S. Hrg. 108–74

SARS: HOW EFFECTIVE IS THE STATE AND LOCAL RESPONSE?

HEARING

BEFORE THE

PERMANENT SUBCOMMITTEE ON INVESTIGATIONS

OF THE

COMMITTEE ON
GOVERNMENTAL AFFAIRS
UNITED STATES SENATE

ONE HUNDRED EIGHTH CONGRESS

FIRST SESSION

MAY 21, 2003

Printed for the use of the Committee on Governmental Affairs

Available via the World Wide Web: http://govt-aff.senate.gov or
www.senate.gov/~govt-aff

U.S. GOVERNMENT PRINTING OFFICE

88–251 PDF WASHINGTON : 2003

For sale by the Superintendent of Documents, U.S. Government Printing Office
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SARS: HOW EFFECTIVE IS THE STATE AND LOCAL RESPONSE?

WEDNESDAY, MAY 21, 2003

U.S. SENATE,
PERMANENT SUBCOMMITTEE ON INVESTIGATIONS,
OF THE COMMITTEE ON GOVERNMENTAL AFFAIRS,
Washington, DC.

The Subcommittee met, pursuant to notice, at 9:04 a.m., in room SD–342, Dirksen Senate Office Building, Hon. Norm Coleman, Chairman of the Subcommittee, presiding.

Present: Senators Coleman, Collins, Levin, Carper, and Lautenberg.

Staff Present: Joseph V. Kennedy, General Counsel; Elise J. Bean, Democratic Staff Director/Chief Counsel; Mary D. Robertson, Chief Clerk; Laura Stuber, Democratic Counsel; Priscilla Hanley (Senator Collins); John Myers (Senator Specter); Marianne Upton and Rianna Brown (Senator Durbin); Bob Hall (Senator Dayton); Tate Heuer (Senator Pryor); Kate Eklund, Jason Hill, Dan Mullkoff, and Ahmed Khalil (Senator Levin); Rebecca Mandell (Senator Lautenberg); and Josh Handler (Senator Akaka).

OPENING STATEMENT OF CHAIRMAN COLEMAN

Senator COLEMAN. Good morning. We are going to call this hearing of the Permanent Subcommittee on Investigations to order. I want to thank everybody for attending my first hearing as Chairman of the Permanent Subcommittee on Investigations in our Nation's capital.

Today, we address the issue of SARS. We address it from the vantage point of the ability of our Nation to address this, and future threats, at a local and State level. We address it from my stated position that it is my hope that this Subcommittee can find ways to improve and reform areas of American life, to improve our lives, and to make us safer and more secure.

And today, against the backdrop of a Nation at war—with the national terror warning raised to its second-highest level—let us be clear that the stakes facing our Nation, and our world, could not be higher. Our ability as a Nation, to defend ourselves, against all enemies—foreign or domestic—or even Mother Nature—depends on our commitment to preparedness.

The front lines of our Nation's war against nature's terror of communicable disease are, and will be, local governments. As a former mayor, I understand that. I will never forget that. The ability of our Nation to defend itself from the terror inflicted by man

through the use of chemical or biological weapons of mass destruction will be through the efforts of local government officials.

My friends, while there has been and remains great tragedy across the world as a result of SARS, and as Secretary of Health and Human Services Tommy Thompson warns us, America is not yet safe from SARS, let me say this. I believe we got lucky this time.

While preparations on the war on terror have better positioned us to respond to threats and potential threats such as SARS, a confluence of events spared our Nation from the tragedy that has visited others such as Canada, Taiwan, and China, a tragedy that not only takes people's lives but is also halting their lives.

For example, since SARS has emerged as a disease to be reckoned with, adoptions of Chinese children by Americans have been halted. In Toronto, untold economic damage has been sustained because of potentially unnecessary reactions to SARS on the part of organizations responsible for addressing the disease. We need to remember that SARS was not the worst disease that has ever plagued civilization, either in terms of ability to spread or its mortality. Even as we dealt with SARS, the World Health Organization was battling cases of Ebola and avian flu elsewhere in the world.

As I am sure our panel of distinguished experts will attest, the evolution and transmission of the next disease is not a question of "if," it is simply a matter of "when," and I believe they will tell you that SARS is not yet done. It may mutate. It may become worse. It is not yet done killing.

Nor are new diseases that will appear in our future, and when they do, our ability to contain them and survive them will largely depend on local responders who treat the first cases. It is vital that we continue our investments in making sure that these responders have the resources, training, and support necessary to protect us. In an era when even a few hundred non-lethal cases imposed significant social and economic costs, we should regard these investments as prudent insurance against both intentional and naturally-occurring threats to our health.

When a new disease such as SARS or the West Nile virus hits local communities, several things have to happen. First, local doctors need to know how to recognize that something new is happening and need to know who to turn to for information and support.

Second, at the national and international levels, agencies must quickly develop information about the characteristics of the disease in order to treat patients and prevent its spread. The World Health Organization, the National Institutes for Health, and the Centers for Disease Control and Prevention perform this role well.

Third, and this is most important, in my opinion, the information these agencies develop must be transmitted back to mayors, hospital administrators, and airport officials so that doctors, airline attendants, researchers, and average citizens know what to do in order to protect themselves.

In the end, our goal ought to be to develop a national response, predicated on the understanding that the bulwark of that response is going to be at the local level—and by local government and elected officials.

And that they must have the resources and the cooperation of the Federal Government to do so.

This hearing will focus on the synergy that is necessary for an effective national response, driven by the talent and know-how at the local level. There are questions we must ask and solutions we must seek. There may be laws that must be changed and behaviors that must be modified.

In the end, there can be no mistake that the issues we address today may very well shape and form our response to the next natural or man-made disease that violates our sense of safety as a human race.

Recently, I sent a letter to the Commissioner of the Minnesota Department of Health. The questions I asked her are relevant today . . . and remain questions we must address locally on a national basis.

What are States doing to prevent further outbreaks of SARS?

Have we identified potential risk factors or are there segments of our population who are at particular risk?

What are States and local governments doing to educate citizens about SARS and other potentially devastating diseases?

Are there changes that must be made to our local, State, and national quarantine laws?

Do local officials know where to turn to for information and support?

What should local officials do in the first days and weeks when faced with a new disease with unknown characteristics?

What are the resources available and what are the resources needed for local governments to be more effective?

Are hospitals equipped to treat small numbers of cases and do they have the proper isolation facilities to accomplish this task?

What are the plans and strategies of hospitals to handle new SARS cases or other potential diseases in the short- and long-term?

Do local and State health departments have the personnel and resources they need to respond to potential disease threats?

Today's witnesses will tell us that SARS was a wake-up call, and I suspect they also support my belief that, so far, we have been lucky.

On the whole, our response to the outbreak was very good. Many of our cases came after the first case in Toronto so that local officials were already alert. It is also possible that Toronto received a more virulent strain than any of our cities experienced.

We will also see that our responses were aided by the effort and resources expended since September 11 and the anthrax attacks. Over the past year, cities, States, and hospitals have begun preparing for a sudden outbreak of infectious disease.

A recent GAO report indicates that we still have some way to go, however. The report found that gaps exist in the disease surveillance system and laboratory facilities and that there are workforce shortages. It also found that planning for regional coordination is still lacking between States, even as they develop plans of receiving and distributing medical supplies for emergencies. Finally, it found that most hospitals around the country lack the capacity to respond to large-scale infectious disease outbreaks.

Our systems did a good job of protecting us this time, but we can always do better. In order to improve, we must first listen. Today's witnesses represent different parts of the national response to infectious disease. They each have a different perspective on how the system works.

In the final analysis, our work is at its initial stages. It is my hope that we emerge from this hearing today with a sense of hope and confidence that the investments we have made in preparation and response are making a difference and that those areas that are preventing us from being more responsive and effective can be changed.

As a former mayor, I am well aware of the power of local officials to confront and manage the dangers of this new era. I also know that those who are here today are eager to offer us more than just anxiety, they also offer us hope that we can, as a Nation, bear the burden of this new era in a positive and results-oriented manner that has been the hallmark of Americans for generations.

With that, I will turn to my distinguished Ranking Member and former Chairman of this Subcommittee for his comments. Senator Levin.

OPENING STATEMENT OF SENATOR LEVIN

Senator LEVIN. Thank you very much, Mr. Chairman. I commend you for convening this hearing. I know that you have had a very successful hearing in Minnesota, but this is your first as Chairman here in the Nation's Capitol and I congratulate you on that and commend you for calling this hearing today on such a critical subject.

The front lines of the SARS battle, as the Chairman has mentioned, are drawn at our airports and our home communities, at border crossings and hospitals, and at local doctors' offices. Local health care providers need training and resources if we are going to protect our country from SARS. We have been relatively lucky so far, but we need more than luck to keep this public health threat under control. We need resources and planning.

Right now, our knowledge of SARS is limited. We don't know where the disease comes from. We don't know how to rapidly and reliably test its presence. We don't have a cure. But we have learned that if we identify SARS patients quickly and isolate probable cases, that we can prevent the disease from spreading. That means our first and most important line of defense is having first responders who are trained to spot SARS symptoms, who have adequate resources, and who have workable, sensible plans to safeguard the public.

We know that some countries have done a better job than others at preventing the spread of SARS. We know that China was not at first up front with its citizens about the disease, and as a result, both confusion and the disease have spread. In contrast, Vietnam successfully contained a possible SARS outbreak through swift action. To protect our own country, we need to learn from the experiences of others as well as to devise ways to support other countries' efforts to stem their SARS infections.

When we look here at home, the facts paint a complex picture of our readiness to fight SARS. On the one hand, we have a public

health system that is engaged in this battle and taking many of the steps that are needed. A few cases are being found, and there are no fatalities to date. But on the other hand, we have inadequate resources to support the good intentions and planning of our health care system.

In my home State of Michigan, the SARS readiness picture is a promising one, but one that requires further support and development. Out of a total of 43 persons evaluated in Michigan for SARS to date, only four suspected cases have been identified. Those cases are being treated with no fatalities to date.

My State of Michigan has taken a number of steps to mount an effective response to the SARS threat. It has determined that it has legal authority to quarantine individuals posing an imminent public threat. The Michigan Department of Community Health has assigned responsibility for combating SARS to a specific State office, the Public Health Preparedness Office. The State has issued guidelines to Michigan hospitals on how to identify and treat suspected SARS patients and sends out regular E-mail updates to hospitals in all 64 local county health departments.

The University of Michigan Medical School has also taken a proactive role. It has created a SARS working group that meets weekly and includes representatives from local community health departments. The working group has set up a communications line called Telecare that takes calls from people with questions about SARS.

These precautions are essential for the reason that they are essential everywhere, but also particularly because Michigan is the largest single area for border crossings between the United States and Canada. To limit SARS risks at its border crossings, Michigan is working actively with the CDC, Customs, border, and port personnel to screen persons entering the United States. If persons crossing the border show symptoms of SARS, Michigan and the CDC have designated three local health departments to evaluate and care for suspected patients, including possible hospitalization and quarantine.

Many of these steps represent new and important improvements, and the near absence of SARS in Michigan shows that they seem to be working. But our officials have also uncovered major shortcomings that need to be addressed.

For instance, when the City of Detroit drew up an action plan for homeland security, one of the first such plans for a major city in the United States, by the way, it determined that the city does not currently have a computerized database that can detect emerging public health problems. Health care workers and family members must have adequate supplies of masks as well as other key health care equipment, such as respirators.

Another issue of importance is that, right now, Michigan doctors have to send their SARS diagnostic tests to CDC labs in Atlanta for analysis. Michigan laboratories want to set up an in-State testing service to speed up the results and to reduce the burden on CDC labs.

Resource needs on the local level show how far we still need to go to protect this country against SARS. They are more than matched by questions on the international and national level. How

do we assist China in getting its SARS outbreak under control to reduce SARS risks worldwide? Should the World Health Organization be given additional authority to monitor in-country disease outbreaks and quarantine procedures?

We can isolate patients, but we cannot isolate our Nation. We need to work with the world community. We need the world community to work together to reduce the threat of SARS and other diseases which know no boundary, just as we need the world community to pull together in our war on terrorism.

Recent press coverage indicates that the SARS threat is perhaps coming under control worldwide. I hope that is true. But responsible government calls for taking steps today to prevent the SARS problem from becoming a public health care nightmare tomorrow. We need the political will to take those steps. We need to invest in public health. A number of those programs have been cut in the proposed budget. That is a short-sighted decision.

Finally, we cannot rely on private philanthropy to deal with this kind of a public need. We have seen some wonderful examples of private philanthropy. The co-founder of Home Depot, Bernard Marcus, took a tour of the CDC's laboratory facilities in Atlanta and was so disturbed by their dilapidated state that he personally pledged $2 million to help the CDC equip a state-of-the-art emergency response center that has played a very critical role in the battle against SARS. But it is just not the way to go, to rely on private citizens to step in to make up for the inadequate resources that the Federal Government has provided in such a vital area. We applaud his generosity. It has made a difference. But we cannot rely on that and we have to do what is necessary ourselves in devoting the resources that are essential.

Mr. Chairman, because I am managing the defense bill on the floor in the Senate this morning, I am unable to stay to hear the testimony. I will surely be briefed on these important proceedings by my staff, but again, I commend you and I ask that the balance of my statement be placed in the record at this time.

Senator COLEMAN. It will be placed in the record. Thank you very much, Senator Levin.

[The prepared statement of Senator Levin follows:]

PREPARED OPENING STATEMENT OF SENATOR LEVIN

Today, the front lines of the SARS battle in the United States are drawn at our airports, our border crossings, our hospitals, and the local doctor's office. Our local health care providers need resources and training to protect our country from a SARS outbreak. We've been relatively lucky so far, but we need more than luck to keep this public health threat under control. We need resources and planning.

Right now, our knowledge of SARS is limited. We don't know where the disease came from, we don't know how to rapidly and reliably test its presence, and we don't have a cure. But we have learned that if we identify SARS patients quickly and isolate probable cases, that we can prevent the disease from spreading. That means our first and most important line of defense is having first-responders who are trained to spot SARS symptoms, have adequate resources, and workable, sensible plans to safeguard the public.

We also know that some countries have done a better job than others at preventing the spread of SARS. We know that China was not, at first, up front with its citizens about the disease and as a result, both confusion and the disease have spread. In contrast, Vietnam successfully contained a possible SARS outbreak through swift action. To protect our own country, we need to learn from the experiences of others, as well as devise ways to support other countries' efforts to stem their SARS infections.

When we look here at home, the facts paint a complex picture of our readiness to fight SARS. The good news is that we have a public health system that is engaged in this battle and taking many of the steps needed. Few cases are being found, and no fatalities to date. But on the other hand, we have inadequate resources to support the good intentions and planning of our health care system.

In my home State of Michigan, the SARS readiness picture is a promising one, but one that requires further support and development. Out of a total of 43 persons evaluated in Michigan for SARS to date, only 4 suspected cases have been identified. All four cases are being treated, with no fatalities to date.

Michigan has also taken a number of steps to mount an effective response to the SARS threat. It has determined that it has legal authority to quarantine individuals posing an imminent public health threat. The Michigan Department of Community Health has assigned responsibility for combating SARS to a specific state office, the Public Health Preparedness Office. The state has issued guidelines to Michigan hospitals on how to identify and treat suspected SARS patients, and sends out regular E-mail updates to hospitals in all 64 local county health departments.

The University of Michigan Medical School has also taken a proactive role. For example, it has created a SARS working group that meets weekly and includes representatives from local community health departments. The working group has set up a communications line called Telecare that takes calls from people with questions about SARS. They have developed a questionnaire for health care providers to screen emergency room patients by asking about their travel history, exposure to potential SARS patients, and symptoms. They are also working on locating a facility that could be used to quarantine a large number of SARS patients, were that to become necessary.

These precautions are essential, in part because Michigan is the largest single area for border crossings between the United States and Canada. Canada is the United States' top trading partner with over $1 billion worth of goods and services crossing the border every day, and more than 40 percent of that trade moving between Michigan and Ontario. To give you some idea of the potential impact SARS could have on Michigan, every day over 36,000 vehicles—trucks, cars, and buses—depart Canada and travel to Michigan. Furthermore, every day the number of people coming into Michigan from Canada on trains, cars, and buses exceeds 70,000. In addition, Great Lakes marine traffic and the Detroit international airport bring in cargos and passengers from all over the world. Together, these border crossings make Michigan a key gateway that must be protected to keep the United States safe from SARS.

To limit SARS risks at its border crossings, Michigan is working actively with CDC, Customs, Border, and port personnel to screen persons entering the United States. If persons crossing the border show symptoms of SARS, for example, Michigan and the CDC have designated three local health departments in Chippewa County, St. Clair County, and Detroit to evaluate and care for suspected patients, including possible hospitalization and quarantine.

Many of these steps represent new and important improvements, and the near absence of SARS in Michigan shows they seem to be working. But our officials have also uncovered major shortcomings that need to be addressed. For instance, when the City of Detroit drew up an Action Plan for Homeland Security, one of the first such plans for a major city in the United States, it determined that the city does not currently have a computerized database system that can detect emerging public health problems. Detroit Mayor Kwame Kilpatrick has now called for establishing a citywide disease surveillance system that, consistent with privacy protections, can track both infectious diseases and bioterrorism incidents, and communicate directly with health care professionals, state officials, and the CDC.

Another ongoing issue is training and protections for local health care providers. In some countries, hospital workers such as nurses have suffered SARS infections despite using recommended safeguards. More work needs to be done to understand how they became sick and to protect them. One part of the problem may be that only certain types of surgical masks provide adequate protection from SARS droplets, and these masks need to be fitted carefully and changed daily. An even more basic issue is to ensure that health care workers and family members have adequate supplies of masks as well as other key health care equipment such as respirators.

Another issue of importance is that, right now, Michigan doctors have to send their SARS diagnostic tests to CDC labs in Atlanta for analysis. Michigan laboratories want to set up an in-state testing service to speed up the results and to reduce the burden on CDC labs. Another open issue is who will pay for significant testing and quarantine costs, should those become necessary.

Resource needs on the local level show how far we still need to go to protect this country against SARS. They are more than matched by questions on the inter-

national and national level. How do we assist China in getting its SARS outbreak under control to reduce SARS risks worldwide? Should the World Health Organization be given additional authority to monitor in-country disease outbreaks and quarantine procedures? How do we encourage rapid development of a SARS vaccine?

We can isolate patients, but we can't isolate our country. We need to work with the world community, and we need the world community to work together to reduce the threat of SARS and other diseases which know no boundaries, just as we need the world community to pull together in our war on terrorism.

Recent press coverage indicates that the SARS threat may be coming under control worldwide, and I hope that is true. But responsible government calls for taking steps today to prevent the SARS problem from becoming a public health care nightmare tomorrow.

We need the political will to take those preventative steps. Last week, the Senate voted for more than $350 billion in tax cuts over the next 10 years. To help pay for its proposed tax cuts, the Administration has proposed cutting spending on a number of important programs, including for public health care. That is a shortsighted mistake.

We can't rely on private philanthropy to deal with the public's need. One example shows why. After the 9–11 and anthrax incidents in 2001, a U.S. citizen who is also a co-founder of Home Depot, Bernard Marcus, took a tour of the CDC's laboratory facilities in Atlanta. He was so disturbed by their dilapidated state that he personally pledged $2 million to enable the CDC to equip a state-of-the-art emergency response center, which has played a key role in the battle against SARS. It is incredible that a private citizen had to step in to make up for the inadequate resources of the Federal Government in such a vital area. While the generosity of Mr. Marcus has made a real difference, we can't rely on that approach to construct a workable disease surveillance system that can identify, monitor, and evaluate the severity of infectious disease outbreaks in the United States.

I was a member of the Detroit City Council during the 1970's. I know that if a contagious disease were to have broken out in my city during those days, my phone would have started ringing and not stopped. The experiences of local health care professionals can tell us a lot about what is and is not working, and I commend Senator Coleman for holding this hearing today—his first, by the way, in Washington as Chairman of the Permanent Subcommittee on Investigations. I look forward to hearing today's testimony.

Senator COLEMAN. Let me turn to the distinguished Chairman of the Committee on Governmental Affairs, Senator Collins.

OPENING STATEMENT OF SENATOR COLLINS

Senator COLLINS. Thank you very much, Mr. Chairman. Let me start by thanking you for holding this important hearing to evaluate the government's response to the outbreak of Severe Acute Respiratory Syndrome, or SARS.

I have a very eloquent opening statement—— [Laughter.]

But I know that you are eager to get to the witnesses today, so I would ask unanimous consent that it be submitted for the record.

Senator COLEMAN. Without objection, Senator. Thank you very much, Senator Collins.

[The prepared statement of Senator Collins follows:]

PREPARED OPENING STATEMENT OF SENATOR COLLINS

Mr. Chairman, thank you for calling this morning's hearing to examine how effective the State and local response has been to the outbreak of severe acute respiratory syndrome—or SARS—in the United States, and to take a look at how well the Federal Government has worked to support and coordinate these efforts.

Severe acute respiratory syndrome, or SARS, is proving itself to be a formidable global threat. There is neither a treatment nor a cure for this deadly, highly contagious virus that is spreading throughout Asia, and into parts of Europe, Canada and the United States. To date, there have been almost 8,000 probable cases of SARS reported in more than 30 countries worldwide and more than 660 people have died.

