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GLOBAL HIV/AIDS AND SEVERE ACUTE RESPIRATORY SYNDROME (SARS)

HEARING

BEFORE A

SUBCOMMITTEE OF THE

COMMITTEE ON APPROPRIATIONS

UNITED STATES SENATE

ONE HUNDRED EIGHTH CONGRESS

FIRST SESSION

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GLOBAL HIV/AIDS AND SEVERE ACUTE RESPIRATORY SYNDROME (SARS)

TUESDAY, APRIL 8, 2003

U.S. SENATE,
SUBCOMMITTEE ON LABOR, HEALTH AND HUMAN SERVICES, AND EDUCATION, AND RELATED AGENCIES,
COMMITTEE ON APPROPRIATIONS,
Washington, DC.

The subcommittee met at 9:03 a.m., in room SD–192, Dirksen Senate Office Building, Hon. Arlen Specter (chairman) presiding.

Present: Senators Specter, Cochran, Harkin, and Murray.

OPENING STATEMENT OF SENATOR ARLEN SPECTER

Senator SPECTER. Good morning, ladies and gentlemen. The Appropriations Subcommittee on Labor, Health, Human Services, and Education will proceed.

I walked into the hearing room and saw all of the directors of the National Institutes of Health. I had a strong sense that we ought not to have called you to Capitol Hill today but ought to have left you in your research institutes to proceed with your important work. But funding is a very big part of your work. So we welcome you here.

The funding stream for the NIH has been the envy of, I think, every other federally-funded organization, which would include the Department of Defense. Nobody has had a doubling of funding over such a brief period of time. And that is in recognition of the outstanding work which NIH has done on making such unique advances on so many of the dreaded diseases.

With the funding has come, I think, a higher visibility for NIH. It is hard to give NIH higher visibility than it always has had. But I think that is true. And that has raised expectations so that the number of people who come to you and candidly who come to this subcommittee is enormous, telling us about their children's ailments principally, their ailments, their parents' ailments. And they want to know why more is not being done.

So that puts a very heavy burden on the National Institutes of Health to do more. But there is—as individuals, we have nothing, if we do not have our health. We all know that. Dr. Zerhouni is too young to really be focused on that in this point in his career.

We had added to the hearing today the age issue and brought in the Centers for Disease Control. And in their intervening time, the issue has arisen on the epidemic on SARS. The morning media is filled with the specification on that problem, as articulated yesterday by Dr. Gerberding, Dr. Fauci at another Senate hearing. We

are calling on the CDC to do more and more with less and less. I do not know how that works out mathematically. Perhaps the subcommittee can be informed today by the astute and brilliant witnesses whom we have here.

But the SARS issue is very, very pressing on the world and on the United States and more so soon on the United States. And we are asking the CDC to do a great deal on the AIDS issue. We are asking the CDC to do a great deal on homeland security. And for some inexplicable reason, there is a reduction in the CDC request by $152 million. So I am sure Dr. Gerberding can tell us how everything can be accomplished, more and more with less and less.

Our distinguished ranking member will be joining us shortly. He has been delayed. But we will proceed at this time. And our initial focus is on the AIDS issue, but we will want to talk about SARS as well. Our first witness is Dr. Julie Gerberding, Director of the Centers for Disease Control. She also serves as associate clinical professor of medicine at Emory University. Her B.A. and M.D. degrees are from Case Western, her internship, residency, and served as chief medical resident at the University of California, San Francisco, and her masters of public health at the University of California, Berkeley.

STATEMENT OF JULIE GERBERDING, M.D., M.P.H., DIRECTOR, CENTERS FOR DISEASE CONTROL AND PREVENTION, DEPARTMENT OF HEALTH AND HUMAN SERVICES

Senator SPECTER. Welcome, Dr. Gerberding. We are going to use the lights, which are 5-minute lights. More recently, I have been recounting, when talking about time limitations, about a recent memorial service held for Ambassador Annenberg. And the time limit for the speakers, including Former President Gerald Ford and Secretary of State Colin Powell and Arlen Specter and others, was set at 3 minutes. So I want you to know how generous a 5-minute allocation is.

Dr. Gerberding, if you run over, we will not flash any lights. The floor is yours.

Dr. GERBERDING. Thank you. I am really pleased to be here this morning. I think it is an honor to be able to provide this information and perspective on the important issues that are facing CDC and the Nation. But I also think it is remarkable that I am sitting here with Dr. Zerhouni from the NIH and my colleague, Dr. Fauci, and all of the other institute directors.

Secretary Thompson has put a large emphasis on trying to get better horizontal integration in HHS. And we truly are working together collaboratively as a team. So some of the things I am talking about this morning are certainly not just CDC issues. They are issues that we are working on side by side, day to day. And there are many others that we could tell you about in the future.

I am going to start by talking a little bit about SARS, the global epidemic that we are dealing with right now. The cases internationally continue to mount. We have more than 2,600 cases. In the United States as of the end of the day yesterday, we had 148 cases that were suspected. We have had no deaths in the United States. But, of course, we are concerned that we may see people with the more severe end of the spectrum of the illness.

We are working very fast and very hard at CDC to understand where this came from and where it is going to go. The leading hypothesis still is that it is caused by a corona virus, a new agent that is genetically dissimilar from the other known corona viruses that usually cause the common cold in people and more serious disease in veterinary animals and birds.

But the corona virus does appear to have a genetic sequence that is unique. We are finding it in more and more patients. We are seeing that people who are sick are developing antibodies to corona virus, which is really strong evidence that it is causing the condition. And we are releasing test results now for corona virus to the state health departments that are taking care of the suspected patients. Actually, in just a 2-week period of time from isolating the virus until the present time, we have been able to develop three potentially useful diagnostic tests that will help us a lot in understanding who really has it and how it is being transmitted.

This is a problem that in the United States is still primarily among people who have traveled to the parts of Asia where the disease is prevalent. You can see that it is a global distribution in large part because of the travelers. But we have had now five cases spread here domestically to household contacts of travelers and three cases in healthcare workers who have taken care of these patients.

We have put out a great deal of guidance. Our communication system has had more calls a day from the public than we ever did at the peak of anthrax. On some days, we have more than 1,500 calls for information and requests on this topic. So we are working very hard.

The two main things that we are doing right now to prevent transmission are, number one, alerting travelers that when they return to the United States, that they should see a doctor if they are ill within 10 days of their arrival. And second, we are alerting all clinicians that if they see a patient with an unexplained respiratory illness who has traveled to Asia or other areas where this is endemic, that they need to think about SARS and isolate the patient until they have evidence to suggest that this is not the case.

So this is a global emerging infectious disease. We see this pattern of emergence time and time again. But this one is particularly noteworthy because it does appear, at least in some cases, to spread very efficiently from person to person.

We learned our lesson with HIV infection. And if I can show the next graphic, the President in his 2004 budget made an announcement about an extremely important global HIV initiative, to really prevent HIV and to provide care and treatment to the some 40 million people internationally who have this condition. CDC has a very important role to play in this. We have $294 million in the President's 2004 request for our global AIDS programs, in particular for the maternal to child transmission prevention work that we will be doing in 14 countries, in Africa, in the Caribbean, and in Asia.

This a program to, first of all, identify mothers who are infected with HIV and to get them on drug treatment, so that their children are not infected. We have some very specific goals there and are interested in moving that along.

On the next graphic—I think we can just go to the last graphic. I could not finish testimony here without appreciating how much you, Mr. Chairman, and Senator Harkin have done to support the buildings and facilities at CDC to make all this good work possible. On this slide, this building right here is the building that is currently undergoing completion as the new bioterrorism laboratory facility where we will be able to do state-of-the-art work in the best possible, high-level containment facilities.

PREPARED STATEMENT

The building next to it is where we are now working on anthrax and SARS and some of the other emerging infectious diseases. So we really appreciate so much the support you have given. And the Secretary and the President in the 2004 budget have continued to understand how important these buildings and facilities are to us.

Thank you.

[The statement follows:]

PREPARED STATEMENT OF DR. JULIE L. GERBERDING

INTRODUCTION

Mr. Chairman, Senator Harkin, other distinguished members of the Subcommittee, I am Julie L. Gerberding, Director of the Centers for Disease Control and Prevention, and Administrator of the Agency for Toxic Substances and Disease Registry. Thank you for the opportunity to appear before you today on behalf of the Centers for Disease Control and Prevention (CDC). Our mission is to protect the health and safety of the American people through activities that range from combating global HIV/AIDS, to preparing our public health system for public health emergencies like bioterrorism, to controlling the spread of infectious diseases like severe acute respiratory syndrome (SARS). These responsibilities require an aggressive approach to leadership and management that allows CDC to balance emerging issues with our vision for safer, healthier people in every community.

GLOBAL AIDS PROGRAM

Under the leadership of the White House Office of National AIDS Policy and with other parts of HHS, and the U.S. Agency for International Development (USAID), CDC is working to implement the President's International Mother and Child HIV Prevention Initiative, announced last summer. We are also prepared to lend our assistance to support the President's Emergency Plan for AIDS Relief, announced in the State of the Union address in January. These initiatives are vitally important.

CDC is one of three HHS operating divisions actively involved in fighting AIDS worldwide. The National Institutes of Health (NIH) has a strong portfolio of basic research in the areas of HIV and tuberculosis, including vital efforts to develop a vaccine to prevent HIV infection and new treatment technologies and strategies. NIH also trains United States and foreign scientists as a critical part of its mission. HRSA, with its leadership in care and treatment and rich experience in professional education, through an interagency agreement with CDC, works internationally to train health care providers to care for people living with HIV and AIDS. CDC has engaged in international applied AIDS research and programmatic efforts since the beginning of the pandemic.

From Tanzania to Vietnam to Haiti, CDC employees are on the ground, working with Ministries of Health, nongovernmental organizations (NGO), faith-based groups, and with other U.S. government entities, such as the Department of State and the USAID, to develop country-specific solutions to the ravages of AIDS.

Under the HHS Global AIDS Program, CDC works directly with 25 countries in Africa, Asia, Latin America, and the Caribbean to prevent new infections, provide care and treatment to those already infected and develop the capacity and infrastructure needed to support these programs. We calculate that these 25 countries account for more than 90 percent of the world's AIDS burden, based on prevalence estimates released at the end of last year by the WHO and UNAIDS. Targeting our resources to those countries most in need makes sense, and allows us to achieve the greatest results for our investment. For fiscal year 2004, the budget for the Global

AIDS Program is $294 million, including $150 million for the President's International Mother and Child HIV Prevention Initiative, jointly implemented by HHS and USAID. The fiscal year 2004 Budget for CDC also includes $11 million for international applied prevention research.

The Global AIDS Program was first funded in fiscal year 2000. It builds on HHS's long and successful history of global initiatives to promote health, in areas such as immunization. As part of the global AIDS program in Thailand, CDC staff worked with the Thai government to develop a national mother-to-child HIV prevention program, the first of its kind in the developing world. As a result of this effort, testing has been implemented in all public hospitals, and it is estimated that perinatal transmission has been reduced to less than 10 percent, preventing more than 1,000 HIV infections in children each year.

Today, our highly trained physicians, epidemiologists, virologists and other laboratory scientists, and public health advisors are providing technical assistance to host-country governments and others working to prevent and control HIV/AIDS. CDC staff are often located directly in host-country Ministries of Health or their affiliated National AIDS Control Programs. Working in close proximity with public health and medical colleagues allows CDC experts to enhance their services to host-country programs. Staff are also co-located with USAID colleagues, promoting complementary programming between the two U.S. agencies.

In addition to HHS employees, the Global AIDS Program currently has nearly 400 locally employed staff, who serve in a range of capacities, from research scientists, laboratory technicians, nurses and midwives to computer specialists, statisticians, sociologists, and support staff. One of the primary goals of the Global AIDS Program is to develop in-country capacity to address HIV/AIDS. Local staff are employed to form a national cadre of trained professionals who can share their knowledge with others, developing an ever-growing cadre of trained personnel.

