SARS: ASSESSMENT, OUTLOOK, AND LESSONS LEARNED

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BEFORE THE

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OVERSIGHT AND INVESTIGATIONS

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SARS: ASSESSMENT, OUTLOOK, AND LESSONS LEARNED

WEDNESDAY, MAY 7, 2003

HOUSE OF REPRESENTATIVES,
COMMITTEE ON ENERGY AND COMMERCE,
SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS,
Washington, DC.

The subcommittee met, pursuant to notice, at 1:30 p.m., in room 2123, Rayburn House Office Building, Hon. James C. Greenwood (chairman) presiding.

Members present: Representatives Greenwood, Stearns, Bass, Deutsch, DeGette, Davis, and Schakowsky.

Also present: Representatives Markey and Green.

Staff present: Alan Slobodin, majority counsel; Peter Spencer, majority counsel; William Carty, legislative clerk; David Nelson, minority investigator and economist; and Jessica McNiece, minority staff assistant.

Mr. GREENWOOD. The subcommittee will now come to order. And without objection, the subcommittee will proceed pursuant to committee Rule 4E. So ordered. And the Chair recognizes himself for an opening statement.

Good afternoon, and welcome. The world continues to fight an unpredictable killer called Severe Acute Respiratory Syndrome or SARS. Much progress has been made in containing this highly infectious disease, as we have just heard during our briefing. And shortly we will hear more details about the so far successful efforts in controlling SARS in the United States.

We will also hear that for all of the good and aggressive work of our frontline public health professionals buoyed by some good luck, we cannot rest assured that the largest threat of this deadly menace is past us.

We hold this hearing today because of the clear need to continue our vigilance in the fight against SARS to determine whether we are appropriately prepared for any possible SARS upsurge, especially next winter, and to identify where we might improve public health response for future deadly infectious disease outbreaks or bioterrorism attacks.

SARS continues to be of urgent concern for a number of reasons. Because it is presently untreatable and its means of transmission is not fully known, because it appears to have potential for rapid international spread in this interconnected globe, and because it has a death rate, that while low in comparison to the rates of AIDS and ebola, would be devastating if SARS spread rapidly and infec-

tions reached numbers of a magnitude of, for example, the 1918 flu pandemic.

Fortunately, there is evidence that SARS is not easily transmissible as influenza, and that the tools of public health have been working well to contain it. On the other hand, there is much the public health authorities do not know and the present uncertain and dynamic situation suggests that the success or failure in containing SARS will probably depend on what happens during the next few months, or perhaps years, rather than what has been done already. In other words, the question is, "Has the Pandora's Box of SARS been permanently opened or can we put the SARS genie back in the bottle?" This hearing will help us learn how to increase the chances of containing SARS.

Is SARS a harbinger of the eventual pandemic the disease experts warn we must be prepared to face? It certainly has focused our attention on broader questions of preparedness which at, present fortunately, have not been put to the test. How would we handle large infection rates or isolate and treat infected people? Is our hospitalization infrastructure prepared? Do public health laws measure up to the realities of the day? And what about gaps in international and local surveillance? Will we be able to develop vaccines and other treatments? Do we have the resources? Are we proceeding now to enhance our overall ability to battle infectious outbreaks?

The broader issues that we will consider today are not new to the public health community nor to this subcommittee. Three years ago the General Accounting Office prepared for this subcommittee a report warning that the Federal Government lacked a plan to combat the inevitable outbreak of pandemic influenza. It is important to see what progress we have made on that front.

Another rather sobering assessment of our current preparedness for a major disease outbreak was released this past March, coincidentally less than a week after the World Health Organization issued its global alert on SARS. The Institute of Medicine Report "Microbial Threats to Health: Emergence, Detection and Response" states quite plainly that even the developed countries of the world are unprepared for an influenza or other infectious disease pandemic.

Other assessments in recent years have called into question the ability to detect new and deadly emerging infectious outbreaks; something that this current SARS experience may be particularly helpful to eliminate.

We have three panels of witnesses today which I believe will provide us with a thorough and well rounded picture of the current situation and the outlook for our ability to combat SARS. They will also provide the needed perspective for us to identify actions and tools that will help ensure that we can be successful should this or any other outbreak spread upon us.

Our first panel will features witnesses from the Health and Human Services Department and its component agencies, some of whom have become familiar faces to the American public. They will provide us with authoritative information on the actions taken in response to SARS and related planning for future outbreaks.

We will also hear on this panel from the General Accounting Office whose expert will discuss how State and local agencies efforts to prepare for bioterrorist attacks can help battle infectious disease outbreaks, and whether hospitals can respond adequately to such outbreaks in other major public health threats.

Our second panel features witnesses from the public health community who will provide some differing perspectives on the SARS outbreak and its lessons for our preparedness. We will hear from people with experience internationally, with the domestic public health community, the clinical perspective, the legal perspective, and from the true front line—the nurse who treated the first probable SARS patient identified within the United States.

Our third and final panel will provide a view from the therapeutic product industries. We will hear from companies who have produced or who are attempting to produce medical products potentially useful in combating SARS and related diseases and gain some perspectives on the issues confronting them in terms of uncertainties, planning and the prospects for breakthroughs.

Let me say we have an informative array of expertise before us. So let me welcome the panelists, and especially those who made special last minute arrangements to travel here to testify. We appreciate your efforts.

And I now recognize the ranking member for his opening statement.

Mr. DEUTSCH. Thank you, Mr. Chairman. I would like to thank you for holding this hearing today in an effort to address fears and concern about the epidemic SARS or Severe Acute Respiratory Syndrome.

Scientists around the world, some of the very individuals who we will hear from today, have moved quickly to identify the SARS virus, develop diagnostic tests and formulate a possible vaccine. Some of the recent statistics showed SARS killing one in five patients hospitalized with the virus in Hong Kong, with over half the population aged over 60. It is these alarming statistics coupled with the uncertainty of how this virus is spread that has triggered a global response to that threat. The WHO, who has recently sent an investigation team to China, the U.S. Government has authorized Immigration and Customs inspectors to use force to detain passengers who appear to have SARS symptoms and States have alerted health professionals of what to do with a suspected case.

In Florida I am please to report that aggressive outreach in the medical community and to the travel industry have taken place already, including extensive meetings and conference calls to the popular theme parks and all partners in the hotel and related travel industry.

Discussions on the various legal and social issues associated with quarantine situations have occurred between Canadian officials and with our Department of Health. AIDS, mad cow, West Nile, ebola and the flu all rank among some of the most serious health concerns worldwide, and much work has gone into their prevention and treatment. Now as the SARS virus ranks among these other well known epidemics, public health officials must cooperate in training and lab development to prepare for an effective response

to possible larger scale future outbreaks, which lead us to where we are here today.

I look forward to the hearing and the witnesses.

Mr. GREENWOOD. The Chair thanks the gentleman.

The gentleman from Florida is recognized for 3 minutes for an opening statement.

Mr. STEARNS. Thank you, Mr. Chairman.

And let me just say, as I said earlier, that I think it is very important to have this hearing so that we can shed light on this troublesome disease.

But I want to say something positive, because I think we will be listening to these different panelists. I think in my understanding, I think rarely have we come together so quickly in this country and the world to, I think, combat this infectious disease. And between the World Health Organization and all the other groups that we have in the international community I think we can be pretty proud of the fact that we have not only alerted other countries. We had a little bad start in China, but at this point I think we are moving in the right direction. This hearing is a good example of that.

And I think we have reason to be encouraged that we are going to be able to find what SARS is all about, and perhaps in the end come up with a vaccine. And with the help of these panelists and others, I am confident we will. And that about it. We deployed experts all over the world very quickly. And now here in the United States I guess the big question is if we have it under control in Canada, and we have our airports covered, then we would not have to worry about the surge of hospitals, help and beds because we would have it under control.

So I think there is a lot of positive, even through SARS is thought of as negatively. But I think in the end, Mr. Chairman, that the international community is reacting pretty quick. And I think we just will continue to learn more about it. And just pray and hope that we have a vaccine.

So, again, I commend your hearing. And the more people tune in and watch and hear and understand this, I think the better off for everybody. And I think we are making a positive step toward that end.

Thank you, Mr. Chairman.

Mr. GREENWOOD. The Chair thanks the gentleman.

The gentlelady from Colorado, Ms. DeGette is recognized for 3 minutes for her opening statement.

Ms. DEGETTE. Thank you, Mr. Chairman.

We have learned a lot, I think, in the United States from the AIDS crises, from the anthrax crises about public health and about how to deal with outbreaks like SARS. And the good news is that our public health system has improved dramatically, as has our method of advising Americans whenever there is any kind of outbreak.

Many countries that have experienced SARS outbreak have been able to control that relatively well because of the hierarchial nature of their health care system and because they were able to put public health processes in place that work, places like Hong Kong, Vietnam, Toronto and others, and that is where there has been

success in containing SARS. But I cannot help but think about some letters that I found in my desk yesterday when I was cleaning it out. High school students in my district, which they sent to me in October of 2001, right after the anthrax scare.

Now, these are high school students in Denver, Colorado, probably one of the least likely groups to be effected by anthrax. But they were all writing me letters just pouring out their thanks to me for coming to their high school and assuring them that they were not going to get anthrax.

And my point is often times with diseases like SARS, anthrax, the fear of the disease or the infection is much worse than the likelihood of being infected. What I am afraid of is things like the United States and international economies, our travel economies, if we get SARS outbreaks in this country around international airports or other places, I worry about the affect on the public from the fear of infection even though it may not be a realistic fear in this country.

And so one thing I think that has not been addressed so far today, I would like to hear some of our panels, particularly our second panel, address these issues as what do we do in our public health system in not only containing this disease and outbreaks, but also in us waging a very nervous public, and they are still nervous from recent events.

Finally, I am interested in hearing from everyone as to the status of research into some kind of vaccine or other programs that can prevent this outbreak as much as possible.

I thank you for holding this hearing, Mr. Chairman. Once again, I think that you are really visionary in figuring out the issues that affect us. And I am looking forward to hearing all the panels.

Mr. GREENWOOD. The Chair thanks the gentlelady.

Does the gentleman from New Hampshire wish to make an opening statement?

[Additional statements submitted for the record follow:]

PREPARED STATEMENT OF HON. W.J. "BILLY" TAUZIN, CHAIRMAN, COMMITTEE ON ENERGY AND COMMERCE

Thank you, Mr. Chairman. This afternoon's hearing to examine the government's response to SARS, what we can learn from it, and what we must prepare for down the road, promises to be very informative. Let me thank you, Mr. Chairman, for preparing the most thorough Congressional look at the SARS situation to date.

As the Committee of jurisdiction over matters of public health, it is essential that we build a solid oversight record early on, so we have the correct perspective to help us monitor developments with respect to SARS, as well as other infectious disease outbreaks—be they produced naturally or by man.

At the outset, we should acknowledge the remarkable, and decisive, actions taken by public health authorities in the United States—at the CDC especially, and NIH, FDA, and HHS—and those working with the World Health Organization (WHO) and various health ministries abroad.

The SARS threat continues and may yet get worse, but we can at least breathe a sigh of relief because it could have been much, much worse already. Some people note that we escaped harm because of luck. We have been fortunate, but I don't think we should let that overshadow the actions of people, of individuals, that really made the crucial difference on the ground, actions that may have saved the lives of hundreds and possibly thousands of our fellow citizens.

In the United States, we should appreciate the decisions of the CDC leadership—Dr. Gerberding, who is before us today—for casting a very wide surveillance net to ensure that SARS cases wouldn't escape detection. This type of thinking and proactive effort is what saves lives.

Decisions by HHS Secretary Tommy Thompson—who said the government's response on potential SARS vaccines "wouldn't be business as usual"—and the rapid moves by Dr. Fauci and others at NIH to be ready to battle any outbreak all suggest we are taking aggressive steps to combat SARS.

This response has been effective to date. And we can trace it right to the decision that led to the discovery of the deadly SARS outbreak, beginning at a hospital in Hanoi this past February.

There, a WHO physician and investigator—one Carlo Urbani—was treating a cascade of deadly infections and urgently pressed Vietnamese health officials to impose protective health measures, which they did, and he raised the initial alarm for Dr. David Heymann and his colleagues at WHO in the field who made the bold decision to issue the rare global alert for SARS.

Carlo Urbani died of a SARS infection, but he saved lives by his decisive actions, in Vietnam and around the world. We should appreciate that.

Mr. Chairman, I think we should remember how decisions and actions by people, by individuals like Dr. Urbani and Dr. Heymann make a difference here, because part of our job on this Committee should be to ensure that such life-saving decisions aren't hampered by poor planning, out-of-date regulations and laws, or other barriers that hinder appropriate public health response.

The panels assembled today will offer us a range of views on what we have learned, and what we might do to improve the process. I look forward to learning about the state of public health laws and surveillance systems, for example, and the state of research and innovation in the area of infectious disease treatment and vaccines.

Innovation—in this case, the development of cutting edge medicines and technologies—is sparked by individual insight and decisions, against a backdrop that encourages such effort. Whether in the area of combating SARS or bioterrorism—such as through Project BioShield—our efforts should be to help provide the certainty and incentive that is necessary to encourage such innovation and for us to reap the benefits from its fruits.

Mr. Chairman, let me also welcome the witnesses for their testimony today at this timely hearing, and I yield back the remainder of my time.

PREPARED STATEMENT OF HON. JAN SCHAKOWSKY, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF ILLINOIS

I want to thank Chairman Greenwood and Ranking Member Deutsch for bringing this important issue before the subcommittee today. I also want to thank our witnesses appearing before the committee to discuss their efforts to combat the spread of SARS.

SARS has presented a serious public health concern to the international community and it is critical that we learn how to identify, treat, contain, and hopefully eradicate this epidemic. Fortunately, no one in the United States has died of SARS and the World Health Organization has removed the US from the list of affected countries. However, we cannot lull ourselves into complacency. We are still vulnerable to a SARS outbreak.

My constituents are particularly concerned about a potential outbreak in Illinois. After all, O'Hare International Airport is in Chicago and has the great distinction of offering more connections to international cities than any other airport in the world. As we know, the majority of people infected with SARS initially contracted the disease on airplanes or in public health settings. I am very interested to learn about protocols in place for both airports and public health settings should there be a sudden outbreak of SARS.

I think this epidemic clearly illustrates how critical it is for us to reinvest in our public health system. Because of President Bush's economic policies, an outbreak of SARS or some other infectious disease in the United States would overwhelm an already stressed public health system. Health programs on the local, state, and federal level are already experiencing funding cuts. They are being forced to take on more responsibilities with fewer resources. Now is not the time to cut funding. Now is the time that we invest in our nations health care systems by increasing funding for trained personnel, adequate laboratories, technology updates, and improved communication networks.

We must take a hard look at the communication systems we have in place in the event of emergency situations. I believe it is essential that all health providers, at every level, have access to information. The only way providers can respond in the event of an emergency is to have a public health system capable of rapid and effective communication.

Another issue before us is the grave threat the President's Medicaid reform poses to our country, one that would be exacerbated in a future public health emergency. If Medicaid is actually overhauled into a block grant, states will have even fewer resources to handle a health emergency than they do today. We must be able to respond quickly and effectively to public health threats, and the Medicaid reform principles on the table would only further undermine these efforts.

Again, I want to thank our witnesses for coming in today and sharing with us the lessons learned since the initial outbreak and explaining how we can work together in the future to combat the spread of SARS.

I want to conclude by saying that we should see SARS for what it is. It is an infectious outbreak that we must immediately respond to. Further, it is yet again another wake up call that we need to pay serious attention to our vulnerable public health system. We must infuse our public health system with funding so that we can adequately respond to our country's health care needs.

PREPARED STATEMENT OF HON. JOHN D. DINGELL, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF MICHIGAN

Severe Acute Respiratory Syndrome (SARS) is a deadly illness that has recently been reported in Asia, North America, and Europe. While most cases of SARS in the United States have occurred among travelers returning from other parts of the world affected by this lethal virus, we should be concerned about the possibility that SARS could spread more widely in the U.S. community.

As of today, it appears that SARS spreads primarily by close person-to-person contact. Most cases of SARS involve people who cared for or lived with someone with SARS, or had direct contact with infectious material from a person with SARS. But researchers have become increasingly suspicious that there are alternative methods of SARS virus transmission because cases of SARS have been reported by people who did not have any close personal contact with a SARS victim. In fact, new laboratory studies have produced the first scientific data that the SARS virus can survive in various places and conditions outside the human body. Recent reports out of Hong Kong, Japan, Germany, and Beijing show that the SARS virus can survive on common surfaces at room temperature for hours or even days.

The outbreak of the SARS epidemic in Toronto is well known. And trucks, jammed with a total of 4,000 tons of trash from Toronto, cross Michigan's Blue Water Bridge and travel down a 90-mile stretch of Interstate 94 every day en route to a landfill in southern Wayne County. If recent reports are correct, and if the SARS virus can survive in various places and conditions for an extended period of time, then this trash could conceivably pose a health risk to the people of Michigan and to the people of America. We need to know more, and quickly, about the nature and extent of this and other possible threats.

PREPARED STATEMENT OF HON. GENE GREEN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF TEXAS

Mr. Chairman, thank you for allowing me to join you here for this oversight hearing on Severe Acute Respiratory Syndrome.

The SARS story reads like something out of a science fiction novel. A new and frightening disease develops in a foreign country, and before we know it, the disease spreads from continent to continent, killing people before they even know what's happening to them.

According to the World Health Organization (WHO), there are more than 6,500 probable cases of SARS and more than 460 of these persons have died. For a disease that has been in existence for less than six months, these are troubling statistics.

But I think the real cause of concern for most people is that this disease seems to be easily transmitted. I know I was particularly troubled when I heard that many individuals in one Hong Kong apartment complex were infected without actually interacting with an affected person.

You know, my daughter is currently doing her residency at the University of Texas Medical Branch (UTMB) in Galveston, Texas, and she plans to specialize in Infectious diseases.

I often say that I'd rather have her specialize in anesthesiology or orthopedics, because I don't want her to come face to face with unknown diseases like SARS.

As a father, and a public policy maker, I am concerned by this outbreak, and am glad that we are having this opportunity to learn about our public health response to the disease, and ways we can learn from this illness to prepare for other public health threats, including possible bioterrorist attacks.

I would like to take a moment to highlight the work that has already been done on SARS in my hometown of Houston, TX.

I have spoken to various folks in the hospitals and public health departments and I was pleased to learn that most have implemented protocol to deal with possible SARS cases.

At Ben Taub hospital, the largest public hospital in Houston, every patient that presents with cold, flu-like symptoms is screened.

If it is determined that the patient has traveled to or has had contact with a person that has traveled to the effected areas the patient is then masked and all medical personnel attending the patient are specially masked.

The patient is then moved to a negative air flow patient room. Currently, there are six rooms that meet the negative air flow criteria.

Dr. Robert Atmar, an internationally recognized infectious disease physician from Baylor College of Medicine, is then made the attending physician for this patient.

At this point, the patient will be moved out of Ben Taub to a quarantine facility as we do not want to shut down Ben Taub to other essential community services, such as trauma.

This is a good plan that takes early measures to prevent the spread of the disease and involves partnerships with other providers in the area. I am proud of the work they have done in this area.

But the most obvious problem with this plan is that Ben Taub only has six negative air-flow rooms.

In a situation where we are facing a massive epidemic of a highly infectious disease, it is clear that our facilities could quickly become overwhelmed.

This is a good opportunity to develop systems that will help us build on what we've learned, so that we can continue our efforts to improve public health.

I know that our witnesses will provide us with some useful information on this matter, and I look forward to their testimony.

Thank you, Mr. Chairman, and I yield back the balance of my time.

Mr. GREENWOOD. All right. In that case the Chair will, first, with unanimous consent enter into the record three documents. First, the statement by Dr. Heymann, Executive Director for Communicable Diseases at the World Health Organization.

[The prepared statement of David L. Heymann follows:]

PREPARED STATEMENT OF DAVID L. HEYMANN, EXECUTIVE DIRECTOR FOR COMMUNICABLE DISEASES, WORLD HEALTH ORGANIZATION

This statement describes the evolution of severe acute respiratory syndrome, or SARS, and explains some of the features that make this new disease an especially challenging threat to international public health. Brief examples of economic, social, and political repercussions illustrate the wide-ranging impact a new disease can have in a closely interconnected and highly mobile world. Lessons learned from efforts to contain SARS, particularly concerning the strengths and weaknesses of systems for surveillance and response, are then used to assess global capacity to respond to other infectious disease threats, most notably the next influenza pandemic and the possible deliberate use of biological agents to cause harm. Priority areas for urgent improvement are identified and discussed.

SARS: A PUZZLING AND DIFFICULT NEW DISEASE

SARS is the first severe and easily transmissible new disease to emerge in the 21st century. Though much about the disease remains poorly understood and frankly puzzling, SARS has shown a clear capacity for rapid spread along the routes of international air travel. At present, the outbreaks of greatest concern are concentrated in transportation hubs or spreading in densely populated areas. WHO regards every country with an international airport, or bordering an affected area, as at potential risk of an outbreak.

The first cases of SARS are now known to have emerged in mid-November 2002 in Guangdong Province, China. The first official report of an outbreak of atypical pneumonia in the province, said to have affected 305 persons and caused 5 deaths, was received by WHO on 11 February. Around 30% of cases were reported to occur in health care workers. Confirmation that cases were consistent with the definition of SARS was made after permission was granted, on 2 April, for a WHO team to visit the province.

In the meantime, SARS was carried out of Guangdong Province on 21 February by an infected medical doctor who had treated patients in his home town. He

brought the virus to the ninth floor of a four-star hotel in Hong Kong. Days later, guests and visitors to the hotel's ninth floor had seeded outbreaks of cases in the hospital systems of Hong Kong, Viet Nam, and Singapore. Simultaneously, the disease began spreading around the world along international air travel routes as visitors at the hotel travelled home to Toronto and elsewhere, and as other medical doctors who had treated the earliest cases in Viet Nam and Singapore travelled internationally for medical or other reasons.

Today, close to 7000 probable cases of SARS have been reported from 27 countries on five continents. More than 450 deaths have occurred. China is reporting a cumulative total of probable cases that will soon reach 6000 as each day's nationwide reporting adds at least 100 new cases. "Hot zones" of particular concern include Toronto, Hong Kong, Singapore, Beijing and, increasingly, much of the rest of China. Although the outbreaks in Hong Kong, Singapore, and Toronto show signs of having peaked, new cases and deaths continue to be reported. Taiwan, with a rapidly growing number of cases and deaths, is a worrisome new development. With the exception of Taiwan, all of these areas belonged to the first wave of outbreaks, prior to a WHO global alert issued on 15 March. Viet Nam, another country in the initial wave of outbreaks, became the first country to control its SARS outbreak on 28 April.

A particularly serious threat. SARS demonstrates dramatically the global havoc that can be wreaked by a newly emerging infectious disease. At this moment, public health authorities, doctors, nurses, scientists, and laboratory staff around the world are struggling to cope with SARS at a time when some hope remains that the disease might still be contained. Economists and market analysts are simultaneously struggling to calculate the present and future costs, initially estimated at $30 billion in the Far East alone. Public panic is widespread, some government officials have lost their jobs, and social stability has been jeopardized in some of the hardest hit areas. Hospitals, schools, and borders have been closed, and several governments have advised their citizens not to travel to hard-hit areas. In Hong Kong, an electronic tracking system developed by the police force for use in criminal investigations has been adapted for contact tracing and monitoring of compliance with quarantine. In Singapore, military forces have been deployed to assist in contact tracing and to enforce quarantines that have halted the normal lives of thousands of people. No visitors are allowed at any public hospital.

SARS needs to be regarded as a particularly serious threat for several reasons. The disease has no vaccine and no treatment, forcing health authorities to resort to control tools dating back to the earliest days of empirical microbiology: isolation and quarantine. The virus comes from a family notorious for its frequent mutations, raising important questions about the future evolution of outbreaks and prospects for vaccine development. Epidemiology and pathogenesis are poorly understood. The initial symptoms are non-specific and common. All available diagnostic tests have important limitations. If tests are poorly conducted or results wrongly applied, patients excreting virus and thus capable of infecting others can slip through the safety net of isolation and infection control. The disease continues to show a disturbing concentration in previously healthy hospital staff—the human resource vital to control. A significant proportion of patients require intensive care, thus adding to the considerable strain on hospital and health care systems. Evidence is mounting that certain source cases, or "superspreaders", make a special contribution to rapid spread of infection. SARS has an incubation period that allows rapid spread along international air-travel routes.

With the notable exception of AIDS, most new diseases that emerged during the last two decades of the previous century or have become established in new geographical areas have features that limit their capacity to pose a major threat to international public health. Many (avian influenza, Nipah virus, Hendra virus, Hanta virus) failed to establish efficient human-to-human transmission. Others (*Escherichia coli* O157:H7, variant Creutzfeldt-Jakob disease) depend on food as a vehicle of transmission. Diseases such as West Nile fever and Rift Valley fever that have spread to new geographical areas require a vector as part of the transmission cycle. Still others (*Neisseria meningitidis* W135, and the Ebola, Marburg, and Crimean-Congo haemorrhagic fevers) have strong geographical foci. Although outbreaks of Ebola haemorrhagic fever have been associated with a case-fatality rate in the range of 53% (Uganda) to 88% (Democratic Republic of the Congo), person-to-person transmission requires close physical exposure to infected blood and other bodily fluids. Moreover, patients suffering from Ebola during the period of high infectivity are visibly very ill and too unwell to travel.

CHRONOLOGY OF THE EMERGING SARS OUTBREAK

SARS was first identified in Viet Nam on 28 February, when Dr Carlo Urbani, an epidemiologist from the Hanoi WHO office, examined a patient with a severe form of pneumonia with no known cause. By 10 March, at least 22 hospital workers in Hanoi's private French Hospital were ill with a similar acute respiratory syndrome, and by 11 March similar outbreaks had been reported among hospital workers in Hong Kong.

SARS occurred at a time of heightened surveillance for atypical respiratory disease. From 11 February, the WHO office in Beijing, which reinforced its staff with two epidemiologists, had been working with the government of China to learn more about the outbreak of atypical pneumonia in Guangdong. Surveillance was heightened further when a 33-year-old man who had travelled with his family to Fujian Province in China died of unknown causes in Hong Kong on 17 February. The next day, Hong Kong authorities announced that avian influenza A(H5N1) virus, the cause of "bird flu", had been isolated from both the man and his nine-year-old hospitalized son. Another member of the family, an eight-year-old daughter, died while in Fujian and was buried there.

On 12 March, after an assessment of the situation in Asia with WHO teams in Hanoi, Hong Kong, and Beijing, a global alert was issued about cases of severe atypical pneumonia with unknown etiology that appeared to place health workers at high risk.

Two days later, on 14 March, WHO received a report from the government of Canada that health authorities had taken steps to alert hospital workers, ambulance services, and public health units across the provinces that there were four cases of atypical pneumonia within a single family in Toronto that had resulted in 2 deaths. At 2 a.m. Geneva time on the following day, 15 March, the government of Singapore notified WHO, by urgent telecommunication, of a similar illness in a 32-year-old physician who had treated cases with a severe respiratory syndrome in Singapore, all subsequently linked to the Hong Kong hotel. This Singapore physician had travelled to the United States for a medical conference, and at the end of the conference boarded a return flight to Singapore in New York. Before departure he had indicated to a colleague in Singapore by telephone that he had symptoms similar to the patients he had treated in Singapore. The colleague notified health authorities. WHO identified the airline and flight, and the physician and his two accompanying family members were removed from the flight at a stopover in Frankfurt, Germany, where the three were immediately isolated and placed under hospital care. As a result of this prompt action, Germany experienced no further spread linked to the three imported cases.

A rare emergency advisory. Later in the morning of 15 March, with this background and chronology of events, a decision was made by WHO to increase the level of the global alert issued on 12 March. The decision was based on five different but related factors. First, the causative agent, and therefore the potential for continued spread, of this new disease were not yet known. Second, the outbreaks appeared to pose a great risk to health workers who managed patients, and to the family members and other close contacts of patients. Third, many different antibiotics and antivirals had been tried empirically and did not seem to have an effect. Fourth, though the numbers were initially small, a significant percentage of patients (25 of 26 hospital staff in Hanoi, and 24 of 39 hospital staff in Hong Kong) had rapidly progressed to respiratory failure, requiring intensive care and causing some deaths in previously healthy persons. Finally, the disease had moved out of its initial focus in Asia and appeared to have spread to North America and Europe.

At this time, the epidemiology of SARS was poorly understood. A virulent strain of influenza had not been ruled out as a possible cause, even though transmission patterns were not characteristic for influenza. There was also some hope that the new disease, like many other new diseases of the recent past, would fail to maintain efficient person-to-person transmission, or that it might attenuate with passage and eventually self-contain. Despite the lack of understanding about the disease, its cause, and future evolution, the need was great to introduce a series of emergency measures to contain SARS outbreaks in the affected areas and prevent further international spread, thus reducing opportunities for the new disease to establish itself. WHO thus decided, on 15 March, to issue a rare emergency travel advisory as a global alert to international travellers, health care professionals, and health authorities.

THE GLOBAL RESPONSE

The existing system for alert and response. In April 2000, WHO formally launched the Global Outbreak Alert and Response Network (GOARN) as a mecha-

nism to link together, in real time, 110 existing networks which together possess much of the data, expertise, and skills needed to keep the international community alert to outbreaks and ready to respond. By electronically linking together existing networks the World Health Organization is able quickly to learn of significant events and to mobilize verification and response activities in spite of WHO's limited resources. From January 1998 through March 2002, the WHO has investigated 538 outbreaks of international concern in 132 countries.

One of the most powerful new tools for gathering epidemic intelligence is a customized search engine that continuously scans world Internet communications for rumors and reports of suspicious disease events. This is the Global Public Health Intelligence Network (GPHIN), a computer application developed by Health Canada and used by WHO since 1997. GPHIN operates as a sensitive real-time early warning system by systematically searching for key words in over 950 news feeds and electronic discussion groups around the world. Human review and computerized text mining are used to filter, organize and classify the more than 18,000 items it picks up every day, of which around 200 merit further analysis by WHO. GPHIN provided some of the earliest alerts to the November outbreak in China.

In outbreak alert and response, every hour counts, as the window of opportunity for preventing deaths and further spread closes quickly. GPHIN has brought tremendous gains in timeliness over traditional systems in which an alert is sounded only after case reports at the local level progressively filter to the national level before being formally notified to WHO. GPHIN currently picks up—in real time—the first hints of about 40% of the roughly 200 to 250 outbreaks subsequently investigated and verified by WHO each year. While the early alert to outbreaks of genuine concern is most important, GPHIN also allows WHO to step in quickly to refute unsubstantiated rumors before they have a chance to cause social and economic disruption.

During outbreak response, WHO uses a custom-made geographical mapping technology to assist in the location of cases and rapid analysis of the epidemic's dynamics. This epidemiological mapping technology is also used to predict environmental and climatic conditions conducive for outbreaks. An event management system, introduced in 2001, is now used to gather and communicate data throughout the course of outbreak investigation and response. The system generates a dynamic picture of operations, aids organization of logistics, and provides a systematic way to prepare better, respond faster, and manage resources more effectively.

SARS: sealing off the opportunities to establish endemicity. SARS has been an extremely demanding test of the effectiveness of WHO and its GOARN partners to mount an adequate response, get teams and supplies into countries, and ensure adequate monitoring and reporting. The urgency of SARS has further challenged WHO to set in motion high-level international scientific and medical collaboration in which natural competition for publication and prestige is set aside in order to identify the SARS causative agent with unprecedented speed and to develop diagnostic tests and effective treatment protocols.

To date, the global response, coordinated by WHO and strongly supported by the U.S. Centers for Disease Control and Prevention and other partners, has been designed to rapidly seal off opportunities for SARS to establish itself as a common disease. The initial emergency plan, mapped out from 12 to 15 March, called for an attack on the ground and in the "air". On the ground, WHO sent teams of experts and specialized protective equipment for infection control in hard-hit hospitals to countries requesting such assistance. In the "air", WHO used the model of its electronically interconnected global influenza network to quickly establish a similar "virtual" network of 11 leading laboratories, connected by a shared secure website and daily teleconferences, to work around the clock on identification of the SARS causative agent and development of a robust and reliable diagnostic test. This network, in turn, served as a model for similar electronically linked groups set up to pool clinical knowledge and to compare epidemiological data. WHO also decided to issue daily updates on its website to keep the general and travelling publics informed and, to the extent possible, counter rumors with reliable information.

Following the emergency advisory issued on 15 March, global vigilance was immediately heightened, with the result that most countries subsequently reporting cases have managed, through prompt detection, isolation and good infection control, to prevent the scale of transmission experienced in the SARS "hot zones". On 2 April and again on 19 April, WHO issued the toughest travel advisories in its 55-year history when it recommended postponement of all but essential travel to designated high-risk areas.

WHO teams continue to provide operational support and specialized expertise in the most seriously affected areas. Requests for additional country assistance continue to be received, most notably from authorities in China. Abundant additional

support is available to all through information posted at the WHO website (www.who.int/csr/sars). Guidance ranges in nature from forms for collecting and reporting data, through guidelines for clinical management and infection control in hospitals, to the materials for local production of diagnostic tests. The evolution of the outbreak is constantly and closely monitored and daily updates are posted on the website. On 17 April, exactly a month after its establishment, the laboratory network announced conclusive identification of the SARS causative agent: a new coronavirus unlike any other known human or animal virus in its family. The laboratory reagents needed to calibrate, standardize and assure the quality of laboratory tests are being made available by WHO, at no cost, to laboratories designated by ministries of health. Earlier this week, network scientists released the first results of studies on the survival time of the SARS virus on various environmental surfaces and in various bodily specimens, including faeces, respiratory secretions, and urine. The results will provide solid scientific guidance for recommended public health measures and may shed some light on why so many staff in sophisticated and well-equipped hospitals continue to become infected.

On 28 March, at the end of the second week of the global response, China, a reluctant partner in the global alert and response at the start, became a full partner in the three working groups that were studying SARS, and concluded that the outbreaks of SARS elsewhere in Asia were related to the outbreak in Guangdong Province. The Chinese government has announced that SARS is being given top priority. A system of alert and response for all emerging and epidemic-prone diseases is being developed. Daily electronic reporting of new cases and deaths, by province, has begun. Equally important, health officials have begun daily televised press conferences, thus taking the important step of increasing the awareness of the population and hospital staff of the characteristic symptoms, the need to seek prompt medical attention, and the need to manage patients according to the principles of isolation and strict infection control.

LEARNING FROM SARS: HOW TO PREPARE FOR OTHER EMERGENCIES CAUSED BY INFECTIOUS DISEASES

When the first suspected SARS cases began appearing in the U.S., many hospital staff cited the WHO advisory, and their subsequent high-level of awareness, as one reason why cases were quickly detected and isolated, with the result that further transmission was either avoided entirely or kept to a very small number of cases. A second explanation offered for the comparatively mild and well-contained SARS situation in the U.S. is the high level of nationwide planning and preparedness that followed the deliberate distribution of anthrax-tainted mail in the US postal system in October 2001.

The International Health Regulations provide the legal framework for global surveillance and reporting of infectious diseases and a mechanism by which measures to prevent international spread can be enforced. The regulations, which are currently undergoing a substantial revision, will be discussed by Ministers of Health at the World Health Assembly later this month. The SARS outbreak provides firm evidence of the need for such regulations and concrete examples of the areas in which revision and updating are urgently needed.

The novel nature of the SARS virus created an extra step in the containment response: scientific identification and characterization of the causative agent to allow development of a diagnostic test, treatment protocols, and a scientifically sound basis for recommending control measures. Experience with SARS has shown that, with strong global leadership by WHO, scientific expertise from around the world can work in a very effective collaborative manner to identify novel pathogens. This function would be invaluable in the event of the deliberate release of a biological agent or during future emergence of a novel or poorly understood pathogen.

WHO is continuing its aggressive containment activities aimed at preventing SARS from becoming a widely established threat. The immediate scientific priorities include development of a robust and reliable diagnostic test, improved understanding of the modes of transmission, and identification of effective treatment regimes. If, despite extraordinary efforts, the disease does become endemic, WHO and its international partners will have to settle in for a long and difficult fight. In this case, existing mechanisms developed for other public health emergencies, such as the Medicines for Malaria Venture, the Global Alliance for Vaccines and Immunization, the Global TB Drug Facility, and the International Coordinating Group for meningitis and yellow fever, would have to be looked to as possible models for ensuring the rapid development of SARS drugs and vaccines and equitable access in all at-risk countries. Use of the influenza network as a model for the SARS labora-

tory network suggests that such an approach brings great speed as well as efficiency.

LESSONS FOR THE FUTURE

Just as the SARS response has been guided by lessons learned during preparedness planning for the next influenza pandemic and for a possible bioterrorist attack, both of these types of potential public health emergencies will benefit from lessons learned as the international response to SARS continues.

The response to SARS has already brought to light a number of positive lessons as well as highlighted a number of challenges for future preparedness planning. The SARS experience has shown the capacity of global alerts, widely supported by a responsible press and amplified by electronic communications, to improve global vigilance and awareness at all levels, from health professionals and national authorities, to politicians and the travelling public. The quick detection and reporting of the first cases in South Africa and India are indicative of the high level of global awareness and the vigilance of the world's health systems. The present climate of high alert also helps explain the speed with which developing countries—from Namibia to Mozambique—have readied their health services with preparedness plans and launched SARS campaigns, often with WHO support, to guard against imported cases.

The SARS experience in Viet Nam has shown that immediate political commitment at the highest level can be decisive. Viet Nam demonstrated to the world how even a very poor country, hit by an especially large and severe outbreak, can triumph over a disease when reporting is prompt and open and when WHO assistance is quickly requested and fully supported.

And finally, stimulation of very rapid, high-level research has been critical in accelerating the scientific knowledge needed to determine the best control interventions.

The major challenges to be addressed in future planning are those of transparency and surge capacity. SARS is now known to have begun in mid-November in Guangdong Province. Cases during the earliest phase of the SARS outbreak there were not openly reported, thus allowing a severe disease to become silently established in ways that made further international spread almost inevitable. This is the most important lesson for all nations: in a globalized, electronically connected world, attempts to conceal cases of an infectious disease, for fear of social and economic consequences, must be recognized as a short-term stop-gap measure that carries a very high price—loss of credibility in the eyes of the international community, escalating negative domestic economic impact, damage to the health and economies of neighboring countries, and a very real risk that outbreaks within the country's own territory can spiral out of control.

The report of the first WHO expert team to investigate the SARS situation in Guangdong Province reached the following conclusion:

> "If SARS is not brought under control in China there will be no chance of controlling the global threat of SARS. Control of a new and rapidly disseminated disease like SARS is challenging, especially in a country as large and diverse as China. Effective disease surveillance and reporting are key strategies in any attempt to control the spread of a serious new communicable disease such as SARS."

Lessons about the importance of transparency are particularly strong. This week observers of China have begun to speculate that the recent openness about SARS—the daily news reports and electronic updating nationwide of cases—may mark a turning point in the way government officials communicate information to the public and facilitate frank reporting by the media. The next weeks and months will determine whether the current outbreaks of international concern can be contained, thus preventing SARS from becoming another endemic infectious disease in human populations that has no vaccine and no effective treatment. It is already clear, however, that the responsibility for containing the emergence of any new infectious disease showing international spread lies on all countries. In a world where all national borders are porous when confronted by a microbial threat, it is in the interest of all populations for countries to share the information they may have as soon as it is available. In so doing, they will allow both near and distant countries—all neighbours in a globalized world—to benefit from the understanding they have gained.

Inadequate surge capacity in hospitals and public health systems has clearly been a major problem with SARS, especially since health care workers have themselves been victims of the disease and are the frontline troops at risk. The shortage of expert staff to co-ordinate national and global responses to a rapidly evolving public health emergency is also an issue needing additional investment and attention. In

some areas, hospitals have been closed. In others, the heavy burden imposed by SARS on existing hospitals has necessitated the hasty construction of new facilities. As another lesson, evidence from SARS has shown that local and national capacities can be assisted by coordinated networks such as WHO's GOARN that can and do mobilize additional support during times of public health emergencies. Further strengthening of the surge capacity of the WHO "hub" of the global alert and response system would also assist in preparedness for future infectious disease threats.

The SARS experience also has some lessons about the importance of international collaboration and strong but politically neutral global leadership. Though exceptional in terms of its impact, severity, rapid international spread, and many puzzling features, SARS is only one of around 50 internationally important outbreaks to which WHO and its partners respond in any given year. The high level of medical, scientific, political, and public attention focused on SARS is helping the world to understand the severity of the infectious disease threat and the importance of international solidarity in the face of this threat. It is also helping the world to understand the importance of global leadership and of politically neutral and privileged access to all affected countries. Finally, the response to the SARS outbreak is helping the public to understand that WHO's activities of global coordination, capacity development, communications, and mobilizing expertise enable rapid response and actually save lives. To date, in the vast majority of countries, these WHO activities have helped health authorities to identify imported SARS cases quickly, prevent a SARS outbreak, and thus avoid the devastating consequences seen elsewhere.

Mr. GREENWOOD. A letter, dated May 5 to me from the Embassy of the People's Republic of China.

[The letter follows:]

EMBASSY OF THE PEOPLE'S REPUBLIC OF CHINA
May 5, 2003

The Honorable JIM GREENWOOD
Chairman of the Subcommittee on Oversight and Investigations
Committee on Energy and Commerce
United States House of Representatives
2436 Rayburn House Office Building
Washington, D.C. 20515-3808

DEAR CHAIRMAN GREENWOOD, today, I am writing to share with you information on the measures taken by the Chinese Government to combat SARS.

The SARS epidemic, which is a new contagious disease, has posed a grave threat to life and health of mankind. Still faced with a serious SARS situation, the Chinese Government has put health, safety and life of the people above everything else, and is determined to face the difficulties squarely. In order to turn around the current situation, we have taken, and will continue to take resolute and effective measures.

First, we have been strengthening prevention efforts across the board to contain the spread of the disease. We have made SARS a statutory epidemic under China's legislation, and established an open and transparent system for epidemic reporting and news briefing, including making daily report to the WHO and publishing it to the communities in the meantime. We have also taken all necessary measures to guard against cross infection in hospitals, and conducted publicity campaigns to increase the public awareness and capability for self-protection so that prevention can be ensured with mass participation.

Second, we have been going all out to treat SARS patients and setting up the SARS funds. China's provinces, regions and municipalities have designated special hospitals and enlarged medical facilities to bring timely treatment to SARS patients. We have set up a two-billion-*yuan* special fund for SARS control and prevention, which will mainly be used to provide free treatment for the patients in rural areas and the needy patients in urban areas.

Third, we have established a national public health contingency response mechanism, a disease monitor and data collection network and an ascertaining network of laboratories. The central government has allocated 3.5 billion *yuan* for infrastructure development of a national disease control system.

Fourth, we have stepped up critical SARS research by mobilizing multidisciplinary experts to explore effective methods of diagnosis and treatment. We have developed a fast diagnostic method and are trying to improve it and testing it clinically. The central government has provided special fund for SARS research.

Fifth, we have increased cooperation with the international community and have been drawing on others' successful experience. We value, and have acted upon, the useful advice by WHO experts after their field inspections in China. At the just-concluded Special China-ASEAN Leaders' Meeting on SARS on April 29 in Bangkok, China and ASEAN issued a joint statement, committing themselves to more effective cooperation in the fight against SARS. Let me say that we also appreciate the U.S. Government's readiness to offer support, as indicated by President Bush in his phone call to President Hu Jintao.

We believe that through the joint efforts of mankind, the problem of SARS will be successfully solved in the end.

Mr. Chairman, the Chinese Government, while tackling the SARS problem, will continue to push forward China's economic cooperation with foreign countries, including the United States. As you know, even under the current circumstances, the Chinese economy still has a lot of dynamism. I believe that with the joint efforts of the people with vision in China and the U.S., our economic cooperation will achieve further progress.

I hope you will find this information useful. I am looking forward to seeing you soon.

With warm regards,

Sincerely,

YANG JIECHI
Ambassador

Mr. GREENWOOD. And a letter addressed to me from the Ministry of Public Safety and Security in Ontario.

[The letter follows:]

MINISTRY OF PUBLIC SAFETY AND SECURITY
COMMISSIONER OF PUBLIC SECURITY
May 7, 2003

The Honourable JAMES GREENWOOD
Chairman
House Energy and Commerce Committees
Subcommittee on Oversight and Investigations
U.S. House of Representatives
2125 Rayburn House Office Building
Washington DC 20515
USA

MR. CHAIRMAN, AND MEMBERS OF THE COMMITTEE: I am pleased to provide this written brief regarding the important issue of *Severe Acute Respiratory Syndrome* (SARS), and tell you about the effective measures we have taken to contain and control this new disease in Ontario. This paper also updates information provided on April 29th, 2003, to the Health, Education, Labor & Pensions Committee.

I also wish to thank US Consul General Antoinette Marwitc and her staff for their strong support of Toronto during our SARS outbreak.

The Centers for Disease Control is also playing a key role in our efforts, and I will elaborate further on this in my remarks.

By way of introduction, I am a medical doctor who serves in a number of capacities within the Ontario government. I am the Assistant Deputy Minister of Public Safety and Security, the Chief Coroner for Ontario and Commissioner of Public Security. The public security office also coordinates Ontario's approach to terrorism and manages emergency situations within Ontario, including such things as SARS, 9/11, Y2K and the Ice Storm of 1998.

The problem with responding to SARS has centered on the fact that we know so little about it. What is it? What are its characteristics? How is it spreading? When are people infectious? How do we test for it? And how do we control and treat it?

In the case of Toronto and the province of Ontario, we faced these questions very early in the known history of SARS and knew only that we were facing the challenge after the disease was already spreading in a local hospital.

Our index case is clear. A Toronto resident contracted SARS in an elevator in the Metropole Hotel in Guangdong, China. That person returned to Toronto, became ill and died. The 43-year old son of that person went to hospital on March 16th for treatment of what turned out to be SARS, and while in the emergency department and after being admitted was not in respiratory isolation. This person in retrospect is believed to have been superinfective and our cluster of cases takes off from this point. This person and the next two persons who were infected through contact in

that emergency department all went on to infect large numbers of other patients, health care workers and family members.

Initial information about SARS was only beginning to flow around March 16th, and it took time to recognize the initial hospital case and the other contacts from that case. Once that recognition was made, we imposed strict and effective isolation measures.

By this time, however, because of the highly infectious nature of our early cases, enough staff and patients were affected that the hospital was closed to new admissions, emergency cases, and transfers. We also started to alert the entire health care system.

On March 25th, we decided that a provincial health emergency should be declared in order to mobilize the full resources of the province. We decided to act quickly and boldly to attempt to eradicate SARS from our community. We started by restricting activity in all of the hospitals in the province while we put in place stringent infection control procedures. Everyone, including all staff, were checked for illness before entering a hospital. Staff were required to gown, glove, and mask in patient areas of hospitals; masks were provided for all patients entering an emergency department, and isolation was required for respiratory patients until their conditions were determined. Initially we also stopped all elective surgery, stopped any visitors or volunteers from coming to hospitals, and organized a new very strict system of ambulance transfers between hospitals.

On the community side we also took strong measures. Public Health vigorously tracked contacts of SARS cases and imposed 10-day isolation or quarantines for all contacts. If persons were found to be ignoring isolation orders, legal remedies were used. The public has also been encouraged not to go to work if they show early symptoms of SARS including headache, malaise or muscle ache, and before they develop fever. Frequent hand washing has been encouraged and a calm approach to the problem advocated. These measures continue to this day.

Before our initial measures had time to take hold, a transfer of a highly infectious patient occurred to a nearby hospital. This patient was another superinfectious individual, and this transfer resulted in more medical staff, their families and other patients getting SARS. This hospital was also closed.

A short time later, we also discovered a potential "leak" into the community. Relatives of one patient who took their patriarch to hospital on March 16th, became infected. They subsequently visited doctors, and a funeral home, and were involved in a religions community. This series of unprotected contacts took some time to trace and piece together, and is referred to as the BLD Cluster (named after the religious group). There were 31 cases within this group, and we ultimately isolated more than 500 people. There have been no new cases from this group since April 9th. However, it is very important to note that all of our so-called "community" cases track back to the original index case. We have had no sporadic or unexplained SARS spread in our community.

Over the Easter weekend we experienced a setback in our efforts. We had some incidents of SARS developing in medical staff working in SARS units. In one instance a very difficult and very long intubation in a SARS unit infected, we believe, 15 staff who were in attendance. We immediately rewrote our procedures, and we have invited Health Canada and the CDC to work with us to study this unfortunate event and recommend the best ongoing infection control standards for our SARS units. We appreciate the fact the CDC agreed to come and are working diligently and well with our people.