It is true that the worldwide toll for SARS is relatively small compared with, say, the three million people who died last year of AIDS. If SARS continues to spread,

however, its death toll could skyrocket. Moreover, while we should be reassured that quick action on the part of the CDC and our State and local health officials has resulted in a relatively low number of probable SARS cases in the United States with no deaths, we should not rest easy. Given that the virus can go wherever a jetliner can travel, it is a very real possibility that we have not yet seen the full extent of this epidemic in our country.

In the wake of recent terrorist attacks and increasing fears about the spread of highly contagious diseases like SARS, our Federal, State and local governments have become increasingly sensitive to the need for an effective, coordinated response to such events. While there is absolutely no evidence that the spread of SARS is part of a planned attack, our institutional capability to deal with such an epidemic is the same whether it is the consequence of a terrorist act or a naturally-occurring event. In fact, a major side benefit of all of our efforts to strengthen our homeland defense capabilities should be an improved ability to respond to all kinds of emergencies.

Over the past 2 years, the Congress has appropriated significant amounts of funding for public health activities at the Federal, State and local levels as part of our bioterrorism preparedness effort. Moreover, the supplemental appropriations bill passed earlier this year contains an additional $16 billion for CDC specifically to address the SARS outbreak. I therefore look forward to hearing whether these additional resources have improved our ability to respond to public health emergencies like SARS.

In addition, since physicians, nurses, and other health care workers on the front lines are likely to be the first individuals to encounter cases of an emerging infectious disease like SARS, it is critical that they have the support and information that they need from Federal agencies like the CDC to identify and effectively contain such an outbreak.

Mr. Chairman, I look forward to examining these and other issues this morning, and once again, I thank you for convening this hearing.]

Senator COLEMAN. We will turn to Senator Lautenberg.

OPENING STATEMENT OF SEANTOR LAUTENBERG

Senator LAUTENBERG. Thanks very much, Mr. Chairman. I, like the Chairperson, will withhold my eloquent statement. It has yet to be written, and—— [Laughter.]

But I do want to say, this is such an important topic and the consideration of how we deal with it is a major question, its effects not only on the individual, but the economy, the circulation of people and taking care of normal obligations raises a very serious problem for us.

My question, and I will end with this, is will it depend on a given State's income capacity to deal with the problem? We know that all the States, with almost no exception, have difficult times meeting their normal obligations right now. Deficits are significant and very few States can just continue as they were before.

Now the question is, if there is an outbreak of SARS, whose responsibility is it, not just to deal with it. We know that we have to have the health professionals and some facility particularly suited to treating SARS patients and whether or not they will be able to be isolated sufficiently. But then the question comes in about the capacity to afford. Now, if a given State is poverty-stricken—let me use that term—will the problem then become one of its neighboring States or the neighboring region, or will it be unintentionally exporting the disease?

So the question is, how do we deal with this? Does it become primarily a Federal concern? I know the Chairman, I listened to your statement and it was very good and apparently Minnesota and you have gotten a great deal of attention paid to this. I don't know whether it has to do with your proximity to Canada and some of

the problems that have erupted there, but this is a good opportunity to hear from our distinguished panel, Mr. Chairman. I look forward to hearing from them.

Once again, the focus at the moment for me is how do we respond to this plague that we are dealing with in the best fashion and is it a responsibility for all the States, shared in equal terms, if the disease presents itself in their boundaries?

Senator COLEMAN. Thank you very much, Senator Lautenberg, and I am sure the panel will be addressing the question and the way you have framed it.

I would like now to welcome the first panel of witnesses to today's hearing, Dr. Julie L. Gerberding, Director of the Centers for Disease Control and Prevention in Atlanta, Georgia; Dr. Anthony S. Fauci, the Director of the National Institute of Allergy and Infectious Diseases at the National Institutes for Health in Bethesda, Maryland; and finally, Dr. Michael T. Osterholm, the Director of the Center for Infectious Disease Research and Policy at the University of Minnesota, Minneapolis, Minnesota.

I thank all of you for your attendance at today's important hearing and look forward to hearing your perspective on what the broader health care community is doing to provide local officials with the information they need to deal with sudden outbreaks such as SARS.

Before we begin, pursuant to Rule 6, all witnesses who testify before the Subcommittee are required to be sworn. At this time, I would ask you to please stand and raise your right hand.

Do you swear the testimony you will give before this Subcommittee will be the truth, the whole truth, and nothing but the truth, so help you, God?

Dr. GERBERDING. I do.

Dr. FAUCI. I do.

Dr. OSTERHOLM. I do.

Senator COLEMAN. Thank you. We will be using a timing system today. Please be aware that approximately 1 minute before the red light comes on, you will see the lights change from red to yellow, giving you an opportunity to conclude your remarks. While your written testimony will be printed in the record in its entirety, we ask that you limit your oral testimony to no more than 5 minutes.

Dr. Gerberding, you have the opportunity to go first with your testimony. We will then hear from Dr. Fauci, and finally, we will finish up with Dr. Osterholm. After we have heard all the testimony, we will turn to questions.

Dr. Gerberding.

TESTIMONY OF JULIE L. GERBERDING, M.D., M.P.H.,[1] DIRECTOR, CENTERS FOR DISEASE CONTROL AND PREVENTION, DEPARTMENT OF HEALTH AND HUMAN SERVICES, ATLANTA, GEORGIA

Dr. GERBERDING. Good morning, Mr. Chairman and Senators. It is really a pleasure to be here to focus in on the local response to SARS because, as we say at CDC, ultimately, all public health is

[1] The prepared statement of Dr. Gerberding appears in the Appendix on page 47.

local and I think it is a timely opportunity to address the issue from that perspective.

The macroscopic view right now is that we have over 7,700 cases of SARS globally with 643 deaths. In the United States, we have 67 probable cases of SARS, and I think I have a graphic here that shows the distribution of both the probable as well as the suspected cases of SARS across the United States. I illustrate it only to indicate that almost all States have been involved in the development of containment protocols for the isolated patients, and certainly this represents an enormous amount of work on the part of clinicians as well as local health officials across our country.

There are many SARS stars and I would like to formally acknowledge the efforts that have been made by the CDC team, but I think in this effort, it is the front-line clinician and the front-line local health officials that really deserve the credit for the fact that, so far, we have been able to contain the epidemic in this country. We have been doing that not using the usual modern interventions, such as vaccines or antiviral treatment, but the old fashioned methods of isolation and quarantine.

The first and foremost component of this is, of course, the alerting and the advice to travelers to affected areas, reminding them of what the risks are and the steps they need to take. We delivered more than one million of these health alert cards, which have proven to be a very important aspect of our response because they remind travelers returning from these areas that they could potentially have been exposed. And if they develop any illness in the next 10 days, they need to contact a clinician and seek medical care.

We know the health advisory notices are working because people are self-referring for care and they are reporting very early at the onset of fever. So I think that has been a very important component of our ability to contain spread in this country. Of course, it only takes one highly-infectious person to set off a cascade of transmission if they are not identified and isolated quickly.

A really critical component of containment at the local level is the front line, the hospital emergency rooms, clinics, and the clinicians who respond quickly to suspecting a case of SARS and implement the appropriate infection control precautions. We learned in Canada that you have to have a very high standard of infection control in the health care environment to prevent spread to other health care officials. This includes not just the containment in the room, but also the masks and the proper utilization of hand hygiene and the other measures to prevent spread. Isolation has been successful in the vast majority of situations where it has been properly introduced in health care settings, but as I said, you have to be highly compliant with those recommendations.

In this country, we have not had to implement quarantine or measures for exposed people other than the active monitoring that health officials have been doing of people exposed to SARS cases in hospitals or in their homes. That really represents the part of this graphic that you don't see. Because for every case here on this map, there are many exposed people that are involved in an ongoing monitoring process, for the 10 days of incubation, to be sure that we detect the earliest possible signs.

In this country, we have only two individuals who have been exposed to travelers and who are probable SARS cases. One of them is a health care worker and one of them was a household contact of a SARS patient. So we think our isolation and monitoring systems have been effective so far.

The last really critical component of this is, of course, communication. We need the communication systems to electronically track illness and information, but we also need the information exchange that goes out through our health alert notification, through our Internet, through our spokespersons at the local level as well as the national and international level.

I think what we have learned in SARS is that we can respond quickly, we can define the virus, develop tests, sequence it, and we can also get the communication and information about that out quickly enough. The question is, are we quick enough to really contain it if we are in the unfortunate situation to have a highly infectious person who sets off a cascade of transmission.

We have seen that it can be done. Containment has been successful, even in developing countries, but it takes a prepared public health system. The weakest link in the system is the link that could allow a leakage and spread to occur. So we have to strengthen the entire public health system from the front-line clinician all the way through the Federal and international health agencies. We can do it, but it is going to take a sustained effort, and I thank you for the opportunity to present that perspective.

Senator COLEMAN. Thank you, Dr. Gerberding. Dr. Fauci.

TESTIMONY OF ANTHONY S. FAUCI, M.D.,[1] DIRECTOR, NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES, NATIONAL INSTITUTES OF HEALTH, DEPARTMENT OF HEALTH AND HUMAN SERVICES, BETHESDA, MARYLAND

Dr. FAUCI. Thank you very much, Mr. Chairman. I appreciate the opportunity to present my testimony before you and Members of the Committee.

As you can see from this slide, many versions of which I have presented before this Committee and similar committees regarding emerging and reemerging diseases, the SARS epidemic that we are facing really falls squarely within the spectrum of what mankind has been experiencing since the beginning of mankind and will experience throughout the evolution of our species to wherever it may go, and that is that interesting interaction between microbes that emerge and reemerge.

Sometimes, these emergences are really minor blips in the radar screen that are curiosities, unfortunate for the people who get afflicted, but they do not have a major global health impact. And then occasionally, we get a disease that does.

In the last century, the 1918 flu pandemic that killed 25 million people worldwide, and the AIDS epidemic that was first recognized in the early 1980's, which we are now in the middle of, is another example of a true global pandemic.

SARS is an epidemic that is still in its evolutionary phase. It has extraordinary potential. The death rate is alarmingly high, and as

[1] The prepared statement of Dr. Fauci appears in the Appendix on page 58.

you mentioned in your opening statement, Mr. Chairman, in many respects, despite the fact that we have had good public health and infection control methods, we have been somewhat lucky, and for that reason what we really need to do is to continue the vigilance that Dr. Gerberding has mentioned, but also pursue a robust research agenda, and I would like to spend just a couple of minutes on that.

We know from very rapid detective work on the part of the CDC, the WHO, and others that the etiologic agent of SARS is a coronavirus. Now, you might recall historically that it took us at least 2½ years to identify the virus associated with HIV. This was done in a matter of weeks and the virus was sequenced so that we know the molecular makeup of it.

It falls within a category of viruses that we have had extensive experience with, the first coronavirus being isolated in 1937 in animals, and then in the mid-1960's in humans. It is most known for the fact that one of the groups of coronaviruses is the cause of the common cold, a very benign disease that rarely, if ever, causes serious consequences.

But also, the coronavirus is seen among domesticated animals, such as pigs, cows, dogs, cats, etc., and this is important when one thinks in terms of where this virus may have come from. And I must say right off that we don't know at this point, but also it shows the importance of developing animal models so that we can study it. As you know, there are no specific therapies or human vaccines, even though we have been studying these types of diseases for a considerable period of time.

What about the research agenda, we have now? Because of the seriousness of the threat and because of the fact that although there are reports, as you mentioned, that things might be leveling off, there are two issues. One, we could just as easily have a rebound, and that is the reason for the vigilance that Dr. Gerberding mentioned, but also, there is the possibility, if not likelihood, that we will not be finished with this even when the cases no longer spread in this season or at this particular time. So we must be prepared for serious consequences in future years.

For that reason, there is a robust research agenda, including basic research and understanding of what we call the pathogenesis of disease. How does it make people sick? That is still somewhat of a mystery, because when one looks at the pathologic specimens of individuals, it is likely that not only the virus is causing direct damage, but the inflammatory response seen in the lungs of individuals with the Severe Acute Respiratory Syndrome is causing a considerable amount of damage.

We also need to think in terms of therapies. We are right now in collaboration with our colleagues at the CDC and at USAMRID screening a number of drugs that have already been developed for other reasons to see if, in fact, we could get what we call a hit or an indication that this particular drug or class of drug might have activity against the SARS virus. We have had some interesting preliminary hits, but they have only been at concentrations of the drug that would not make them at all feasible to use in a pharmacological sense. But it at least points us in the right direction of the class of drugs.

We are also, now that we have the sequence, doing targeted drug design against potential particularly vulnerable parts of the virus replication cycle.

And then there is the question of vaccine. Again, since this virus, lucky for us, grows very robustly in tissue culture using monkey tissue culture cells, the virus is now being grown in a number of institutions, including the National Institutes for Health, for the purpose of making the first generation of a vaccine, which is a killed vaccine. We will likely be successful in proving a concept in an animal model, but once we do that, it will take years, at least, to develop a safe and effective vaccine for humans.

So in summary, Mr. Chairman, the research agenda is robust and the challenge of emerging and reemerging infectious diseases will be with us forever and SARS is a dramatic example of that. Our most critical weapons against the threats are vigilance, public health and infection control capabilities, and the robust research agenda that I briefly summarized for you and which I have described.

With these factors working in synergy, we feel confident that they will provide the best hope of protecting the citizens of the world and of our Nation against the inevitable threats to public health that will follow. Thank you, Mr. Chairman.

Senator COLEMAN. Thank you very much, Dr. Fauci. Dr. Osterholm.

TESTIMONY OF MICHAEL T. OSTERHOLM, PH.D., M.P.H.,[1] DIRECTOR, CENTER FOR INFECTIOUS DISEASE RESEARCH AND POLICY, UNIVERSITY OF MINNESOTA, MINNEAPOLIS, MINNESOTA

Dr. OSTERHOLM. Thank you, Mr. Chairman. I want to applaud you and the Members of the Subcommittee for addressing this very timely and critical issue in terms of the effectiveness of our Nation's response to SARS. I believe that this international public health crisis is here to stay, as you so eloquently stated, and will pose an ever-increasing risk to the citizens of the United States. My comments reflect my professional experience in State and Federal public health programs, academia, as well as my participation in such groups as the National Academy of Sciences Institute of Medicine.

In that latter regard, I want to refer the Subcommittee to a very important report which was issued in March of this year, just as SARS became a public crisis. Ironically, our committee, which for the past 2 years detailed the reasons why emerging infectious diseases are of such importance, actually considered the very issue of a type of SARS-like agent becoming a critical public health problem. Our committee report also provides a series of recommendations for assuring that we have an effective and timely detection and response to these new agents in the future. I urge the Subcommittee to review this report.

I am here today to address the critical need for our country to continue in its beginning journey to prepare its homeland security against both human-made and Mother Nature-made biological

[1] The prepared statement of Dr. Osterholm appears in the Appendix on page 68.

agent attacks. In general, we must capitalize on the collaborative preparation to respond to the everyday growing threat of emerging infections, as well as the potential for the use of biologic agents as terrorism weapons.

Before I detail my concerns and suggestions for the Subcommittee, I want to take this opportunity to offer my highest compliments to the response to the SARS epidemic both abroad and at home. This response has involved a number of Federal agencies, particularly the Department of Health and Human Services and Department of Homeland Security, as well as State and local public health departments as well as front-line health care facilities and workers.

Specifically, I would like to acknowledge the leadership of my two co-witnesses, Dr. Gerberding and Dr. Fauci, who have continued to play critical roles in defining a proactive and well-articulated response on behalf of our Federal public health agencies. Both of these individuals have served as trusted and articulate voices in hundreds of media appearances and policy briefings. As a result, I believe that this time, the American public has received the facts in a meaningful and very thoughtful way.

In addition, State and local health agencies have put in countless hours investigating possible SARS cases, working with local health care delivery systems to accommodate the needed infection control security for individuals who might have contact with SARS patients, as well as serving as a credible public voice for the many questions that have arisen from the local community.

While our experience today with SARS can be interpreted as having been successful in our efforts to limit its impact in this country, like you, Mr. Chairman, I have to admit we have been lucky. As you have heard during the past several weeks, the City of Toronto has known firsthand the devastating impact of the SARS epidemic. This impact includes not only the morbidity and mortality associated with the disease, but the economic and social implications of being labeled a community with SARS transmission.

We must never forget, what happened in Toronto could just as easily have happened in Buffalo, Cleveland, Detroit, or Minneapolis-St. Paul. Imagine what any one of these American cities would have experienced had an epidemic unfolded in their community and subsequently had an international advisory issued urging no travel to that community.

As an epidemiologist who has investigated hundreds of infectious disease outbreaks, including some caused by previously unrecognized infectious agents, both my learned opinion and my best bet is that we have not yet begun to see the worst of SARS. It is my belief that despite the heroic efforts made by countless professionals in the health care and medical care systems to control localized epidemics in locations such as Toronto, Hong Kong, Hanoi, and Singapore, the ongoing transmission of SARS in parts of China and Taiwan signals a very important message that this is a disease transmitted via respiratory route that has now seeded itself in a sufficant number of humans such as to make its elimination impossible.

If this is true and this disease follows the pattern of other similarly transmitted agents, we can expect to see increasing case numbers associated with seasonality, in other words, in the winter months in the Northern Hemisphere. In short, the reduction in new cases throughout the world is undoubtedly due in part to the heroic efforts just mentioned and also likely reflects the waning of cases during the summer months.

Believing this to be true, I am convinced with the advent of an early winter in the Northern Hemisphere in just 6 short months, we will see a resurgence of SARS that could far exceed our experience to date. If this projection is correct, we have every reason to believe that this disease may show up in multiple U.S. cities as we continue to travel around the world in unprecedented numbers and speed. Imagine now the possibility of simultaneous disease outbreaks in multiple U.S. cities.

You may ask, is this likely to occur? Honestly, no one knows, but as a student of the natural history of infectious diseases, I am convinced that, just as we saw in the early days of HIV, we are now in the early days of the SARS epidemic.

I have provided for the Subcommittee a series of points that I believe must be considered in response to the SARS epidemic. First, we are under-invested in our public health system. You will hear from other panels to the extent to which that has occurred.

Also, we must coordinate the roles of Federal, State, and local agencies in our response to this problem. I believe that you have sitting at this table in Dr. Gerberding and Dr. Fauci, two of the leaders for which their agencies must play prime roles and primary response roles to this particular problem.

Finally, it is going to be important for us to understand the resources and capabilities of our health care delivery systems and the private sector in responding to this problem and the need for the critical coordination and resource development in these areas.

In conclusion, let me just say I again want to thank you for this very important and timely hearing. I only wish that this would be the last hearing necessary in terms of responding to the SARS crisis, but I fear that will not be the case. Nevertheless, your ongoing oversight of the resource needs and collaboration of Federal, State, and local public health agencies will provide a critical road map for helping us to assure our Nation's safety and security from all of the emerging infectious diseases of the future. Thank you.

Senator COLEMAN. Thank you very much, Dr. Osterholm.

I would be interested to know whether, Dr. Gerberding and Dr. Fauci, if you share Dr. Osterholm's perspective that we have not yet seen the worst of SARS? Clearly, he has raised the concern that when the winter months approach, and in Minnesota, we know about those winter months, that we can expect to see new cases. Do you share that perspective?

Dr. GERBERDING. I hope he is wrong, but I fear that he is correct. Most of the respiratory viruses follow this pattern and I think we need to be vigilant and anticipate that could be the case.

Senator COLEMAN. Dr. Fauci.

Dr. FAUCI. I share both Dr. Osterholm and Dr. Gerberding's concern. As Dr. Gerberding mentioned, it would be distinctly unusual

for a respiratory disease that is spread the way this is spread to all of a sudden just disappear.

Senator COLEMAN. I want to get focused on the local level. I have some basic questions, but let me ask a broader question first. As I have listened to the testimony, what should Toronto have done differently? I would ask you all to—if you ruled the roost, what would you have told them to do or what should they have done that was different?

Dr. GERBERDING. I think there is very little that they could have done differently because the patient who was infectious arrived there before information about the epidemic was available. So they didn't have that opportunity to put into place the kinds of systems that we now know are necessary for containment. That was bad luck.

Senator COLEMAN. Dr. Fauci.

Dr. FAUCI. It could just have easily have happened to us. We often get asked that question. We really, in general, don't have better public health measures nor better experience, at the local level than other developed nations, particularly like Canada, have. They didn't know it was coming and it hit them. We knew it was coming just days before. We did a very good job, particularly under Dr. Gerberding's leadership at the CDC, but we could have been hit much worse. So I don't think that there is any reasonable criticism of how the Canadians handled it. They did a very good job.

Senator COLEMAN. Dr. Osterholm, any comment?

Dr. OSTERHOLM. Yes.

Senator COLEMAN. And by the way, I am not looking to criticize. I am just trying to understand, is there something in that experience that now the message should go out to every other city, go down this path rather than another path. Dr. Osterholm.

Dr. OSTERHOLM. Lest you think this was rehearsed, I happen to agree strongly with my colleagues here at the table, but let me add one additional point. Also being from the lakes of Minnesota, you understand well what it is like to have a leaky boat. If you have got one leak, you can bail for quite a while and do quite well. That was a single hit in one city.

What I am very concerned about is that if we see a greater pressure on a worldwide basis in terms of cases in the developing world, they are going to spin out many more new infections that will come into the developed world through travel. What do we do if we are experiencing four, five, six, seven, or eight of these outbreaks in 10 cities simultaneously? Resource allocation issues will end up to be very different.