Great progress has been made to date. For example, CDC staff in Uganda are helping expand public health and medical information systems. Services have dramatically improved thanks to our technical and financial support. At The AIDS Support Organization, or TASO, essential program information, such as the number of male versus female patients, how many patients have active tuberculosis, how many are practicing safer sexual behaviors, and so on, is now readily available from a CDC database. With specialized training and software, local epidemiologists, public health and medical professionals can easily produce epidemiologic statistics, surveillance information and data. This improved informatics capability provides essential information to target prevention services to uninfected partners and children of HIV-infected persons and to provide needed treatment and care services to those living with HIV and AIDS.

CDC has also improved care and treatment of opportunistic infections, tuberculosis being the single most significant culprit. Worldwide, one third of AIDS deaths are due to tuberculosis. Although globally there has been significant progress with tuberculosis control efforts, current trends may be stalling, in part, due to lack of access to care and treatment of persons with HIV/AIDS. CDC's successful work with the Botswana Ministry of Health serves as an excellent model for more broadly integrating HIV and TB care and treatment. The project, labeled "BOTUSA"-for Botswana-USA, aims to develop integrated services, while supporting national tuberculosis control. It has prevented significant mortalitydeath and morbidity, including the prevention of multi-drug resistant tuberculosis, in the face of explosive HIV and TB co-epidemics. Lessons learned from this work are now being translated to other African GAP country settings.

All of this work now forms the foundation for HHS support for and involvement in the President's Emergency Plan for AIDS Relief, which is focused on 14 of the hardest-hit nations, accounting for 50 percent of all HIV infections. This five-year plan is expected to prevent seven million new infections—60 percent of the projected new infections in the targeted countries. Up to two million HIV-infected people will be treated with anti-retrovirals, and care will be provided to 10 million HIV-infected individuals and AIDS orphans. Implementation will be based on a "network model" being employed in countries such as Uganda: a layered network of central medical centers that support satellite centers and mobile units, with varying levels of medical expertise as treatment moves from urban areas to rural communities. The model will employ uniform prevention, care, and treatment protocols and prepared medication packs for ease of drug administration. It will build directly on clinics, sites, and programs established through USAID, HHS, non-governmental organizations, faith-based groups, and willing host governments.

The first stage of the unprecedented President's Emergency Relief Plan is his International Mother and Child HIV Prevention Initiative, which has already begun in the same 14 countries and is jointly implemented by HHS and USAID. CDC's

budget request for fiscal year 2004 contains $150 million to support this initiative, an increase of $110 million over the fiscal year 2003 enacted level.

HHS and USAID staff have worked with host governments and NGO's to develop preliminary country-specific plans of action that will target one million HIV-infected women annually within 5 years or less, provide them with HIV counseling and voluntary testing, essential prenatal care and support services and—most importantly—with the life-saving drugs that will help their babies be born free of HIV infection. We expect that this initiative will reduce mother-to-child HIV transmission by 40 percent among the women treated. A second goal of the initiative is to improve health care systems to provide care and treatment not only to mothers and babies, but to fathers, other children, and the broader community as well. Strengthening health care systems is essential to the success of the President's broader Emergency Relief Plan. Every day, an estimated 2,000 infants are born with HIV. Inexpensive, feasible treatments are available to save infants from this deadly infection, and appropriate care and treatment for family members can prevent them from being orphaned. Through the Mother and Child Prevention Initiative, we are working to make those treatments available in the countries where they are most needed. At the same time, we are putting into place the infrastructure that will serve as the foundation for the broader care and treatment programs envisioned in the President's Emergency Plan for AIDS Relief. We look forward to continuing to work with our United States and international partners to provide the essential training, technical assistance and financial support to governments and scientific institutions around the globe to help them help their people.

SEVERE ACUTE RESPIRATORY SYNDROME (SARS)

Just as we are committed to combating the growing epidemic of HIV/AIDS around the world, CDC is engaged in combating emerging infectious diseases, as well. Since late February 2003, CDC has provided support to WHO in the investigation of a multi-country outbreak of unexplained atypical pneumonia referred to as severe acute respiratory syndrome (SARS).

On April 4, 2003, President Bush issued an Executive Order to update the list of communicable diseases that are quarantinable, to include SARS. The Order also delegated to Secretary Thompson the authority to approve Surgeon General regulations designed to prevent introduction of communicable diseases into the United States and to approve quarantine sites selected by the Surgeon General. While we have no plans at this time to seek any use of the expanded authority, we took the step of issuing the Executive Order as a prudent precaution, so that we would be ready to meet a severe public health risk involving SARS in the event that one should develop in the future—which we are, of course, working to prevent.

On Friday, March 14, CDC activated its Emergency Operations Center (EOC) in response to reports of increasing numbers of cases of SARS in several countries. On Saturday, March 15, CDC issued an interim guidance for state and local health departments to initiate enhanced domestic surveillance for SARS; a health alert to hospitals and clinicians about SARS; and a travel advisory suggesting that persons considering nonessential travel to Hong Kong, Guangdong, or Hanoi consider postponing their travel. HHS Secretary Tommy Thompson and I conducted a telebriefing to inform the media about SARS developments.

Of the 115 reported suspected cases among U.S. residents, 109 have traveled to mainland China, Hong Kong, Singapore, or Hanoi, Vietnam, 4 had household contact with a suspected case, and 2 are healthcare workers who provided medical care to a suspected case. Cases in the United States have had relatively less severe manifestations of SARS, compared to cases reported in other countries. Forty-three of the 115 cases have been hospitalized. As of April 3, 2003, twelve remain in the hospital, and none have died.

Cases of SARS continue to be reported from around the world. The disease is still primarily limited to travelers to Hong Kong, Hanoi, Singapore, and mainland China; to health care personnel who have taken care of SARS patients; and to close contacts of SARS patients. Based on what we know to date, we believe that the major mode of transmission is through droplet spread when an infected person coughs or sneezes.

CDC is participating on teams assisting in the investigation in mainland China, Hong Kong, Taiwan, Thailand, and Vietnam. In the United States, we are conducting active surveillance and implementing preventive measures, working with numerous clinical and public health partners at state and local levels. CDC has deployed approximately 30 scientists and other public health professionals internationally and has assigned almost 300 staff in Atlanta and around the United States to work on the SARS investigation.

CDC has issued interim guidance to protect against spread of this virus for close contacts of SARS patients, including in health care settings or in the home. We have also issued interim guidance for management of exposures to SARS and for cleaning airplanes that have carried a passenger with suspected SARS. We have issued travel advisories and health alert notices, which are being distributed to people returning from China, Hong Kong, Singapore, and Vietnam. We have distributed more than 200,000 health alert notice cards to airline passengers entering the United States from these areas, alerting passengers that they may have been exposed to SARS, should monitor their health for 10 days, and if they develop fever or respiratory symptoms, they should contact a physician.

WHO is coordinating daily communication between CDC laboratory scientists and scientists from laboratories in Asia, Europe, and elsewhere to share findings, which they are posting on a secure Internet site so that they can all learn from each other's work. Our evidence and that of many of our partners indicate that a new coronavirus is the leading candidate for the cause of this infection.

Rapid and accurate communications are crucial to ensure a prompt and coordinated response to any infectious disease outbreak. In the past three weeks, CDC has held multiple teleconferences with state health officials to provide them the latest information on SARS spread, implementation of enhanced surveillance, and infection control guidelines and to solicit their input in the development of these measures and processes. Secretary Thompson and I, as well as other senior scientists and leading experts at CDC, have held numerous media telebriefings to provide updated information on SARS cases, laboratory and surveillance findings, and prevention measures. CDC is keeping its website current, with multiple postings daily providing clinical guidelines, prevention recommendations, and information for the public.

Currently, CDC is recommending that persons postpone non-essential travel to mainland China, Hong Kong, Singapore, and Hanoi, Vietnam. Persons who have traveled to affected areas and experience symptoms characteristic of SARS should contact a physician. Health care facilities and other institutional settings should implement infection control guidelines that are available on CDC's website. SARS patients should not go to work, school, or other public places until at least ten days after they are fully asymptomatic. If a SARS patient is coughing or sneezing, he should use common-sense precautions such as covering his mouth with a tissue, and, if possible and medically appropriate, wearing a surgical mask to reduce the possibility of droplet transmission to others in the household. It is very important for SARS patients and those who come in contact with them to use good hand hygiene: washing hands with soap and water or using an alcohol-based hand rub frequently and after any contact with body fluids.

For people who are living in a home with SARS patients, and who are otherwise well, there is no reason to limit activities currently. Contacts with SARS patients must be alert to the earliest symptom of a respiratory illness, including fatigue, headache or fever, and the beginnings of an upper respiratory tract infection, and they should contact a medical provider if they experience any symptoms. The experience in the United States has not demonstrated spread of SARS from household contacts into the community.

The SARS experience reinforces the need to strengthen global surveillance, to have prompt reporting, and to have this reporting linked to adequate and sophisticated diagnostic laboratory capacity. It underscores the need for strong global public health systems, robust health service infrastructures, and expertise that can be mobilized quickly across national boundaries to mirror disease movements. A strong and flexible public health infrastructure is the best defense against any disease outbreak.

BUILDINGS AND FACILITIES

Our efforts to combat SARS illustrate the critical need for a strong public health infrastructure and strong physical infrastructure at CDC. As CDC Director, I place the highest priority on rebuilding our physical infrastructure. CDC has made substantial progress on master planning efforts related to buildings and facilities for its Atlanta-based headquarters. The following examples illustrate the progress we will continue to make in fiscal year 2003 and plan for in fiscal year 2004.

ROYBAL CAMPUS/CLIFTON ROAD

The new Emerging Infectious Diseases Laboratory currently under construction is anticipated to replace 5 existing Roybal Campus lab buildings. It will feature a rapid response laboratory for bioterrorism events and other public health emergencies; additional "hot lab" space for esearching the most deadly pathogens; a new

training lab; and, other infectious disease laboratory space. We expect to occupy this key facility in mid-2005.

A new West Campus Central Utility Plant is under construction. This urgently required facility will provide utility support for the new Emerging Infectious Disease Laboratory and other facilities.

The new Scientific Communications Center will allow CDC to much more effectively and directly communicate essential scientific information to the public health community worldwide. Construction is expected to be completed in late 2004, with commissioning and occupancy completed by mid-2005.

Design for a new Headquarters and Emergency Operations Center is almost complete. This facility will house CDC's leadership in a secure location, provide secure strategic command, control and communications during emergencies, house the Agency's permanent Emergency Operations Center and bioterrorism personnel, and provide a new data center for CDC scientists.

Design for the new Transshipping Facility and Campus Infrastructure Upgrades is underway. This project is intended to provide a single point of entry for freight, mail, and packages to the Roybal campus. This project will relocate this critical function from the laboratory core to outside the security setback zone.

Detailed project planning is underway for the East Campus Lab Consolidation Project. This project consists of a new lab and lab support tower to house BioSafety Level two-third lab space, a new vivarium, a new insectary, and expanded and modernized central lab support functions.

CHAMBLEE CAMPUS

CDC owns 50 acres of property in Northeast Atlanta, approximately 8 miles from the Roybal Campus. This is the site of the infamous army barracks and wooden structures that house important environmental health and parasitology work for CDC. To date, eight huts have been bulldozed and several new structures are underway or complete. Construction for the Environmental Toxicology Lab began in 2002. We expect to occupy the building in early 2005.

CONCLUSION

I would like to reiterate my thanks for the opportunity to be here to discuss CDC's efforts to combat global HIV/AIDS and to prevent the spread of SARS, as well as our progress in updating our buildings and facilities. I would like to express my thanks to you, Mr. Chairman, and to the members of this Subcommittee, for your continued support of our activities to enhance the public's health and safety. I look forward to working with Congress to fulfill CDC's essential public health mission, and I would be happy to answer any questions you might have.

