is noticing the panic in hospitals, because this is a disease that you cannot protect yourself from. It is spread through the air. And I just do not see everybody back here wearing masks. And unfortunately, the ones that get the disease the most are those age 18 to 40, and that is the economic base of a country, and when they die, because when you get the disease prior to chemotherapy, prior to us developing any drugs, what do you think your chance of survival, guys, is? Two out of three people died within 5 years.

I mean, you want to talk about an epidemic that scared the hell out of people. Two out of three people dying within 5 years. And that is why we put them in TB sans. You did not notice them dying and they were not around.

When chemotherapy came along, drugs, the problem was all over, and we said: Good deal, that is great. Unfortunately, if you look at the rest of the world, as Barry Bloom said, you have 7 to 8 million new cases a year. You have 2 to 3 million deaths a year. You are going to have 30 in the next decade, 30 million in the next decade.

But what really bothers me is that one out of three people in the world are walking time bombs like the people just behind me, harboring live TB bugs. And we have kind of got a huge stake in this thing because, if you think about all these folks, where do you spread TB the most? In confined areas. How do we travel? In airplanes. We have international trade. We have international students. We have multinational companies. We have immigrants.

And if you will notice, in our own country a great deal of our disease comes from folks coming on in, because we have managed to control this disease, we got rid of it, and so most of our people—the good news is that most of our people under the age of 40 have never had contact with TB and are, therefore, not infected.

The bad news is that most of our people under the age of 40 have never had contact with TB, are not infected, and when somebody comes in with a drug-resistant organism because we have treated people poorly in other countries, we are now susceptible. One of our kids gets the disease, we then spread it to the rest of our kids, and what you have is a new epidemic in our country and we are back to the era of sanitariums.

So comes the question, is there a solution that can work? And yes, there is. WHO has actually come up with a program that works. As mentioned by the AID groups, it is called DOTS, directly administered therapy. And what it requires, all it requires, is that somebody watch the patient take the drugs. That means the pa-

tient has to take all the drugs and cannot take only one or the other, and if they are not there they do not take it and, therefore, you do not get drug resistance.

Now, as Dr. Douglas pointed out, what you need is a health structure. What has been unique is that they have introduced DOTS into 70 countries already and it does not require changing the health structure. What you have is primary health care workers in many of these countries, just village workers, and when they start giving medications out it actually increases their status.

What is interesting is that when people start to get well, other folks come on over to them, and suddenly you have created a health system. You have enhanced the health system of the country, not had to go and create a whole new program.

So if you take a look at what has happened in the 70 countries where they have introduced it, you have cure rates in China, India, Bangladesh, Nepal, and Peru where it has been implemented of 90 to 95 percent. That is compared to 40 percent anywhere else. In Russia where they have not done this, you have gone from 50,000 cases in 1991 to 85,000 new active cases in 1995. If you are wandering through Russia, do not breathe.

Specifically what can be done? Well, I thought about this a great deal, and WHO has started to move TB toward the top of its priority. It has got good wisdom. No. 1, I would actually encourage, ask the Senate to encourage, WHO to move TB up a little higher and to use some of their assessed moneys toward that program.

No. 2, encourage the World Bank to continue what it started to do, and that is lend money for the specific purpose of controlling TB. Why? Because it hits the economic base of the country, the folks age 18 to 40.

No. 3, we really, really need the leadership and strength of the USAID. They made TB a focus as part of AIDS. I would love to see them make TB as a focus for TB.

PREPARED STATEMENT

Finally, if we could put some of our own money into WHO's DOT program and not to go out there and treat everybody, but what has been very apparent is that WHO uses it as seed money. They go in, they start a program, it becomes very convincing to that government, and that country puts their own money into it. So I do not want to see us—I do not think we can take care of the entire world, but we can certainly use our money as seed money to make things happen.

So we have the cure. We can stop the disease, and all we need is the will, the commitment. You know, it is the old story: Pay now or pay later.

Thank you, sir.

[The statement follows:]

PREPARED STATEMENT OF JOHN SBARBARO, M.D., M.P.H.

My name is John Sbarbaro and I am M.D., M.P.H. affiliated with the University of Colorado Health Sciences Center and the medical adviser to the Global TB Education Fund. The witnesses who have come before me have told a compelling story of the threat infectious diseases pose for the United States and people around the world. Now I want to tell you the story of one infectious disease in particular—tuberculosis.

The reality of controlling tuberculosis is that the answer is not waiting in a lab. We have had a cure for tuberculosis for over forty years. We're ready to go. Controlling this deadly epidemic rests in the hands of policymakers such as yourselves.

TB is the leading infectious disease killer of adults worldwide: One out of every three people in the world today carry live TB bacteria in their body—walking time bombs—with 8 million new cases of contagious TB emerging every year. And that number is increasing.

TB kills more people than AIDS and all the other infectious diseases combined: 3 million deaths per year—hitting especially hard those between the ages of 18 and 40, which most often means income-earning parents, giving tuberculosis the morbid distinction of being the disease that creates more orphans and condemns more children to poverty than any other; and 30 million deaths will occur in the next decade from what is right now, in most cases, is still a treatable disease.

And TB constitutes a clear, present, and continuing danger to U.S. citizens for the simple reason that it is: spread through the air; fatal if not properly treated and perhaps worst of all, mistreatment accelerates the emergence of virtually untreatable drug resistant; and strains that threaten us all and raises the specter of a return to era of sanitariums.

The U.S. has a huge stake in this epidemic and must take action

The U.S. overcame its TB epidemic in the mid-fifties by combining the discovery of effective antibiotics with well directed government TB control programs. It then packed its bags and checked out of the TB control effort.

While we were able to close our nationwide collection of sanitariums, TB-related medical school curricula, funding for TB research and government programs also disappeared.

The good news is that most of our citizens under the age of 40 have had no contact with TB and therefore are not infected.

The bad news is that most of our citizens under the age of 40 have had no contact with TB and therefore are at risk of new infection in this world of increasing international travel, immigration, trade, and the growth of multi-national companies. And if we continue to let TB treatment in the epidemic countries be done poorly, the new TB infections will be caused by untreatable, drug resistant organisms.

Since we cannot prevent the disease from coming into our country, its clear that we have to control the epidemic at its source—the poorer countries of this world.