So I would urge that we understand the Toronto experience, as much as it was a potential problem, imagine if that had been simultaneous in many different North American cities and what resources we would have been able to provide on a local, State, and Federal level. I think that is the concern that we must have for the future.

Senator COLEMAN. Do local responders today have a single point of contact to get information or to report concerns? Is there a hotline to one place that folks, by the way, not just in the Minneapolis, St. Paul, or Chicago, but in the St. Cloud, the Sleepy Eyes, the smaller communities, is there within our country today at the local

level an awareness of a single point of contact, either to report information or get information?

Dr. GERBERDING. I would like to think that the fact that CDC does serve as a broker of information is a useful tool at the local level. We certainly have a website that has been visited more than two million times over the SARS epidemic. We also operate a hotline for clinicians and a hotline for the general public so people can have access to that information, even in other languages, on a regular basis.

But we also recognize that we can't prescribe the details of the response or the measures at the local level and so that system has to include input up and down the entire public health system.

Senator COLEMAN. Dr. Osterholm, I know you have experience working at that local level——

Dr. OSTERHOLM. There actually are—it's a variety of different systems that exist at State and local areas, but like Dr. Gerberding said, I agree that there are well-recognized points of contact.

The problem we have, however, is that as the number of problems continue to increase, I see nothing in our human biology to suggest that the number of new problems are not going to increase. Today, telephones are ringing off the hook at health departments throughout the United States. As a result of the BSE issue in Canada, is it safe to eat my hamburger?

The same people that often have to answer these questions are the same people that are responding to SARS, who are responding to trying to get people vaccinated for smallpox, and who are dealing with any number of infectious disease problems. And so it is like when your 911 system gets overloaded. What is happening is while those points of contact exist, they are all occurring simultaneously. So SARS has now been added onto the back of that point of contact.

Senator COLEMAN. Thank you. Senator Lautenberg.

Senator LAUTENBERG. Thanks, Mr. Chairman.

The hearing that we are holding here demonstrates its importance as we listen to the testimony. Frankly, I wish we had a more optimistic picture than we have seen.

The question for me is, when was the first evidence of SARS discovered? Do we know where?

Dr. GERBERDING. In retrospect, we believe that the first cases of SARS, or at least the first outbreaks of SARS were occurring in the Guangdong Province in November and December. We did not get reliable information from that area and that is one of the weaknesses in our global detection system, that we don't have the sentinels out there that we can trust or that we can get information from when it is happening.

It was recognized in February in Hong Kong because a traveler from Guangdong was involved in an outbreak that occurred in a hotel in Hong Kong and that really initiated the international cascade. So it was several weeks after the epidemic was initiated in China that it became known in the Western world, and then it was a couple of weeks after the outbreak in Hong Kong that we were able to isolate the virus and recognize that this was not influenza or not some common problem, that this was, in fact, a new coronavirus infection.

Senator LAUTENBERG. Is it assumed that we are dealing more capably with this because we have had, as Dr. Fauci said in his testimony, a chance to take a look right after the problem came up in Toronto and prepare ourselves a little better for it, because I am interested in the fact that this locale, this region seemed to have induced the quickest spread of the disease. Could something like this have resulted from an activity by people who were looking to manufacture something? You get an obvious connection here between the threats that we have been enduring. Mr. Chairman, it is really a terrible scenario that we look at.

Dr. Osterholm, the calls that I have been getting don't relate so much to SARS but to fear of a problem that is facing us. In this case, this Committee has significant jurisdiction over homeland security and I have had the kind of calls that say, well, should I not go to New York, from people in my State, in my region. Should I not plan my vacation with my kids to Florida? We are talking now about different kinds of dangers, but nevertheless, dangers.

The thing that concerns me is the tendency to try to isolate ourselves from the communities in which we live, work, travel, etc., because as I heard, isolation looks like, if I understood you right, Dr. Gerberding, isn't isolation the first step that you take when someone is suspected of having SARS?

Dr. GERBERDING. Isolation is what we do when someone is infectious and we put them in the hospital and use the precautions for preventing spread. Quarantine is what we do with uninfected people who might have been exposed, and the quarantine can be anything from complete segregation to simply, you have been exposed, take your temperature every day and let us know if you have a fever. We haven't had to implement the more aggressive forms of quarantine in this country, we haven't recommended them here, but that is a step that was necessary in other parts of the world to control the problem.

With respect to your issue about is this terrorism—everything about this disease looks natural. Its mode of transmission, its pattern, everything is consistent with the natural evolution of a coronavirus. But we have had an open mind about this from the very beginning, and, of course, we were alert to that in the same way that you were.

Dr. FAUCI. Senator, one point that I might make has to do with information and the kind of calls that you get and the kind of calls that we get and why it is so important to do what we have been trying to do, is to be very proactively up front in trying to educate the American people as to what a real risk is and how you should respond to the risk.

You might recall that back during the anthrax crisis, when the anthrax attacks were in Florida and in New York and in Washington, DC, we were getting calls from people in Los Angeles and in Pittsburgh saying, should we be taking ciprofloxacin, because they read this in the newspaper. Well, there is absolutely no reason for them to take ciprofloxacin if they are not exposed. And I think the point that Dr. Gerberding is making is very important.

We should be very vigilant, but we shouldn't have people now in our country be afraid to go anywhere in this country.

Senator LAUTENBERG. Exactly, and that is the kind of message that I am looking for, and that is if it is a natural phenomena, natural conditions often, if something goes awry, create a danger—street crossings, etc., airplane flying in normal course, car driving, all those things. I would like not to have a message that says, hey, we have to retreat to our homes. We can't function. We couldn't function.

One thing that Dr. Osterholm said that rings my bell, and that is we are not spending enough on the whole public health issue, and this brings it full forward to us. You heard Senator Levin's comment about the fact that the fellow from Home Depot decided to reach into his pocket to make the facility workable, that is part of the Federal Government.

It is a terrible thing, because I believe that security and strength has to be built from within the society as well as that which protects us externally beyond our boundaries. The demands today, there is an awareness that we never saw before that results from the instant access to communications, the awareness of people to things that I don't think were quite as they were before. We have not only got to work with the condition itself, but with the fallout that results from knowledge and—you said two million hits on the website. Is it thought that they were primarily from the professional community? I am talking about health care providers, first responders, etc., or is it John Q. Citizen who is looking for some information to protect themselves and their families?

Dr. GERBERDING. I think we see both. Our website has information for clinicians. It also has information for the general public and we hope people do go there as a credible source of information.

But I really agree with your point about trying to balance, there is a problem. These are the sensible things that need to be done to control it. On the other hand, we don't want to overdo it and have people unnecessarily concerned or take steps that really are detrimental to the kind of balance that we want to have in our life, and that has been our challenge with this one.

Senator LAUTENBERG. Mr. Chairman, just 1 minute more. Dr. Fauci, did you suggest in your comments that this is a relatively low-lethality disease?

Dr. FAUCI. No, not at all. In fact, to the contrary. If you look at influenza, which is spread much more readily than SARS, the mortality is less than 1 percent in a normal year of influenza. If you look at a very bad situation, like the pandemic of 1918, that was just a few percent, 3 or 4 percent. The mortality right now, if you look at it, is between 8 and 9 percent, and some may think as high as 14 or 15 percent.

Senator LAUTENBERG. Thanks, Mr. Chairman. Thank you very much.

Senator COLEMAN. Thank you, Senator Lautenberg.

I want to focus again now, in following up a little on some of the concerns that Senator Lautenberg just raised. At that local level, not the public side now, the private side, we have Northwest Airlines in Minneapolis-St. Paul, a direct connecting link to China. I know that they have been impacted by fear of flying.

Can you talk a little bit about, on the private side, the kind of information that a Northwest Airlines or someone else is getting?

Who is telling them whether they have to sanitize planes? Who is providing information about whether it is safe to be on the same plane that flew to somewhere in China but is on another route? Who has that responsibility? Who has that information, and how do folks on the private side get the right information?

Dr. GERBERDING. CDC has a large responsibility for the health conditions in our transit system and that particularly is handled by our Division of Quarantine and Global Migration. So our quarantine officers are at the borders and are responsible for any of the health measures that need to be taken on vessels or on airplanes or other means of transportation. So we have been working with the trade associations representing airlines as well as airline crews to get information out about what is necessary as well as what the concerns and issues are at the individual employee level.

Just last week, we prepared, at CDC, a videotape, a 2-minute video briefing that will be available to all the airlines to show on board the plane to help the passengers understand what is going on, why are they getting this card, and what does this all mean. So we do this in partnership and are very open to being responsive to additional needs.

Senator COLEMAN. Is there a greater need to communicate to the general public, those who are getting on one of those airplanes, to answer any concerns they have about infection passing on, and if there is, who has that responsibility?

Dr. GERBERDING. Again, it is a partnership. I don't think there is ever enough communication in the setting of a health problem, at least enough reliable communication. But we work through the local health agencies as well as through the media to try to get information in the hands of travelers. We are also working with the associations of travel agents and people who are going to get the kinds of questions when someone is booking their reservation. So there are a lot of different channels of information and we are pushing it out there as fast as we can.

Senator COLEMAN. Dr. Osterholm, I know you again know in your experience in dealing with the local level with some of these issues of infectious diseases. Talk to me a little bit about the mechanism for the average citizen to have concerns dealt with.

Dr. OSTERHOLM. Well, first of all you are really dealing with competing interests here. We have 24/7 television cameras today that are going to, in some cases, fuel the fire of fear. I am very afraid of that issue. But on a whole, I think that most of the media has been quite responsible reporting on the SARS issue and has tried to represent the facts. In particular, the print media has done a very good job of detailing that.

What we need to do is do a better job of driving the public to reliable information. For example, the CDC has on its web site right now, two very thoughtful documents about should people travel to this country for business purposes, if they come from a SARS-infected area, or should they travel to those counties? We at the University of Minnesota, for example, have a number of foreign students coming to our campus from China very soon. We have used the CDC documents extensively to help us decide what to do. I think that has been very helpful.

So part of it is making people aware that information is there. Again, we are making great efforts that way.

Senator COLEMAN. And finally, Dr. Fauci, you talked about a robust research agenda. How is the funding for that agenda?

Dr. FAUCI. Well, right now we are, as you well know, between budget cycles, so we are using our emerging infectious diseases resources to jump-start programs and we are now in the process of putting together a projection of what our resources will be needed for. In fact, at a hearing that Senator Specter held, our Appropriations Chair asked Dr. Gerberding and I to do that, and we are in the process of doing that and putting it through the clearance of our Department. So we are actually working on that right now.

Senator COLEMAN. Thank you. We are going to have a vote, I believe, at 10 o'clock, but I will turn to my distinguished colleague. Senator Lautenberg, do you have any additional questions, and if you do, after Senator Lautenberg's question, we will finish with this panel, have a 10-minute recess so that we will be able to go vote, and then continue the hearing. Senator Lautenberg.

Senator LAUTENBERG. Where does the responsibility lodge between CDC, NIH, etc? How do you bring the various departments together? How are they coordinated?

Dr. GERBERDING. Secretary Thompson has made a very strong commitment to have all one HHS, and it actually is working that way. One of the ways we coordinate is through the Secretary's command center. So every morning, I get an update from our people all over the world on the state of SARS and then I sit down through a video terminal and speak directly to the Secretary's command center, where Dr. Fauci and Dr. McClellan and others from the various Federal agencies participate, as well as people from the Department of State, Department of Defense, and other areas, and I give a morning update on the status of the SARS epidemic. We identify any major strategic decisions that the Department or that the Federal Government needs to address, and then the Secretary and his team take it from there.

So the coordination of the response has been working beautifully through our operations center model. I think, in general, we have an extremely collaborative relationship with NIH. Dr. Fauci and I are in constant communication and I think we pass that baton back and forth with great enthusiasm and sometimes even a little fun.

Senator LAUTENBERG. How does the non-specific medical information, the demographics, and the geographic, where does that kind of data reside?

Dr. GERBERDING. We publish each day a daily SARS report that gets distributed through the various people who are tracking the epidemic. This is also on our website. We make information available to the media through a similar mechanism.

Each week, at least once a week, we also have a televised briefing for the public and the press where we give the updated information or describe what is going on, and then through our health alert system, which is the way we communicate urgent information to State and local health officials and clinicians, any time there is something new, like last night we changed the case definition for SARS, so we pushed that out through the system so that people on the front line know what is going on.

We also have regular phone calls, many with health officers, with clinicians, with various stakeholders in the effort. So it sounds like a lot of different things going on, and that is the case, but it is actually very well coordinated through our operations center.

Senator LAUTENBERG. Dr. Osterholm, you are free of any government restraints here. What do you think we, in government, could do besides just providing funds? Is there anything else that you would recommend to help us get a handle on this threat that we see from SARS?

Dr. OSTERHOLM. I think the issue of funds is a very clear piece of it, particularly for the State and local level. We also have the issue of human resources, meaning do we have the trained individuals in this country we need to respond?

I think earlier, Senator, you asked a question that I think is right at the heart of the issue here today, what is the source of this epidemic? And from a perspective of humankind today, it is mind-boggling to think about, that there are actually 6.1 billion people on the face of the earth. One out of every nine people who has ever lived in the history of mankind is on the face of the earth today, and most of those people live in the developing world in conditions that Charles Darwin would have written about as the ideal microbial laboratory.

For example, the largest population of hogs in the world live in China, along with the largest population of people, and most of those pigs live in the backyards of these people, as well as the largest aquatic bird population of the world. Should we be surprised we are going to see all kinds of new infectious agents coming out of there as these factors mix and match in this kind of environment?

So I think that this government has to be prepared to understand that what has historically happened with new infectious agents should not be used as a measure of what will happen in the future. Travel, as well as all these other demographic factors I talked about will continue to change. I think that is a very important fact, and we can't plan on resources by biennium or budget cycles for a problem that we can't anticipate 2 and 3 years down the road. We are going to have more and more of these unexpected problems where we need the ability to move resources and get resources quickly.

Senator LAUTENBERG. Mr. Chairman, there is a message to remember.

Senator COLEMAN. Sobering.

Senator LAUTENBERG. Thank you all very much.

Senator COLEMAN. Thank you all very much.

This hearing will be recessed for 10 minutes.

[Recess.]

Senator COLEMAN. This hearing is called back to order.

I would like to introduce now our second panel of witnesses at this time. We welcome Dr. Rod Huebbers, the President and CEO of the Loudoun Hospital Center in Leesburg, Virginia; Dr. Thomas R. Frieden, Health Commissioner of the New York City Department of Health; and finally, Mary Selecky, the Secretary of Health of the Washington State Department of Health in Olympia, Washington, and President of the Association of State and Territorial Health Officials.

I thank all of you for your attendance at today's hearing. I look forward to hearing your testimony this morning and your unique perspective on how local and State officials have responded to the SARS outbreak and whether there are any lessons that we can use to improve our response to the next outbreak.

Pursuant to Rule 6, all witnesses who testify before the Subcommittee are required to be sworn. At this time, I would ask all of you to please stand and raise your right hand.

Do you swear the testimony you will give before this Subcommittee will be the truth, the whole truth, and nothing but the truth, so help you, God?

Mr. HUEBBERS. I do.

Dr. FRIEDEN. I do.

Ms. SELECKY. I do.

Senator COLEMAN. We will be using a timing system today, as I said for the first panel. Please be aware that approximately 1 minute before the red light comes on, you will see the lights change from green to yellow, giving you an opportunity to conclude your remarks. While your written testimony will be printed in the record in its entirety, we ask that you limit your oral testimony to no more than 5 minutes.

Mr. Huebbers, you will proceed first with your testimony. We will then hear from Dr. Frieden and finish up with Ms. Selecky. After we have heard all of your testimony, we will turn to questions. Mr. Huebbers.

TESTIMONY OF RODNEY N. HUEBBERS,[1] PRESIDENT AND CHIEF EXECUTIVE OFFICER, LOUDOUN HOSPITAL CENTER, LOUDOUN HEALTHCARE, INC., LOUDOUN COUNTY, LEESBURG, VIRGINIA

Mr. HUEBBERS. Good morning, Mr. Chairman, and thank you for the opportunity to appear before this Subcommittee. My name is Rodney Huebbers and I am the President and CEO of Loudoun Healthcare, which is a community nonprofit health care organization serving Loudoun County, Virginia, as the principal health care provider, and we are the local first line of defense that we have been talking about this morning.

Loudoun County is the second fastest growing county in the United States. We are bordered on the east by Dulles Airport, which is a key factor for us, to the north by the Potomac River, and to the west by the Blue Ridge Mountains and the Shenandoah River, and we are also home to a diverse business and residential population. We are also home to the FAA's center for the National Capital Region and we are a major emergency evacuation route for the District of Columbia.

With respect to our size and experience, at the time of presentation in our emergency departments, Severe Acute Respiratory Syndrome had not been yet identified nor clinically defined with respect to symptoms of treatment. On February 17, 2003, a woman who had recently traveled to Guangdong Province in China presented in our ER with pneumonia-like symptoms. We obtained a

[1] The prepared statement of Mr. Huebbers with additional testimony attached appears in the Appendix on page 73.

personal history of the patient, including her recent travel itinerary, which included a report of unusual pneumonias being seen in Guangdong Province.

While symptoms did mirror pneumonia, a typical dry cough and respiratory distress proved an unknown, prompting the patient's isolation in a negative-pressure room as a means of infection control. Subsequently, the hospital's infection control chief and the Loudoun County Health Department were notified as part of our infectious disease algorithm that we had established. In turn, the Virginia Department of Health and Centers for Disease Control and Prevention were also notified.

Prior to this SARS presentation, it is important to note that before September 11, our hospital had a specific disaster plan in place that included coordination with county, State, and Federal authorities, and following September 11, with the advent of all the biological and chemical terrorism threats, our protocols were further refined on paper as well as in practice.

Loudoun County has been confronted with a variety of communicable disease issues, including anthrax, Virginia's first human death from West Nile virus, as well as three locally acquired cases of malaria, and literally, Loudoun Hospital is the front-line provider and had been in all those cases. So, hence, we have practical experience from which to draw conclusions as to our own protocol evolution and the quality of assistance from regulatory offices.

As to the performance of Loudoun Hospital's ER triage training as well as our already heightened awareness in the development of infection protocols combined to serve us well on February 17. The documentation of symptoms, along with a predetermined history, including the travel inquiry volunteered by the patient's family, in consultation with the Loudoun County Health Department, proved critical in the initial decision to isolate and contact infection control authorities. From there, the notification algorithm worked very well as designed.

While the patient herself was of great concern, so, too, were the clinical and non-clinical staff who had either incidental or clinical contact with the patient. Again, SARS was not known at this time, but given the symptomatic issues identified, it was obvious that infection was a distinct possibility. Our emergency response team began the process of identifying those with whom the patient had contact with during the admission process, and within hours, we had a list of individuals and had begun contacting them for testing.

At the time of the SARS presentation, the hospital's most notable infection control protocol in place was for tuberculosis. Now, of course, we have a SARS protocol which, based upon information supplied by various authorities, has been amended in keeping with clinical findings.

As for staff reaction during and following our SARS presentation, I would characterize it as informed and collaborative. Given the unknown symptoms of SARS at the time, common sense, admission information, and proper infection protocols combined for an adequate medical response on behalf of the patient and staff alike. The hospital's existing emergency preparedness committee lecture series on emerging diseases and bioterrorism threats, evolving policies and algorithms related to infection control, and improved com-

munication with Northern Virginia hospitals via dedicated rapid notification radio frequency, continue to provide threat mitigation.

There were some gaps identified during our review that, in this case, did not impact patient care. They include insufficient testing materials pre-placed in Northern Virginia for all the individuals we needed to test. There were procedures in place to transport specimens quickly to the Virginia State Lab, but the procedures for quickly shipping these specimens to Atlanta during the weekend were lacking. Multiple agencies were involved, which at times pitted patient care against regulatory expectations. At times, the staff was torn between specimen collection and delivery, symptomatic consultation with multiple agencies, and actually caring for the patient and others.

In particular, our patient only spoke Chinese. Had it not been for a family member accompanying the patient, vital information impacting patient care may not have been communicated easily.

At our hospital, we have provided additional instruction in the taking of sample and chain of custody procedures to accelerate the diagnostic process, and a general concern of ours continues to be multiple isolation patients requiring negative pressure rooms.

Three elements, however, played a key role in the successful outcome of this case. Plans were in place in the emergency room to isolate the patient and notify key personnel. Effective communication patterns preestablished throughout the public health sector from hospital to Federal authorities worked well. And positive working relationships between the hospital and the local public health office proved critical in diagnosis and in containment.

In conclusion, the largest single gap experienced between our hospital and expectations of State and Federal health authorities as well as the public to whom we are dedicated is the additional cost associated with clinical education, supplies, and ultimately prevention on a local, regional, and national infectious disease issue. Local hospitals like Loudoun Hospital have spent considerable time, man hours, and capital in emergency preparedness for all levels of trauma and infection associated with accidental or hazardous situations. It has taxed us heavily, and while we carry the burden to meet expectations, assistance by way of appropriated dollars would certainly provide the means to assure a successful rapid response by your front-line provider.

Although all the links in the chain of defense must be strong, it is imperative that the strongest link be at the local level with the front-line provider.

I thank you very much again for the invitation to present here today.