Senator SPECTER. Thank you very much, Dr. Gerberding.

I am going to yield to my distinguished colleague, Senator Harkin, for his opening statement.

Senator HARKIN. Thank you very much, Mr. Chairman. I will have some questions about SARS when we get to questions.

Senator SPECTER. Thank you very much, Senator Harkin.

STATEMENT OF HON. ELIAS ZERHOUNI, M.D., DIRECTOR, NATIONAL INSTITUTES OF HEALTH, DEPARTMENT OF HEALTH AND HUMAN SERVICES

Senator SPECTER. Dr. Zerhouni, Director of the NIH, had been the Executive Vice Dean of Johns Hopkins University School of Medicine, Chair of the Department of Radiology and Radiological Science, and Professor of Radiology and Professor of Biomedical Engineering. His M.D. is from the University of Algiers School of Medicine. And he completed his residency in diagnostic radiology at Johns Hopkins.

Dr. Zerhouni, we know your participation on this panel is brief. And we will be calling on you more extensively on the NIH portion of the hearing. But we are interested in your views on the AIDS issue and SARS issue, if you wish to proceed.

Dr. ZERHOUNI. Well, thank you, Mr. Chairman, thank you, Senator Harkin, for your support of NIH. You mentioned it. And I would like to really thank you and the committee and your leadership for accomplishing the doubling of the NIH budget. And I can assure you that all the directors and myself are committed to making sure the expectations that have been raised are met.

I would like to be very brief. NIH has worked extensively with CDC over the past 2 months on the SARS epidemics. And we have mobilized all of our resources across NIH, including resources of NHLBI in the clinical center to help and support the effort of CDC and the WHO. Dr. Fauci will go into the details of our actions.

In terms of global AIDS, we have also worked very closely with the administration and the entirety of NIH to expend our efforts in the global scene, because we believe that security for our Nation will involve our ability to develop responses the world over. SARS is one example of how quickly we can respond to emergencies when the investments underneath, the investments in research, and the investment also in bioterrorism that we have been able to make over the past 2 years in bioterrorism, the past many years in AIDS, are paying off in the absolute incredible speed with which the virus was identified and the measures that we are taking that will be expounded upon by Dr. Fauci to respond through research to the epidemics.

Senator SPECTER. Thank you very much, Dr. Zerhouni.

STATEMENT OF HON. ANTHONY S. FAUCI, M.D., DIRECTOR, NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES, NATIONAL INSTITUES OF HEALTH, DEPARTMENT OF HEALTH AND HUMAN SERVICES

Senator SPECTER. We turn now to Dr. Anthony S. Fauci. Dr. Fauci has appeared so frequently before this subcommittee in recent years that we are about to make you an honorary member of the subcommittee, Dr. Fauci.

We ask you to come to this side of the podium to give your testimony soon.

Dr. Fauci is the Director of the NIH Allergy and Infectious Disease Institute. He came to NIH in 1968, after completing his residency at the New York Hospital Cornell Medical Center. A native of Brooklyn, he received his M.D. degree from Cornell Medical College.

Thank you for joining us, Dr. Fauci. And we again look forward to your testimony.

Dr. FAUCI. Thank you very much, Mr. Chairman, Senator Harkin. It is a pleasure to be here with you again today. Before I start, I want to reiterate what Dr. Zerhouni and Dr. Gerberding said about the extraordinary collaboration and collegiality that has gone between the CDC and NIH, not only in HIV, but most recently SARS.

I also want to take this opportunity to congratulate Dr. Gerberding and her colleagues at CDC for the enormous effort that they have put into controlling this epidemic, even though it is still in its incipient phase. I think we are where we are right now because of the extraordinary work of the CDC. And I wanted to take this opportunity to mention that to you publicly.

Let me just take a few minutes to talk to you first about the international HIV/AIDS epidemic. As you can see from this poster, the epidemic is truly global with 42 million living with HIV and over 60 million having been infected. In 1984, the NIH did their first international HIV/AIDS work in Haiti. And then in 1985, in collaboration with the CDC, the very earliest collaboration, in Projet SIDA in the former Zaire.

Since that time, the international HIV/AIDS research activity has expanded enormously. As you can see from this map with the countries in red in which we have international HIV activity, we now have 85 countries with 278 international research projects, 28 training grants. Of note and importance is that although NIAID is the major player because this is an infectious disease, 15 NIH institutes are involved in this collaborative effort. So it is truly an NIH effort.

Some of the activities that have gone on in these projects are briefly outlined here. I do not have time to go through all of them. But as you can see, they cover the spectrum from community-based programs to training and infrastructure, therapeutic approaches, vaccine development, and prevention.

With regard to the prevention effort, we have efforts that are quite complementary to what is going on with the CDC with their global AIDS program. We have our prevention trials network, our vaccine trials network. And now, given the President's Emergency Plan for AIDS Relief to provide therapy, care, and prevention, we will be doing research in the arena of therapy, which we hope will inform the best way to treat individuals within the context of their own country and to build the infrastructure so that they can carry it out themselves without us. That is our ultimate goal, to create a situation where there will be a lasting infrastructure within the country. By infrastructure, I mean intellectual capital and the skills to treat individuals.

Let me quickly go on to spend a minute on SARS, which you mentioned and for which Dr. Gerberding has described the work of the CDC. This is a slide, Mr. Chairman, that I have shown on multiple occasions to this committee. And I keep adding diseases to it. It is a map of this country showing just within the last 20 years reemerging and emerging diseases. Emerging disease is a disease like HIV/AIDS, in which there is no prior experience, Reemerging is something that we have experienced over the past few years, such as West Nile Virus. It is a disease we knew about, but not in this part of the world. And now it is in this country. SARS is an example of truly an emerging new disease.

Many of these have very minor impact. You might have cases that are dozens, handfuls, that are restricted to a geographic area. Every once in a while, you have an emerging or reemerging disease that has global impact. Clearly, SARS has already graduated to that point. But as Dr. Gerberding said, we are not clear at this point in time where it is going to go, because it is truly an evolving epidemic.

Dr. Gerberding mentioned the prevailing evidence, very strong evidence, that this is a corona virus. We, as researchers at the NIH, are assuming that this is true, and I believe it is true. And

we are now performing accelerated research in order to develop the countermeasures against this particular disease.

Prior to this, there were already at least 20 NIH grantees involved in corona virus research. Because, after all, corona virus are very common groups of virus. The one we are seeing now with SARS is much different, although it falls within that class.

Then finally, this is just a brief sketch of some of the NIH research endeavors that have already started. The CDC isolated the virus, and gave it to the NIH investigators. And now we have started on everything from the basic research in understanding how this virus works, to the sequencing of the virus, to the determinations of its pathogenic capabilities. Of importance is that although the virus itself may damage the body and the lungs, there may be an immunological component, because we know that there are many viruses—not many, but at least a few—whose damage to the body is not only the virus pathogenesis, but an immune response, such as respiratory syncytial virus and measles.

The most important work right now is going on with vaccines. We took the virus that Dr. Gerberding and her colleagues gave to the NIH. We are growing it very vigorously in culture, which in some respects is quite good news, because the fact that you can grow it means that you can then go to a first generation of a vaccine, namely a killed, inactivated vaccine, which we will be putting into an animal model, I would predict, within the next few months, so that hopefully within a year or a little bit more we will have at least proved the concept in an animal model that a vaccine might be able to work. How long it will take to get a vaccine that will be useable in humans will obviously be subject to the vicissitudes of the science.

Then there is drug screening, on which we are collaborating with the CDC, and USAMRIID. Immune-based therapy, for example, taking people who have recovered from infection, isolating their immunoglobulins that have shown that they can protect or at least recover the person from SARS and using passive infusion. These protocols are now being developed at the NIH in collaboration with the CDC.

Finally, we have clinical research, which we will be conducting at the clinical center in much the same way as we did in the very early years of HIV/AIDS.

PREPARED STATEMENT

So in summary, Mr. Chairman and Senator Harkin, I provided you with briefly two cogent examples of emerging infectious diseases that have important international implications. Together with HHS and our other partners, particularly the CDC, the NIH is poised and eager to meet these domestic and international threats to the public health. And I want to close by thanking you and this committee for your vision and generosity in providing for us, over so many years, the resources to meet these critical challenges.

Thank you.

Senator SPECTER. Thank you very much, Dr. Fauci.

[The statement follows:]

PREPARED STATEMENT OF DR. ANTHONY S. FAUCI

Mr. Chairman and members of the Committee, thank you for inviting me here today to discuss two global health threats, HIV/AIDS and Severe Acute Respiratory Syndrome, or SARS. These are just two among many threats we face from emerging and re-emerging infectious diseases—which include the threat of bioterrorism. I will first discuss the international aspects of the NIH research program on HIV/AIDS. I will then outline how NIH has responded to SARS in the six weeks that have passed since this disease was first recognized. I will close with a few thoughts on how the United States can strengthen its ability to react effectively to global emerging or re-emerging disease threats.

GLOBAL HIV/AIDS

HIV, the emerging virus that causes AIDS, was identified just 20 years ago. Today, approximately 42 million people worldwide are living with HIV/AIDS. HIV/AIDS is truly a global pandemic with no end in sight. Sub-Saharan Africa is hardest hit, with more than 29 million people infected. South and South-East Asia together account for more than 6 million infected people, with 1.2 million more in Eastern Europe and Central Asia, and 1.9 million in Latin America and the Caribbean. During the past year, approximately 14,000 people worldwide were infected with HIV every day. Over the next seven years, it is projected that approximately 45 million more people will become infected. Without the implementation of effective prevention and treatment measures, it is anticipated that by the year 2020 approximately 70 million people will have died of AIDS.

The global impact of HIV/AIDS demands a global response. The President's overall budget request for AIDS research at NIH for fiscal year 2004 is $2.9 billion, of which $274.7 million will be used for research in countries other than the United States. Of course, the progress NIH makes in the arena of HIV research will benefit the entire world, whether the research is conducted in this country or abroad. However, collaborative research conducted in developing countries seriously afflicted with HIV/AIDS is highly focused on specific health issues that are most critical to the countries in question.

The NIH international HIV/AIDS research portfolio addresses a broad range of HIV-related health issues. NIH currently supports 260 international AIDS research projects in over 80 countries, as well as more than 30 clinical network sites. The NIH international HIV/AIDS research agenda includes the development of vaccines and other prevention strategies, identification of culturally appropriate social and behavioral interventions to stop transmission of HIV, testing of therapeutic approaches for HIV and common co-infections such as tuberculosis and malaria, discovery of new ways to prevent HIV transmission at birth and through breast-feeding, and basic research. All of these international AIDS research projects require the direct involvement of foreign researchers as equal partners in their design, conduct, and analysis. NIH also helps to strengthen research in resource-poor countries by training scientists, clinicians, and health care workers in research techniques, and by enhancing local laboratory, clinical, and data management capabilities. In this regard, in 1999, NIH established two large international networks for clinical HIV research. One of these, the HIV Vaccine Trials Network (HVTN) evaluates vaccines for safety and efficacy, and works to ensure that vaccine candidates are appropriate to the regions where they will be used. This network currently has sites in 13 countries and soon will be expanding. The HIV Prevention Trials Network (HPTN), which currently operates in 14 countries, evaluates the safety and efficacy of other prevention strategies, such as cost-effective drug therapies to reduce mother-to-infant transmission, behavioral interventions to help prevent sexual transmission of HIV, prevention and control of sexually transmitted diseases that increase the probability of HIV transmission, and topical microbicides that provide a chemical barrier to transmission. In addition to these two major international efforts, other NIH-supported clinical HIV research networks also are being expanded internationally, and are working in close collaboration with the HPTN and the HVTN

As another example of our global outreach, NIAID in 2001 launched an innovative program called the Comprehensive International Program of Research on AIDS (CIPRA) to help investigators in developing countries carry out comprehensive, long-term HIV/AIDS research tailored to the needs of the local population. In order to be eligible, researchers must conduct the work in a country with a per capita income less than $5,000. CIPRA is specifically structured to allow applicants to build comprehensive, multidisciplinary projects from the ground up. The program initially helps these scientists to plan a research program, establish collaborations, and build administrative and research infrastructure. As their research capacity grows, they can seek additional CIPRA funding. CIPRA now has three multidisciplinary re-

search projects—one in Beijing, China, and two in South Africa. Planning and organizational grants have been awarded in Trinidad and Tobago, Peru, Zambia, Russia, and Vietnam, among other countries.