Our actions, both in hospitals and in the community, have proven to be effective. Both hospitals have now been through more than two incubation periods (20 days) without any further spread or new cases and so both hospitals are in the process of reopening. All our known SARS cases are in SARS units in our hospitals or, if well enough, at home in isolation finishing recovery.

I would like to note that Dr. Julie Gerberding, Director of the U.S. Centers for Disease Control and Prevention, has endorsed Ontario's approach. She said: "One of the specific lessons I learned in Canada, if it becomes necessary, you have to be bold. And you have to do it quickly. You have to be aggressive in implementation. There isn't time for a lot of committee meetings or discussions and debate. You've got to get the job done."

There has also been a lot of attention paid to the now-rescinded World Health Organization travel advisory issued against Toronto. WHO did not visit Toronto or discuss our outbreak, or its management, directly with us before taking this action; nor did they give us the required warning before issuing it. We believe that this advisory was based on old data and an incomplete understanding of our situation.

The WHO advisory unnecessarily and wrongly alarmed our own population, resulted in huge economic loss, and demonstrated that it wastes valuable health re-

sources in other countries such as the US by causing authorities to think they might have cases of SARS from Toronto when in fact there is no possible epidemic link to our cases. It emphasizes the need for reliable information and careful screening based on facts, not erroneous news reports.

Finally, I will comment on where we are today.

We have many SARS patients who are now well and back in the community.

As of May 6th, Ontario had:

- 28 active probable SARS patients in hospitals—11 fewer than April 29th
- 1 active probable SARS patient at home finishing his/her order, the same as April 29th
- 179 SARS patients discharged and back in the community, up 23 from April 29th, and
- 23 SARS patients have died (up 3 from April 29th), virtually all of these had significant other medical conditions and most were elderly.

There has been no spread of SARS through casual community contact. More than 20 days have passed since the last transmission among close contacts outside health care settings.

We continue to work with the CDC on infection control for our medical staff who are working within SARS units. This, along with finding and isolating new travel cases that arrive from outside Ontario, is our current challenge.

The streets of Toronto are as safe from SARS as the streets of London, Paris or Washington. In fact, a BBC reporter told me recently that he saw far more masks in London than Toronto. However, the lesson for all us that it only takes one case to start the new breakout.

Thank you for this opportunity to present our experience in Ontario. On behalf of the Ontario government, let me express our appreciation for your interest and understanding.

Sincerely,

JAMES G. YOUNG, M.D.
Commissioner of Public Security

Mr. GREENWOOD. Those documents will be made part of the record.

And now we welcome our witnesses. We have an august panel and we are delighted to have you here.

Let me introduce our witnesses. They are Mr. Jerome Hauer, Acting Assistant Secretary for Public Health and Emergency Preparedness at the U.S. Department of Health and Human Services. Welcome, sir.

Dr. Julie Gerberding, Director of the Centers for Disease Control and Prevention. You have been very busy. We welcome you as well.

Dr. Anthony Fauci, M.D., Director of the National Institute of Allergy and Infectious Disease. Welcome. Good to have you with us.

Dr. Murray Lumpkin, Principal Associate Commissioner of the Food and Drug Administration. Thank you.

And Ms. Jan Heinrich, Director of Health Care and Public Health Issues, The United States General Accounting Office. Welcome.

I believe that you understand that we are holding an investigative hearing. And it is the practice of this subcommittee when holding investigative hearings to take testimony under oath. Do any of you object to giving your testimony under oath? Very well.

We should also advise you that pursuant to the Rules of the House you are entitled to be represented by counsel. Do any of you wish to be represented by counsel? This is not an Enron hearing, so we suspect you probably would not. But we would we ask you to rise and raise your right hand, please.

[Witnesses sworn.]

You are under oath. And we will begin with Mr. Hauer and ask for your opening statement, sir.

TESTIMONY OF JEROME M. HAUER, ACTING ASSISTANT SECRETARY FOR PUBLIC HEALTH AND EMERGENCY PREPAREDNESS, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES; JULIE L. GERBERDING, DIRECTOR, CENTERS FOR DISEASE CONTROL AND PREVENTION; ANTHONY S. FAUCI, DIRECTOR, NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASE; MURRAY M. LUMPKIN, PRINCIPAL ASSOCIATE COMMISSIONER, FOOD AND DRUG ADMINISTRATION; AND JANET HEINRICH, DIRECTOR, HEALTH CARE AND PUBLIC HEALTH ISSUES, THE UNITED STATES GENERAL ACCOUNTING OFFICE

Mr. HAUER. Thank you, Mr. Chairman and members of the committee. I am Jerry Hauer, Acting Assistant Secretary for Public Health Emergency Preparedness. I appreciate this opportunity to share our Department's response to the SARS virus within the context of public health emergency preparedness. Dr. Gerberding, Dr. Fauci, and Dr. Lumpkin will speak to the clinical details of the response, so I will keep my comments focused on the overall coordination.

The Department of Health and Human Services continues to work vigorously to ensure that the Nation is ready to respond to terrorism and other public health emergencies as we strength our public health infrastructure against bioterrorism, we are simultaneously enhancing our ability to respond to emerging public health threats. There is no question that the work we have done over the past 18 months has prepared us to meet the challenges we are facing in managing the SARS outbreak.

Rarely have the international and national health communities worked so well and so rapidly together in response to an emerging infectious disease. As soon as the international community became aware of the SARS situation in March, the Director General of the World Health Organization was in communication with experts at HHS headquarters in Washington and the CDC in Atlanta. Despite the seriousness of the virus' impact worldwide, we have reason to be encouraged by the response to SARS for several reasons.

First, the identification of the agent that causes the disease was completed in record time. In contrast to diseases including HIV, legionella, and Lyme Disease which took over a year or even longer to pinpoint. We had and continue to have daily video conference calls to share information, map the response, and coordinate our activities. We have deployed teams of experts and support staff to each of the impacted countries, including Canada, mainland China, Hong Kong, Taiwan, the Philippines, Singapore, Thailand and Vietnam to collect first-person data and to assist in conducting surveillance and epidemiologic studies, and the implementation of infection control precautions and other interventions.

We are partnering with industry to organize a full-court press on vaccine development. We are taking maximum advantage of technology to facilitate information sharing; the map of the SARS virus genome was published on the Internet soon after it was successfully sequenced by an international team of laboratories lead by CDC and Health Canada.

Improvements in laboratory capacity and coordination that were made recently as part of our enhancing of our overall public health

preparedness has contributed to the speed and accuracy with which we have responded to SARS. The technology built into the Secretary's Command Center has been indispensable, providing a forum for real-time, face-to-face exchange of information with public health officials in Atlanta, Toronto, Geneva and most recently in Hong Kong and China. The Command Center maps the distribution of SARS cases across the globe with geographic information system software for use during our planning discussions.

The Command Center did not exist a year ago, it became operational last November. Although the situation in Canada appears to be coming under control, it is critical that we are prepared to confront an outbreak of SARS on U.S. soil. Our recent efforts to enhance the Nation's preparedness to respond to a small pox outbreak have laid the foundation for managing a potential SARS event in cities throughout the country. One of the most important elements of an effective response plan is the development of hospital surge capacity, including the ability to isolate a number of infectious patients.

In fiscal year 2002 we awarded $1.1 billion to 50 States, three municipalities and the American territories to enhance public health preparedness and to upgrade the readiness of hospitals and other health care entities to address bioterrorism and other public health emergencies. In fiscal year 2003 CDC and HRSA will award additional $1.4 billion to further enhance State and local preparedness. I should note that these preparations are applicable to a broad range of public health emergencies. Our team is unified and ready to deal with a variety of health response issues.We are taking a variety of steps to ensure that States and other awardee jurisdictions have the resources they may require immediately to strengthen and upgrade their readiness. In fiscal year 2002, we awarded $1.1 billion to 50 States, 3 municipalities, and the American territories to enhance public health preparedness and to upgrade the readiness of hospitals and other healthcare entities to address bioterrorism and other public health emergencies. In fiscal year 2003, CDC and HRSA will award an additional $1.4 billion to further enhance State and local preparedness.

The bioterrorism preparedness funding has made a material difference at the State and local levels. Over 90 percent of the 50 States and three municipalities that have been awarded funds have developed systems for 24/7 notification or activation of their public health emergency response plans, and 87 percent of these grantees have developed interim plans to manage and distribute pharmaceuticals, equipment and supplies from the Strategic National Stockpile.

While our State and local partners work to improve their preparedness and response capabilities, the Department is implementing an aggressive research and development program. Dr. Fauci will address this momentarily.

The FDA works very closely with these partners to provide advice during the development process with a view toward facilitating subsequent submissions for regulatory review.

The research and development efforts are on a very compressed timetable and reviews of their progress are discussed on a regular basis by an interagency team consisting of NIH, CDC and FDA.

These are truly challenging times for our Department. I believe that we are up to the task and we look forward to working closely with Congress to ensure that the Nation is prepared to respond to bioterrorism and other public health emergencies such as the SARS virus.

Mr. Chairman, thank you for the opportunity to appear today. My colleagues and I would be happy to take any questions.

[The prepared statement of Jerome M. Hauer follows:]

PREPARED STATEMENT OF JEROME M. HAUER, ACTING ASSISTANT SECRETARY FOR PUBLIC HEALTH EMERGENCY PREPAREDNESS, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Thank you, Mr. Chairman and members of the Committee. I am Jerome M. Hauer, Acting Assistant Secretary for Public Health Emergency Preparedness. I appreciate this opportunity to share our Department's response to the SARS virus within the context of public health emergency preparedness. Dr. Gerberding, Dr. Fauci, and Dr. Lumpkin will speak to the clinical details of the response, so I will keep my comments focused on more global issues and coordination.

The Department of Health and Human Services continues to work vigorously to ensure the Nation's response readiness to terrorism and other public health emergencies. We are doing this by pursuing a multi-pronged approach that consists of enhancing public health and hospital preparedness at state and local levels, and conducting research and development on countermeasures for the biological, radiological, and chemical agents most likely to be used as weapons of mass destruction. As we strengthen our public health infrastructure against bioterrorism, we are simultaneously enhancing our ability to respond to emerging public health threats. There is no question that the work we've done over the past 18 months has prepared us to meet the challenges we are facing in managing the SARS outbreak.

Rarely have the international and national health communities worked so well and so rapidly together in response to an emerging infectious disease. As soon as the international community became aware of the SARS situation in March, the Director General of the World Health Organization was in communication with the experts at HHS headquarters in Washington and the CDC offices in Atlanta. Despite the seriousness of the virus' impact worldwide, we have reason to be encouraged by the response to SARS for several reasons. First, the identification of the agent that causes the disease was completed in record time. CDC identified the coronavirus within a few short weeks of receiving the first specimens from Asia. In contrast, scourges including HIV, legionella, and Lyme Disease took a year or even longer to pinpoint. The unprecedented cooperation between the World Health Organization, HHS headquarters and CDC headquarters in Atlanta resulted in significant progress. We had and continue to have daily video conference calls to share information, map the response, and coordinate our activities. We have deployed teams of experts and support staff to each of the impacted countries, including Canada, mainland China, Hong Kong, Taiwan, the Philippines, Singapore, Thailand and Vietnam to collect first-person data and to assist in conducting surveillance and epidemiologic studies, and the implementation of infection control precautions and other interventions.

We are partnering with industry to organize a full-court press on vaccine development. We are taking maximum advantage of technology to facilitate information sharing; the map of the SARS virus genome was published on the Internet soon after it was successfully sequenced by an international team of laboratories including CDC and Health Canada.

Improvements in laboratory capacity and coordination that we've made recently as part of enhancing our overall public health preparedness has contributed to the speed and accuracy with which we've responded to SARS. The technology built into the Secretary's Command Center has been indispensable—providing a forum for real-time, face-to-face exchange of information with public health officials in Atlanta, Toronto and Geneva. Secretary Thompson has communicated directly with officials in China via telephone conference call. The Command Center maps the distribution of SARS cases across the globe with geographic information system software for use during our planning discussions. The Command Center did not exist a year ago—it became operational last November.

Although the situation in Canada appears to be coming under control, it is critical that we be prepared to confront an outbreak of SARS on U.S. soil. To this end, I recently co-chaired a meeting of the Council of Governments with Mike Byrne of the

Department of Homeland Security to bring together health professionals from across the national capital region to aggressively prepare for an outbreak of the SARS virus here. One of the most important elements of an effective response plan is the development of hospital surge capacity. I should note that these preparations are applicable to a broad range of public health emergencies. Our team is unified and ready to deal with a variety of health response issues.

We are taking a variety of steps to ensure that states and other awardee jurisdictions have the resources they may require immediately to strengthen and upgrade their readiness. In FY 2002, we awarded $1.1 billion to 50 states, 3 municipalities, and the American territories to enhance public health preparedness and to upgrade the readiness of hospitals and other healthcare entities to address bioterrorism and other public health emergencies. In FY 2003, CDC and HRSA will award an additional $1.4 billion to further enhance state and local preparedness. In addition, HRSA will provide $28 million to academic health centers and other health professions training entities for a new initiative—bioterrorism preparedness education and training for clinical providers.

The bioterrorism preparedness funding has made a material difference at the state and local levels. Over 90% of the 50 states and three municipalities (New York City, Chicago and Los Angeles County) that have been awarded funds have developed systems for 24/7 notification or activation of their public health emergency response plans, and 87% of these grantees have developed interim plans to manage and distribute pharmaceuticals, equipment and supplies from the Strategic National Stockpile. In 95% of the jurisdictions, systems are being developed to receive and evaluate urgent disease reports on a 24/7 basis. Ninety-one percent indicated that they could initiate a field investigation within six hours of an urgent disease report.

While our state and local partners work to improve their preparedness and response capabilities, the Department is implementing an aggressive research and development program to develop and acquire biological, chemical, nuclear and radiological countermeasures. These initiatives have involved close coordination among NIH, CDC, FDA, DoD, and the Office of the Assistant Secretary for Public Health Emergency Preparedness. Research programs at NIH, involving a broad array of scientific initiatives, provide new approaches for developing countermeasures to threat agents most likely to be used as terrorist weapons. NIH is conducting and supporting basic research in immunology, microbiology, disease pathogenesis, genome sequencing and proteomics related to the organisms/toxins that could be used as bioterrorist agents. Both NIH and CDC support not only early product development efforts but also advanced development that is carried out in collaboration with industry partners. The FDA works very closely with these partners to provide advice and guidance during the development process with a view towards facilitating their subsequent submissions for regulatory review.

The research and development efforts are on a very compressed timetable and reviews of their progress are discussed on a regular basis by an interagency team consisting of NIH, CDC and FDA.

The most exciting news in the R&D arena is, of course, Project BioShield, announced by the President on February 3, 2003. BioShield is a comprehensive and ambitious effort to develop and make available modern, effective drugs and vaccines to protect against attacks by biological and chemical weapons. BioShield seeks to: encourage industry participation in the effort develop and procure next-generation medical countermeasures by establishing a stable source of funding; ensure that NIH has the authority to expedite the research and development of promising countermeasures; and to give the FDA authorization that would permit and facilitate the emergency use of preventive and therapeutic countermeasures that have not yet completed the formal process for full FDA licensure.

These are truly challenging times for our Department. I believe that we are up to the task and we look forward to working closely with Congress to ensure that the Nation is prepared to respond to public health emergencies in general and terrorism in particular.

Mr. Chairman, thank you for the opportunity to appear before the committee. My colleagues and I will be glad to take any questions that you and other members of the Committee may have.

Mr. GREENWOOD. Dr. Gerberding?

TESTIMONY OF JULIE L. GERBERDING

Ms. GERBERDING. Thank you, Mr. Chairman. I really appreciate the opportunity to speak here in front of the committee. And I also thank you and the committee because I understand that this com-

mittee took on the issue of security long before 9/11. And I think you certainly helped us have the beginning platform of preparedness at CDC. So, thank you think for that.

I would like to just give you an update on the SARS epidemic as it looks from the CDC perspective. You have already heard from Dr. Heymann that this is a global epidemic. And when you think about the global epidemic, I think it is also helpful to think about the global collaboration that has so quickly come together under WHO's leadership to lead to a much greater understanding about how to contain this and what we might successfully do to prevent its continued spread. But that also tells us about the speed with which this problem was distributed throughout the international community. We have had to meet that speed with some speed of our own at CDC.

On March 14 we initiated our Emergency Operations Center to increase our response capacity to handle SARS, because we recognized immediately that this was going to be a complex multi-jurisdictional outbreak investigation and we were going to need lots of coordination and lots of logistics support for our overall effort. Within 24 hours we were able to communicate guidance to State and local health officials through our Health Alert Network, and we held a press briefing with Secretary Thompson to alert the public about the problem. We sent out information to clinicians to help them understand what a case of SARS looked like and what they should do in terms of protecting themselves and the health care workers, and so forth.

So since that first 24 hour period we have emphasized speed of response. And I think the fact that we were able to identify the virus within just a few weeks of having our first sample, that we were able to sequence the genome and publish it on the Internet so that the scientific community could take advantage of that information, and that within just a few weeks we were able to develop a diagnostic test that we are working with FDA on right now to make available throughout our 120 laboratory response network facilities: These are remarkable achievements of speed. However, it is very sobering to appreciate that despite all of this technology capacity and our strong emphasis on communicating information and science to people, that we are experiencing ongoing vulnerability because until this disease is contained everywhere in the world, it remains a problem for all of us.

The steps we are taking now to protect Americans from SARS include the ongoing travel advisories to prevent exposure to travelers in Hong Kong, China and Taiwan. Singapore was on that list until yesterday, but they have been able to go two incubation periods without a new case in the community, and so we have now lessened their travel advisory status.

We also are alerting incoming travelers about their risk of having SARS if they have been an area where the disease is ongoing within the past 10 days. And travelers returning are receiving these health alert cards that advise them to contact a clinician if they have any symptoms, including fever or other nonspecific symptoms so that the clinicians can protect themselves before the person even shows up in the emergency room or the clinic.

We have distributed more than 850,000 of these at portals of entry in the United States, and are working with Department of Homeland Security and the Customs officials to make sure that we achieve 100 percent coverage.

This has been an evolutionary process, and we are confident that we are getting at least 98 percent of passengers right now, but we aim for perfection. So we are working our way up to the full 100 percent.

We also are advising clinicians to remain vigilant about potential SARS cases and to be sure to report them to local health officials, and we have disseminated very specific guidance to health care workers about self protection.

We know, as Dr. Heymann said, that this is primarily transmitted face-to-face and requires fairly sustained and prolonged contact for transmission to occur. But there are those worrisome situations such as the hotel in Hong Kong, where it seemed perhaps to be an airborne and environmental problem. And so we have advised airborne precautions and droplet precautions, as well as contact precautions, to make sure that our health care workers are fully protected against any mode of transmission that could come up in the health care environment.

Looking at this globally, the common denominator for leaking the SARS infection into the community has been spread to health care workers in the hospital and then their infection causing transmission in their homes. So our highest priority is protecting our health care workers and ensuring that the patients get the care they receive in a safe and humane manner.

I last want to emphasize the importance of the fear issue here. I am an infectious disease doctor, so I have had a lot of experience with this in the AIDS era, and we have had anthrax and West Nile and smallpox, so we see this time and time again that whenever there is an epidemic of a disease, it is followed very quickly by an epidemic of fear. We have put a very high premium on communicating the truth as it evolves in this process, and we also are communicating our uncertainties as honestly and openly as we can. But I do feel that we need to send very strong messages to people that this is about a virus, not about a group of people or a community or a population. And that we are prepared to contain the virus, we know what to do to contain it, and our public health system has stepped up to the plate to do that. But we still need to remain vigilant.

Thank you.

[The prepared statement of Julie L. Gerberding follows:]

PREPARED STATEMENT OF JULIE L. GERBERDING, DIRECTOR, CENTERS FOR DISEASE CONTROL AND PREVENTION, DEPARTMENT OF HEALTH AND HUMAN SERVICES

Good afternoon, Mr. Chairman and Members of the Committee. I am Dr. Julie L. Gerberding, Director, Centers for Disease Control and Prevention (CDC). Thank you for the invitation to participate today in this timely hearing on a critical public health issue: severe acute respiratory syndrome (SARS). I will update you on the status of the spread of this emerging global microbial threat and on CDC's response with the World Health Organization (WHO) and other domestic and international partners.

As we have seen recently, infectious diseases are a continuing threat to our nation's health. Although some diseases have been conquered by modern advances, such as antibiotics and vaccines, new ones are constantly emerging, such as Nipah

virus, West Nile Virus, vancomycin-resistant Staphylococcus aureus (VRSA), and hantavirus pulmonary syndrome. SARS is the most recent reminder that we must always be prepared for the unexpected. SARS also highlights that U.S. health and global health are inextricably linked and that fulfilling CDC's domestic mission—to protect the health of the U.S. population—requires global awareness and collaboration with domestic and international partners to prevent the emergence and spread of infectious diseases.

EMERGENCE OF SARS

In February, the Chinese Ministry of Health notified WHO that 305 cases of acute respiratory syndrome of unknown etiology had occurred in Guangdong province in southern China since November 2002. In February 2003, a man who had traveled in mainland China and Hong Kong became ill with a respiratory illness and was hospitalized shortly after arriving in Hanoi, Vietnam. Health-care providers at the hospital in Hanoi subsequently developed a similar illness. During late February, an outbreak of a similar respiratory illness was reported in Hong Kong among workers at a hospital; this cluster of illnesses was linked to a patient who had traveled previously to southern China. On March 12, WHO issued a global alert about the outbreak and instituted worldwide surveillance for this syndrome, characterized by fever and respiratory symptoms.

Since late February, CDC has been supporting WHO in the investigation of a multi-country outbreak of unexplained atypical pneumonia now referred to as severe acute respiratory syndrome (SARS). 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.

CDC's interim surveillance case definition for SARS has been updated to include laboratory criteria for evidence of infection with the SARS-associated coronavirus As of May 5, 2003, a total of 6,583 probable cases of SARS have been reported to WHO, and 461 of these persons have died. In the United States, there have been 65 probable SARS cases reported, of which 6 are laboratory confirmed, and none have died. In addition, 255 suspect cases of SARS have been reported and are being followed by state and local health departments.

CDC RESPONSE TO SARS

CDC continues to work with WHO and other national and international partners to investigate this ongoing emerging global microbial threat. We appreciate the continued support of Congress in our efforts to enhance our nation's capacity to detect and respond to emerging disease threats. The recent supplemental appropriation of $16 million to address the SARS outbreak will aid our identification and response efforts. SARS presents a major challenge, but it also serves as an excellent illustration of the intense spirit of collaboration among the global scientific community to combat a global epidemic.

CDC is participating on teams assisting in the investigation in Canada, mainland China, Hong Kong, the Philippines, Singapore, Taiwan, Thailand, and Vietnam and at WHO headquarters in Geneva. 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. As part of the WHO-led international response thus far, CDC has deployed approximately 50 scientists and other public health professionals internationally and has assigned over 500 staff in Atlanta and around the United States to work on the SARS investigation.

CDC has organized SARS work teams to manage various aspects of the investigation, including providing domestic and international assistance and developing evolving guidance documents. These work teams have issued interim guidance regarding surveillance and reporting; diagnosis; infection control; exposure management in health-care settings, the workplace, and schools; biosafety and clean up; specimen handling, collection, and shipment; travel advisories and health alerts; and information for U.S. citizens living abroad and for international adoptions. We have updated our travel advisories and alerts for persons considering travel to affected areas of the world. We have distributed more than 850,000 health alert notice cards to airline passengers entering the United States from mainland China, Hong Kong, Singapore, Taiwan, Vietnam, and Toronto, Ontario, Canada, alerting them

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. We have begun distributing health alert notices at selected sites along the U.S.-Canada border.

WHO is coordinating frequent, regular 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. They are exchanging reagents and sharing specimens and tissues to conduct additional testing.

On April 14, 2003, CDC announced that our laboratorians have sequenced the genome for the coronavirus believed to be the cause of SARS. Sequence information provided by collaborators at National Microbiology Laboratory, Canada, University of California at San Francisco, Erasmus University, Rotterdam and Bernhard-Nocht Institute, Hamburg facilitated this sequencing effort. The sequence data confirm that the SARS coronavirus is a previously unrecognized coronavirus. The availability of the sequence data will have an immediate impact on efforts to develop new and rapid diagnostic tests, antiviral agents and vaccines. This sequence information will also facilitate studies to explore the pathogenesis of this new coronavirus. We are also developing and refining laboratory testing methods for this novel coronavirus, which will allow us to more precisely characterize the epidemiology and clinical spectrum of the epidemic. These discoveries reflect significant and unprecedented achievements in science, technology, and international collaboration.

In order to better understand the natural history of SARS, CDC is investigating aspects of the epidemiologic and clinical manifestations of the disease. In collaboration with our partners, we have implemented or planned investigations to describe the spectrum of the illness, to assess the natural history of the disease, to estimate the risks of infection, and to identify risk factors for transmission. These investigations are being conducted in concert with ongoing surveillance and epidemiologic efforts.

Rapid and accurate communications are crucial to ensure a prompt and coordinated response to any infectious disease outbreak. Thus, strengthening communication among clinicians, emergency rooms, infection control practitioners, hospitals, pharmaceutical companies, and public health personnel has been of paramount importance to CDC for some time. CDC has had multiple teleconferences with state health and laboratory 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. WHO has sponsored, with CDC support, a clinical video conference broadcast globally to discuss the latest findings of the outbreak and prevention of transmission in healthcare settings. The faculty was comprised of representatives from WHO, CDC, and several affected countries who reported their experiences with SARS. The video cast is now available on-line for download. 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.

PREVENTION MEASURES

Currently, CDC is recommending that persons postpone non-essential travel to mainland China, Hong Kong, Singapore, and Taiwan. We are recommending that U.S. travelers to Toronto, Canada, and Hanoi, Vietnam, observe precautions to safeguard their health, including avoiding settings where SARS is most likely to be transmitted, such as health care facilities caring for SARS patients. Persons planning travel to Toronto or Hanoi should be aware of the current SARS outbreak, stay informed daily about SARS, and follow recommended travel advisories and infection control guidance, which are available on CDC's website at www.cdc.gov/ncid/sars.

Persons who have traveled to affected areas and experience fever or respiratory symptoms suggestive of SARS should use recommended infection control precautions and contact a physician. They should inform their healthcare provider about their symptoms in advance so any necessary arrangements can be made to prevent potential transmission to others. Health care facilities and other institutional settings should implement infection control guidelines that are available on CDC's website.

We know that individuals with SARS can be very infectious during the symptomatic phase of the illness. However, we do not know how long the period of contagion lasts once they recover from the illness, and we do not know whether or not

they can spread the virus before they experience symptoms. The information to date suggests that the period of contagion may begin with the onset of the very earliest symptoms of a viral infection, so our guidance is based on this assumption. SARS patients who are either being cared for in the home or who have been released from the hospital or other health care settings and are residing at home should limit their activities to the home. They should not go to work, school, or other public places until ten days after their fever has resolved and respiratory symptoms are absent or improving.

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. The experience in the United States has not demonstrated spread of SARS from household contacts into the community. 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.

EMERGING GLOBAL MICROBIAL THREATS

Since 1994, CDC has been engaged in a nationwide effort to revitalize national capacity to protect the public from infectious diseases. Progress continues to be made in the areas of disease surveillance and outbreak response; applied research; prevention and control; and infrastructure-building and training. However, SARS provides striking evidence that a disease that emerges or reemerges anywhere in the world can spread far and wide. It is not possible to adequately protect the health of our nation without addressing infectious disease problems that are occurring elsewhere in the world.

Last month, the Institute of Medicine (IOM) published a report describing the spectrum of microbial threats to national and global health, factors affecting their emergence or resurgence, and measures needed to address them effectively. The report, *Microbial Threats to Health: Emergence, Detection, and Response,* serves as a successor to the 1992 landmark IOM report Emerging Infections: *Microbial Threats to Health in the United States,* which provided a wake-up call on the risk of infectious diseases to national security and the need to rebuild the nation's public health infrastructure. The recommendations in the 1992 report have served as a framework for CDC's infectious disease programs for the last decade, both with respect to its goals and targeted issues and populations. Although much progress has been made, especially in the areas of strengthened surveillance and laboratory capacity, much remains to be done. The new report clearly indicates the need for increased capacity of the United States to detect and respond to national and global microbial threats, both naturally occurring and intentionally inflicted, and provides recommendations for specific public health actions to meet these needs. The emergence of SARS, a previously unrecognized microbial threat, has provided a strong reminder of the threat posed by emerging infectious diseases.

CONCLUSION

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. As CDC carries out its plans to strengthen the nation's public health infrastructure, we will collaborate with state and local health departments, academic centers and other federal agencies, health care providers and health care networks, international organizations, and other partners. We have made substantial progress to date in enhancing the nation's capability to detect and respond to an infectious disease outbreak; however, the emergence of SARS has reminded us yet again that we must not become complacent. We must continue to strengthen the public health systems and improve linkages with domestic and global colleagues. Priorities include strengthened public health laboratory capacity; increased surveillance and outbreak investigation capacity; education and training for clinical and public health professionals at the federal, state, and local levels; and communication of health information and

prevention strategies to the public. A strong and flexible public health infrastructure is the best defense against any disease outbreak.

Thank you very much for your attention. I will be happy to answer any questions you may have.

Mr. GREENWOOD. Thank you, Dr. Gerberding.

Dr. Fauci?

STATEMENT OF ANTHONY S. FAUCI

Mr. FAUCI. Mr. Chairman and members of the committee, thank you for the opportunity to testify before you here today.

SARS, unfortunately, is not really a surprise because SARS is an example of what we have experienced as shown on this map here over the last decades, and in fact through all of civilization; the emerging and re-emerging of diseases. SARS is one of those that has significant public health impact.

An emerging disease is a brand new disease that we have not seen before. HIV/AIDS is a classic example of an emerging disease with major public health impact. West Nile virus is a re-emerging disease, because it is not new. It just re-emerged in the wrong location, namely in 1999 here in the United States and now essentially the entire country and in North America. SARS is one of those.

Several of these new emerging and reemerging diseases occasionally are little blips on the radar screen where they are curiosities, but they either spread from an animal to a human but don't efficiently go to human-to-human or else they just infect a relatively small number of people. We have seen instances of that, for example, with ebola in Africa.

SARS is different. It has several characteristics. One, it is transmissible relatively easily with regard to face-to-face contact, but luckily not beyond that except for some occasions, as you have heard from previous witnesses. However, it is a very important disease that we need to take seriously. And in the research community with our public health colleagues at the CDC and WHO, we are doing just that.

It is our unfortunate our global societies were beset with SARS. However, it is fortunate that in fact this is a virus that belongs to a category of viruses that we do have experience with, namely the coronaviruses which, incidentally, are the cause of approximately 20 percent of common colds.

The other fortunate situation—in the setting of misfortune of being in an epidemic—is that this particular virus grows well in culture. It has been isolated, as you know, by the CDC, by individuals in the Hong Kong and now it is growing in a number of laboratories. It grows well in a type of tissue culture that would make it amenable to grow it for the development of vaccines.

Another important point is that animals are infected with this. This is normal. Coronaviruses in general. We don't know where this virus came from, but it would not be surprising that it did what many microbes do, that is, jump species from an animal to a human. We saw that with H5N1 influenza virus, which went from an animal to a human. Fortunately it didn't go human-to-human. HIV/AIDS did, though. It went from a chimpanzee to a human but then had the capability of rapidly spreading. So that is the unfortunate aspect of this particular emerging disease.

I want to spend the last minute or so on telling you a bit about the vaccine agenda and the other research activities at NIH.

As I mentioned, the virus grows well in culture in a cell type called vero cells, which is a monkey cell. Others have already infected monkeys successfully. The plan with regard to vaccine development is several fold. The first and easiest is to grow the virus up, kill it or inactivate it and vaccinate an animal model, in this case a non-human primate monkey model. Then, to challenge that monkey following the vaccination with the killed virus and determine if you could prove the concept that you would be able to protect an animal. That would take a matter of several months and likely by the end of this calendar year we will or will have not proven the concept that you can protect an animal. After that, again if we are lucky, it will take a couple of years at least to develop a vaccine.

The other vaccine candidates are more of a molecular model where we use tried-and-true techniques of taking the genes from the SARS virus, the relevant genes, and inserting them into what we call a vector of a harmless virus like adenovirus. We can do that because we now have the sequence of the SARS virus and we are already involved in research that is proceeding rapidly to do just that; to insert those genes into an adenovirus vector.

There is the DNA virus approach, there is the live attenuated and there is the purified protein. All of these things have hit the ground running.

And I might make the comment, Mr. Chairman, that this has happened because we have had to face emerging and reemerging diseases for decades, particularly the rather large acceleration of effort that has accompanied our approach toward protection with countermeasures against bioterrorism. That has been very important in positioning us where we are right now.

And finally, drug development. Drug development is very important in collaboration with our colleagues with the CDC and at the USAMRIID we are screening large amounts and large numbers of drugs that either already exist on the shelf and are approved or are there, have been developed but not used successfully for other diseases, other viruses. If that fails, and even if we do get some success, we will then target antiviral development against the particular vulnerable components of this coronavirus. So the research enterprise is rapidly responding to the public health crises that our public health colleagues have responded to quite successfully up to now.

I would be happy to answer questions, Mr. Chairman.

[The prepared statement of Anthony S. Fauci follows:]

PREPARED STATEMENT OF ANTHONY S. FAUCI, DIRECTOR NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES, NATIONAL INSTITUTES OF HEALTH

Mr. Chairman and Members of the Committee, thank you for the opportunity to discuss how the National Institutes of Health (NIH) is responding to the global outbreak of Severe Acute Respiratory Syndrome, or SARS. I am pleased to appear today with my colleagues from our sister agencies, within the Department of Health and Human Services. As of April 29, 2003, 5462 cases of SARS have been reported across the globe, with 54 probable cases identified in the United States; there have been no deaths from SARS thus far reported in the United States. The relatively low number of probable cases reported in the United States is likely the result of early diagnoses and effective public health measures put in place by the CDC and

state and local health authorities to contain the imported SARS cases and prevent secondary transmissions.

While travel alerts and advisories and recommended infection control measures can help slow the progression of the SARS epidemic, these alone are not long-term solutions to this new and unpredictable disease. Instead, we must develop safe and effective treatments and vaccines that can protect the American people. The SARS epidemic is still evolving and it is unclear whether the incidence of the diseases will decline, plateau or accelerate. Therefore we must be prepared for any eventuality.

Like HIV/AIDS, Ebola and West Nile virus, SARS reminds us that emerging and reemerging infectious diseases are constant threats to national and international public health. Dr. Gerberding and her CDC team, together with the World Health Organization (WHO) and others, have done an outstanding job in identifying and tracking the SARS epidemic, illuminating the clinical features and etiology of the disease, and providing the world with information about the epidemic in real time.

Complementing the efforts of the CDC and WHO, the National Institute of Allergy and Infectious Diseases (NIAID), a component of NIH, has a significant role in the efforts against SARS, notably in diagnostics, therapeutics and vaccine development, drug screening, and clinical research. As has been the case with other emerging infectious diseases, we anticipate that the strong NIAID research base in disciplines such as microbiology, immunology and infectious diseases will facilitate the development of new interventions to help counter SARS.

The CDC and WHO have accumulated evidence, which we now believe is close to definitive, that SARS is caused by a novel coronavirus that may have crossed species from an animal to humans, although this latter point has certainly not been proven. This hypothesis is based on the detection and isolation of coronaviruses from unrelated SARS patients from different countries and on the finding that SARS patients mount an immunological response to coronavirus as they proceed from the acute illness to the recovery or convalescent stage. Furthermore, data from the Netherlands show that non-human primates infected with this coronavirus develop a SARS-like disease, suggesting that this virus is the cause of SARS. Although some questions remain, the strong evidence for a causative role for a coronavirus has prompted the ongoing development of diagnostic tools, therapies, and vaccines that target coronaviruses.

Coronaviruses are best known as one of the causes of the common cold, a benign condition that very rarely results in life-threatening disease. The coronavirus associated with SARS is a type of coronavirus, possibly of animal origin, that has not been previously identified.

NIAID RESEARCH ON SARS

NIAID maintains a longstanding commitment to conducting and supporting research on emerging infectious diseases, such as SARS, with the goal of improving global health. In carrying out its global health research mission, the Institute supports a myriad of activities, including intramural and extramural research and collaborations with international agencies and organizations.

Since the earliest indications that we were dealing with a new disease, very likely caused by a newly recognized virus, the NIAID has marshaled its resources to rapidly initiate the development of diagnostics, therapeutics, and vaccines against SARS. NIAID has assembled a multi-disciplinary working group to develop a broad-based program that addresses the research needed to combat SARS. Key intramural laboratories have begun to pursue a range of research strategies to develop a SARS vaccine as well as therapeutics, including immune-based therapies, and our extramural programs are poised to help as well. We also have initiated and expanded collaborations with our colleagues in other federal agencies, academia, and private industry. In addition, NIAID recently released three "Sources Sought" announcements, a special mechanism to rapidly identify contractors who can develop treatment strategies, vaccines, and antibody preparations to address SARS.

SURVEILLANCE AND EPIDEMIOLOGY

NIAID supports a long-standing program for the surveillance of influenza viruses in Hong Kong, led by Dr. Robert Webster of St. Jude's Children's Research Hospital in Memphis. Dr. Webster and his team in Hong Kong have collaborated with WHO, CDC, and others in helping to illuminate the SARS outbreaks in Asia. At the request of WHO, NIAID assigned a staff epidemiologist to provide technical assistance during the early stages of the epidemic. In addition to global surveillance activities, NIAID will support epidemiological studies of populations at potentially greater risk for SARS, including individuals with HIV/AIDS.

DIAGNOSTICS RESEARCH

As Dr. Gerberding has indicated, the CDC already has made significant progress in developing diagnostic tests for SARS. As part of these efforts, NIAID-sponsored researchers in Hong Kong also devised a diagnostic test based on polymerase chain reaction (PCR) technology as well as a diagnostic tool using the immunofluorescence assay technique. In other research, the NIAID-funded Respiratory Pathogens Research Unit (RPRU) at Baylor College of Medicine has developed methods to detect known human coronaviruses using cell culture and molecular diagnostic tools and can also assess the host immune response to known coronavirus infections. During this calendar year, NIAID will expand this capacity for research on emerging acute viral respiratory diseases. Also, NIAID is using existing funding mechanisms, such as the contract with St. Jude's Hospital, to help support the development of other sophisticated diagnostic tools.

It is anticipated that a sensitive and specific diagnostic test for SARS may be available within six to 12 months. Within one to three years, it may be possible to develop a rapid, accessible easy-to-use test for SARS that could be widely deployed in diverse healthcare settings.

VACCINE RESEARCH

As the SARS epidemic continues, it will be necessary to consider a broad spectrum of vaccine approaches. NIAID is supporting the rapid development of vaccines to prevent SARS through both our extramural and intramural programs, including the NIAID Vaccine Research Center on the NIH campus. NIAID scientists have received samples of the SARS coronavirus from CDC and have already successfully grown the virus in cell culture, a first step towards developing a vaccine. Initial efforts have focused on the development of an inactivated (or killed) virus vaccine. As more knowledge about SARS becomes available, other types of vaccine candidates will soon follow, including novel approaches such as vector-based and recombinant vaccines, DNA-based vaccines, and live-attenuated vaccines.

Fortuitously, vaccines against common veterinary coronaviruses are routinely used to prevent serious diseases in young animals, such as a vaccine given to pigs to prevent serious enteric coronavirus disease. Insight from veterinary coronavirus vaccines could prove useful as we develop vaccines to protect humans.

To accelerate SARS vaccine research and development efforts, NIAID has initiated contracts and other relationships with companies, institutions and other organizations with specialized technologies, cell lines and containment facilities relevant to SARS research for the purpose of supporting the development of reagents needed for vaccine development, and developing animal models such as mice and relevant species of monkeys. For example, the NIAID Vaccine Research Center recently expanded an existing agreement with GenVec, a biopharmaceutical company in Gaithersburg, Maryland, to begin the development of a candidate vaccine against SARS. NIAID is negotiating with other companies to develop additional candidate vaccines. Another important component of SARS vaccine research will be to identify ways to generate mucosal immunity against the SARS coronavirus. Within the next six to 12 months, NIAID anticipates that it will be possible to demonstrate whether an inactivated vaccine against SARS is a workable concept, e.g., to show that we can protect a monkey against the SARS virus. If so, Phase I trials of such a candidate vaccine can be accelerated. If research and development proceed on schedule and if animal testing is successful, a first-generation inactivated SARS vaccine could become available within several years.

THERAPEUTICS RESEARCH

With the emergence of SARS, NIAID responded rapidly to a request from CDC to evaluate candidate antiviral agents through a collaborative antiviral drug-screening project at the U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID). To date, NIAID has supplied approximately 40 FDA-approved antiviral drugs to USAMRIID such that their efficacy against the SARS coronavirus can be evaluated. The Institute also is pursuing the development of novel antivirals, such as compounds that block viral fusion with and entry into host cells. In addition, NIAID has initiated discussions with the pharmaceutical industry about candidate antiviral drugs already in the research "pipeline," and is reviewing a proposal for a clinical trial of antiviral therapy to be conducted by investigators of the NIAID Collaborative Antiviral Study Group and the NIH Clinical Center.

In addition to antiviral drugs, NIAID is supporting the development of passive immunotherapy (monoclonal and polyclonal antibodies) as a therapy for SARS.

Within the next one to three years, it may be possible to have available therapeutic monoclonal antibodies for SARS.

CLINICAL RESEARCH

Clinicians treating SARS patients have not yet identified treatment strategies that consistently improve prognosis, beyond good supportive and intensive care. Conventional antibiotics do not work, a fact that is consistent with SARS being a viral disease. NIAID is pursuing several strategies to determine whether any existing drugs or combinations of treatments can simultaneously block viral replication and boost the immune response to the virus.

At the NIH Clinical Center in Bethesda, MD, and through the NIAID Collaborative Antiviral Study Group, NIH is developing protocols to admit SARS patients for evaluation and treatment, should this become necessary. This will be an opportunity to evaluate the pathogenesis of the illness and the efficacy of antiviral and immune-based therapies in patients with SARS. We also plan to evaluate approaches to improve management of patients with severe forms of the disease, such as the passive transfer of antibodies from SARS patients who have recovered from the disease.

In addition to ensuring state-of-the-art treatment of potential patients, our clinical experts will be able to study the clinical characteristics of patients with SARS. We are particularly interested in answering key questions about the disease mechanisms of SARS. For example, are severe outcomes such as acute respiratory distress and mortality entirely caused by the presence of virus, or does the immune system play a role in causing the severe outcomes in some patients? What are the sites and the duration of viral shedding? What is the nature of the immune response? These are central questions to address because they may open up avenues for treatment as well as better preventive strategies.

BASIC RESEARCH

NIAID's long-standing commitment to and investment in emerging disease research is allowing us to expeditiously pursue research on SARS. For example, NIAID continues to support the Emerging Viral Disease Research Centers, which have been conducting SARS antibody studies and will be able to assist in the development of animal models for SARS. NIAID currently is supporting 18 grants on coronavirus research. Also, the study of patients, as well as specimens in NIAID laboratories, will facilitate our understanding of the natural history of the SARS virus and its potential animal reservoir, and help illuminate the risk factors and epidemiology of SARS. NIAID will support and conduct basic research studies on the pathogenesis of the disease and viral replication mechanisms, in order to identify targets for antiviral drugs, diagnostic tests, and vaccines. Finally, the Institute will support and conduct genomic sequencing, proteomics, and bioinformatics of coronaviruses.

The identification or development of animal models that mimic human SARS is critical to our understanding of the SARS virus and how it causes disease. Of note, an existing NIAID animal model of a virus infection that causes a disease in mice very similar to SARS has been identified. The relevance of this animal model to SARS will be evaluated and may prove an important tool for defining treatment approaches that involve modulation of the immune system. NIAID will also support the development of other relevant animal models for SARS.

INFRASTRUCTURE

A central concern when working with the SARS virus or SARS patients is the availability of facilities with the required safety level for the clinicians and staff, as well as for the community. Our ongoing plans to develop high-level containment facilities, towards which funds were appropriated in FY 2003, will facilitate SARS research, as well as planned studies of potential bioterror agents and other emerging diseases. Research with the SARS coronavirus will occur in Biosafety Level-3 facilities.

CONCLUSION

Mr. Chairman, thank you again for allowing me to discuss NIH's efforts to address SARS. Despite ongoing research and early successes, we still have much to learn about the disease. As you have heard, NIAID-sponsored coronavirus research, studies of other viral diseases, and clinical research already have positioned us well in our quest for tools to detect, treat, and prevent SARS. In the weeks and months ahead, NIH will continue to collaborate with our sister agencies, the CDC and the Food and Drug Administration, as well as other relevant agencies, to accelerate and

expand our research aimed at improving the diagnosis, prevention, and treatment of SARS.

I would be pleased to answer your questions.

Mr. GREENWOOD. As indicated by the buzzers that have been interrupting your testimony, we have a series of five votes on the floor of the House of Representatives. And so I think it would be best rather than to try to cram your testimony in, Dr. Lumpkin, we will recess here.

It will probably be at least 30 minutes or 40 minutes until we get back. But we will recess to the call of the Chair, which will be in about 30 to 40 minutes.

[Brief recess.]

Mr. GREENWOOD. The committee will come to order.

I apologize to all of our witnesses, particularly those on the third panel, but we are finished voting for the day and we should not have any further interruptions.

So I believe we are just about to hear from Dr. Lumpkin. And so you are recognized, sir.

TESTIMONY OF MURRAY M. LUMPKIN

Mr. LUMPKIN. Correct. Thank you, sir.

Mr. Chairman, members of the subcommittee, I appreciate very much the opportunity of being with you here today to discuss the FDA's role in our response to the threat from SARS, and particularly to be here with my HHS colleagues and with my colleague from GAO.

I know that many people tend to think of FDA's role primarily being one of looking at marketing applications and the review of marketing applications. And I think as you have heard from Dr. Fauci and others, and as you will hear later, many of us hope that very soon that will be one of our responsibilities as far as SARS is concerned. But right now we do not have any marketing applications in any of our centers at FDA for products specifically for SARS. But this really shouldn't be a surprise, given as you have heard from Dr. Fauci and from Dr. Gerberding how early we are in our knowledge of this particular disease, and a lot of science about this disease is yet to be learned.

Nonetheless, FDA is playing what I think is a very crucial role in the national and international battle against SARS in five specific areas.

The first area is that we are working very proactively with both the private and the public sector to try to expedite the development of a reliable, validated diagnostic tool. Clearly, this is one of the things that we need, and I will talk about this a little bit more in just a few minutes.

Second, we are working very proactively with the public and private sector to try to identify potential therapeutic agents. And if they can be identified, then to work with them on their development schemes so that we can get good marketing applications with good data for these particular products as soon as possible.

Third, we are working as proactively as we can with the public and private sector to see whether, indeed, it is possible to develop a safe and effective vaccine. And if it is, then to do so as quickly

as possible. And as you have heard from Dr. Fauci, the mechanisms for doing that in the research community are well underway.

The fourth thing we are doing is trying to work with our colleagues at HHS and at other public and private sectors to assess the adequacy of the medical supplies we have in this country that would be needed to support critically ill patients on a large scale if we needed to do that in this country. Even though we do not have, as you have heard, a specific therapy for this particular disease, we have seen around the world that if we were to have a large outbreak in this country, there is going to be a need to provide medical support and to have the medical facilities to provide that kind of support.

And last, I think we have taken what we believe is a prudent action to protect our Nation's blood supply until we learn more about whether this SARS agent, indeed, can or cannot be spread by blood transfusions and the transfusions of other blood products.

I just want to spend a couple of minutes, because I know we are pressed for time this afternoon, just highlighting some of these particular activities.

Regarding the development and approvals of diagnostics, as I think you have already heard, our colleagues at CDC have done an extraordinary job in a very short amount of time to develop some experimental devices and diagnostics for this particular disease. We have worked very closely with them to develop an investigational device exemption under which they will soon be providing this particular test to a series of labs around the country so that it can be further evaluated and its reliability validated. And I think we believe that this is the kind of thing that will clearly lead to the development of an improved definitive diagnostic test.

We are also working with the private sector as they develop diagnostic tests that they wish to bring to market. And I think clearly as you have heard, SARS is a disease that is serious and life threatening for which we do not have approved diagnostic tests at this time, and so as we get marketing applications, this is clearly an indication for which we can do priority reviews of these applications. And it is the kind of situation where we think this kind of very proactive interaction during the development will help expedite the development and ultimate approval for marketing.