Senator COLEMAN. Thank you very much, Mr. Huebbers. Dr. Frieden.

TESTIMONY OF THOMAS R. FRIEDEN, M.D., M.P.H.,[1] COMMISSIONER, NEW YORK CITY DEPARTMENT OF HEALTH AND MENTAL HYGIENE, NEW YORK, NEW YORK

Dr. FRIEDEN. Good morning, Chairman Coleman. I am Dr. Thomas Frieden, Commissioner of the New York City Department of

[1] The prepared statement of Dr. Frieden appears in the Appendix on page 86.

Health. Thank you for the opportunity to discuss New York City's response to SARS.

Every single day, New York City welcomes more than 100,000 incoming air travelers, of whom more than 30,000 are coming from international destinations. On Saturday morning, March 15, just 3 days after the World Health Organization first issued its SARS alert, we were notified of a traveler from Singapore with suspected SARS. The traveler was a physician himself, an infectious disease specialist, like myself actually, who cared for two index patients with SARS in Singapore. He had attended a large conference in New York City. He saw a New York City doctor for his illness, then flew home to Singapore. He was taken off the plane in Frankfurt, Germany, and hospitalized. His wife and mother-in-law, who were both traveling with him, both developed SARS.

That afternoon and evening, we faced a series of critical decisions and rapidly took the following actions. With facilitation from CDC, we spoke with the patient's doctor and determined that the patient met the case definition. We interviewed the patient by phone from his isolation room in Germany. We determined who he had been in contact with in New York City and we contacted them. We notified the conference he had attended. We found the doctor who treated him in New York City and monitored him and his staff for illness.

The same day, using blast fax and E-mail technology, we contacted health care workers throughout New York City, including every emergency department, every intensive care unit, and many others about SARS and the importance of rapid detection isolation. We heightened the index of suspicion in our state-of-the-art syndromic surveillance system. This system tracks every ambulance run, most emergency department visits, many pharmacy prescriptions, and absentee data.

We created a public communications strategy, including targeted outreach to Asian communities. We emphasized that this is a disease of travel, not ethnicity.

Our response illustrates that a detection and response to an infectious disease outbreak, whether natural or intentional, requires both a strong public health infrastructure and an effective working relationship with the medical community.

Today, we have a stronger system, thanks to Federal funding. We are able to be available 24/7 to evaluate potential SARS cases, ensure that appropriate lab specimens are obtained, provide guidance about patient isolation and care, and actively monitor all cases. We continue to prepare for a possible outbreak, and when needed, we have mandated the isolation of patients.

Partly due to early proactive response and partly due to our good fortune in not having had a super-spreader, SARS has not spread in New York City. However, given outbreaks around the world, New York City and the United States cannot afford to be complacent. A disease that spreads like the common cold, kills one out of six people it infects, and for which there is no rapid test, no vaccine, no cure, and no way to predict its future course is something we must all be extremely concerned about.

Federal funding is woefully inadequate for our city. For example, bioterrorism funding is not currently directed toward the extraor-

dinary needs of places high on the list of potential targets. Cities like New York, already a target more than once, must be prioritized. More than 11 million people live or work in New York City every day, with a population density 300 times greater than the national average.

We appreciate the Federal funding that has already been provided, but it is not nearly enough. I request a chart that I will provide be read into the record.[1] It shows that, incredibly, New York City ranks 45 out of 54 grant recipients in Federal per capita bioterrorism funding, 10 percent less even than the national average. New York City gets one-sixth as much per capita as Washington, DC, one-fourth as much as Wyoming, one-third as much as Vermont, Alaska, North and South Dakota.

The spread of SARS could rapidly overwhelm our ability to respond. My department has immediate needs requiring at least $104 million additionally. Our most urgent unmet need is to upgrade our public health laboratory. Despite fiscal crisis, the city has dedicated more than $30 million to upgrading the lab, but this is only about half of what is needed. We must retrofit facilities for emergency use, plan and establish sites for mass preventive treatment, acquire equipment and technology for rapid response. New York City public hospitals need an additional $35 million to address their immediate emergency response needs.

To ensure speed and effectiveness, it is critical that Federal funding continue to come directly to New York City. We must continue to strengthen the Nation's public health infrastructure. CDC's laboratory and infectious disease resources need to be greatly increased. Threats of terrorism and new and reemerging infectious diseases will remain a concern for the foreseeable future. Only a concerted, sustained Federal investment in public health will ensure our capacity to respond and protect our communities. Thank you.

Senator COLEMAN. Thank you very much, Dr. Frieden. Ms. Selecky.

TESTIMONY OF MARY C. SELECKY,[2] SECRETARY, WASHINGTON STATE DEPARTMENT OF HEALTH, OLYMPIA, WASHINGTON, AND PRESIDENT, ASSOCIATION OF STATE AND TERRITORIAL HEALTH OFFICIALS

Ms. SELECKY. Thank you, Mr. Chairman and Members of the Subcommittee. I am Mary Selecky, Secretary of Health in Washington State and President of the Association of State and Territorial Health Officials.

In my remarks today, I would like to make four points. Substantial Congressional investments in preparedness funding have enabled States to respond more effectively to emerging infectious diseases, such as SARS.

Second, great progress has been made in enhancing public health capacity, but as you just heard, much more needs to be done and sustained support is essential.

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[1] The chart appears in the Appendix on page 136.
[2] The prepared statement of Ms. Selecky appears in the Appendix on page 94.

Third, Federal, State, and local public health agencies in collaboration with their international counterparts and other key partners are working cooperatively to address this serious public health concern.

And fourth, as Dr. Osterholm said, the greatest obstacle to our efforts to combat SARS and future threats like this is the serious workforce shortage facing health agencies at the local, State, and Federal levels, both public and private. That shortage must be addressed if we hope to quickly, efficiently, and effectively respond to emerging infectious diseases.

For the past 2 years, Congress has appropriated significant amounts of funding for public health preparedness activities at the Federal, State, and local levels. There is no doubt that these resources have improved our ability to respond to SARS. In Washington State, we have 29 suspect and probable cases. We have a double-digit number. Other States have single-digit numbers. We all have to have the same capacity.

With the investments that have been made in Washington State, public health preparedness funds have added four epidemiologists to our State communicable disease epidemiology unit, providing us with the additional capacity needed to respond to SARS questions and to assist local health agencies and local clinicians, including our hospital partners. These same funds have been used to organize 9 public health emergency preparedness regions among our State's 35 counties that are organized in local public health. We have added additional epidemiologists and we have provided leadership across the State, State and local together, in being able to deal with SARS.

Washington State, like most other States, is using the health alert network that Dr. Gerberding mentioned to disseminate official messages from CDC across the public health system and through local health agencies, as noted in New York, to clinicians and hospitals, and we are all using websites, borrowing, and sending around to each other.

Cooperation and collaboration among public health agencies and other key partners is critical to our SARS activity. Our colleagues at CDC have done a terrific job in identifying and tracking the epidemic. As you heard, through numerous conference calls, video conference broadcasts, international broadcasts, we have shared the information across a wide spectrum.

As a former local health official for 20 years in a very rural part of Washington State, the Fifth Congressional District, I know firsthand about the importance of the capabilities that must be in place so that all citizens are protected. In a local rural area, we rely clearly on our fellow local, our State, and our Federal health agencies, but we all have distinct roles to play.

We are a State that borders another country and we are next to British Columbia. We serve as a major port of entry and we, the State, as well as the locals, must work together with our international partners in order to address issues like this, and let me give you our example.

On March 22, a container ship was due to arrive in Tacoma, Washington, after visiting Singapore, Hong Kong, and Taiwan.

Several of the 26 crew members had developed non-specific upper respiratory symptoms that fit the evolving case definition.

As the ship approached, my staff worked closely with the local health department, Tacoma, Pierce County, CDC's Division of Global Migration and Quarantine to plan a response. We had questions about the symptoms, who had the authority, would we isolate, would we quarantine, who is it that would address this issue? The Port of Tacoma was engaged, as well as the shipline owner. We were all working together, and this was new territory for all of us. Calls for assistance and questions quickly overwhelmed CDC's Division of Global Migration and Quarantine. If there is anything singular that stands out, there has been underfunding of that particular part of CDC.

We boarded the ship together. We determined that we were not dealing with SARS at that moment. We were able to work together to alert the other ports in California and Hawaii as to what had gone on; it is that cooperative and collaborative relationship of which I speak.

For a moment, I will highlight some of our workforce concerns. The same public health workers who work on communicable diseases at the State and local level, and even most recently with smallpox vaccinations, upcoming summer West Nile virus, or should anthrax ever appear, are the same ones that are today answering the phone about BSE, beef in Canada, and have been dealing with SARS. They are public health nurses, disease investigators, environmental health specialists, and laboratorians. We need them all.

Clearly, the recent progress that has been made in strengthening our public health infrastructure has helped, but much more needs to be done. Questions will arise if we in this country could deal with what Toronto went through. I believe we could, but we would be stretched to the max. We, as you yourself said, have been lucky. Someone is smiling on us.

In closing, I wish to thank Congress for the preparedness funding that has come. It was a critical beginning, but it can't be a two-shot effort. It clearly must be sustained. Thank you.

Senator COLEMAN. Thank you very much, Ms. Selecky.

Thank you to the entire panel. Dr. Frieden, your chart will be entered into the record.

Let me first start with Mr. Huebbers, and again, with all the testimony, I am very impressed with the quickness with which we responded. You talked about an evolving definition of SARS. Mr. Huebbers, you mentioned when this first report came in, there were some unusual things happening in Guangdong Province. I think you indicated SARS has not yet been designated as what we were dealing with. Where did you get your information from? Was it official, unofficial? How did that work?

Mr. HUEBBERS. Actually, in reality, what occurred was we identified that it was unusual when the patient presented the symptoms and we contacted public health. We have a fairly fast-acting triage process, that when we deem something is highly unusual, it goes beyond—involves administrators and everybody else, and literally went on the Internet and went to a search engine, typed in "Chinese pneumonia" and came to a website that had indications or

had information there about the disease. And at the same time I am doing that at home, people at the hospital were doing it, because this occurred at about 11 o'clock at night. So that is—we were able to get that information between public health and articles that were on the website.

Senator COLEMAN. I am not sure whether this is a question for you or Ms. Selecky, but the way in which you responded, is that a product of you being near Dulles, part of the kind of major Washington community? Do you have a level of sophistication that perhaps the rural area that Ms. Selecky worked in wouldn't have?

Mr. HUEBBERS. I would say most probably. It was a combination of we did get lucky. We have, because of our proximity to Dulles, we have had experience in dealing with malaria, anthrax, and West Nile. But we are in a unique situation because of being near Dulles and the Washington area.

Senator COLEMAN. Talk to me about the capacity, and I am going to ask Dr. Frieden that same question. When we listened to the first panel, the concern is fall comes, increased capacity. Do you have the ability to handle multiple cases? Is there bed space available?

Mr. HUEBBERS. We agree, and actually had started planning several weeks back, because we agree with the hypothesis that come the fall or winter of next year, we are not going to see the end of SARS. Actually, we believe at Loudoun that this is just the beginning.

We have already met with both regional and State health officials. We have the capacity at what we would call our old hospital—we are in a new facility that is 5 years old. The old campus has been maintained. We can bring that campus online in a very quick fashion to handle upwards of 100 patients, and, in fact, that has been part of our planning process. Both regional and State officials agree, and its ability to handle surge capacity is critical.

Our issue is money. To do that, to bring it online and sustain it from here on in, which the community, being the second fastest growing county in the country, there is also the need for some capacity there, but we just don't have the funds to do it. I mean, in an emergency, we would figure it out, but——

Senator COLEMAN. I have to go vote again. Dr. Frieden, I am going to come back to this issue of surge capacity in an area like New York. We will adjourn this hearing for not more than 10 minutes to allow me to vote and come back.

[Recess.]

Senator COLEMAN. This hearing is called back to order.

Dr. Frieden, what we were talking about and Mr. Huebbers had talked about, surge capacity. Talk to me about New York, bed space available, how do you create capacity?

Dr. FRIEDEN. Well, in New York City, we have the experience of West Nile virus. We have the tragic experience of the World Trade Centers. We have the experience of anthrax. And so we have dealt with surge capacity in the past, and I think our gaps in this area are primarily three.

The first and most urgent is laboratory capacity. This is true at the national, many State, and certainly our local and other local levels. In the health care system, the laboratory is often the poor

relation in the landscape of medical care and public health, and that is the case here, as well. We would need to be able to test, presuming that we have a rapid and accurate test down the line that can definitely rule in or rule out infection within less than 3 weeks, which is what we are dealing with now. Presumably, if we have a test, we would need to be able to do it rapidly, 24/7, 7 days a week, and we don't have that capacity.

The second issue is surge capacity in terms of isolation beds, medical facilities, and, potentially, quarantine facilities. We have to consider what we would rather not have to do, but if we had large groups of people who needed to be separated from others, we would have to find places for those people to be.

Hospitals have been downsizing, but there is a difference between having space and having staff. And so the critical distinction is between beds and staffed beds. We know that SARS affects hospitals directly. Today's paper talks about nurses and doctors resigning en masse in Taiwan. The challenge would be not just to find the physical space, but the staff to be able to attend to patients.

And, of course, personnel is also a critical issue, as Dr. Osterholm and Ms. Selecky mentioned. We have the same staff who are doing smallpox, the same staff who are responding to outbreaks of infectious diseases every day of the year, the same staff who are dealing with West Nile virus, and with our syndromic surveillance system. These are the staff who are answering calls on SARS or other things and it really is not a sustainable situation to be in, even without a major outbreak, and with a major outbreak, it strains the system to the breaking point.

Senator COLEMAN. Understanding that staff, it is hard to just kind of put together this is the SARS team and have them waiting for the fall, the next outbreak, but talk to me a little bit about the ability to investigate. I read somewhere an article, maybe in the *New York Times* this weekend, that talked about setting up teams and New York City having teams. Are those infectious disease teams or are they SARS teams or tell me a little bit about how you are doing that.

Dr. FRIEDEN. We are very fortunate in New York City. We have many dozens of highly trained medical epidemiologists. We have disease investigators in a wide variety of programs relating to everything from typhoid to tuberculosis, West Nile virus, and so we are able to field teams to track individual patients or outbreaks and we do that all the time. That is the bread and butter work of public health. If we get a case, we have a cluster of pertussis or measles, we are able to rapidly respond and contain that before it becomes a major public health problem. Again, if the team is working on one thing, they can't be working on something else, so that limits our ability.

We also shouldn't forget that although we need to continue and strengthen our ability to respond to infectious diseases, the thing that is killing seven out of ten Americans now is non-communicable diseases and local public health departments, State health departments, and Federal agencies have not fully stepped up to the plate of that challenge. And so as we try to deal with the things that are killing people today, we need to not stop dealing with the things

that are likely to be coming back as significant problems now and in the future.

Senator COLEMAN. That is very helpful, and I do want to note, Dr. Frieden, that I certainly support your call for bioterrorism funding that needs to be prioritized. I think that is important, and we are certainly having discussions about that in this body. But I do think that we have to be moving in that direction. The reality is, in New York or Washington, threat levels are different than in, as I said before, Sleepy Eye or Hibbing, Minnesota, and I think we should recognize that certainly in the funding stream, so that conversation is going on.

Ms. Selecky, I keep getting back to that rural perspective. I know you are not in that role now, but are you confident that folks at a rural level, hospital rural level, if faced with a patient that showed some SARS signs, that they would have the capacity to react in the appropriate manner?

Ms. SELECKY. Mr. Chairman, we are much better prepared today than we were in the past and it will get better. I think, clearly, our ability to do very quick communication, the investment we have done as a public and private system in how we communicate and getting real-time information back and forth has been important.

I still live in that rural area of Washington State. I have to stay in the State capital during the week, but I travel that 7 hours across the great State of Washington and I have responsibility for 39 counties, be they rural or urban, as do my counterparts across the country. Our ability to make sure that people are aware of what is emerging, what is happening—I will use West Nile as an example.

It could be in an urban area, or our first dead raven with West Nile virus was in Ponderey County, where I used to be the health officer. It was just as important for that person who picked up that dead bird to be able to take it to their local health department, who then sent it to us at the State level—we all have roles. But our level of sophistication at the State level was greater than at the local level. We share the information and we worked with our Federal partners. That is as good of an example as with SARS.

Our hospitals have been squeezed to such small margins, be they public hospital districts that rely on tax dollars to open the door, or larger hospitals in our urban area that are counting on great numbers of encounters to help them open the door. But they both need the same amount of information for identification. That is what is really important, is about understanding information through the system.

Senator COLEMAN. But they both don't have the same level of resources.

Ms. SELECKY. No, they do not.

Senator COLEMAN. As I listened to Mr. Huebbers talk about the protocol that they followed in terms of backtracking, finding out where folks were, going through the whole process, I would suspect, in some of those rural hospitals, you wouldn't have the capacity.

Is this something that we should be looking at a regional approach to, to have certainly the investigatory capacity, or does it

have to simply fall on the shoulders of those at the grassroots level?

Ms. SELECKY. Quite frankly, the charge that Congress has given to us in the States is to look at how this would work within our States. The fact that you have said to States, you need to come up with a plan, it needs to include all of these partners, and you are responsible for making sure the system works inside your State, is absolutely essential.

We have somewhere in the neighborhood of 5,000 hospitals. To disperse the money from a central location at the Federal level to 5,000 doesn't build the system. To hold the States responsible for the coordination of that system is important.

Now, in Washington State and in the State of Nebraska, for example, a regional approach was used. In some other States, in New York, New York City clearly has its own needs that are very different than other parts of New York, whether it is up in Eire County or wherever the case is. And I think that is what has allowed the States to do is that flexibility. Mandating a regional approach, I am not sure that is a one-size-fits-all, but it is one that has been encouraged for us to share those resources across boundaries.

Senator COLEMAN. When you had the example of the cargo ship coming in, who called the shots? Who was in charge? Who had ultimate authority?

Ms. SELECKY. That was clearly an interesting sorting out, because at that time, SARS was not listed as one of those diseases over which CDC had authority to do quarantine and isolation. And because the ship would dock in a local community, what we had sorted out would be, as in Washington State, our rule, which we had already updated, the local health official has the first call. The State health official is there for back-up, and the Feds are in a tertiary, and that was appropriate—but the important part is us working together collaboratively.

We all went onto the ship. It was an incredibly learning moment, the thought of staff going up a Jacob's ladder from a tugboat to get on the ship to see what was going on before we would allow them to come to port, because we didn't want that one little crack through the wall, as it were, to happen. We were very fortunate, but indeed, as what followed was the President did declare that SARS would be one of those diseases for which you could quarantine and isolate, if that is what was needed.

Senator COLEMAN. Getting back to the question of who is in charge, and we are going to have a legal expert in the next panel, but I am kind of throwing it open to everyone here, are folks confident they have got the legal authority to take tough steps if that is called for? If we move to a quarantine situation, is there any question about your legal capacity to do the things that you believe as health professionals need to be done to ensure the safety of your community? I will start with Ms. Selecky.

Ms. SELECKY. One comment I would make. I know in Washington State, we do, and it is written in certainly the law and the rule that we have the enforcement authority to ask our local law enforcement or our State patrol to assist us. But the actual enforcement of how you get that done, I think in a society that prides itself on individual freedoms and individual liberties, when we

have to take collective action as government officials to protect the public's health, is going to be a very tough test in this country.

Senator COLEMAN. Dr. Frieden.

Dr. FRIEDEN. There is reasonable Federal guidance on this, but it remains a State and local issue and a State and local jurisdiction. In New York City, actually 10 years ago, I helped to modify the statute for how we detain patients with infectious and potentially infectious tuberculosis, when I was in charge of tuberculosis for New York City, and we put into place a system that has been tried, tested, and, in fact, challenged in court and upheld in court, whereby we can both protect the public's health and also protect an individual's right to due process and to an individualized determination of whether they actually need to be detained.

We had to actually use those powers in two cases so far in the SARS outbreak, for individuals who did not wish to remain isolated. And so we do have the authority to do it. We have done it. We are also further modernizing that statute now to address a wide variety of potential public health threats—smallpox, contact to smallpox and other communicable diseases.

Senator COLEMAN. Is that an issue that you think there should be a single standard for the country, or do you——

Dr. FRIEDEN. Absolutely not.

Senator COLEMAN. OK.

Dr. FRIEDEN. Absolutely not. I think it is a very important question, Mr. Chairman. There are important differences between different States and different localities and the cookie-cutter approach can actually be very damaging because the statute here has to interact with a wide range of other statutes and resources. While a Federal guidance and a model statute is helpful, in fact, when you get around to implementing it in a local area, you have very specific local jurisdictional issues that may be different.

New York City, for example, is an independent vital registration area, independent even though it is within New York State, and so that has a whole host of other implications, which means that the State's statute really has to take that into cognizance. The City has its own Board of Health with legislative authorities.

Senator COLEMAN. Great. Thank you very much. Mr. Huebbers.

Mr. HUEBBERS. Because we have had the experience with malaria, anthrax, West Nile, and SARS now, we have tested the system and we think it works pretty well both locally and on the State level, so we are comfortable.

Senator COLEMAN. Great. Thank you.

I want to thank the panel. You have been very helpful.