The single most important tool that is needed to fight this epidemic is an effective vaccine. One of the most serious obstacles that vaccine developers face is the ability of HIV to rapidly mutate, which leads to a great deal of heterogeneity in the virus. Thus, a vaccine that might work in a part of the world where one form of the virus predominates would not necessarily work in another region. NIAID recently has developed a candidate HIV vaccine that addresses this problem directly. The candidate is designed to induce antibodies that can bind to proteins from the three most prevalent HIV subtypes, or "clades." It is hoped that this new vaccine candidate will provide broad protection against all three of these subtypes, which together are responsible for approximately 90 percent of HIV infections worldwide. A pilot safety trial of this vaccine already is under way, and expanded tests conducted through NIAID's HVTN are planned for several U.S. sites, as well as sites in Haiti and South Africa. Many other vaccine candidates are in various stages of clinical development.

In addition to vaccines, we are pursuing many other strategies to prevent HIV transmission. Some of these have begun to produce results. For example, a pivotal NIH-supported study conducted in Uganda demonstrated that a single dose of the drug nevirapine given to an HIV-infected woman at the onset of labor, combined with a single dose for the infant just after birth, was 50 percent more effective in preventing transmission to the baby than was a short course of the drug AZT. Research is now underway to determine if the use of nevirapine or other drugs can prevent transmission through breastfeeding, a major mode of mother-to-infant transmission. Other HIV prevention strategies include development of effective chemical and physical barrier methods, research on the use of these methods among different populations, and a study of how antiretroviral therapy might prevent transmission by reducing how much virus a patient sheds in their genital track or in breast milk.

In the United States and other western countries, potent combinations of anti-HIV drugs (highly active antiretroviral therapy, or "HAART") have dramatically reduced the numbers of new AIDS cases and deaths due to HIV/AIDS. Meanwhile, the toll of AIDS has accelerated elsewhere in the world, especially in poor countries where expensive HAART regimens are beyond the reach of all but a privileged few. Fortunately, this disparity in access to life-saving medications may be changing. Building on the research infrastructure that NIH has helped establish in Africa and elsewhere in the developing world, we are actively working with our international colleagues to link the provision of anti-HIV therapies to efforts in prevention research, with the goal of facilitating a comprehensive approach to the AIDS pandemic in poor countries. Implementation of this strategy will be considerably enhanced by the recently announced President's Emergency Plan for AIDS Relief, which will create an opportunity for us to address important operational research questions within the context of the treatment, prevention and care components of the President's Plan.

The development of research infrastructure in the resource-poor countries with whom we collaborate is critical to the NIH mission in NIH international HIV/AIDS research. Specific international needs include the establishment of representative and stable groups of volunteers for safety and efficacy studies, as well as increasing the number of workers trained in basic, clinical and behavioral research, data management, and clinical bioethics. NIH international programs, such as the Fogarty International Center's AIDS International Training and Research Program, provide traineeships at U.S. academic and medical schools. In-country training also is provided in many host nations through these programs. A new initiative recently was launched to provide foreign researchers who have been trained in the United States with pilot funds upon their return to their own country in order to ensure their continued capability to conduct AIDS research and continue collaborations with their U.S. counterparts. Another new initiative is the targeting of training in the area of clinical operational health services research on AIDS and tuberculosis. All of these examples underscore our belief that the best way to meet the global pandemic of HIV/AIDS is through global outreach and collaboration.

SARS

The world currently is facing a new, evolving and potentially very serious infectious disease threat—the Severe Acute Respiratory Syndrome or SARS. Only six weeks have passed since SARS was first recognized but it already has become a worldwide health emergency, with quarantines, travel disruptions, widespread fear, and the threat of serious economic damage. As of April 5, 2003, the World Health

Organization (WHO) had reported more than 2,400 SARS cases in 18 countries, including 89 deaths. In the United States, 115 suspected cases in 28 states had been reported to the Centers for Disease Control and Prevention (CDC) as of that date. Since the epidemic is still evolving, it is impossible at this time to predict its ultimate outcome this year or its potential in future years. However, an effective response to this threat must involve both public heath measures and biomedical research.

As a result of the work of the CDC and WHO, as well as NIH and other organizations around the world, scientific progress on SARS has been swift and impressive. Research led by CDC strongly implicates as the cause of SARS a new coronavirus that may have recently crossed species from an animal to humans. The suspect virus has been grown in the laboratory in cell culture, its genetic sequence has been determined, and that sequence has been used to help develop a specific diagnostic test.

NIAID is the NIH institute with primary responsibility for research on emerging infectious diseases. In the short time since SARS came to the attention of the world, NIAID has made significant contributions, many of which were facilitated by the flexibility of NIAID biodefense efforts to include work on emerging acute viral diseases. It is clear that naturally emerging infectious diseases can be no less a threat to global health than the deliberately released microbes of a bioterror attack. NIAID efforts related to SARS include the following:

Surveillance and epidemiology.—NIAID supports a research team in Hong Kong dedicated to the surveillance of emerging infectious, especially influenza viruses. This group also has identified a coronavirus in association with SARS and has been complementary to the CDC's efforts. In addition, at the request of WHO, NIAID assigned a staff epidemiologist to provide epidemiological and logistical assistance in Geneva during the early stages of the SARS epidemic.

Vaccine Research.—NIAID's intramural research laboratories, including the Vaccine Research Center, are already working to develop a vaccine to prevent the disease. Of note, researchers in the NIAID Laboratory of Infectious Diseases are now actively growing the SARS coronavirus in tissue culture for the purpose of developing a vaccine. Furthermore, NIAID is collaborating with CDC, FDA, the United States Army Medical Research Institute of Infectious Diseases (USAMRIID), and other agencies to develop strategies for SARS coronavirus vaccine development. NIAID also is consulting with companies and other organizations that have reagents, cell lines, animal models, and other technologies relevant to vaccine development.

Therapeutics Research.—NIAID responded rapidly to a request from CDC to evaluate candidate antiviral therapeutic agents through a collaborative antiviral drug-screening project at USAMRIID. NIAID also has initiated discussions with pharmaceutical companies on candidate antiviral drugs, and is reviewing a proposal for a clinical trial of antiviral therapy to be conducted by members of the Institute's Collaborative Antiviral Study Group and the NIH Clinical Center. Furthermore, NIAID-supported researchers at Utah State University will evaluate the efficacy of existing antiviral drugs against SARS using a cell-culture system and similar coronaviruses that infect the human respiratory tract, but do not cause disease.

Clinical Research.—In collaboration with the CDC, NIAID is prepared to accept patients with SARS for evaluation and treatment at the NIH Clinical Center. Moreover, NIAID-funded extramural research laboratories, such as the Respiratory Pathogens Research Unit at the Baylor College of Medicine in Houston, have molecular and cell-based diagnostic tests for known coronaviruses. The already planned expansion of these laboratories in 2003 will increase our capacity to address emerging acute viral diseases, such as SARS. NIAID also will support clinical trials of candidate vaccines and drugs that are active against coronaviruses as they become available.

Basic Research.—NIAID has a long-standing interest and involvement in basic research on coronaviruses (see above) and currently funds 18 projects in this area; we plan to expand this effort in response to the recent outbreak. Also, the study of SARS patients, as well as patient laboratory specimens in NIAID laboratories, will be important in illuminating the natural history of the SARS agent, its potential animal reservoir, its pathogenic mechanisms and its basic biology. These studies will in turn help to identify targets for antiviral drugs, diagnostic tests, and vaccines.

Other Activities.—NIAID, together with the NIH Clinical Center staff, are collaborating with CDC on technical approaches to confirming the identity of the new virus, as well as the clinical management and care of SARS patients.

BUILDING RESPONSE CAPABILITY

SARS is only the latest in a long series of emerging and re-emerging infectious diseases to confront us. We can be quite certain it will not be the last. In order to meet these challenges successfully in the future, we need a vigorous research program in infectious diseases supported by a robust national research infrastructure—including strong scientific expertise. Because basic research findings contribute to the development of better tools to identify and interdict microbial threats, we need our research program to be well integrated with public health surveillance and response systems. In order to accomplish these ends, NIAID works constantly to strengthen our basic and applied research programs on the many host, pathogen, and environmental factors that influence disease emergence, while supporting the development of diagnostics, vaccines, and therapies necessary to detect and control diseases as they appear.

It is important to make two specific points concerning how we can strengthen our ability to respond to emerging infectious disease threats.

First, these threats are global, and modern air travel has effectively made the world considerably smaller than it once was. It is therefore essential that we work collaboratively with scientists in other countries, particularly in developing countries where the burden of emerging infectious diseases has an extraordinary impact. NIAID funds research on emerging and global infectious disease threats in 120 countries around the world, and works through the NIH Fogarty International Center to carry out training and research programs to enhance the skills of scientists in developing countries. Support for this kind of international effort is a productive investment that will greatly improve our chances of meeting emerging threats quickly.

Second, research on many diseases must be conducted in specialized containment facilities to obviate the threat to laboratory personnel and nearby communities. NIAID has established a comprehensive plan for building the needed facilities. This plan calls for a national network consisting of several Regional Centers of Excellence for Biodefense and Emerging Diseases Research, one to two National Biocontainment Laboratories with BSL-4 capability, and eight or nine Regional Biocontainment Laboratories, rated at the BSL-3 level. NIAID also plans to expand BSL-3 and BSL-4 capacity within its own facilities, both on the NIH campus in Bethesda and at the Rocky Mountain Laboratory facility in Montana. Together, these facilities will provide state-of-the-art laboratory space to support biodefense and emerging disease research, and will allow for a greater "surge" research capacity in the event of an unanticipated public health threat.

CONCLUSION

After the emergence of SARS, HIV/AIDS, West Nile Virus, drug resistant bacteria and other infectious disease threats—including bioterrorism—it is clear that emerging or re-emerging infectious diseases pose serious threats to global public health and security. At NIAID, we accept the challenges that countering these threats pose, and are committed to basic and applied research to strengthen the nation's ability to cope with both known infectious diseases and those that will inevitably emerge in the future.

Thank you for the opportunity to testify. I would be happy to answer any questions you may have.

Senator SPECTER. Dr. Gerberding, you were quoted in the morning press as saying that the main reason for the low death rate in the United States is probably that we have a much broader case definition in this country. What do you mean by a much broader case definition? And had there been a different definition, would there be a difference in reporting death cases in the United States?

Dr. GERBERDING. You know, the syndrome, Severe Acute Respiratory Disease, has been defined as the pneumonia that is caused by this virus. But we know that there is a spectrum of illness. And some people who have the infection do not progress to that very severe form where they have to be hospitalized and often ventilated.

So our goal was to first of all understand all of the people who were carrying it and contain the spread from those people. In order to do that, we needed to not just count the sickest ones, but we needed to find anybody who had traveled to this part of the country

and had a fever and unexplained respiratory illness. So we have included in our 148 people folks who have traveled to Asia and have a fever and a mild cough or other respiratory illness, but do not meet the full syndrome of the severe pneumonia.

We did this very purposefully so that we would have the broadest net and capture the most people that needed to be isolated to protect others. But we know that we have some people on this list who probably do not have SARS at all. And obviously, by definition, they are less sick than the people that are being reported by WHO. On the WHO list, the World Health Organization is listing the people who have the severe pneumonia. So that is——

Senator SPECTER. For people who might be concerned that they might have SARS, give us a statement as to what the symptoms are, what people should be looking out for, if they find certain symptoms that they note about themselves.