Regarding therapeutics, along the same lines, we have been working with CDC to get in place protocols for emergency use of various therapies should that become necessary in this country and also to work with them and others to look at various compounds to see if, indeed, they might have activity against this particular virus. And if they do, then to be able to work with them to develop the data needed to show the community at large, that indeed a product could offer a safe and effective therapy.

The same is true in vaccines, and both with vaccines and with drugs we are committed to using all of the fast track authorities that we have to expedite the development and the approval of these.

I think one thing, as far as vaccines is concerned, we have learned a lot from the history of vaccine development. There are a lot of very positive things. There are also some negative things that have happened in the history of vaccine development. I think the

main thing we have learned is that we want to do it quickly, but we want to do it right the first time because so many people are going to be dependent upon that.

In conclusions here, I would just like to say that our Commissioner asked me to apologize to you for not being here today. He is in Indiana at a previous commitment. But he said that I was to tell you that, indeed, we will use all of the fast track authorities that we have. We are committed to working with our colleagues at HHS to bring reliable diagnostic tools and safe and effective treatments and vaccines for SARS to the American people.

Thank you.

[The prepared statement of Murray M. Lumpkin follows:]

PREPARED STATEMENT OF MURRAY M. LUMPKIN, PRINCIPAL ASSOCIATE COMMISSIONER, FOOD AND DRUG ADMINISTRATION, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

INTRODUCTION

Mr. Chairman and Members of the Subcommittee, I am Dr. Murray Lumpkin, Principal Associate Commissioner at the Food and Drug Administration (FDA or the Agency). I appreciate the opportunity to appear today to discuss FDA's role in the national and international response to the emerging threat of severe acute respiratory syndrome (SARS).

FDA is presently helping in five specific areas in the battle against SARS by working with other government agencies, industry and academia to:

- Facilitate the development of reliable diagnostic tools;
- Facilitate the development of safe and effective treatments for patients suffering from SARS;
- Facilitate the development of a safe and effective SARS vaccine;
- Help assure that adequate supplies of various medical products are available in the event of the broader spread of SARS in the United States; and
- Help safeguard the blood supply against the potential threat of SARS.

Our goal is to continue to work closely with public and private entities to protect the U.S. population from the public health risk associated with SARS and to facilitate the development of products in which American practitioners and patients can have confidence to help those afflicted with this disease.

DEPARTMENT OF HEALTH AND HUMAN SERVICES COORDINATION

The Department of Health and Human Services (DHHS or the Department) is providing overall national direction, guidance and coordination in the fight against SARS. Under this umbrella, FDA is working closely with other agencies, such as Centers for Disease Control and Prevention (CDC) and National Institutes of Health (NIH), as well as with the private sector, State health officials, and other relevant agencies, to expedite the development of reliable diagnostic, preventive, and treatment tools for SARS and to provide emergency access to promising products as needed.

FDA'S ROLE

The epidemic of SARS has been very fast moving. Because of the novelty of this pathogen and the lack of previous experience with this specific disease, as with other public health agencies, FDA is presently in the initial stages of its response to the disease. Yet the Agency has already taken a number of steps to address a possible escalation of SARS cases in the United States. Let me elaborate on specific measures with which the Agency is involved.

DEVELOPMENT AND APPROVAL OF DIAGNOSTICS

Currently, there are no marketing applications for a SARS diagnostic product before the Agency. This is not surprising given that we are still in the preliminary stages of our understanding of SARS. However, FDA is working closely and proactively with other government agencies such as CDC and NIH, as well as with the private sector, to foster the development of reliable diagnostic tools that will help identify the microbiological agent of SARS from patient specimens and will help confirm whether or not a patient is or has been infected with this SARS agent.

The mission of FDA's Center for Devices and Radiological Health (CDRH) includes guaranteeing the safety and reliability of diagnostic tools, such as those under development that will allow the identification of the SARS agent. CDRH is working with CDC, who along with others in the SARS Laboratory Network organized by World Health Organization (WHO), is helping further the scientific understanding of the virus. A diagnostic test for SARS, based on the detection of RNA sequences in the novel coronavirus, is currently under development along with an ELISA (enzyme-linked immunosorbent assay) test for antibodies to the SARS-related virus. The first of these tests, using polymerase chain reaction (PCR) technology, will help with acute diagnoses of patients, while the ELISA test will be used to confirm a case during or after convalescence. CDC developed these prototype experimental reagents over the past two months in an effort to address this unmet public health need. FDA rapidly reviewed information for the investigational use of this test, and is working closely with CDC to develop appropriate information for patients and health professionals, and an approach for further evaluation of this new test. Working with our CDC colleagues, FDA guided CDC in drafting an investigational device exemption (IDE) for the PCR technology assay. This IDE has been provisionally approved. This test methodology will be distributed to approximately 100 specialized laboratories around the country. Under the terms of this test's wider distribution, patients and practitioners will receive clear information about the test when it is used to assist in diagnosing SARS. Hopefully, this information will facilitate the development and evaluation of an approved diagnostic test as quickly as possible.

As SARS is a serious and life-threatening disease for which there are no presently approved diagnostic tests, the disease meets our standard for priority review to expedite the development of new tests and the review of these tests marketing applications. CDRH is already reaching out to industry to ensure that any development plans for new tests are well designed and that premarketing applications submitted to the Agency are of such quality that a priority review can swiftly proceed. In addition, FDA has already cleared or approved dozens of tests for use in differential diagnosis of acute respiratory syndromes and has put in place a postmarket surveillance program to measure how well these tests are working. These tests do NOT diagnose SARS; rather they help to diagnose other conditions that may have symptoms similar to SARS. In this way SARS can be ruled out as the diagnosis in these patients.

DEVELOPMENT AND APPROVAL OF THERAPEUTICS

Although to date there have been no marketing applications for therapeutic products for the treatment of SARS submitted to FDA, the Agency is indeed working to help facilitate the development of safe and effective treatments for patients suffering from SARS. The Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER) are both responding to this need by identifying drugs and other therapeutics products that may be effective in combating the SARS agent or modifying the course of the disease. CDER is working expeditiously with CDC and NIH to design and implement both emergency protocols and protocols for properly controlled clinical trials for using these anti-viral products to treat SARS patients who meet certain medical criteria for inclusion in the protocols. Because of this close collaboration, the U.S. is now better prepared to respond quickly to any escalation of SARS cases and to evaluate the potential effectiveness of treatments and thus help patients and practitioners around the world further their understanding of the best ways to treat this disease.

With regard to specific therapeutics, CDER is engaged with those who are trying to identify compounds for additional screening and is interacting with pharmaceutical companies on these compounds. CDER has identified 16 compounds, mostly nucleoside analogues, from ten companies for in vitro screening against the coronavirus and has provided those companies contact information from the NIH and U.S. Army Medical Research Institute for Infectious Diseases (USAMRIID) screening program. CDER is also working with NIH and USAMRIID to prioritize candidate products for initial in vitro susceptibility testing with the USAMRIID assay.

Much has been written in the press about a drug called ribavirin. The oral and inhalation dosage forms of this product are already approved in the U.S. for treating certain viral infections. The intravenous formulation of ribavirin is still an experimental drug only available in the U.S. under an Investigational New Drug (IND) Application. Various places outside the U.S. have used the intravenous and oral formulations of the product to try to treat those most severely affected by SARS. CDER worked with CDC on the development of an emergency use protocol, which has now been allowed to proceed, that would allow suspected SARS patients who meet cer-

tain medical criteria to be treated with intravenous ribavirin should the need arise. To date, no one in the U.S. has been treated with intravenous ribavirin under this protocol. In addition, CDER has assessed the adequacy of ribavirin supplies if it shows therapeutic promise and there is increased demand for the drug in the event that SARS spreads to many more patients.

Unfortunately, in the USAMRIID susceptibility assay, ribavirin did not appear to inhibit the growth of the SARS agent. The relevance of this laboratory finding to the clinical situation remains to be determined; however, what role, if any, ribavirin will play in future therapeutic regimens for SARS in still quite unclear.

No matter what the product being used, it is important to note that caution must be exercised and patients and family members must be fully informed when participating in trials that study investigational drugs to treat SARS. As there is usually little available information about these investigational agents, and the safety and efficacy profiles in SARS have not yet been defined, use must be predicated on adequate informed consent.

Again, SARS is a disease whose novelty and nature make it a prime candidate for therapeutic development under FDA's previously established programs to expedite the drug development and review process through our "fast track" program. The "fast track" program is designed to quickly facilitate the development and review of new drugs intended to treat serious or life-threatening conditions and that demonstrate the potential to address unmet medical needs ("fast track products"). This program emphasizes the critical nature of close, early communication between the Agency and a sponsor, outlines procedures such as pre-IND and end-of-phase-I meetings as methods to improve the efficiency of preclinical and clinical development, and focuses on efforts by the Agency and drug sponsor to reach early agreement on the design of the major clinical efficacy studies that will be needed to support approval. Most importantly, under this program, as various elements of a marketing application are completed these pieces of the application can be submitted for review as soon as they are finished, rather than having to wait for the entire application to be completed, analyzed, assembled, and submitted. In these cases, FDA can begin review of the marketing application much earlier. FDA has made clear that it considers SARS candidate therapies eligible for "fast track" designation.

DEVELOPMENT AND APPROVAL OF VACCINES

FDA is part of the team striving to develop a safe and effective SARS vaccine. On April 9, 2003, Dr. Jesse Goodman, Director of CBER, joined Secretary Thompson and key leaders from NIH, CDC, and the National Vaccine Program Office to answer questions from vaccine manufacturers concerning approaches to developing a SARS vaccine. CBER is strongly committed to working proactively with industry and government partners to facilitate such development under the same type programs for these kinds of public health needs as those utilized by CDRH and CDER. The Center is pursuing multiple potential vaccine development strategies. CBER is working with other government agencies and the private sector to address many of the most difficult issues in early vaccine development. In this process, CBER provides guidance on the use of animal test data and on safe manufacturing practices. The Center will also be a major participant in the design of clinical trials and in defining the needs of special populations (such as pregnant women). As the SARS vaccine program is in its infancy, much painstaking work will be necessary to assure that the development and manufacturing processes meet the standards required to develop and produce safe and effective vaccines from which people have benefitted so much over the years. While we hope that a safe and effective SARS vaccine can be developed, and we will do everything feasible to help facilitate and speed the development process, at this early stage of scientific knowledge about the nature and stability of the virus and the human immunological response to the virus, it would be imprudent and unfair to over-promise about any possible timeline for a SARS vaccine.

As with therapeutic products, FDA can and will expedite the vaccine review process to address critical needs. Given the potential public health impact of SARS infection, FDA places a high priority on facilitating the development and review of such products. We work to maintain open and continued dialogue with vaccine manufacturers and to assist firms that seek to enter the vaccine manufacturing market. FDA routinely meets with manufacturers during all stages of the development of vaccines and prior to submission of a licensing application to facilitate the regulatory process and provide guidance on requirements for new vaccines. The Agency also encourages and works with manufacturers to enhance their production capabilities and capacities.

FDA's Center for Veterinary Medicine (CVM) has investigated products used in the treatment of animal coronaviruses, and that information has been relayed to CBER and the wider community so that any potential relevance to SARS can be investigated. For example, effective and safe vaccines are marketed for enteric diseases caused by coronaviruses in cattle, swine, dogs, and cats; effective and safe vaccines, both live and killed, are marketed for avian infectious bronchitis caused by a coronavirus; and diagnostic test kits are marketed for feline infectious peritonitis, and for avian infectious bronchitis due to coronaviruses.

ASSURING AN ADEQUATE SUPPLY OF RELATED MEDICAL PRODUCTS

FDA is working with manufacturers to assure adequate supplies of various medical products that would be needed in the event of a broader spread of SARS in the U.S. For example, CBER, CDER, and CDRH are developing master lists and evaluating the adequacy and supplies of respirators, emergency medical supplies (gowns, gloves, masks), complex medical devices (ventilators, cardiac monitors), and the routine therapeutic products required to adequately support critically ill patients.

PROTECTING THE NATION'S BLOOD SUPPLY

While there is no evidence that the SARS agent can be spread by blood, in mid-April, FDA nonetheless issued guidance to the nation's blood establishments on measures to further safeguard the blood supply against the threat of SARS while further scientific knowledge about the potential spread of this agent is obtained. This decision was based on the preliminary scientific data indicating that SARS is caused by a unique coronavirus that may be present in the blood of some infected persons early in their illness. Although the SARS epidemic has been limited in the U.S. and transfusion transmission of SARS has not been documented to date, it seemed prudent to act as quickly as possible to implement measures to restrict its spread, and in particular to protect the blood supply so that, if it is ultimately shown that the agent can be spread by blood, we will have taken steps to protect the nation's blood supply. The new SARS guidance sets forth measures for temporarily deferring potential donors who may have been exposed recently to SARS or recently had SARS. These measures include limited additional questioning of potential donors to help ascertain if they may be at elevated risk for SARS due to recent travel to known high risk areas as defined by CDC or due to exposure to a person with SARS or suspected SARS. FDA regularly exchanges information with CDC, NIH, the Department of Defense, and blood collection and distribution organizations to monitor SARS epidemiology and pathogenesis, in particular, as it relates to blood safety. FDA will continue to monitor this evolving situation and revise or supplement the guidance as needed to preserve the safety and availability of the blood supply, based on the best available information.

It is important to re-emphasize that transfusion transmission of SARS has not been reported. However, CDC and others are conducting studies to clarify if the implicated coronavirus is present in the bloodstream during the asymptomatic incubation period of early infection. The public health need for testing donors, therefore, has yet to be established but FDA believes, given the state of scientific knowledge at this time, that this is the most prudent way to proceed. In addition, FDA is also in dialogue with SARS test kit manufacturers to help lay the groundwork for development of blood screening assays, should it be necessary.

SARS AS A MODEL FOR BIOTERRORISM RESPONSE

The President's Initiative on Countering Bioterrorism is comprised of a number of essential elements in which FDA plays an integral role. One such element is the expeditious development and licensing of products to diagnose, treat or prevent outbreaks from exposure to pathogens that have been identified as bioterrorist agents. These products must be reviewed and approved prior to the large-scale distribution necessary to create and maintain a stockpile. FDA scientists must guide the products through the development and marketing application review processes, which includes review of the manufacturing process, pre-clinical testing, clinical trials, and the licensing and approval process. This process is extremely complex and early involvement of FDA scientists is crucial to the success of the expedited development and review process. Our scientists must have expertise in these areas in order to expedite the licensing and approval process for these products. The resources that FDA has received to support bioterrorism preparedness and the expertise we have gained in rapid response and proactive approaches to product development have been helpful as we respond to SARS.

Preparedness for and response to an attack involving biological agents are complicated by the large number of potential agents (most of which are rarely encoun-

tered naturally), their sometimes long incubation periods and consequent delayed onset of disease, and their potential for secondary transmission. In addition to naturally occurring pathogens, agents used by bioterrorists may be genetically engineered to resist current therapies and evade vaccine-induced immunity.

How we respond to emerging infectious diseases can serve as a model for preparedness and response to a bioterrorism event in that we are dealing with a previously unknown infectious agent that has proven rapid worldwide diffusion and secondary transmission. The SARS experience reinforces the need for strong public health systems, robust health service infrastructures, and expertise that can be mobilized quickly across national boundaries to mirror disease movements. It has highlighted the need for on-going coordination and communications among international public health organization, counterpart public health organizations in other countries, Federal, State and local governments in our country, the public health and medical infrastructures thought the U.S., and with private industry.

CONCLUSION

Clearly, much remains unknown about SARS at this time. FDA is carefully tracking and participating as a full partner where we have expertise to offer in the scientific undertakings to further define, treat, and, ultimately, defeat SARS. In meeting its public health mandate in this situation, we are ensuring that FDA resources are aggressively, safely, and intelligently deployed in the battle against this new virus. We will continue to work closely and share information with our partners in CDC and NIH, as well as with the private sector and other relevant agencies, to speed the development of reliable diagnostic, preventive, and treatment tools for SARS.

Thank you very much for the opportunity to testify today. I welcome your ideas and your questions.

Mr. GREENWOOD. Thank you very much, Dr. Lumpkin. Appreciate that.

Ms. Heinrich.

TESTIMONY OF JANET HEINRICH

Ms. HEINRICH. Mr. Chairman and members of the committee, I appreciate the opportunity to be here today as you consider the Nation's preparedness to manage public health threats such as the SARS epidemic.

My remarks will focus on what we know about State and local preparedness to respond to a large scale infectious outbreak, preparedness of hospitals for such an event and the relationship of Federal and State planning for an influenza pandemic to preparedness for emerging infectious diseases. All of these issues have become much more pertinent in light of the SARS epidemic.

We recently released our review of State and local preparedness for bioterrorism. In visiting selected States and cities, local officials reported varying ability to respond to a major public health threat. They recognized gaps in communication and were beginning to address them, however gaps remain in elements such as disease surveillance, laboratory capacity and a trained work force. Although States have moved to electronic systems to compile data on disease in a community, for the most part they still rely on voluntary reporting of unusual diseases by health care providers. Such passive systems suffer from chronic under reporting and time lags between diagnoses of the condition and the health department's receipt of the report.

To increase their capacity to test and identify disease organisms, State officials were planning to purchase new equipment for public health laboratories and hire laboratory personnel. Hiring epidemologists and trained laboratory personnel to do the appropriate investigations in an emergency has been hampered by a gen-

eral shortage of people with the necessary skills, as well as non-competitive salaries.

Other recent work we have done shows that progress in improving public health response capacity has lagged in hospitals. Persons with symptoms of infectious diseases would likely go to emergency departments for treatment. Most of these emergency departments across the country have experienced some degree of crowding and may not be able to handle a large influx of patients during a potential SARS outbreak.

In addition, although most hospitals reported participating in basic planning activities and providing training to staff on recognition of symptoms of likely biological agents, few have acquired the medical equipment and isolation facilities they would need.

The completion of final Federal influenza pandemic response plans seems to be a feasible step with potential benefit. These plans would address problems related to the purchase, distribution and administration of supplies of vaccines and antiviral drugs during a pandemic and could facilitate the public health response to emerging infectious diseases by avoiding uncertainty during crises.

Key decisions related to vaccines and antiviral drug distribution have yet to be made, such as determining the amount of vaccines and antiviral drugs that will be purchased at the Federal level, the division of responsibility between the public and private sectors, and how populations groups will be prioritized and targeted to receive limited supplies.

In summary, many actions taken at the State and local level to prepare for a bioterrorism event have enhanced the ability of our agencies at the local level to respond to management of a major public health threat, but significant gaps remain. Clearly progress has been made, but much more needs to be done.

Mr. Chairman, I would be happy to answer any questions.

[The prepared statement of Janet Heinrich follows:]

PREPARED STATEMENT OF JANET HEINRICH, DIRECTOR, HEALTH CARE AND PUBLIC HEALTH ISSUES, UNITED STATES GERNERAL ACCOUNTING OFFICE

Mr. Chairman and Members of the Subcommittee: I appreciate the opportunity to be here today to discuss the work we have done pertaining to the nation's preparedness to manage major public health threats, such as the emerging infectious disease known as SARS.[1] The initial response to an outbreak of infectious disease would occur at the local level, with support from state and federal agencies, and could involve disease surveillance,[2] epidemiologic investigation,[3] health care delivery, and quarantine management. The SARS outbreak has not infected large numbers of individuals in the United States, but it has raised concerns about the nation's preparedness to manage these components of response should it, or other infections, reach large-scale proportions.

Public health officials and health care workers have learned lessons applicable to preparedness for large-scale infectious disease outbreaks from experiences with other major public health threats. Because of prior worldwide influenza outbreaks—known as pandemics[4]—federal and state agencies have begun to focus special attention on planning for such events. Similarly, following the anthrax incidents of fall

[1] SARS is the abbreviation for severe acute respiratory syndrome.

[2] Disease surveillance uses systems that provide for the ongoing collection, analysis, and dissemination of health-related data to identify, prevent, and control disease.

[3] An epidemiologic investigation seeks to determine how a disease is distributed in a population and the factors that influence or determine this distribution.

[4] Influenza pandemics are worldwide influenza epidemics that can have successive "waves" of disease and last for up to 3 years. Three pandemics occurred in the twentieth century: the "Spanish flu" of 1918, which killed at least 20 million people worldwide; the "Asian flu" of 1957; and the "Hong Kong flu" of 1968.

2001, the Congress expressed concern that the nation may not be prepared to respond to a large-scale bioterrorist event. State and local response agencies and organizations have recognized the need to strengthen their infrastructure and capacity to respond to bioterrorism. The improvements they are making will also strengthen their ability to identify and respond to other major public health threats, including naturally occurring infectious disease outbreaks. Planning for a response to bioterrorism and influenza pandemics targets the public health resources essential for a response to emerging infectious diseases.

To assist the Subcommittee in its consideration of our nation's capacity to respond to a major public health threat such as SARS, my remarks today will focus on (1) the preparedness of state and local public health agencies for responding to a large-scale infectious disease outbreak, (2) the preparedness of hospitals for responding to a large-scale infectious disease outbreak, and (3) the relationship of federal and state planning for an influenza pandemic to preparedness for emerging infectious diseases.

My testimony today is based largely on our recently released report on state and local preparedness for a bioterrorist attack.[5] For that report, we conducted site visits to seven cities and their respective state governments. We also reviewed each state's spring 2002 applications for bioterrorism preparedness funding distributed by the Department of Health and Human Services' (HHS) Centers for Disease Control and Prevention (CDC) and Health Resources and Services Administration (HRSA), and each state's fall 2002 progress report on the use of that funding. In addition, I will present some findings from a survey we conducted on hospital emergency department capacity and emergency preparedness,[6] as well as some information updating our 2000 report on federal and state planning for an influenza pandemic.[7]

In summary, while the efforts of public health agencies and health care organizations to increase their preparedness for major public health threats such as influenza pandemics and bioterrorism have improved the nation's capacity to respond to SARS and other emerging infectious disease outbreaks, gaps in preparedness remain. Specifically, we found that there are gaps in disease surveillance systems and laboratory facilities and that there are workforce shortages. The level of preparedness varied across cities we visited, with jurisdictions that have had multiple prior experiences with public health emergencies being generally more prepared than others. We found that planning for regional coordination was lacking between states. We also found that states were developing plans for receiving and distributing medical supplies for emergencies and for mass vaccinations in the event of a public health emergency.

We found that most hospitals across the country lack the capacity to respond to large-scale infectious disease outbreaks. Most emergency departments have experienced some degree of crowding and therefore in some cases may not be able to handle a large influx of patients during a potential SARS or other infectious disease outbreak. Although most hospitals report participating in basic planning activities for such outbreaks, few have adequate medical equipment, such as ventilators that are often needed for respiratory infections such as SARS, to handle the large increases in the number of patients that may result.

The public health response to outbreaks of emerging infectious diseases such as SARS could be improved by the completion of federal and state influenza pandemic response plans that address problems related to the purchase, distribution, and administration of supplies of vaccines and antiviral drugs during an outbreak. CDC has provided interim draft guidance to facilitate state plans but has not made the final decisions on plan provisions necessary to mitigate the effects of potential shortages of vaccines and antiviral drugs in the event of an influenza pandemic.

BACKGROUND

SARS is a respiratory illness that has recently been reported principally in Asia, Europe, and North America. The World Health Organization reported on May 5, 2003, that there were an estimated 6,583 probable cases reported in 27 countries,

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[5] U.S. General Accounting Office, *Bioterrorism: Preparedness Varied across State and Local Jurisdictions* GAO-03-373 (Washington, D.C.: Apr. 7, 2003).

[6] These findings include those related to emergency department capacity, which we reported in U.S. General Accounting Office, *Hospital Emergency Departments: Crowded Conditions Vary among Hospitals and Communities,* GAO-03-460 (Washington, D.C.: Mar. 14, 2003) and hospital emergency preparedness for mass casualty incidents from ongoing work. We did our work on the survey from May 2002 through May 2003 in accordance with generally accepted government auditing standards.

[7] U.S. General Accounting Office, *Influenza Pandemic: Plan Needed for Federal and State Response,* GAO-01-4 (Washington, D.C.: Oct. 27, 2000).

including 61 cases in the United States. There have been 461 deaths worldwide, none of which have been in the United States. Of the 56 probable cases in the United States reported through April 30, 2003, 37 (66 percent) were hospitalized, and 2 (4 percent) required mechanical ventilation. Symptoms of the disease, which may be caused by a previously unrecognized coronavirus,[8] can include a fever, chills, headache, other body aches, or a dry cough.

A Canadian official recently reported that more than 60 percent of probable SARS cases in Canada, where the bulk of North American cases have occurred, resulted from transmission to health care workers and patients. Canada's experience with managing the SARS outbreak has shown that measures used to prevent and control emerging infectious diseases appear to have been useful in controlling this outbreak. One of the measures that it has undertaken to control the outbreak is isolating probable cases in hospitals, including closing two hospitals to new admissions.[9] Other measures include isolating people, either in their homes or in a hospital, who have had close contact with a SARS patient and providing educational materials regarding SARS to people who have traveled to locations of concern.

In order to be adequately prepared for a major public health threat such as SARS in the United States, state and local public health agencies need to have several basic capabilities, whether they possess them directly or have access to them through regional agreements. Public health departments need to have disease surveillance systems and epidemiologists to detect clusters of suspicious symptoms or diseases in order to facilitate early detection of disease and treatment of victims. Laboratories need to have adequate capacity and necessary staff to test clinical and environmental samples in order to identify an agent promptly so that proper treatment can be started and infectious diseases prevented from spreading. All organizations involved in the response must be able to communicate easily with one another as events unfold and critical information is acquired, especially in a large-scale infectious disease outbreak. In addition, plans that describe how state and local officials would manage and coordinate an emergency response need to be in place and to have been tested in an exercise, both at the state and local levels and at the regional level.

Local health care organizations, including hospitals, are generally responsible for the initial response to a public health emergency. In the event of a large-scale infectious disease outbreak, hospitals and their emergency departments would be on the front line, and their personnel would take on the role of first responders. Because hospital emergency departments are open 24 hours a day, 7 days a week, exposed individuals would be likely to seek treatment from the medical staff on duty. Staff would need to be able to recognize and report any illness patterns or diagnostic clues that might indicate an unusual infectious disease outbreak to their state or local health department. Hospitals would need to have the capacity and staff necessary to treat severely ill patients and limit the spread of infectious disease. In addition, hospitals would need adequate stores of equipment and supplies, including medications, personal protective equipment, quarantine and isolation facilities, and air handling and filtration equipment.

The federal government also has a role in preparedness for and response to major public health threats. It becomes involved in investigating the cause of the disease, as it is doing with SARS. In addition, the federal government provides funding and resources to state and local entities to support preparedness and response efforts. CDC's Public Health Preparedness and Response for Bioterrorism program provided funding through cooperative agreements in fiscal year 2002 totaling $918 million to states and municipalities to improve bioterrorism preparedness and response, as well as other public health emergency preparedness activities. HRSA's Bioterrorism Hospital Preparedness Program provided funding through cooperative agreements in fiscal year 2002 of approximately $125 million to states and municipalities to enhance the capacity of hospitals and associated health care entities to respond to bioterrorist attacks. In March 2003, HHS announced that the CDC and HRSA programs would provide funding of approximately $870 million and $498 million, respectively, for fiscal year 2003. Among the other public health emergency response resources that the federal government provides is the Strategic National Stockpile, which contains pharmaceuticals, antidotes, and medical supplies that can be delivered anywhere in the United States within 12 hours of the decision to deploy.

Just as was true with the identification of the coronavirus as the likely causative agent in SARS, deciding which influenza viral strains are dominant depends on data

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[8] The coronavirus is one of a group of viruses that are responsible for some but not all common colds. They are so named because their microscopic appearance is that of a virus particle surrounded by a crown.

[9] The two hospitals have since been reopened.

collected from domestic and international surveillance systems that identify prevalent strains and characterize their effect on human health.[10] Antiviral drugs and vaccines against influenza are expected to be in short supply if a pandemic occurs. Antiviral drugs, which can be used against all forms of viral diseases, have been as effective as vaccines in preventing illness from influenza and have the advantage of being available now. HHS assumes shortages of antiviral drugs and vaccines will occur in a pandemic because demand is expected to exceed current rates of production. For example, increasing production capacity of antiviral drugs can take at least 6 to 9 months, according to manufacturers.

STATE AND LOCAL OFFICIALS REPORTED VARYING LEVELS OF PUBLIC HEALTH PREPAREDNESS FOR INFECTIOUS DISEASE OUTBREAKS

In the cities we visited, state and local officials reported varying levels of public health preparedness to respond to outbreaks of diseases such as SARS. They recognized gaps in preparedness elements such as communication and were beginning to address them. Gaps also remained in other preparedness elements that have been more difficult to address, including the disease surveillance and laboratory systems and the response capacity of the workforce. In addition, we found that the level of preparedness varied across the cities. Jurisdictions that had multiple prior experiences with public health emergencies were generally more prepared than those with little or no such experience prior to our site visits. We found that planning for regional coordination was lacking between states. In addition, states were working on plans for receiving and distributing the Strategic National Stockpile and for administering mass vaccinations.

Progress Has Been Made in Elements of Public Health Preparedness, But Gaps Remain

States and local areas were addressing gaps in public health preparedness elements, such as communication, but weaknesses remained in other preparedness elements, including the disease surveillance and laboratory systems and the response capacity of the workforce. Gaps in capacity often are not amenable to solution in the short term because either they require additional resources or the solution takes time to implement.

Communication

We found that officials were beginning to address communication problems. For example, six of the seven cities we visited were examining how communication would take place in a public health emergency. Many cities had purchased communication systems that allow officials from different organizations to communicate with one another in real time. In addition, state and local health agencies were working with CDC to build the Health Alert Network (HAN), an information and communication system. The nationwide HAN program has provided funding to establish infrastructure at the local level to improve the collection and transmission of information related to public health preparedness. Goals of the HAN program include providing high-speed Internet connectivity, broadcast capacity for emergency communication, and distance-learning infrastructure for training.

Surveillance Systems and Laboratory Facilities

State and local officials for the cities we visited recognized and were attempting to address inadequacies in their surveillance systems and laboratory facilities. Local officials were concerned that their surveillance systems were inadequate to detect a bioterrorist event, and all of the states we visited were making efforts to improve their disease surveillance systems. Six of the cities we visited used a passive surveillance system[11] to detect infectious disease outbreaks.[12] However, passive systems may be inadequate to identify a rapidly spreading outbreak in its earliest and most manageable stage because, as officials in three states noted, there is chronic underreporting and a time lag between diagnosis of a condition and the health depart-

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[10] CDC participates in international disease and laboratory surveillance sponsored by the World Health Organization, which operates in 83 countries.

[11] Passive surveillance systems rely on laboratory and hospital staff, physicians, and other relevant sources to take the initiative to provide data on illnesses to the health department, where officials analyze and interpret the information as it arrives. In contrast, in an active disease surveillance system, public health officials contact sources, such as laboratories, hospitals, and physicians, to obtain information on conditions or diseases in order to identify cases. Active surveillance can provide more complete detection of disease patterns than a system that is wholly dependent on voluntary reporting.

[12] Officials in one city told us that although it had no local disease surveillance, its state maintained a passive disease surveillance system.

ment's receipt of the report. To improve disease surveillance, six of the states and two of the cities we visited were developing surveillance systems using electronic databases. Several cities were also evaluating the use of nontraditional data sources, such as pharmacy sales, to conduct surveillance.[13] Three of the cities we visited were attempting to improve their surveillance capabilities by incorporating active surveillance components into their systems.

However, work to improve surveillance systems has proved challenging. For example, despite initiatives to develop active surveillance systems, the officials in one city considered event detection to be a weakness in their system, in part because they did not have authority to access hospital information systems. In addition, various local public health officials in other cities reported that they lacked the resources to sustain active surveillance.

Officials from all of the states we visited reported problems with their public health laboratory systems and said that they needed to be upgraded. All states were planning to purchase the equipment necessary for rapidly identifying a biological agent. State and local officials in most of the areas that we visited told us that the public health laboratory systems in their states were stressed, in some cases severely, by the sudden and significant increases in workload during the anthrax incidents in the fall of 2001. During these incidents, the demand for laboratory testing was significant even in states where no anthrax was found and affected the ability of the laboratories to perform their routine public health functions. Following the incidents, over 70,000 suspected anthrax samples were tested in laboratories across the country.

Officials in the states we visited were working on other solutions to their laboratory problems. States were examining various ways to manage peak loads, including entering into agreements with other states to provide surge capacity, incorporating clinical laboratories into cooperative laboratory systems, and purchasing new equipment. One state was working to alleviate its laboratory problems by upgrading two local public health laboratories to enable them to process samples of more dangerous pathogens and by establishing agreements with other states to provide backup capacity. Another state reported that it was using the funding from CDC to increase the number of pathogens the state laboratory could diagnose. The state also reported that it has worked to identify laboratories in adjacent states that are capable of being reached within 3 hours over surface roads. In addition, all of the states reported that their laboratory response plans had been revised to cover reporting and sharing laboratory results with local public health and law enforcement agencies.

Workforce

At the time of our site visits, shortages in personnel existed in state and local public health departments and laboratories and were difficult to remedy. Officials from state and local health departments told us that staffing shortages were a major concern. Two of the states and cities that we visited were particularly concerned that they did not have enough epidemiologists to do the appropriate investigations in an emergency. One state department of public health we visited had lost approximately one-third of its staff because of budget cuts over the past decade. This department had been attempting to hire more epidemiologists. Barriers to finding and hiring epidemiologists included noncompetitive salaries and a general shortage of people with the necessary skills.

Shortages in laboratory personnel were also cited. Officials in one city noted that they had difficulty filling and maintaining laboratory positions. People that accepted the positions often left the health department for better-paying positions. Increased funding for hiring staff cannot necessarily solve these shortages in the near term because for many types of laboratory positions there are not enough trained individuals in the workforce. According to the Association of Public Health Laboratories, training laboratory personnel to provide them with the necessary skills will take time and require a strategy for building the needed workforce.[14]

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[13] This type of active surveillance system in which the public health department obtains information from such sources as hospitals and pharmacies and conducts ongoing analysis of the data to search for certain combinations of signs and symptoms, is sometimes referred to as a syndromic surveillance system. One federal official has stated that research examining the usefulness of syndromic surveillance needs to continue. See S. Lillibridge, *Disease Surveillance, Bioterrorism, and Homeland Security,* Conference Summary and Proceedings Prepared by the Annapolis Center for Science-Based Public Policy (Annapolis, Md.: U.S. Medicine Institute for Health Studies, Dec. 4, 2001).

[14] Association of Public Health Laboratories, "State Public Health Laboratory Bioterrorism Capacity," *Public Health Laboratory Issues in Brief: Bioterrorism Capacity* (Washington, D.C.: October 2002).

Level of Preparedness Varied across Cities We Visited

We found that the overall level of public health preparedness varied by city. In the cities we visited, we observed that those cities that had recurring experience with public health emergencies, including those resulting from natural disasters, or with preparation for National Security Special Events, such as political conventions,[15] were generally more prepared than cities with little or no such experience. Cities that had dealt with multiple public health emergencies in the past might have been further along because they had learned which organizations and officials need to be involved in preparedness and response efforts and moved to include all pertinent parties in the efforts. Experience with natural disasters raised the awareness of local officials regarding the level of public health emergency preparedness in their cities and the kinds of preparedness problems they needed to address.

Even the cities that were better prepared were not strong in all elements. For example, one city reported that communications had been effective during public health emergencies and that the city had an active disease surveillance system. However, officials reported gaps in laboratory capacity. Another one of the better-prepared cities was connected to HAN and the Epidemic Information Exchange (Epi-X),[16] and all county emergency management agencies in the state were linked. However, the state did not have written agreements with its neighboring states for responding to a public health emergency.

Planning for Regional Coordination Was Lacking between States

Response organization officials were concerned about a lack of planning for regional coordination between states of the public health response to an infectious disease outbreak. As called for by the guidance for the CDC and HRSA funding, all of the states we visited organized their planning on the basis of regions within their states, assigning local areas to particular regions for planning purposes. A concern for response organization officials was the lack of planning for regional coordination between states. A hospital official in one city we visited said that state lines presented a "real wall" for planning purposes. Hospital officials in one state reported that they had no agreements with other states to share physicians. However, one local official reported that he had been discussing these issues and had drafted mutual aid agreements for hospitals and emergency medical services. Public health officials from several states reported developing working relationships with officials from other states to provide backup laboratory capacity.

States Have Begun Planning for Receiving and Distributing Items from the Strategic National Stockpile and for Administering Mass Vaccinations

States have begun planning for use of the Strategic National Stockpile.[17] To determine eligibility for the CDC funding, applicants were required to develop interim plans to receive and manage items from the stockpile, including mass distribution of antibiotics, vaccines, and medical materiel. However, having plans for the acceptance of the deliveries from the stockpile is not enough. Plans have to include details about dividing the materials that are delivered in large pallets and distributing the medications and vaccines.

Of the seven states we visited, five states had completed plans for the receipt and distribution of items from the stockpile. One state that was working on its plan stated that it would be completed in January 2003. Only one state had conducted exercises of its stockpile distribution plan, while the other states were planning to conduct exercises or drills of their plans sometime in 2003.

In addition, five states reported on their plans for mass vaccinations and seven states reported on their plans for large-scale administration of smallpox vaccine in response to an outbreak. Some states we visited had completed plans for mass vaccinations, whereas other states were still developing their plans. The mass vaccination plans were generally closely tied to the plans for receiving and administering the stockpile. In addition, two states had completed smallpox response plans, which include plans for administering mass smallpox vaccinations to the general population, whereas four of the other states were drafting plans. The remaining state

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[15] Presidential Decision Directive 62 created a category of special events called National Security Special Events, which are events of such significance that they warrant greater federal planning and protection than other special events. In addition to major political party conventions, such events include presidential inaugurations.

[16] Epi-X is a secure, Web-based exchange for public health officials to rapidly exchange information on disease outbreaks, exposures to environmental hazards, and other health events as they are identified and investigated.

[17] HHS is planning to purchase approximately 2,700 ventilators by September 2003 to supplement those now available in the Strategic National Stockpile to enhance preparedness for a potential outbreak of SARS in the United States.

was discussing such a plan. However, only one of the states we visited has tested in an exercise its plan for conducting mass smallpox vaccinations.

MOST HOSPITALS LACK RESPONSE CAPACITY FOR LARGE-SCALE INFECTIOUS DISEASE OUTBREAKS

We found that most hospitals lack the capacity to respond to large-scale infectious disease outbreaks. Persons with symptoms of infectious disease would potentially go to emergency departments for treatment. Most emergency departments across the country have experienced some degree of crowding and therefore in some cases may not be able to handle a large influx of patients during a potential SARS outbreak. In addition, although most hospitals across the country reported participating in basic planning activities for large-scale infectious disease outbreaks, few have acquired the medical equipment resources, such as ventilators, to handle large increases in the number of patients that may result from outbreaks of diseases such as SARS.

Most Emergency Departments Have Experienced Some Degree of Crowding

Our survey found that most emergency departments have experienced some degree of overcrowding.[18] Persons with symptoms of infectious disease would potentially go to emergency departments for treatment, further stressing these facilities. The problem of overcrowding is much more pronounced in some hospitals and areas than in others. In general, hospitals that reported the most problems with crowding were in the largest metropolitan statistical areas (MSA) and in the MSAs with high population growth. For example, in fiscal year 2001, hospitals in MSAs with populations of 2.5 million or more had about 162 hours of diversion (an indicator of crowding),[19] compared with about 9 hours for hospitals in MSAs with populations of less than 1 million. Also the median number of hours of diversion in fiscal year 2001 for hospitals in MSAs with a high percentage population growth was about five times that for hospitals in MSAs with lower percentage population growth.

Diversion varies greatly by MSA. Figure 1 shows each MSA and the share of hospitals within the MSA that reported being on diversion more than 10 percent of the time—or about 2.4 hours or more per day—in fiscal year 2001. Areas with the greatest diversion included Southern California and parts of the Northeast. Of the 248 MSAs for which data were available,[20] 171 (69 percent) had no hospitals reporting being on diversion more than 10 percent of the time. By contrast, 53 MSAs (21 percent) had at least one-quarter of responding hospitals on diversion for more than 10 percent of the time.

Hospitals in the largest MSAs and in MSAs with high population growth that have reported crowding in emergency departments may have difficulty handling a large influx of patients during a potential SARS outbreak, especially if this outbreak occurred in the winter months when the incidence of influenza is quite high. Thus far, the largest SARS outbreaks worldwide have primarily occurred in areas with dense populations.[21]

Most Hospitals Reported Planning and Training Efforts, but Fewer Than Half Have Participated in Drills or Exercises

At the time of our site visits, we found that hospitals were beginning to coordinate with other local response organizations and collaborate with each other in local planning efforts. Hospital officials in one city we visited told us that until September 11, 2001, hospitals were not seen as part of a response to a terrorist event but that city officials had come to realize that the first responders to a bioterrorism incident could be a hospital's medical staff. Officials from the state began to emphasize the need for a local approach to hospital preparedness. They said, however, that it was difficult to impress the importance of cooperation on hospitals because hospitals had not seen themselves as part of a local response system. The local government officials were asking them to create plans that integrated the city's hospitals and addressed such issues as off-site triage of patients and off-site acute care.

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[18] GAO-03-460.

[19] Diversions occur when hospitals request that en route ambulances bypass their emergency departments and transport patients that would have been otherwise taken to those emergency departments to other medical facilities.

[20] The 248 MSAs include those MSAs for which (1) more than half of hospitals in the MSA returned surveys and (2) more than half of those hospitals that returned surveys provided data on diversion hours.

[21] These areas include mainland China and the Hong Kong Special Administrative Region within the People's Republic of China; Singapore; Taiwan; and Toronto, Canada.

In our survey of over 2,000 hospitals,[22] 4 out of 5 hospitals reported having a written emergency response plan for large-scale infectious disease outbreaks. Of the hospitals with emergency response plans, most include a description of how to achieve surge capacity for obtaining additional pharmaceuticals, other supplies, and staff. In addition, almost all hospitals reported participating in community interagency disaster preparedness committees.

Our survey showed that hospitals have provided training to staff on biological agents, but fewer than half have participated in exercises related to bioterrorism. Most hospitals we surveyed reported providing training about identifying and diagnosing symptoms for the six biological agents identified by the CDC as most likely to be used in a bioterrorist attack. At least 90 percent of hospitals reported providing training for two of these agents—smallpox and anthrax—and approximately three-fourths of hospitals reported providing training about the other four—plague, botulism, tularemia, and hemorrhagic fever viruses.

Most Hospitals Lack Adequate Equipment, Facilities, and Staff Required to Respond to a Large-Scale Infectious Disease Outbreak

Most hospitals lack adequate equipment, isolation facilities, and staff to treat a large increase in the number of patients for an infectious disease such as SARS. To prevent transmission of SARS in health care settings, CDC recommends that health care workers use personal protective equipment, including gowns, gloves, respirators, and protective eyewear.[23] SARS patients in the United States are being isolated until they are no longer infectious. CDC estimates that patients require mechanical ventilation in 10 to 20 percent of SARS cases.[24]

In the seven cities we visited, hospital, state, and local officials reported that hospitals needed additional equipment and capital improvements—including medical stockpiles, personal protective equipment, quarantine and isolation facilities, and air handling and filtering equipment—to enhance preparedness. Five of the states we visited reported shortages of hospital medical staff, including nurses and physicians, necessary to increase response capacity in an emergency. One of the states we visited reported that only 11 percent of its hospitals could readily increase their capacity for treating patients with infectious diseases requiring isolation, such as smallpox and SARS. Another state reported that most of its hospitals have little or no capacity for isolating patients diagnosed with or being tested for infectious diseases.

According to our hospital survey, availability of medical equipment varied greatly between hospitals, and few hospitals seemed to have adequate equipment and supplies to handle a large-scale infectious disease outbreak. While most hospitals had, for every 100 staffed beds, at least 1 ventilator, 1 personal protective equipment suit, or 1 isolation bed, half of the hospitals had, for every 100 staffed beds, fewer than 6 ventilators, 3 or fewer personal protective equipment suits, and fewer than 4 isolation beds.

KEY FEDERAL DECISIONS FOR INFLUENZA PANDEMIC PLANNING COULD FACILITATE RESPONSE TO EMERGING INFECTIOUS DISEASES

The completion of final federal influenza pandemic response plans that address the problems related to the purchase, distribution, and administration of supplies of vaccines and antiviral drugs during a pandemic could facilitate the public health response to emerging infectious disease outbreaks. CDC has provided interim draft guidance to facilitate state plans but has not made the final decisions on plan provisions necessary to mitigate the effects of potential shortages of vaccines and antiviral drugs. Until such decisions are made, the timeliness and adequacy of response efforts may be compromised.

In the most recent version of its pandemic influenza planning guidance for states, CDC lists several key federal decisions related to vaccines and antiviral drugs that have not been made. These decisions include determining the amount of vaccines

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[22] Between May and September 2002, we surveyed over 2,000 short-term, nonfederal general medical and surgical hospitals with emergency departments located in metropolitan statistical areas. (See U.S. General Accounting Office, *Hospital Emergency Departments: Crowded Conditions Vary among Hospitals and Communities,* GAO-03-460 (Washington, D.C.: Mar. 14, 2003) for information on the survey universe and development of the survey.) For the part of the survey that specifically addressed hospital preparedness for mass casualty incidents, we obtained responses from 1,482 hospitals for the third section of the survey addressing emergency preparedness, a response rate of about 73 percent.

[23] CDC, *Interim Domestic Guidance for Management of Exposures to Severe Acute Respiratory Syndrome (SARS) for Healthcare and Other Institutional Settings* (Apr. 12, 2003), http://www.cdc.gov/ncidod/sars/exposureguidance.htm (downloaded May 5, 2003).

[24] CDC, *Frequently Asked Questions: Severe Acute Respiratory Syndrome (SARS),* http://www.cdc.gov/ncidod/sars/faq.htm (downloaded May 5, 2003).

and antiviral drugs that will be purchased at the federal level; the division of responsibility between the public and the private sectors for the purchase, distribution, and administration of vaccines and drugs; and how population groups will be prioritized and targeted to receive limited supplies of vaccines and drugs. In each of these areas, until federal decisions are made, states will not be able to develop strategies consistent with federal action.

The interim draft guidance for state pandemic plans says that resources can be expected to be available through federal contracts to purchase influenza vaccine and some antiviral agents, but some state funding may be required. The amounts of antiviral drugs to be purchased and stockpiled are yet to be determined, even though these drugs are available and can potentially be used for both treatment and prevention during a pandemic.

CDC has indicated in its interim draft guidance that the policies for purchasing, distributing, and administering vaccines and drugs by the private and public sectors will change during a pandemic, but some decisions necessary to prepare for these expected changes have not been made. During a typical annual influenza response, influenza vaccine and antiviral drug distribution is primarily handled directly by manufacturers through private vendors and pharmacies to health care providers. During a pandemic, however, CDC interim draft guidance indicates that many of these private-sector responsibilities may be transferred to the public sector at the federal, state, or local levels and that priority groups within the population would need to be established for receiving limited supplies of vaccines and drugs.

State officials are particularly concerned that a national plan has not been issued with final recommendations for how population groups should be prioritized to receive vaccines and antiviral drugs. In its interim draft guidance, CDC lists eight population groups that should be considered in establishing priorities among groups for receiving vaccines and drugs during a pandemic. The list includes such groups as health care workers and public health personnel involved in the pandemic response, persons traditionally considered to be at increased risk of severe influenza illness and mortality, and preschool and school-aged children.

Although state officials acknowledge the need for flexibility in planning because many aspects of a pandemic cannot be known in advance, the absence of more detail leaves them uncertain about how to plan for the use of limited supplies of vaccine and drugs. In our 2000 report on the influenza pandemic, we recommended that HHS determine the capability of the private and public sectors to produce, distribute, and administer vaccines and drugs and complete the national response plan.[25] To date, only limited progress has been made in addressing these recommendations.

CONCLUDING OBSERVATIONS

Many actions taken at the state and local level to prepare for a bioterrorist event have enhanced the ability of state and local response agencies and organizations to manage an outbreak of an infectious disease such as SARS. However, there are significant gaps in public health surveillance systems and laboratory capacity, and the number of personnel trained for disease detection is insufficient. Most emergency departments across the country have experienced some degree of overcrowding. Hospitals have begun planning and training efforts to respond to large-scale infectious disease outbreaks, but many hospitals lack adequate equipment, medical stockpiles, personal protective equipment, and quarantine and isolation facilities. Federal and state plans for the purchase, distribution, and administration of supplies of vaccines and drugs in response to an influenza pandemic have still not been finalized. The lack of these final plans has serious implications for efforts to mobilize the distribution of vaccines and drugs for other infectious disease outbreaks.