I would like to call our final panel of witnesses at this time. We welcome Lawrence O. Gostin, the Director of the Georgetown University Center for Law and the Public's Health; Dr. Bruce R. Cords, Vice President for Environment, Food Safety and Public Health at Ecolab in St. Paul, Minnesota; and finally, Vicki Grunseth, Chairman of the Metropolitan Airports Commission in Minneapolis.

I thank all of you for your attendance at today's hearing. Welcome. Pursuant to Rule 6, all witnesses who testify before the Subcommittee are required to be sworn. At this time, I would ask you all to please stand and raise your right hand.

Do you swear that the testimony you give before this Subcommittee will be the truth, the whole truth, and nothing but the truth, so help you, God?

Mr. GOSTIN. I do.

Dr. CORDS. I do.

Ms. GRUNSETH. I do.

Senator COLEMAN. Thank you very much.

As I have indicated before to the other panels, we will be using a timing system today. One minute before the red light comes on, you will see lights change from green to yellow, giving you an opportunity to conclude your remarks. While your written testimony will be printed in the record in its entirety, as I have indicated to the other panels, we ask you to limit your oral testimony to no more than 5 minutes.

Mr. Gostin, we will have you go first with your testimony. Then we will hear from Dr. Cords and finish up with Ms. Grunseth. As with our last panel, after we have heard all the testimony, we will proceed to questions. Mr. Gostin.

TESTIMONY OF LAWRENCE O. GOSTIN,[1] DIRECTOR, CENTER FOR LAW AND THE PUBLIC'S HEALTH, GEORGETOWN UNIVERSITY LAW CENTER, WASHINGTON, DC

Mr. GOSTIN. Good morning, Mr. Chairman. I am Lawrence Gostin. I am a professor of law at Georgetown University and Johns Hopkins University and Director of the Center for Law and the Public's Health, which is a CDC-collaborating center.

I am going to talk about, first, antiquated laws in the United States; second, a model State emergency public health act that we wrote at the request of the Centers for Disease Control and Prevention; third, a new model law for non-emergencies, including potentially for SARS; and then fourth, if I have got time or during questions, I will talk about the public health infrastructure and the ethics and logistics of quarantine. It is a big agenda.

The CDC and the Department of Health and Human Services, as well as the Institute of Medicine, have all recommended reform of antiquated public health laws, and the reason why that is true is that most public health laws—actually, New York City is one of the exceptions—are very antiquated. They go back to the last 19th and early 20th Century, and as a result, they have a number of very serious problems.

First, they may have ineffective powers, particularly for novel infectious diseases. If you take the New York example, just in the middle of the tuberculosis epidemic, they had to change their laws, and we don't want that to happen with SARS. We want to be prepared. So many of these laws may be ineffective for basic public health powers like reporting, testing, physical examinations, medical treatment, isolation, and quarantine.

Second, these laws may be constitutionally suspect because most of them were passed before the Supreme Court's modern constitutional era. As a result, they don't have clear criteria for action, and also they don't have procedural due process or a fair hearing. This would have potentially very serious public health consequences be-

[1] The prepared statement of Mr. Gostin appears in the Appendix on page 101.

cause in the midst of an epidemic, you have to ask, is my law constitutional? It may result in indecision and delays. That is part of the reason why in some of the earlier modeling exercises, TOPOFF I and Dark Winter, there were problems with quarantine and one sees it with every new novel infectious disease.

And finally, these laws are inconsistent, although I do very much agree with testimony from New York City that we do not want a cookie-cutter approach. On the other hand, we don't want completely inconsistent rules, so that even within a single State, they will have different rules for different diseases, and then if you have adjoining States, like Maryland, Virginia, and the District of Columbia, or New York, Connecticut, and New Jersey, if you are dealing with an epidemic and you have completely different rules in those States, it doesn't make any sense because diseases, pathogens, cross State lines and you need some form of uniformity. But obviously, it has to fit in with the structure of the public health and legal system within a particular State.

I do agree that CDC, particularly Dr. Julie Gerberding, and State and local health departments have done an excellent job in relation to SARS, but there is a great deal of progress that needs to be done, particularly on legal powers.

After September 11 and the anthrax outbreak, the CDC asked the Center for Law and the Public's Health to draft an emergency powers act. It is called the Model State Emergency Health Powers Act. That act has been transformed by the National Conference of State Legislators into a checklist and most of the States have used that checklist against their own laws. Twenty-two States and the District of Columbia have passed the model law or a version of the model law. That is great progress, but there are still significant problems.

One is that many States have not passed the model law, and the other is that the model law requires the governor to declare an emergency, and for an undeclared potential emergency, like SARS, you run into significant problems.

It is for that reason that the Center is currently working with the Robert Wood Johnson Foundation and its Turning Point Initiative, with a consortium of States and national experts throughout the public health sector to draft a model public health law that would apply to SARS and all emerging infectious diseases, basically getting our public health laws into the 21st Century. That statute has now been sent out to a wide variety of national organizations, attorneys general, public health commissioners, legislatures, and others across the country for comment. It has been ongoing for 2 years and it is expected to be ready for consideration by the States by the fall legislative sessions. Again, it is not intended as a cookie cutter. We don't want States to simply adopt it. But we want to make sure that they have model language they can use for a uniform approach.

And then, finally, I just wanted to reinforce what all your other panelists have told you about the public health infrastructure. I am a member of the Institute of Medicine and also a member of IOM's Board on Health Promotion and Disease Prevention and I served as a committee member for its report on "The Future of the Public's Health in the 21st Century," which just came out recently.

That report reiterated what CDC and others have said, which is that public health infrastructure is, in the words of the IOM, still in many respects, "in disarray." They have insufficient laboratory structures, insufficient workforce development, insufficient surveillance capacity, and insufficient data systems.

And the reason for that is the United States spends more on health than any other country in the world, but we spend less than 5 percent of all health dollars on public health, that is, population health and prevention. We need to do better than that, and in fact, as a result, the richest, most powerful, most wonderful country in the world has health indicators that lag well behind most other leading economic powers.

I will just simply conclude with a brief examination of logistics of a mass quarantine, because one of the concerns I have is that we are prepared for a small quarantine, but most hospitals only have a couple of negative pressure rooms. If we have to have a mass quarantine, the logistics of providing care, treatment, sanitary facilities, infection control, clothing, methods of communication, hearings are not in place, and I think it is something that we need to do both legally and as a matter of ethics.

So thank you very much, Mr. Chairman.

Senator COLEMAN. Thank you very much, Mr. Gostin. Dr. Cords.

TESTIMONY OF BRUCE R. CORDS, PH.D.,[1] VICE PRESIDENT, ENVIRONMENT, FOOD SAFETY AND PUBLIC HEALTH, ECOLAB INC., ST. PAUL, MINNESOTA

Dr. CORDS. Thank you. Good morning, Mr. Chairman. Thank you for the opportunity to speak to you regarding our company's response and challenges relating to the global SARS crisis. My name is Bruce Cords. I am currently Vice President of Food Safety and Public Health for Ecolab, headquartered in St. Paul, Minnesota. I am responsible for food safety and public health technology strategies across all Ecolab divisions. In this role, I have the lead technical responsibility for the company's response to the SARS crisis.

Ecolab provides products and services in over 160 countries with global sales of $3.4 billion in 2002. Among other things, Ecolab's expertise is in the practical application of disinfection and cleaning technology to help manage and respond to exposures in the workplace and in a wide variety of community environments. These include health care facilities, schools, lodging, restaurants, food processing facilities, military installations, and public transportation.

Our customers, worldwide, depend on Ecolab to provide advice, products, and systems to address problems with infectious diseases such as SARS. As the outbreak of SARS was peaking in March and April, many international hotel chains asked for help to make sure that they had the latest training and information to deal with the virus. We continue to receive numerous information requests regarding SARS from both customers and industry officials.

We have been closely monitoring the situation via the World Health Organization and CDC. There is still much to be learned, and until many of the open questions have been answered, we can only make recommendations based on the best scientific informa-

[1] The prepared statement of Mr. Cords appears in the Appendix on page 121.

tion available from sources such as CDC and the World Health Organization.

As an aside, Dr. Gerberding and her staff at CDC have done an excellent job of regularly updating the public and health officials on the global status of outbreaks and any new information on the virus and its epidemiology.

Initially, experts believed that the virus would survive for only a few hours on environmental surfaces. More recent information from the Chinese University of Hong Kong suggests that the virus may survive for days on environmental surfaces. Some examples include plastered walls, 24 to 36 hours; plastic surface, 36 to 72 hours; on stainless steel for 36 to 72 hours; and even on a paper file cover for 24 to 36 hours. This possibility of extended survival, places more importance on cleaning and disinfection of potentially contaminated surfaces.

Some of the examples of questions we are receiving include: If we suspect the hotel room has been occupied by a SARS-infected person, what cleaning and disinfection procedures should be followed? What hand care products and procedures are effective against the SARS virus? How do you inactivate SARS on carpet and upholstery? What are recommended cleaning and disinfection procedures for an airplane that has arrived from a country with active SARS infections?

As you may know, the EPA has not approved any commercial products for claims against the SARS virus. Consequently, we and other companies have followed the general recommendations provided by the CDC to prevent the spread of the disease. The CDC specifically recommends, (1) aggressive hand washing and the use of an alcohol gel hand sanitizer containing 60 to 95 percent denatured ethanol or isopropanol; (2) disinfection of environmental surfaces such as faucets, hand rails, restrooms, elevators, and other surfaces touched by multiple individuals with an EPA-registered hospital disinfectant; and (3) use of gloves and respirators for people in direct contact with potentially infected persons or environments.

We have provided our customers with this information through direct contact with our district sales managers, our technical support staff, and have also made the information available on our public website, ecolab.com. The information provided includes general information on how the virus may be spread, Ecolab hand care and disinfection products which are consistent with CDC recommendations, and specific decontamination procedures for institutional settings.

I want to emphasize that simply identifying products does not provide the user with the "how to" guidance they need. For example, in response to the earlier question, "if we suspect a hotel room has been occupied by a SARS patient, how do I clean it?", we give them specific information such as: (1) the personnel cleaning the room should wear a surgical mask and rubber gloves; and (2) cleaning personnel should clean frequently-touched surfaces, disinfect, such as light and air control switches, faucets, toilet flush levers, doorknobs, TV and radio controls. There are many items that may be missed without specific instruction. They also ask questions about laundry. We recommend that the laundry be segregated and

heated to a temperature adequate for virus inactivation. So we basically give them specific procedures on the "how to use." We do not simply sell them the product and say, "Go to it." We give them the actual procedures.

As mentioned earlier, no commercial products carry a claim of efficacy against this virus. Today, the CDC recommendations are based on extrapolation of data to other related viruses. Ultimately, products must be tested against the virus and products which carry an efficacy claim against this virus would provide the highest degree of confidence and performance.

For this to occur, a reliable method for enumeration of the virus must be developed. It is my understanding the CDC is working in this area at the present time. The EPA must then approve a protocol for testing commercial products against the virus or a surrogate. During the recent foot-and-mouth disease threat and anthrax incident, Ecolab worked closely with EPA to expedite product approvals. Likewise, we look forward to EPA working to expedite approvals for products effective against SARS so that these products are available should the virus reappear in the United States.

In summary, based on the latest scientific information, and working with appropriate government authorities, Ecolab will continue to provide our global customers with information on products and best practices to prevent the spread of this disease. Thank you for your attention.

Senator COLEMAN. Thank you very much, Dr. Cords. Ms. Grunseth.

TESTIMONY OF VICKI GRUNSETH,[1] CHAIR, METROPOLITAN AIRPORTS COMMISSION, MINNEAPOLIS, MINNESOTA

Ms. GRUNSETH. Thank you, Mr. Chairman. I am Vicki Grunseth, Chair of the Metropolitan Airports Commission in Minneapolis. The Commission operates Minneapolis-St. Paul International Airport, MSP, and six reliever airports in the seven-county region of the Twin Cities.

MSP is the eighth busiest airport in the United States and the 12th busiest in the world. In the year 2000, 37 million passengers went through MSP. We annually have 500,000 operations. I want to thank you for the opportunity to appear today on behalf of the aviation industry.

SARS is obviously a major concern for airports. The airport is like an artery through which people and things pass into the heart of our country. Most of the things that flow through the artery are good. Many, in fact, are critical to our economic strength. But threatening things can flow into middle America through the airport artery, too, including potentially life-threatening viruses like SARS. If we don't act swiftly to stop them or contain them, they can wreak havoc in the heartland and throughout our Nation.

Stopping SARS is important to us first and foremost from a public health consideration, but it is also important to us from an economic standpoint. We need to ensure the traveling public has the information they need to feel safe while flying. I want to speak for a few minutes about the Metropolitan Airport Commission's role in

[1] The prepared statement of Ms. Grunseth appears in the Appendix on page 125.

responding to SARS. Next, I want to highlight the airlines' efforts to combat the spread of the disease. And finally, I want to address the assistance the collective aviation community has received from the Federal Government.

In many respects, MSP operates like a municipality. We have our own 911 communications department, and our own fire department, our own police department. Each of our fire fighters is a trained emergency medical technician. Typically, they are the first responders to an emergency at the airport.

Consider the population of people potentially threatened by SARS at our airport. On average, 100,000 passengers travel through Minneapolis-St. Paul every day. That doesn't count their colleagues, their friends, their family that drop them off or pick them up. There are thousands of people who work at the airport, 17,000 airline employees, 3,500 food and retail workers, 2,200 ground transportation providers, 1,400 Federal agency staff and 540 Airport Commission employees. Clearly, the potential for the spread of infection is enormous if we don't respond effectively to diseases like SARS.

We have a physician on contract to the Metropolitan Airports Commission who reviews airline plans for responding to SARS. Northwest Airlines, which accounts for 80 percent of the operations at MSP, includes service to Asia. Northwest screens passengers at ticketing and boarding areas in affected areas, such as Hong Kong, China, Singapore, and Taiwan, and I should add Toronto. Airline representatives ask passengers whether they have experienced SARS-like symptoms and whether they have been in contact with infected persons during the last 10 days. If travelers have, they are referred to a medical facility to be assessed for their suitability to fly.

If anyone exhibits SARS-like symptoms during the flight, they are isolated from other passengers as much as is possible. It is important to note that not a single case of SARS has been transmitted on airline flights since the World Health Organization recommended in late March that passengers from affected nations be screened. The World Health Organization's leadership, together with swift Federal action and cooperation from the aviation community, has effectively minimized the potential transmission of SARS on aircraft.

Working with international health officials, the Federal Government provided valuable resources to airlines like Northwest and airports like MSP to prepare for and to respond to suspected SARS incidents. First, we benefit from the Centers for Disease Control and Prevention. Like most Americans, we first heard of SARS from the news media. Within days, though, we had access to reliable, science-based information from the CDC. The CDC website, in particular, serves as a clearinghouse for reliable SARS-related information. The site specifically addresses information regarding SARS and air travel. It advises travelers and provides information that enables airports to develop a higher awareness of the disease and its potential threat.

We also found very useful the information from the World Health Organization which was communicated to us through the Transpor-

tation Security Administration and through our trade association, Airports Council International-North America.

The second and perhaps most important resource is the Federal staff assigned to our airport to specifically respond to the SARS threat. On April 16, the CDC assigned a staff member to MSP as a central resource for SARS information and planning. The CDC has maintained staff at MSP on a rotating basis since that time, and our understanding is they will remain there for the duration of the crisis. Their presence has been pivotal to our SARS response. In addition, they provide round-the-clock phone support from a quarantine supervisor in Chicago.

The process has worked very well. As you may know, we had an infant arrive from Beijing at MSP who exhibited SARS symptoms and we were able to deal effectively with that child and passengers on the plan. We were prepared, we operated in a coordinated fashion, and we took the steps necessary to safeguard the traveling public.

The Metropolitan Airports Commission is very grateful to the assistance provided by the CDC. Federal interaction and coordination is the key to our ability to respond effectively. We don't know what is going to flow into the airport artery, but whenever possible, we want to stop harmful things from flowing out of it.

Thank you for the opportunity to address you today. I will be pleased to answer any questions.

Senator COLEMAN. Thank you, Ms. Grunseth.

I will kind of work in reverse order. I was going to ask a question about whether the Airport Commission has an epidemiologist as part of your staff. I take it that CDC helps fill that role?

Ms. GRUNSETH. We don't. We have a physician that we contract with to provide information, but the CDC is now providing that information on site.

Senator COLEMAN. Do you see a need for a specific agreed-upon protocol for handling these cases or is it sufficient simply to rely upon that relationship with CDC as to how best to proceed?

Ms. GRUNSETH. I think in this case, our first information came by some action taken by the Airports Council, which is our trade association, and they worked in conjunction with the CDC to get accurate information out to the airports.

Senator COLEMAN. Northwest is, in effect, a tenant of your community.

Ms. GRUNSETH. Right.

Senator COLEMAN. They, as I understand it, are doing the screening. Is that screening protocol something that is discussed with the Airports Commission? Do you have any input in that? How do you, again, assuming they have got a big stake in making sure that there is safety, but is that something that they work with you in terms of quality and the completeness?

Ms. GRUNSETH. They have their own direct relationship with the CDC and then, in addition, with Dr. Jetzer, who serves as our Airports Commission consultant liaison to the airlines. I think it is kind of a triumvirate that exists.

Senator COLEMAN. Great. Thank you.

I have to say generally, and I am going to say it again, I am actually very pleased to hear the very positive statements about CDC

and what they are able to provide. Clearly, there are some resource issues, capacity issues, and a whole range of issues that a number of witnesses have talked about, but I must say, I began this hearing with some trepidation about our capacity to respond, where we were going in the future with this and other similar circumstances that we are bound to face, as Dr. Osterholm laid out. But I certainly leave with a much better sense of what the CDC is doing in coordination with folks at the local level. So I think that message has been delivered.

Dr. Cords, talk to me a little bit about the private sector-public sector interaction in terms of research. What is it that—you talked about the amount of time that this virus may be alive, may be active, and you indicated that is changing, that the perception of that is changing. How closely is the private side able to interact with CDC to get the information that you need?

Dr. CORDS. Their website is fairly complete, plus we have contacts that we talk to on a regular basis. So we are up to date on everything that they are doing. One of the things before we can do a whole lot more research on disinfectants and which ones are more effective or less effective than others is an enumeration method. We have to be able to count the virus or to determine effectiveness of products.

One of the things we are doing now is recommending the use of hospital-level disinfectants, which have a little bit more strength than a general disinfectant you would have in your home. Some of those products have claims, and have been tested, against related viruses of the corona family. But none have ever been tested against this specific virus and I think that needs to be done. We know it is different than the common cold corona virus. We have seen that, in terms of its infectivity and its effect on humans. But does that mean that it could be a little bit different in terms of its resistance to disinfectants? We don't know that and I think we need to find that out pretty fast.

Senator COLEMAN. Who does the testing?

Dr. CORDS. There aren't very many labs set up to do it now, and I would imagine the first screening tests for that would be done by CDC. Then there are a few labs that would have the proper level of containment to handle this type of testing. I am not sure how widely we are going to distribute this kind of a virus. It may be better to compare it to a virus and then have a surrogate that is actually the test organism or the test virus.

Senator COLEMAN. Who would make that decision?

Dr. CORDS. CDC and EPA.

Senator COLEMAN. Is there any role for universities in this?

Dr. CORDS. There may be a role for universities. I doubt that very many would have that level of a containment facility.

Senator COLEMAN. You talk about, in your testimony, you talked about EPA approving a protocol and the importance of moving quickly, and this may be a question for Dr. Gostin, but how expeditious is the process today? Does there need to be some change, either statutorily or administratively, to accelerate the approval process?

Dr. CORDS. I think if the EPA acts as they did during the anthrax threat we will have rapid crisis exemption to certain products

that had been tested against either anthrax itself or had been tested against surrogates. Even though people didn't have them on their label, they basically gave us a crisis exemption. So in that case, they moved quite rapidly.

Senator COLEMAN. And Dr. Gostin, just from your knowledge of the EPA approval process, are we in good shape, structurally good shape today with the process that allows us to move very quickly to deal with the threats of SARS or SARS-like conditions?

Mr. GOSTIN. Yes. I think the Federal agencies, the regulatory agencies like EPA and FDA have done a lot better. They have learned their lessons from past epidemics and I think they are moving much more quickly.

Senator COLEMAN. You indicated that 22 States have model laws that certainly go beyond the antiquated systems we have before. By calculation, that leaves 28——

Mr. GOSTIN. That is right.

Senator COLEMAN [continuing] Way over half that don't. What has to be done to accelerate the pace at which those other 28 States deal with their quarantine and public health laws?

Mr. GOSTIN. It is highly controversial because you have—ideas of quarantine and compulsory testing and screening and the like raise a number of civil liberties issues. What we need to do is try to get the message across that actually these modern laws need to be and actually are, in terms of our model law, very attentive to constitutional rights, and so that you want to try to have it both ways. You want to have strong, decisive modern laws that are also protective of civil liberties. I think if we can start to get that leadership at the Federal and State level there, then we will do a better job in getting people to try to enact these statutes.

Senator COLEMAN. Who should be carrying the ball on that? Is it States' attorneys general or the National Attorneys General Association? Is there a role for Congress?

Mr. GOSTIN. Well, we are working certainly with the Federal Government, with CDC and the Department of Health and Human Services who have urged it, and at the State level, we are working with the National Association of Attorneys General, the Association of State and Territorial Health Officers, NASHO, National Conference of State Legislatures, all of the right people.