Dr. GERBERDING. The most important question is, have you traveled to Asia, to the parts of the world where this disease is spreading? The second question is, have you had contact with somebody who has traveled there or who is known to have SARS in the last 10 days? If the answer to either of those——

Senator SPECTER. When you say 10 days, if it were a different period of time, would there be a different conclusion as to exposure?

Dr. GERBERDING. Thank you. Yes. We think the incubation period is somewhere between 2 and 10 days, possibly 10 to 12 days. So if you have not come down with the illness within, say, 10 days of your travel, you do not have it.

Senator SPECTER. So you either get it within that period or you have not.

Dr. GERBERDING. Right. If you are outside of that period, you can relax. So if you have been exposed and you have a fever or you develop the stuffy nose, headache, tiredness, fatigue syndrome that we see with early virus infections, and especially if you develop a cough or difficulty breathing or shortness of breath, then you should be concerned. Ten days of exposure and any kind of fever plus respiratory symptoms is a strong indication that you need to contact your clinician and get evaluation.

Senator SPECTER. The morning press cites the health officials as expressing a dual view as to uncertainty about whether the epidemic was coming under control or would continue to spread. Is there any reason to think that this epidemic is coming under control?

Dr. GERBERDING. When you look at the global map and you see that the virus is already in so many countries, it means that the public health systems in all of those countries would have to implement effective containment measures. Here in the United States so far, our system has risen to the occasion. And we have been doing a good job of preventing spread.

But in Hong Kong and probably in China, virus has already spread in the population. It is going to be very difficult to contain it.

Senator SPECTER. How have we in the United States done a good job in containing the spread?

Dr. GERBERDING. We have done two things. First of all, we have alerted incoming travelers. And I can give you a copy of this. This is a card that everybody arriving from Asia gets that says if you develop any illness within 10 days of arrival, you need to get to your clinician. So we are trying to put the word out widely among all travelers to that area, that they could potentially have been exposed.

The second thing we are doing is alerting all clinicians. On Friday, we had a satellite broadcast, an international live broadcast, that included CDC experts, WHO experts, and doctors in Asia all talking about SARS to get clinicians educated, to think about this illness when they see a traveler coming in with a respiratory illness, and to act very quickly to isolate them so they do not spread the infection to others.

Senator SPECTER. My red light is on. So let me just ask you one final question. Dr. Heymann, David L. Heymann was quoted as saying we have to be ready for the worst. Dr. Gerberding, what is the worst?

Dr. GERBERDING. The worst case scenario that I can imagine would be a global pandemic of this illness, which means that it would be spreading in the communities in all of the countries of the world. We know we are dealing with a virus that can be transmitted extremely efficiently from person to person. Some people we call super transmitters look like they are especially contagious.

So the worst case scenario would be that we would have rapid spread throughout the world before we get the NIH vaccine or before we get antiviral therapy to treat people. I do not think that is going to happen. But we are looking at that as the worst case. And we are doing the things that we need to be doing now as fast as we can do them to try to prevent that.

Senator SPECTER. Senator Harkin.

Senator HARKIN. Thank you very much, Mr. Chairman.

Can I go back a step? Dr. Fauci, one question that I was asked this weekend was—they heard about SARS. And they said, "Well, where did it come from?" And I said, "Well, China." No, that was not what they meant. The question they were asking me was, how do these new viruses develop? I mean, how does something like this happen? Do they mutate or what? And I said, "Well, I will ask the guy who knows."

Dr. FAUCI. It is not at all an uncommon phenomena that diseases that ultimately infect man are diseases that jump species from an animal to a man. And when they jump species, they have a relatively naive host, at least for the period of time until the civilization or the population gets used to it. We have not yet definitively proven that that has happened. But it is highly likely. There are three known groups of corona viruses. Two infect humans, and one is a veterinary type of a virus, which we call zoonotic. It infects fowl. It infects pigs. It infects dogs and cats. It is likely, and we will know that when the full sequencing can be matched, that that is exactly what happened.

We have seen that with HIV/AIDS from chimpanzees to man. We see that with influenza that goes generally from fowl and pigs to man. It would not at all be an unusual situation.

Now two things can happen, Senator Harkin, when something jumps species. We saw that with the H5N1 in Hong Kong a few years ago and most recently where it goes from an animal to a human, but it does not have good capability of spreading from human to human. So it is a dead end. People can get sick from the animal to human, but they do not spread it. We dodged the bullet with the H5N1 in Hong Kong, because we could have had a serious flu epidemic from that.

In this situation, it is likely that this jumped from animal to human. But the one thing that it did have, the bad news about all of this, it now has the capability of spreading and spreading relatively well under certain circumstances from human to human.

So that is the reason why we are concerned. There is really no need to panic; but we really need to take this very seriously, because we are still in the evolving stage of the epidemic. And we are not sure entirely where it is going to go, what direction, iit will take.

Senator HARKIN. But if the gestation period is 2 to 10, 12 days, something like that, it would seem to me that that kind of lends itself to focusing on where it really started from and where it is most concentrated.

Dr. FAUCI. Right.

Senator HARKIN. And I assume that is what is being done right now.

Dr. FAUCI. Exactly. Exactly. And that is the reason why the individuals who are being—well, there are a couple things that are going on. Clearly you need significant precautions, because it is very tend—it tends very heavily to go from a patient to a healthcare worker or from a person who is in close family contact, even though there is some good evidence now that it can go beyond that and spread much more easily under certain circumstances, as Dr. Gerberding mentioned, with some very efficient transmitters.

But in terms of public health measures, when you have someone who is sick, you want to get them to a point where you can isolate them so that they do not—or at least make sure that they are in a medical facility in which the spread is not easily accomplished. The yellow card that Dr. Gerberding mentioned to you, as I mentioned in my opening statement, I believe is a very important mechanism that has curtailed what might otherwise have been even more spread within this country.

Senator HARKIN. Again, I always feel that sometimes when these things happen, you have to be careful that you do not overblow them. But then you do not want to estimate it either. I mean, you have to kind of keep this thing in balance. I do not want to—unduly want to get people alarmed. I just—in putting this in perspective, how many people die of flu in this country every year, Dr. Gerberding?

Dr. GERBERDING. We say that approximately 15,000 people die, annually, at least in part due to flu infection or complications of flu. So in terms of the magnitude of effect right now, we are not seeing anything anywhere near influenza. But of course with influenza, we do have a vaccine. And we have treatment. And there are things that we can do to protect people. With this new corona virus, or whatever it is that is causing SARS, we do not have that

backup in our system yet. And we are just at the very beginning, you know, just a few weeks into our experience with it. So we do need to take it very seriously.

Senator HARKIN. But 15,000 people die of flu every year in this country, right?

Dr. GERBERDING. Correct.

Senator HARKIN. And more in other countries, I assume. I do not know what the data is from other countries.

Dr. GERBERDING. Flu is clearly a very prevalent, very common respiratory illness during the winter months. And unfortunately, not everyone who should get their flu vaccine does. And so we continue to see a lot of illness and death from it.

Senator HARKIN. I see my red light is on. Thank you very much. Thank you, Mr. Chairman.

Senator SPECTER. Dr. Fauci, when we project the President's allocation of $15 billion for AIDS over the next 5 years, what is your expectation as to where that money will be spent?

Dr. FAUCI. According to the President's plan, about 52 or so percent of it will be on treatment, about 33 percent will be on prevention, and about 15 percent on care. It will be channeled, according to the——

Senator SPECTER. 15 percent where?

Dr. FAUCI. Would go to care of patients.

Senator SPECTER. Any of that $15 billion on research?

Dr. FAUCI. The research will not be included in that $15 billion. The NIH is poised to seize the opportunity of people being treated in these developing countries to utilize our research funds to be able to inform better how one can treat these individuals. And for that reason, we are starting, we actually have, our international networks in the countries that are targeted countries.

Senator SPECTER. Research funds to inform better? What do you mean by that?

Dr. FAUCI. Yes. We know in this country the clinical networks that we set up years ago, Mr. Chairman, have been very influential in allowing us in this country and developed nations to understand how to use these drugs, the complications, how you can best approach an individual, when to start therapy, when to modify therapy. It is unclear how populations that have other diseases, that have different types of health problems, when you introduce a rather sophisticated regime of therapy into that population, how you can best use it.

So the research endeavors that will be performed will be performed in order to better inform the clinicians about how to use these drugs.

Senator SPECTER. Dr. Gerberding, when we take a look at your budget, we see the allocation on your buildings being cut by $152 million. This subcommittee took the lead 4 years ago, after visits by some of us to Atlanta, to see the deplorable conditions. And we then added in fiscal year 2001 $175 million and supplemented that with $250 million in 2002 and $266 million in 2003. And I think it is important to note that we never heard from the Secretary of Health and Human Services in that period of time that there was a problem at CDC in Atlanta. It was only when we made the trips there.

How are you going to get along on $114 million on CDC construction allocation which is currently in the budget?

Dr. GERBERDING. First of all, again, we are just very grateful for the committee's support of buildings and facilities. We know that we would not be where we are today without your help. But——

Senator SPECTER. Well, are you grateful for the—coming to the point, are you grateful for the $152 million cut?

Dr. GERBERDING. We have a 10-year plan. And we have looked at that plan at a rate of about $250 million a year. So when we do not have the $250 million, it means that we have to slow down the pace of accomplishing our master plan. What is the good news about the $114 million is that it does allow us to build our permanent emergency operations center and/or terrorism issues, as well as some of the redundancies in power and electricity and basic core functions at CDC where we are really vulnerable right now. So we are very appreciative of the support for that.

Senator SPECTER. And the balance of your budget was cut by some $8 million. Aside from the $152 million cut on construction, the balance of your budget on the allocation by the administration is $8 million less. And you are being asked to do more and more and more on AIDS and SARS and homeland defense and on the next problem that is going to arise and the one after that. Can you handle it with less money?

Dr. GERBERDING. Well, one of the things that we are being asked to do, which I really agree with, is we are being asked to work more efficiently. And the reductions in the budget lines that you do see are reductions in the administration and management side, not in programs. So my——

Senator SPECTER. So if you increase your efficiency, we can reduce budgets.

Does that go for NIH, Dr. Zerhouni?

Dr. ZERHOUNI. Do you want me to——

Senator SPECTER. Yes. That was a question, Dr.

Dr. ZERHOUNI. Well, clearly, I think from our standpoint, we work very closely with the Department and the Office of Management and Budget. Obviously, the final calls are always made by the President. And we work within the constraints of that for——

Senator SPECTER. No, they are not, Dr. Zerhouni. They are made by the Congress.

Dr. ZERHOUNI. I understand, but——

Senator SPECTER. The Constitution says the Congress makes the appropriations.

Dr. ZERHOUNI. I understand. So what we are doing is really planning for the maximum impact, if you will, on our primary missions and try to in fact find deficiencies in areas that could be made more efficient. So I think the efficiency approach is certainly something that allows us to look at how to deploy the resources given to us in the most mission-critical areas of the agency.

Senator SPECTER. Well, my red light is on, so I will not ask another question before yielding to Senator Cochran. But I would note this observation. This subcommittee has an overall budget for three departments—Health and Human Services, and Education, and Labor, so that we are balancing all funds for the National Institutes of Health and CDC against programs like Head Start and

against worker safety on construction jobs and on many, many other health items, like rural health.

So that when this subcommittee gets a total budget, and we are going to come to NIH, which has had a very, very modest increase, we have to reassess priorities. And it is becoming more and more difficult to do. When we started the upward spiral of NIH back in 1995, we asked the Budget Committee for an additional billion dollars and got turned down and got turned down on the floor. And then we found it other places on priorities. So having lost on our application for $1 billion, we decided the next year to ask for $2 billion. That is the way you operate in the Congress. We got turned down again. We again found the money.

But we said to Secretary of Health and Human Services Thompson that he is going to have to be a tougher advocate. He is going to have to be a tougher advocate. And if you can solve the problems on efficiencies, that is great, should have been doing that a long time ago, if you can be more efficient.