Practically speaking, it is much more cost effective in the long run to contribute to controlling TB in another country than to treat just the citizens and visitors of our country when they fall sick as a result of a TB infection acquired elsewhere.

Morally speaking—this is a disease that right now we can actually cure. Treatment is effective and of equal importance, treatment is the best prevention available today as it stops the spread of the disease. Treatment not only helps the sick individual but it protects families and the community.

This is one fight that the U.S. should lead; but to date, as a nation, we've hardly even been involved.

Today's TB epidemic is not a failure of science, it is as failure of public policy

Today's TB epidemic is not the result of a failure of science; it results from a failure of public policy. The disease can be controlled and yet more people will die this year than in any other year in history.

Years ago we found the cure for tuberculosis, but we have not focused on continuing to apply it. It is a lack of political will that has allowed TB to return and it will take the full force of political determination to bring this epidemic back into check.

In a perverse and deadly irony, the more we allow tuberculosis to spread, the more deadly the disease becomes as a result of poor and partial treatment. It is estimated that there may be as many as 50 million people infected with drug-resistant TB in the world today. Drug-resistant strains of TB are a man-made phenomena and can be prevented—they are created through public and medical malpractice which result in intermittent or ineffective TB treatment.

The U.S. is proof that tuberculosis can be managed. During the 1980's we ignored TB in this country and beginning in 1989 we experienced mini-TB epidemics in our large cities. We responded by re-building our TB control programs and our TB rates are again falling at about 6 percent a year. But we are a well organized, well funded country.

Can this be done in poor countries? The answer is a resounding yes.

A small but dynamic unit at the World Health Organization—The Global Tuberculosis Programme—has not only redirected world wide attention to TB—but has actually come up with a control strategy that works in poor countries.

Their program is simple, cost effective, doesn't require big bureaucracy and most importantly, it cures people. They call it DOTS—"directly administered treatment—short course"—similar to DOT in this country but with a simple management system which even the poorest countries can use to prove they are making progress.

The program can work in any health care system—it has been proven effective everywhere from New York City to China—but requires that the patient be directly observed whenever taking their TB drugs—thereby minimizing the potential for premature discontinuation of treatment and at the same time, leaving no chance for the development of drug resistant organisms.

This small WHO unit has already convinced 70 of the world's 216 countries to begin using this DOTS TB control strategy—these nations encompass 23 percent of the world's population, but the DOTS approach has not yet been spread to all who need it in these countries.

In New York City where the U.S. DOT program has been instituted, new TB cases have fallen 46 percent and new drug resistant cases have dropped 82 percent.

In only 4 years, in 9 TB epidemic countries, 1.2 million TB cases have been entered into the WHO DOTS programs and 85 percent of them have been cured compared to less than 40 percent cure in areas where the DOTS program is not being used.

WHO has documented a 95 percent cure rate in China where over 90,000 new infectious cases were treated with DOTS in 1995. Over 150,000 infectious cases were under DOTS treatment in 1996 and will show similarly high cure rates.

Similar cure rates have been documented in Bangladesh, Nepal, Peru and parts of Africa, and small areas in Indonesia and India, where DOTS programs are starting.

On the other hand in Russia where the DOTS program has not been implemented, the number of TB cases has grown from 50,000 in 1991 to 85,000 in 1995. I would predict that drug resistance rates in that country are also soaring as they are in Latvia and Lithuania, where the prevalence of multi-drug resistant TB is already above a terrifying 10 percent level.

Overall, sadly, and frankly inexcusably, as a result of too little being done too late by those with the money and power to act, only 10 percent of the world's population suffering from active tuberculosis is being treated with DOTS right now. While this is an enormous advance from just a few years ago, it is grossly inadequate and definitely not in U.S. national interests.

The U.S. can make a difference

The U.S. can make a difference. And not just by spending more money in the U.S. At this point in time, the U.S. is basically in control of its TB problem. It must have the same impact throughout the world or the TB problem will return to our shores.

We should insist that the World Health Organization leadership place TB control and the use of the DOTS strategy near the top of its priority list and insist that it support this priority with more of its own WHO funds.

We should urge multi-lateral institutions like the World Bank to devote at least 5 percent of their lending towards controlling infectious diseases—with an appropriate emphasis on tuberculosis—and this commitment should be at least for the next two decades. This is not an esoteric illness, it has real economic implications. Remember, TB hits the working age group—the economic base of a developing country.

We need the strength and leadership of the USAID to really focus on TB itself—not just as a complication of HIV/AIDS. USAID should be in front of good global tuberculosis control, not behind. This is something America can do that is good for the world and good for America. Not many foreign assistance programs can draw such a connection.

And, we should commit some of our own money to advance a unified worldwide TB control program by financially supporting WHO's Global TB Programme (which functions in the same way as our CDC TB Elimination Division) and by supporting the division's NGO partners—for example: the International Union Against TB.

Simply put: We need to expand the worldwide implementation of the DOTS strategy.

Finally: As has been noted by previous speakers, we are going to need funding for additional research—there's no doubt about that. But right now we already have the tools to save lives today. If we properly treat someone with TB today, they will begin getting better tomorrow and we will have prevented the disease from spreading or worse yet, mutating into a potentially incurable drug-resistant form.

What we really need is the will, the commitment, and the leadership to get the job done.

If we don't, we'll see a continuation of what presently exists—too little, too late, and too timid—and the result is an epidemic that threatens us all.

SEED MONEY

Senator LEAHY. Using it as seed money, how do you choose where to plant the seed?

Dr. SBARBARO. The country has got to be interested. You have got to convince it that, No. 1, it is a problem. And that—you know, as soon as a government realizes that even the elite are not protected—you know, I have got somebody who helps me in my home. Is that person coughing? Well then, your kids and you are at risk. It suddenly becomes very apparent that this is a disease that knows no class, it is not economically based, although it is spread in poorer areas, as Dr. Bloom pointed out. But those poor areas mingle with everybody.

They have been able to convince 70 countries to start. Once you start that, the economic advantage both to the country and the reduction in disease burden helps.

All these folks are going to bring this disease into our country. We have a real—we really have got something at stake here. To help them is to also help us, and I think that has been made by all four of my colleagues.