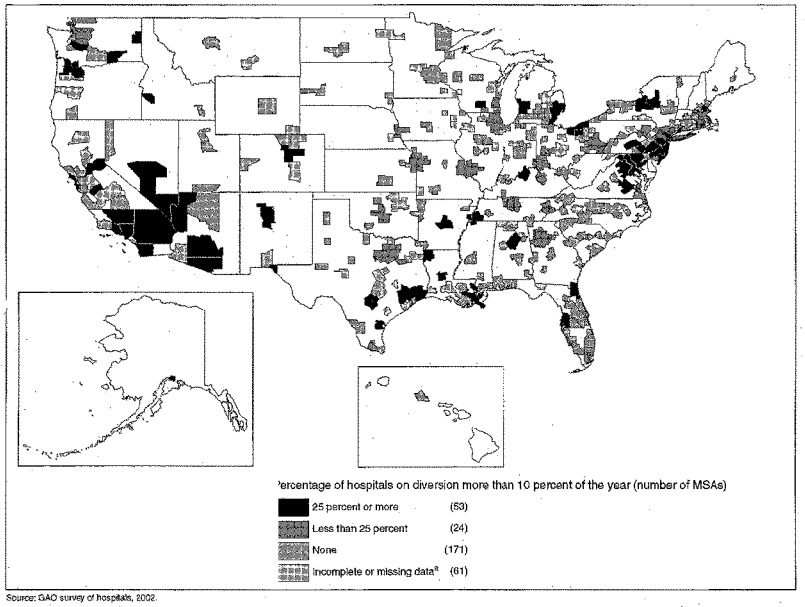
Mr. Chairman, this completes my prepared statement. I would be happy to respond to any questions you or other Members of the Subcommittee may have at this time.

CONTACT AND STAFF ACKNOWLEDGMENTS

For further information about this testimony, please contact me at (202) 512-7119. Robert Copeland, Marcia Crosse, Martin T. Gahart, Deborah Miller, Roseanne Price, and Ann Tynan also made key contributions to this statement.

[25] GAO-01-4.

Figure 1: Percentage of Hospitals on Diversion More Than 10 Percent of the Time, by MSA, Fiscal Year 2001



Source: GAO survey of hospitals, 2002.

Note: Percentage of hospitals reflects those hospitals that responded to the survey; responses were not weighted to represent all hospitals in the MSA.

[a]MSAs with a response rate of 50 percent or less or MSAs with 50 percent or more of data missing for responding hospitals. In 12 MSAs, no hospitals responded; these MSAs were excluded from the map.

Mr. GREENWOOD. Thank you very much.

And the Chair recognizes himself for 10 minutes for questions. And let me begin with you, Mr. Hauer. Dean Barry Bloom in his testimony for today's second panel to follow you states in his written statement, "Neither the CDC nor the NIH currently has the resources or flexibility to use its funds to allocate personnel and resources rapidly to meet ever changing emerging infections without neglecting other health responsibilities." The question is do you agree with that statement?

Mr. HAUER. No, I don't. I think the SARS outbreak has shown that both the flexibility exists and the ability to address multiple issues exists. I think that CDC has shown in an incredible degree to address emerging threats while at the same time maintain focus on other issues.

Mr. GREENWOOD. Okay. The New York Times is reporting in today's paper, in today's edition, that the administration has authorized Immigration and Customs agents at the Nation's airports to use force to detain arriving possible SARS carriers. The question is, has the Department of Homeland Security consulted with HHS about what precautions need to be taken for the Immigration and Customs agents?

Mr. HAUER. Let me defer that question to Dr. Gerberding, because CDC is working closely with DHS on this issue.

Ms. GERBERDING. CDC has the Division of Global Migration and Quarantine, and it is their responsibility to deal with quarantine at our Federal borders.

Our quarantine officials have the responsibility for conducting the medical assessments, but they do not have the law enforcement authority. So traditionally it has been the Customs officials who have the responsibility for enforcing the authority of our quarantine individuals.

In the particular case of SARS where we recognize that it could be necessary to exercise quarantine authorities at our borders, we work very collaboratively with the Department of Homeland Security to engage their assistance. We doubt we will need to ever use that level of enforcement, because almost always this happens on a voluntary basis. But it is important to know where you would turn for the enforcement capacity if you needed it, and that, I think, is what the New York Times article is referencing.

Mr. GREENWOOD. Very well. And let me address a question directly to you, Dr. Gerberding. The GAO reports that the public health response to outbreaks of emerging infectious diseases such as SARS could be improved by the completion of Federal and State influenza pandemic response plans that address problems related to the purchase, distribution and administration of supplies of vaccines and antiviral drugs during an outbreak. Do you agree with that?

Ms. GERBERDING. I do agree with that.

Mr. GREENWOOD. Okay. The GAO also reports that the CDC has provided interim draft guidance to facilitate State plans but has not made the final decisions on plan provisions necessary to mitigate the effects of potential shortages of vaccines and antiviral drugs in the event of an influenza pandemic. Do you agree with that?

Ms. GERBERDING. I partially agree with it. We have made some draft recommendations. We are working with our partners in the Department of Health and Human Services to get a collaborative organized approach here, because obviously it is not just up to CDC, we have to work with FDA and NIH, and with Assistant Secretary Hauer's office to make sure that we are all on the same page here.

We are expecting the department to have a uniform pandemic flu plan before next flu seasons. That is, obviously, a high priority right now given the lessons we have learned from SARS.

Mr. GREENWOOD. Dr. Jared Schwartz on the second panel states in his testimony that, "Our public health system would benefit from an interconnected electronic communications network to monitor for disease outbreaks." The question is what actions is CDC taking to establish such an interconnected electronic communication network?

Ms. GERBERDING. I have a vision of a completely interconnected system that starts in the health care delivery system and moves through the local and State health agencies and throughout the Federal partners here, and that it is a two-way communication system or a multi-directional communication system so it is not just about us getting information from the local jurisdictions, but it is about creating knowledge and information of use to those people.

We have made already substantial investments in this, and the billion dollars that have gone out just this past year for State and local preparedness includes a significant investment in enhancing this network further. It is not finished yet, but it is very functional. We use it for our health alerting now, and we have more than 90 percent of local health departments engaged in that alerting capacity.

We have electronic reporting of some sort in almost every State. I think 30 States are now engaged in using the uniform standardized integrated data system, which includes standards for architecture and vocabulary. So our intent is to have a seamless system. We are working very fast to make that vision become a reality.

Mr. GREENWOOD. Okay.

Let me turn to you, Dr. Fauci, and ask you can you walk us through the pathology of SARS? What happens to an individual once infected with this virus?

Mr. FAUCI. All of the steps of the pathophysiological mechanisms have not been worked out, but we have a pretty good idea of what goes on.

An individual gets exposed and infected with the virus, generally from a droplet that contains the virus from an infected individual. It gets into the nasal and oral passages and, very likely as most viruses do, they then from that point generally go to lymph node areas and start to replicate. Patients develop what we call we viremic state where individuals have virus that circulates throughout the body. That generally leads to symptoms that are due both to the virus itself as well as to what we call cytokines, which are proteins that the body secretes in response to noxious stimuli such as microbes.

These cytokines cause fever, they cause headache, they cause muscle aches and a general flu-like syndrome. That part of the

SARS pathophysiology is likely similar, if not identical, to many of the microbes that cause flu-like syndromes.

What this microbe then has the capacity to do is that it seeds itself in the lungs, and that is why you start to get the dry cough and then some of the shortness of breath. And in people who go into advance disease, they develop what we call pulmonary infiltrates.

An infiltrate means if you look at the chest x-ray, it is dense. You don't see that nice crystal-clear appearance that you look at when you see an x-ray. You get infiltrates in the lung and its most severe form, the lung is so infiltrated that it actually looks like it is "whited out," as we call it.

Now, the important thing is that we are starting to see that individuals who get infected and go to this advanced stage, the actual inflammatory response and immunological response to the virus itself is contributing greatly to the inability to move air in and out into the infiltrates. So when you look at a chest x-ray, it is not just a lot of virus that is whiting out the chest x-ray, it is the inflammatory response to that virus.

Now what happens is that the vast majority of people, and you have heard discussion this afternoon about mortality rate, but the 90 percent or so of people who survive, immunologically their body can ultimately clear the virus and then the inflammation disappears. In those individuals who succumb, the inflammation is so overwhelming that they die a respiratory death. They need to go on a respirator and they die with a syndrome that is called acute respiratory distress syndrome, which has a very high mortality when you get to that point.

Mr. GREENWOOD. And what seems to be the determining factor? I know their age seems to be a critical issue.

Mr. FAUCI. Yes.

Mr. GREENWOOD. As to who gets sick and who gets sicker.

Mr. FAUCI. Well, certainly in any serious respiratory illness, including influenza and certainly including SARS, individuals who are elderly or who have other underlying diseases have a compromise of their ability to mount an inflammatory or an immunological response. Their mortality is almost always greater than a young, robust, vigorous healthy person. However, microbes like the coronavirus of SARS and in certain situations with influenza when you have a really bad year, young individuals even though they are healthy, can actually get sick enough to succumb. So although the weight of it is heavily weighted toward older individuals and those who might have underlying conditions, young healthy individuals are not exempt from getting serious complications including death.

Mr. GREENWOOD. And how do you treat a patient?

Mr. FAUCI. Well, right now it is with what we call supportive therapy. Supportive therapy means it is nonspecific. We don't have a specific antiviral drug. So if someone would come into the hospital in the serious beginning of a respiratory problem, you would have to see that their respiratory function is able to be supported. So you give them supported therapy, which might include putting them on a respirator. You would try to keep their airways clear, because when you have those many infiltrates in your lung, you

generally have secretions that need to be cleared. You have to have intensive nursing care, which prior to the realization that it was transmissible that way, that certainly was the way the nurses and the doctors were getting infected, via the intensive care that you have to give to someone who has a serious pulmonary disease.

You also look at the fluid and the electrolytes. Because when people get into dire straights with systemic disease, their body's ability to balance the fluid that is in your blood vessels versus that which goes out into the tissue is very much disrupted, so you need to balance the fluid. And then you need to be alert for any secondary infections. Because when people have difficulty moving air in their lungs, they are more prone to a secondary bacterial infection. When they are in bed, they are prone to urinary tract infection.

All of those things. But they do not directly go against the SARS virus. They come under the category of what we call supportive care.

Mr. GREENWOOD. Thank you. My time has expired.

The gentleman from Florida for 10 minutes.

Mr. DEUTSCH. That you, Mr. Chairman.

Thank you, Dr. Fauci. And I appreciate your help in issues that we have worked together over the last several years.

WHO is now reporting that the SARS virus can live for days in the stool and urine of patients. Additionally, Hong Kong scientists suspect that the virus can live in sewage. Do you think that we should be concerned about the potential for the SARS microbes to remain viable on certain objects such as trash which are being imported into the United States from SARS infected such as China? Did you want to try to answer that? Are you qualified? I mean, is that your area?

Mr. HAUER. Julie, do you want to take a shot and then I will be happy to fill in?

Ms. GERBERDING. First of all, finding the SARS virus in stool of human beings is not surprising because we know this is a commonsite of infection in animals. So we have evidence that the SARS virus can be found in diarrheal stool of some people, and we are not surprised to find that it can last alive on certain on certain surfaces for periods of time. But our evidence tells us that that is not likely to be the way it is being transmitted. Rather, it is being transmitted person-to-person through respiratory droplets.

The exception to that in an apartment complex in Hong Kong is very complicated because their sewage system is very different from ours. Basically due to a failure to keep the sewer separate from the bathroom plumbing, there was a problem where there was reflux of the sewage back into the bathroom sinks, and then a fan in these bathrooms was pulling air up into the ceiling and potentially aerosolizing sewage into the bathrooms. That is a very extreme and uncommon situation, and that is something that we would not be likely to be concerned about in the kind of plumbing regulations we have in this country. We do not have proof that that is how those people were infected, but it is the leading hypothesis according to the Hong Kong experts.

Our concern about stool or contaminated objects is why we have recommended that health care workers wear gloves and that people maintain good hand hygiene to protect themselves against SARS

should they happen to come in contact with a contaminated object. But the major concern is still that direct sustained face-to-face contact with someone who is sick. And that really is the common denominator here.

Mr. DEUTSCH. Okay. Yes, go ahead.

Mr. FAUCI. Mr. Deutsch, let me just add to that explanation, which I agree with completely. That we need to be careful when we hear reports of experiments that are relevant and do inform us and help us. But many times experiments do what we call spiking the virus on a particular surface, on a table, whatever, in an experimental fashion to see if it will live there. The fact that it does really doesn't necessarily mean that that is a major threat. The major threat is still, as Dr. Gerberding delineated, through to the respiratory droplet route.

Historically we went through some of the same things with HIV/AIDS back, in fact I even testified before this committee on that, that we investigated. Experimentally put HIV in a petri dish or HIV in this and HIV in that and said well gee, does that mean that if I have a cut on my hand and I go sit down next to a table with someone and rub my hand, can I get HIV/AIDS. The answer is that for practical public health purposes the answer is no, but it is important to know the viability of these microbes under certain circumstances.

So we are still left with the major modality being what was described thus far this afternoon.

Mr. DEUTSCH. Thank you.

Thus far the SARS epidemic has been relatively confined to North America, Europe and parts of Asia. Although the possibility that this virus could spread to other areas is obviously possible at this point. How is the NIH or CDC preparing for the possibility that this disease might spread to the Third World countries who have the additional disadvantage of having to combat other dire health situations such as the poor health system, high numbers of HIV infected residents?

Ms. GERBERDING. We are concerned about the possibility of spread into additional countries with very inadequate public health infrastructures. What is containing this epidemic right now is the old fashioned public health approach, and that is detecting cases, isolating them and quarantining exposed people during their incubation period. If we have a problem emerge in countries that have very limited public health capacity, they are not going to be able to easily do these things. And, of course, WHO teams will do everything possible to assist. But a priority right now is to do everything possible to keep that from happening.

What we are really doing is buying some time and focusing so much on containment right now in the hope that we will be able to prevent the kind of scenario you are describing before we get a vaccine or some kind of treatment.

Mr. DEUTSCH. Are there additional precautions or preparations for that possibility? I mean, assuming it would occur in a country without an adequate public health care system?

Ms. GERBERDING. One of the important things going on right now that has not come up in the discussions so far is the incredible investment in the affected countries in quarantine; China, Hong

Kong, Taiwan are very aggressively quarantining anyone who is possibly exposed. This really reduces the probability that a traveler who is exposed and incubating is going to leave that country and set up a chain of transmissions somewhere else. So that is to the advantage of all of us in terms of protecting the rest of the globe from traveling cases. Of course, it is not perfect and we still have to remain vigilant.

WHO is calling a meeting of all of the health countries and the World Health Assembly is happening next week, and this discussion about what we can do collectively to try to make sure that we are doing everything possible to either prevent or respond to the emergence and containment contingencies in a new country is going to be a very major point of discussion and already some resolutions have been prepared for the assembly to take this on.

Mr. DEUTSCH. Typically people with compromised immune systems from HIV or organ transplants or cancer chemotherapy suffer worse from infections. Do we have any indication that people with HIV/AIDS have the highest susceptibility or affected more seriously than people with health immune systems?

Ms. GERBERDING. So far the clinical information has indicated that age is the major risk factor. We have not seen HIV infection emerge because there have not been any HIV infected patients that I am aware of in the U.S. or Canada who have been in the case lists. It is possible that they are in there and it is not common enough for us to know about or see. But we are noticing that diabetes, other chronic medical conditions are more common in the patients who have the worst disease compared to those that have minor cases of SARS. So it would be expected that those people with immunosuppression may have a worse outcome.

Mr. DEUTSCH. Is NIH doing the majority of the testing and studying of the SARS virus at this point?

Mr. FAUCI. There is a considerable amount of work that is going on at the CDC. The way it turned out, the CDC isolated the virus, gave it to the NIH who are now growing it up for the purpose of the vaccine development that I mentioned in answer to a previous question. And in addition, the CDC, the NIH and USAMRIID are in a collaborative venture in screening drugs to determine if they have activity against the SARS virus. So it is work that is going on both at the CDC, the NIH and actually at FDA also.

Mr. DEUTSCH. Are there any universities involved?

Mr. FAUCI. Oh, yes. Yes. Yes.

Ms. GERBERDING. We have gotten numerous requests from the private sector, from the academic sector and from international entities for either the virus or for genetic components of the virus. And we have been able to streamline the application process to remove some of the bureaucratic barriers to making it available. So as soon as people complete their biomedical licensing agreement, we can expedite and release of the materials to them.

We have taken a very open posture on this. And I think that this is unprecedented that we have been able to get new agents or this kind of information so quickly.

Like I mentioned earlier, we have put the sequence of the virus up on the Internet as well.

Mr. FAUCI. We actually have 18 grantees who are working on coronavirus that antedated the SARS virus. And we are trying now to get them samples.

As Dr. Gerberding mentioned, one of the critical limiting factors is getting samples to individuals to be able to study and making sure they have the proper facilities within which to study them. And we are right now already starting to work on a reagent repository to supply our grantees and contractors on the outside.

Mr. DEUTSCH. My last question is similar to the question I asked earlier to the gentleman from WHO, obviously you are aware of Taiwan's relationship not being in the WHO and he described, which I was aware of, going through CDC. Do you think that is an impediment in terms of what is going on in Taiwan at the present time?

Ms. GERBERDING. We have a tradition of engaging in specific health issues in Taiwan so there are a number of relationships that are already set up there.

CDC has something called an international emerging infections program in Thailand that provides regional assistance to various countries in Asia. So the CDC staff at our Thailand field station were the first to be able to engage in Taiwan.

It has worked very well. We have had consecutive teams of people going there with different kinds of expertise, and we have been able to respond to the requests from the Minister of Health there for technical assistance. But as the problem enlarges, more people are needed and fresh sets of eyes and fresh perspectives are certainly welcome. So we are very happy that the WHO individuals can now join our teams there.

Mr. DEUTSCH. Thank you.

Mr. BASS [presiding]. Thank the gentleman from Florida.

The Chair will recognize himself for 10 minutes.

Thanks for being here today. I guess to start off with, for me the bottom line question, and for Americans to know, if this disease gets established in this country and in the near future, say in the next year, and gets out of control, so to speak, how many Americans are going to die?

Ms. GERBERDING. Of course, I do not know the answer to the question. I wish we could have a stronger predictive power to really appreciate where this will next, and what we can be doing now to prevent that.

As Dr. Fauci pointed out, although it is certainly capable of being efficiently transmitted, particularly in certain situations, it is not nearly as infectious, thank goodness, as influenza. So what we would predict is that we could see limited chains of transmission from, say, health care workers who get infected and then have this problem develop. But we know some things from the lessons we have learned from Canada and the other countries.

And one of the lessons is we have to be bold and we have to act fast, and we cannot sit around and have a lot of committee meetings or discussions about what public health action steps to be taken. We need to implement quarantine. If we have a problem in the hospital, we need to shutdown the hospital, cancel elective surgery and maximize the contain of the virus or either cohorting or infection control practices.

Mr. BASS. Well, theoretically is the death rate is, say, 5 or 6 percent and everybody got it, it would be 14 million people at the worst, right?

Ms. GERBERDING. That is a scenario that certainly came to my mind when I first heard about what was happening in Asia in the early stages of the epidemic.

I think that is extremely unlikely. But, again, we are contingency planning to identify what steps we would take. And even though I do not think we are going to end up in that situation with SARS, we could end up in that situation if we had another flu pandemic.

As Mr. Hauer knows from the Department's perspective, one of the major efforts right now is to have a plan that allows us that kind of regional surge capacity. We are purchasing ventilators for the stockpile. Secretary Thompson has asked us to purchase 3,000 ventilators——

Mr. HAUER. 3,000 additional.

Ms. GERBERDING. [continuing] for the stockpile to supplement the 100,000 that our Nation already has. But we have got, really, to look at all of the elements of care in a situation like that. And there are still some gaps that need to be filled.

Mr. BASS. Ironically, this may be the first test of the Homeland Security system that we are setting up in this country right now. I guess, Dr. Gerberding, you mentioned that you were working fast to make this vision a reality. I think that is somewhat out of context. The fact is that communication between CDC, Health and Human Services and all local law enforcement and hospitals and everything else are going to be critical to this.

I am wondering if you can describe CDC's quarantine authority as amended under the President's Executive Order exactly what it is.

Ms. GERBERDING. The Federal quarantine authority resides in the borders, the points of entry into our country. So we have the responsibility for ships or planes that are arriving here. Our responsibility is to ensure the health of arriving passengers and to make sure that communicable diseases are not brought into the country.

The States have the authority for intrastate issues of public health and disease containment. But if there is an issue of a border between States, Federal jurisdiction can then apply if the States fail to resolve the health threat. So we have some residual authority at the interstate transfer of infectious disease.

What that really means in simple terms is that we have quarantine officers strategically positioned at our borders. They have a long tradition of assessing ill patients arriving on planes. They have the authority to board planes and ships and evaluate illness there. And they have the authority to request or in cases where voluntary request is not successful, require people to either enter isolation if they are sick or quarantine if they are believed to pose a health risk to others.

Mr. BASS. Are people at the borders asking incoming individuals if they have a fever or they are sick or every single person or not?

Ms. GERBERDING. We are not asking individually every single person coming in. But our goal from the people coming in from the places where SARS is a problem, is that every person receives that

yellow health alert card that gives them advice about seeing a clinician if they get sick.

In addition, our quarantine officers and their deputies are meeting the planes as they arrive and asking the crew and officials on the plane is there a problem, has anybody been sick, do you notice that anybody appears to be ill on this plane. And if there is a suspicion, they will ask that passenger to step aside and have a quick assessment. And if there is reason to be concerned about SARS or another infectious disease, they get taken to the appropriate clinic evaluation facility.

Mr. BASS. So are you using this quarantine authority as was directed under the President's Executive Order to its fullest extent right now?

Ms. GERBERDING. What the Presidential authority provided was the capacity to include SARS specifically as an illness for which we could require a quarantine. There are only a few——

Mr. BASS. When was the last time you had that, you used that authority, actually quarantine? Do you know or not?

Ms. GERBERDING. Well, quarantine can be voluntary or it can be required. We have been using the voluntary quarantine authority fairly often meeting passengers coming in with suspected illnesses. We have used it a few times in the context of bioterrorism.

I cannot tell you exactly when we last used the requirement when someone failed to comply with it voluntarily. But I can find out for you for the record. It has been a while, I will put it that way.

Mr. BASS. You have described how State and Federal authorities are responsible for intrastate quarantining. Do they have the adequate knowledge information communication? I know this may be somewhat repetitive with your discussion in response to another question, but how do you feel about that?

Ms. GERBERDING. Well, I think that with the reorganization of the Department of Homeland Security and the awareness that SARS is an issue that does raise a quarantine and isolation needs, we have a Memorandum of Understanding that we have developed with the Department of Homeland Security. They have already stepped up to the plate to assist in the distribution of these health alert cards and to help us identify potentially ill passengers. There will be additional training in terms of protection for themselves and reassurance that they are not putting themselves in harm's way.

So we are continuing to engage in an ongoing basis of interaction to ensure both the effectiveness, but also the safety of the personnel involved.

Mr. BASS. Can you get SARS twice do you know or not?

Ms. GERBERDING. I do not know the answer.

Mr. BASS. Maybe Dr. Fauci knows. Have you heard anything about that? Can you get it again once you get it?

Mr. FAUCI. We do not know that. There have been some reports of individuals who left the hospital and then came back who were apparently well. But when you carefully look at those individuals, there were other reasons for them to go back in the hospital.

So the stage that we are in right now, I do not think there is enough data to make any statement about whether or not you can get SARS twice.

Ms. GERBERDING. If I could just add something. With coronaviruses that cause the common cold, there actually are examples of reinfection with the same strain. So the immune response that Dr. Fauci described may not be long term and we do not know yet. We will just have to wait to see.

Mr. BASS. Ms. Heinrich, I was wondering if you could address the issue of a pandemic response plan. Do you think that with the lack of an influenza pandemic response plan have comprised response efforts to a broader SARS outbreak?

Ms. HEINRICH. Our point here is that if you have made the decisions about how you are going to purchase vaccine and antivirals that are expected to be in short supply and you have thought through your plans for distribution, and you have been very clear about how you are going to prioritize the populations that will be receiving these medications that are in short supply, you are going to be in a better position when you are in a crises mode, such as a large epidemic.

In SARS at this point it is not directly applicable. Because as we have heard, we do not have drugs and do not have vaccines. But with the promising research, it sounds like we might in the future. And so I would say it has not compromised our current response.

Mr. BASS. I guess this point was made, indirectly at least. It looks to me as if the SARS epidemic could be really catastrophic in countries where people are under nourished and lack access to health care. For example, a country like North Korea where people are eating grass, probably the fatality rate would just be astronomical. I do not know whether this is the proper panel to address that kind of issue. The issue for this disease, though, may be really in developing nations where very quickly it has the qualities to be cataclysmic. I do not know if anybody wants to comment on that. If not, I will stop.

Okay. Dr. Gerberding, did you want to comment, and Dr. Fauci?

Mr. FAUCI. Certainly——

Mr. BASS. What would this do in North Korea, for example? It is right next to China.

Mr. FAUCI. Well, I think we have to make the point again that we have been making this afternoon is that although we take this very, very seriously as a potential for a cataclysmic event, if you had a scenario where the virus did get into North Korea and the public health officials implemented the types of surveillance, isolation and quarantine that is going on now in countries that are beginning to control it, it is not impossible, but there would be little chance that it would spread like influenza could spread because influenza is so much more easily spread than SARS. But we cannot guarantee that. We take it seriously and we are concerned about developing nations, not only nations that have difficulty economically and with nutrition and with general health, but also nations that don't have the public health infrastructure to be able to implement the surveillance, the isolation and the quarantine. So there is concern on both our parts, I am sure.

Mr. BASS. My time has expired.

The Chair recognizes Ms. DeGette for 10 minutes.

Ms. DEGETTE. Thank you, Mr. Chairman.

Dr. Fauci, I listened with interest to what you said a few minuets ago about making the virus and the components widely available for research and development of vaccines and so on. It struck we are walking kind of a fine line here, because at the same time we are in race to eradicate SARS, we are also in a race to prevent bioterrorism. And I wonder if you have any concerns about terrorists trying to use the SARS virus if you are making it so widely available to researchers?

I could easily see a bioterrorist trying to take and distribute the SARS virus. Dr. Gerberding?

Ms. GERBERDING. One of the criteria for distributing the virus or components of the virus from CDC is that the recipient entity has to demonstrate that they have the appropriate safety procedures, but also that they have the appropriate containment procedures.

And we have had some criticism initially that we are not just immediately sending the virus out. And part of that relates to the fact that we do want to be sensitive to your concerns.

This is not a virus that has the characteristics that would make a particularly efficient terrorism agent, but it is certainly causing harm and fear, and has the other elements of a potential terrorism target. So it has to be taken seriously from that framework.

Ms. DEGETTE. Dr. Fauci?

Mr. FAUCI. We use the virus, Ms. DeGette, in a containment facility that is called BSL 3+, which is biosafety level three with a little bit more. So we do not allow the virus to go to any investigator that does not have, as Dr. Gerberding said, the capability of the proper safety containment of that.

Ms. DEGETTE. And would that be the same containment level that you just described?

Mr. FAUCI. Right. Exactly.

Ms. DEGETTE. So I just want to be able to assure my constituents. When you say that you are distributing this and you are breaking down bureaucratic barriers, you are not saying that you are cutting any corners on keeping it safe?

Mr. FAUCI. No. No. Not at all. And I would not use the word "widely distributed." I would use the word——

Ms. DEGETTE. That was not my word.

Mr. FAUCI. No. No. Well, if I used it, I apologize. I do not think I did, but if I did it was not the correct word.

We will be making it available to qualified investigators. Not only when we talk about reagents do we mean the virus itself, but we mean the appropriate antisera as well as the molecular components of it, which we use to probe for the presence of virus. And that is not something that, in and of itself, is infective or dangerous.

Ms. DEGETTE. Thank you.

Dr. Gerberding, I am wondering, you have explained some of the precautions that we are taking with planes and so on. But in your written testimony you have said that the United States could still enhance our public health infrastructure to better detect and respond to an infectious disease outbreak. I am wondering if you can

explain what, if anything, you think that we need to do to enhance our capacity in this area?

Ms. GERBERDING. Well, sadly as I know you know, our public health system was really allowed to deteriorate for decades. It is tattered. And we, I think, see great heroism. Our system has been asked to respond to anthrax, to West Nile virus, to a smallpox vaccination program, and now to SARS. Boom, boom, boom. The people throughout the entire system have, in my view, heroically stepped up to the plate and have accomplished miracles.

They have done that with a great degree of effectiveness and courage. And I think the investments that we have made in trying to shore up our public health system in the last many months have made a tremendous impact. Clearly the billion dollars that has gone out is not going to solve the problem, but we are much better off today than we were even a year ago.

Ms. DEGETTE. Doctor, I apologize. We get limited time. And I know everything has been heroic. But what more do you think specifically can we be doing as Congress right now to help you in this effort?

Ms. GERBERDING. There are really six target areas here. One is preparedness planning. It is the plans, the products, the people and the practice that we need to make these systems work.

The second is laboratory capacity. Our laboratories are getting a bit better because of these investments, but a lot of them are in dire straights and we have got a ways to go to shore them up and rehabilitate and renovate them.

A third relates to the epidemiologic capacity to investigate and respond and notice when something has happened.

A fourth relates to the information network, the capacity to rapidly communicate back and forth. The next is training. We have a tragedy in our public health workforce. We need trained professionals everywhere.

And finally, it is sort of the overall communication strategy. How do we deliver information to the public in a way that is informative but not fearmongering?

These are all critical capacities that are included in the grant program that we have put out, but we are going to need sustained investments to really bring them as far as they need to.

Ms. DEGETTE. Thank you.

Mr. Chairman, I am wondering if I can unanimous consent to have Dr. Gerberding supplement her testimony today by flushing out each one of those six areas that she has described for us, specific recommendations that you have where you need more resources and if possible, the kinds of money that you would need. I assume it would be quite costly and this is an ongoing issue.

The Chairman and I traveled together down to Atlanta and saw some of the facilities. And I have seen the facilities up at Fort Collins that include, you know, grass growing up through the floor of research labs. So I know exactly what you are talking about. And I think it would be very helpful for the committee to have that supplement.

Mr. GREENWOOD. If you could submit that, and perhaps put a little more detail in your answer to Ms. DeGette's question, and submit it in writing. The committee would appreciate that.

[The following was received for the record:]

I am enclosing as my answer, my response to a similar question asked recently by the Senate Appropriations Committee, Labor, Health and Human Services, and Education Subcommittee. Please note that my response represents my professional judgment as CDC Director and is provided without the constraints of the competing priorities that the President and his advisors must consider as budget submissions to the Congress are developed.

RESPONSE TO PROFESSIONAL JUDGEMENT REQUEST

Senator SPECTER: "I understand the constraints under which you operate, but I want, for the official record, directly from you, the expert, your professional judgment concerning what resources CDC needs to protect the public's health.

Please address all relevant public health issues, such as terrorism and Homeland Security, emerging infectious diseases, including SARS, buildings and facilities, the obesity epidemic, and other critical research that needs to be done by your agency. I am requesting that this information be delivered to the Subcommittee with ten (10) working days at the latest."

Dr. GERBERDING: This response represents my professional judgment as CDC Director and is provided without the constraints of the competing priorities that the President and his advisors must consider as budget submissions to the Congress are developed.

We believe that the President's budget is strong in its efforts to protect the public's health, especially in the context of all health priorities and needs. As I have stated publicly, I support the CDC request in the President's budget for fiscal year 2004. I am pleased that the President's request includes key increases in the areas of chronic disease prevention, global HIV/AIDS, and public health information systems, just to name a few.

We are facing continued threats to health, such as terrorism, emerging diseases, the aging of the population. There are also expanding opportunities to improve health through science, technology, and communications. In summary, these actions fall into three broad categories:

- *Investments* in public health research, buildings and facilities, and public health communications.
- *Preparing for Health Threats Here and Abroad,* which includes investments in terrorism and emergency preparedness and response; global disease detection; and security; and,
- *Transforming Knowledge into Impact,* which includes investments in public health program accountability and health status assessment.

I have provided more detailed information about these actions below. This professional judgment estimate includes increases of $1.2 billion in FY 2004 and approximately $1.8 billion per year for each of the next 4 years, for a total funding of $15 billion.

CDC Professional Judgment Estimate

(dollars in billions)

	FY 2004	FY 2005	FY 2006	FY 2007	FY 2008
CDC/ATSDR Request/prior year base	$6.5	$7.7	$9.5	$11.3	$13.1
Prof. Judg. Increase	$1.2	$1.8	$1.8	$1.8	$1.9
CDC/ATSDR Prof. Judg. Total	**$7.7**	**$9.5**	**$11.3**	**$13.1**	**$15.0**

Terrorism, emerging global infectious diseases, and the obesity epidemic pose continued threats to health at the onset of the 21st Century. At the same time innovations in science, information technology and communications offer opportunities to improve health

I. BRINGING PUBLIC HEALTH INTO THE 21ST CENTURY

Public Health Research

Meeting the public health challenges of the 21st Century demands that our nation create the scientific evidence base. CDC's leadership and credibility is entirely dependent on the quality of the scientific evidence at the core of its public health programs, policies, and practices. Our nation's substantive economic investment in biomedical research has created new knowledge about the causes of illness, allowing us to diagnose and treat an astonishing array of medical conditions, and increas-

ingly identifying effective prevention interventions. However, in order for these new discoveries to truly benefit people in all communities, they must be translated into effective public health programs. CDC's public health research—driven by concrete, human needs identified by frontline public health progams—can move knowledge from academic journals into the communities and clinics that reach people where they live. CDC's public health research moves basic research discoveries from the laboratory to the community, or "from the bench to the trench."

CDC's response to SARS illustrates important facets of public health research—rapid pathogen identification, diagnostic testing, mechanisms of disease transmission, effectiveness of isolation methods, and effectiveness of prevention strategies. The experience with SARS, West Nile virus, anthrax, and other recent health threats shows the benefits of a cadre of public health researchers—at CDC, in academia, and in the private sector—to respond to emerging health threats.

Public health research helps to define the best strategies for detecting new diseases, assessing the health status of populations, motivating healthy lifestyles at all life stages, communicating effective health promotion messages, and acquiring and disseminating information in times of crisis. Public health research can help overcome barriers that prevent people in every community from benefiting from the interventions we already know are effective.

Public health research generates solutions. The pragmatic nature of public health means those solutions will be relevant to the health needs of a variety of populations in a variety of settings. This kind of practical, applied research enables our nation to plug the gap between what the laboratory tells us and the way people actually behave.

Funds could be used to Build a comprehensive public health research agenda to prepare this nation for the threats of the new century These funds could help expand CDC's current research portfolio and further add to our strong record of public health accomplishments. The program would consist of three parts. First, an investigator-initiated, peer-reviewed extramural grant program to derive the knowledge necessary to translate biomedical science into effective programs that directly affect quality and length of life and address health disparities. Second, an extramural peer-reviewed grant program to accelerate our capacity to respond rapidly to emerging and urgent public health threats, such as SARS. Third, extramural programs to engage and support the best innovative scientists in our medical and public health schools in the field of public health research.

Substantial and sustained investment in public health research could generate targeted public health interventions that work for this nation's increasingly diverse population. Stronger, more robust public health research could translate to stronger, more robust public health programs and a healthier public.

Public Health Communications and Information Systems

CDC could take greater advantage of 21st Century communications and information technology in its role as the premier credible source of information to help guide public health decisions, and expand its capacity to give people the information that will help them take charge of their own health decisions. To affect the public health, CDC should effectively market health information, in the same way that businesses market their products, by capitalizing on the growing array of communication tools to reach diverse populations where they are.

In addition to the communications research that will help design cost-effective and impactful health communications strategies, we could exploit communications and information technology to help constituents and stakeholders have access to the information they need at the time they need it. A comprehensive Public Health Information Network could seamlessly connect people across our nation with CDC, other HHS agencies, state and local public health agencies, healthcare organizations, and many other stakeholders. This network could serve as the backbone for: emergency health alerts, distance learning, knowledge management, disease detection, reporting and surveillance functions, health tracking, secure data transmission, and many other functions important to public health. The public health information network could not only create and disseminate the information to promote health and safety in this country, but is a cost-effective means to support global public health advances. The Public Health Information Network is already in development, but funding could allow us to scale up and speed up its implementation.

Physical Infrastructure

CDC is engaged in an intensive effort to rebuild our physical infrastructure. Using innovative procurement and design methods, we continue to build on time and on budget. Our ten-year master plan will replace World War II-era buildings with facilities that will meet the scientific research challenges of the 21st Century. For ex-

ample, our Fort Collins, Colorado laboratory, which leads the nation's response to such diseases as West Nile virus, plague, and several Select Agents, will be moved from decades-old leased space to a modem safe and secure facility. Sustained investment in buildings and facilities improvement could allow CDC to recruit and retain world-class scientists and support them with state-of-the-art laboratory and research facilities so they can continue effectively protecting the public's health at home and abroad, to respond to public health emergencies, and to remain on the leading edge of emerging infections.

II. TRANSFORMING KNOWLEDGE INTO IMPACT

Program Accountability

The 21st century health care system should be accountable to taxpayers for investments in public health programs. CDC could achieve substantial improvements in the public's health by implementing evidence-based programs through state and local health agencies that we already know are working in some locales. Expansion of programs that work will benefit people who now are not able to access health promotion, screening, and prevention programs, and could translate to a significant improvement of the health status of the nation.

For example, robust programs to prevent chronic diseases, which account for 70% of all deaths each year, could generate significant returns.

- If every state adopted the programs we know can control the onset and severity of diabetes, we could prevent 10,000 to 21,000 cases of eye disease and blindness, 165,000 cases of kidney failure, and up to 43,000 amputations.
- If every state implemented the programs we know can reduce obesity at full capacity, we could effect a substantial reduction in the prevalence of obesity, which costs the health care system an estimated $93 billion each year, and a corresponding reduction in the incidence of associated conditions like diabetes, heart disease, osteoarthritis, and cancer.
- At full capacity, CDC's domestic HIV prevention programs could cut in half the number of new HIV infections in the U.S., from an estimated 40,000 per year to 20,000 per year; increase to 95% the proportion of HIV-infected people who know they are infected; and link eight out of ten HIV-infected people in the U.S. to appropriate treatment services.
- CDC studies find that we can reduce the risk of alcohol-exposed pregnancies by ⅔ with full implementation of programs that counsel high-risk women.
- Full implementation of CDC's injury prevention work promoting restraint use among motor vehicle occupants could save up to 9,000 lives and prevent as many as 160,000 non-fatal injuries each year.
- Full implementation of CDC's occupational safety and health initiatives would reduce the direct costs of occupational injuries, which Liberty Mutual's 2002 Workplace Safety Index estimates at more than $40 billion.
- Putting a comprehensive environmental health program into every state would eliminate childhood lead poisoning, which affects more than I million children under the age of six, by the year 2010. Eliminating lead poisoning would reduce the prevalence of learning disabilities, behavior problems, and other serious problems associated with high blood lead levels.

Assessment of Health Status

Health policy decision-makers can improve decisions with better state and local data. Equally, improved, accurate information about the health status of Americans will help improve the allocation of resources in the highest priority health needs. Reliable health information underpins every effort to improve health, and our nation may be missing opportunities to make the strongest impact. At the national level, core health surveys could benefit from expanded funding. Changing needs, populations and technologies call for more resources to keep pace. Considerable gaps remain in our understanding of racial and ethnic disparities in health, and CDC's performance in generating information required to track health goals and holding programs accountable has been limited. CDC could build an effective, nationwide system to deliver the information needed to improve health.

III. PREPARING FOR HEALTH THREATS HERE AND ABROAD

Terrorism Preparedness and Emergency Response

CDC plays a critical role in ensuring that the nation's public health system is prepared to respond to public health emergencies, particularly with respect to chemical, biological, radiological and nuclear terrorism, and to emerging infectious diseases such as SARS. CDC has taken substantial strides in strengthening the system. Yet substantially more work remains.

CDC, states and communities could use additional funds to address:

- Comprehensive regional preparedness planning and exercise, including plans for isolation and quarantine of potential infected persons (with increased personnel at ports of entry, which would have assisted with SARS.)
- Further improvement of CDC and regional laboratories to provide coordinated surge capacity in times of pandemics or terrorist attack,
- a nationwide electronic data system to detect emerging threats, that use existing confirmation from national sources (such as pharmacy chains) and local sources (such as emergency department visits) to detect and monitor terrorism and emerging infectious diseases,
- Comprehensive network of satellite communication and other communications capacity to ensure health information can reach all clinicians in times of crisis.

Global Disease Detection System

CDC could continue to strengthen the capacity of the public health community, both at home and abroad, to respond to global threats, such as SARS, pandemic flu and bioterrorism attacks. CDC's Global Disease Detection System would seamlessly connect local and state health departments with CDC's and its detection system through these components:

- Provide technical support to ensure clinicians and laboratories around the globe can diagnose emerging infectious disease events.
- Link clinicians and laboratories via secure methods with CDC and the WHO to ensure real time reporting of emerging threats
- Support sentinel sites in key regions around the globe to ensure in-country disease detection and reporting and prompt referral to a regional laboratory service
- Provide for emergency transport of infectious specimens, evacuation of contagious patients, and movement of CDC's Emergency Response Teams worldwide. These capacities are critical to mitigate the consequences of a catastrophic public health event, whether the cause is an intentional act of terrorism or the natural emergence of a deadly infectious virus, like SARS.

Security

While CDC is engaged in protecting the health of this country and the world, a substantial investment is required to assure the security of CDC assets. These include personnel, scientific equipment and laboratory specimens. These resources need to be protected in times of normal operations, during emergencies, and when continuity of operations is required.

We believe that the President's budget is strong in its efforts to protect the public's health, especially in the context of all health priorities and needs. As I have stated publicly, I support the CDC request in the President's budget for fiscal year 2004.

Ms. GERBERDING. I will certainly do that.

Ms. DEGETTE. Thank you.

I am wondering if anybody on the panel can talk to us about what specifically is the status of the search for a vaccine. We have heard about that you are putting out proposals and so on. But where are we with that search, and does someone have any idea how soon we might have some kind of vaccine?

Dr. Fauci?

Mr. FAUCI. Yes. There are multiple concepts that are being pursued. The one that it is the simplest and most straightforward we are pursuing at the NIH with our own investigators as well as in collaboration with industry. And that is to grow the virus up, inactivate or kill it, vaccinate a monkey model, an animal model and challenge the animal. That is something that will take several months to prove or disprove the concept that you can feasibly protect an animal. Once that is shown to be possible or not, then you move into phase one studies. And then, as we are already are partnering with industry, to scale up to have enough to give phase one for safety, then phase two for more safety and then ultimately to do a Phase 3 trial.

Also we can invoke, if necessary, the animal capabilities of being able to show true effectiveness in an appropriate and relevant animal model.

There are other approaches that are simultaneously ongoing that are more molecularly based where you take the genes, now that we know the sequence of the SARS virus, insert them into other benign viral carries like adenovirus.

We have already started a collaboration with GenVec company through the Vaccine Research Center at NIH to pursue that approach.

There is an approach to make large amounts of purified protein through a baculovirus vector.

And then there is the DNA approach.

And then finally, we have not started this yet but certainly this is something we would consider, is the live attenuated virus approach.

So it is a combination.

Ms. DEGETTE. And what kind of timeframe? I mean, those two latter ones I think would take longer.

Mr. FAUCI. Yes. They take very long. I would think at best the one—the two that are actually ongoing now are the vector approach with the adenovirus and the whole killed or inactivated.

To prove a concept that you can do it in animal is going to take up to a year. So, hopefully, by the end of this calendar beginning of next calendar year we will be able to show that.

Even at rather rapid speed to get a vaccine that is safe, effective and approved for use and distribution in humans will take a few years. So it is not going to be something that is going to be overnight.

Ms. DEGETTE. Thank you very much.

Thank you. I yield back.

Mr. GREENWOOD. The gentlelady from Chicago is recognized. Ten minutes.

Ms. SCHAKOWSKY. Thank you, Mr. Chairman.

And thank you panel. Appreciate it very much.

I wanted to ask Dr. Gerberding about—I know some questions were already asked about what happens in the protocol at airports. But O'Hare Airport has the most international flights of any, and so it effects our area.

I am wondering you said and then they are referred. If you could follow through with and then they are referred to an appropriate setting, is it diagnoses, determination, quarantine, what? What happens when they are possibly suspected of having SARS?

Ms. GERBERDING. Thank you.

I do not know specifically at O'Hare if the medical evaluation clinic is onsite at the airport, or whether they utilize a nearby medical facility of some sort. But I will be happy to provide you that information. It is probably onsite, because it is such a large airport.

Ms. SCHAKOWSKY. The CDC has a division of Global Migration and Quarantine based in O'Hare International Airport. Does that mean yes, we do have?

Ms. GERBERDING. CDC has its facility there. We have personnel there.

Ms. SCHAKOWSKY. Right.

Ms. GERBERDING. But in terms of an actual medical clinic.

Ms. SCHAKOWSKY. Okay. That is not it.

Ms. GERBERDING. So what happens is a quarantine officer in the SARS environment if a flight is landing in O'Hare that has come, let us say, from Hong Kong.

Ms. SCHAKOWSKY. Yes.

Ms. GERBERDING. The flight is met by a quarantine officer or a deputy, a Federal official who is deputized to act on their behalf. The crew is interviewed to determine whether or not there were any passengers that were ill or appeared to be ill. If there was such a passenger, the quarantine officer would assess that passenger, board the plane, interview or assess the situation. And if there was a concern, they may do one of several things.

They may take a more extensive interview and do a very quick physical assessment of the patient. If there seemed credible reason to be concerned, they would remove the passenger from the airplane and take them either to the medical clinic at O'Hare or whatever is the dedicated medical assessment facility. In addition, they would ask the remaining passengers to provide information about where they could be contacted if there did seem to be a communicable threat to them.

This is a time consuming process, and part of the reason when we have to board a plane to assess a situation, there is a long delay. The plane sits on the ground. And one of the things that is going on there is that the passengers are being asked to provide information.

Ms. SCHAKOWSKY. So you do all this before anybody gets off?

Ms. GERBERDING. Correct.

Ms. SCHAKOWSKY. Yes.

Ms. GERBERDING. Now if something has gone awry and that step was missed, then it is also possible to go back in and find the passengers. At least for a period of time the airlines keep the manifest of passengers. But that is a much more time consuming process, because we do not have all the address information and it takes a lot of detective work and a lot of work on the part of the State health officers.

Ms. SCHAKOWSKY. You said you have not utilized the quarantine? All of it has been voluntary so far?

Ms. GERBERDING. We had a situation before the President's Executive Order was signed where an individual with arrival from a SARS country who had an illness did not agree to stay for the evaluation of their illness. They left the airport and we had no authority at that point in time to retain them. That individual then traveled on a train, and this resulted in a very extensive search for potentially exposed people and a lot of extra work for our health departments. That was one of the major examples that helped us identify the key importance of getting that Executive Order signed, and that is really why I think the President was able to expedite action on that issue.

Ms. SCHAKOWSKY. Is there anything in the Executive Order that has provisions to protect people who do not have SARS from being detained and quarantine? Anything to protect the rights of people for whom this may not be appropriate?

Ms. GERBERDING. Yes, I understand the concern. We are trying to balance here the public issue with the rights and inconvenience to individual citizens. And I can only say that we have had quarantine officers involved in these kinds of assessments for many decades now. And I think that we are public health officials and we really do try to be respectful of citizens rights. And we do not take an action like this lightly.

There are in individual States and in individual courts provisions for maintaining someone in quarantine. There is a right of appeal and some other steps that can be taken if there is a more prolonged intervention.

Most often what happens is there is a concern, there is an assessment. It is deemed to be not a threat and the individual is inconvenienced temporarily, but they can go on their way.

Ms. SCHAKOWSKY. And is there a limit of the number of the days a person would be held in quarantine?

Ms. GERBERDING. The authority allows quarantine of exposed persons for the period of time at which they would present a threat to others. More to the point, and just for a point of clarification, isolation is what happens to people who have quarantine, is what happens to people who are exposed but not sick. So mostly what we are talking about in airports is isolation of potentially infectious people. And we can under various authorities retain someone in isolation for as long as they pose a threat to the health of other individuals.

Ms. SCHAKOWSKY. And how long is that? How long is the exposure period?