But where these funds are indispensable, you are going to have to make your case, Dr. Zerhouni, and you are going to have to make your case, Dr. Gerberding and Dr. Fauci and all the rest of you. And I know it is not easy within the administration circles with the controls of the Office of Management and Budget. But there was only so much stretch that this subcommittee can initiate on the funds we have.

It is an overall process. And you have to be advocates and so do your patients and so do the people who are looking to you for help, as part of the overall political process to bring the kinds of funds which are indispensable for you to carry on your job. This subcommittee is determined not to see you have a cut of $152 million on your building program. It is going to bring it to a halt. Or $8 million less on operations.

But advocacies are going to have to be exercised at all levels. And you are doubtless the most effective advocates for your own program.

Senator Cochran.

OPENING STATEMENT OF SENATOR THAD COCHRAN

Senator COCHRAN. Mr. Chairman, thank you very much.

I notice that in the memorandum we have here that our staff has prepared, we are given information about the need for improving the physical facilities in Atlanta, particularly because of obsolete laboratories that need to be replaced or modernized and that CDC has implemented a construction master plan to consolidate the Atlanta operations into two campuses. And we have estimated costs at about $250 million per year.

Dr. Gerberding, is it your expectation that the budget request will be sufficient to meet the needs for this next physical year, or should we look to increasing that in order to meet this construction master plan that has been developed?

Dr. GERBERDING. I really thank you for the question. Your Honor, this is a year of really tough priorities for everyone. And we were very grateful that there was a budget line for buildings and facilities, because we know how easy it is to take it out of the budget altogether. And I think it was a great thing to see that there

was the support in there for the critical structures that we had asked for. And that was for our operations center and some of the other things for the physical security at CDC.

When we have a 10-year master plan, if we do not get on target every year, that slows the plan down. And so we have to regroup and look at what are the options. If we do not get the full budget mark in a given fiscal year, that means we have to delay construction or accommodate it in some way. And so we are looking at ways to do that.

Senator COCHRAN. Before the budget submission was prepared by the administration, we did not know what SARS stood for. But now we do. I think I have it right now, Severe Acute Respiratory Syndrome. Well, I notice that yesterday you were here testifying in the Senate before the committee chaired by Senator Judd Gregg of New Hampshire. And I think that was the main focus of that hearing was to look at what was being done and what the threat is to the population of the United States.

In the budget submission, should we look to provide additional funding for CDC to be used for work in this area?

Dr. GERBERDING. Right now what we are doing is accommodating the SARS outbreak in the United States on sort of the foundation of the investments that we have made in terrorism and public health preparedness. So we are using the operations center that we built for terrorism to coordinate this effort. We are using the laboratory surveillance systems that we built for terrorism to support this.

Right now the problem is small enough where we can handle the emergency or the crisis with the resources that we have for public health preparedness. If this scales up, we are going to have to keep a real track of the budget implications, because we do not know where it is going to go. And we will need to do a good job of documenting what we need or what we have spent in order to deal with it.

Senator COCHRAN. Well, I know that as we proceed through the appropriations process, we will stay in touch with you and your staff and be sure that whatever amount we recommend for CDC contains funds sufficient to deal with this outbreak.

Dr. GERBERDING. Thank you.

Senator COCHRAN. Dr. Zerhouni, welcome. It is good to see you again. The last time we were together you were in Mississippi. And we appreciated the honor of your visit to our State, the first time a director of the National Institutes of Health had ever been to our State. So we felt particularly grateful for your being there.

One of the things we talked about and reviewed during that meeting was the Jackson Heart Study, which is a step toward trying to identify what we can do about health disparities and why the African-American community in that part of Mississippi has more incidence and problems with heart disease, hypertension, and related cardiovascular problems.

I think I understood from your remarks when you were in Mississippi that this is one of the major initiatives of NIH, to look at disparities and try to develop a strategy for dealing with them. With that in mind, do you expect there is a possibility that we could increase review so that it would include other areas of the

United States, like the Mississippi Delta or other places in the United States where research is really needed on this subject if we are to deal effectively with the problem?

Dr. ZERHOUNI. Well, I think—thank you, Senator, for the question. And thank you for your hospitality in Mississippi. I have to say that Southern hospitality deserves all the good words that I heard about it before.

We wanted to make sure that our health disparities portfolio responded to the priorities and to the emerging challenge that we see in health disparities. When you look at all the progress we have made, we have made tremendous progress across diseases, across the population groups of our country. But when you look, for example, at a decrease in cardiovascular mortality, you realize that even though a decrease in all population groups, there still remains a significant difference in particular in the African-American populations for heart disease. But then when you look at certain regions of the country, Southeastern United States suffers from a much higher rate of stroke, for example, cardiovascular disease, diabetes, and so on.

As a strategy for NIH, we want to review the entire infrastructure for health disparity research in the country. And two components of that are going to be very critical. Number one is to build the scientific infrastructure that needs to be there in the communities that are affected to be able to enlighten and inform the best interventions. And the Jackson Heart Study is a prototype of that. This is a study conducted within the community, in partnership with all the institutions. And it is a successful study. It is really a good example of how we could do this.

Now you were referring to the Mississippi Delta and other regions. We also are investing, for example, in the stroke belt with Morehouse College, for example, and the National Center for Primary Care, where we are in fact developing an entire network of 136 community centers that could conduct research for, in fact, reducing health disparities. The major issues that we have is to build the infrastructure as well in the areas where health disparities are a problem, as well as address the issues from the research standpoint so that we can then convey the actions that need to be taken with our partners at CDC and others.

So that is the strategy. And we are looking at the entire country in that regard. And we are investing increasingly in the infrastructure for research on health disparities.

Senator COCHRAN. Thank you very much.

PREPARED STATEMENT

Thank you, Mr. Chairman. Mr. Chairman, I would like for my statement to be printed in the record.

Senator SPECTER. Without objection, Senator Cochran, your full statement will be made a part of the record.

[The statement follows:]

PREPARED STATEMENT OF SENATOR THAD COCHRAN

Mr. Chairman, thank you for holding this hearing on a number of very crucial issues. At this important time in our nation, we must assure that we are setting clear priorities and investing wisely in the health and safety of all Americans. The emergence of Severe Acute Respiratory Syndrome (SARS) and the continuing role

of America in the Global HIV epidemic are evidence that the work of the NIH and CDC is critical to the well-being of America and the world.

The $30 billion proposed in the fiscal year 2004 budget for the NIH and CDC to conduct biomedical research and provide public health infrastructure is a wise investment because both infrastructure and research increase our understanding of disease, improve our ability to respond to naturally occurring disease outbreaks, and protect our nation from terrorist attacks.

In funding the NIH and CDC, we must anticipate and plan for events such as the SARS virus. We know that we will constantly face unanticipated threats and we should be prepared for them. When we do not provide adequate funding, our public health officials cannot respond as quickly as is needed and are forced to shift resources.

We have also found that these unanticipated issues do not go away. We are still dealing with the West Nile Virus and will likely deal with SARS for years to come. I am pleased that the committee is examining these issues and I hope we will continue to provide the resources for research and facilities that are needed to prepare for and respond to whatever threats may emerge.

I am pleased that funding for the National Institutes of Allergy and Infectious Disease has increased from the 2002 level of $2.5 billion to a proposed level of $4.3 billion in fiscal year 2004. This investment in research will result in the knowledge and understanding that will lead to new treatments for infectious diseases such as HIV/AIDS, West Nile Virus and SARS.

However, over that same time frame, funding for HIV/AIDS and other infectious disease research funding at the CDC has grown at a much slower rate. [HIV/AIDS funding increased by about $53 million from a fiscal year 2002 level of $835 million to $887 million in fiscal year 2003. In addition, funding levels for the National Center for Infectious Disease at the CDC have slightly decreased from the fiscal year 2002 level of $348 million to just over $343 million in fiscal year 2003. The fiscal year 2004 proposed level is $332 million.]

We must adequately fund both public health infrastructure and basic research in order to counter infectious disease threats. We know these two components work together. It is my hope that we will increase funding for all of these vital activities. Thank you.

Senator SPECTER. Senator Harkin.

Senator HARKIN. Just a couple follow-up questions on the global AIDS situation. Dr. Gerberding, do you have any data on how much different organizations are spending for the drugs that keep people healthy, the retroviral-type drugs that keep healthy? There is like three drugs that go into kind of a cocktail or something like that that people take in this country and it has shown to be effective for keeping HIV under control. Do we have any idea about how much we are spending globally to administer all the people, like in sub-Saharan Africa? How much did we say, about 29 million persons living with HIV right now? Do we have any idea how much we are spending just on healthcare?

Dr. GERBERDING. We can get you information about what is being spent right now. I will be happy to do that for the record. I think in this country we have many drugs to choose from. And the combination therapy that you mentioned for treatment of AIDS is the standard of care. And it is quite expensive. But the pharmaceutical companies have made the decision to work toward lowering drug prices so that drugs can be equitably purchased and be made available at prices that are affordable, even in developing countries.

There has been a huge change in philosophy and direction. And it is exactly that change in the pricing structure that allows us to be optimistic that the President's initiative really can get in there and include, as Dr. Fauci said, not just prevention services, but also care and treatment. But we can get you the specifics on that.

[The information follows:]

ANTI-RETROVIRAL (ARV) TREATMENT PROGRAMS

Implementing successful ARV programs require much more than simply purchasing the drugs themselves. Drug regimens associated with ARV are very complicated often requiring taking multiple pills, multiple times a day. In addition, medical monitoring is necessary to ensure that ARV therapies are effective. To successfully implement ARV programs, countries require both a physical and medical infrastructure. Related costs in supporting anti-retroviral treatment programs include but are not limited to the following: development of guidelines for safe and effective ARV therapies and patient monitoring; hiring and training qualified health care workers; and implementing distribution systems including transportation, storage facilities, quality controls and systems to track inventory, etc. One of the key elements of CDC's Global AIDS Program is to build infrastructure and capacity to support comprehensive programs of HIV/AIDS prevention, care and treatment. In fiscal year 2002, CDC spent approximately 11.4 percent of its global AIDS budget on care and treatment activities, including care and treatment for TB and other opportunistic infections. In addition, 47.5 percent of the budget was spent on building infrastructure and capacity in countries to deliver successful programs.

In fiscal year 2003, CDC is supporting pilot projects to determine how best to meet infrastructure needs in individual countries and be able to implement ARV therapy in the most effective way. CDC funds partners who purchase ARV therapy, and therefore, CDC does not pay for it directly. Their negotiations with suppliers result in various prices.

Senator HARKIN. I would like to delve into that.

Dr. Fauci, do you have something to add?

Dr. FAUCI. Yes, Senator Harkin. Currently in sub-Saharan Africa, as an example, there are only about 50,000 people that are under therapy. Most of that comes from the purchase of people who can afford it. And the prices now in the area that we are talking about generally are either generics or markedly reduced price. So, for example, in the Uganda situation, where there are about 7,000 people who are under therapy, the average that they pay for a triple combination that you mentioned is between $350 and $450.

There are also some programs in which the——

Senator HARKIN. That is per year.

Dr. FAUCI. Yes, per year, per year, which is considerably less than the drug prices in a developed Nation like the United States and in Western Europe. But, for example, as a Nation, there are very few programs that are organized programs in which treatment is being distributed. And that actually is the rationale for the President's Emergency Fund for AIDS Relief, which would get 52 percent of that $15 billion into the actual treatment of people, at least in the targeted 14 countries, 12 in sub-Saharan Africa and 2 in the Caribbean.

Senator HARKIN. I am told by the AIDS Healthcare Foundation that you are right, that in Uganda and places like that, they could get this anti-retroviral drug for about $300 a year, maybe $350, I do not know, but around $300 a year; that in other parts of the country, it is up to $1,500, same drugs, and it costs $15,000 a year here for the same drugs in the United States. Does that sound right?