Senator LEAHY. So much of this is interrelated. It is caught up in everything from civil wars and the mass movement of refugees that we see in Rwanda, to a chaotic society like Nigeria today.

Earlier this morning I was speaking to a group about anti-personnel landmines, and the effort that I have been involved in and so many others have been involved in around the world, to ban antipersonnel landmines.

I recall where we used the Leahy War Victims Fund to provide prosthetics for victims of landmines in Uganda. I was there with my wife, Marcelle, Tim Rieser, and others. We were looking at people who had been injured by landmines, and my wife was helping one of the medical people with a young child, to bathe him and dress him. He was horribly crippled.

We asked the translator, what had happened? It was from polio. She was saying to me afterward: Do we not—for God's sakes, polio is so easy to get rid of. Do we not have a program? Do we not give them money? Do we not help? It turned out we did. But the people who had to administer the vaccine could not get to the village because of the landmines.

So this little boy never stepped on a landmine, but he was crippled as much as if he had.

The reason I asked the question of how you pick the seed or where do you plant the seed, is there enough stability, so that WHO or AID or anybody else can operate there?

We have this problem even here at home. My kids are growing up, just out of law school and struggling to make ends meet, like everybody else. But you just assume of course—the kid is coming along, the pediatrician says you come in at such and such a time and you get these shots, and you come in, you just do it.

But now we are finding even in our country, where there are programs and everything else, people are not doing it.

Dr. SBARBARO. To give you some hope, Senator, I have to point out we did this in New York, and if you can do it in New York you can do it anywhere. And we actually cut the rates down by 45 percent.

Senator LEAHY. Well, let us say that—we do not have all the money in the world, but let us say—well, actually we do have all the money in the world. We just do not want to spend it. [Laughter.]

But let us say we had an additional \$50 million a year for 5 years to devote to this problem. What would you do? I ask anybody in the panel who wants to answer. Do you try to wipe out one or two of the priority diseases, or do you build the infrastructure to be able to identify and contain diseases before they become epidemics? How would you use the money? Dr. Bloom?

Mr. BLOOM. I do not see those as alternatives. I think you have to do both, and you have to ask where you get the most return. I think that one of the places you get returns from is knowledge, public goods. There are programs at WHO that deal with infectious diseases that I think do an extraordinary job of not only acquiring knowledge and transmitting it to developing countries, as you heard in the TB program, but they actually show that they can work.

An example is when it was proposed that we vaccinate all the world's children, all the wise people figured that could not be done: too expensive; how are we ever going to get it out there? Well, in 1992—I can tell you what the 1992 figures were very well. Some 80 percent of the kids in the world got vaccines, and 36 percent in New York. So we can get vaccines out there and, as you know, to wipe it out in the hemisphere.

That happened because it was done in a single country and shown to work. So if it is done and done well, it has an impact, creates a competition, and other countries will want it.

WHO extra-budgetary programs, the tropical disease research program, for example, on malaria; the United Nations AIDS Program on setting up areas to test vaccines in AIDS that will be as important to us as it is to the people in those countries; the emerging infectious program of David Heymann to link surveillance centers around the world. These will provide vast knowledges, amounts of knowledge that countries can use, and then to target those that are willing to use them through AID to actually get it done.

Thank you.

Senator LEAHY. If I could just follow up on that, Dr. Bloom and maybe with Dr. Heymann. You have got an organization, WHO, and one of the ones you hear, is that you have 200 bosses—the member countries and Dr. Bloom from country A has this priority, Dr. Daulaire from country B has another priority, and on and on.

WHO tries to do everything because everybody wants you to do everything. But don't you have to do some kind of a triage? I mean, if there are six or seven diseases that cause 70 percent of the deaths, is it not better to go after those six or seven diseases, even if it means others are left out?

Of course, if you are part of the ones with that disease No. 9 or 10 that has only 5 percent, but you are in that 5 percent, that is the one most important to you. How do you do this?

Dr. HEYMANN. Thank you for that question. I think first of all, I think the number of countries that belong to WHO, essentially all countries in the world, are a reinforcing factor for such underlying activities as we are trying to develop now, which is stronger surveillance and control within countries.

What I have shown you in my briefing paper is that WHO is setting up a framework which meets the needs of countries in the north which want to contribute to the south. It sets up a framework where they can work bilaterally, and it also strengthens underlying surveillance and control activities.

Each country does have different priorities. Each country must address these priorities. But they can address them with certain generic things, as Dr. Daulaire said also, strengthening those surveillance systems and detection systems and control systems, so that the health care system is available and able to do what is necessary to fight the local priority diseases.

It is true that WHO at headquarters has a diverse program. WHO is refocusing. I am pleased to tell you that 12 percent of budget in the next biennium will be reallocated to what our executive board has said are priority programs, which includes infectious diseases.

We have tried to estimate a budget for the next 2 years of what WHO would need to set up this surveillance network, so that we would have a framework which would include the global monitoring and alert systems, the laboratories in countries, global information access electronically, national and regional strength in surveillance and control, that underlying preparedness to face, detect and face epidemic diseases and routine infectious diseases such as AIDS, diarrhea, and malaria, and finally an international preparedness that will make sure there are enough vaccines, that will make sure there are enough drugs which are necessary to take care of these programs.

We have estimated \$26 million in 2 years to set up the framework. That framework then permits USAID, the European Union, United States Task Force, the European-Japan Common Agenda on Emerging Diseases, to build within that framework bilaterally to strengthen global surveillance and national surveillance and control.

Thank you.

Senator LEAHY. Dr. Daulaire, what would you do with that \$50 million?

Dr. DAULAIRE. Well, let me answer your question in two parts, Senator Leahy. First, the issue that we have been faced with repeatedly over the past 4 years has been that the Congress has come to us with money for specific reasons—polio eradication is one example—but it has been one of these shell game procedures in which we are given the money, but that money then is removed from the rest of our budget. So my first plea would be, if we were to get \$50 million—

Senator LEAHY. Make it a real \$50 million.

Dr. DAULAIRE. Make it real, that is right. Do not just put it underneath everything else.