Ms. GERBERDING. It depends entirely on the infectious disease. But for SARS we do not know. We actually do not know the full period of infectivity. But WHO has developed criteria for discharge and has made the decision based on observation of the many patients that have been ill so far, that once the person is recovering from their infectious illness and they can wear a mask to cover their own face and mouth when they cough or sneeze, that they can be released from the hospital and are allowed to go home.

Ms. SCHAKOWSKY. And when you speak of isolation, that is in the hospital?

Ms. GERBERDING. Most often it occurs in the hospital. But in this country where we have cast such a wide net and probably have many cases listed as probable SARS cases who do not have SARS, we do have many patients who have been in isolation in their homes. They have the capacity to do that, and there is a system of monitoring and evaluation that has assured the responsible health officials that that is an appropriate step.

Ms. SCHAKOWSKY. Thank you.

I cannot see from here, is Ms. Heinrich? Ms. Heinrich, I was looking through, though I have not read carefully the GAO report, did you take into consideration at all things like changes in Medicaid and Medicaid funding, and how that might impact the ability of public health systems to respond to a SARS outbreak?

Ms. HEINRICH. We were drawing from several reports that we have done in terms of putting together this testimony. And when you are looking at the State and local levels in preparedness, we did not look specifically at Medicaid funding.

The component of our report that focused on emergency room crowding and hospital capacity, we certainly did look at Medicaid funding as well as uncompensated care or lack of insurance and certainly found that in those communities where you have a higher rate of no insurance or you had hospitals that were more dependent proportionately on Medicaid funding, they had more problems with crowding. And what we are contending is that if our hospitals are having difficulty with crowding now, and it was occurring to a greater extent in communities that have large populations, and that is indeed where across the world we are seeing the SARS epidemic play out to the greatest extent, yes that would be a factor in terms of being able to respond to a large SARS epidemic.

Ms. SCHAKOWSKY. So any decrease in Medicaid funding would exacerbate the problem of a proper response to a SARS outbreak?

Ms. HEINRICH. It certainly has the potential to, yes.

Ms. SCHAKOWSKY. Okay. Thank you.

Mr. Chairman, I would just like to ask now that I be able to put my statement into the record. And I thank you.

Mr. GREENWOOD. Without objection, the gentlelady's statement will be incorporated into the record.

The Chair wishes to——

Ms. DEGETTE. Mr. Chairman, while we are on the subject, I would ask unanimous consent to place Mr. Dingell's statement and any other members who wish to place——

Mr. GREENWOOD. Without objection, the record will remain open for that purpose.

We have kept you quarantined for about three and a half hours, and we have decided it is safe to release you.

Thank you very much for not only your testimony, but all the work you do on behalf of the country. Thank you.

You are excused. And we would call the second panel.

And our witnesses from the second panel will be Mr. Barry R. Bloom, Dean of the Harvard School of Public Health.

Dr. Georges Benjamin, Executive Director of the American Public Health Association.

Dr. Jared N. Schwartz, College of American Pathologists.

And Mr. James G. Hodge, Jr, Deputy Director of Center for Law & the Public Health of Johns Hopkins Bloomberg School of Public Health.

And Ms. Karin Kerby, Registered Nurse, Loudoun Hospital Center in Leesburg, Virginia.

We thank you for your presence today and for your patience.

And I need to inform you that this is an investigative hearing. And when this subcommittee holds investigative hearings we take testimony under oath, and I need to ask if any of you object to giving your testimony under oath this afternoon. Okay. Seeing no such objection, I would advise you that pursuant to the Rules of this committee and the House, you have the right to be represented by counsel this afternoon. Do any of you wish to be represented by counsel?

Okay. If you would then stand and raise your right hands.

[Witnesses sworn.]

You may be seated. You are under oath.

And, Dr. Bloom, we will begin with you and you are recognized for 5 minutes for your opening statement. Welcome.

You will need to push that button on your microphone and pull it close.

TESTIMONY OF BARRY R. BLOOM, DEAN, HARVARD SCHOOL OF PUBLIC HEALTH; GEORGES C. BENJAMIN, EXECUTIVE DIRECTOR, AMERICAN PUBLIC HEALTH ASSOCIATION; JARED N. SCHWARTZ, COLLEGE OF AMERICAN PATHOLOGISTS; JAMES G. HODGE, JR., DEPUTY DIRECTOR OF CENTER FOR LAW AND THE PUBLIC HEALTH OF JOHNS HOPKINS BLOOMBERG SCHOOL OF PUBLIC HEALTH; KARIN KERBY, REGISTERED NURSE, LOUDOUN HOSPITAL CENTER

Mr. BLOOM. Thank you, Mr. Chairman and members of the subcommittee. I am appreciative of the opportunity to share my thoughts, and am very grateful to be able to here.

I am Barry Bloom, Dean of the Harvard School of Public Health.

You have heard, I think, extraordinarily good testimony from a group of experts. I would like to just focus on three issues as briefly as I can.

The first is a question that is raised about the earlier questions on terror, is SARS to be taken as seriously and is it a frightening threat? And it would seem to me it is for a number of reasons.

One is that anything transmitted by the respiratory route has a history of having the potential to do very bad things. Twenty to 40 million people succumbed to the 1918 flu, as you know. Perhaps you know less well that when measles was introduced into the Hawaiian Islands, again a new virus in a new community, it wiped out in 18 months 90 percent of the population.

And finally tuberculosis, now respiratorial disease endemic to many countries around the world, infects 8 million people and kills 2.4 million every year.

So it really must be taken seriously and the challenge then is how to communicate that without causing unnecessary terror, and that is what ways we have to empower people to protect themselves.

A second point is that I believe that the agencies that have taken a stand on this issue, starting with the courageous decision of WHO knowing that it was going to cost billions of dollars in lost trade to whatever countries were put under global alert, would cause enormous inconvenience. These are decisions that are not taken lightly and the people that you have heard here today, I think have had an enormously courageous and foresighted way of thinking about it. The impact is enormous if they guessed wrong as in the case of plague in India. India lost $2 billion. A not so big epidemic in Peru cost $2 billion. And the estimates here is that even with the early warnings, China may lose up to $60 billion from its economy according to the Economist Magazine.

So that I think that these agencies have done a fantastic job. And I think that to the question why we have not got more of an outbreak here, Dr. Gerberding and everyone says that we have been lucky, and that is wonderful. But I think that the preparedness that came from bioterrorism that you heard from Mr. Hauer and the other speakers in every State has been a complete disconti-

nuity in public health over the previous time before September 11, it is not fully protective of any new disease.

I would point out that a patient in Toronto who spent 12 hours in an emergency room is one of the key people who have spread to the Scarborough Grace Hospital. You don't have to be greatly imaginative to know that someone could come into an emergency room at some hospital in this country and spend very long periods of time before they were isolated. We have to tighten up on that. But respiratory infections, flu pandemic and SARS is on everybody's mind, and I think has been done terrifically.

Third, I did give in my written testimony the view that these agencies are making do with less than is adequate and I think are gravely under funded. I would find it hard to justify an increased effort against emerging infectious diseases when the budget, as I understand it between the fiscal year 2002 and 2003 budgets, dropped by in essence a half a billion dollars.

I find it extraordinary that the emerging infections budget in that same timeframe for the National Center for Infectious Diseases, except for three targeted diseases, was reduced by $10.5 million. These are people who are responsible for dealing with food and all kinds of other infectious diseases now being mobilized in an exhaustive way.

I was at CDC and a week ago the bags under their eyes are enormous. At every level these people are working at full capacity, going to Geneva, going to China with very few resources that are flexible enough to allow them to do what we need them to do.

So my plea would be they do need more resources. I would say, for example as you will hear in a moment, that if we want to strengthen our international capabilities, only 5 percent of the NIH budget or Dr. Fauci's budget is spent on international research. And we need to strengthen that.

Finally, my final point would be why do we need to strengthen that? Not only is it a good thing and a right thing to do for the country that has the greatest biomedical establishment in the world, but to protect against emerging infection requires information.

Why would any country make that information available to the United States of America if it threatened their economies, unless there was some return? And my view is with collaborations between the CDC and WHO, between the NIH and universities and health centers in developing countries, with collaborations between universities that train people and experts in China or North Korea, that is the best insurance we have to protect this country against emerging infections. And in so doing, it will not only protect our health, but I believe and as I have indicated, will change the image of this country from self-interest to human interest.

Thank you.

Mr. GREENWOOD. Thank you very much, Mr. Bloom.

Dr. Benjamin?

TESTIMONY OF GEORGES C. BENJAMIN

Mr. BENJAMIN. Good evening. And thank you very, very much for being here. And also let me just thank the committee for their support for public health.

I have been at the American Public Health Association for about 5 months. Prior to that I was the health officer for the State of Maryland, which basically means that I had to go through West Nile virus, anthrax, malaria and if infectious diseases weren't enough, a few snipers in our community.

We have as a public health community learned a lot since 1999. And let me just talk about those briefly and then let me talk about some of the things that I think we do need to do, and more specifically within our States and the local communities.

No. 1, obviously we have learned to get ahead of an epidemic. You know, when West Nile virus entered our community, there was a kind of, "well, we do not quite want to deal with that issue," and there was a kind of "go slow but let us deal with it" mentality. You do not see that with SARS. We saw a very aggressive, let us get out ahead of this epidemic and get our arms around it very quickly. And more importantly, it was done before it hit the shores of this country.

The second thing is the concept of communicating frequently and widely. You do not hear a lot of complaints by practicing clinicians that they are not hearing the information about SARS because there is a lot of communication going on not only between the Federal Government and the local State and local public health officials, but also with our clinical colleagues as well.

We learned a lot about getting clear consistent messages, how extraordinarily important that was so that we are speaking from the same sheet of music so that as the media brings us up on split screen, we are pretty much trying to say, to the extent we can, the same thing unless there is a big disagreement. And then you certainly hear those publicly.

Learn to use and apply the science that we know and not guess. Because that creates some problems and you hear a lot of people trying to tell you exactly what we do know, trying to tell you what we do not know and not doing a lot of guessing, because this is clearly a new virus and we just need to watch it as it goes forward.

We certainly learned that the best treatment of fear is good information and you share that information broadly so that people are not as afraid as they could be without good information.

And we also learned, finally, that public health is actually good and it is possible to protect the public, but more importantly only able to do so if adequately staffed and adequately resourced.

We know there are several capacities that the public health system needed locally. We clearly need the ability to prevent an outbreak through good science. And we also need the ability to know when a disease has entered the community, be able to track that disease, provide a definitive diagnoses clinically, but from a laboratory perspective to confirm it. To be able to contain the disease, much of what you talked about with the last panel. Ensure proper treatment. But those capacities come at a cost. Because local health departments and State health departments are having to do that by pulling resources from a variety of places.

Certainly the public health preparedness dollars we got helped a lot, but I can tell you that the base upon which they were built is being continually eroded by reductions at the State and local level, by other problems with the public health system. And the fact that

this is going to take a while and we are going to have put a sustained investment in public health.

And finally, I think that one of the things we really want to do is begin thinking about not simply throwing money at every single crises that comes up. That we need to sit down and say okay, what is the blueprint for the best public health system on the planet, and then let us figure out what we want and fund it properly. And it will take us a few years to get there, but I think that this is probably the most important health issue that we need to do over the next several years, is rebuild this public health system and do it in an organized, thoughtful manner with enough money to do the job, and that means doing it at both the Federal level, at the State level and at the local level.

Thank you very much.

[The prepared statement of Georges C. Benjamin follows:]

PREPARED STATEMENT OF GEORGES C. BENJAMIN, EXECUTIVE DIRECTOR, AMERICAN PUBLIC HEALTH ASSOCIATION

Mr. Chairman and members of the subcommittee, my name is Dr. Georges Benjamin and, I am the executive director of the American Public Health Association (APHA). APHA is the oldest and largest public health association in the world, representing approximately 50,000 public health professionals in the United States and abroad. I am very grateful for the opportunity to discuss Severe Acute Respiratory Syndrome (SARS) and its implications for the future.

THE PROBLEM OF EMERGING INFECTIONS

SARS is an emerging infectious disease. It is not the first and certainly will not be the last. In fact, within the past 30 years, we have seen 35 new infectious diseases around the world several within our own borders. One can anticipate that the problem of emerging infectious diseases is likely to become more acute in the future, not less. In fact, infectious disease in general continues to be a major public health problem despite the wonder of antibacterial agents, improvements in health care and a better understanding of the pathogenesis of disease. The best illustration of this issue is the U.S. death rate from infectious disease. This rate, which dropped in the first part of the 20th century, is now double what it was in 1980.

The Institute of Medicine of the National Academy of Sciences attributed the surge in infectious disease to 13 specific changes in the world and the way we live. Those 13 factors are microbial adaptation and change; human susceptibility to infection; climate and weather; changing ecosystems; human demographics and behavior; economic development and land use; international travel and commerce; technology and industry; breakdown of public health measures; poverty and social inequality; war and famine; lack of political will; and bioterrorism.

LESSONS HAVE BEEN LEARNED

The lessons learned from managing two recent infectious outbreaks, West Nile and anthrax (one apparently naturally occurring and one intentional), have helped the public health community address SARS. These lessons demonstrated the need for a strong public health system as one component of an integrated homeland security program. We also learned what capacities we need to ensure preparedness and where some of the gaps remain that must be filled. Ensuring an effective public health infrastructure is a top priority for the APHA. An adequate public health infrastructure to manage the infectious disease threat is one where there is an adequate work force that is well trained, with the proper tools and resources to effectively respond to current and emerging infections. SARS is an excellent example of the need for a strong public health system and the infrastructure required for it to be effective. This infrastructure includes the capacity to:

- Prevent disease outbreaks;
- Know when a new disease has entered the community;
- Provide definitive diagnosis and laboratory verification;
- Track the spread of the disease;
- Contain the disease;
- Ensure effective treatment;

- Demonstrate an adequate legal framework for this work;
- Effectively communicate with the public, medical and public health providers and other stakeholders; and
- Partner on a local, regional, national and global level.

The effective use of many of these capacities have been demonstrated at the federal, state, and local level in the initial response to SARS, and represents a significant improvement over our response to the anthrax attacks of 2001 and some improvement over the early response to West Nile virus.

In the fall of 2001, I was Secretary of health for the state of Maryland. During the anthrax outbreak, as with West Nile virus two years before, we learned a lot that helped the public health community to better prepare to respond to SARS. We learned that any disease outbreak is a community event that can quickly grow in scope and size. These events require a high degree of coordinated communication and cross-jurisdictional cooperation. It is critical that in times of crisis, the public trust their public health officials and receive a clear, consistent message. In order to accomplish this, we have learned that rapid, early communication by credible spokespersons is essential.

During the current SARS event, the U.S. Department of Health and Human Services communicated early and frequently to a broad range of both medical and public health providers. What is important is that this communication occurred before the disease entered the borders of our country and gave us a head start on preparedness. These briefings were held by experts who were able to adequately tell us what they knew and what they did not know. Today there are frequent SARS briefings from either the high-tech, secure, command center at the Department of Health and Human Services or the Centers for Disease Control and Prevention (CDC) new Emergency Operations Center.

The Health Alert Network, which received its first real workout after September 11th, has become a mainstay of communication to the medical and public health community. CDC has set up and is using a free registry to provide clinicians with real-time information to help prepare for and respond to terrorism and other emergency events. Participants receive regular e-mail updates on terrorism and other emergency issues and on training opportunities relevant to clinicians. This highly focused, centrally coordinated effort has made a difference in the ability of local public health authorities to control the outbreak and also to educate clinicians and the public in their communities. This rapid and consistent message has allowed for those clinicians and medical facilities to properly manage suspect and probable SARS cases in the United States with minimal risk to others.

Anthrax also taught us that it was important to aggressively coordinate our external communications efforts, not just our response efforts, very early in order to ensure that we had control of the message and that we spoke with a single, consistent voice. This approach is imperative to avoid confusion, misinformation and panic. This is extremely important in an event like SARS when our understanding of the science shifts rapidly. Both the World Health Organization (WHO) and the CDC have done a much better job at being clear about telling us what they know and what they do not know, and quickly sharing new knowledge when it becomes available.

We need to be proactive in monitoring the global situation. SARS is a good example of a proactive approach and how with good public health practice and some luck, we have had only a few cases and no deaths in the United States. More than 20 years ago HIV—the virus that causes AIDS—emerged from Africa and since then has killed millions of people and devastated entire communities and countries. When West Nile first hit our shores it also was not new. West Nile virus was first isolated in Uganda in 1937 and was later recognized in Egypt in the 1950s and in Israel in 1957. In the 1990s, outbreaks occurred in Algeria, Romania, the Czech Republic, the Democratic Republic of the Congo and Russia. When it finally reached our shores in 1999 we were perplexed and surprised. It has now spread throughout North America and will probably enter the few remaining communities during the coming summer. The response to SARS has been much more proactive with every community on alert and vigilant.

Similarly, when the anthrax outbreak occurred in our region, much of the management focus initially was narrowly directed at the District of Columbia with less attention to Maryland and Virginia. This made it very difficult to have an effective regional strategy. SARS not only required managing a regional strategy around individual cases but a global one as well. This is a substantial improvement over our response to the anthrax attacks. I do want to caution, however, that our limited experience with suspect and probable SARS cases is limited and we should not get overconfident in our capacity to manage and coordinate a large biological event.

The CDC and the WHO have been doing yeoman's work on SARS and there has been unprecedented global communication. The WHO has been effective in helping to contain SARS and coordinating research at major institutes around the world once the disease became known. As cases popped up from China to Canada, WHO officials linked a network of 11 laboratories in nine countries to identify the agent causing the illness and devise treatments. In the past, international laboratories have competed to solve an epidemiological challenge. But in this case, labs have been exchanging data on a daily basis. Lines of communication between research facilities, physicians treating cases, and the public have been strengthened. Recently, scientists in Canada and the United States have broken the genetic code of the coronavirus that apparently causes SARS.

There are also global lessons to be learned. The WHO's Global Outbreak Alert System, set up after its experience with Ebola, and unfortunately proved inadequate because China failed to alert the WHO immediately. Currently, notifications are voluntary and limited to yellow fever, plague and cholera. The SARS experience should be used to identify gaps in the global response system. SARS also serves as a reminder that there is no alternative to effective multilateral institutions and global cooperation. While SARS is a human tragedy, what is remarkable is how quickly—leaving aside earlier Chinese secrecy—the world has joined together in responding to it. In June, WHO will host an international scientific gathering to plan the next steps in dealing with the disease.

NEEDS FOR THE FUTURE

SARS has reminded us once again that in this age where we not only have a global economy but a globalization of disease, the 20th century's model of protecting ourselves from disease is no longer sufficient. We need to look at new, more strategic models of doing business.

The SARS outbreak and others, including anthrax and West Nile, have also exposed gaps in our own public health system in the United States. We are at a critical juncture in public health. For many years, experts have been warning us that our nation's public health infrastructure is in disarray. Recent preparedness funding has provided for improvements in the public health preparedness infrastructure, however gaps remain. There still is a lack of adequate personnel and training, laboratory surge capacity and there are still holes in our communications networks. There remain serious gaps in our disease surveillance systems. These and other shortcomings have been known for sometime, but have also been more recently documented by the Institute of Medicine, the General Accounting Office and others as current pressures on the public health system make these failings more visible. One big problem today is the erosion of the foundation upon which we are building the new preparedness system due to funding cuts at the federal, state and local level in core public health programs. Today these programs allow for a surge capacity in public health to address emerging issues. This foundation needs to be strengthened.

Perhaps never before has it been so important to shore up our public health system. This system is being asked to support our response to some of the most threatening emerging diseases of our time and to prepare for diseases yet unknown. In this age when biological and chemical terrorism is added to the portfolio of public health threats, we need to be assured that the system works and works well.

I want to thank you for your support for the emergency supplemental funding this year for both the smallpox preparedness and the SARS response effort. These funds are critically important. However, it is time for Congress to take the next step and support the public health system in a more holistic way—to support public health as a system—not crisis by crisis. The public health system serves as the front line for our nation's public health defense system against emerging and reemerging infectious diseases. From anthrax to West Nile to smallpox to SARS, the CDC is our nation's and the world's expert resource and response hub, coordinating communications and action and serving as the nation's laboratory reference center. It continues to need strong support from Congress.

Public health is being asked to do more with less. Unless we start supporting our public health base in a more holistic way, we are going to continue to need to come to Congress for special emergency requests for funds as each new threat emerges. Funding public health outbreak by outbreak is not an effective way to ensure either preparedness or accountability.

In the absence of a robust public health system with built-in surge capacity, every crisis "du jour" also forces trade offs-attention to one infectious disease at the expense of another, infectious disease prevention at the expense of chronic disease prevention and other public health responsibilities. This is true especially given the current budget pressures facing states and the federal government.

It is time to think more strategically about the future of our nation's public health system, to develop a blueprint for where we want to be 10 years from now and how best to fund it. Because of their impact on society, a coordinated strategy is necessary to understand, detect, control and ultimately prevent infectious diseases. We believe that far more significant investments in public health will need to occur if we are to prepare the nation's public health system to protect us from the leading causes of death, prepare us for bioterrorism and chemical terrorism, and respond to the public health crises of the day.

I hope we all recognize that this SARS event is not over and that we still have a ways to go to ensure containment. In the future we will always be one plane ride away, one infected person away, and one epidemic away from a global tragedy. We cannot lower our guard, not today, not tomorrow.

Mr. Chairman and members of the subcommittee, I thank you for this opportunity to testify before you today about one of the most important public health issues of our time. On behalf of the American Public Health Association, I look forward to working with you to strengthen our nation's public health system.

Mr. GREENWOOD. Thank you, Dr. Benjamin.

And let me correct the record, it is Dr. Bloom, not Mr. Bloom. Dr. Schwartz for 5 minutes, please.

TESTIMONY OF JARED N. SCHWARTZ

Mr. SCHWARTZ. Good afternoon, Chairman Greenwood and committee members. On behalf of the College of American Pathologists I appreciate this opportunity to participate in today's hearing on SARS.

The College is a national medical specialty society representing over 16,000 pathologists who diagnose disease through laboratory medicine. I serve as the College's Chair of its national laboratory preparedness committee, but I am also here as a practicing pathologist, microbiologist and laboratory director from Charlotte, North Carolina. I will bring you a first hand clinical and local perspectiveness to the preparedness needs for SARS, none public health. My testimony will focus on the critical role of clinical laboratories in combating SARS work force protection and the need for a strong public/private health sector partnership at the community level. When a patient presents with symptoms of SARS, your local community's physicians and nurses and laboratory are the first in line to combat this new disease. They have significant responsibility for the preliminary diagnoses and ongoing care of patients who may become infected with SARS. As with the bioterrorist anthrax event, the first signs of trouble emerged locally. It was a vigilant physician who identified the Nation's first anthrax case in Florida. The pathologist reviewing a blood smear in the laboratory identified the anthrax bacillus.

Pathologists working with other laboratory professionals and other medical professionals through the use of laboratory testing, examination of tissue samples and the performance of autopsies are responsible for determining the cause of disease in patients. This occurs everyday in your community. And this, at the local community level, is where the battle will be won or lost in the war against SARS if there is an outbreak.

This will become extremely important when large number of patients with symptoms of fever and cough present during the next flu seasons, particularly if there are no diagnostic tests for SARS readily available at the local level, and we have heard it could be years away. Like many other respiratory viruses, SARS could become dormant through some seasons, only to return in others. This

apparent current lull in the U.S. should not be viewed as victory or that work has been done. We should use this time to marshal our resources and enhance our local community's capacity to respond. This is an opportunity that should not be squandered. Failure could be catastrophic economically and in human terms, as seen in China and other outbreak locations.

And I ask each of you to ask the question, "what is going on in my community?" CDC's communication and coordination with clinical laboratories and hospitals concerning bioterrorism has markedly improved. The work on SARS has been outstanding, excellent. But more regional planning to ensure a coordinated plan between the Nation's clinical laboratories, non public health, and hospitals and public health resources are desperately needed.

No preparedness and containment strategy without health care worker safety. Recent data from China suggests that up to 18 percent of SARS cases are health care workers. Sick health care workers cannot take care of patients.

In your hometown patients will present to the local emergencies rooms or your private practitioner. The patient specimens will be sent to the laboratory for examination by technologists and pathologists. The specimen arrives in the laboratory as an unknown. Laboratory professionals and other health care workers need to follow the CDC recommendations for protection. Budget constraints cannot be a barrier for a worker's preparedness.

As was learned from our fighting troops in Iraq, success in decreasing casualties in a war is dependent on having the very best resources, equipment and training. Nothing less should be available to our Nation's hospital and laboratory workers in their battle against bioagents.

The SARS experience today teaches many lessons. One of the most important is the need to enhance the vital link between private and the public health sector, particularly at the local level. While it is clearly important to prepare, coordinate, respond and communicate globally, we must implement locally to successfully control the outbreak of SARS and other microbial threats.

I caution, however, against reinventing a new system for every disease that comes along. This is costly and unworkable. We should continue to improve existing mechanisms for dual protecting against both biologic agents used in terrorism as well as naturally occurring pathogens.

A significant weakness in our public health system is that it remains fragmented. Every county and State can have different procedures and methods for reporting infectious diseases and handling outbreaks. We need a system for seamless reporting. We certainly applaud the continuing modernism of the public health system, and they need more resources. The world is interconnected. Our Nation's clinical and public health resources must be just as interconnected.

The College of American Pathologists has programs to educate and train laboratory professionals to improve response capabilities. We are currently expanding our laboratory preparedness education tool designed for pathologists and laboratorians to identify potential bioterrorist agents, to also be able to identify emerging pathogens such as SARS.

In conclusion, maintaining the health of the public is the responsibility of both the public and private health sectors. A failure in either will be a failure in our ability to control SARS and other microbial threats.

The College of American Pathologists is committed to continued collaboration with Congress and Government agencies to respond to public health emergencies and bioterrorism. We believe that private sector resources such as those we can offer and others can contribute much to the coordination and improvement of our collective efforts in this battle against microbes from all sources.

Thank you very much. Glad to answer questions.

[The prepared statement of Jared N. Schwartz follows:]

PREPARED STATEMENT OF JARED N. SCHWARTZ, COLLEGE OF AMERICAN PATHOLOGISTS

Chairman Greenwood, Congressman Deutsch, distinguished Committee members. I am Dr. Jared Schwartz, a practicing pathologist and microbiologist from Charlotte, North Carolina, Chair of the College of American Pathologists (CAP) National Laboratory Preparedness Committee and Secretary Treasurer of the College. I was also recently appointed by Health and Human Services Secretary Tommy Thompson to the Clinical Laboratory Improvement Advisory Committee. On behalf of the CAP, I appreciate the opportunity to participate in today's hearing before the Energy and Commerce Subcommittee on Oversight and Investigations to assess the emerging threat of Severe Acute Respiratory Syndrome (SARS) and what we can do to improve our ability to contain its spread and safeguard the public.

The CAP is a national medical specialty society representing over 16,000 pathologists who provide pathology services in community hospitals, independent clinical laboratories, academic medical centers and federal and state health care facilities across the country. CAP members have extensive expertise in providing and directing laboratory services and serve as inspectors in the College Laboratory Accreditation Program. In addition, the CAP provides laboratories with a wide array of proficiency testing programs and educational solutions to assist in the improvement of the laboratory's performance. These programs combined are designed to improve the quality of laboratory services and to ensure the accuracy and reliability of test results.

ROLE OF THE CLINICAL LABORATORY IN IDENTIFYING SARS

As a Physician Director of a large integrated laboratory, I understand first-hand the challenges we face in both accurately identifying and responding to the public health threat of emerging pathogens, such as SARS. It is important to recognize that your local laboratory and community hospital are the first line of defense against this new disease. The laboratory and its hospital facility are responsible for the initial evaluation, preliminary diagnosis and ongoing care and treatment of patients who become infected with SARS. My testimony will focus on the critical role of the clinical laboratories and community hospitals as the first contact with individuals who can be infected with SARS or other communicable pathogens. We must prepare ourselves now for an oncoming surge of new patients.

Most individuals with possible SARS have, in fact, other causes for their symptoms and present a diagnostic challenge for both clinicians and laboratory professionals. This highlights the essential role of the clinical laboratory—that laboratory in a hospital or established as an independent adjunct to the hospital lab providing diagnostic services to residents of a local community. The CAP represents pathologists who are Physician Directors of our nation's clinical laboratories, perform forensic and anatomic pathology, with the common objective of providing a diagnosis as to the cause of disease through laboratory medicine. The clinical laboratory has a major responsibility for ruling out SARS cases so they can be appropriately treated and for referring those cases where SARS cannot be ruled out to the public health system for definitive diagnosis and management. As such, pathologists are on the front lines in diagnosing viral and other causes of microbiological disease. This outbreak of SARS demonstrates the critical role of the clinical laboratory, as partners with government and public health laboratories, to contain any new emerging pathogen, particularly at the community level.

Diagnosing a patient with SARS may be significantly delayed without the vigilance of a pathologist, clinical scientist and other laboratory professionals. The lab-

oratory has the responsibility to rule out flu-like cases that are not SARS so individuals receive proper treatment and are not inappropriately quarantined. By the same token, the laboratory will also have the responsibility to determine and refer those flu-like cases where SARS may in fact be present as new tests become available. This analysis is critical because it allows for actions and resources to be quickly and effectively targeted to those individuals where SARS is diagnosed or cannot be ruled out. The laboratory staff and the pathologist medical decision-makers are essential to the proper treatment and thus helping to control the spread of the disease. If not accurately identified, patients with SARS could be sent home to infect others instead of being treated and if necessary quarantined. Pathologists also conduct autopsies both as forensic medical examiners and at community hospitals to determine the cause of death. In this role, pathologists serve as an early warning system in detecting new diseases and provide critical information to our public health system about the course and etiology of the disease in the population.

ASSESSING SARS AS A PUBLIC HEALTH THREAT

Prior to assessing the impact of a SARS epidemic in the Untied States, it is important to understand why this illness has emerged as such an important global public health threat. In many ways, SARS is no different from any other flu-like illness to which Americans are frequently exposed. SARS shares many of the components of common respiratory illness—it appears to be caused by a virus, it is spread by respiratory droplets and its symptoms can mimic other respiratory infection. Why then have governments, the media and public health officials around the world moved with unprecedented speed to alert the public to the possible threat of SARS? The answer is multi-factorial. SARS appears to be a new virus and no vaccine is available, at this time, to prevent this disease. This leaves the population vulnerable to attack. SARS can spread rapidly and kill. The frequent international travel of the population; crowded living conditions; the ability to be exposed without personal contact (from respiratory droplets or from surface contact); among others all contribute to a formula for worldwide outbreaks. U.S. health officials are investigating 54 probable cases of SARS in this country with another 237 cases under close surveillance. Worldwide, 6,234 cases have been reported in 27 countries associated with 435 deaths. The economic impact of SARS in affected countries has been devastating despite the relative small number of cases as compared to cases of influenza worldwide.

Although it is encouraging to know that SARS cases are declining in some areas, we cannot become complacent. SARS is likely to follow seasonal patterns much like many other respiratory viruses. SARS could become dormant through some seasons only to return in others. That's why this apparent current lull should not be viewed as victory or that our work has been done. To the contrary, we should use this time to marshal our resources and collaborate with other countries to combat this threat and enhance our local communities' response capabilities. This is an opportunity that should not be squandered.

SARS is one of many new infections that have surfaced in the recent years—West Nile, Hantavirus, Ebola, Nipah, Hendra, AIDS among others. Subsequent to 9/11, we also experienced an unprecedented bioterrorist attack with anthrax. In fact, one of the anthrax attacks occurred here in our nation's capital. There is no reason to believe that these outbreaks—either through natural occurring agents or the intentional distribution of microbiological agents will not continue. Furthermore, it is important to note that whether the infectious and dangerous agent is the result of mother nature or a terrorist, our health system both public and private must be prepared to respond. And, in many ways, the response needs are the same.

We applaud the Centers for Disease Control and Prevention in recognizing the importance of a responsive and complete public health infrastructure to meet these threats. Much as been done to improve the CDC's communication and coordination with clinical laboratories regarding bioterrorism. Similarly, the CDC's communications to the medical community on SARS has been excellent. However, more needs to be done particularly in regional planning and ensuring a seamless link between the nations clinical laboratories, hospitals and public health resources if our nation is to contain this outbreak as well as other microbial threats.

CURRENT STATE OF DIAGNOSTIC TESTING

Diagnostic tests for SARS are currently under development. The tests can give both false positive and false negative results. A recent Canadian study found that just 40% of likely SARS patients actually tested positive for the virus. At this point, the technology to perform SARS tests is available only at sophisticated public health laboratories. There is a need for readily available diagnostic tests which clinical lab-

oratories can use at the local level. Unfortunately, a test of this nature could be years away. The uncertainty in SARS testing reinforces the important contribution of the clinical laboratories in being able to perform those tests that can clearly identify those individuals with symptoms of SARS who have the common flu or bacterial pneumonia—thereby screening out individuals who are not infected with SARS. This will become extremely important when large numbers of patients with symptoms of fever and cough present for diagnosis during the onset of the next flu season.

PROTECTING THE CLINICAL LABORATORY WORKFORCE

No preparedness and containment strategy can succeed without adequate healthcare workforce protection. We have all heard the news stories about health care workers who have contracted SARS in the course of caring for patients infected with the disease. An emphasis must be placed on finding the most effective ways to protect health care workers. Failure to do so will not only spread the disease to other hospital patients and the population at large, but will also put at risk the very individuals we will need to rely on if an outbreak occurs.

In the U.S., patients first present to the local emergency department or to a private health care practitioner for care. Patient specimens are then sent to the laboratory to determine the presence of disease, and in this case, the possibility of SARS. However, when the specimen arrives at the laboratory for analysis, the presence of SARS is not known. This reinforces the need for laboratory professionals and other front line health care workers to follow universal precautions in handling and collecting specimens. Laboratory procedures such as centrifuging and opening sample containers may release microbial agents to the air that can spread the disease to workers and patients in the area. The clinical laboratory and local medical provider community will look to the CDC and other government health agencies to provide them with the latest and most scientifically valid knowledge about respirator effectiveness and use, handling precautions and modes of transmission. With hospitals and providers operating on shoestring budgets, this becomes an even more critical issue. Health care infrastructure weaknesses should not be a barrier to our preparedness efforts. As was learned from our fighting troops in Iraq, success in decreasing casualties in a war is dependent on having the very best resources, equipment and training. Nothing less should be available to our nation's hospital and laboratory workers in their battle against bioagents.

LESSONS LEARNED—NEED FOR A STRONG PUBLIC-PRIVATE HEALTH SECTOR PARTNERSHIP

The SARS experience can teach us many lessons. From my perspective as a pathologist in my local community working with clinicians and public health officials, one of the most important lessons is the need to enhance the vital link between the private and public health sector, particularly at the local level. While it is clearly important to prepare, coordinate and respond globally, we must implement locally to successfully control the outbreak of SARS and other diseases. Proper policies and procedures for coordination and communication between the private sector laboratories and the public health system have improved since 9/11 but need to be strengthened so that potential SARS cases, and other emerging threats, can be quickly identified and managed. However, I would caution against reinventing our system for each new disease that comes along. This would be a costly and unworkable approach. Actions taken at the federal, state and local level in collaboration with our private health care system has done much to improve our response capabilities with respect to bioterrorism. We should continue to improve and refine these existing mechanisms for dual use in terms of both biological agents used in a bioterrorist act as well as microbial agents that are naturally occurring.

As a private sector initiative, the CAP has developed programs to educate and train pathologists and laboratory personnel to improve response capabilities. The College has developed a Laboratory Preparedness educational tool designed for laboratories to better identify microbiological agents that could be used in a bioterrorist attack. This program sends surrogate microbial samples to laboratories. These safe samples mimic biological agents and are sent to the laboratory in a blind manner so we can assess the laboratory's ability to accurately identify select agents of bioterrorism. The program also educates laboratories about how to properly coordinate with the public health infrastructure for referral and reporting activities. There are plans underway to expand this program to ensure that clinical labs are prepared to identify emerging pathogens, including SARS.

As we think about lessons learned from this outbreak, its comforting to know that progress has been made in terms of public health system procedures for responding

to biological threats of any nature, but the system remains fragmented. Every county and state can have different procedures and methods for reporting infectious disease and handling outbreaks. This does not allow for seamless reporting from the clinical laboratories and local health providers and does not allow for integrated electronic surveillance systems. The technology is available to implement interoperability coordination and electronic reporting and its adoption should be accelerated. A March report from the prestigious Institute of Medicine indicates that today's outlook with regard to microbial threats to health is bleak. Microbial threats will present us with new surprises every year. We applaud the continued modernization of the public health system. However, there is a critical need for more coordination at the highest level in order to ensure full implementation at the local level. Our public health system would benefit from an interconnected electronic communication network to monitor for disease outbreaks. The world is interconnected on a daily basis—our nations clinical and public health resources should be just as interconnected.

The CAP was pleased to assist CDC in providing timely communication to laboratory personnel following the anthrax outbreaks and working to improve the private sector clinical lab connection to the public health networks. We are committed to continued collaboration with the Department of Health and Human Services and other government agencies to respond to public health emergencies and bioterrorism events. We have witnessed the severe economic consequences and panic that has resulted in other countries from SARS outbreaks. We need to be sure our local communities have a coordinated plan to handle their outbreak in the near future. The CAP believes that private sector resources, such as those we offer, can contribute much to the coordination and improvement of our collective efforts in our battle against microbes from all sources.

CONCLUSION

In closing I would like to reemphasize the key points of my testimony:

1. SARS is one of many new infections that have surfaced in the recent years. Since 9/11 we have also experienced an unprecedented bioterrorist attack. There is no reason to believe that this trend—either through natural occurring agents or intentional distribution of microbiological agents will not continue. Regardless, the need for preparedness is the same, both nationally and locally.
2. The outbreak of SARS demonstrates the critical role of the clinical laboratory, as partners with government and public health laboratories, to contain any new emerging infectious disease. As the point of initial evaluation for individuals who can be infected with SARS, clinical laboratories are one of the first lines of defense against this new disease. Significant responsibility rests with the clinical laboratories for the preliminary diagnosis of the patient, including the ability to accurately rule out non-SARS cases and appropriate referral of those displaying characteristics of SARS.
3. Education on workforce safety is extremely important. Laboratory professionals and other front line health care workers must be fully informed about the need to follow universal precautions in handling and collecting specimens. Our health care workers deserve the very best equipment and technology to protect them as they combat this disease.
4. It is expected that SARS will follow a seasonal pattern, becoming dormant through some seasons and returning in others. This possible lull provides an opportunity to marshal our resources and work with other countries to combat this threat. This is an opportunity that should not be squandered.
5. As we think about lessons learned from this outbreak, its comforting to know that progress has been made in terms of public health system procedures for responding to biological threats of any nature, but the system remains fragmented. The world is interconnected on a daily basis—our nations clinical laboratories, hospitals and public health resources should be just as interconnected.
6. There is much to learn about the etiology and diagnostic testing for SARS. Questions remain about the cause of the disease and how best to identify it in patients. Proper policies and procedures for coordination and communication between the private sector laboratories and the public health system have improved since 9/11 but need to be strengthened so that potential SARS cases, and other emerging threats, can be quickly identified.
7. The diagnosis of SARS may be significantly delayed if not for a vigilant pathologist, clinical scientist and other laboratory professionals. Pathologists, through conducting autopsies for the cause of death, serve as an early warning system

to detect new diseases and provide critical information about the course and etiology of the disease in the population.

8. As a private sector initiative, the CAP has developed programs to educate and train pathologists and laboratory personnel to improve response capabilities. The CAP has developed a Laboratory Preparedness educational tool designed to educate laboratories to better identify microbiological agents that could be used in a bioterrorist attack with plans underway to expand the questions to SARS. We look forward to working with the public and private sector in similar efforts.

Mr. GREENWOOD. Thank you, Dr. Schwartz.

Mr. Hodge, you are recognized for 5 minutes, sir.

TESTIMONY OF JAMES G. HODGE

Mr. HODGE. Thank you, Mr. Greenwood. Thank you members of the committee. It is a pleasure to be able to join you here as a public health lawyer and scholar at the Center for Law & the Public's Health at Georgetown and Johns Hopkins Universities.

Mr. Chair, you have very appropriately termed this hearing in appropriate ways in the sense of lessons learned from SARS to date. And I think the fundamental lesson that I bring to the table and to this committee today is that we very much need to see law as a tool for public health improvements. It has played an integral role in relation to our national response to SARS. And yet at the same time, additional legal reform, particularly among the States where so much of public health power resides, is very much ongoing but very much needed.

We have heard time and time again here today of the impact of SARS in the community and the ways in which it is spread, specifically in other nations, and what that may mean here in the United States. I think very appropriately our response to the Federal, tribal, State and local governments is quite nicely and in commendable ways limited the spread of this disease to date in the United States thanks very much to leadership from CDC, from its parent at HHS, FDA, NIH. We have heard from many of these folks as well, as well as Dr. Benjamin's American Public Health Association.

Public health authorities, as we have noted, have engaged in a variety of techniques to bring this disease under control in the United States. Everything from surveillance techniques to trap suspected and actual cases, used epidemiologic investigations to build knowledge about the disease. We have engaged in implemented travel advisory, we have provided information to people about SARS. And we have also, as we have seen, engaged in isolation and quarantine techniques.

Each and every one of these actions owes its authorization to the law in one phase or the other, be it at the Federal, State, local or tribal level, be it constitutional, statutory, administrative, regulatory or even in some cases court-based case law. However, specifically statutory public health law, which in general authorizes so much of what may occur through public health agencies, particularly at the State level, has serious deficiencies. And these may actually in same ways impede or limit the ability of public health authorities during certain types of epidemics like SARS to respond effectively.

Some of these public health laws, as we have studied systematically through our Center, may be antiquated, they may be fragmented, they are often inconsistent.

By antiquated, I mean quite simply they are old. Some of these laws may be on the books in various States for a 100 years or so. Old laws do not necessarily make bad laws, of course, unless of course they fail to comply with modern constitutional norms, modern public health science standards, even ethical norms. And that we do see in some statutory authorizations. They are fragmented in many cases.

One of the key features that we see among State public health laws in particular is how specific they are to various conditions or diseases. This phenomenon has not been seen yet in SARS, but as you reread and reveal State code in various jurisdictions you see specific responses to diseases like HIV/AIDS, tuberculosis, venereal diseases; all of the sorts of step-by-step processes, and they are inconsistent. The State public health laws across the States vary drastically. They may even have inconsistencies between local and State laws in various individual States.

The Department of Health and Human Services, CDC, our institutive medicine have all recently recommended the need for statutory reform in public health law.

And I am very pleased to alert this committee to the fact that our Center has been very generously funded through CDC and other resources to develop some model law proposals which we think could be helpful, including what we call the Model State Emergency Health Powers Act, very much drafted quickly after the anthrax exposures in the fall of 2001. This model act introduces a series of modern provisions that very much try to balance individual liberties and individual dignity with the need for public health powers and/or surveillance and other techniques.

This has been introduced in some form or another in 39 States, presently passed in 22 of those States including a version here in the District of Columbia. And then this model act has actually been folded into a much larger, even more comprehensive model State public health act as part of a turning point project under the Robert Wood Johnson Foundation.

Together with my colleague at the Center, Professor Larry Goston we are at the forefront of trying to work on final draft of this particular comprehensive proposals. And we very much believe and hope that this type of model law does not necessarily issue a mandate to States nor the Federal Government of exactly how to legislate in the form of public health protections, but provides the type of guidance that we systematically heard from so many policymakers across the Nation that is really quite missing.

So together these model proposals, additional scholarship, the efforts that are occurring through various agencies like APHA and so many other public health associations, and fantastic schools of public health as well, I think are working very much together to evolve public health law as the meaningful tool that it is becoming in relation to responding to these particular types of conditions like SARS.

Thank you very much.

[The prepared statement of James G. Hodge, Jr. follows:]

PREPARED STATEMENT OF JAMES G. HODGE, JR., DEPUTY DIRECTOR, CENTER FOR LAW AND THE PUBLIC'S HEALTH AT GEORGETOWN AND JOHNS HOPKINS UNIVERSITIES; FACULTY, GEORGETOWN UNIVERSITY LAW CENTER AND THE JOHNS HOPKINS BLOOMBERG SCHOOL OF PUBLIC HEALTH

SARS AND PUBLIC HEALTH LAW: CHALLENGES, RESPONSES, AND REFORM [1]

EXECUTIVE SUMMARY

The spread of SARS in the U.S. presents significant challenges for federal, tribal, state, and local public health authorities, as well as the private health sector. Laws at each level of government may facilitate the planning, preparation for, response to, and prevention of existing and future SARS cases. Ideally, public health laws authorize government to employ proven powers while respecting individual rights. As such, laws are tools for improving public health outcomes.

However, there is considerable variation among existing public health laws, particular at the state and local levels. These laws may be antiquated, inconsistent, and fragmented. They may not reflect the most current scientific, ethical, and legal norms or standards for public health practice. Such laws may limit or actually interfere with effective communicable disease controls. Not surprisingly, calls for state public health law reform have emanated from federal and state authorities.

In response, faculty at the *Center for Law and the Public's Health* developed the Model State Emergency Health Powers Act (MSEHPA) in 2001. Introduced in whole or part in 39 states and passed in 22 states (and D.C.), MSEHPA provides a structured, balanced approach to using law to control communicable diseases, the spread of which may constitute a public health emergency. Additional work on a larger "Turning Point" project to develop a larger model state public health law is ongoing. Upon completion in late 2003, this model law will provide a comprehensive, structural approach for states considering extensive reform. These existing and future public health law reforms will help improve our national public health system, and its ability to control new and emerging threats like SARS.

INTRODUCTION

There is perhaps no duty more fundamental to American government than the protection of the public's health. Protecting communal health is the quintessential goal of federal, tribal, state, and local public health authorities. Yet, in the last decade alone, novel threats to the public's health have emerged. Beginning in 1999, West Nile Virus (WNV) began to spread across the nation through mosquitos carrying the virus from infected birds. Thousands of persons have been infected, and several deaths (particularly among older persons) have occurred. In the ensuing weeks following the terrorism of September 11, 2001, public health and law enforcement officials discovered that some person or group had intentionally contaminated letters with deadly anthrax spores. These letters were mailed to individuals in government and the media in several states and the District of Columbia. Thousands of persons were tested for exposure, hundreds were treated, and five died from inhalational anthrax.

In 2003, severe acute respiratory syndrome (SARS) has emerged as another serious threat to public's health in the United States. Unlike WNV and the anthrax exposures, persons infected with SARS may transmit the disease to others through close human contact. Additional modes of infection are being investigated. To date, the Centers for Disease Control and Prevention (CDC) reports 291 cases of SARS in the U.S., of which 54 are listed as probable (advanced symptoms of the disease have been diagnosed). No deaths from the disease have occurred domestically, although the World Health Organization conservatively reports 435 deaths worldwide among 6,234 cases (as of May 3, 2003).

The underlying challenge for the U.S. public health system concerning an emerging, infectious disease like SARS is to prevent new or recurring infections, as well as reduce morbidity and mortality, to the fullest extent possible. From an epidemiological perspective, this can be difficult. SARS is relatively easily communicated from person to person. Persons who have been infected may acquire the disease again [although public health professionals are investigating this potential for reinfection]. There is currently no cure or vaccine for SARS. Effective treatment is lacking. In less than 6 months, SARS has spread to 30 countries, largely through per-

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[1] This document is based, in part, on Gostin, LO, Hodge, JG. *The Model State Emergency Health Powers Act—a brief commentary.* Seattle: Turning Point Statute Modernization Committee, 2002; 1-42. I would also like to thank my *Center* colleagues, Lance Gable, JD/MPH, and Lesley Stone, JD, for their research and editing assistance with this document.

sons who have traveled from infected areas. Even if the disease is controlled for a time, it has the potential to flare again if adequate precautions are not taken, especially in larger urban centers that have a regular influx of foreign travelers or returning passengers from foreign destinations.

For these and other reasons, SARS has become a dominant focus of the nation's public health system. Federal, tribal, state, and local public health authorities have effectively utilized modern epidemiologic surveillance and investigations to build knowledge about the diseases, project its potential spread, and identify at-risk persons. In collaboration with the private sector (e.g., physicians, health care workers, hospitals, and primary care institutions), public health authorities have worked diligently to apply a range of measures to slow, detect, and eradicate the spread of SARS from person to person. Persons with known cases of SARS have been isolated (usually voluntarily) from others to prevent infection. Close contacts of infected persons have been asked to limit their exposure to others and engage in a series of hygienic practices. Individuals entering the country [especially from known infected areas] have been targeted for potential screening or provided information about SARS. Places where SARS may have contaminated surfaces or other items with which humans may come into contact have been temporarily closed for decontamination.