Certainly, leadership in Congress would be very helpful to underscore this, and it would even be possible, if one wanted to go this way, to have as a condition of funding for a number of public health activities to make sure that States do have modern, effective public health laws.

Senator COLEMAN. That is a very helpful suggestion.

Kind of concluding with one open to all three of you, do you think the public has a good sense of what the threat is and how we are handling it? Do you think the general average citizen out there is comfortable with what airports are doing, what the private side is doing, what the legal situation is? Ms. Grunseth.

Ms. GRUNSETH. I think the theme I heard this morning and that you hear all the time is information is a good thing and people, if they can inform themselves, they are not afraid of what they know. They are afraid of what they don't know, and contrast that with the situation in China, which was, I think, the exact opposite. If

we can watch combat operation in Iraq 24 hours a day, we can probably handle more information about things like infectious diseases.

Senator COLEMAN. Dr. Cords, from the business community, the hotel patrons, etc., do you think they have a level of comfort in terms of the information that is out there and ability to deal with this?

Dr. CORDS. I think they have a level of comfort with what is available to deal with it today. I don't think they appreciate, as Mike Osterholm said this morning, that we could be looking at a second wave. I think there is a bit of a relaxation going on right now and I am not sure that people are anticipating a second wave of the virus.

Senator COLEMAN. Thank you. Mr. Gostin, any final comments?

Mr. GOSTIN. I think that we have done a much better job than we did with anthrax, where we had problems of communication, and I think the Federal leadership and the State leadership is much better and people have a better idea of risk perception.

But my big worry, it is a worry about the public and also a worry about political leadership, is that we tend to look at silos. It is bioterrorism, it is SARS, it is the next disease. What we really need to do in America is to make sure that we have a generally strong public health infrastructure. We have neglected not only the law but the infrastructure of public health for more than a century and now what we have to do is stop the silo funding and more generalized funding and capacity level at the State and local level.

Senator COLEMAN. That message is certainly being heard here today.

Due to time constraints, the Subcommittee was unable to invite all of the parties affected by this issue to present oral testimony. This week, we have received written statements from the American Public Health Association and Discovery Labs, Inc. Without objection, these statements will be included in the record.

I want to thank all our panel members for being here today. I have a closing statement. I will simply enter that into the record. I will note that I am encouraged by what we have accomplished. I am still deeply concerned about what the future may hold.

This hearing is adjourned.

[Whereupon, at 11:51 a.m., the Subcommittee was adjourned.]

APPENDIX

Testimony
Before the Permanent Subcommittee on Investigations
Committee on Governmental Affairs
United States Senate

CDC Response to Severe Acute Respiratory Syndrome (SARS)

Statement of
Julie L. Gerberding, M.D., M.P.H.
Director
Centers for Disease Control and Prevention
Department of Health and Human Services

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For Release on Delivery
Expected at 9:00 AM
on Wednesday, May 21, 2003

Good morning, 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 19, 2003, a total of 7,864 probable cases of SARS have been reported to WHO, and 643 of these persons have died. In the United States, there have been 67 probable SARS cases reported, of which 6 are SARS CoV confirmed, and none have died. In addition, 286 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 1 million 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 also continue to distribute 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.

Last week, CDC called for businesses and universities to continue plans for meetings and events–including college graduations–that involve travelers from areas affected by SARS. CDC issued new guidance aimed at assisting businesses, universities, and other organizations that have employees from affected countries or that expect to host visitors from affected countries. CDC's Interim Guidance for Businesses and Other Organizations with Employees Returning from Areas with SARS can be found at http://www.cdc.gov/ncidod/sars/business_guidelines.htm. CDC's Interim Guidance for Institutions or Organizations Hosting Persons Coming to the United States from Areas with SARS can be found at http://www.cdc.gov/ncidod/sars/hostingarrivals.htm.

Prevention Measures

Currently, CDC is recommending that persons postpone non-essential travel to mainland China, Hong Kong, and Taiwan. We are recommending that U.S. travelers to Toronto, Canada, and Singapore 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 Singapore 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.

CDC and State Activities

CDC is working with the states to determine priority needs related to the SARS outbreak. Currently, CDC is working to determine the amount of funding from the $16 million supplemental that will be available to states, and how that funding will be divided among states. CDC expects to award funds via the Epidemiology and Laboratory Capacity for Infectious Diseases (ELC) program cooperative agreement. Eligible state and local health departments should be announced soon and proposals solicited from them by the end of May.

CDC has made enzyme immunoassay (EIA) reagents for SARS-associated coronavirus available to state public health laboratories. These EIA reagents look for antibodies to SARS-associated coronavirus. As of May 14, CDC had shipped EIA reagents to 40 state public health laboratories.

CDC staff are working with the Association of State and Territorial Health Officials (ASTHO) and the National Association of County and City Health Officials (NACCHO) to develop contingency plans for a large scale SARS outbreak in the U.S. should this happen. On May 20, CDC will host a satellite broadcast entitled Public Health Community Preparedness for SARS. To contain the spread of a contagious illness, public health authorities rely on many strategies. This broadcast will provide information to state and local health department personnel and other stakeholders on two strategies, isolation and quarantine, that are used to control SARS.

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.

Testimony
Before the Permanent Subcommittee on Investigations
Committee on Governmental Affairs
United States Senate

NIH's Response to the Global Outbreak of Severe Acute Respiratory Syndrome (SARS)

Statement of
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For Release on Delivery
Expected at 9:00 AM
on Wednesday, May 21, 2003

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 May 14, 2003, 7,628 cases of SARS have been reported across the globe, with 64 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.

On May 30, 2003, NIAID will host a scientific workshop at the NIH campus in Bethesda, Maryland, to address SARS research needs. The workshop will feature international experts in the fields of coronavirus biology, vaccine development, antiviral drug development, laboratory diagnosis, SARS epidemiology, etiology, and clinical management. The purpose of this meeting is to identify the scientific, technical, and other challenges that must be addressed to develop vaccines, antiviral therapeutics, and other interventions in response to 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.

SARS: How Effective is the State and Local Response?

Testimony of
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Permanent Subcommittee on Investigations
Committee on Government Affairs
United States Senate
May 21, 2003

Mr. Chairman and members of the Subcommittee, my name is Michael T. Osterholm, PhD, MPH. I am the Director for the Center for Infectious Disease Research and Policy (CIDRAP) at the University of Minnesota. I am also a Professor in the School of Public Health at the University.

Mr. Chairman, I want to applaud your efforts and those of the members of the Subcommittee to address this very timely issue regarding the effectiveness of our nation's response to Severe Acute Respiratory Syndrome (SARS). I believe that this international public health crisis is here to stay and will pose an ever increasing risk to the citizens of the United States. My comments today reflect my professional experience in state and federal health public health agencies and academia, as well as my participation in groups such as the National Academy of Science Institute of Medicine. By way of understanding the point of my comments please let me briefly review my professional experiences.

For 24 years, I served at the Minnesota Department of Health, including 14 years as the State Epidemiologist. Following the September 11th terrorist attacks, I was appointed by Secretary Tommy G. Thompson to his Advisory Council on Public Health Preparedness. In addition, I have served as a special advisor to Secretary Thompson on issues related to bioterrorism and public health preparedness. On April 1st, 2002, I was appointed by Secretary Thompson to be his representative on the interim management team to lead the Centers for Disease Control and Prevention (CDC). I served in that role until the appointment of my colleague, Dr. Julie Gerberding as the Director of the CDC on July 3rd of that year. Finally, for the past two years I have served on the National Academy of Sciences Institute of Medicine (IOM) Committee on Microbial Threats to Health in the 21st Century. This IOM Committee issued its report in March of this year just as SARS was coming to public recognition. Ironically, our committee detailed in that report why the emergence of new infectious disease agents of critical public health importance can be expected with increasing frequency in the future. Our committee report also provided a series of recommendations for assuring that we have an effective and timely detection and response system to these new agents in the future. I urge your review of this report.

I am here today to address the critical need for our country to continue in its beginning journey to prepare its homeland security against both human-made and Mother Nature-made biologic agent attacks. In general, we can and must capitalize on the collaborative preparation to respond to the every day growing threat of emerging infections, as well as to the potential for the use of biologic agents as terrorism weapons.

Before I detail my concerns and suggestions to the subcommittee, I want to take this opportunity to offer my highest compliments to the response to the SARS epidemic both abroad and at home. This response has involved a number of federal agencies, particularly the Departments of Health and Human Services and Homeland Security, as well as state and local public health departments and front line health care facilities and workers. Specifically, I believe the leadership of my co-witnesses, Drs. Gerberding and Fauci continues to play a critical role in defining a proactive and well articulated response on behalf of our federal public health agencies. Both of these individuals have served as

trusted and articulate voices in hundreds of media appearances and policy briefings. As a result, the American public has received the facts in a meaningful and thoughtful manner.

In addition, state and local public health officials have put in countless hours investigating possible cases of SARS, working with local healthcare delivery systems to accommodate the needed infection control security for those individuals who might have contact with SARS patients, as well as also serving as a credible public voice for the many questions that have arisen from a concerned local community.

While our experience to date with SARS can be interpreted as having been successful in our efforts to limit its impact in this country, I must also admit that we have been "lucky"! As you have heard during the past seven weeks, the city of Toronto has known first hand the devastating impact of a SARS epidemic. This impact includes not only the morbidity and mortality associated with the disease, but the economic and social implications of being labeled a community with SARS transmission. We must never forget that what happened in Toronto could just as easily have happened in Buffalo, Cleveland, Detroit or Minneapolis-St. Paul. Imagine what any one of these American cities would have experienced had an epidemic unfolded in their community and subsequently, have an international advisory be issued urging no travel to that location.

As an epidemiologist who has investigated hundreds of infectious disease outbreaks, including some caused by previously unrecognized infectious agents, both my learned opinion and best bet is that we have not yet begun to see the worst of SARS. It is my belief, that despite the heroic efforts made by countless professionals in the public health and medical care systems to control localized epidemics in locations such as Toronto, Hong Kong, Hanoi and Singapore, the ongoing transmission of SARS in parts of China and Taiwan signals a disease transmitted via the respiratory route that has now seeded itself in a significant number of humans as to make its elimination impossible. If this is true, and this disease follows the patterns of other similar respiratory transmitted agents, we can expect to see increasing case numbers associated with seasonality. In short, the reduction in new cases throughout the world is in part due to the heroic efforts just mentioned and also likely reflects the waning of cases during the summer months. Believing this to be true, I am convinced that with the advent of early winter in the northern hemisphere in just six short months, we will see a resurgence of SARS that could far exceed our experience to date. If this projection is correct, we have every reason to believe that this disease may show up in multiple US cities as we continue to travel around the world in unprecedented numbers and speed. Imagine now the possibility of simultaneous SARS outbreaks in multiple US cities. You may ask how likely is this to occur? Honestly, no one knows. But, as a student of the natural history of infectious diseases I am convinced that like the early days of the HIV epidemic, the worst of SARS is yet to come.

I provide this brief and less than optimistic view of our current status with SARS as a milepost reference for both our activities to date and needed capabilities to respond in the future.

Our ability to respond to SARS in future days as well as other yet unknown but already in the pipeline emerging agents requires consideration of three specific issues. First, the United States remains under invested in public health even though terrorism and new diseases like SARS have raised the public health system's profile. This under investment is not just a function of financial resources, but involves a shortage of qualified and trained personnel who will serve on the front lines of our ever increasing battles. Second, we need to assure that our federal, state and local responses to these emerging infectious disease problems are coordinated around those agencies and institutions which are best prepared to respond. The role of this Subcommittee for Investigations, in identifying how the federal government can assure coordination and collaboration of the many different federal partners will be welcome. Finally, in order to successfully address SARS and other emerging infectious diseases it will be critical for the linkage to occur between the resources and capabilities of federal, state and local public health agencies with the health care delivery system and private sector organizations responsible for supplying critical tools such as vaccines, antiinfectives and infection control-related products.

Let me briefly review each of these areas. While more than $2 billion has been or will shortly be made available to state and local health departments as part of our federal effort to enhance public health preparedness and specifically bioterrorism preparedness, we have witnessed dramatic cuts in state and local support as a result of the record and well publicized deficit problems at those levels of government. Senator Coleman, as a recent Mayor of the City of St. Paul, I am sure you can understand the pain of what Minnesota cities are currently experiencing in terms of reconciling these large budget deficits. I believe, that with further analysis it will be demonstrated that while our nation has taken several important steps forward in terms of public health preparedness as a result of the federal support. Nonetheless, requirements of that support for very specific activities such as smallpox vaccination and the distribution of the national pharmaceutical stockpile as well as the reduction in state and local support and staff cuts and hiring freezes, results in a system that is in retrenchment as opposed to building. I applaud the infusion of federal resources into this area but urge extreme caution in interpreting this to mean we now have a prepared system. In particular, the workforce challenges facing us with respect to public health and bioterrorism preparedness are so significant that resources alone will not address the need. I do not have sufficient time to detail these issues with you today, but please note that there are several organizations which have or are currently evaluating the shortage of trained public health professionals. In addition we must consider the rapidly graying of the public health workforce and the relative absence of resources and training programs to bring new and skilled public health workers into the system.

For example, we do not have an identified resource to provide support to students seeking to enter Schools of Public Health for the purposes of developing the necessary skills to become the epidemiologists and public health administrators responsible for the ongoing disease surveillance activities necessary to detect outbreaks or investigate and control recognized outbreaks. To date, I have identified at least eight outstanding Masters level students in the School of Public Health at the University of Minnesota who would like to

pursue a doctorate degree to better prepare them for this area. Unfortunately, we have not been able to identify a source of student support for this qualified group of individuals to pursue additional educational training. This situation repeats itself routinely throughout Schools of Public Health in this country.

In regard to my second point, while the SARS epidemic involves many aspects of our daily lives from immigration and travel to health care delivery and economic security, it must never be forgotten that this is basically a public health and basic science research issue. In that regard, we are fortunate that the Centers for Disease Control and Prevention and the National Institutes of Health have taken credible and proactive leadership roles in response to this problem. This Subcommittee can assist our response to SARS and other emerging infections by assuring that Congress continues to recognize the critical leading role that these governmental agencies must play in a comprehensive and unified response. I will be happy to discuss with the Subcommittee ways in which coordination and collaboration can be achieved.

Finally, any response to SARS and any other emerging infectious disease will necessarily require resources and collaboration of public health agencies with the health care delivery system and the private sector organizations responsible for supplying critical tools such as vaccines, antiinfectives and infection control-related products. I know we will hear more about that issue from members of subsequent panels. Ideally, through federal leadership and resources, as well as those of the private sector, we will one day have an effective vaccine which will make our plans for responding to SARS very different than they are today. But in the meantime, other private sector organizations that will provide patient care will be critical partners in our national response.

In conclusion, I again want to thank you Mr. Chairman and the other members of the Subcommittee for holding this important and timely hearing. I can only wish that this will be the last hearing necessary in terms of responding to the SARS crisis, but I fear that is not the case. Nevertheless, your ongoing oversight of the resource needs and collaboration of the federal, state and local public health agencies will provide a critical roadmap for helping to assure our nation's safety and security from emerging infectious diseases.

TESTIMONY OF RODNEY N. HUEBBERS, PRESIDENT AND CHIEF EXECUTIVE OFFICER,
LOUDOUN HOSPITAL CENTER, LOUNDOUN HEALTHCARE, INC.,
LOUNDOUN COUNTY, LEESBURG, VIRGINIA

Good Morning Mr. Chairman and members of the Subcommittee, and thank you for the opportunity to appear before the Senate Permanent Subcommittee on Investigations.

My name is Rodney Huebbers and I am President and CEO of Loudoun Healthcare, a community non-profit healthcare organization serving as Loudoun County, Virginia's principal healthcare services provider. At Loudoun Hospital Center, a 145-bed acute-care facility, we have provided quality healthcare to the Loudoun Community since 1912 by offering state-of-the-art healthcare services with 60 specialties, 454 providers and 1400 employees lending support.

Loudoun County, Virginia is the second fastest growing county in the United States. We are bordered on the east by Dulles International Airport, to the north by the Potomac River, and to the west by the Blue Ridge Mountains and the Shenandoah River. It is home to a diverse business and residential population, from high tech companies to a thriving rural economy. Loudoun is also home to the FAA's center for the National Capital Region and is a major emergency evacuation route from the District of Columbia.

Loudoun Hospital Center's role in relation to these county dynamics is, of course, to provide first-line acute healthcare whether it be in the realm of preventative medicine, elective procedures, emergency response or rehabilitative services. Given the Subcommittee's specific interest in SARS – both our response as well as assistance from state and federal authorities – I

will limit my formal testimony to our emergency response protocols and observations as requested by Mr. Kennedy, General Counsel for the Subcommittee.

I have provided in our formal filing with the Subcommittee supplemental information including the Virginia Department of Health's original press release with respect to Loudoun Hospital Center's treatment response to the first probable case of SARS in the United States as well as several pages of questions and answers as have been documented by our staff.

With respect to our SARS experience, at the time of presentation in our ER "Severe Acute Respiratory Syndrome" had not yet been identified nor clinically defined with respect to symptoms or treatment. On February 17, 2003 a woman who had recently traveled to Guangdong Province in China presented in our ER with pneumonia-like symptoms. We obtained the personal history of the patient, including her recent travel itinerary, which included a report of unusual pneumonias being seen in Guangdong Province. While symptoms did mirror pneumonia, an atypical dry cough and respiratory distress proved an unknown prompting the patient's isolation in a negative pressure room as a means of infection control.

Subsequently, the hospital's infection control chief and the Loudoun County Health Department were notified as part of our infectious disease notification algorithm. In turn, the Virginia Department of Health and the Centers for Disease Control and Prevention were also notified.

Prior to this SARS presentation, it is important to note that before 9/11 our hospital had a specific disaster plan in place that included coordination with county, state and federal authorities. Following 9/11 and with the advent of nuclear, biological or chemical terrorism threats, our disaster protocols were further refined on paper as well in practice. Loudoun County

has been confronted with a variety of communicable disease issues including anthrax, Virginia's first human death from West Nile virus as well as three locally acquired cases of malaria. Hence, we have practical experience from which to draw conclusions as to our own protocol evolution and the quality of assistance from regulatory offices.

As to the performance of Loudoun Hospital's ER, triage training as well as the development of infection protocols combined to serve us well on February 17th. The documentation of symptoms along with pre-determined history including a travel inquiry, information volunteered by the patient's family, and consultation with the Loudoun County Health Department proved critical in the initial decision to isolate and contact infection control. From there, the notification algorithm worked as designed.

However, while the patient herself was of great concern, so too were the clinical and non-clinical staff who had either incidental or clinical contact with the patient. Again, SARS was not known at this time, but given the symptomatic issues identified it was obvious that infection was a distinct possibility. Our Emergency Response team, including ER, Infection Control, HR, Communications and County and Regional Health Department staff, began the process of identifying those with whom the patient had had contact during the admission process. Within hours we had a list of individuals and began contacting and testing.

At the time of the SARS presentation, the hospital's most notable infection control protocol in place was for tuberculosis. Now, of course, we have a SARS protocol, which, based upon information supplied by various authorities, has been amended in keeping with clinical findings.

As for staff reaction during and following our SARS presentation, I would characterize it as informed and collaborative. Given the unknown symptoms of SARS at the time, common sense,

admission information and proper infection protocols combined for an adequate medical response on behalf of patient and staff alike. The hospital's existing emergency preparedness committee, lecture series on emerging diseases and bio-terrorism threats, evolving policies and algorithms related to infection control, and improved communication with regional Northern Virginia hospitals via a dedicated rapid notification radio frequency continue to provide threat mitigation.

With respect to response of county, state and federal medical authorities, Loudoun County's Health Department was responsive and of great assistance in consultation and collection of samples as directed by the CDC. Thanks to a federal bio-terrorism grant permitting the addition of the Health Department's epidemiological expert, our case was thoroughly investigated with adequate consultation with counterparts at the Virginia Department of Health and the Centers for Disease Control and Prevention in Atlanta. In addition, the investigation and testing of any employees with patient contact was initiated and resulted in the finding that no other person had contracted SARS as a result of incidental or clinical contact.

There were some gaps identified during our review that, in this case, did not impact patient care. They include:

- Insufficient testing materials pre-placed in Northern Virginia for all the individuals we needed to test. Fortunately, the county health department received these materials by courier from Richmond.
- There were procedures in place to transport specimens quickly to the Virginia state's lab, but the procedures for quickly shipping these specimens to Atlanta during a weekend were lacking.

- In this particular case multiple agencies were involved, which at times pitted patient care against regulatory expectations. Specifically, the hospital staff was, at times, torn between specimen collection and delivery, symptomatic consultation with multiple agencies and actually caring for the patient as well as possible others infected. Streamlining information dissemination should prove a priority.
- In our particular case, the SARS patient spoke only Chinese. Had it not been for a family member accompanying the patient, vital information impacting patient care and subsequent infection control would have not been communicated easily.
- At our hospital, we have provided additional instruction in the taking of samples and chain-of-custody procedures to accelerate the diagnostic process.
- A genuine concern of ours continuous to be multiple isolation patients requiring negative pressure rooms.

Three elements played a key role in the successful outcome of this case with respect to the patient and infection prevention:

- Plans were in place in the emergency room to isolate the patient and notify key personnel.
- Effective communication patterns pre-established throughout the public health sector, from hospital to federal authorities, worked well.
- Positive working relationship between the hospital and the local public health office proved critical in diagnosis and containment.