Second, what we have also found is that the more we get micro-managed—you have to spend it on—for instance, going back to the polio initiative, the first legislation for that stated that we could only use that money to purchase polio vaccine. With all due respect to my colleague on the left who produces vaccines, this is not where we had a comparative advantage, nor was it where the greatest need was in terms of the polio eradication effort worldwide. And we discussed it with the Congress and were able to get that lifted.

I think the key issue needs to be to focus on where we are going to have the major impact, broadly speaking, on public health. So the third part of my response would be, if you were to give me \$50,000 today personally and ask me to invest it, I would not put it all in Microsoft. Maybe I should, but I would not.

Senator LEAHY. No; you would have done that 15 years ago.

Dr. DAULAIRE. That is right.

But what I would do and what we would do at AID is to put it into a portfolio. We would be looking for some things with short-term quick returns—eradication efforts in specifically targeted diseases where we could get a quick bang for the buck. We would be putting some things into longer term payoffs, such as research, moving the technology forward. And we would be putting most of it into the application of existing technology in disease control programs.

I think that TB, as Dr. Sbarbaro has said, is really the key unresolved issue in public health in the world today. We could certainly do more in that area. We would have to do it through the strengthening of health systems and integrating it into the systems that are already there.

Senator LEAHY. Dr. Douglas, would you like to add to this?

Mr. BLOOM. Yes; I would. I think you have heard that you could do a lot in terms of building up infrastructure with a fairly small amount of money, and I think that I support what Dr. Daulaire and others have said, is that you really should not try and micro-manage this, but rather let the experts make sure that the money is going to the most important diseases and ways of handling the most important diseases, whether it is—it may well not be purchase of medication. It may be setting up a structure in which that can be used, which was my Mectizan story.

Let me give you another example of something that is needed, and that is epidemiology. That is the study of a disease in a population, whether or not it exists. We have developed, as have several other companies, a vaccine which is called a HIB, vaccine, which is now one of the routine vaccines administered to children in the United States and Western Europe. It has virtually eliminated childhood meningitis in this country in the 1990's. It is one of the medical miracles of the 1990's and you never hear about it. It is an amazing achievement.

It is not available in most of the poorer countries of the world. A study was recently done in Gambia which showed that not only was meningitis eliminated from these kids, but a significant segment of pneumonia. And if you remember Dr. Bloom's pie chart,

that acute respiratory disease in childhood is one of the three or four largest killers in the world.

We need to understand whether that problem exists worldwide. If it does, you have today a vaccine infrastructure worldwide that immunizes 80 percent of the world's kids with all the appropriate vaccines. HIB could be added to that for a very low cost to the world, or to the United States or something. We are not talking about megadollars to do that, and that would be a wonderful achievement if the epidemiological base for going forward was there. And the epidemiology could be done for a very small amount of money, and it is not being done today.

Dr. SBARBARO. Senator, I noticed you looked at me, but one aspect of a wise person is to know when he has got real expertise on his right. I am not going to second-guess Daulaire and Heymann, no way.

If you could nooge them to take care of TB a little bit more, I would sure like their expertise, though.

Senator LEAHY. I think of some of the things that happen in this country. You go and get your sprained ankle taken care of in a hospital and you end up with some kind of an infection, staph infection or something else, resistant to penicillin. I see more and more resistant infections, and I also see that we are using more and more antibiotics for a whole lot of things. They pass them out like chewing gum in some places. We add them to animal feed all over the world.

Are we creating our own monster?

Dr. SBARBARO. Yes.

Dr. DOUGLAS. Of course. Yes; we are. I will take at least a first crack at that. There is no question that the widespread use and overuse and abuse of antibiotics is one of the reasons for the emergence or the rapid emergence of resistant strains. It has happened with viruses, it has happened with bacteria. It is going to happen with the AIDS drugs. It is a natural phenomenon.

There are certain settings in which it occurs. If you inadequately treat, underdose, patients, give small doses of drugs or skip doses, that is a situation in which emergence of resistance will occur.

What is the ultimate solution? One of the ultimate solutions that everybody always jumps at is we should invent more drugs. It is harder and harder to invent new antibiotics and it is a very expensive process.

Another solution is to develop vaccines so that you do not even get these infections in the first place. The example of streptococcus pneumonia, for example, is a wonderful one. It was mentioned earlier by one of our speakers, the major cause of pneumonia. There is a vaccine for older persons which will prevent pneumococcal infection and in development for younger persons, again, a vaccine that could be used worldwide will prevent the occurrence of that infection, and then you do not have to worry about the emergence of antibiotic-resistant strains.

Dr. DAULAIRE. Let me add to that, Senator. Mistreatment and inadequate treatment are at the root of the widespread development of antibiotic resistance. Throughout the developing world today you can go to almost any street stall pharmacy and purchase almost any pharmaceutical product, certainly almost any antibiotic. The

common way in which illnesses are treated, and often it is the common cold, is with a day or two of an antibiotic, because it is readily accessible in that context and it is reasonably inexpensive. People go and they use their own money for it.

Often it is promoted and enhanced by poorly trained physicians in these countries. I have actually seen this in our own country, so it is not restricted to the developing world, where people make hip-pocket decisions on treatment. And again, a poor patient who has to shell out money for a drug, they may be able to buy a few days supply, but very often what they will do is they will save—once they are starting to feel a little bit better, and this is particularly true with TB, they will save their medicine for another time.

This is an enormous contributor. And what we have found in our programs—I cut my teeth in a field trial on treatment of childhood pneumonia. What we found is that it took real assiduous followup with patients to make sure that they took their entire course of antibiotics. That is how you both treat the disease effectively and prevent the development of antibiotic resistance among the organisms.

Senator LEAHY. Yes?

Dr. HEYMANN. Thank you, Senator.

I would just like to add that it is not only a problem in developing countries, misuse of antibiotics; in countries like the United States and Canada as well. Canada just published an article in "The Lancet," a well known medical journal, where—I cannot quote the exact figure, but between 30 and 40 percent of antibiotics were used when they should not have been used. It happens in this country as well for influenza, because a patient demands an antibiotic when he sees or she sees a physician. Physicians and others must educate the public that antibiotics are not always indicated.