Dr. FAUCI. $15,000 may be a little high, somewhere around $12,000, if you include some of the——

Senator HARKIN. $12,000. If someone has HIV in the United States, they are paying $12,000 a year for an anti-retroviral drug that people—that could be made generically and that could be and is being administered in Africa for $300 to $350 a year.

Dr. FAUCI. Right.

Senator HARKIN. That is true.

Dr. FAUCI. That is true. And that is the difference perennially between a generic——

Senator HARKIN. Well, I mean, that just really—this is a question you should not have to answer. Maybe I will just make the statement. That just seems to me to be outlandish, that someone in the United States who is suffering from HIV, has to pay $12,000 to $15,000 a year for a drug that is readily available for $300 a year. Something is wrong. And if we could get it for $300 a year, it would seem to me—what I want to get a handle on is how much money are our taxpayers, I assume the worldwide community, putting into healthcare on AIDS? And are they buying the drugs for $15,000 or $5,000 or $10,000 when they could be getting them for $300 a year? And we have to get a handle on this, because I take it from our dialogue here that those drugs are available at that price, at around $350 or $400 a year or something like that, they are available.

Dr. FAUCI. They are available either as generics or as out-of-patents drugs. And that gets into the argument, as you know, very complicated, that at least in NIH and CDC is not something that we can get involved with——

Senator HARKIN. I understand that.

Dr. Fauci [continuing]. That has all to do with the relationship between generic drugs and their prices and then what would the drug companies do if all of a sudden they had no profit margin? They would stop making drugs. It is that balance that we keep hearing about back and forth.

Senator HARKIN. Well, somebody is making them for $300 or $400.

Dr. FAUCI. Yes.

Senator HARKIN. And I cannot imagine they are making them and losing money.

Dr. FAUCI. Yes. But the problem is they do not make the investment of the hundreds and hundreds of millions of dollars to develop the drug. The generics just produce them. And that is the perennial argument between the big companies and the generics.

Senator HARKIN. But the generics cannot do it until the patent runs out.

Dr. FAUCI. Right. Right. Well——

Senator HARKIN. They have had the patent protection, Mr. Fauci.

Dr. FAUCI. Yes. But the—for example, the group in India, the Sipler Group, that is using the drugs, those patents have not run out yet. And they are still making them in generic.

Senator HARKIN. Thank you, Senator.

Senator SPECTER. Thank you, Senator Harkin.

Senator Murray.

Senator MURRAY. Thank you very much, Mr. Chairman. I know you want to go to the second panel. I just wanted to ask a couple questions about SARS.

As you know, Washington State is a gateway to Asia. And we are very concerned about a lot of what we are hearing. A lot of my constituents travel back and forth there several times a year. And we are concerned about the health impact and the potential economic impact in Washington State. And I know that CDC has issued warnings to many passengers who may have traveled to a par-

ticular region or country. But as you know, when you get on a plane, you do not know where it has been before.

I am just curious if CDC is working with the international air carriers and talking with them about how they can reduce the spread of SARS.

Dr. GERBERDING. Yes, we are. First of all, WHO has issued an alert to the departure airports in Asia to screen passengers for any respiratory illnesses that could be consistent with SARS. And I do not know to what extent those countries have been able to implement the advice yet, but there is an effort under way to alert not just the passengers when they arrive here, but passengers before they get on a plane in the first place, which really makes a lot of sense.

We are doing a number of things to assess the health status of airplanes. And we have just completed or are about to distribute a short video for passengers that you will be able to watch on an international flight that explains what SARS is and what to do. We are working with the airline industry about should they detect somebody in flight, what are the sensible precautions that could be taken until you get the plane on the ground and alert the quarantine officer in the port of entry.

Then finally, should you have a patient with SARS on a plane, what is the appropriate way to disinfect the airplane and so on and so forth. And then that also leads to concerns among the crew of airplanes about their own personal safety and what kind of precautions do they need and what is really the air quality on airplanes. So these are all questions that we are aggressively pursuing answers to and doing the best we can to build up sensible precautions in the interim.

Senator MURRAY. And you are working with international air carriers, as well as——

Dr. GERBERDING. Yes. We are working with international air carriers and the International Association of Flight Attendants. And we are also doing some research, looking at cohorts of people who have traveled on planes with someone in retrospect who is recognized to have SARS so that we can understand among the passengers who were potentially exposed, does anybody get SARS? If so, where were they in the airplane, what kind of exposure did they have, and so forth.

So we are doing that with international partners through WHO. And I think that will really help give us the science base from making additional recommendations.

Senator MURRAY. And you are following the planes as well as the passengers.

Dr. GERBERDING. Exactly.

Senator MURRAY. The other question I had has to do with healthcare workers. I have noticed that many of the individuals who have contracted SARS are healthcare workers. What are you doing within our own country to notify emergency room personnel, doctors and others, so that they are watching for this?

Dr. GERBERDING. We are doing a number of things. We did do—on the 14th of March, CDC activated its operations center to step in and deal with this epidemic. On the 15th, we issued the initial alert to clinicians across the United States and the initial guidance

on how to isolate patients and how to protect themselves. And we have been updating that regularly. You can find that on our web page.

In addition, we have set up a series of regular conference calls with clinician professional organizations around the country to give them the latest updates so that they can redistribute it to their members. Many of us are going around the country speaking to clinician groups. For example, I was just at the American College of Physicians, where I addressed 5,000 internists, sort of the kind of people that an adult with a respiratory illness might seek attention from.

Friday we did a global satellite video conference for clinicians around the world to tell them about recognizing SARS and how to isolate and take care of the patients. So—we also operate a hotline for clinicians in the United States. They can call up and get information from CDC experts on how to manage a patient and so forth. So we are being as aggressive as we can to put the word out, take a travel history if you see someone with a respiratory illness. And if there is any question, isolate the patient until you have additional information to show that it is not necessary.

Senator MURRAY. And one last question. Oftentimes us getting information to minority populations is difficult, especially with something like this. We want to make sure the Asian communities are aware. Are we doing language, different language, information pamphlets or information so that we make sure everybody has all the information they need here?

Dr. GERBERDING. Yes, we are. There are several things happening. That travel alert that I am sorry you do not have a copy of, but we will get you one, is in several Asian languages. And we will be adding Spanish to that, also.

We have just last week established something that we are calling sort of the Asian community team at CDC to pull in our in-house experts with language skills and cultural experience in various Asian communities to try to help us assess how can we do a better job of targeting our communication, but also being sensitive to the potential for bias or stigma attached with this.

The last thing that we want to have happen here is that our Asian communities would suffer unfair prejudice as a consequence of this illness. This is not an illness of Asians. It is an illness of people who have been in a particular part of the world where the virus is spreading.

So we will be expanding on our Web site more information in additional languages. And the WHO Web site is translated into several Asian, at least some Asian languages to help people get information off the Internet that way. There is a lot more we can do.

Senator MURRAY. Okay. Very good. Thank you very much, Dr. Gerberding.

Senator SPECTER. Thank you, Senator Murray.

Dr. Gerberding, we thank you for your participation. If you would like to be a director of the NIH or one of the institutes, you may stay.

If you choose to retain your current position at CDC, you are free to excuse yourself. Thank you very much for joining us.

Dr. GERBERDING. Thank you. I think I will keep to my present job.

Dr. ZERHOUNI. We would not mind having her as a director at NIH.

Dr. GERBERDING. Thank you.

ADDITIONAL COMMITTEE QUESTIONS

Senator SPECTER. There will be some additional questions which will be submitted for your response in the record.

[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 ARLEN SPECTER

CDC GLOBAL AIDS PROGRAM AND ARV TREATMENT

Question. What percentage of the GAP budget of $184 million in the current year is dedicated to operational research on life-saving antiretroviral treatment?

Answer. Approximately 13 percent of the fiscal year 2003 budget for the Global AIDS Program (GAP) [excluding the $40 million earmarked by Congress for the President's mother-to-child HIV prevention initiative] is directed to care and treatment efforts, including operations research on antiretroviral therapy (ART). GAP is supporting or initiating pilot HIV care and treatment projects that include ART in a number of countries in Africa and Asia. These pilot projects, which have been developed in collaboration with the Ministry of Health of each country could, given adequate funding and expanded infrastructure, be rapidly expanded to provide care and treatment for large numbers of HIV-infected persons in the next few years. They will provide operational research data to develop antiretroviral treatment programs.

Question. How much of the $40 million increase in the current year's appropriations is supporting operational research on ARV treatment delivery?

Answer. Since all of the $40 million increase is earmarked for the International Mother and Child HIV Prevention Initiative, none is budgeted for operational research on antiretroviral treatment delivery. Some of the funds will be used to support HIV care for women and their family members who receive services to prevent mother-to-child HIV transmission. Country program plans are in development and budgets will be allocated after plans are approved by the Initiative Steering Committee, headed by the White House Office of National AIDS Policy.

Question. Should that percentage be higher, given the urgency of President Bush's goal of bringing 2 million people in developing nations into treatment?

Answer. The goal of providing ART to 2 million people is part of the larger initiative President Bush announced in the State of the Union in January. The initiative will be based on a "network model" being employed in countries such as Uganda. This involves a layered network of central medical centers (CMCs) that support satellite centers and mobile units, with varying levels of medical expertise as treatment moves from urban to rural communities. The model will employ uniform prevention, care, and treatment protocols and prepared medication packs for ease of drug administration. It will build directly on clinics, sites, and programs established through the U.S. Agency for International Development, the Department of Health and Human Services, non-governmental organizations, faith-based groups, and willing host governments. Operational research will inform implementation of this model.

Question. President Bush has included an additional $110 million next year for CDC GAP. What percentage of that do you anticipate would go to operational research on ARV treatment?

Answer. These funds have been requested for the International Mother and Child HIV Prevention Initiative, which includes care and treatment of mother and child following birth and, where capacity exists, providing care and treatment for eligible family members. While we don't anticipate spending any of this funding directly on operational research, we anticipate spending about 10–15 percent of MTCT funding for monitoring and evaluation, which will provide data for operational research.

Question. What is the status of current ARV operational research efforts?

Answer. CDC staff are currently working with Ministries of Health in GAP-affiliated countries to conduct operational research to address country-specific questions

about scaling up pilot programs to the national level. The majority of these programs are still in development. A program in Kenya recently began treating patients. Programs in Uganda and Thailand will begin treating patients in the next few months.

Question. How many pilot ARV clinics do you have in your program?

Answer. Currently, CDC supports four pilot clinics in the treatment programs, one that has begun in Kenya and one in Uganda and two in Bangkok, Thailand that will begin soon. In addition, CDC has been supporting the U.N. Drug Access Initiative (DAI) in Abidjan, Côte d'Ivoire, since 1998. The DAI continues to provide antiretroviral therapy to more than 2,000 HIV-infected adults and children in six clinics in Abidjan, despite the ongoing civil wars in the northern and western parts of the country.

Question. What was the selection process used in choosing those partners?

Answer. CDC collaborates with the Ministry of Health in each country to identify sites in which to develop and implement HIV care and treatment projects. Most of these projects include several other collaborators. For example, the HIV care and treatment pilot program for residents of the Kibera Slums in Nairobi, Kenya, is a collaborative project with the Kenya Ministry of Health, KEMRI (the Kenya Medical Research Institute), KICOSHEP (Kibera Community Self Help Programme, a community-based organization in Kibera since 1991), AMREF (the African Medical and Research Foundation), Mbagathi Hospital, and GAP/Kenya.

Question. Where are those clinics, and what is their current patient census overall?

Answer. The clinics for the HIV care and treatment pilot are located in:

—The Kibera Slums in Nairobi, Kenya

—The Tororo Health District in rural Uganda (near the southern border with Kenya)

—The Drug Relief Center at the BMA College & Vajira Hospital and the methadone maintenance outpatient clinics at Taksin Hospital in Bangkok, Thailand

The patients for the program in Nairobi are being selected from voluntary counseling and testing sites in Kibera, which has a population of more than 500,000. The patients for the project in rural Uganda will be selected from more than 2,000 participants in an ongoing safe water vessel and cotrimoxazole project, while the patients for the project in Bangkok will be selected from participants attending methadone maintenance clinics located in two large hospitals.