In conclusion, the single largest gap experienced between our hospital and expectations of state and federal health authorities, as well as the public to whom we are dedicated, is the additional cost associated with clinical education, supplies, and ultimately prevention of a local, regional or national infectious disease issue. Local hospitals, like Loudoun Hospital Center, have spent considerable time, man-hours and capital in emergency preparedness for all levels of trauma and infection associated with accidental or intentional hazard situations. It has taxed us heavily and, while we carry the burden and meet expectation, assistance by way of appropriated dollars would certainly provide the means to assure a successful rapid response by your front-line healthcare providers.

Appropriated funds would be allocated initially to deal with surge-capacity issues, including facilitation of critically ill patients requiring respirators as well as building and equipping more isolation rooms with negative pressure capability.

I thank the Subcommittee again for both invitation and very kind attention.

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TO: Senate Permanent Subcommittee on Investigations **DATE**: May 5, 2003

FROM: Rodney Huebbers/President & CEO

CC:

SUBJECT: Additional Testimony Submission

Please find below a series of questions and answers provided to the Subcommittee as additional written testimony for consideration:

- Q: What established planning procedures were in place to handle an epidemic of communicable disease when the recent suspected case of SARS surfaced in Loudoun County? Did Loudoun County officials need to take any additional actions and procedures to respond to the suspected case of SARS?

  A: Prior to the SARS incident, Loudoun County had already dealt with locally acquired malaria, West Nile Virus, Anthrax and, of course, continues to make preparations for possible Smallpox incidents. Both the hospital as well as the county's established infection control standards and procedures had been well documented, taught and tested prior to 17 February when the patient presented to Loudoun Hospital Center ("LHC"). For the record, please find attached LHC's current SARS protocol.

  Please note the program deals with patient screening, environmental controls, employee screening, clinical education, surveillance and abatement, and respiratory protection.

  All policies and procedures are based upon CDC guidelines with specific incident training in relation to biological and chemical agents as a result of 9/11. Specific training has been provided for front line triage personnel given their initial assessment role.

  I would like to note that infection control standards within the United States and U.S. controlled facilities world-wide have always been high and established within a consultative

framework from local, regional and national health authorities. This consultative approach has proven more than a traditional paradigm, but a key pro-active element that is serving a vital preparation and educational interaction as we mobilize to meet current or future incidents – whether perpetrated or accidental.

Suffice it to say that since 9/11 if not before, the concerns related to infection control have migrated out of a specific epidemiological department to general public health venues. If there is an additional action which 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 including bulletins from health authorities, Internet resources and media coverage.

With respect to the second part of this question, both the hospital and the county health office had instituted two tracking elements in relation to infection monitoring. Specifically, a surveillance log documenting each presenting patient's symptoms is kept by the hospital and reviewed daily by the county health office. Symptoms are plotted and graphed as we look for atypical indicators. In addition, there is a systematic review detailing initial and subsequent employee contact with an infectious patient. This second survey was particularly critical in tracking clinical staff that had direct or incidental contact with the 17 February SARS patient. At the time of presentation, neither the hospital nor the county health office was familiar with what would become identified as SARS. Consequently, this tracking element provided us a critical means to identify and evaluate our own staff in relation to symptomatic complications.

- Q: Which procedures were effective in preventing the spread of the disease between emergency and hospital staff, along with other people who came into close contact with the infected patient? Have you discovered any gaps in the County's planning and preparedness for an epidemic of respiratory disease such as SARS?

  A: Hospitals should assume all patients suspected of having SARS 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 like wearing masks, adding proper hand hygiene, which is a critical factor in disease prevention. Specifically, PPE requirements include gowns, gloves, N-95 masks, and goggles.

  Administrative measures such as communication, education of staff and enforcement of policies and procedures are critical for infection control as well.

- Q: How are hospital, city and county officials educating the general public on major health threats? What recommendations have the hospital, city and county officials developed to prevent transmission of SARS and other disease outbreaks?

  A: Speaking for the hospital, we have an excellent relationship with both local and regional media, which, of course, proves a primary information conduit to the general public. Given the attributed SARS case of 17 February, both my office and the Loudoun County's Health

Officer, Dr. David Goodfriend, have had interview opportunities that we have used to convey to the public not only information about SARS as an infection but assurances with respect to staff preparedness, isolation capabilities and symptomatic treatments. We have also posted information and links on our respective Web site homepages for those desiring detailed SARS information. Those links include the CDC in Atlanta and the World Health Organization. Taken together, we believe these opportunities have substantially assured our constituency – both the public and healthcare professionals – that we are mitigating both the virus itself as well as the natural concerns associated with such a public health incident.

With respect to recommendations to prevent transmission, I do have suggestions ranging from informational to structural design considerations, including:

- At the time of presentation, a gap exists between the time a patient with a possible viral condition confers with a triage nurse and actual isolation, thus providing for the possible exposure of both clinical staff and other patients waiting to be treated or about to present. Two suggestions have come out of discussions between my office and Loudoun County's Health Department which include 1) individuals concerned about viral symptoms they are experiencing should be advised to call their family physician initially, not present in an ER. The reason for this is that their family doctor may ask initial questions regarding symptoms, recent travel and associations and develop a profile that, in his judgment, may be unrelated to a SARS exposure or prove vital in expedient treatment of the condition. In addition, the physician may place a call to the local ER reception desk and alert the staff that he/she is referring a patient for ER care which allows the staff to make proper infection control arrangements including private admittance to the facility as well as greeted by a properly clad clinical professional; 2) isolation rooms designed on exterior walls have the advantage of exterior entrances thereby greatly reducing incidental contact with the public once upon hospital grounds which, in turn, mitigates subsequent infection.
- In conjunction with the health department, we have developed what we refer to as screening tools for infectious diseases. I am providing the committee a copy of LHC's protocol for suspected SARS that includes diagnosis/evaluation information and procedures, directory information and tests to be performed. This is what we refer to as a screening tool. It is available to all the staff in the ER and in infection control.
- Both my office and the health department have dedicated staff whose job it is to monitor local, regional, national and international news for suspect medical reports which may have a bearing upon a case presented to us. For example, given the fact that at the time of presentation on the 17th of February a family member shared the patient's travel itinerary, which included Gungdong Province of China, we were able to ascertain from the Internet conditions within the province as well as quickly review CDC and WHO reports. We certainly don't consider news reports definitive from a clinical perspective, but they are indicators that would be irresponsible to ignore.
- Communication and information sharing between family physicians, their local hospitals and county health departments is proving critical in the identification, care and treatment of new, rare or general outbreaks of an infectious nature. Communication platforms need to be established or enhanced to effectively deal with

communicable conditions. In Loudoun County, there has been established an effective e-mail medical control communication from Infection Control Practitioners to hospital medical departments for both new clinical information as well as follow-up on known infection cases.

- Fortunately Northern Virginia has established healthcare member coalitions consisting of regional hospitals that evaluate information and coordinate rapid response to medical emergencies. We have even established the MEDCOMM Operation Procedures that establishes a radio frequency for rapid notification. Every region should be encouraged to develop such notification protocols.
- Finally, physicians operating within our county are aware that cultures, which prove positive for viral or bacterial infection, are reportable to the county health department. These are flagged in the lab and tracked. This is how an outbreak of Varicella (Chicken Pox) was identified, treated and contained in our own county.

- Q: What is the potential resource needs of state and local public health systems for responding to SARS and other disease outbreaks, particularly airborne diseases and influenza? Do our state and local public health systems have the necessary resources to respond adequately to this type of public health threat?

  A: Specifically, funding for emergency preparations and subsequent critical care is a major need. We are very grateful to Congressman Frank Wolf, Senators Allen and Warner as well as our state delegation for their effort to secure $400,000 in federal appropriations to assist LHC in meeting preparation requirements. However, that does not address the total balance that LHC or the county has invested in emergency preparations to date – and our preparation is on going. Additional funding would permit training of additional personnel, stockpiling of necessary supplies as well as development of enhanced response planning and execution.

- Q: What is the ability of the U.S. health care system to treat large numbers of individuals with respiratory failure and contagious disease? Approximately, how many patients can be treated in specific metropolitan areas at once?

  A: The U.S. government has strategically located push packs to set up MASH response units around the nation. This is good as far as it goes, but assisting state, counties, EMS and even hospitals in working with pharmaceutical and equipment suppliers as well as disaster coordination and planning would be of significant help. Crises are going to be dealt with by local and regional response teams – the better we are financed and coordinated the better the result we expect and experience.

The following pages represent Loudoun Hospital Center's "Protocol for Suspected SARS Patients" as of May 5, 2003 as well as the Virginia Department of Health's initial press notification regarding Loudoun Hospital Center's SARS incident:

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Protocol for Suspected SARS Patients

Patients **should not** be sent to the lab, X-ray, or outpatient services for screening.

All patients should be evaluated in the *isolation room* at the **ED-Cornwall** (#4), whenever possible. If this absolutely **cannot** take place, (i.e.: walk-in) the patient is to be evaluated at the **ED-Lansdowne** in Room (#3).

If the patient is being sent in by a physician, advance notice should be given to the ED. The patient is to be directed to the ambulance entrance where they will be met by staff.

- The following PPE is required for the staff (gown, gloves, N-95 mask and goggles)
- The following PPE is required for the patient and must be put on outside immediately upon arrival (Surgical mask and gown)
- An airborne isolation room that has negative air pressure must be used when evaluating and treating the patient.
- Standard, contact and airborne precautions are to be instituted.
- If the patient has a friend or relative escorting him/her, the visitor must wear an N-95 mask and gown. The visitors must stay in the isolation room.

The patient with fever and respiratory symptoms (of unknown etiology with onset since February 1,03) should be initially asked if he/she has recently traveled outside the U.S, has had contact with someone who has traveled outside the U.S., or is a healthcare worker. The patient should then be escorted back to the negative pressure room immediately and not stay in the waiting area.

Diagnosis/Evaluation:

- **Early symptoms:** Temperature > 38° (100.4), myalgias, headache, sore throat, dry cough, shortness of breath, or difficulty breathing.
- **Later symptoms:** Hypoxia, pneumonia (bilateral often), ARDS, thrombocytopenia, leukopenia.

Note: To be considered as a "rule out SARS patient" the following criteria must be met

1.) __ **Temperature >100.4**
2.) __ AND **one or more clinical findings of respiratory illness as stated above**

AND one of the following below

3.) __ **Travel (includes transit in an airport in an area with suspected or documented community transmission of SARS) within 10 days of onset of symptoms to any area with suspected or documented community transmission of SARS (Hong Kong, Guangdong Province, Mainland China, Hanoi, Vietnam, Singapore, Taiwan, *Toronto Canada)***
4.) __ **Close contact within 10 days of onset of symptoms with a person with a respiratory illness and travel to a SARS area (as defined as having cared for, having lived with, or having had direct contact with respiratory secretions or body fluid)**
5.) __ **Close contact within 10 days of onset of symptoms with a person under investigation or suspected of having SARS.**

SARS are now classified as "Suspect" or "Probable." Probable cases are suspect cases with x-rays showing pneumonia or respiratory distress. It should be noted that even if there is a proven reason for the respiratory symptoms, the patient should still be considered a rule out SARS if the three criteria above are met.

Tests to be performed: ***(* These are specimens that will need to be sent to the DCLS by our laboratory. DCLS will package, record and ship them to the CDC) All specimens must be labeled with a biohazard sticker and lab should be notified of a "Suspect" or "Probable" case of SARS. For those cases that are determined to be low probability or risk, lab is to be instructed to hold the specimens for 12 days)***

1) Nasal Pharyngeal swab x 2 (lab will place in viral media **stat**) *. Please do not use a regular culturette!
2) Throat culture (Use a regular culturette for this test)
3) U/A *
4) Legionella urine
5) CBC (lavender top tube x 2), Whole blood (red top tube x 2) and Serum (gold top tube x 2) *
6) Blood cultures x 2
7) RSV and Influenza A and B (1cc minimum must be obtained)
8) Pulse oximetry
9) Sputum for AFB and mycobacterium (If specimen can be obtained. DO NOT INDUCE)
10) Chest X-ray
11) Stool (CoV=Coronovirus)
    - ** *Benita Boyer at the Health Department needs to be notified of any suspected SARS cases at (703-737-8389) or (877-320-7207) or (571-233-7314). She will notify the State lab that specimens will be sent. If unable to reach Benita, page Dr. Goodfriend at 703-771-5829.*
    - Dr. A. Pastor should be notified at (703) 707-7240 (pager)
    - Tony Raker (Public Relations) at (703) 858-8059 or 703-707-7612 (pager)

- Linda Belmonte (Infection Control) at 703-858-6628 or 703-787-2549 (pager)

Patients who are discharged to home should be provided the Public Health Sheet that can be downloaded at www.cdc.gov.

The discharged patient is to be instructed to monitor his/her temperature for 10 days and record the information should the Health Dept. require this information at a later date.

NOTE: For all non-suspect cases in which specimens are collected but not sent on to CDC, the hospital is to store the specimens for 12 days while the patient's symptoms are being monitored. The attending physician is to acknowledge the disposition of the specimens by filling out the attached form that should be sent down to the lab with the specimens.

SARS Protocol 4/1/03, revised 4/3/03, revised 4/7/03, revised 4/10/03, revised 4/22/03, revised 4/28/03, revised 5/1/03

Lab Instructions for R/O SARS

Patient Name:_____MRN:_____
Date:___/___/___ **Location:** Landsdowne/Cornwall

This form is to accompany specimens sent to the lab.

_____ The patient is a **"Probable" or "Suspect"** case of SARS. Benita Boyer from the Health Department is aware of the case and acknowledges that the specimens (*) should be sent to the State Lab. **All specimens for "probable or suspect" cases must be sent to Lansdowne for processing.**

_____ The patient is a **"Non-Suspect"** case of SARS. The lab specimens are to be held in the Loudoun Hospital lab for 12 days.

The specimens with the stars are the ones that will be packaged and sent to DCLS. Note: one of the two nasal pharyngeal swabs and one blood set will be processed in the Loudoun lab.

— Nasal Pharyngeal swab x 2 (lab to place in viral media stat)*
—Throat culture (use regular culturette)
—U/A *
—CBC (lavendar top tube x 2), Whole blood (red top tube x 2), and Serum (gold top tube x 2)*
—Blood cultures x 2
— RSV and Influenza A and B
—Sputum for AFB and mycobacterium
—Stool (CoV=Coronovirus)*

Attending Physician:_____
(Print)

Attending Physician Signature:_____
(Sign)

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Virginia Department of Health News
Protecting You and Your Environment

Contact: Lucy Caldwell

Public Information VDH,

703/246-2486 or pager,

703/701-5632

VDH Investigates Possible Loudoun County SARS Case; Patient Doing Well

March 20, 2003

Doctors and epidemiologists at the Virginia Department of Health are investigating the possibility that a Loudoun County resident may have been the first suspected case of severe acute respiratory syndrome (SARS) case in the United States. The patient was successfully treated and released a month ago from a local hospital. The person had traveled to Guandong Province, China, and became ill. Upon return to the U.S. in mid-February, the patient reported to the doctor and was prescribed antibiotics. When the condition did not improve, the attending doctor sent the patient to the emergency department of Loudoun Hospital Center on February 17. The local Health Department was contacted and a surveillance process began immediately.

According to Dr. David Goodfriend, Loudoun County Health Department Director, the investigation process was thorough and complete. "The emergency department staff took all precautions, isolated the patient, and evaluated the condition. They did an outstanding job of looking at the patient's symptoms, connecting them with the patient's travel history, and diagnosing atypical pneumonia," he said.

Dr. Goodfriend stressed that all of the patient's close contacts were medically evaluated and none became ill. The patient is recovering at home and in good condition. "This case was successfully investigated prior to any awareness of SARS; and the treatment underscores how important the relationship between primary care physicians, hospitals, and public health personnel has become," Dr. Goodfriend said.

The Virginia Department of Health has communicated with healthcare providers across Virginia to ensure that they are informed of the symptoms of SARS and will be able to respond appropriately to any suspect cases.

Last week, the U.S. Centers for Disease Control and Prevention (CDC) issued a public health advisory for the recent outbreak of severe acute respiratory syndrome in several countries. SARS cases have been reported in China's Guangdong Province, Taiwan, Hong Kong, Viet Nam, Singapore, Thailand, Canada, Slovenia, Germany, and the United Kingdom.

SARS symptoms include: coughing, fever, and shortness of breath or difficulty breathing developing on or after Feb. 1, 2003, in persons who have recently traveled or close contact with those that have traveled to countries where the illness has already been found. Individuals who have these symptoms and who have recently traveled to any affected site, or have had close contact with anyone who has these symptoms, should see a healthcare provider right away.

For more information, log onto the Virginia Department of Health's Web site at www.vdh.state.va.us or call the CDC Public Response hotline at 888/246-2675 (English), 888/246-2857 (Espanol) or 866/874-2646 (TTY).

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Testimony
Thomas R. Frieden, M.D., M.P.H.
Commissioner
NYC Department of Health and Mental Hygiene
regarding
Severe Acute Respiratory Syndrome (SARS)
Before the
The Senate Committee on Governmental Affairs'
Permanent Subcommittee on Investigations
United States Senate
May 21, 2003

Good morning, Chairman Coleman, Ranking Member Levin and Members of the Committee. I am Dr. Thomas R. Frieden, Commissioner of the New York City Department of Health and Mental Hygiene (DOHMH). Thank you for the opportunity to discuss New York City's response to Severe Acute Respiratory Syndrome, also known as SARS.

New York City is one of the world's largest hubs for international travel and commerce. Every day, we welcome almost 100,000 incoming air travelers, including some 30,000 from international locations. On Saturday morning, March 15, my Department was notified that one traveler was a patient from Singapore with suspected SARS. He had attended a large conference in New York City. The patient, an infectious disease physician, had cared for two of the index SARS patients in Singapore. The patient saw a physician in New York City for his illness, then boarded a plane to fly back to Singapore, and was taken off the plane in Frankfurt, Germany, where he was hospitalized. His wife and mother-in-law, with whom he was traveling, both developed SARS.

That Saturday afternoon and evening, we faced a series of decisions that illustrate the challenges of addressing the threat of SARS and the importance of good, basic public health services – services which have weakened to the point of endangering the public's health in many parts of the country. Although New York City is fortunate to have robust communicable disease investigation and monitoring capacity, many areas do not have this capacity. And New York City, like many areas, has critical needs in the area of public health laboratory capacity, surge capacity, and other areas. All too often, clinical and public health laboratories are the poor relations in the health field, and unfortunately this is all too often what is happening at the national, state, and local levels in the United States today.

When we heard of the SARS case, we rapidly took the following actions:

1. With facilitation from CDC, contacted the patient's physicians and interviewed the patient by telephone in his isolation room in Germany.
2. Determined that the patient met the case definition for SARS.
3. Determined with whom the patient had come into contact in New York City.
4. Advised the hotel where he had stayed of what precautions, if any, they should take.
5. Notified the organizers of the conference which he had attended and informed them of what precautions they should take, and provided them with materials so they could make a presentation to the conference participants the next day.
6. Identified persons who may have come into contact with the patient, and ensured that they would be rapidly assessed if they developed illness.
7. Found the physician who had treated the patient, and ensured that he and his entire office staff were aware that they should not come to work if they became ill.
8. Informed health care workers that Saturday evening, particularly those staffing emergency departments and intensive care units throughout the city, through an urgent blast fax/email, of the diagnosis of SARS and of the importance of rapid detection and isolation. Since then, we have distributed SARS information signs for posting at the entrance to emergency departments and clinics, reminding patients and staff of the need to monitor for SARS. We have also provided detailed guidance on the importance of immediately placing potential SARS cases into an isolation room, the need for all medical care staff to wear full protective equipment, and the importance of reporting all suspect or probable cases.
9. Heightened our index of suspicion in our syndromic surveillance system – tracking all ambulance runs, most emergency department visits, many prescriptions, and absentee data;
10. Decided on a public communication strategy including targeted outreach to our Asian community to address their specific concerns about SARS and to try to alleviate the stigmatization that has resulted from this outbreak by clarifying that this is a disease of travel, not ethnicity.

Our response to the threat of SARS illustrates that the detection of and response to any infectious disease outbreak, whether natural or intentional, requires a strong local public health infrastructure with an effective working relationship with the medical community.

Thanks to recent funding from the CDC, our Communicable Disease program has been able to hire additional medical, nursing and surveillance staff

with the expertise required to handle these substantial efforts. Department staff are available 24 hours a day, 7 days a week to discuss potential SARS cases with health care providers and to determine if a case meets the CDC criteria for SARS. If a case does meet the criteria, we ensure that appropriate laboratory specimens are obtained and provide detailed information to the medical provider on guidelines for isolation in both the hospital setting and at home upon discharge. DOHMH staff actively monitor all cases through daily telephone calls for 10 days after their symptoms subside, to ensure that they stay in isolation until they are no longer contagious. Also, all patients and their household contacts are provided detailed instructions on how to prevent spreading or contracting the virus. Given the great diversity of our City, all educational materials for our case-patients and their close contacts have been translated into the appropriate languages, and the DOHMH has access to bilingual translation services to ensure that all persons fully understand our instructions.