I would like to just address also the issue of antibiotic resistance in animals, because this is an issue which must be studied more. What we do know is that antibiotics are used increasingly in animal husbandry. And if you look at a graph, for example, of salmonella in the Netherlands, an organism which causes typhoid, you can see it is a normal inhabitant in certain animals, and you can see that resistance to antibiotics is increasing in those animals.

If you look at resistance of the same organisms in the human population, there is a parallel increase in resistance. Now, these are not necessarily linked, but they are circumstantial evidence that there is a parallel increase in resistance in both animals and in humans which are infected with organisms which also infect animals. Now, bacteria have a means of transferring resistance from one to another outside a human body. So this may be occurring in the environment or it may be occurring within animals and then transferred to humans.

But there is a parallel increase in the Netherlands which shows clearly the same trend in human and animal infections of one organism.

Senator LEAHY. What about, you talk about a global system for surveillance and control. If that had been in place, 15 or 20 years ago, would we have identified an AIDS epidemic, No. 1? No. 2, is it conceivable that it could have been isolated?

Dr. HEYMANN. I would like to take a crack at that, Senator. In the first ebola outbreak in 1976 in Zaire, specimens were collected from villages around the outbreak site, many, many blood specimens. These were stored at CDC. Some 10 years later when there was a test for HIV and when HIV had been recognized, because in 1976 it was not yet recognized, but 10 years later those bloods were screened for HIV, and already they had a level of HIV of 1 percent of HIV in 1976.

AIDS was a rural disease in Africa which was not spreading. We know it did not spread greatly because 10 years later in 1986 when those bloods were screened that had been collected in 1976, bloods were also collected again from those same villages. HIV remained 1 percent.

What happened to HIV was, it was not recognized in rural areas of Zaire or other places where it was occurring. It got into major metropolitan areas, where behavior encouraged an amplification of that disease, and the disease amplified and spread worldwide.

If there had been systems which could have detected something unusual even in 1 percent of the population in 1976, we may have been able to understand that there was a disease which was present, which maybe was present, many, many years before that and which could be contained. So I think the answer is strong surveillance systems in countries can help to identify diseases early and permit a response and possibly containment where they are occurring.

Dr. DAULAIRE. Let me add, Senator, there is no question but that early identification would have had a considerable impact on the dynamics of the HIV-AIDS pandemic. I also very much doubt that we could have contained it at that point. By the time that HIV began its incursions into Asia, we knew about the disease very well. We had good tracking mechanisms, and that has certainly helped to slow its spread, although Asia is today the site of the largest number of new infections of HIV per year in the world, surpassing Africa.

What we could have done by an earlier detection and by a better surveillance mechanism was to change the dynamics of this epidemic, slow it and give us more time to get it under control rather than letting it get out of control, as it has.

Senator LEAHY. Let us take a situation closer to home. In September 1995 the New York Times stated, "There is a new virus attacking thousands of people less than 10 miles from our borders. Yet we greet this nearby epidemic with an eery silence." They were talking about dengue.

Then look at some other numbers I have here: Nicaragua, 35,000 cases of malaria, 17,000 cases of dengue, 2,000 cases of dengue haemorrhagic fever.

I look at cities like New Orleans or Houston, where you could replicate some of the situation that might raise that. Now, does this strike us as something where AID should put up our first line of defense, or who does? Or are we? Maybe we are?

Dr. DAULAIRE. We are in fact involved in this. I should mention, Senator Leahy, that I personally had dengue fever, if not the dengue haemorrhagic fever. It is an unpleasant thing to have, but I had a mild case.

Senator LEAHY. Somebody described it to me, they call it the broken bone.

Dr. DAULAIRE. Break-bone fever.

Senator LEAHY. Break-bone fever.

Dr. DAULAIRE. Mine did not break.

Senator LEAHY. But it felt like it did?

Dr. DAULAIRE. Oh, yes.

First of all, we have to recognize, AID actually is spending about \$1 million a year strengthening programs in Central and South America dealing with dengue fever. So yes, we do have a response.

On the other hand, is this one of the leading public health challenges in the world today? We think it probably is not. There are about 200 people—I mentioned earlier 17 million people die of infectious diseases around the world. About 200 die of dengue haemorrhagic fever in Latin America each year.

Now, that does not minimize the problem. There are hundreds of thousands who get infected annually and it has the potential to become a real problem for us as well. So our approach is to deal with environmental issues, because it is a mosquito-vector disease, and also to deal again with the health systems, because with proper case management the case fatality, the number of deaths for every 100 cases of dengue haemorrhagic fever, is less than 1 percent. So it is something that can be dealt with at the health systems level without this enormous case fatality.

Senator LEAHY. Well, let us take one that many people are more apt to get, and that is malaria. There are one-quarter of a billion people contracting it each year and a couple million people dying of malaria. I remember on a trip to Africa taking some malaria prevention medicine which had such terrible side effects that one of our pilots became suicidal, not the sort of thing you want to have happen to the pilot of your airplane. You want pilots to have a good attitude toward life and a strong sense of self-preservation, especially as they are landing at about 200 miles an hour.

My wife became sick and we realized it was the medication. She stopped the medication and was fine. I see Dr. Denis Carroll here, who works with malaria at AID.

I have seen these mosquito nets. They are insecticide-impregnated mosquito nets. I am told they cost about \$5, which for those of us in this room is nothing, but in many parts of the world you want to use it the \$5 is an enormous amount of money. Do we have a program to get these things to people who need them? Second, if we start making enough of them does the price go down? Third, are we ever going to see a vaccine for malaria? That's three questions.

I bet you are glad you are here.

Dr. CARROLL. Thank you, Senator Leahy.

Actually, I am glad I am here. And it is worth noting that particular bednet you have there comes from a program that AID has carried out in central African republic. What is worth noting about the bednet is that it is a technology which, with impregnation using insecticides for treating that netting material, the World Health Organization over the last several years has shown dramatic impact on the health and well-being of children in sub-Saharan Africa.

In large portions of the areas that have been tested, survival rates of up to 30- to 40-percent reduction in child mortality by appropriate use of the bednet. You however point out one of the real problems associated with the bednet, and that is the cost, \$5. And that is \$5 for a single net, and we do know from the studies that we have done and from our field experience that you are likely to have to deal with three or more nets per household. So you are talking about a much larger bite out of the personal income of families. And on top of that, you are talking about a recurring cost of about \$1 to \$2 a year for retreating that net with the insecticide.