Question. How many patients in these clinics are now in ARV treatment?

Answer. The only GAP-supported pilot HIV care and treatment program providing ART is the Kibera Project in Kenya, where approximately 200 (as of May 2003) patients have started ART.

Question. How many patients are scheduled for ARV treatment this year?

Answer. In CDC funded projects, during the next 12 months, the care and treatment project in Kenya plans to enroll 500–1,000 patients, the project in Uganda about 1,000, and the one in Thailand approximately 150. By the end of 2003, more than 1,000 total patients could be enrolled in these three programs, depending upon when the projects in Uganda and Thailand begin.

Question. What is the overall time frame for the operational research on ARV treatment through GAP?

Answer. The funding cycle for HIV care and treatment projects is usually 3 years, but CDC plans to continue supporting these antiretroviral therapy programs and collecting operational research data through monitoring and evaluating these programs for the foreseeable future.

Question. Who will pay for purchase of medications at these sites—antiretroviral medications as well as opportunistic infection medications?

Answer. CDC provides funding and technical support for these HIV care and treatment pilot programs. For the three projects described above, CDC provides funding for medications, including antiretroviral therapy and those for opportunistic infections, to selected collaborating organizations, which in turn purchases drugs for the program. In Kenya, AMFAR purchases drugs for the program. In Thailand, the Bangkok Metropolitan Administration (BMA) will purchase the medications for the project. In Uganda, TASO (The AIDS Support Organization), the first indigenous AIDS organization in Africa and a major collaborator in the project, will purchase the drugs.

Question. Who will pay for staff and laboratory costs?

Answer. In most of these projects, the collaborating organizations or institutions provide staff, but CDC often supports additional staff, as well as most, if not all, of the laboratory testing.

Question. What effort was made to draw on expertise from ARV treatment programs in the United States, particularly those developed under the CARE Act?

Answer. CDC has drawn heavily on the experience with treatment programs in the United States. Many technical staff working on CDC's Global AIDS Program (GAP) worked on U.S. HIV care-related projects before joining GAP. Moreover, CDC collaborates with Health Resources and Services Administration (HRSA), the government agency that administers the Ryan White CARE Act. In particular, CDC funds a HRSA-managed program (I–TECH) to provide training and technical assistance for international HIV care programs that CDC supports. I–TECH is designed to draw on expertise from the network of AIDS Education and Training Centers in the United States. CDC has also initiated partnerships with 10 universities to provide technical assistance. Collaborators from these universities (Harvard Medical School; Baylor College of Medicine; Howard University; University of North Carolina at Chapel Hill; University of California, San Francisco; Tulane University; University of Medicine and Dentistry in New Jersey; University of Maryland; Columbia University; and Johns Hopkins University) have extensive experience with ARV programs in the United States. Finally, CDC funds other U.S. national organizations, such as the National Alliance of State and Territorial AIDS Directors (NASTAD) and the Association of Public Health Laboratories (APHL) that have provided support related to HIV care, such as program management and laboratory services.

UGANDA ARV TREATMENT

Question. What plans does CDC GAP have to study and support through operational research "ramp up" of ARV treatment delivery to large numbers of Ugandans? How many patients there are now on ARV's?

Answer. The number of HIV-infected persons in Uganda has been estimated between 800,000 to 1.9 million. Of these, only 5,000–10,000 are estimated to be receiving ART (antiretroviral therapy) in the whole country. The CDC-Uganda Program is currently providing both financial and technical support at two important institutions for HIV care in Uganda: the Mildmay Center, located in the outskirts of Kampala; and the Mulago Hospital in Kampala. CDC has provided financial support and technical assistance to the Mildmay Center over the past two years to build capacity of health care providers working at the Mildmay Center and from health care venues throughout the country. In the past year, approximately 70 percent of the support that this facility receives was provided by the CDC. Between 5,500 and 6,000 HIV-positive persons are cared for at the Mildmay Center, including approximately 1,000 children. Approximately 750 persons are receiving ART at this center. The facility not only acts as a state-of-the art HIV/AIDS clinic, but also a training center in HIV care and laboratory diagnostics. CDC-Uganda has recently supported the development of a model Pediatric HIV outpatient clinic and training center at the Mulago Hospital, which is the National Referral Hospital for Uganda. The model facility involves collaboration between the CDC, its University Technical Assistance Program (UTAP) partner the Baylor College of Medicine, and the Government of Uganda. These two projects aim to improve and expand access to care for HIV-positive patients residing in Kampala and the immediate surrounding area and to serve as centers for training and referral. Furthermore, CDC, in conjunction with The AIDS Support Organization (TASO), will soon launch a rural ART pilot project in the districts of Tororo and Busia. The Home-Based AIDS Care Project (HBAC) is a pilot project that aims to provide comprehensive treatment, including ART and TB care, to 1,000 HIV-infected persons and their families, including children with HIV. This project is the outgrowth of the Safe Water Vessel Project, a two-year-old collaboration between CDC and TASO-Tororo, which provides safe water and cotrimoxazole to 750 households of HIV-positive persons living in the district of Tororo. HIV-positive persons and their families currently participating in the Safe Water Vessel Project will be among the first evaluated for enrollment into the Home-Based AIDS Care Project. This program will provide comprehensive care and ART treatment to HIV-infected persons and will serve as a model for expanding ART care to rural communities in Africa. New patients, referred to the CDC Clinic in Tororo by TASO, will also be considered for enrollment.

We estimate that CDC-implemented programs will increase the total number of people on ART in Uganda by 20 percent in the next year. Moreover, the CDC/TASO Tororo pilot program has been designed to answer fundamental questions to inform ART scale-up efforts for Uganda in particular and Africa in general.

Question. Is CDC's AIDS clinic with UNAIDS in Uganda operational?

Answer. CDC has worked closely with the UNAIDS Drug Access Initiative since its inception. The success of this program has been documented in published articles in scientific journals as well as through meetings in Uganda and internationally. The program supports the use of ART at five centers in Uganda. Although CDC provided free testing for CD4 cell counts and viral loads to accurately monitor patient

care, participants purchased the medications themselves. All of the centers involved in this initial pilot project are currently providing ART care and have greatly expanded service in the last 2 years.

Question. There are other major community-based pilot treatment sites in Uganda, such as AIDS Health care Foundation's Masaka clinic with 200 patients in care. Have they and others been invited to participate in the GAP Program?

Answer. Since 1998, CDC has collaborated with other organizations in Uganda working on ART-based care for persons with HIV/AIDS. As a partner in the UNAIDS Drug Access Initiative, CDC provided technical support to the Joint Clinical Research Center, Mildmay, Mulago Hospital, Mengo Hospital, Nsambya Hospital, and the Ministry of Health, which together provide almost all of the ART care outside of private clinics in Uganda. CDC has provided advice to the AIDS Healthcare Foundation's Masaka clinic since its origin, and communicates regularly regarding technical matters of providing ART care, including laboratory testing to its 100 patients on ART. CDC has a similar relationship with the Academic Alliance for AIDS Care and Prevention in Africa, a U.S. and Canadian university collaboration with Mulago Hospital and Makerere University to improve training related to HIV/AIDS care in Uganda. CDC as well as the other major partners working in HIV/AIDS care, are a part of the national committee developing ART guidelines.

Recently CDC, through the University Technical Assistance Program and the International Training and Education Center on HIV (I–TECH), which is funded by CDC and administered by the Health Resources and Services Administration, has expanded its resource base to include leading academic institutions from the US, including Baylor College of Medicine; the University of Washington; and the University of California, San Francisco. Collaborations with these U.S.-based institutions, and the Mulago Teaching Hospital, the Tororo District Hospital, TASO-Tororo and the Mildmay Center, allow CDC to be at the forefront of advancing programs for the care of children and adults with HIV/AIDS both in urban and rural environments. CDC supports many other HIV/AIDS-related projects and programs in Uganda, often through direct collaborations with WHO, UNAIDS, UNICEF, USAID, the AIDS Information Centre, Makerere University and others.

Question. What role will CDC GAP's pilot ARV projects play bringing large numbers of patients into treatment?

Answer. The pilot ARV projects supported by CDC are playing an important role in bringing large numbers of patients into care and treatment. Through pilot projects like these, Ministries of Health gain: (1) critical information about how to establish and manage large HIV care programs, (2) an experienced cadre of clinicians, program managers, and other staff who will become trainers and technical assistance providers in their countries as programs expand, and (3) strengthened critical human and physical infrastructure and referral patterns needed to provide expanded services.

Question. Dr. Gerberding was asked at the hearing how much CDC is paying for anti-retroviral medications deployed overseas compared to U.S. pricing for such medications: She said she did not have that data, that the pharmaceutical industry was doing a good job at lowering prices, and she promised to provide data. How soon will we have such data?

Answer. CDC does not pay for these commodities directly, but rather funds partners, e.g., BMA, TASO, Univ/MOH, to purchase them. Their negotiations with suppliers result in various prices. Therefore, we do not have access to their pricing data. Through the President's Mother and Child HIV Prevention Initiative and the larger Emergency Plan for AIDS Relief, we hope to have access to therapies at sharply reduced costs, due to economies of scale and negotiated agreements.

HONDURAS ARV TREATMENT

Question. Does GAP have any presence in Central America? If not, why not? Honduras seems a particularly compelling area in need. It accounts for more than half of the AIDS cases in all of Central America. The official government estimated countrywide HIV prevalence is 1.9 percent in 2001 although surveillance studies in SPS in 2002 revealed almost a 7 percent rate among pregnant women, a 12 percent rate among commercial sex workers and a 15 percent rate among men having sex with men. The estimated overall prevalence in the San Pedro Sula area per local experts is 7 to 10 percent. The estimated number of adults and children living with AIDS in Honduras at the end of 2001 was 57,000 with 14,000 current living orphans. Why has Honduras not been prioritized?

Answer. CDC has not been active in Honduras, but expects to open a regional office by the end of the year to provide technical assistance, especially regarding surveillance, in Central America, including Honduras. That office will be located in

Guatemala and is a cooperative effort of both CDC and the United States Agency for International Development (USAID). Collectively, the needs of developing countries in preventing HIV infection and in providing care and treatment for those already infected far outstrip the fiscal and human capacity of CDC's Global AIDS Program. Providing substantial financial support for national ART programs is beyond our capacity at this time; therefore, collaboration with others, including USAID and the Global Fund To Fight AIDS, TB, and Malaria (GFATM) is essential. The GFATM is funding a number of ARV treatment projects, including projects in Honduras.

—The government of Honduras has been granted $26 million from the Global Fund for AIDS/TB/Malaria, of which it states it will decrease by at least 50 percent AIDS mortality and hospitalizations (source <http://www.undp.un.hn/PDF/varios/fondo__VIH.pdf>). CDC's website says it will identify countries with an expressed interest in ARV deployment (<http://www.cdc.gov/nchstp/od/gap/strategies/4__4__antiretrovirals.htm>). Since Honduras has need for assistance and has financial resources through the fund for ARV deployment, has CDC GAP considered Honduras? If not, how soon can it do so?

Honduras was approved by the Global Fund for a grant of $20.5 million over five years to undertake a major scaling-up of the country's campaign against HIV/AIDS, tuberculosis and malaria. The United Nations Development Programme, the UN's global development network, will implement and oversee the venture. CDC will provide technical assistance to Honduras in this effort as requested, through its regional office in Guatemala, when that office is operational later this year.

CONCLUSION OF HEARING

Senator SPECTER. Thank you all very much for being here. That concludes our hearing.

[Whereupon, at 10 a.m., Tuesday, April 8, the hearing was concluded, and the subcommittee was recessed, to reconvene subject to the call of the Chair.]

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