The practice of these and other public health measures in response to SARS rely upon existing and new legal powers at the federal, state, and local levels. Through an Executive Order, President Bush has included SARS among a short list of diseases for which the Department of Health and Human Services (HHS) may employ limited quarantine or isolation measures. Federal, state, and local public health authorities have utilized existing laws to monitor SARS through ongoing surveillance, investigate factors leading to the spread of the disease, determine contacts of SARS "cases," and implement quarantine and isolation measures. A foreign tourist in New York City was involuntarily detained in a hospital for days because of suspected SARS symptoms. College roommates of a suspected SARS case in Minnesota were voluntarily quarantined for 3 days. A twelve-year old boy who likely contracted SARS from a trip to Toronto has been isolated in Florida. Local authorities in Wisconsin charged a man with failing to cooperate with a public health investigation of SARS. These and other examples of SARS-related legal responses are not new to epidemic diseases. As a health official with the Wisconsin Division of Public Health recently stated, "The ideas of isolation, quarantining, closing buildings, prohibiting public gatherings have been around since the early 1900s . . . Those are the basic tools."[2]

NEED FOR PUBLIC HEALTH LAW REFORM

Law has long been considered an essential tool for improving public health outcomes, especially among state and local governments that have traditionally been the repositories of public health powers. Statutory laws and administrative rules generally guide the activities of public health authorities, assign and limit their functions, authorize spending, and specify how authorities may exercise their delegated authority. Laws can establish norms for healthy behavior and create the social conditions in which people can be healthy.

However, obsolescence, inconsistency, and inadequacy in existing state public health laws expose flaws and can render these laws ineffective, or even counterproductive. State public health statutes have frequently been constructed in layers over time as lawmakers responded to varying disease threats (e.g., tuberculosis, polio, malaria, HIV/AIDS). (To date, no state has legislatively sought to amend its public health powers in response to SARS). Consequently, existing statutory laws may not reflect contemporary scientific understandings of disease (e.g., surveillance, prevention, and response) or legal norms for protection of individual rights. Administrative regulations may supplement existing statutes with more modern public health approaches, but also be limited by original grants of delegated rule-making authority. Existing public health laws may pre-date vast changes in constitutional (e.g., equal protection, due process) and statutory (e.g., disability discrimination, privacy, civil rights) law that have changed social and legal conceptions of individual rights. Public health authorities acting pursuant to these provisions may be vulnerable to legal or ethical challenges on grounds that their actions are unconstitutional or preempted by modern federal or state laws.

The independent evolution of health codes across states, tribal authorities, and locales has led to variation in the structure, substance, complexity, and procedures

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[2] Associated Press, *Milwaukee: State Ready for SARS, Officials Say,* St. Paul Pioneer Press, 4/29/03 @ 1B.

for detecting, controlling, and preventing disease. Without a coordinated, national public health system, disease detection and reporting systems, response capabilities, and training capacity differ extensively among jurisdictions. These differences could hamper coordination and efficient responses in a multi-state public health emergency (perhaps involving a large outbreak of SARS). Confusion and complexity among inconsistent state public health laws may create ambiguities that also prevent public health authorities from acting rapidly and decisively in an emergency. Public health authorities may be unsure of the extent of their legal authority, the chain of command during an emergency, or the proper exercise of existing legal powers.

Reforming current state public health laws is particularly important to strengthen key elements of public health preparedness:

Planning, Coordination, and Communication. Most state statutes do not require public health emergency planning or establish response strategies. Essential to the planning process is the definition of clear channels for communication among responsible governmental officials (e.g., public health, law enforcement, emergency management), the private sector (e.g., health care workers and institutions, pharmaceutical industry, NGO's), and the public. Coordination among the various levels (e.g., federal, tribal, state, local) and branches (e.g., legislative, executive, judicial) of government is also critical. State public health laws can implement systematic planning processes that involve multiple stakeholders. However, many public health statutes not only fail to facilitate communication, but may actually proscribe exchange of vital information among principal agencies due to privacy concerns. Some state laws even prohibit sharing data with public health officials in adjoining states. Laws that complicate or hinder data communication among states and responsible agencies could impede thorough investigation and response to public health emergencies.

Surveillance. Ongoing, effective, and timely surveillance is an essential component of public health preparedness. As with SARS, early detection could save many lives by triggering an effective containment strategy that includes reporting, testing, partner notification, and isolation or quarantine. Some existing state laws may thwart effective surveillance activities. Many states do not require immediate reporting for all the critical agents identified by the CDC. At the same time, states do not require, and may actually prohibit, public health agencies from monitoring data collected through the health care system. Private information that might lead to early detection (e.g., unusual clusters of fevers or gastrointestinal symptoms) held by hospitals, managed care organizations, and pharmacies may be unavailable to public health officials because of insufficient reporting mechanisms or health information privacy concerns.

Managing Property and Protecting Persons. Authorization for the use of coercive powers are the most controversial aspects of public health laws. Nevertheless, their use may be necessary to manage property or protect persons in a public health emergency. There are numerous circumstances that might require management of property in the interests of protecting the public's health—e.g., decontamination of facilities; acquisition of vaccines, medicines, or hospital beds; or use of private facilities for isolation, quarantine, or disposal of human remains. Consistent with legal fair safeguards, including compensation for takings of private property used for public purposes, clear legal authority is needed to manage property when needed to contain serious health threats.

There may also be a need to exercise powers over individuals to avert significant threats to the public's health. Vaccination, testing, physical examination, treatment, isolation, and quarantine each may help contain the spread of infectious diseases. Although most people will comply with these programs during emergencies for the same reason they comply during non-emergencies (i.e., because it is in their own interests and/or desirable for the common welfare), compulsory powers may be needed for those who will not comply and whose conduct poses risks to others. These people may be required to yield some of their autonomy or liberty to protect the health and security of the community.

RECOMMENDATIONS FOR PUBLIC HEALTH LAW REFORM

The federal Department of Health and Human Services (HHS), the Centers for Disease Control and Prevention (CDC), and the Institute of Medicine (IOM) (part of the National Academy of Sciences chartered by the U.S. Congress) have each cited the need for public health statute reform. In its November 2002 report, *The Future of the Public's Health in the 21st Century,* IOM noted that "public health law at the federal, state and local levels is often outdated and internally inconsistent." IOM recommended HHS appoint a national commission to provide guidance to

states in reforming their laws to meet modern scientific and legal standards. HHS' Office of Inspector General is currently assessing the status of state bioterrorism laws. Additional public and private sector legal assessments are ongoing.

Threats of bioterrorism and emerging infectious conditions like SARS have vaulted the state public health law reform to national prominence. Faculty at the *Center for Law and the Public's Health at Georgetown and Johns Hopkins Universities* have led two important initiatives to reform public health laws. Following the anthrax attacks in October, 2001, CDC asked the Center to prepare draft legislation that states could use in reviewing their existing laws related to response to bioterrorism and other potentially catastrophic public health emergencies. Center faculty drafted the **Model State Emergency Health Powers Act** (MSEHPA) in collaboration with national entities (i.e., National Governors Association, National Conference of State Legislatures, Association of State and Territorial Health Officials, National Association of County and City Health Officers, and the National Association of Attorneys General). MSEHPA presents a modern synthesis of public health law for controlling infectious diseases during emergencies that balances public health needs with the rights and dignity of individuals. The Act was completed in December, 2001, and is available at the *Center's* website [www.publichealthlaw.net] (a copy of the Act is available at www.publichealthlaw.net/ Resources/Modellaws.htm.

MSEHPA has been widely used by state and local law- and policy-makers, health officials, and representatives in the private sector as a guide for considering reforms of existing legal protections. As of April 21, 2003, it has been used by most states in assessing their existing laws regarding public health emergencies. The Act has been introduced in whole or part through legislative bills or resolutions in 39 states, and passed in 22 states.

Although MSEHPA was drafted as a stand-alone model act, it was previously conceived as part of a larger, multi-year project convened by the *Turning Point Public Health Statute Modernization National Collaborative,* [www.hss.state.ak.us/dph/APHIP/collaborative] (hereinafter "National Collaborative") to develop a **Model State Public Health Act**. Many of the provisions of MSEHPA are part of this larger model act. The purpose of the National Collaborative is to transform and strengthen the legal framework for the public health system through a collaborative process to develop a model state public health law. Through intensive research and consensus building among national, state, and local experts and public health representatives, the **Model State Public Health Act** shall provide legislative language concerning public health administration and practice by public health agencies at the state and local levels. The National Collaborative, comprised of a multidisciplinary panel of experts in public health, law, and ethics, has already developed various portions of the multi-chapter, comprehensive model public health act for states. The Turning Point Model Act is scheduled for completion later in 2003, but has already been referred to or introduced in part through a state resolution in Hawaii and a comprehensive reform bill in North Carolina.

IMPROVING EMERGENCY PUBLIC HEALTH RESPONSES THROUGH LAW: THE MODEL STATE EMERGENCY HEALTH POWERS ACT

MSEHPA provides a modern illustration of a public health law for controlling infectious diseases like SARS during emergencies that balances the needs of public health with the rights and dignity of individuals. Though developed quickly following the anthrax exposures in the Fall of 2001, the Act's provisions and structure are based on existing federal and state laws and public health practice.

MSEHPA includes a modern series of legal provisions that equip public health authorities with necessary powers to respond to catastrophic public health emergencies while also respecting individual and group rights. The Act vests state and local public health authorities with modern powers to track, prevent, and control disease threats resulting from bioterrorism or other public health emergencies. These powers include measures (e.g., testing, treatment, and vaccination programs; isolation or quarantine powers; travel restrictions) that may infringe individual civil liberties (e.g., rights to due process, speech, assembly, travel, privacy). However, the exercise of these powers is restricted in time, duration, and scope. Coercive public health powers, particularly isolation and quarantine, are exercised on a temporary basis, only so long as reasonably necessary, and only with respect to persons who justifiably may pose risks to others because of their contagious conditions. In addition, procedural due process and the dignity of individuals are respected. For example, their rights to contest the coercive use of public health powers, even during an emergency, are secured.

Although some have suggested that MSEHPA sets forth new and expansive powers for public health authorities, this is actually not the case. The Act does not cre-

ate new powers for public health authorities; each of the Act's provisions are based on existing theory and practice of public health law. Rather, MSEHPA organizes and modernizes these legal powers to facilitate a coordinated approach to public health emergency response.

Central Purposes. MSEHPA addresses each of the key elements for public health preparedness discussed above. Among its central purposes, the Act:

1. Sets a high threshold definition of what constitutes a "public health emergency" [Art. I];
2. Requires the development of a comprehensive public health emergency response plan that includes coordination of services, procurement of necessary materials and supplies, housing, feeding, and caring for affected populations, and the administration of vaccines and treatment [Art. II];
3. Authorizes the collection of data and records and access to communications to facilitate the early detection of a health emergency [Art. III];
4. Vests the power to declare a public health emergency in the state governor, subject to appropriate legislative and judicial checks and balances [Art. IV];
5. Grants state and local public health officials the authority to use and appropriate property to care for patients, destroy dangerous or contaminated materials, and implement safe handling procedures for the disposal of human remains or infectious wastes [Art. V];
6. Authorizes officials to care and treat ill or exposed persons, to separate affected individuals from the population at large to prevent further transmission, collect specimens, and seek the assistance of in-state and out-of-state private sector health care workers during an emergency [Art. VI];
7. Requires public health authorities to inform the population of public health threats through mediums and language that are accessible and understandable to all segments of the population [Art. VII]; and
8. Authorizes the governor to allocate state finances as needed during an emergency, and creates limited immunities for some state and private actors from future legal causes of action [Art. VIII].

Public Health Emergencies. Most of the public health powers granted to state and local public health authorities through MSEHPA are triggered by the governor's declaration of a public health emergency in response to dire and severe circumstances. A declared state of emergency terminates as soon as the health threat is eliminated, or automatically after 30 days, unless reinstated by the governor or annulled through legislative or court action. Bioterrorism events involving intentional efforts to spread infectious diseases may present a scenario for a declaration of emergency. Public health emergencies can also arise through the spread of emerging infectious diseases, like SARS, through unintentional means. MSEHPA covers either scenario under its inclusive definition of what constitutes a "public health emergency," summarized as (1) the occurrence or imminent threat of an illness or health condition, caused by bioterrorism, a highly fatal biological toxin, or novel or infectious agent that (2) poses a high probability of a significant number of human fatalities or incidents of serious, permanent or long-term disability in the affected population.

Some civil libertarians and others have objected to the Act's emergency declaration. They view the declaration of a state of emergency as an authorization for public health authorities to do virtually anything to abate the existing threat. This includes infringing individual rights in the interests of protecting public health. Indubitably, during an emergency, certain civil liberties may need to be restricted as compared to the exercise of these rights in non-emergencies. Yet, the Act specifically protects individual interests from authoritarian actions in government. The governor of a state may be empowered to declare a state of public health emergency, but the legislature, by majority vote, may discontinue the declaration at any time. Similarly, courts may review whether a governor's actions fail to comply with the standards and procedures in MSEHPA. Thus, each branch of state government has a role in sustaining an emergency declaration consistent with constitutional principles of checks and balances.

Furthermore, the provisions of MSEHPA better protect individuals than most existing state laws. Under the Act, a public health emergency is viewed as a distinct event that requires specific governmental responses. The Act sets a very high threshold for the declaration of a public health emergency and further conditions the use of a defined and limited set of powers on the declaration and continuation of the emergency status. In many state public health laws, however, there are no definitive statutory criteria for the declaration of a public health emergency. Rather, existing state emergency management laws may be used to broadly address public health emergencies. Declaring a general state of emergency in response to a bioterrorism event may allow government to act in indeterminable ways to address the

public health threat. Lacking effective statutory guidance, public health authorities may have to rely on existing, antiquated statutory laws, or regulations that are hastily created in specific response to potential or unknown threats.

Information Sharing and Surveillance Measures. MSEHPA enhances existing state surveillance and reporting practices to facilitate the prompt detection of a potential or actual threat by requiring:

- Health care providers to report cases of bioterrorist-related or epidemic diseases that may be caused by any of the infectious agents listed in federal regulations or other non-listed agents;
- Coroners and medical examiners to report deaths that may have resulted from an emerging or epidemic infectious disease or from a suspected agent of bioterrorism;
- Pharmacists to report unusual trends in prescriptions for antibiotics and other medications used to treat infectious diseases in addition to substantial increases in the sale of various over-the-counter (OTC) remedies; and
- Veterinarians or veterinary laboratories to report animals having or suspected of having any diseases that may be potential causes of a public health emergency.

Reports are to be made within 24 hours to the appropriate health authority, and should contain identifying information about the reporter and subject of the report. Upon receiving a report, public health officials can use the information to ameliorate possible public health risks. They may contact and interview individuals mentioned in the report and obtain names and addresses of others who may have been exposed to the individual. The Act encourages the sharing of this data among public safety and emergency management authorities at the federal, state, local, and tribal levels to prevent, treat, control, or investigate a public health emergency. To protect individual privacy, officials are restricted from sharing any more information than necessary to control or investigate the public health threat. Stricter regulations in the Act govern access to the medical records and charts of individuals under quarantine or isolation where individual privacy interests may be heightened.

Managing Property. Once a public health emergency has been declared, MSEHPA allows authorities the power to seize private property for public use that is reasonable and necessary to respond to the public health emergency. This power includes the ability to use and take temporary control of certain private sector businesses and activities that are of critical importance to epidemic control measures. To safely eliminate infectious waste such as bodily fluids, biopsy materials, sharps, and other materials that may contain pathogens or otherwise pose a public health risk, authorities may take control of landfills and other disposal facilities. To assure safe handling of human remains, officials may control and utilize mortuary facilities and services. They are also authorized to take possession and dispose of all human remains. Health care facilities and supplies may be procured or controlled to treat and care for patients and the general public.

Whenever health authorities take private property to use for public health purposes, constitutional law requires that the property owner be provided just compensation. Correspondingly, the Act requires the state to pay fair compensation to the owner of any facilities or materials temporarily or permanently procured for public use during an emergency. Where public health authorities, however, must condemn and destroy any private property that poses a danger to the public (e.g., equipment that is contaminated with anthrax spores), no compensation to the property owners is required although states may choose to make compensation if they wish. Under existing legal powers to abate public nuisances, authorities are able to condemn, remove, or destroy any property that may harm the public's health.

Other permissible property control measures include restricting certain commercial transactions and practices (e.g., price gouging) to address problems arising from the scarcity of resources that often accompanies emergencies. MSEHPA allows public health officials to regulate the distribution of scarce health care supplies and to control the price of critical items during an emergency. In addition, authorities may seek the assistance of health care providers to perform medical examination and testing services.

Protection of Persons. Section 601 of MSEHPA states: "During a state of public health emergency, the public health authority shall use every available means to prevent the transmission of infectious disease and to ensure that all cases of contagious disease are subject to proper control and treatment." MSEHPA allows public health authorities to ask any person to be vaccinated or submit to a physical exam, medical testing or treatment, or provide a biological sample. Each of these measures may be needed to assist the individual and evaluate the epidemiologic consequences of an emerging condition during an emergency. These measures may be taken without any form of due process (e.g., right to a hearing) because individuals are free to choose to participate or not. Any person who may be impacted by a declaration

of a public health emergency that gives rise to systematic vaccination or testing programs may challenge the basis for declaring the emergency in court.

Although participation in vaccination, testing, or treatment programs is voluntary, those who choose not to participate and whose contagious condition may pose risks to others may be subjected to isolation or quarantine measures. The Act's quarantine and isolation provisions may be used to limit the freedom of individuals exposed to or infected with a contagious disease to circulate in the general public. Quarantine and isolation are classic public health powers. During non-emergencies, their practice is typified by limiting the transgressions of a very small number of persons whose behavior may lead to infecting others with a serious, contagious disease (like SARS) or other potential harms. During a public health emergency, where potentially thousands of persons are exposed or infected with a contagious disease, the use of quarantine or isolation powers may be widespread to protect community populations.

MSEHPA attempts to balance the welfare and dignity of individuals with communal interests in implementing quarantine or isolation measures. Accordingly, public health authorities must: (1) use Athe least restrictive means necessary to prevent the spread of a contagious or possibly contagious disease to others.@ Arbitrary or discriminatory quarantines will not satisfy this standard; (2) maintain safe, hygienic conditions for persons in isolation or quarantine that minimize the risk of further disease transmission; (3) provide adequate food, clothing, medication, health care, means of communication, and other necessities; and (4) adhere to strong due process protections for affected individuals.

Except where failure to quarantine or isolate persons immediately may significantly jeopardize the health of others, public health officials must obtain a court order before implementing these measures. The court can approve the use of isolation or quarantine only if the public health authority can show the measures are reasonably necessary to prevent or limit the transmission of a contagious or possibly contagious disease to others. Persons or groups subject to quarantine or isolation must receive written copies of orders accompanied by an explanation of their rights. They are entitled to be represented by counsel at individual or collective hearings to challenge the order generally or the conditions, terms, and treatment of their confinement. Even in cases of immediate quarantine or isolation, a court order must be sought as soon as possible.

Private sector HCWs are encouraged to assist in vaccination, testing, examination, treatment, quarantine, and isolation programs. The Act allows public health authorities to condition future licensing status of in-state HCWs on their providing assistance (where possible), and to waive licensing requirements for out-of-state HCWs who are willing to help. Thus, the Act does not compel any private HCW to participate in public health measures during an emergency. It does provide some strong incentives to encourage participation because of the critical role of private sector HCWs during a public health emergency.

Health Information Privacy. In the events leading to or during a public health emergency, MSEHPA envisions the need for a wide variety of federal, state, and local actors in the public and private sectors to share information that may relate to an individual's health status. Private sector HCWs may need to report identifiable health data to local public health authorities who may need to share this data with state and federal authorities to respond to a potential threat. Although there is a strong need to share such data for public health purposes, MSEHPA respects the privacy interests of individuals concerning their health data. The Act (1) limits the amount of information that may be conveyed to that which is necessary to respond to the public health emergency; (2) limits access to such data during an emergency to those persons having a legitimate need to acquire or use the information to provide treatment, conduct epidemiologic research, or investigate the causes of transmission; and (3) prohibits most disclosures outside the public health context. Additional privacy protections from the *Model State Public Health Privacy Act* of 1999 [by Lawrence O. Gostin and James G. Hodge, Jr] supplement MSEHPA, and are largely replicated in the comprehensive **Model State Public Health Act**.

CONCLUSION

Preparing for and preventing public health threats like SARS in the United States requires a strong national public health infrastructure. Federal, state, tribal, and local public health authorities must collaborate with public and private sector partners in preparedness planning and emergency responses. Working to improve public health detection, prevention, and response capabilities requires effective training, additional resources, use of existing and new technologies, and public health law reform. Inadequacies in existing state public health laws can fail to au-

thorize, or may even thwart, effective public health action. Law reform is needed to improve public health planning, detection, and response capabilities.

MSEHPA (and the forthcoming comprehensive model public health law) present a modern statutory framework of public health powers that allows public health authorities to better plan, detect, manage, and control public health emergencies. The provisions of the Act are balanced against the need to safeguard individual rights and property interests. Reaching this balance is not easy. Tradeoffs and compromise are inevitable. Legal reform may not be a panacea for the unforeseeable conflicts between individual and community interests that may arise from emerging threats like SARS. There continue to be sharp debates about the extent to which the state should restrict individual rights to safeguard the public's health and safety. Finding an acceptable balance that allows government to fulfill its duty to protect the public's health while respecting individual rights is a worthy goal. Ultimately at stake is the health of each individual, protected through a public health system that relies upon each person's contribution to the larger whole.

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Mr. GREENWOOD. Very good, Mr. Hodge. Thank you very much. Ms. Kerby, for 5 minutes. Welcome.

TESTIMONY OF KARIN KERBY

Ms. KERBY. Good afternoon Mr. Chairman, members of the committee. My name is Karin Kerby. I am a registered nurse and a Team Leader at Loudoun Hospital Center's emergency room in Leesburg, Virginia. I would like to thank you for the invitation to testify today especially on the issue of clinical staff safety as it relates to infectious disease triage and treatment.

On the morning of February 17, 2003, the Nation's capital had just experienced a 2-foot snowfall. As I made it in to my job, little did I know that awaiting me was the first suspected case of SARS in the U.S. At that point, there was, to our knowledge, no such dis-

ease. This was weeks before an emerging pattern was recognized and addressed by the WHO and the CDC.

This patient had just arrived by ambulance into our emergency department. Her symptoms were easy to recognize: she had acute shortness of breath, fever and cough. Her oxygen level was such that she required supplemental oxygen therapy and her chest x-ray revealed pneumonia. This particular patient was quickly moved from her stretcher into a room with oxygen. This happened to be our negative airflow room which, when activated, creates an environment where infectious airborne elements are vented away from the rest of the emergency department.

Approximately 2 hours after her arrival I received a phone call from her nephew which helped guide the course of events. He related to me that the patient had just returned from the Guangdong Province in China. He had just received information from their family in China that there was an "atypical pneumonia" in their area from which people were dying. This information correlated with what I had read in the Washington Post just a few days previous.

I alerted the emergency department physician and isolation procedures were reinforced and contacts with the Health Department and Infection Control were made.

The protocol that we developed after 9/11 guides us in reporting suspected bioterrorism and infectious cases. While the physician contacted the infectious disease specialist, I immediately called the Loudoun County Health Department's epidemiologist, Benita Boyer, to consult. She confirmed that there was a reported outbreak of an unidentified pneumonia in China, and agreed that this patient should be kept in isolation at this point.

The CDC, in conjunction with our Health Department and emergency department at the hospital, launched an epidemiological investigation, contacting every person who had come in contact with this patient; even isolating the emergency room physician for 3 days because she had a mild upper respiratory symptoms. Remember, SARS did not become a known entity until weeks later.

This event shows how, on any given day in any emergency department or physicians' office, a new, emerging threat to our society's health can present and infiltrate. An enormous amount of work and planning has taken place since 9/11 as we have struggled to research and develop protocols to respond to the threat of smallpox, and in our community the reality of anthrax, West Nile Virus and malaria. Countless hours and thousands of dollars of unbudgeted funds have had to be poured into training, surveillance, decontamination equipment and education of our staff.

However, no matter how prepared and equipped one is, there will always be that moment of vulnerability before we can respond when an unknown virus or bacteria may infect a triage nurse; it is a risk we in emergency medicine choose to take.

This event could have had a very different outcome. For example, had she been without proper isolation precautions and infection control measures, not only would our staff but our community would have been negatively affected.

Suffice it to say that since 9/11, if not before, the concerns related to infection control have migrated out of epidemiological de-

partments to the general public awareness via county health departments and local hospital ERs.

From my perspective as a staff nurse on the front line in the emergency department, I would offer these observations:

Hospitals should assume all patients suspected of having SARS risk factors are highly infectious until proven otherwise, since the various modes of transmission of SARS remain unclear.

To protect vulnerable patients, staff, visitors and the surrounding community, hospitals should activate all transmission precautions; including airborne, droplet, contact and contaminated material control measures.

Caregivers should not ignore the basics of personal protective equipment, which includes gowns, gloves, N-95 masks, goggles as well as particular attention to hygiene.

No. 2: No amount of training or preparedness can substitute for a well-informed public aware of an infectious disease and how to limit its spread. The difference between a person presenting to the emergency department stating, "I might have been exposed", and a person or physician calling us ahead to forewarn us of their arrival cannot be emphasized enough. Being able to isolate individuals BEFORE they enter a health care facility is absolutely imperative to stemming the spread among healthcare workers. The only way this can be accomplished is via public education.

Case in point: this past week I overheard a conversation between a Southeast Asian couple and their English as a second language instructor. I overheard them saying "We just heard about something called SARS." That was just last week. Why?

There is a large contingent of people in this country who either do not speak English, do not own computers, who work two or three jobs and never read a newspaper or watch TV. I submit that public education needs to immediately go forward in multiple languages using a variety of media to inform everyone of this disease.

As we have seen in Hong Kong, Toronto and China the impact on health has been devastating from infected health care workers to the overwork of those left to serve, creating unsafe isolation environments due to fatigue. Continued development of surge capacity plans for response to outbreaks, quarantine and the economic impacts must continue to be addressed between local hospitals, county and State health departments as well as Federal health authorities.

Thank you. I will be happy to address any questions you may have.

[The prepared statement of Karin Kerby follows:]

PREPARED STATEMENT OF KARIN KERBY, REGISTERED NURSE, TEAM LEADER, EMERGENCY DEPARTMENT, LOUDOUN HOSPITAL CENTER

Good afternoon Mr. Chairman, members of the committee. My name is Karin Kerby and I am a registered nurse and Team Leader for the Emergency Department at Loudoun Hospital Center in Leesburg, Virginia. I would like to thank the Committee for the invitation to testify today specifically on the issue of clinical staff safety as it relates to infectious disease triage and treatment.

On the morning of February 17, 2003, the nations' capital had experienced a 2-foot snowfall the previous day. As I made it in to my job, little did I know that awaiting me was the first suspected case of SARS in the U.S. At that point, there was, to our knowledge, no such disease. This was weeks before an emerging pattern was recognized and addressed by the W.H.O. and C.D.C.

A patient had just arrived by ambulance into our ED. Her symptoms were easy to recognize: acute shortness of breath, fever and cough. Her oxygen level was such that she required supplemental oxygen therapy and chest X-ray revealed pneumonia. This particular patient was quickly moved from her stretcher into a room with oxygen. This was our negative airflow room which, when activated, creates an environment where infectious airborne elements are vented away from the rest of the Emergency Department.

Approximately 2 hours after arrival I received a phone call from her nephew which helped guide the course of events. He related to me that the patient had just returned from the Guangdong Province in China. He had just received information from family in China that there was an "atypical pneumonia" in their area from which people were dying. This information correlated with what I had read in The Washington Post. I alerted the ED physician and isolation procedures were reinforced and contacts with the Health Department and Infection Control were made.

The protocol that we developed after 9/11 guides us in reporting suspected bioterrorism and infectious cases. While the physician contacted the infectious disease specialist, I immediately called the Loudoun County Health Department's epidemiologist, Benita Boyer, to consult. She confirmed that there was a reported outbreak of an unidentified pneumonia in China, and agreed that the patient should be kept in isolation at this point.

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This event shows how, on any given day in any Emergency department or physicians' office, a new, emerging threat to our society's health can present and infiltrate. An enormous amount of work and planning has taken place since 9/11 as we have struggled to research and develop protocols to respond to the threat of smallpox, and in our community the reality of Anthrax, West Nile Virus and malaria. Countless hours and thousands of dollars of *unbudgeted* funds have had to be poured into training, surveillance, decontamination equipment and education of our staff.

However, no matter how prepared and equipped one is, there will always be that moment of vulnerability before we can respond when an unknown virus or bacteria may infect a triage nurse; it is a risk we in emergency medicine choose to take.

This event could have had a very different outcome. For example, had she been without proper isolation precautions and infection control measures, not only would our staff but community been negatively affected.

Suffice it to say that since 9/11, if not before, the concerns related to infection control have migrated out of Epidemiological Departments to general public awareness via county health department's and local hospital ER's. If there is an additional action that has come about not just related to SARS, but infection threats in general, it has been this migration to the forefront of triage and public venues for education.

From my perspective as a staff nurse on the front line in an Emergency department, I submit the following observations:

1. Hospitals should assume all patients suspected of having SARS risk factors are highly infectious until proven otherwise, since the various modes of transmission of SARS remain unclear. To protect vulnerable patients, staff, visitors and the surrounding community, hospitals should activate all transmission precautions; including airborne, droplet, contact and contaminated materials control measures. Caregivers should not ignore basics of Personal Protection Equipment, which includes gowns, gloves, N-95 masks, goggles as well as particular attention to hygiene.
2. No amount of training or preparedness can substitute for a well-informed public aware of an infectious disease and how to limit its spread. The difference between a person presenting to the ED stating, "I might have been exposed"... and a person or physician calling ahead to forewarn of their arrival cannot be emphasized enough. Being able to isolate individuals BEFORE they enter a health care facility is absolutely imperative to stemming the spread among healthcare workers. The only way this can be accomplished is via public education. Case in point: this past week, in a conversation between a Southeast Asian couple and their ESL instructor I overheard the following: The couple asked about "something called SARS". They were just last week hearing about this! Why? There is a large contingent of citizens in this country who do not speak English, who do not own computers, who work 2 or 3 jobs and never read a newspaper or watch TV. I submit that public education needs to immediately

go forward in multiple languages using a variety of media to inform everyone of this disease.

3. Hospitals in the US are not generally equipped to handle large outbreaks of this disease. Most hospitals have limited numbers of isolation beds, many of which are already taken by Tuberculosis patients. The expense involved in creating more negative-airflow rooms to accommodate more patients is almost cost-prohibitive and few hospitals have the budgeted amounts to spend on this as-yet emerging threat.
4. As we have seen in Honk Kong, Toronto and China, the impact on healthcare has been devastating, from infected healthcare workers to the overwork of those left to serve creating unsafe isolation environments due to fatigue. Continued development of surge capacity plans for response to outbreaks, quarantine and the economic impacts must continue to be addressed between local hospitals, county and state health departments as well as federal health authorities.

Thank you. I will be happy to address any questions you may have.

Mr. GREENWOOD. Thank you very much. It is very interesting, indeed.

The Chair recognizes himself for 10 minutes for questions.

And let me begin with Dr. Bloom. In your testimony on page six you discuss the creation of scientific linkages between health ministries and institutions around the world, and in this country, including the World Health Organization sharing in technology and knowledge to protect all of us from emerging threats. Do you believe that the public health and scientific response to SARS has in fact created the start of such a scientific linkage?

Mr. BLOOM. I wish I were so optimistic. I think it has created both the opportunity and the awareness of the value, but those linkages are very hard to establish.

As I indicated, funding for students from developing countries for any kind of educational program here are extremely difficult to come by. Collaborative research projects between countries and institutions in the U.S. are very difficult to establish. It is very hard to get long term commitments.

The greatest desire and need have been——

Mr. GREENWOOD. Commitments from whom?

Mr. BLOOM. Pardon me?

Mr. GREENWOOD. Hard to get commitments from whom?

Mr. BLOOM. From the Federal Government, from most of the usual foundation sources. The amount of resources with the exception of the Gates Foundation, which is a private rather pioneering organization and trying to create that is a rare exception.

My sense from our students, a tremendous interest in global health from domestic students as well as international students, and that which is most desired in these countries is our knowledge, the access to knowledge, which I would argue we should be willing to provide in return for the information we need about the health status to protect our own country.

Mr. GREENWOOD. Thank you.

Let me direct a question to Mr. Hodge, if I might.

If a State or local quarantine law was found invalid to confine patients infectious with a deadline disease, are there Federal laws and regulations that would serve as a secondary source of quarantine authority?

Mr. HODGE. A very good question, Mr. Chair. We heard some testimony from Dr. Gerberding to that effect, and I can honestly say I think she very much got it right. The Federal authority in relation to quarantine or isolation is rather limited to the use of that

for the purpose of border protections as well as intrastate spread of a particular epidemic disease or otherwise.

So as a result to the extent to which we have the quarantine or isolation authority in every other setting, it largely does reside at a State or local level. And it is the case that we have seen certain instances of the use of that be egregious in relation to constitutional norms or otherwise. And I do not mean recently, but certainly in our Nation's history in the past.

I would dare say that the scenario more likely to spin is that a court reviewing a statutory authorization for quarantine may look to impose the sort of constitutional protections that these statutes might not.

Our model act, for example, talks about the need for potentially advanced due process where necessary, the potential to keep that use of a course of power to the least restrictive means necessary, not to be overboard or, certainly, in anyway try to infringe individual rights beyond what is needed.

So I think in deference to what Dr. Gerberding said, the use of Federal quarantine power would be legitimate in a federally constitutional sort of way, but otherwise we would have to defer to a State or local authority.

Mr. GREENWOOD. And this is a question of Ms. Kerby. Do you believe your hospital center has been positively impacted by the Federal investments in bioterrorism preparedness, and did it help your hospital's preparedness in this response to the SARS case you just described?

Ms. KERBY. I do believe that they have been encouraging. The funds that we have been allocated have actually not arrived, but we have been assured that—we have gone forward with most of our planning and preparedness with unbudgeted funds. And we are anticipating support from the Federal Government.

Mr. GREENWOOD. Okay.

Dr. Benjamin, in your testimony you stated that the problem of emerging infectious diseases is likely to become more acute in the future and that the Institute of Medicine attributes the surge of infectious diseases to 13 specific changes in the world and in the way we live. Which changes are most important, and are these changes ones that are realistically within our control to alter?

Mr. BENJAMIN. A great question. You know, I think there are several things that are important, maybe two or three.

One, obviously, we humans are coming more in contact with parts of the world in which we probably had not been in contact before. That is one. But I think the biggest is the speed in which we do everything. Speed of travel makes a significant difference on the impact of this world in terms of these emerging infections, how quickly they can get to us.

And the other part that was kind of not talked about a lot is the fact that we are on the verge of having the capacity to make these organisms ourselves. And that is also a significant threat in terms of emerging infections. And maybe not to do harm to ourselves, but simply all you have to do is have someone to work with an organism in a lab and that organism get out. So you still have significant problem with that.

So, I mean, those two or three things, I think, as I think through those issues are probably the biggest ones that we have to deal with.

Now, what do we do about them? We are probably going to continue to move very fast in travel. And I do not know if that is going to change much. But I do think we can certainly give it more thought as we do the science. We certainly can be more thoughtful about the effects of the environment on our plant. I do not think we understand exactly all the impacts of that, but we can certainly be a lot more thoughtful of that.

I think what it really means is all those 13 factors argue for a much stronger public health system so that we can act quicker when these things happen.

Mr. GREENWOOD. The last time I got on an airplane to fly back to the United States, as I was leaving my hotel room I saw the basket, I hadn't completed eating the basket of fruit on the table. And being sort of tightwad, I decided to put all of the remaining fruit into my bag. And I thought maybe I would eat it on the way to the airport, but I did not. And so I got to the airport and I had to unload these beautiful pieces of fruit into the trash can.

Mr. BENJAMIN. Yes.

Mr. GREENWOOD. We have a pretty good system of being asked now. I was asked do you have any fruit with you, and that sort of thing, any plants and a variety of questions. Pretty good at that aspect, but of course there is nobody asking me or being able to determine what sort of critters might be in my body.

Do we need to get to the point where we start to think seriously with international travel being what it is and, as you said, Americans going into remote places with greater and greater frequency in a global business environment, for instance, global tourist environment where we need to have different kinds of screening or at least different questions asked of passengers before they board planes to come to the U.S. and after they get off the plane and are coming through Customs?

Mr. BENJAMIN. Let me state that——

Mr. GREENWOOD. And I would ask anyone who would like to respond to that to do so.

Mr. BENJAMIN. Yes. Let me step back and say I do not know that questioning is the right answer. I think we need to understand what protections we need to put in place to identify people who are at risk. And not do some of the things we had to do after September 11, very draconian things in terms of us now getting through the airport and those kinds of things. I think we need to study it.

Mr. GREENWOOD. I mean, it is one thing to take my shoes off at the airport. Now do I have my temperature taken now?

Mr. BENJAMIN. Yes. Well, see, those are some of the kinds of things, you know. Ask the question, you know, the fact that you have a temperature, does that really put everyone at risk? It may or may not. This is a very, very broad case definition. And I would suspect if someone simply did a study on the number of people that went through airports that had fever, you may very well find that that number is higher than one might think. I do not know that, but I think we need to study it.

So that is the kind of practical research that absolutely has to be done so that we can answer your question.

Ms. KERBY. If I might, I have had some experience with a few patients who have traveled and then come to our emergency departments, having had received the little yellow informative thing from the CDC. They do not read it, other than to see that, oh, I need to go to a doctor if I have a fever. They do not read all of it knowing—we are trying to tell them they need to call ahead, they need to consult with someone on the phone and not sit in a waiting room.

So my point once again is education in all languages and all venues so people will be better prepared to understand it. They just do not get it.

Mr. GREENWOOD. One wonders if that ought to be something one sees on the video screen in an airplane in the way as opposed to something that is handed and more paper that we do not read.

Any other comments in response to my question?

Okay. My time has just about expired. And the gentlelady from Colorado is recognized for 10 minutes.

Ms. DEGETTE. Thank you, Mr. Chairman.

Ms. Kerby, as I heard your rivetting story about the patient who came in, I could not help but wonder what would have happened under two scenarios. The first one, what would have happened if that room had not been available, just coincidentally? Because you would have just put that patient in a regular room, I assume, right?

Ms. KERBY. That is correct.

Ms. DEGETTE. And the second thing I was wondering is what would have happened if the family member had not called and said "Oh, we heard this rumor that something was going on in China." And what I am wondering is at that early stage, that was February you said?

Ms. KERBY. Yes, ma'am.

Ms. DEGETTE. I am wondering in your view could there have been better alerts, at least to hospitals and health care professionals that there was something going on in China, so at least even if all this global effort we are making now had not been called for yet, if you would have had some way as an institution to know there was something going on and to look for those symptoms?

Ms. KERBY. I think that currently the CDC does an incredible job of alerting us. Our health department are constantly sending us updates on any emerging threat.

When you look back to this particular situation, there was a very small window where information came out of China, and that is what I happened to have read in the paper. If I am not mistaken, it was about a week's worth of information and then it was shut down again and the information did not come out of China. So I think we were hampered by the lack of information.

So, I do not see how it could have been any different at that time. Right now the openness of the entire world at this point seems to be helping all of us be aware.

Ms. DEGETTE. But see here is the thing, and maybe someone else has a comment on this as well, if you read it in the newspaper there was information about this that was coming to the United

States. Does anyone else have a view of how we can take even limited information like that and make it of some use to health care institutions? Because, frankly, if that person had not been isolated and the family member had not called, we would have had a much more serious SARS outbreak in this country right now that we were dealing with.

Mr. BENJAMIN. Let me say that right now as an example, CDC has told us about some early influenza cases that we need to be concerned about in another country. So that kind of thing does happen when you get the information, and it has gone out to both the public health community and the practicing medical community through their health alert network.

Now, again, the problem is, is that when I used to work in hospital emergency departments you get one of those little things and you print it out, and it gets tacked on the information board. And it may very well not be read by all and taken down at some point in time and trashed.

So, consistent communications is just, as Ms. Kerby said, the only way to do it is to just continue to keep it in the minds of the public, the minds of the public health community, the minds of the acute care medical community.

Ms. DEGETTE. But it sounds like with SARS we knew something was going on in the early stages in China, at least for a short window, and it sounds like those kind of warnings were not at that early stage given to hospitals. And believe you me, I think it is fantastic what the CDC does. But I am just wondering if there is something else we could be doing?

Ms. Bloom?

Ms. BLOOM. Part of the problem was and is the fact that the World Health Organization, for example, or any other national government cannot get into a country unless they are invited in. So, in fact, there is a Net program called ProMed that in November of last year was reporting an atypical pneumonia epidemic in Guangdong China, but no one could verify that because no one could get in. And that becomes very difficult unless you have actual people on the ground, and that would be one advantage to maintaining long term linkages.

Ms. DEGETTE. Do you think that the recent experience with SARS will help some of these countries like China understand that they do need to let the World Health Organization in earlier? Do you think it will help with the worldwide communication?

Ms. BLOOM. It has clearly transiently done so, and the question and the kind of intimation that concerned me from Dr. Heymann's statement is the pipeline still open for information or as we try to reach the more remote areas, will the data be accessible. We do not know.

Ms. DEGETTE. Dr. Bloom, continuing with you, in your testimony you criticized the decision to cut the National Center for Infectious Diseases at CDC by $8 million in fiscal year 2003, and I think you talked about that specifically as we are increasing other areas. I am wondering if you have any recommendations to the Congress and the President for the next budget request, and what evidence you would have to support those requests?

Ms. BLOOM. I am enormously grateful for the question. I am not a budget expert. But I think the advice that you have heard from this panel, I would support strongly, which is there is something called emerging infections. We do not know what they are, what they will be, whether they will be new or old. We know they will come and that some of them will be serious. And the agencies have money so targeted for anthrax or smallpox that when something new comes, I do worry. What if we were to have West Nile coming up soon, while people are in China and Singapore and all over the world from CDC looking at SARS? And if there were a food borne outbreak in this country in addition, would they have the surge resources? And my sense is what we need is funding for a category called emerging infections. And I would trust these people to have the best judgment imaginable where to put their personnel and resources to make the biggest difference.

Ms. DEGETTE. Do you have a comment on——

Mr. BENJAMIN. Yes, I can get that number back to you for the record, but——

Ms. DEGETTE. I would appreciate that.

Mr. BENJAMIN. But the American Public Health Association is part of something called the CDC Coalition, and we have been specifically asked this year as we go through the rest of the appropriations process for the CDC.

Ms. DEGETTE. Thank you.

Well, while I am on you, Dr. Benjamin, I have another question, which is in your written testimony and also you alluded in your verbal testimony today, you say that Congress needs to start supporting our public health base in a more holistic way. I am wondering if you can elaborate on your recommendations to this committee to ensure that the Nation's public health care infrastructures are adequately prepared and able to deal with these public health crises?

Mr. BENJAMIN. You know, one of the things that we do with public health systems is we basically play a shell game. We fund something on the left and we take it away on the right. You know, and not recognize the inner relationship between the two. Let me give you a couple of examples.

When we are doing smallpox vaccinations, many of the people that helped us do those vaccinations are school health nurses. So if you cut the school health programs, you have not gotten any additional capacity. Or if you use the Federal funds to hire epidemiologists and then the State funds get cut, you have not accomplished any additional capacity.

Purely at the Federal level when we had the anthrax attacks, in fact right after September 11 to man a lot of the epidemiologic support in the Washington metropolitan region here, we were taking folks from our chronic disease program, from our AIDS programs, from our injury programs; a broad range of programs. Obviously that, from a public health perspective, that is our surge capacity when something happens. So when that overall capacity disappears or diminishes, you are actually taking away capacity.

So, you know, it is great that we are putting a billion dollars into public health, you know, each year for the last couple of years, but at the same time we are not looking at the whole system recog-

nizing relationships between some of these other very, very important programs, which not only protect us for bioterrorism, but protect us for diseases that are here today. So they protect us for, you know, adult immunizations, childhood diseases, food safety; all of those kinds of things are extraordinarily important as the base to build a strong preparedness system, Ms. DEGETTE. Thank you.

I yield back.

Mr. GREENWOOD. Did the gentleman from Florida wish to inquire?

In that case, the Chair thanks each and everyone of the panelists for your traveling to be with us and for your very valuable assistance. Thank you.

You are excused. And the Chair would call the third panel, which consists of Mr. John M. Brenna, President and Chief Operating Officer of Computerized Thermal Imaging, Inc. from Lake Oswego, Oregon.

Dr. Robert J. Capetola, President and Chief Executive Officer, Discovery Laboratories, Inc. of Doylestown, Pennsylvania.

Dr. Paul H. Fischer, Ph.D., Chief Executive Officer of GenVec, Inc.

Dr. Nils Lonberg, Ph.D., Senior Vice President, Scientific Director of Mederex, Inc. from Milpitas, California.

Welcome, gentlemen. I think most of you have been here all afternoon and so you know the drill. This is an investigative hearing, and when we hold investigative hearings we take testimony under oath. And so I need to ask if any of you object to giving your testimony under oath. Seeing no such objection, then I would need to advise you that you are entitled to represented by counsel today if you choose. Do any of you wish to be represented by counsel? Okay.

In that case, if you would stand and raise your right hands.

[Witnesses sworn.]

You are under oath.

And, Dr. Brenna, we will begin with you and ask you to give an opening statement for about 5 minutes.

TESTIMONY OF JOHN M. BRENNA, PRESIDENT AND CHIEF OPERATING OFFICER, COMPUTERIZED THERMAL IMAGING, INC.; ROBERT J. CAPETOLA, PRESIDENT AND CHIEF EXECUTIVE OFFICER, DISCOVERY LABORATORIES, INC.; PAUL H. FISCHER, CHIEF EXECUTIVE OFFICER, GenVec, INC.; NILS LONBERG, SENIOR VICE PRESIDENT, SCIENTIFIC DIRECTOR OF MEDEREX, INC.; AND DENIS R. BURGER, CHIEF EXECUTIVE OFFICER, AVI BIOPHARMA

Mr. BRENNA. Good afternoon, Mr. Chairman and members of the subcommittee. On behalf of Computerized Thermal Imaging I thank you for the opportunity today to testify as to how infrared imaging can be used for SARS screening. My name is John Brenna and I am the President of the company. The material I will present is based on recent experiences learned from our technology being used in China for SARS Screening.

Before I begin, Computerized Thermal Imaging is a small manufacturing company, specializing in medical and industrial applications for infrared camera technology. These cameras are sensitive

scientific instruments that measure heat and temperature changes. Our industrial products were developed for non-destructive testing, principally for turbine blades to reveal minute imperfections that could result in a catastrophic turbine blade failure.

Our medical products are used primarily in the field of pain management. And in 1999, we started an FDA Pre-Market Approval process for a noninvasive infrared breast imaging system, which studies have shown can be used as an diagnostic adjunct to mammography x-ray to reduce biopsies of benign masses. This product application is currently pending, and we are working with FDA to obtain approval.

The CDC tells that SARS is an atypical pneumonia transmitted by contact with body fluids and air particles coughed or sneezed by an infected person. Symptoms may include respiratory distress, coughing, shortness of breathe, and breathing difficulty and is accompanied by a fever greater than 100 degree Fahrenheit. A chest x-ray finding of pneumonia or respiratory distress syndrome is the only known way now to confirm SARS: although other companies are working on various serum blood tests.

Our authorized dealer in China has been working with various provincial health care administrators over the past several weeks and have installed six of our infrared cameras specifically for SARS screening. Four of the cameras are located at hospital entrances, one at a railway depot ticket counter, and one at an airport with a special health care screening gate. The magnitude of the challenge facing China is staggering, with over 300 major airports, over 1,000 railway stations and over 12,000 medical hospitals. These are crowded mission critical facilities that are, unfortunately, terrific amplifiers for any airborne disease.

The early learning experiences indicate that using infrared camera technology for SARS screening has been beneficial. When a human image is taken with an infrared camera, we know that skin temperature is lower than the normal 98.6 degrees Fahrenheit body temperature. This is the result of well studied heat evaporation, conduction and convection principles.

Medical specialists in China use a facial temperature baseline of 33 degrees centigrade or 91.4 degrees Fahrenheit as the upper limit for normal healthy temperature. When an infrared image indicates a body temperature above this baseline, the subject's body temperature is taken with a thermometer and then checked for respiratory distress symptoms. A chest x-ray at the screening location or nearby clinic may then be used to confirm the presence of a pneumonia.