So it is not free and it is not certainly an easy economic challenge to the populations. We do not have the answer right now as to how you deal with that. We are concerned about the high cost.

We are right now supporting and beginning to undertake the first large-scale voluntary use programs in Africa in two African countries right now, and we are hoping to, through these experiences, better understand how to address the issue of affordability, among other possible problems associated with it.

Senator LEAHY. This is an area where private industry could come in and help, too.

Dr. CARROLL. I can note that in these areas where we are working we have the benefit of a partnership with Bayer, which is, in much the way that Merck has made Mectizan available for purposes of the onchocerciasis control activities in Africa, Bayer is joining with us in making available the insecticides that we need in order to move forward with these trials right here.

So that we are exploring, we are testing how we can work with the private sector and how we can create appropriate private-public sector partnerships to address the issues of affordability.

Senator LEAHY. Unfortunately, I have to leave for a meeting with the President at the White House, who is then going to be in about 30 minutes up here on the Hill.

I have many more questions. I look at some of the facts that staff prepared for me in getting ready for this. They talked about after the collapse of the Soviet Union the public health system fell apart. I guess by 1995 there were 25,000 cases of diphtheria, 5,000 people died.

Diphtheria is something we have had a vaccine for, I do not know, certainly all my lifetime, I guess most of this century. So it disappears, and then you let down your guard, and, boom, it is right back there again.

ADDITIONAL COMMITTEE QUESTIONS

Could I suggest this to each of you. You could probably think of more questions than I could. If there are further items that you think we should have covered but did not here, further thoughts you have—all your statements will be part of the record—send them to me, and we will include them in the record.

We do not think of these things affecting us, but I hope that everybody who has listened today realizes there is nobody in this room who is immune from the issues we are talking about. We may be immune from river blindness as Americans, but we are not immune from many other diseases. I said before that we have a moral responsibility on river blindness.

[The following questions were not asked at the hearing, but were submitted to the Department for response subsequent to the hearing:]

QUESTIONS SUBMITTED BY SENATOR CAMPBELL

TUBERCULOSIS

Question. Rates of Tuberculosis infection are extremely high among the poor in developing countries, but the United States also has its share of cases. Wherever people are impoverished, lacking proper medical care and living in overcrowded conditions, the disease may be found.

Frighteningly, the strains of TB found today are becoming increasingly drug-resistant. Medical costs to cure tuberculosis skyrocket once resistant strains emerge. The cost of treating a TB patient in the United States can jump from several thousand dollars for outpatient treatment to \$250,000 to treat multi-drug resistant TB.

(A) In what ways can we seek to ensure that U.S. foreign aid funding used to fight tuberculosis is having the most on-the-ground impact in the countries with high incidence of TB?

Answer. USAID has sought to ensure that the funds available for tuberculosis programs are used most effectively. The majority of funds (\$7.5 million) have been allocated to purchase infant BCG vaccine (Bacillus-Calmette-Guerin), which minimizes the complications and shortens the course of pediatric tuberculosis. USAID has also supported operations research and evaluations of national TB control programs to determine the most cost-effective methods to accurately diagnose and treat patients. This research has helped to identify a broad range of health providers (in addition to hospital-based physicians) who can care for patients in remote and underserved areas. USAID is also developing a CD-ROM-based interactive computer program to optimize TB case management. By increasing the number of providers capable of providing care to tuberculosis patients, standardizing and streamlining optimal training of providers, and ensuring the availability of services to those in need, USAID hopes to improve and shorten the course of treatment of TB patients, and maximize resources so that more patients can be appropriately treated.

Additionally, USAID works to maximize the on-the-ground impact of efforts to fight TB through our health systems development and strengthening programs, which represent about 9 percent of our health care budget. While we do not "count" this funding as TB-related since it impacts the control of virtually all major public health problems, our efforts in system strengthening mean that the more closely targeted TB efforts have a chance of succeeding where they otherwise would not.

IMMUNIZATIONS

Question. Immunizations are a simple and cost effective way to save children's lives—it costs as little as \$17 to immunize a child for life against measles and five other deadly diseases.

Reports indicate that the United States could save millions of dollars in treatment and prevention costs if these diseases were completely eradicated around the world. For example, the total amount of external aid needed for a five year period to eradicate polio is approximately \$130 million per year. Reports indicate the U.S. alone could save twice that much a year once the virus is eliminated.

(A) Can you talk a little about the progress that has been made in terms of vaccinating against easily preventable diseases, and how much more still needs to be done?

Answer. Globally, today, immunization rates approach 80 percent, compared with only 44 percent in 1985 when USAID launched its Child Survival Program. In many USAID-assisted countries, immunization rates are even higher. A 1995 survey in Honduras, for example, showed that 94 percent of children less than one year old were vaccinated for all immunopreventable diseases (measles, polio, DPT, and BCG) by 1993. Worldwide, an estimated three million lives of children are saved annually as a result of immunization against childhood diseases, and one half million cases of polio are avoided.

In 1994, polio was officially declared eradicated in the Western Hemisphere. USAID, the largest external donor to this effort, concentrated particularly in the poorest countries such as Bolivia and Haiti where vaccination rates lagged seriously behind those across the rest of the continent. Worldwide, as coverage rates have doubled over the past decade, polio cases have been cut by two-thirds. USAID's new Polio Eradication Initiative is now focusing on sub-Saharan African and South Asia.

Since more than 100 million infants a year need immunizing, much remains to be done, particularly in Africa where immunization coverage averages under 50 percent. Although immunizations are an effective and efficient tool for saving children's lives, access to health care is still difficult for rural populations in many of the least developed countries. For example, delivering immunizations on a sustainable basis is problematic in the middle of the new Democratic Republic of the Congo. USAID is working with both public and private sector systems to strengthen immunization systems and their outreach in such situations. Certification of a "polio free" developing world (notably Africa) is especially challenging. With that in mind, we need to be prudent in anticipating the "eradication" or "elimination" of other diseases, such as measles.

(B) How can we best ensure that our investment results in programs which reach poor people in their communities and programs with the highest possible impact? What are your views on current ways to measure the impact of these programs on-the-ground to be sure we are investing wisely and effectively?

Answer. USAID has focused its efforts on reaching the poor in developing countries. We work with grassroots organizations such as NGO's to deliver rural services. We work with governments on policy reform to shift resources and attention to basic care and prevention. We work with our donor colleagues to help build systems which reach the poor, strengthen management and referral capabilities, and which help assure sustainability.

USAID promotes impact monitoring and evaluation in all of its projects. We work with host country governments and NGO's to develop monitoring and evaluation systems designed to track indicators at the grassroots level, such as children immunized, persons receiving "quality care," women understanding how to recognize infection, and people knowing when to immunize their children.

(C) One hundred million infants per year need immunizations. Can you tell me a little about the progress made in vaccine self-sufficiency on the part of developing countries?

Answer. Significant improvement has taken place in the number of countries that are now paying for all or part of their vaccines. At least 20 developing countries are now paying their entire vaccine bill. Fifteen more pay more than half of their own vaccine costs. But in many of the least developed countries, host country resources cover only 5 to 25 percent of the costs of their total vaccine needs.

To promote vaccine self-sufficiency, USAID is working with host countries to strengthen their capabilities to (1) issue tenders to procure vaccines competitively on the international market; (2) regulate vaccine quality at the national level; (3) improve vaccine handling and delivery; (4) improve and introduce more efficient schedules for vaccination; and (5) reduce vaccine wastage. This strategy—which focuses on strengthening the capacity of local governments and non-governmental organizations—is one of the main reasons for the continued high immunization coverage levels in most developing countries since 1990.

Vaccine self-sufficiency is, however, a multi-faceted goal. USAID has directly promoted vaccine self-sufficiency by helping host countries develop strategies for reducing waste and inefficiency. For example:

- In Krygystan, changes in vaccination guidelines and practices between 1995 and 1996 reduced wastage of DPT vaccine by almost 50 percent;

- Introduction of vaccine vial monitors, which indicate whether vaccines exposed to excessive heat and therefore possibly damaged are still effective, have helped to reduce wastage of oral polio vaccine by up to 30 percent, saving an estimated \$10 million a year globally;

Implementation of improved schedules for immunization in the five Central Asian Republics is estimated to save \$1 million a year.

VITAMIN AND MINERAL DEFICIENCIES

Question. Deficiencies in essential vitamins and minerals can lead to blindness, mental retardation, physical deformities and even death. Yet treatment of these deficiencies can be simple and inexpensive.

(A) Among the most cost-efficient interventions available is the administration of vitamin A, either orally or through fortified foods. Can you tell me more about efforts underway in this endeavor? How can we help to ensure that the limited foreign aid funding for vitamin A programs is actually used as appropriated?

Answer. USAID is spending more than \$20 million annually on interventions to address micronutrient deficiencies in populations in need. More than one-half of the Agency's sub-earmark for micronutrients is spent to reduce vitamin A deficiency.

USAID-supported research was key in proving that vitamin A improves child survival dramatically, by 20 to 30 per cent in deficient populations. USAID has agreed

to “push the envelope for vitamin A delivery to children in need.” Over the next five to seven years, we will focus our efforts in three to four countries where vitamin A deficiency is a problem and where we believe that U.S. government resources can make a real difference to child survival. We will also coordinate with our bilateral and multilateral donor colleagues to promote and deliver vitamin A to vulnerable populations.

We are presently helping to fortify foodstuffs in Bolivia (sugar), Guatemala (sugar), El Salvador (sugar), Sri Lanka (flour), and anticipate supporting future fortification efforts in Zambia and the Philippines. These activities will dramatically improve vitamin A sufficiency in needy populations and are expected to improve child survival dramatically.

Use of Funding: By working with public and private sector entities on fortification efforts, we are helping to create an internal market which will improve distribution and limit inappropriate use of U.S. government resources. Public-private partnerships, which are built on the local economy and focus on creating local demand, are self-sustaining. Vitamin A fortification, along with iron and iodine fortification of foods can help to foster widely sustainable ways of reducing micronutrient deficiencies.

(B) What types of efforts are underway to add vitamin A to foods that are regularly traded to the developing world?

Answer. At present, USAID is not exploring efforts to fortify foods that are traded to the developing world. Our approach is to focus on locally produced foods and add fortificants appropriately so they will be routinely consumed by the local population, and thus be a more sustainable effort.

AIDS/HIV

Question. AIDS/HIV is one of the most frightening of the new diseases encountered in the last 20 years. The rate of infection among developing countries is staggering; everyday more than 6,000 new people are infected, half of whom are adolescents. The disease is rapidly spreading to the heterosexual population, with new infections concentrated in 15 to 25 year olds.

(A) What is the best way for the U.S. to efficiently utilize global AIDS funding to prevent the further spread of this terrible virus, both at home and abroad?

Answer. USAID, working closely with host country governments, indigenous NGO's, the private sector, and the international donor community, has been the world's leader in developing state-of-the-art prevention interventions, and is the world's largest donor to this effort. In the past year, USAID, in collaboration with its partners, has redesigned its portfolio to respond to the growing and changing worldwide epidemic. This has resulted in an expanded strategy which will incorporate successful programs developed over the past several years, as well as strategies which address new and developing aspects of the epidemic such as the surging tuberculosis, childhood mortality and orphan rates. This expanded response will focus on:

- (1) Field support to missions (technical assistance, training, materials production, support of communication campaigns and delivery of STI clinical services) to implement interventions which reduce sexually transmitted infections and high risk behaviors.
- (2) Field support to missions to implement condom distribution interventions for HIV/AIDS prevention and control.
- (3) Identification, refinement, and improvement of “best practices” through operations research, field testing of program interventions, and the review of scientific studies and publications.
- (4) Field support in the design, monitoring, and evaluating of programs; collection and dissemination of technical lessons learned to field missions, cooperating agencies, governments and international donors to ensure the understanding and use of successful strategies.

USAID will also support activities to establish and improve HIV/STI surveillance systems, build local PVO/NGO capacity, conduct selected biomedical research (specifically to support the development of a vaginal microbicide, inexpensive STI diagnostics, and potentially to adopt a proven vaccine for use in resource-poor settings). We will also provide technical assistance and operations research to assist Missions in the development of rational, strategically sound basic care alternatives for HIV infected persons and support for the survivors which would enhance their prevention goal, promote policy dialogue, and support UNAIDS and the six cosponsoring agencies of the United Nations.