Now I have an example of the kind of images that are used in this process. By using gray scale, imaging techniques and temperature thresholds there are no interpretation requirements. The screening test is either positive or negative. And you will note the normal image on my right is an image of a subject exhibiting a facial temperature below 33 degree centigrade. And highlighted in red, okay, is the suspicious image detecting a skin temperature above 33 degrees centigrade. That suspicious condition can also be signaled by an audible alarm.

Early results provided by our dealer distributor, indicate that half of the subjects screened, who had temperatures exceeding 33°

centigrade required further examination and treatment. The other half of the subjects following initial examination were found to be false positives caused by some form of physical exertion, pharmaceuticals, menopausable activity or metabolic disorder.

The Computerized Thermal Imaging infrared camera is a scientific instrument designed to image the human body skin temperatures. And let me briefly explain.

First, the camera is "radiometric" meaning it measures actual skin temperature. Most other cameras measure "relative" heat, which differentiates humans from inanimate objects, as used in military or weather forecasting applications.

Second, the camera was designed with "high sensitivity", meaning using a Mercury Cadmium Telluride detector providing optimal measurements for human temperatures in the 20 to 40 degree centigrade range.

This technology detects infrared transmissions in the wavelengths range of 8 to 12 microns. The human body's peak emission wavelength is about 10 microns. Thus, our technology is optimized for human applications.

Most other infrared cameras operate in the three to five micron range and are designed for industrial applications.

And finally, the system captures images dynamically in near real time, providing the capability for high volume throughput for volume screening as passengers and subjects pass through security check points.

In a single screening line one system can image up to 12 subjects per minute or over 700 per hour yielding a "positive" or "negative" test result.

In closing, we are learning much from the experiences in China. Infrared camera technology offers much promise as a first defense early warning indicator. We know that Mercury Cadmium Telluride detectors optimally capture human infrared frequencies. And that "radiometric" technology works best for human temperature measurement accuracy.

I would strongly recommend to this subcommittee that additional Government research and development support be considered for advancing infrared technology as a SARS screening device, including consideration for establishing a trial site or sites at a high risk or at high risk international entry locations.

I thank you for the opportunity to appear today.

[The prepared statement of John M. Brenna follows:]

PREPARED STATEMENT OF JOHN M. BRENNA, PRESIDENT, COMPUTERIZED THERMAL IMAGING

Good afternoon ladies and gentlemen. On behalf of Computerized Thermal Imaging I thank you for the opportunity today to testify before this sub-committee as to "How Infrared Imaging could be used for SARS Screening". My name is John Brenna and I am the president of the company. The material I will present is based on recent experiences learned from our technology being used in China for SARS Screening.

Before I begin, Computerized Thermal Imaging is a small manufacturing and research and development company located in Portland, Oregon and Ogden, Utah. Our core competence is specializing in medical and industrial applications for Infrared Camera technology. These cameras are sensitive scientific instruments that measure heat and temperature changes.

In industry, our technology is used for non-destructive testing, principally for turbine blade testing where conventional forms of testing fail to reveal minute imperfections that could result in a catastrophic failure.

Our medical products are used primarily for the location and therapeutic treatment of pain and pain management. In 1999, we started the FDA Pre-Market Approval process for an infrared breast imaging system that provides physiological information, which studies have shown can be used as an diagnostic adjunct to mammography x-ray to reduce biopsies of benign masses. This product application is currently pending, and we are working with FDA to obtain approval.

We are fortunate to have an authorized dealer in China who has been working with various provincial healthcare administrators over the past several weeks, and has installed six of our infrared cameras specifically for SARS screening. Four of the cameras are located at hospitals, one at a railway depot and one at an airport. The magnitude of the challenge facing China is shown by their having over 300 major airports, over a 1000 railway stations and over 12,000 hospitals.

Their early learning experiences indicate that, using Infrared camera technology for SARS screening has been beneficial.

We know that SARS is an atypical pneumonia transmitted by contact with body fluids and air particles coughed or sneezed by an infected person. Symptoms may include respiratory distress, coughing, shortness of breath and breathing difficulty and is accompanied by a fever greater than 100 degrees Fahrenheit. A chest x-ray finding of pneumonia or respiratory distress syndrome is the only known way now to confirm SARS: although other companies are working on serum blood tests.

As I mentioned earlier, our infrared cameras are at four hospitals, one railway station and one airport; these are crowded, mission critical facilities that are, unfortunately, terrific amplifiers for any airborne disease.

When a human image is taken with an infrared camera, we know that skin temperature is lower than the normal 98.6 degrees Fahrenheit body temperature, because of well-studied heat evaporation, conduction and convection principles. Medical specialists in China use a facial temperature baseline of 33 degrees centigrade or 91.4 degrees Fahrenheit as the upper limit for normal healthy temperature.

Let's now turn to the practical application of the technology to SARS Screening and the logistical considerations that must be addressed.

At the airport, a special health-screening gate was established to detect facial temperatures exceeding 33 degrees centigrade, before a passenger passes through security. At the railway station, passengers are screened at the ticket counter and at the hospitals all patients and visitors are screened.

A temperature reading above 33 degrees centigrade signals a potential fever. When a fever like symptom is detected, the subject's body temperature is taken with a thermometer and then checked for respiratory distress symptoms. A chest x-ray at the screening location or nearby clinic may then be used to confirm the presence of pneumonia.

These are example images of the screening process. You will note the "normal" image of a subject exhibiting facial skin temperature below 33 degrees centigrade and the abnormal image detecting skin temperature above 33 degrees centigrade. The abnormal condition can also be signaled by an audible alarm. (See attachment)

This is what the Infrared camera system looks like. (See attachment)

Early results provided by our dealer distributor, indicate that half of the subjects screened, who had temperatures exceeding 33 degrees centigrade required further examination and treatment. The other half of the subjects, for which examination was required, were false positives caused by some form of physical exertion or pharmaceuticals.

The Computerized Thermal Imaging infrared camera is a scientific instrument designed to image the human body skin temperatures. Let me explain in more detail:

First, the camera is "radiometric" meaning it measures actual skin temperature. Most other cameras measure "relative" heat, which differentiates humans from inanimate objects, as used in military or weather forecasting applications.

Secondly, the Computerized Thermal Imaging camera was designed with "high sensitivity" using a Mercury Cadmium Telluride detector providing optimal measurements for human temperatures in the 20 to 40 degree centigrade range.

This technology detects infrared transmission in the wavelengths range of 8 to 12 microns; those are wavelengths between 8 and 12 millionths of an inch. The human body's peak emission wavelength is about 10 microns. Thus, our technology is optimized for human applications.

Most other infrared cameras are either not radiometric, meaning they do not measure actual temperature, or do not operate in the 8 to 12 micron spectral range for sufficient resolution and accuracy. Most operate in the 3 to 5 micron range and are designed for industrial applications.

And last, the Computerized Thermal Imaging system captures images dynamically in near real time, providing the capability for high volume throughput as subjects pass through security check points. Just one of the systems can image up to 12 subjects per minute or over 700 per hour yielding a "positive" or "negative" test result. Subject images for storage and retention purposes are structured in common Microsoft ACCESS and compatible with standard WORD and Microsoft programs.

In closing, we are constantly learning from the experiences in China. Infrared Camera technology offers much promise in SARS screening as it measures facial body temperature as a first defense early warning indicator. We know that Mercury Cadmium Telluride detectors optimally capture human infrared frequencies. And that "radiometric" technology works best for temperature measurement accuracy.

The SARS death toll is rising. SARS clearly is a global microbial threat.

I would strongly recommend to this sub-committee that additional government research and development support be considered for advancing infrared technology as a SARS screening device; including consideration for establishing a trial site or sites at high risk international entry locations.

I thank the sub-committee for this opportunity to describe infrared camera technology as a potential means for first defense SARS Screening.

Mr. GREENWOOD. Thank you, Mr. Brenna. That is certainly interesting.

Dr. Capetola?

TESTIMONY OF ROBERT J. CAPETOLA

Mr. CAPETOLA. Mr. Chairman, thank you very much. Members of the committee as well.

My name is Bob Capetola. By training I am an experimental clinical pharmacologist, having spent about 30 years in the pharmaceutical business and drug discovery through drug development and having been fortunate enough to put a lot of drugs on the market that are in use today.

Our company is a biotechnology company devoted toward development and commercialization of surfactant replacement therapy for respiratory diseases. And as you saw from our written testimony, the primary diseases that we are focused on at the moment at critical care diseases, principally focused in premature babies at the moment, but also as you see, from phase two trials we are in a condition called acute respiratory distress syndrome, which is the ultimate manifestation of something like SARS.

So our company, as you saw today from the testimony of the first two sessions, the major focus of a industry and government effort at the outset of something like this is to throw the resources toward the two primary focuses, and that would be antiviral drug screening and also the development of vaccines.

I think having been experienced in this business for several decades, you are probably aware from previous testimony that antiviral drugs are probably the most difficult drug discovery targets in all of the pharmaceutical business, principally because they are so simple. And if they are so simple, they do not have defined targets that can differentiate them from normal cell processes. Even a bacteria is many fold times more complicated than a virus, and that is why we have very effective antibiotic drugs but not very effective antiviral drugs.

Vaccination in terms of treating therapy at the outset is probably the best approach in the near term. But you heard what the near term means from Dr. Fauci, 3 years at best, most likely five to seven if everything goes very, very well. And that is if the virus does not mutate at a rate that would be unexpected.

So while companies are here discussing ways of essentially killing the virus, our company is focused on treating the patients with the fundamental pathological defect that they are undergoing and ultimately leads to their chronic sickness and ultimately, perhaps, morbidity and mortality. And that is in the lung, the lung exists to house about 250 million little air sacs. These air sacs go by the name of alveoli. And each one of us here has those. And we have inside that air sac in a monolayer something called the human surfactant system.

Now during an inflammation of the lung, whether it be from the SARS virus, the pneumococcal bacteria, whether it be from trauma, aspiration of gastric contents, near drowning, smoke inhalation, anything that traumatizes that alveolar or that air sac network, leads to a migration into that air sac of classic white blood cells which can destroy, along with the protein and fluid that come from the circulatory system, destroy the surfactant that exist in the lungs. That is why these SARS patients go into the hospital. And if they progress to the point where they need mechanical ventilation, that really means that most of the little air sacs have collapsed. And they have collapsed because so much of the surfactant system is destroyed.

Surfactants keep the lungs open. Surfactants are critical for life. They are critical for breathing.

So our company is devoted toward the development of these products in a variety of respiratory diseases. One of them is the ARDS condition. ARDS stands for acute respiratory distress syndrome. These would be the sickest patients that would go through the SARS episode. These patients are in the critical care unit. They are mechanical ventilation. If you do not open up a bunch of those lung air sacs that we talked about previously, these patients are going to have decreased oxygenation in their arterial blood, and that is when the vital organs begin to shutdown.

So our approach, and the approach that we are in right now as phase II B trial in the United States with ARDS and soon to enter ten sites in Toronto, is likely to enter a SARS patient in the not distant future, is to treat the patients basic defect. That is, we are not going to kill the virus, but we are going to keep the patient alive long enough by replacing the damaged surfactant so that their endogenous immune system can take over and, perhaps, maybe get the patient well sooner and off the ventilator. Because it is an axiom in critical care medicine the length of time on the chemical ventilation is associated with a poor clinical outcome.

So in the interest of time, we have put a pretty extensive written testimony which describes how surfactants work. They are not, certainly, trivial drugs. They are very complicated biotechnology drugs. And all that we ask that this committee serve to be a catalyst in conveying this important message that the surfactant replacement therapies can be included in the assessment of therapies currently under consideration by the various health authorities.

Thank you.

[The prepared statement of Robert J. Capetola follows:]

PREPARED STATEMENT OF ROBERT J. CAPETOLA, PRESIDENT AND CHIEF EXECUTIVE OFFICER OF DISCOVERY LABORATORIES, INC.

Severe **A**cute **R**espiratory **S**yndrome (**SARS**) is an acute respiratory illness in which patients have difficulty breathing.[1] The path of SARS is a highly contagious viral infection[2] that leads to pneumonia, and in severe cases, progresses to life-threatening **A**cute **L**ung **I**njury (referred to as ALI), the most serious manifestation of which is Acute Respiratory Distress Syndrome (referred to as ARDS). A prominent characteristic of ARDS is the destruction of a patient's lung surfactant.[3] Surfactants are produced naturally in the lungs and are essential for breathing. (*See* Illustration 1). Should these surfactants degrade or be destroyed, millions of alveoli, or tiny air sacs, in the lung collapse, airflow becomes constricted and the lungs do not absorb sufficient oxygen. (*See* Illustration 2).

No proven treatment for SARS presently exists. For now, SARS treatment amounts to keeping patients isolated and dealing with their symptoms while the infection runs its course. SARS patients are currently getting the same treatments as patients suffering from pneumonia or other respiratory infections, including antibiotics to combat bacterial infections, mechanical ventilation to help them breathe, and treatment for fever.[4] With the number of world-wide SARS cases approaching 6,000, the lack of an effective treatment has resulted tragically in at least 400 deaths, or a mortality rate of greater than 6.5%.

Although public health officials are hopeful that the spread of SARS may have temporarily peaked, at least outside China, most researchers fear that SARS will return in force next winter.[5] An additional concern is that the virus could be quickly mutating and new SARS strains, possibly more virulent forms, are likely to develop. Indeed, Hong Kong has recently reported that a dozen former SARS patients had relapsed, indicating that treating the disease may be even more difficult than expected.

World health authorities, including the United States National Institutes of Health, are taking a logical first step to address the SARS virus by searching for an effective antiviral treatment. They are urgently screening a number of virus-fighting drugs, medicines already on the market or close to it, including protease inhibitors and compounds that block viral replication. No antiviral presently exists that is specifically aimed at this coronavirus (the form of virus identified by the CDC and the World Health Organization as the cause of SARS). Even the ribavirin/steroid "cocktail" that doctors in Asia and Canada had been using extensively to treat SARS has been abandoned because of lack of effectiveness in combating the disease and harmful side effects, with many patients suffering anemia and liver inflammation because of it. Dr. Anthony Fauci, Director of the National Institute of Allergy and Infectious Diseases, has commented that he hopes to have a possible vaccine ready for human testing in just over a year. But Dr. Fauci has cautioned that it would still be years before a vaccine would be available for distribution and that its development can never be guaranteed.

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[1] The Centers for Disease Control (CDC) has identified that SARS patients can experience dry cough, shortness of breath and difficulty breathing because of lung congestion.

[2] Scientists believe that SARS is caused by a newly discovered coronavirus, a member of a family of viruses linked previously to mild cold symptoms in humans. *Sorting the Facts, Guesses and Mysteries of SARS,* The Wall Street Journal, May 2, 2003, at B1 (hereinafter *Facts and Mysteries of SARS*).

[3] ARDS is characterized by an excess of fluid in the lungs, decreased oxygen levels, and the destruction of surfactants present in lung tissue. *See generally* Gregory TJ, Steinberg KP, Spragg R, Gadek JE, Hyers TM, Longmore WJ, Moxley MA, Cai G-Z, Hite RD, Smith RM, Hudson LD, Crim C, Newton P, Mitchell BR and Gold AJ, Bovine Surfactant Therapy for Patients with Acute Respiratory Distress Syndrome, Am J Respir Crit Care Med 155:1309-1315 (1997); Ashbaugh DG, Bigelow DB, Petty TL and Levine BE, *Acute Respiratory Distress in Adults,* Lancet 2:319-323 (1967); Hallman M, Spragg RG, Harrell JH, Moser KM and Gluck L, *Evidence of lung surfactant abnormality in respiratory failure: study of bronchoalveolar lavage phospholipids, surface activity, phospholipase activity, and plasma myoinositol,* J Clin Invest 70:673-683 (1982); Pison U, Seeger W, Buchhorn R, Joka T, Brand M, Obertacke U, Neuhof H and Scmit-Neuerburg KP, *Surfactant abnormalities in patients with respiratory failure after multiple trauma,* Am Rev Respir Dis 140:1033-1039 (1989); Pison U, Overtacke U, Brand M, Seeger W, Joka T, Bruch J and Schmit-Neuerburg KP, *Altered pulmonary surfactant in uncomplicated and septicemia-complicated courses of acute respiratory failure,* J Trauma 30:19-26 (1990); Gregory TJ, Longmore WJ, Moxley MA, Whitsett JA, Reed CR, Fowler AAI, Hudson LD, Maunder RJ, Crim C and Hyers TM, *Surfactant chemical composition and biophysical activity in acute respiratory distress syndrome,* J Clin Invest 88:1976-1981 (1991).

[4] *See Facts and Mysteries of SARS* (discussing that the current treatments for SARS consist solely of providing supportive care).

[5] *See* Id. Many respiratory illnesses are most prevalent in cold weather. Researchers fear that although SARS may decline during the summer months it will return in force next winter.

While these efforts need to be continued and supported both scientifically, financially and politically, the harsh reality is that SARS patients have difficulty breathing—they are suffering the destruction of their essential lung surfactant system and are at risk for life-threatening ALI or ARDS. No approved therapies for ARDS currently exist. Current therapy for ARDS patients remains entirely supportive and mechanical ventilation is the present standard of care. In the face of the SARS crisis, a logical precaution for world health officials to take is to ensure that an adequate number of mechanical ventilators are available. Indeed, the United States government has recently improved its ability to respond to a SARS outbreak by adding 3,000 mechanical ventilators and has asked the states to identify space for extra hospital beds during an emergency. However, mechanical ventilation is an unfortunate last resort—the only way to oxygenate and keep the vital organs functioning. It is used only to assist in the patient's breathing while an attempt to adequately address the underlying cause of the disease is made. However, mechanical ventilation is very costly and it is axiomatic in critical care medicine that the longer a patient is on mechanical ventilation the higher the likelihood that mortality and morbidity results. Even with mechanical ventilation, the reported mortality rate for ARDS is between 40-50% worldwide.

Public health officials have focused on a search for effective agents to combat SARS and have recognized the need for improving mechanical ventilation resources and attendant facilities. The next logical step for world health authorities is to fully evaluate therapies that can restore proper lung function in SARS sufferers. Surfactants are essential for breathing and one of the prominent characteristics of ARDS is the destruction of lung surfactants. (*See* Illustration 3). Surfactant Replacement Therapy has the potential to address the SARS crisis. The goal of Surfactant Replacement Therapy is to maintain or restore proper lung function. Surfactant Replacement Therapy will not directly address the SARS virus. However, SARS patients are suffering destruction and degradation of their lung surfactant system. If the condition of a SARS patient degrades to ARDS, Surfactant Replacement Therapy has the potential to be a treatment by using the same or similar logical approach that we are presently using in our ongoing ARDS trial. If a SARS patient exhibits symptoms of progressing to ARDS, our engineered lung surfactant, as an inhalable aerosol, has the potential to prevent the widespread surfactant destruction that can occur as a result of SARS.

The remainder of this statement is about the possible benefits of Surfactant Replacement Therapy for the treatment of SARS.[6] I will discuss the critical role that lung surfactants play in proper pulmonary function and how Surfactant Replacement Therapy is already being used for the treatment of severe respiratory diseases. I will also describe our engineered version of human lung surfactant—its safety and pharmacological profile, our ongoing Phase 2 clinical trial for the treatment of patients suffering from ARDS and the potential for our engineered surfactant as an inhalable aerosol formulation to maintain lung function in SARS patients. Discovery has the only surfactant technology engineered to mimic the essential properties of human lung surfactant. We focus exclusively on treating respiratory diseases.

LUNG SURFACTANT TECHNOLOGY AND CURRENT SURFACTANT REPLACEMENT THERAPY

Surfactants are produced naturally in the lungs and are essential for breathing. Should surfactants degrade or be destroyed, the air sacs in the lungs collapse, airflow becomes restricted and the lungs do not absorb sufficient oxygen. (*See* Illustrations 1 and 2).

Surfactants are protein and lipid (fat) compositions that cover the entire alveolar surface, or air sacs, of the lungs and the terminal conducting airways which lead to the alveoli. Surfactants facilitate respiration by continually modifying the surface tension of the fluid normally present within the alveoli that line the inside of the lungs. In addition to lowering aveolar surface-tension, surfactants play other important roles which include lowering the surface tension of the conducting airways and maintaining airflow and airway patency (keeping the airways open and expanded). Loss of patency leads to compromised pulmonary function. (See Illustration 4). Human surfactants include four known surfactant proteins, A, B, C and D. It has been established, through numerous studies, that surfactant protein B (SP-B) is essential for respiratory function.

[6] Damage to the human lung surfactant system is a component of ARDS, and both the chemical composition and functional activity of lung surfactant are altered in patients with ARDS. Thus, compromise of the lung surfactant system plays an important role in the development of ARDS. Since many of the major pulmonary consequences of ARDS may be directly influenced by surfactant dysfunction, replacement treatment with Discovery's engineered humanized surfactant is potentially efficacious in this disorder.

Pulmonary surfactants have additional properties such as:

(i) Physical barrier to inhaled particles and noxious agents;I14(ii) Host defense against infection; and
(iii) Anti-inflammatory properties

There is a large body of scientific evidence associating the loss or lack of endogenous surfactant function with respiratory diseases. (*See, e.g.,* Illustration 4). Clinically, all of these diseases are characterized by one or more symptoms such as shortness of breath, chest tightening, and loss of pulmonary function as measured by FEV_1, FVC, PO_2, and PCO_2. Studies demonstrate that Surfactant Replacement Therapy would be a viable pharmacological approach for patients suffering from respiratory diseases such as Acute Lung Injury, ARDS, asthma, and Chronic Obstructive Pulmonary Disease.

Presently, surfactants are approved as replacement therapy only for Respiratory Distress Syndrome in premature infants, a condition in which infants are born with an insufficient amount of their own natural surfactant. The most commonly used of these approved replacement surfactants are derived from pig and cow lungs. Though the animal-derived surfactants are clinically effective, they have drawbacks and cannot readily be scaled or developed to treat broader populations and other respiratory diseases such as ARDS or SARS.

Animal-derived surfactant products are prepared using a chemical extraction process from minced cow and pig lung. Because of the animal-sourced materials and the chemical extraction processes, there is significant variation in production lots and, consequently, product quality specifications must be broad. In addition, the protein levels of these animal-derived surfactants are inherently lower than the protein levels of native human surfactant. The production costs of these animal-derived surfactants are high, relative to other analogous pharmaceutical products, generation of large quantities is severely limited, and these products cannot readily be reformulated for aerosol delivery to the lungs.

DISCOVERY LABS SURFACTANT REPLACEMENT THERAPY

Discovery's engineered version of human lung surfactant is designed to precisely mimic the most essential attributes of natural lung surfactant. Discovery's surfactant technology contains a proprietary peptide that mimics human lung surfactant protein B (SP-B), the protein in natural pulmonary surfactant known to be the most important surfactant protein for promoting surface-tension lowering and oxygen exchange.[7] Discovery's surfactant has anti-inflammatory properties and can be engineered as a liquid instillate or an inhalable aerosol as therapy for specific diseases being treated. (*See* Illustrations 5 and 6). Our engineered humanized surfactant can be manufactured less expensively than the animal-derived surfactants, in sufficient quantities, in more exact and consistent pharmaceutical grade quality, and has no potential to cause adverse immunological responses in young and older adults, all important attributes to potentially meet significant unmet medical needs. In addition, we believe that our engineered humanized surfactants might possess other pharmaceutical benefits not currently found with the animal surfactants such as longer shelf-life, reduced number of administrations to the patient's lungs, and elimination of the risk of animal-borne diseases including the brain-wasting bovine spongiform encephalopathy (commonly called "mad-cow disease"). Our humanized surfactant technology was invented at the world-renowned Scripps Research Institute and was further developed and licensed to us by Johnson & Johnson.

There is significant scientific and clinical literature establishing the safety and pharmacological activity of our proprietary surfactant technology. To date, hundreds of subjects have received Surfactant Replacement Therapy with Discovery's lead surfactant product, Surfaxin®, and such treatment has been well-tolerated.[8] Surfaxin is in three Phase 3 and two Phase 2 clinical trials addressing critical respiratory indications where there are few or no therapies currently available. Surfaxin has been shown to remove inflammatory and infectious infiltrates from patients' lungs when used by our proprietary lavage (or "lung wash") and replenish the vital surfactant levels in the lungs.

Discovery's Surfactant Replacement Therapy for ARDS—Phase 2 Clinical Trial

Currently, Discovery is developing Surfaxin for the treatment of Acute Respiratory Distress Syndrome in adults (ARDS). Acute Respiratory Distress Syndrome

[7] Discovery's humanized surfactant product candidates, including our lead product, Surfaxin®, are engineered versions of natural human lung surfactant and contain a humanized peptide, sinapultide. Sinapultide is a 21 amino acid protein-like substance that is designed to precisely mimic the essential human surfactant protein B (SP-B).

[8] *See, e.g.,* Discovery Laboratories, Inc., Study KL4-ARDS-02, April 3, 1998, clinical report.

in adults is a life-threatening disorder for which no approved therapies exist anywhere in the world. (*See* Illustration 7). It is characterized by an excess of fluid, inflammatory cells and debris in the lungs that leads to decreased oxygen levels in the patient. One prominent characteristic of this disorder is the destruction of surfactants naturally present in lung tissue that are essential to the ability to absorb oxygen. Current therapy for ARDS patients remains entirely supportive and mechanical ventilation is the present standard of care.

Discovery's approach to treating ARDS is based on the scientific rationale supporting Surfactant Replacement Therapy as an effective lavage, or "lung wash," designed to alter the course of this disease by rinsing out damaging infiltrates and debris in the lungs and restoring normal surfactant function. (*See* Illustrations 8 and 9). We are presently conducting a Phase 2 open-label, controlled, multi-center clinical trial of Surfaxin for adults in up to 110 patients with Acute Respiratory Distress Syndrome. This trial will compare the safety and effectiveness of standard of care, including mechanical ventilation, to high concentrations of Surfaxin administered to patients via a proprietary lavage technique that administers the drug sequentially through a tube, called a bronchoscope.

In July 2002, we completed the first part of this trial, a dose escalation safety and tolerability study in 22 patients in four groups (of up to six patients per group). In consultation with the trial's Independent Safety Review Committee that was comprised of three prominent pulmonologists, we determined that the Part A portion of the trial procedure is generally safe and tolerable and that it was appropriate to proceed onto the larger safety and efficacy portion of the study. These early results, although in a small number of patients, are encouraging because they suggest that the most effective dosages are the higher Surfaxin concentrations. In fact, some of the sickest patients were in the highest dose groups and, nevertheless, in these groups we experienced the most promising results, including no mortality and a significant reduction in the number of days on mechanical ventilation. (*See* Illustration 10).

The following table presents summary data of certain key clinical endpoints from the dose-ranging part of the trial:

Patient Group	Number of Patients	Surfaxin Dosage*	Clinical Results	
			Mortality ((#) and % of Patients)	Average Days On Mechanical Ventilation
A	5	22,800 mg	(3)-60%	20.8
B	6	34,200 mg	(2)-33%	17.5
C	6	57,000 mg	(0)-0%	12.8
D	5	61,000 mg	(0)-0%	17.2

* Based on phospholipid content.

The last part of this Phase 2 trial, Part B, will evaluate safety and efficacy of Surfaxin in direct comparison to standard of care at approximately 50 centers in the United States and Canada. The primary endpoint of this part of the trial is to determine the incidence rate of patients being alive and off mechanical ventilation at the end of day 28 with one of the key secondary endpoints being mortality.

The FDA has granted Fast-Track Approval Status and Orphan Drug Designation for Surfaxin for the treatment of Acute Respiratory Distress Syndrome for adults. The European Medicines Evaluation Agency has granted Orphan Product designation for Surfaxin for the treatment of Acute Lung Injury in adults (which in this circumstance encompasses Acute Respiratory Distress Syndrome).

If the necessary activities and adequate resources could be properly organized, including, but not limited to (1) training of medical personnel in the bronchopulmonary segmental surfactant lavage procedure, (2) regulatory procedures, and (3) supply of sufficient drug, this program could be positioned to evaluate Surfactant Replacement Therapy for the most severe SARS patients on mechanical ventilation by mid-to late-summer of 2003.

Discovery's Inhalable Aerosol Surfactant—Positioned to enter Phase 1b / 2a Clinical Trials

Discovery recently prepared its proprietary engineered version of lung surfactant as an inhalable aerosol formulation that successfully retained the critical therapeutic properties of fully-functioning natural lung surfactant. This development now evolves surfactant therapy to the point where inhalable aerosol formulations of engineered lung surfactant have the potential to be developed to treat respiratory diseases that so far have been unable to benefit from Surfactant Replacement Therapy. The immediate focus of our aerosol development program is on surfactant-based

therapy to help restore lung function of hospitalized patients suffering from severe respiratory conditions (for example, SARS), hopefully avoiding the progression to ARDS, the need for mechanical ventilation, thereby preventing respiratory conditions from becoming severe, even life-threatening events.

Discovery's lung surfactant was aerosolized as a liquid formulation that exhibited all of the essential pharmacological properties of a functioning surfactant, including the surface-tension lowering abilities necessary to restore lung function and keep the airways open and expanded. An aerosolized Surfactant Replacement Therapy may be effective as a preventive measure for patients at risk for Acute Lung Injury by providing a functioning surfactant to act as an anti-inflammatory and to maintain proper lung function.

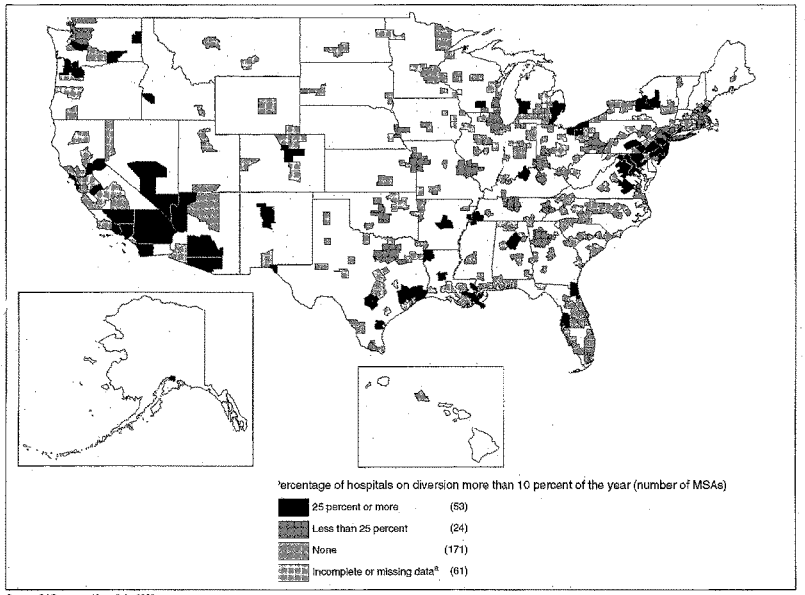
Importantly, our inhalable aerosol surfactant could be readily administered to ambulatory patients with a number of already-available devices or could be used with aerosol generators designed for in-line use with mechanical ventilators. With a highly communicable disease such as SARS, this could be a closed system reducing the risk of disease transmission to health care workers and others. We have every reason to expect that our inhalable aerosol Surfactant Replacement Therapy would demonstrate the same safety and pharmacological profile exhibited throughout our surfactant pre-clinical and clinical programs to date, including our five ongoing Phase 3 and Phase 2 studies. Our present development plan calls for us to enter Phase 1b/2a clinical trials to evaluate our inhalable aerosol Surfactant Replacement Therapy by late-2003 or early-2004. However, with a concerted effort by all necessary parties, this program can be positioned to evaluate the possible benefits of Surfactant Replacement Therapy for SARS patients by early-fall of 2003.

CONCLUSION

Scientists around the world have moved with unprecedented speed to identify the SARS virus and screen potential treatments. Public health officials have employed intense efforts to contain its spread and are exploring numerous medical treatments, focusing on antivirals, vaccines, and mechanical ventilation. The logical next step is for world health authorities to fully evaluate pulmonary therapies aimed at restoring or maintaining proper lung function in SARS sufferers. SARS patients have difficulty breathing and are suffering degradation and destruction of their lung surfactant system. Surfactants are critical for breathing and the goal of Discovery's Surfactant Replacement Therapy is to maintain or restore proper lung function.

Surfactant Replacement Therapy has the potential to play an important role in addressing the SARS crisis. Discovery's surfactant technology, engineered to mimic the essential properties of human lung surfactant, is the only surfactant technology that could play this role. We focus exclusively on treating respiratory diseases. In summary, Discovery and its medical advisors are convinced that Surfactant Replacement Therapy has the potential to be an effective therapy to treat a variety of respiratory diseases, including SARS. We ask this Committee to be a catalyst in conveying the message that Surfactant Replacement Therapy be included in the assessment of therapies currently under consideration by the various health authorities.

Figure 1: Percentage of Hospitals on Diversion More Than 10 Percent of the Time, by MSA, Fiscal Year 2001



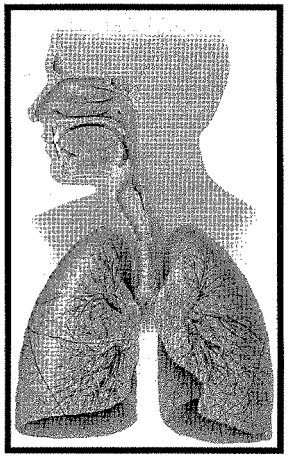
Source: GAO survey of hospitals, 2002.

Note: Percentage of hospitals reflects those hospitals that responded to the survey; responses were not weighted to represent all hospitals in the MSA.

[a]MSAs with a response rate of 50 percent or less or MSAs with 50 percent or more of data missing for responding hospitals. In 12 MSAs, no hospitals responded; these MSAs were excluded from the map.

Surfactants - Critical to Breathing

DISCOVERY LABORATORIES, INC.



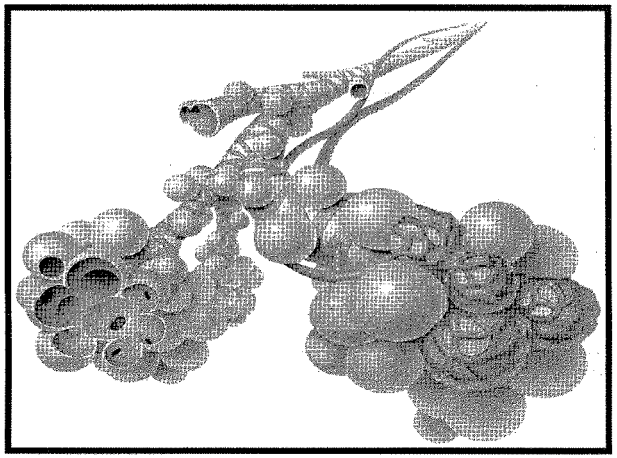
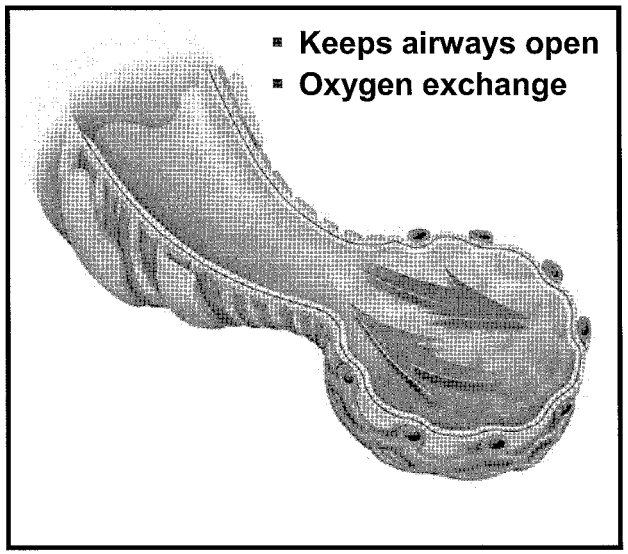


ILLUSTRATION 1

- Protein and lipid mixture produced in the lungs
- Covers surface of terminal conducting airways & air sacs (alveoli)
- Critical to all air breathing animals

Surfactants - Allows Breathing

DISCOVERY LABORATORIES, INC.



- Keeps airways open
- Oxygen exchange

Composition

DPPC

and

Surfactant Proteins

SP-A

SP-B

SP-C

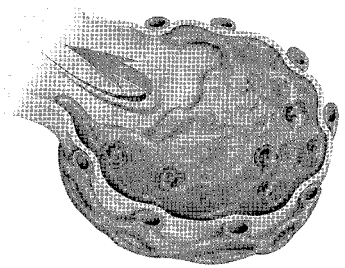
SP-D

Lowers surface tension in air sacs and airways - without surfactant, air sacs will collapse

ILLUSTRATION 2

ARDS

(Acute Respiratory Distress Syndrome in Adults)

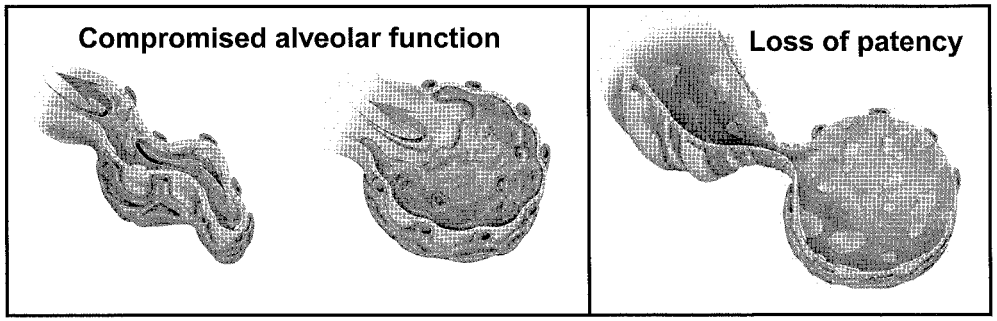


Regardless of cause, endogenous surfactant is degraded or destroyed

ILLUSTRATION 8

Surfactant and Respiratory Diseases

DISCOVERY LABORATORIES, INC.

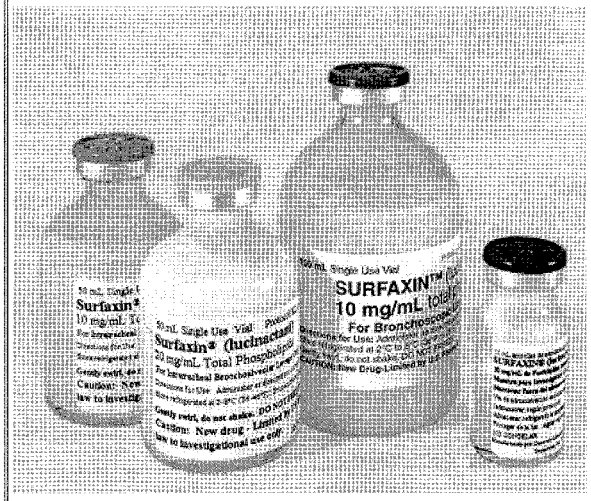


- **Respiratory Distress Syndromes**
  - RDS and MAS in infants
  - ALI, ARDS - SARS
- **Inflammatory Disease**
  - Asthma
  - COPD - Chronic bronchitis
  - Cystic fibrosis
- **Lung Infection**
  - Pneumonia and RSV
- **Upper Airway Diseases**
  - Otitis media
  - Rhinitis/Sinusitis
  - Sleep apnea
- **Fibrotic lung disease**

ILLUSTRATION 4

Surfaxin®

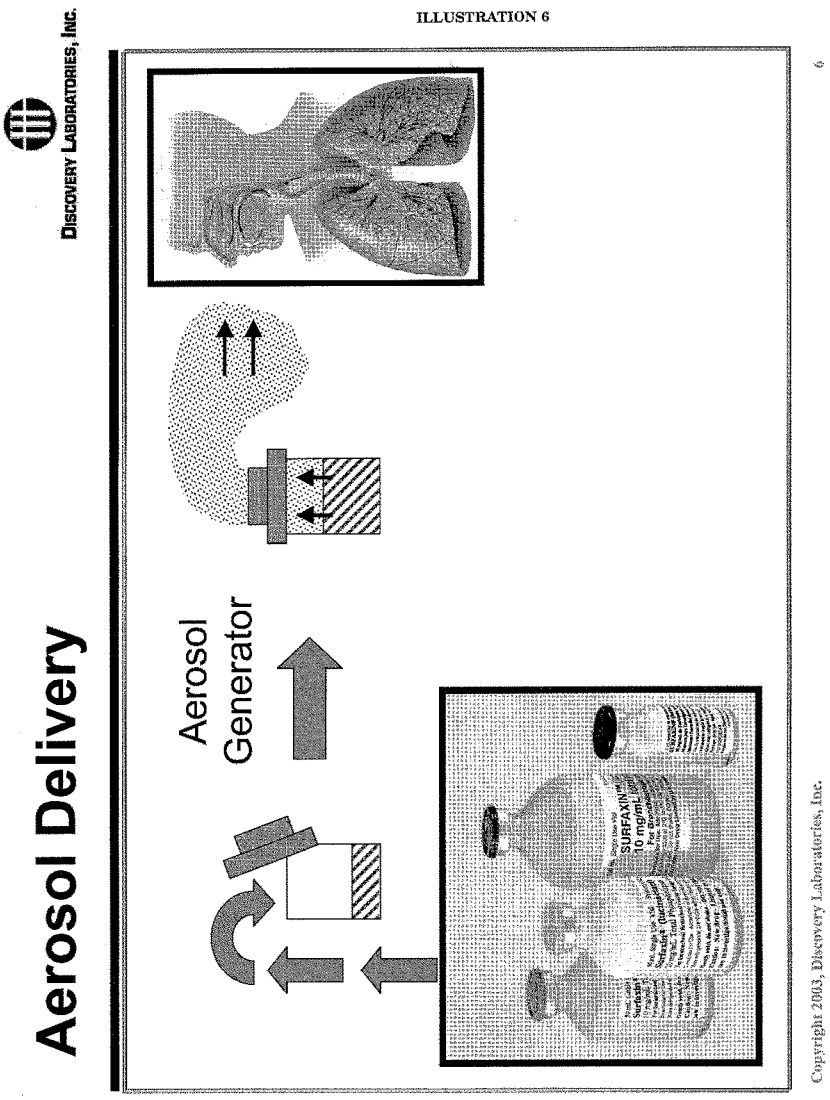
DISCOVERY LABORATORIES, INC.



- Acute Lung Injury/ Acute Respiratory Distress Syndrome (ALI/ARDS) of Adults
- Respiratory Distress Syndrome (RDS) of premature infants
- Meconium Aspiration Syndrome (MAS) of full-term infants

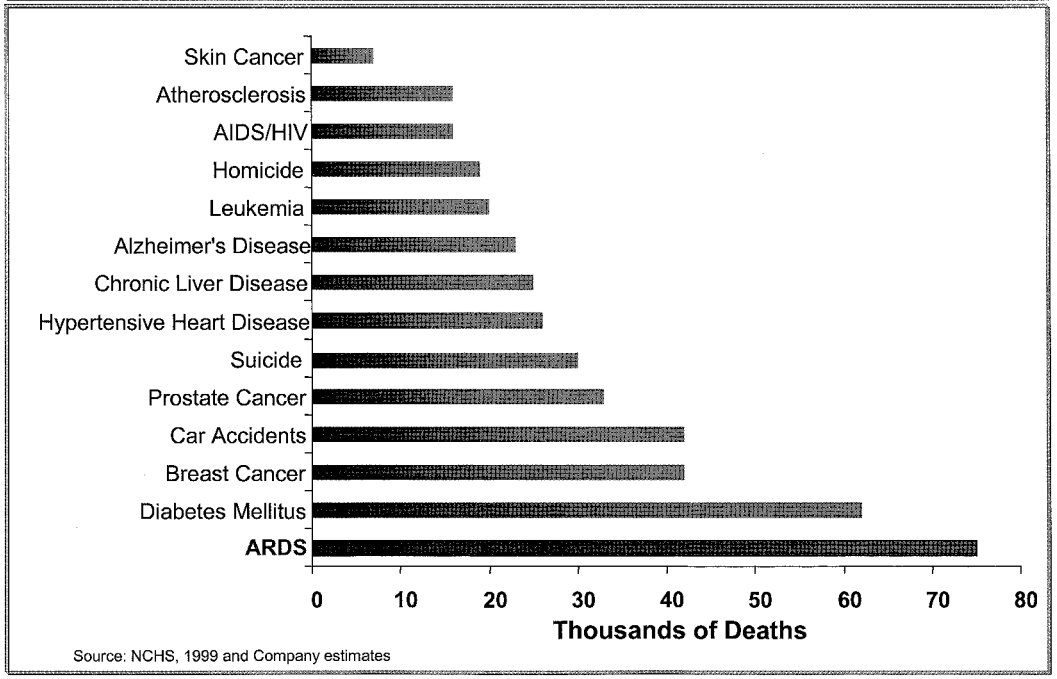
ILLUSTRATION 5

ILLUSTRATION 6



ARDS - A Leading Cause of Death

DISCOVERY LABORATORIES, INC.



Source: NCHS, 1999 and Company estimates

ILLUSTRATION 7

Surfaxin®
A Common Theme and Objective

DISCOVERY LABORATORIES, INC.

To replace deficient or inactivated surfactant in respiratory distress syndromes with a potent, long-acting, high quality surfactant

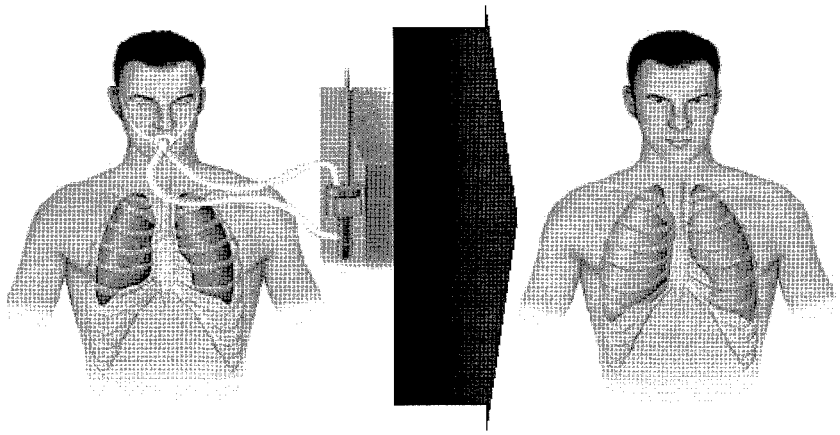
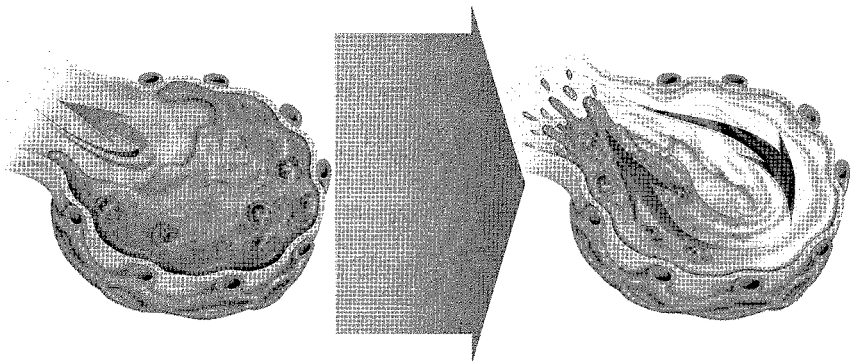


ILLUSTRATION 8

ARDS - Discovery's "Lung Wash"

DISCOVERY LABORATORIES, INC.



- "Drain abscesses in the lung" with large volumes of Surfaxin®
- Remove inflammatory substances
- Leave behind functioning surfactant for lungs to absorb oxygen

ILLUSTRATION 9

ARDS Phase 2 Clinical Trial

DISCOVERY LABORATORIES, INC.

Part A - Dose-ranging safety and tolerability - Q3 2002

- **22 patients in 4 groups receiving higher doses of Surfaxin®**

Patient Group	*Number of Patients*	*Surfaxin Dosage*	*Clinical Results*		
			Mortality ((#) and % of Patients)	*Average Days on Mechanical Ventilation*	*Incidence of Patients Alive and Off Ventilation*
A	5	22,800 mg	(3) – 60%	20.8	40% (2/5)
B	6	34,200 mg	(2) – 33%	17.5	66.7% (4/6)
C	6	57,000 mg	(0) – 0%	12.8	66.7% (4/6)
D	5	61,000 mg	(0) – 0%	17.2	100% (5/5)
Standard of care			**30-50%**	**21 - 28 ($8,500/day)**	

Part B - Evaluate vs. standard of care; 40 centers in U.S. - up to 90 additional patients - results in Q4 2003

ILLUSTRATION 10

Mr. GREENWOOD. Thank you, Dr. Capetola.
Dr. Fischer?

TESTIMONY OF PAUL H. FISCHER

Mr. FISCHER. Chairman Greenwood, and members of the subcommittee, thank you for having invited me here today to discuss SARS outbreak and the potential for developing a vaccine to prevent this disease.