To maximize the impact of these primary prevention interventions, USAID's revised strategic approach will insure that:

- (1) the most appropriate countries, settings, and vulnerable populations are reached;
- (2) the number of beneficiaries of behavior change and STI interventions is increased;
- (3) programs focus more closely on how to renew and refresh behavior change interventions to maintain long term behavior change for safer sex practices;
- (4) partners at country level (mainly indigenous NGO and CBO's who perform the bulk of the most effective interventions) collaborate closely to increase technical and management capacity, and ultimately achieve autonomy and long term sustainability.

(B) What measures have been shown to be most effective and cost-efficient in educating people and preventing the spread of HIV in developing countries?

Answer. More than 70 percent of HIV transmission is through heterosexual contact. USAID's strategy, therefore, focusses primarily on preventing sexual transmission. Over the past five years, the effectiveness of the three primary interventions to reduce sexual transmission, cited below, has been dramatically proven:

- (1) Reducing the prevalence of other sexually transmitted infections. In Tanzania and Malawi, studies have documented a 42-percent decrease in new HIV infections after the implementation of proper clinical management of sexually transmitted infections.
- (2) Increasing the distribution of condoms. In Thailand, increasing the use of condoms in commercial sex establishments has led to a decrease in HIV prevalence from 3.6 percent in 1993 to 2.5 percent in 1995 (a 30-percent drop).
- (3) Changing high risk sexual behavior through behavior change communication. In Uganda, this approach has resulted in a 35-percent reduction in HIV prevalence in young women aged 15–24 through a program encouraging delayed onset of sexual activity and safer sexual practices.

Overall, since 1989, USAID-funded programs have educated over 15 million persons, trained over 150,000 persons as educators, improved STI programs in 19 countries, and distributed over 200 million condoms.

SURVEILLANCE

Question. The Institute of Medicine reported in its 1992 "Emerging Infections" report that the surveillance of diseases needs to be improved both within the U.S. and overseas. Of the 15 recommendations made in the IOM report, the first five are all related to improving disease surveillance. It also recommends that the National Institutes of Health, the Department of Defense and the Centers for Disease Control all work together toward this goal.

(A) Could you please take a moment to discuss what the U.S. currently does to monitor the outbreaks of infectious diseases abroad and what U.S. agencies are involved?

Answer. Several U.S. Government agencies are involved in surveillance, including the Department of Defense (DOD); the Department of Health and Human Services (DHHS), including the Centers for Disease Control and Prevention (CDC); the Department of State; USAID; and to a lesser degree, the U.S. Customs Service, and Departments of Agriculture and Transportation.

To focus on the major players, the Department of Defense monitors outbreaks through its own extensive system of reporting, which includes its laboratories overseas. The Department of Health and Human Services, especially through the Centers for Disease Control and Prevention, has an extensive informal network of epidemiology and laboratory connections, with reporting channels for the World Health Organization as well. USAID's Office of Foreign Disaster Assistance is also involved in surveillance as well, although primarily at a second stage; that is, in keeping up with outbreak situations, including notifications from embassies, and from its networks of emergency and disaster relief organizations.

USAID's focus in surveillance is in the development of host country capabilities in surveillance, a critical element in assuring sustainable and effective surveillance over the long run. USAID is particularly active today in supporting polio surveillance which may serve as the foundation for integrated surveillance in some African countries.

(B) What are your views on what can be done to improve monitoring capabilities and prevent a widespread epidemic?

Answer. Inadequate in-country capabilities for epidemiologic surveillance and inadequate incorporation of epidemiologic principles into health systems' operations are major hindrances to the recognition and timely control of infectious diseases, including Emerging, Reemerging and Infectious Diseases (ERID's).

Acute outbreak epidemiologic investigations are invaluable tools when they are required. At least equally important, however, but sometimes overlooked, are systems to monitor epidemiologic trends over time—for example, changing patterns of antimicrobial resistance, changing risk groups for illnesses, new population groups being affected, etc.

Health systems which lack systems to identify and monitor “usual” patterns of disease often will not be able to recognize “unusual” events or outbreaks of new problems, or changes in the patterns of previously “controlled” diseases. Therefore, health systems without routinely available and applied epidemiologic expertise, without the interest and mandate to monitor diseases and investigate outbreaks, and without budget, support-staff, and transport for epidemiologic activities will, predictably, have difficulties recognizing and containing ERID’s.

To have adequate in-country epidemiologic capabilities requires not only specialized, epidemiologically-sophisticated professional staff, but also dedication of substantial health system resources to support routine as well as “emergency” epidemiologic work.

Note: Each country needs, at the very least, a core group of well-trained epidemiologists. In smaller countries, it may be wishful thinking that the rare, trained epidemiologist(s) will be able to work full-time on epidemiology; however, it is important that this highly trained resource should be immediately available, and used, at least for urgent work on putative outbreaks.

To sustain this commitment over time (i.e., between emergencies) requires health system managers, and political leaders, to understand and accept the value of investments in epidemiologic work. Competent epidemiologic capacity cannot be established on an emergency basis in response to sudden crises. Competent epidemiologic capacity must pre-exist outbreaks. Few developing country governments judge the expenditures and efforts to maintain competent epidemiology systems to be worthwhile investments when compared to other demands. USAID plays a critical role in building this capacity through training and institutional strengthening.

In addition, a portion of USAID’s funding is made available to deal rapidly with potentially catastrophic or epidemiologically important outbreaks, ranging in scale from such circumstances as the Ebola outbreak in 1995, to recent investigations of the potentially important, resurgences of monkeypox and O’nyong-nyong fever in central Africa.

CONCLUSION OF HEARING

Senator LEAHY. So I thank all five of you or all six of you who have testified here today or who have briefed us, as Dr. Heymann has today, and thank you very much for being here.

The subcommittee will stand in recess subject to the call of the Chair.

[Whereupon, at 12:15 p.m., Thursday, May 15, the hearing was concluded, and the subcommittee was recessed, to reconvene subject to the call of the Chair.]