My name is Paul Fischer, and I am the CEO of GenVec. GenVec is a publicly held biopharmaceutical company focused on the development and commercialization of novel therapies for severe diseases with inadequate therapy. We are currently in a clinic testing products that use our specialized technology to treat various forms of cancer, including pancreatic cancer as well as advanced heart disease and macular degeneration, which is a major cause of blindness.

GenVec is also pleased to be collaborating with the U.S. Government for the development of new vaccines including AIDS, malaria, Dengue fever virus, and most recently SARS.

I would like to take this opportunity to especially thank the NIH, the NIAID Vaccines Research Center. Only a few short weeks ago I had a telephone conversation with Dr. Gary Nabel, Director of the Vaccine Research Center. In 30 minutes, we had agreed to expand our work to include a vaccine for SARS, and within hours our teams were discussing the strategy of how that might be done. Two weeks after that discussion, an amendment to our existing research contract, which is now administered by SAIC of Frederick, gave GenVec the green light to start working on the construction of the initial vaccine vectors against SARS. And that within 2 weeks that whole process was completed and researchers were actually able to get to work. I think that is great. An indication of what is often not thought of, which is a rapid response by Government.

I believe this is precisely the type of leadership on the part of the Government, facilitating rapid action by the private sector, which is needed to effectively really put together and rally these resources and expertise to address SARS and other potential epidemics.

GenVec is proud to be part of this effort, and we hope SARS will end up being simply a page in a medical history books, but for now, there is much to be done and a great deal of concern.

So any quick read of the news, and certainly all of what we have heard today, has indicated that this is an epidemic which we really do not know that much about, but does include pneumonia like syndrome. It is rapidly becoming clear that the death rate may be higher than we thought. There is a number of unknowns. But what we do know are several key things.

If we are unable to isolate and contain this pathogen, it could lead to an extensive and widely traumatic event.

So what are we going to do to directly attack this problem? In our quest to defeat SARS, or for that matter, other new pathogens, several factors are key:

First speed. Speed is crucial. The SARS virus could become seasonal and return year after year. In fact, this is likely. It will also mutate and change.

Flexibility is critical. The approach could and should accommodate the potential changing or slightly different strains of the virus from year-to-year, since viruses do tend to change each year, and they become resistant not only to drugs, but also vaccines.

Of course, safety is important. Any contemplated measure, particularly a preventative one to which you may expose a large number of people, such as with a vaccine, is important. Safety is key here. And avoiding the use of live viruses is the preferred strategy when that is possible so that the recipient populations, whether healthcare workers or the general public, are placed at the minimum risk possible.

And we also need to be able to manufacture these vaccines and be able to distribute them in a cost effective way.

GenVec's approach is to use technology of an inactivated cold virus, which is the adenovector, and you have heard Dr. Fauci actually mention that several times today. In this case what we are doing is using the cold virus as a vehicle to deliver a small fragment of DNA of the SARS virus that codes for an important protein that would stimulate an immune response by the body. So we are actually only using a small fragment of information, essentially the blueprint of these proteins, putting them into a different vector, a vector which itself cannot replicate or cause disease. It then sort of tricks the body into expressing the protein of the SARS virus. The body then recognizes that as a foreign protein, that particular interaction primes the pump, so to speak, teaches the body about this protein and it recognizes it as a foreign protein so that if in the future that individual who is vaccinated actually gets confronted with the real virus, it mounts a very immediate and rapid immune response. That is the goal.

The extensive experience that we have had working with the NIH, for example, on our AIDS program, has actually allowed us to move very quickly into this using this information we have in AIDS to leverage the technology. So that is why within weeks we could jump on this problem with the NIH. The technology also needs to be flexible so that we can modify it.

We have to assume that there will be changes in the code protein, that in fact the virus will mutate. If we have the right delivery vehicle and we understand the gene, then it is simple understand what those mutations are, put them right back in and have a new vaccine ready to go very rapidly.

In fact, this whole approach is one we have been working with in other areas, including with the Navy in their agile vaccine program. They are, obviously, interested from a bioterrorism point of view, but in our case we are also working with them on malaria as well as the Dengue fever virus.

So what are the next steps? Well, these synthetic genes that I mentioned are actually being made now, being put together. The information that allowed us to do that you have heard about today came quickly from the cooperation of a number of agencies. The sequence is known. Those synthetic genes are now being readied to be put into these vectors, these vaccine candidates at GenVec, and we will actually begin doing that within weeks.

We actually expect to have new vaccine candidates available for testing within months. The NIH will actually do that testing in

animal models. You heard about some of that earlier from Dr. Fauci again. And we think clinical grade production of these vectors could begin as early as they share them.

Now, depending on the results of those animal models and the safety and efficacy of this approach, we could be in clinical trials as early as next year.

So, in conclusion, what I would like to say is that the investments that have been made over the last decade in the core biology of genomics, the information technology, bioinformatics and with the biotechnology industry itself in learning how to make things such as these new vectors has allowed us to deal with this at least initial phase of response to the SARS outbreak very rapidly. That investment being put into the biomedical research community has actually primed the pump, again, to be able to jump on this problem.

So as we move forward, I would like to see that kind of support continue. I would really like to pat on the back the NIH for their rapid response to this. The Government has been very quick to respond to this problem, and in actually involving the private sector, in this case GenVec, to start on this program without a lot of red tape. It was actually 15 days from the time we had that conversation to actually been through the network and have that contract expanded.

Thank you.

[The prepared statement of Paul H. Fischer follows:]

PREPARED STATEMENT OF PAUL H. FISCHER, CHIEF EXECUTIVE OFFICER, GENVEC, INC.

INTRODUCTION

Chairman Greenwood and Members of the Subcommittee, thank you for having invited me here today to discuss the SARS outbreak and the potential for developing a vaccine to prevent this disease.

My name is Paul Fischer, and I am the CEO of GenVec, Inc. GenVec is a publicly held biopharmaceutical company focused on the development and commercialization of novel therapies for severe diseases with inadequate therapy. We are currently in the clinic, testing product candidates that utilize our specialized technology to treat various forms of cancer, including pancreatic cancer, as well as advanced heart disease, and macular degeneration, which is a major cause of blindness.

GenVec is also pleased to be collaborating with the U.S. Government for the development of new vaccines, including AIDS, malaria, dengue fever virus, and most recently, SARS.

I'd like to take this opportunity to especially thank the NIH/NIAID's Vaccine Research Center. Only a few short weeks ago, I had a telephone conversation with Dr. Gary Nabel, Director of the Vaccine Research Center. In 30 minutes, we had agreed to expand our work to include a SARS vaccine, and within hours our teams were discussing strategy. Two weeks after our discussion, an amendment to a research contract being administered by SAIC of Frederick, MD giving GenVec the green light to initiate construction of vaccine vectors for testing against SARS by the NIH/NIAID was completed, and our researchers were able to get to work. I believe that this is precisely the type of leadership on the part of the government, facilitating rapid action by the private sector, which is needed to effectively rally resources and expertise to address SARS and other potential epidemics. GenVec is proud to be part of this effort, and we hope that SARS will one day be simply a page in the medical history books—but for now, there is much to be done.

SARS: THE PROBLEM

As any quick check on the news tells us, the SARS epidemic is a rapidly evolving story. It is unclear whether SARS will become a major recurrent health problem, or at what rate the coronavirus that induces SARS, triggering pneumonia-like symptoms in patients, mutates. What we do know is that as of May 5th, as reported in

the Wall Street Journal, some 6,234 SARS infections have been reported, claiming some 435 lives in China, Hong Kong, Canada and elsewhere. We also know that the treatment of patients affected by SARS is time-consuming and costly, that the full-blown disease leaves people weakened for an extended period of time, and that the virus is capable of surviving for prolonged periods under a variety of conditions. While containment is certainly a worthwhile strategy, we also know that there are areas of the world where containment can become increasingly difficult. We have seen the alarming rate of infection in China. The disease could easily recur and spread to other sectors of the world. The isolation and treatment protocols required to contain it may not be widely available and the results could be traumatic. In seeking to counter the impact of SARS, time clearly is our enemy.

SARS: THE SOLUTION

In our quest to defeat SARS, or other new pathogens, several factors are key:

- Speed is crucial. The SARS virus could become seasonal and return year after year, and will likely mutate.
- Flexibility is critical. The approach should accommodate potential mutations, since viruses tend to mutate over time and become resistant to drugs or vaccines.
- The safety of any contemplated preventative measures, such as a vaccine, is important. Avoiding the use of live viruses is a preferred strategy when feasible, so that the recipient populations—whether healthcare workers or the general public—are placed at the least possible risk.
- Ease of manufacture is also a concern, as only a vaccine or other preventative that can be rapidly produced and distributed can be widely effective.

GENVEC'S APPROACH

GenVec's technology involves the use of an inactivated cold virus, known as an adenovector. The genes that the adenovirus needs to replicate are removed, and the resulting adenovector acts as a delivery vehicle for the gene of interest. In the case of a potential SARS vaccine, the adenovector will carry small pieces of the DNA from the SARS virus as its payload—not the entire genome for SARS, but only enough to position the body to generate an immune response to target all SARS proteins. This response will then be retriggered, on a greater scale, if the vaccine recipient is actually challenged by the disease.

The extensive experience that GenVec's researchers have accumulated during the course of our work is being placed at the disposal of the current project to rapidly construct test candidates. Our goal is to cooperate with the NIH/NIAID in preparing several vaccine candidates for evaluation, and then modifying the vaccine or vaccines that show the greatest degree of promise to be safe and effective as needed. We hope to have one or more vaccines result from our work that can be rapidly modified in response to future potential mutations. Vaccines of this type could be used to help contain an outbreak by protecting first responders and individuals at high risk, and could eventually be of potential use as a widely-delivered vaccine, such as the flu vaccine is today.

NEXT STEPS

Synthetic SARS genes are already being made and within weeks the first adenovectors will be under construction at GenVec. New vaccine candidates should be ready for preclinical testing in animals by the NIH within months. Clinical grade production is possible this current year; and depending on the results of the preclinical studies, the first trials in human subjects could begin next year.

CONCLUSION

The investments that have been made over the last decade in core biology, genomics research, information technology and the biotech industry have made this rapid response to the SARS outbreak possible. GenVec has been able to put the same approach we have just outlined today to work in our collaborative research with the Navy for the production of agile vaccines against dengue fever and malaria. In the case of these and other biological threats, time is of essence and the lessons we learn in our laboratories now can and will be put to use to help defend against the health threats facing our nation and the world today, and potentially facing us tomorrow.

Mr. GREENWOOD. Thank you, Dr. Fischer.

Dr. Lonberg?

TESTIMONY OF NILS LONBERG

Mr. LONBERG. Thank you. Thank you for giving me the opportunity to speak.

I am going to talk about how a particular class of biotechnology products, monoclonal antibodies, could play a role in combating SARS. Also, how one U.S. biotechnology company in partnership with a non-profit publicly owned research and manufacturing group are working together in this effort.

And I want to make three points. First of all, monoclonal antibody technology is one of the tools of modern biotechnology that can be employed to combat the SARS virus.

Second, finding new medicines is never a quick fix. We are not competing with isolation and quarantine here; however, we will be working as rapidly as possible. And I will try to give you some idea of how quickly we can work.

Finally, the Federal Government can play a role in facilitating the efforts of biotechnology companies in the emerging disease area.

A little bit of background. Medarex is collaborating with the Massachusetts Biologic Laboratories in this project.

Medarex is a publicly listed US biotechnology company with facilities in New Jersey and California.

MBL is a nonprofit FDA-licensed manufacturer of vaccines and other biologic products in the United States and we have been working together with MBL on other infectious disease projects. And it is because of that ongoing collaboration that we have been able to jump very quickly into this area.

First, I am going to give you a little bit of background on antibiotic therapy. Antibodies are a critical natural component of the body's immune defense against viruses and other infectious agents.

Vaccines stimulate the body to produce antibodies that will recognize a particular virus. In the absence of an effective vaccine, therapeutic preparations of exogenous antibodies can potentially provide protection from infection. This type of therapy has been around for over 100 years, in fact the first Nobel Prize in medicine went to Behring for the development of this form of therapy. Early forms of antibody therapy used serum from immunized large animals, such as horses, and human and animal serum products are still used today. However, we now have neutrals that allow for the development of genetically engineered monoclonal antibodies based therapeutic drugs. And there are 12 monoclonal antibody based therapeutic products that are now approved by the FDA. The 12 monoclonal antibody based therapeutic products are used in a variety of different indications, including cancer, heart disease, arthritis and infectious diseases.

The one particular example that I think is relevant here is Synagis. Synagis was developed by MedImmune in Gaithersburg, Maryland. It is directed against a virus called Respiratory Syncytial Virus. Synagis was developed as a safe—non-blood product derived—and consistent—molecularly characterized—alternative to a human serum derived therapy. It is approved to prevent serious lower respiratory tract disease caused by RSV in high risk pediatric patients. And the success of Synagis suggests that similar

monoclonal antibody based therapeutic may be useful for preventing SARS infection.

So the point that I want to make is that antibody based products for the prevention of infectious disease are a well established part of our current therapeutic arsenal.

Medarex has it's own proprietary technology, proprietary technology for the generation of human monoclonal antibodies. These are designed to be well tolerated and safe in humans.

We use genetically engineered strains of mice that carry human immune system genes within their genome. So we have slightly humanized the mouse and these mice now breed stably and we can use them to make human antibodies directly.

There is now ten different human antibody based drugs in human clinical testing that are based on our technology. Some are being developed by Medarex alone, and others by major pharmaceutical companies like Novartis and Johnson & Johnson.

What are we going to do together with MBL?

We are going to immunize transgenic mice with the SARS virus antigens We are going to generate a panel of potential therapeutic candidates. Test these candidates for their ability to neutralize the SARS virus. Select a lead candidate and then develop a manufacturing cell line.

These first five steps are the preclinical development stage. And we have gone through preclinical development very rapidly in the past. The most rapidly we were able to go through it is about a year, but I think that it is unlikely in this particular case that we would be able to move that rapidly. I think it is not unrealistic to think that it would be possible to do it in as little as 2 years.

The next steps involve testing the material for safety in animals and humans and for efficacy in humans. And it is that clinical testing that carries the greatest uncertainty in as far as the amount of time that it will take.

The last point that I want to make is how biotech companies make pipeline decisions and what possible role the Federal Government could have in this process.

Resources for biotech companies are extremely scarce and must be allocated based upon calculated value of future product. This calculated value is derived from estimates of the chance of success, time to development, cost of goods, price of drug, size of market, and the competition. For an emerging disease such as SARS, it is very difficult to calculate any of the above. And for this reason, the Federal Government can play a role to encourage biotech and pharmaceutical companies in this area by removing some of these uncertainties, such as establishing a defined market or by underwriting some of the research and development costs.

I think that the NIH has actively been underwriting some of the research and development costs for biotechnology companies, and we certainly appreciate that. We received some NIH funding for the development of our technology platform.

The biggest uncertainty is figuring out what the market is going to be. And that uncertainty may be established relatively rapidly for the case of SARS. However, another case such as bioterror we are still scratching our heads 2 years later and wondering who is going to be the customer, for example, for an antibody that could

be used for preventing infection from anthrax. And so I think the Federal Government may be able to step up to the plate there Thank you.

[The prepared statement of Nils Lonberg follows:]

PREPARED STATEMENT OF NILS LONBERG, SENIOR VICE PRESIDENT, MEDAREX, INC.

I will try to give you a very brief snapshot of how a particular class of biotechnology products (monoclonal antibodies) could play a role in preventing SARS infections. And, in particular, how one US biotechnology company in partnership with a non-profit publicly owned research and manufacturing group are working together in this effort. I will try to leave you with Three take-home messages:

1. Monoclonal antibody technology is one of the tools of modern biotechnology that can be employed to combat the SARS virus.
2. Finding new medicines is never a quick fix; however, we will be working as rapidly as possible.
3. The government can play a role in facilitating the efforts of biotechnology companies in the emerging disease area.

Medarex is collaborating with the Massachusetts Biologic Laboratories (MBL) to develop a monoclonal antibody to prevent Coronavirus associated SARS.

Medarex is a publicly listed US biotechnology company with facilities in NJ and CA.

MBL, University of Massachusetts Medical School is the only non-profit FDA-licensed manufacturer of vaccines and other biologic products in the United States. MBL has seven FDA licensed vaccines and/or polyclonal antibody products. In addition MBL has manufactured 4 monoclonal antibodies for clinical trials in collaboration with NIH and/or private collaborations.

Antibodies are a critical component of the body's immune defense against viruses and other infectious agents.

Vaccines stimulate the body to produce antibodies that will recognize a particular virus.

In the absence of an effective vaccine, monoclonal antibodies (i.e., genetically engineered antibodies) can potentially provide protection from infection.

Antibody based therapies have been employed since their first discovery over a hundred years ago by Kitasano and Behring.

The first such therapies used serum from immunized large animals such as horses and sheep.

Human and animal serum products are still used today; however, we now have new tools that allow for the development of genetically engineered—monoclonal—antibody based therapeutic drugs.

There are now 12 monoclonal antibody based therapeutic products that are approved by the FDA.

The 12 monoclonal antibody based therapeutic products are used in a variety of indications, including cancer, heart disease, arthritis, and infectious diseases.

One of these monoclonal antibodies, Synagis' (MedImmune, Gaithersburg MD), is directed against a virus called Respiratory Syncytial Virus (RSV).

Synagis® was developed as a safe (non-blood product derived) and consistent (molecularly characterized) alternative to a human serum derived therapy, RespiGam®.

The success of Synagis® suggests that a similar monoclonal antibody-based therapeutic may be useful for preventing SARS infections.

Medarex is focused primarily on the development of monoclonal antibodies derived from its own proprietary technology for the generation of human monoclonal antibodies.

This technology uses genetically engineered strains of mice that carry human immune system genes within their genomes

There are now 10 different human antibody based drugs in human clinical testing based on Medarex's technology. Some are being developed by Medarex and others by major pharmaceutical companies like Novartis and Johnson & Johnson.

To develop a SARS drug, Medarex and MBL plan to:

1. Immunize transgenic mice with SARS virus antigens
2. Generate a panel of potential therapeutic candidates
3. Test these candidates for their ability to neutralize the SARS virus
4. Select a lead candidate
5. Develop a recombinant manufacturing cell line that produces large quantities of the lead candidate.
6. Test this material for safety in animals and humans
7. Test for efficacy in humans.

The first 5 steps may be completed in as little as two years. The development of laboratory and animal model assays for step 3 will be critical.

Human efficacy testing will probably be the most time consuming step.

How do biotech companies make pipeline decisions?

Resources are scarce and must be allocated based on calculated value of future products

The value of future products is derived from estimates of chance of success, time to development, cost of goods, price of drug, size of market, and competition

For emerging disease indications it is very difficult to calculate a risk adjusted value for a future product (for SARS we do not yet know enough to calculate any of the above with a reasonable degree of certainty).

The government can play a role to encourage biotech and pharmaceutical companies in this area by removing some uncertainties (such as establishing a defined market) or by underwriting some of the research and development costs.

Mr. GREENWOOD. Thank you, Dr. Lonberg.

Dr. Burger?

TESTIMONY OF DENIS R. BURGER

Mr. BURGER. Good afternoon. I am Denis Burger. I am CEO of AVI BioPharma. Among other drug development programs, we make specific antibiotics for viruses, including SARS.

I would like to thank the committee for inviting me here this afternoon to participate in this hearing. It is an honor to share with you our science, technology and vision.

To begin, I would like to describe the research and development at AVI and what we have been doing since being founded in 1980. AVI's technology is called antisense, it enables us to develop a wide variety of products for a variety of diseases rapidly.

Antisense technology is now beginning to reach its potential. AVI is conducting clinical trials to evaluate antisense drugs against cardiovascular disease, cancer and other indications, but it is our application of antisense for viral infections in the past 2 years that is most relevant in our discussion this afternoon on the spread and containment of SARS.

I would like to cover two key points in my testimony. First, AVI's antisense drugs target and inhibit the source of the infection, not the symptoms. In the case of SARS, the infection is an RNA virus.

Second, the way we develop antisense drugs represents a new kind of rapid drug development that we believe may have significant impact in today's threatening viral landscape. We are making specific antibiotics for viruses.

AVI's NeuGene antisense drugs are like key blanks that can be cut precisely to match a virus' or a disease's genic lock. Each antisense drug is designed to block the activity of a particular gene or organism responsible for disease, whether human, bacterial or viral.

When an antisense drug comes in contact with a viral target, it binds to specific portions of the gene sequence and like fabric caught in a zipper, prevents the virus from replicating.

Once the SARS outbreak was attributed to a human coronavirus, scientists at AVI knew there was a good chance our technology could be effective. We have spent the past several years researching the use of antisense on other RNA viruses, including hepatitis C and West Nile virus, and have had success against these diseases. In fact, we have completed preclinical testing for our West

Nile drug and expect to file an Investigational New Drug application with the FDA later this year.

We knew that once the sequence of the human coronavirus was identified, we could rapidly manufacture an antisense drug for testing in the laboratory and animals. We accomplished this in less than 2 weeks, a response time faster than any other technology I'm aware of. This drug is now in the hands of NIAID for evaluation at USAMRIID.

The developmental process I'm describing represents a new way to shut down viral infections. Rather than simply addressing the symptoms of the disease, AVI's antisense drugs actually slow the infection by targeting and shutting down the viral replication. This reduces viral "load" in the body and gives the immune system a chance to mount an effective response, similar to antibiotics for bacterial infections. The importance of this type of rapid response platform for viral outbreaks should not be understated. We hope to learn a great deal from the testing of our compounds in the weeks and months to come, and also to have our coronavirus antisense drug available to other WHO affiliated laboratories.

AVI's approach to viral therapeutics is different and new, but it is founded on 20 years of solid scientific research. We are making progress in all aspects of our development platform, but the opportunity to address a public health issue of this magnitude is work we embrace and we plan to devote considerable resources toward it. We truly hope to make a difference in the treatment of SARS, and appreciate your focus on the subject.

Thank you.

[The prepared statement of Denis R. Burger follows:]

PREPARED STATEMENT OF DENIS BURGER, CEO, AVI BIOPHARMA, INC.

Good afternoon and thank you for the introduction. I'm Denis Burger, CEO of AVI BioPharma. AVI is a biopharmaceutical company with headquarters in Portland, Oregon, with research and manufacturing facilities in Corvallis, Oregon.

I'd like to thank the committee for inviting me to participate in today's hearing. It is an honor to share information about our science, technology and vision as you endeavor to understand and effectively address the spread of SARS.

To begin, I'd like to turn briefly to the research and development AVI has been conducting since our company was founded in the early 1980s. AVI's drug development platform, a technology called antisense, enables us to develop therapeutics to address a range of life-threatening illnesses.

Antisense technology is now beginning to reveal its potential. AVI is conducting clinical trials to evaluate antisense drugs against cardiovascular disease, polycystic kidney disease and cancer, but it is our application of antisense to viral infections in the past two years that is most relevant in our discussion of the spread and containment of SARS.

I'd like to cover two key points in my testimony. First, AVI's antisense drugs target and inhibit the source of infection, not just the symptoms. In the case of SARS, the infection is caused by a single-strand RNA virus, a coronavirus.

Second, the way we develop antisense drugs represents a new kind of rapid response therapeutics that we believe may have significant impact in today's threatening viral landscape. We are making specific antibiotics for viruses.

AVI's NeuGene antisense drugs are like key blanks that can be cut precisely to match a disease's lock. They are made from snippets of DNA-like material known as oligonucleotides, or "oligos," the technical term for a stretch of genetic material. Each antisense drug is designed to block the activity of a particular gene or organism responsible for disease, whether human, bacterial or viral.

When a NeuGene compound comes in contact with its viral target, it binds to specific portions of the sequence and, like fabric caught in a zipper, prevents the organism from replicating.

Once the SARS outbreak was attributed to a human coronavirus, the scientists at AVI knew there was a good chance our technology would apply. We have spent the past several years researching the use of antisense on other single-strand RNA viruses, including hepatitis C virus, calicivirus and West Nile virus, and have had success in animal "outbreak" trials against two of those targets. In fact, we have completed preclinical testing for our West Nile virus compound and expect to file an Investigational New Drug (IND) application with the FDA later this year.

Earlier this winter AVI initiated preclinical studies evaluating our antisense compounds against two animal variants of the coronavirus and achieved antiviral activity against these targets in culture.

As a result, we knew that once the sequence of the new human variant was identified, we could rapidly synthesize and purify research quantities of a coronavirus antisense drug for testing in culture or in an animal model. We accomplished this in less than two weeks, a response time faster than any other technology I'm aware of.

The developmental process I'm describing represents a new way to shut down viral infections. Rather than simply addressing the symptoms of the disease, NeuGenes actually slow the rate of infection by targeting and shutting down the virus's replication mechanism. This reduces viral "load" in the body and gives the immune system a chance to mount an effective response.

In the case of the SARS virus, we all witnessed the rapid international effort to determine the virus's genetic structure, and we've heard about possible mutations in that structure. Another advantage of the antisense approach is that we are able to target portions of the viral sequence that we believe are conserved during mutations of the organism. This is certainly true of hepatitis C virus and the species-jumping calicivirus, two of our first viral targets, which have shown mutations.

In nine clinical trials for the nonviral indications I mentioned earlier, we have achieved a positive safety record with no drug-related adverse effects to the approximately 200 patients we have treated. In the case of viral antisense drugs, the viral gene sequence we target is not found in the human genome, so the body simply does not recognize or process the drug unless the viral target is present. We have confidence in the safety profile of our antisense chemistry, but I should add that we have not yet tested viral antisense in human subjects.

The importance of this type of rapid response platform for viral outbreaks should not be understated. We hope to learn a great deal from the testing of our compounds in the coming weeks and months, and have made our coronavirus antisense available on a limited basis to other WHO-affiliated laboratories.

We are committed to undertaking the broadest evaluation of the compound possible, both because the demographics of the disease demand rapid and decisive response and because replication of results is critical. AVI's approach to viral therapeutics is different and new, but it is founded on 20 years of solid scientific research.

We are making progress in all aspects of our development platform, but the opportunity to address a public health issue of this magnitude is work we embrace and that we plan to devote considerable resources toward. We truly hope to make a difference in the treatment of SARS, and appreciate your focus on the subject.

Mr. GREENWOOD. Thank you, Dr. Burger.

The Chair recognizes himself for 10 minutes for inquiry.

Let me start with Dr. Capetola.

You heard Dr. Fauci say when I asked him earlier what the treatment was for SARS patients, it is basically supportive treatment and that ultimately it involves ventilators. Could you walk us through the steps? What would it take, assuming that this disease in fact spreads and becomes more of a problem in the United States than it is now, what are the steps and the time lines that it would take to have your product available to treat these patients, either in place of ventilators or as an alternative?

Mr. CAPETOLA. Well, we have two approaches to it, Mr. Chairman. One is the trial that I described, which is called a phase II B trial. From the written testimony, with these very severe patients that have ARDS, the acute respiratory distress syndrome, we finished the rising dose trials some months ago and have published that data. Now we are in the next phase of it, which is going to enroll up to about 110 patients.

In these patients that have the very, very severe disease, we take the humanized engineered surfactant that we have and we actually go in with a bronchoscope and we wash the pus out of their lung, whether it is from a SARS virus and pneumococcal virus, just inflation in general. Because we want to restore and get rid of the fluid and proteinase and oxidants, and all the bad things that exist in those little air sacs and restore the alveoli, little air sacs, to their normal open state and get the patient off the ventilator. We are doing that as we speak.

We set up a division about a year and a half ago in Redwood City, California with Ph.D chemical engineers devoted toward aerosolizing our technology. And that is ready to go as we speak. We have done all the science behind it. We know we can aerosolize——

Mr. GREENWOOD. When you say "ready to go," ready to——

Mr. CAPETOLA. We can enter clinical trials——

Mr. GREENWOOD. Ready to begin clinical trials?

Mr. CAPETOLA. [continuing] within any time. The safety considerations have all been taken care of, because the patients that we are doing, you probably know from the written testimony, we are doing the world's largest pharmaceutically sponsored trial in premature babies ever conducted. And that is a phase III trial. The data from that trial is going to be released this October.

So between the dosages and exposure to have to humans there, is the massive doses that were given to ARDS patients. The aerosol product is not a toxicological concern, we do not think.

But we have scaled that up and we know we can produce an aerosol that becomes an effective surfactant. We have the devices ready to go with it. It is just a question of time and resources, and finding a defined patient population.

You heard from testimony of Dr. Lumpkin, Fauci as well as Dr. Gerberding, there is two approaches to this thing. You can do it scientifically or unscientifically.

Unscientifically, we can make the drug available as we speak. Scientifically, we would want to engage into proper clinical trials, which is defining the patient population, defining the controls and understanding the outcomes from these so that we can express the data and represent it in a scientifically valid form.

But just to answer your question again and to summarize. In the very sick patients we are doing those trials as we speak. We are ready. We can scale it. We cannot scale it for the whole world yet, but we manufacture the compound in several sites and we can make enough to meet quite a bit of a demand.

In the less severe patients ready for the aerosol approach to it, we are ready to enter clinical trials.

Mr. GREENWOOD. But you think your clinical trials are going to be finished when?

Mr. CAPETOLA. The premature babies are going to be finished October. The end of this year the ARDS trials phase II B trial will be finished. Phase III in that could be started as early as March 2004.

Mr. GREENWOOD. Okay. So then in each of those cases then the FDA needs to do its work at the end of your trials and make do its approval process.

Mr. CAPETOLA. Absolutely. That is correct.

Mr. GREENWOOD. And theoretically if there was a crises, the FDA would want to prioritize and fast track their approval process.

Mr. CAPETOLA. We have for the ARDS indication already, we have the fast track designation by the FDA as we speak.

Mr. GREENWOOD. Okay. Thank you.

Mr. CAPETOLA. You are welcome.

Mr. GREENWOOD. Mr. Brenna, can you walk us through, you talked about I think you recommended that there be a trial done at a particular site. Walk us through your vision of the future as to how the technology that you demonstrated today could be widely used in this country to identify patients or travelers coming into the country with fever, and then if for instance if at every airport and at every seaport where, and for that matter road bridge, where travelers came into this country you had this kind of detection equipment, then what? So someone gets off an airplane and they walk past a thermal imager and we see that they have a temperature exceeding temperature, then what would we do?

Mr. BRENNA. I think we are learning quite a bit from the Chinese model over the past few weeks and we are trying to gather and collect as much information regarding the success they are having with the systems and the experience being gained at the four hospitals, the airport and the railway station.

Before entering the airports, passengers would go through a special health care screening gate. If there is a temperature exceeding the baseline, as I mentioned before, 33 degrees centigrade, that patient goes on into another area. And they are examined. They are looked at and their temperatures are taken. They fill out a questionnaire as to what possibly could elevate the temperature beyond normal 98.6 or 33 degrees in the infrared world.

From that point, if a respiratory syndrome is suspected, the patient either at the airport or at a nearby clinic will be chest x-rayed. It is mandatory at this point.

And that is about all we know at this point. We do know it is working. We——

Mr. GREENWOOD. But do you envision, I mean is it your vision that someday in this country we would want travelers entering the country to routinely be imaged in this way and diverted for some further action or not?

Mr. BRENNA. Well, I have a major concern. In fact, that was exacerbated this morning in The New York Times article when I read that 51 flights come into this country everyday from Bejing, Hong Kong and Singapore. And those are the highest infected sites for SARS at this point. And I definitely would encourage incoming high risk international ports of entry for temperature screening.

The results so far that we have obtained from China, half of the patients or half of the, let us say, suspects who exhibit below or normal temperature, okay—let me rephrase that. A temperature above 33 degrees centigrade, half of those required further examination and the chest x-ray. The other half were false positives caused by some type of metabolic activity, menopausal, pharmaceutical type effect, or just physical exertion. So we are learning quite a bit about it.

I think it is a very inexpensive price to pay for security purposes. In fact, I look at that false positive rate as being very positive; that we are learning from this experience.

Mr. GREENWOOD. But to get back to my point here or my question, in terms of your vision for this technology for its routine application, is it your thought that perhaps rather than this be a routine activity at all points of entry in the United States, that this is a technology that might be useful in a particular instance where there is a new outbreak of some kind that is potentially very infectious and it might be used to screen only those patients—I keep saying patients—only those travelers from particularly high areas where there is a high infection rate? Is that what you are thinking?

Mr. BRENNA. I think that is a starting point for this. I am not sure we could limit this to SARS, but if there are other diseases which are airborne in nature, that can elevate temperature, I think this is an excellent screening device.

I am very impressed with what I have seen so far by the PRC in terms of adapting this technology at airports, hospitals, all visitors, incoming patients, railroad ticket counters especially for mass transit. And when I look at the magnitude of the number of airports, railroad stations, hospitals, we are looking at over 300 major airports, over a 1,000 railroad facilities, over 12,000 hospitals. That type of a problem could occur here.

Let us take, for example, one step forward points of entry, shipping.

So if you asked what my vision is, yes, I think for the short term, high risk international risk entry points I think would require some type of screening at this point. If we do not, and without having the cure or a better of understanding of SARS, then we run the risk of having that disease take over this country.

Mr. GREENWOOD. The Chairman's time has expired.

The gentleman from Florida is recognized for 10 minutes.

Mr. DEUTSCH. Thank you, Mr. Brenna.

The Hong Kong government tells us that the infrared cameras installed on both sides of the border of China have identified 37 individuals out of the hundreds of thousands that cross daily as having temperatures in excess of 100 degrees Fahrenheit. Does that number suggest that the Hong Kong/Guangdong border equipment is working or not working?

Mr. BRENNA. I think I missed the last part of your question.

Mr. DEUTSCH. Is 37 out of several hundred thousand, does that mean the equipment is working or not working?

Mr. BRENNA. I am not sure I understood that number before 37. We have six systems in two provinces. I don't have a total number. And I am not sure I understood where that 37 came from. I believe they were from Hong Kong or Singapore. We are not in that area——

Mr. DEUTSCH. I do not know if you were here when the official from the WHO, but I mean that is actually the number that he confirmed earlier in this hearing.

Mr. BRENNA. Okay.

Mr. DEUTSCH. And it is 37 out of several hundred thousand. I mean, it is neat cool equipment, but I mean is it working. I mean, which is really the question.

Mr. BRENNA. Our feedback is, yes. I do not have the type of data to support that were presented by the WHO this morning.

If I understood that number, I thought it was between Hong Kong and Singapore, if I am not mistaken.

Mr. DEUTSCH. All right. I mean, if you can follow up with our staff, I would appreciate it.

Mr. BRENNA. I will.

Mr. DEUTSCH. Thank you.

Mr. Fischer, do you have any anticipated time table for when different phases of your research will be completed?

You have to turn on the microphone.

Mr. FISCHER. We are actually putting the vaccine candidates together now. We have planned to present to the NIH within months the initial candidates that they can be looking at in their animal models, so that by the end of the year we will have initial data we believe in those animal models as to whether we are getting a robust immune response against the SARS proteins of interest. If that is the case, we will then in parallel, actually, be making the vector for potential clinical testing so that early to mid next year we would be in the clinic to be able to evaluate the safety of the initial candidates.

Mr. DEUTSCH. I mean phase one, I mean do you have a——

Mr. FISCHER. Well, as you hear today, I think the NIH, the FDA, the CDC; there is going to be a lot of cooperation with the health authorities to look at how best to expedite the testing of these. Phase one testing in this case could go very rapidly, because we are really looking at safety only. We think that that will be expedited.

The next stage is to look at that with a dose dependence in a phase two setting, which will take a little bit longer. And the key for a situation such as this is where would you actually test it in terms of challenging. And I think that is what I mean by challenging, is actually giving a patient the virus itself, which at this point would not be realistic, or be an area of the world such as China where there is an endemic high infection rate. That is the part that I think will require significant interaction between the health care authorities, the FDA. And part of the key question there is has the epidemic increased, is it getting worse or is it slowing down. So the risk benefit of that analysis will happen, I think on an ongoing basis as we see how the epidemic emerges.

Mr. DEUTSCH. Mr. Capetola, what are the potential dangers or suspected side effects or contradictions of surfactant replacement therapy?

Mr. CAPETOLA. Well, it differs according to the patient population that we are treating. In the large trial that I described in very premature babies, these are babies that are one to three pounds, for the most part, who are born without their own surfactant. So essentially we are just replacing what is missing in these little children until their own genes are turned on within the first day.

And when you are putting things down into the lung like an intratracheal administration in those patients, you get temporary desaturation, you can get temporary cessation of breathing for a few second. But for the most part these drugs are considered, and as you probably know from the written testimony, in that patient population there are animal derived products on the market which

are considered the greatest single breakthrough in neonatal medicine in terms of reducing infant mortality. So not a lot of side effects that cannot be controlled by the neonatologist at the bedside.

In the adult population, it is even safer we think in our opinion, according to the phase II data, because there is 19 major segments of the lung and as a pulmonologist or trauma surgeon goes into each one of the segments, that's only one nineteenth of the surface area, and they could control the patient's medical condition in a fairly robust way.

So, we do not know enough to fully access the safety yet. We will know that after phase III, but so far we are very encouraged by what we see.

Mr. DEUTSCH. Thank you.

Mr. Burger, are there any known or potential health risks identified or associated with antisense technology.

Mr. BURGER. Our antisense chemistry has completed nine human clinical studies in nonviral indications; cancer, cardiovascular restenosis, polycystic kidney disease, drug metabolism. So in treating over 200 patients, we have not seen a single drug-related adverse event, so it is remarkably safe. It is stealthy, if you will. This small molecule is not recognized by your body, so it is specific for the gene target, yet is not recognized and therefore, so far, quite safe.

Mr. DEUTSCH. Do you have any anticipated time table for when antisense technology might be available for the general population?

Mr. BURGER. For SARS?

Mr. DEUTSCH. Yes.

Mr. BURGER. We expect to be in phase I B studies with our West Nile agent later this year, presumably by the time summer comes around. We are intending to file an IND shortly.

We have the SARS antisense agent in the hands of NIAID now for testing at USAMRIID. If those tests were positive, and we have been effective against five or six other similar RNA viruses and other animal coronaviruses, so we anticipate it is going to be able to stop the replication of the SARS agent. If it does in clinical studies, then the next step is to sit down with the FDA, assess risk-benefit, and how quickly to initiate clinical studies. That could be months.

Mr. DEUTSCH. Mr. Lonberg, in your testimony you stated the Government can play a role in encouraging biotech and pharmaceutical companies by removing some uncertainties such as establishing a defined market by underwriting some of the research and development costs. Clearly there are difficulties with this request to us. And if the Government were to enter into a contract with a pharmaceutical company for 10 years, what would happen if a better, safer, more effective drugs was developed, let us say 2 years down the road at that point in time?

Mr. LONBERG. I guess what I am proposing is not a contract up front, but rather a defined market. If the Government says——

Mr. DEUTSCH. Would you bring the microphone a little bit closer?

Mr. LONBERG. Sorry.

If the Government states that up front that over X years they are going to purchase so many doses of a therapy that meets this specification as opposed to a therapy from a particular company, that would define the market.

Mr. DEUTSCH. Has venture capital dried up for projects such as yours?

Mr. LONBERG. Our company is not dependent on venture capital for its funding. We are a publicly traded company.

At this point funding, venture capital funding and public market funding for biotechnology companies is quite scarce.

Mr. DEUTSCH. And why is that?

Mr. LONBERG. I think a thorough analysis of that would probably require somebody with a different set of expertise than myself. But I can least out that there are boom and bust cycles in biotechnology. And we are not at a boom cycle right now.

Mr. DEUTSCH. If the Government eliminates your risk by guaranteeing the eventual market, should the Government then be able to help you formulate the price or otherwise share in the resulting rewards?

Mr. LONBERG. I am certainly not suggesting the Government would be eliminating risk. And I am also not advocating that the Government step in and do something. I think that is a public policy decision and that is up to you to think about. I am just trying to convey to you what decisionmaking, what components go into our decisionmaking. And the biggest problem we have with something like SARS or with bioterror is that we cannot identify the market up front. And I think that is why you do not see a lot of biotech companies jumping in at this point.

Mr. DEUTSCH. Thank you very much.

Mr. LONBERG. Thank you.

Mr. GREENWOOD. The Chair thanks the gentlemen. And if I may say so, I find it so exciting and so encouraging to see the entrepreneurial world out there so busy producing and experimenting and learning about these products that are going to mean so much to the human race. And thank you for doing that work.

Thank you for testifying before us today. Thank you for your patience and we thank you for being with us.

The Chair will hold the hearing record open for 30 days for additional submissions to the record.

The hearing is adjourned.

[Whereupon, at 6:41 p.m., the subcommittee was adjourned.]

[Additional material submitted for the record follows:]

AMERICAN PUBLIC HEALTH ASSOCIATION
WASHINGTON, DC
May 12, 2003

The Honorable JAMES GREENWOOD
Chair
House Energy and Commerce Committee
Subcommittee on Oversight and Investigations
2125 Rayburn House Office Building
Washington, DC 20515

DEAR CHAIRMAN GREENWOOD: On behalf of the American Public Health Association (APHA), the largest and oldest organization of public health professionals in the nation, representing more than 50,000 members from over 50 public health occupations, I write to thank you for the opportunity to testify before the Oversight and Investigations Subcommittee on the public health response to the SARS epidemic last Wednesday, May 7.

During the hearing, Representative Diana DeGette requested that APHA supply for the subcommittee's hearing record our request for the National Center for Infectious Diseases (NCID) for FY04. NCID plays a critical role in preventing and controlling infectious diseases. Specifically, the center focuses on four areas:

- surveillance and response to detect, investigate, and monitor emerging pathogens, the diseases they cause and the factors influencing their emergence;
- applied research through the integration of laboratory science and epidemiology to optimize public health practice;
- infrastructure and training to strengthen the nation's public health system to support surveillance and research, and to implement prevention and control programs; and
- prevention and control to ensure timely implementation of prevention strategies and to enhance communication of public health information about emerging diseases.

In our best professional judgment, NCID will require funding of at least $467 million in FY04 to support these efforts to protect the nation and the world from infectious diseases, including emerging and re-emerging infectious diseases like SARS and West Nile, and to combat the growing problem of antimicrobial resistance. APHA believes that it is essential to fully fund NCID to avoid repeated requests for emergency funding from Congress every time new threats emerge. We are hopeful that Congress will restore the proposed cuts to NCID in the president's budget and fund the center at $467 million in FY04.

Thank you again for allowing us to share our views on these important issues with you and members of the Subcommittee. We look forward to working with you on other important public health issues in the future.

Sincerely,

GEORGES C. BENJAMIN, MD, FACP
Executive Director

cc: Representative Diana DeGette

PREPARED STATEMENT OF JOHN M. BRENNA, PRESIDENT, COMPUTERIZED THERMAL IMAGING, INC.

Dear Mr. Chairman and members of the sub-committee: I would like to submit the following information as a supplement to the material presented to the Subcommittee on Oversight and Investigations on May 7, 2003 concerning SARS. At the Subcommittee meeting, I described how Infrared imaging technology developed by, Computerized Thermal Imaging, Inc., was being used in China as part of a SARS Screening protocol for public facilities, such as airports, railway stations, bus terminals and hospitals. Since that meeting, we have gained additional experience in China, and have extended our Infrared Camera technology for SARS Screening to Canada. I would like to briefly share those experiences, as I believe they can be very useful to the Subcommittee and to the U.S. agencies responsible for protecting our citizens from biological threats.

Approximately ten weeks have elapsed since our Infrared cameras were installed in China as a first line of defense for SARS screening. To date, there are 10 systems in operation. Two systems are now in constant use at Nanjing International Airport, two at the Nanjing Railway Station and two systems at the Nanjing Bus Terminal. Four units are used at the following Chinese hospitals: Golou Hospital, a 100+ year old U.S. missionary hospital, Nanjing Peoples Hospital & Rehabilitation Center, largest hospital in JiangSu province, JiangSu Province Traditional Chinese Hospital, Beijing Anti-SARS Hospital, and XiaTang Shan Hospital. We have official contact information at these facilities that may be helpful to the Subcommittee in the future.

On May 7, 2003, the day of my testimony, our company was finalizing its response to a tender issued by the Public Works & Government Services Canada (PWGSC) on behalf of Health Canada. CTI's Infrared camera was ultimately selected for this important pilot program designed to assess the usefulness of Infrared imaging as a SARS screening tool at Canadian airports. Three systems are currently installed at the Toronto International Airport, two in Terminal 2 and one in Terminal 3. After 4 weeks in Toronto, they will be moved to Vancouver International Airport where the evaluation process will be repeated. Based on the data collected in Toronto and Vancouver, Health Canada officials will determine how, where and when Infrared cameras will be used in Canadian airports, as well as other public facilities.

To date, over 50 Canadian operators have been trained to use special SARS-screening software developed by CTI based on it's now substantial China experience. CTI representatives are working with Health Canada and Greater Toronto Airport Authority (GTAA) officials on an on-going basis to assist in establishing formal screening procedures and to show how to use the system's full capabilities to simplify the many facets of their screening program. The CTI system's inherent flexibility has been very useful in this process. Its database structure allows operators

to quickly identify passengers exhibiting suspiciously high temperatures and record their images. It automatically records time and date on each image to further speed the process. Suspicious images can then easily be networked to on-line workstations where additional evaluation post-processing analysis, printing, etc., can occur and where information can be added such as subject's name and other important data without disrupting the normal flow of traffic. Once this data is captured, the CTI system generates reports summarizing activity levels such as number of suspicious images per shift and other information deemed important by screening supervisors. Response to CTI for this type of functionality has been very positive from both Canada and China. Temperature recording accuracy and data management are a necessity for this type of screening system.

Limited performance data at this time makes it difficult to conclude that Infrared imaging is a cure all tool for screening viruses like SARS. However, early indications and results suggest that it does support a first defense strategic approach. Chinese officials are convinced of its usefulness as evidenced by installation of additional Infrared cameras on a routine basis. Initial input from Health Canada officials has been very encouraging. Canadian citizens have given the program considerable attention, since several new SARS cases surfaced in recent weeks. Without the clear and present danger of a SARS outbreak in the United States, our citizens have put little pressure on government officials to execute similar airport-based virus screening programs. However, I believe that they will enthusiastically support a government-sponsored program that is prepared to take serious measures, like those used in China and Canada, should an outbreak occur in the U.S.

Listed below are early statistics from our experience in China that should be useful in considering a U.S. pilot SARS-screening program:

Number of Subjects Screened with Infrared imaging: It is important to note these are "post" SARS traffic levels. a) 4,000/day at Nanjing Airport; b) 4,000/day at Nanjing Bus Terminal; and c) 10,000/day at 2 Nanjing Railway Stations.

Infrared Screening Results: a) Total subjects detained for medical evaluation—2,400; b) Total subjects quarantined as SARS suspects—50; and c) Total SARS cases confirmed—10.

Pre SARS Traffic Levels: It is important to note the negative effect SARS is having on transportation. a) 25,000/day at Nanjing Airport; b) 20,000/day at Nanjing Bus Terminal; and c) 60,000/day at 2 Nanjing Railway Stations.

Negative impact on China's economy from the SARS outbreak: estimated $100B

It is important to note that Infrared Screening has allowed a large majority of passengers to continue on their way without significant delay, just a few seconds/person for the Infrared image. Most passengers who exhibited suspicious facial temperatures were only delayed 5 to 10 minutes as interviewers and medical personnel determined if there was a sufficient basis for further medical evaluation such as oral or ear temperature measurement, respiratory function assessment and/or chest x-ray. Only those subjects with a history of travel to SARS-affected areas or had contact with known SARS victims, and/or exhibited a sufficiently high fever and cough were held over for more extensive evaluation. The Infrared Screening strategy appears to be working as a first defense system. A number of subjects, upon further examination required quarantine as well as those actually diagnosed with SARS.

In conclusion, I believe that appropriate U.S. agencies should seriously consider conducting an Infrared imaging-based SARS screening pilot project at several high-risk points of entry, similar to the programs being administered in China and by Health Canada at the Toronto and Vancouver international airports. CTI is available to facilitate communications between U.S. Health Officials and the various Chinese and Health Canada Administrators to develop either a trial pilot program or preparedness plan.

If at all possible, I would like to request any assistance that can be offered by the Subcommittee in facilitating communications between our company and appropriate U.S. agencies such as the Center for Disease Control, the Department of Homeland Defense and/or the Transportation Safety Administration to further discuss the use of Infrared Imaging for SARS Screening.

Thank you again for the invitation to speak at the May 7, 2003, Subcommittee meeting, and the opportunity to supplement my initial testimony. I hope that you find the additional information useful. Please let me know if I can be of any further service.

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