With our active outreach to the medical community, we have had more than 180 calls regarding potential cases, every one of which has been evaluated by our Communicable Disease staff. Most did not meet the criteria for SARS, and to date there have only been 22 cases – including 3 probable and 19 suspect cases – all of whom recently traveled to affected areas in Asia or Canada. All of the cases have since recovered. None of these potential SARS cases had a serious illness and none has yet tested positive for the new SARS-related coronavirus. Thus far, there has been no community transmission of SARS in New York City, as we have had no secondary cases among household or health care worker contacts. In fact, I would not be surprised if none of these 22 cases turned out to actually have coronavirus infection as the clinical criteria we use for surveillance purposes are quite broad, and our aim is to err on the side of caution as the risk of missing a case is very high.

Partly due to our early and proactive response and partly due to luck, SARS has not become an emergency in New York City. But given the outbreaks in China, Hong Kong, Singapore, Toronto, and Taiwan, we cannot afford to be complacent. We continue to work on our contingency planning to ensure that we are ready to respond to an outbreak. Efforts include planning for a large-scale surveillance and epidemiologic response if we see local transmission; developing the capacity to conduct SARS testing at our public health laboratory using the assays provided by the CDC; continuing to develop multi-lingual educational materials to address the many community concerns that SARS has raised; working closely with hospitals to provide guidance on preparing for and responding to a hospital-wide or community outbreak; and developing contingency plans for an event in which large-scale isolation and quarantine measures are needed to control a significant SARS outbreak.

Given the large number of travelers coming to New York City, we need to remain vigilant as long as the outbreaks continue overseas. It would not be unexpected if a highly contagious SARS patient arrived in New York City with the

potential to initiate a large outbreak. As the West Nile virus outbreak in 1999 also illustrated, infectious disease outbreaks in distant countries should be both a national and local concern, given the ease and volume of air travel today.

The best approach to prepare for new and emerging diseases like SARS is to strengthen the nation's public health infrastructure. With recent bioterrorism preparedness grants from CDC and HRSA, my Department has significantly improved its ability to respond to infectious diseases threats. The systems we have put in place will help us respond to both natural and intentional outbreaks, as the issues that arise are, in many ways, the same. In most jurisdictions, the public health agency is now recognized as a first responder, requiring the staff and the technology to ensure a 24/7 response and a sound and redundant emergency communication system.

Our emergency preparedness initiatives have helped us to improve communication among the Department, medical providers and hospitals, as well as within our Department, and between other city agencies and the public. We have enhanced our website to make it an up-to-date health information source for the medical community and the public, with daily updates on SARS. These basic infrastructure enhancements enabled us to promptly post on our website patient information sheets in Chinese and Vietnamese shortly after outbreaks were confirmed in China and Vietnam. We have also developed speaker's bureaus to provide presentations to community groups and answer questions, and have issued press releases in Chinese to the Chinese media. Because of the fear and stigmatization caused by this new disease, we strive to communicate openly with local immigrant communities and address their concerns.

One of New York City's most significant accomplishments has been the development of a syndromic surveillance system. The syndromic surveillance system collects health data gleaned from 911 calls, emergency department logs, pharmaceutical purchases, and workplace absenteeism and analyzes these findings every day of the year to detect any increase or clustering of symptoms that might represent an infectious disease outbreak. The system is programmed to detect increases in "syndromes," such as flu-like symptoms, which could indicate that the initial phases of illness are occurring in a group of people recently exposed to a biological agent. This data provides the potential for earlier detection of a large outbreak than a traditional surveillance system dependent on medical provider reporting.

The additional personnel made possible by the federal grant have been essential to the Department's response to SARS. Over the past few months, more than 20 DOHMH Communicable Disease staff have been deployed to investigate potential SARS cases. Without this additional staff, employees would have to be diverted to an even greater extent than they have been from other

essential public health duties in order to accommodate SARS monitoring and planning activities.

Since the events of September 11, 2001, New York City's public health, hospital and emergency management sectors have collaborated closely to continuously strengthen New York City's ability to respond effectively to chemical, radiologic and biological terrorism. However, any disaster requires the coordination of multiple public sector agencies, including well-trained first responders. The City's Office of Emergency Management (OEM) plays a crucial role in this coordination, not just within the City, but also with surrounding communities. OEM is a key partner in emergency preparedness planning to combat public health threats, whether man-made or naturally occurring.

If community transmission of SARS does take place in the future, DOHMH would move rapidly to protect others from exposure. If necessary, as we have already done in two cases, DOHMH would invoke its legal authority to ensure that individuals remain isolated and do not spread the disease to others. We are currently in the process of amending the NYC health code, to strengthen our authority to detain – with full respect for the individual's right to due process – suspected or confirmed cases or contacts of contagious diseases that pose an immediate threat to the public's health (e.g., smallpox, pneumonic plague and outbreaks caused by unknown agents). We are also in the process of identifying appropriate isolation and quarantine facilities that could be used in the event of large-scale, contagious respiratory disease outbreaks, as would occur if there were community transmission of SARS in New York City. These facilities would also be needed in the event of a smallpox or pneumonic plague outbreak.

One concern is the large number of staff that would be required to respond to a SARS outbreak in which large-scale isolation and quarantine were required. A significant event would require federal assistance to provide everything from supplemental medical and security staff to food and wage reimbursement for quarantined and isolated civilians. We recommend that FEMA develop contingency plans for providing critical supplementary services in the event of a large-scale disease outbreak in the United States. As we have learned from the SARS outbreak in China, a poorly-controlled disease outbreak and the potential unrest that would follow would not only strain hospitals and public health departments, but also police, fire, public transportation and human services resources. It would also have enormous negative economic impact. We suggest expanding the national Disaster Medical and Mortuary Assistance Teams, developing a national medical reserve corps which addresses emergency licensing and credentialing issues, and developing the capacity to install emergency temporary housing and hospital facilities in an urban setting for use during a large isolation and quarantine scenario.

DOHMH has made significant steps toward emergency preparedness. However, the Department still has a number of benchmarks to reach. Perhaps

our most urgent need is the city's Public Health Laboratory, which is a critical and essential part of the New York City's public health infrastructure. Funding cuts in the early 1990s drastically reduced the Public Health Laboratory's capacity to respond to public health emergencies, and the Department is currently renovating and modernizing the laboratory facility. The facility, designed in the late 1950s, is not conducive to modern technologies and laboratory practice. Without the proper security, surge capacity and technological enhancements, the Public Health Laboratory could become incapacitated during a large disease epidemic or bioterrorist attack, just when it would be needed the most. Despite New York City's fiscal crisis, the City has made available more than $30 million of its own capital funds for renovation, but this is only about half of what is required. As it is the only public health reference laboratory for eight million New Yorkers, it is essential that we identify funds to complete this project. We must ensure that the proper resources are in place before an epidemic occurs.

In fact, there is a critical need to rebuild the infrastructure of public health laboratories across the country. Many laboratories have suffered from waning financial support over the past several decades. The response to SARS requires that CDC transfer technology to laboratories already hampered by inadequate facilities and by increasing caseloads of pathogens such as West Nile and SARS. Laboratories will need a usable set of clinical tests, some of which we understand are soon to be released by CDC; acceptable testing and reporting algorithms that distinguish between recently acquired infections and older infections; very clear standards, as well as financial and technical assistance in the development and building of adequate and safe facilities to perform such testing; and resources to develop and staff the computer systems to accommodate the testing and tracking of these new pathogens.

Federal grant money provided for hospital emergency preparedness has been woefully inadequate to meet the needs required by a city of our size and complexity. In this federal fiscal year, $2.9 million was distributed equally among 72 acute care facilities in New York City, which amounted to only $40,000 per facility. The funding for the new grant period beginning in July 2003 was increased to almost $13 million, and we have been given authority to distribute up to 20 percent of this award immediately. However, while we have been able to complete some initiatives, our hospitals still have a large number of critical benchmarks to reach. Additional funding is needed to assist hospitals in expanding surge capacity through building additional airborne isolation rooms, stockpiling and maintaining inventory for a three-day supply of pharmaceutical supplies, conducting internal tabletop drills and increasing security at hospitals. A terrorist attack could happen in any location, and, with the widespread use of public transportation in New York City, victims exposed to chemical, biological or radiological agents could travel to many locations before realizing they had been exposed. Likewise, with a naturally-emerging disease like SARS, a contagious patient could present anywhere. Therefore, all hospitals in our city need the capacity to identify, isolate and treat large numbers of contagious patients.

It is essential that the allocation of national bioterrorism funding be targeted toward the extraordinary needs of large, densely populated cities that are high on the list of potential terrorist targets. The current funding formula does not take these factors into consideration. New York City's need for extraordinary levels of preparedness is driven by its disproportionate risk. As a financial, cultural, and media capital of the world, it is a prime target for terrorists – which has already been demonstrated by the two attacks on the World Trade Center, as well as the anthrax-contaminated letters targeting major media organizations in NYC. New York also has a unique susceptibility to imported infectious diseases with more than 65,000 international air travelers arriving and departing each day. More than eight million residents live within just 321 square miles, giving us a population density of about 25,000 per square mile, which is orders of magnitude greater than the national average. And our population increases to ten million each workday as regional commuters funnel into the City's three central business districts. The impact of a bioterrorism attack or an emerging infectious disease on New York City is potentially devastating, with national and worldwide implications.

I would like to emphasize the important role of the CDC in New York's City SARS response. The CDC has shown leadership by providing public health departments and the medical care community with up-to-date information on this evolving international outbreak and by rapidly distributing educational materials through its website and frequent teleconferences. The CDC's laboratory expertise is an invaluable national resource. Health departments throughout the country look to the CDC laboratories to rapidly develop new testing methodologies, and to disseminate these assays to state and local public health laboratories. The responsiveness of CDC as our national reference laboratory was demonstrated by the West Nile outbreak, when within six months of the introduction of this new virus, serologic and nucleic assays were developed and distributed to public health laboratories nationwide to expand our capacity to monitor the rapid spread of this new virus.

However, we are concerned about the ability of CDC to continue as one of the world's pre-eminent public health agencies. The CDC has endured significant budget cuts over the past decade, and its laboratories and its expertise have been negatively impacted. Responding to outbreaks that involve numerous states, as well as responding to the threat of imported diseases from overseas, requires the leadership and the experienced staff of the CDC to ensure a coordinated local and national response. It also requires significantly more financial resources.

The best protection against the threat of a new disease is a strong public health infrastructure working in close partnership with the medical community. It is more imperative than ever that our nation's public health infrastructure be financially supported and strengthened. In New York City, my department has

identified immediate needs requiring at least $104 million. These needs include the cost of upgrading our laboratory, retrofitting our facilities for emergency use, planning and establishing points of distribution (POD) sites for preventive mass treatment, and equipment and computer software to enhance our capacity to respond to chemical, biological and radiological events. In addition, our public hospitals alone need more than $35 million to address their immediate needs to prepare for public health emergencies. And this does not even begin to address the financial needs of other first responders, such as fire, police, the EMS system, and our emergency preparedness coordinators. To ensure speed and effectiveness in the grant process, it is of critical importance that federal funding continues to come directly to the City. The threats of terrorism and of new or re-emerging infectious diseases will remain a concern for the foreseeable future. Only a concerted, sustained federal investment in public health will ensure our capability to respond and protect our communities.

Thank you for the opportunity to testify on this important matter. I will be happy to try to answer any questions you may have.

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Statement of

MARY C. SELECKY
SECRETARY
WASHINGTON STATE DEPARTMENT OF HEALTH
and
PRESIDENT
ASSOCIATION OF STATE AND TERRITORIAL HEALTH OFFICIALS

Before the

PERMANENT SUBCOMMITTEE ON INVESTIGATIONS

of the

UNITED STATES SENATE

Hearing on

"SEVERE ACUTE RESPIRATORY SYNDROME"

MAY 21, 2003
Representing

THE ASSOCIATION OF STATE AND TERRITORIAL HEALTH OFFICIALS
(ASTHO)

Mr. Chairman and distinguished members of the Subcommittee, my name is Mary C. Selecky. I am the Secretary of the Washington State Department of Health, and I am honored to be testifying before you today as the President of the Association of State and Territorial Health Officials (ASTHO). I would like to thank the Chair and subcommittee members for convening this hearing on one of the most challenging issues facing the public's health and those charged with protecting it -- emerging infectious diseases, and specifically severe acute respiratory syndrome or SARS.

Not a day goes by that the public is not reading or listening to a news report or warning about SARS. While public concern mounts, federal, state, and local public health agencies working with their international counterparts and other partners are aggressively responding to SARS. The World Health Organization (WHO) and the Centers for Disease Control and Prevention (CDC), in particular, are to be commended for their prompt attention to this worldwide health emergency.

In my remarks today, I would like to make four points:

1. Substantial Congressional investments in preparedness funding have enabled states to respond more effectively to emerging infectious diseases such as SARS.
2. Great progress has been made in enhancing public health capacity, much more needs to be done, and sustained support is essential
3. Federal, state and local public health agencies in collaboration with their international counterparts and other key partners are working cooperatively to address this serious public health concern.

4. The greatest obstacle to our efforts to combat SARS and future threats like it is the serious workforce shortage facing health agencies at the local, state, and federal levels. That shortage must be addressed if we hope to quickly, efficiently and effectively respond to emerging infectious diseases.

For the past two years, Congress has appropriated significant amounts of funding for public health preparedness activities at the federal, state, and local levels. There is no doubt that these resources have improved our ability to respond to SARS. They are particularly critical when dealing with a new disease such as SARS, and when the case count is growing. In Washington we currently have 26 suspect and two probable SARS cases. Public health preparedness funds have added four epidemiologists to our state communicable disease epidemiology unit, providing us with critical extra capacity to respond to all the SARS questions and to assist local health agencies and clinicians. These same funds have been used to organize nine public health emergency preparedness regions among our state's 35 local health agencies. The regional leads have also hired additional epidemiologists, and are providing leadership and support in the response to SARS as well as in emergency preparedness. Washington State, like most other states, is using the national Health Alert Network to disseminate official messages from the Centers for Disease Control and Prevention (CDC) across the public health system, and through local health agencies to physicians. Timely and accurate communications are absolutely essential when dealing with an infectious disease outbreak.

Cooperation and collaboration among public health agencies and other key partners has been critical to our SARS activities. Our colleagues at the CDC have done a terrific job in identifying and tracking the epidemic. Through numerous conference calls, videoconference broadcasts, and

HAN advisories, CDC has provided us with the latest information on SARS spread, infection control guidelines, and other information critical to combating the outbreak. They have sought and received our input and that of local health officials in the development of guidelines and public health measures. We have used similar mechanisms to rapidly convey all SARS information to our local health partners and clinicians.

As a former health officer for the Northeast Tri-County Health District in rural eastern Washington State, I know first hand about the importance of the capabilities that must be in place to assure that all citizens are protected. Local, state and federal health agencies each have a distinct and important role to play.

As a state that borders another country, and serves as a major port of entry, Washington must coordinate and collaborate with international health officials and with port agencies. We have always had good communication and coordination with health officials in British Columbia, and have increased that communication regarding SARS. We have also, with the local health agency responsible for King County, begun meeting with port officials for Seattle Tacoma International Airport to help them refine their entry processes, and to assure they know what to do should they receive a passenger who is suspected of having a communicable disease.

Let me give one example, drawn from my own experience. On March 22, a container ship arrived in Tacoma, Washington, after visiting Singapore, Hong Kong, and Taiwan. Several of the 26 crewmembers developed non-specific upper respiratory symptoms that may have fit the evolving SARS case definition. As the ship approached our state, my staff worked closely with the Tacoma-Pierce County Health Department and the CDC's Division of Global Migration and

Quarantine to plan a response. We had questions about whether the crew's symptoms were consistent with SARS, what authority we had to board and investigate, and who had authority to issue isolation or quarantine orders should it become necessary. We also worked with the port of Tacoma on actions they could take to limit public contact with the ship. The owner of the ship gave us full cooperation as we made our plans.

While CDC's Division of Global Migration and Quarantine was helpful, their resource limitations made it difficult to respond to all of the questions and calls for assistance pouring in from around the country. They also were not clear about various agencies' authority to manage potential international cases of the disease. By the time the ship approached Seattle, however, we had clarified responsibilities and developed a course of action. My staff boarded the ship, accompanied by staff of the local health agency and the Division of Global Migration and Quarantine. Together they examined the crew and determined that, since all were recovering from their illness, they did not present a threat to the public. Continuing, ongoing interaction with the Division of Global Migration and Quarantine was necessary as the ship departed Tacoma for ports in California and Hawaii. We worked with the CDC to make sure that state health officials in those jurisdictions were notified and could monitor the ship and its crew. We were able to deal effectively with this episode because public health leaders at all levels of government and their key partners worked together.

Stories like that one are the good news. The bad news is that local and state health departments face a serious shortage of trained public health professionals. According to a National Association of State Personnel Executives report, states are facing up to a 40% loss in employees due to retirements in the next 5 years, and the health workforce is the area in which the resulting

shortages will be most severe. We can have all of the sophisticated equipment and tests in the world, but without trained professionals to gather, analyze, interpret and disseminate data, our public health system will falter. We need to address workforce issues at the same time we address hardware, communications capabilities, bricks and mortar, and other aspects of our infrastructure.

SARS has highlighted some of our workforce concerns. The same public health workers who work on communicable diseases at the state or local level are expected to respond to emergencies -- most recently smallpox vaccinations, anthrax, and West Nile Virus. The public health nurses, disease investigators, environmental health specialists and other public health officials who are dealing with these other issues must also conduct investigations of suspected or probable SARS patients, ensure the proper retrieval of specimens, and help institute control measures. Above all, we must maintain active communication with the public. We can and do mobilize in times of crisis and can borrow staff from other areas of public health - but doing this stresses the entire system and is only possible for short periods. And the strains are not only felt at the state and local levels. CDC also needs additional manpower to cope with ever-mounting threats and challenges.

The last point I want to make is that despite the recent progress we have made in strengthening our public health infrastructure to deal with diseases such as SARS and other emerging threats to the public health, much more needs to be done. To date Washington State has investigated 28 suspect or probable SARS cases. What if we faced a situation like the one that has engulfed Toronto and that number suddenly increased to a few hundred? We would need many more epidemiologists to investigate all the cases and to take preventative actions. We would need

additional communications staff to handle media and public concerns. We would need laboratorians, public health nurses and many more specialists. Would we have the surge capacity to handle that number and for what period of time? Summer is fast approaching and West Nile Virus is already on our radar screen. Can we handle SARS, West Nile Virus **and** the usual food borne outbreaks at the same time? We hope so; but we recognize – and you need to recognize -- that limited resources hamper our ability to deal quickly and effectively with the vast array of public health challenges that face us daily.

In closing, I wish to thank Congress for the preparedness funding it has provided in the last two years. It was a critical beginning, but this cannot be seen as a "two shot" effort. Decades of neglect of our nation's public health infrastructure make continued federal investments essential. The public health community stands ready and willing to tackle SARS and other public health concerns. We look to you to help ensure that we have the necessary resources to do our job.

Thank you for this opportunity. I would be pleased to answer any questions you may have.

SARS: THE IMPACT ON STATE AND LOCAL JURISDICTIONS[1]

Testimony of the Center for Law and the Public's Health
Georgetown and Johns Hopkins Universities
Prepared for the
Permanent Subcommittee on Investigations
U.S. Senate

Senator Norm Coleman, Minnesota
Chairman

May 21st, 2003

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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. The presenter acknowledges the work of James G. Hodge, Jr. in the preparation of this statement. See Lawrence O. Gostin, *Public Health Law in an Age of Terrorism: Rethinking Individual Rights and Common Goods*, 21 HEALTH AFFAIRS 79-93 (2002); Lawrence O. Gostin, Jason W. Sapsin, Stephen P. Teret, Scott Burris, Julie Samia Mair, James G. Hodge, Jr., Jon S. Vernick, *The Model State Emergency Health Powers Act: Planning and Response to Bioterrorism and Naturally Occurring Infectious Diseases*, 288 JAMA 622-628 (2002). See also, Lawrence O. Gostin, *Public Health Law: Power, Duty, Restraint* (University of California Press and Milbank Memorial Fund, 2000).

Executive Summary

The spread of SARS in the U.S. presents significant challenges for tribal, state, and local public health authorities. 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.

At the request of Centers for Disease Control and Prevention (CDC), 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 comprehensive 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 mosquitoes carrying the virus from infected birds. Thousands of persons have been infected, and several deaths (particularly among older persons) 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 potentially 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 persons 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. Other potential modes of infection are being investigated. To date, the CDC reports 348 cases of SARS in the U.S., of which 65 are listed as probable. No deaths from the disease have occurred domestically, although the World Health Organization conservatively reports 643 deaths worldwide among 7,864 cases.

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 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 no cure or vaccine for SARS. Effective treatment is lacking. In less than 6 months, SARS has spread to 30 countries, largely through persons who have traveled from infected areas. Even if the disease is largely controlled for a specified period of 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. The CDC, under the outstanding leadership of Julie Louise Gerberding, MD, MPH, has performed admirably in keeping SARS under control. State and territorial health officers, as well as city and county health officers, have similarly responded in a professional manner. The response of state and local health officials has been all the more remarkable given the continuing shortage of funds for public health preparedness. Even with the influx of additional resources for bioterrorism, states and localities still need substantial support for all the aspects of a strong public health infrastructure, including laboratories, surveillance, data systems, and workforce. The need for a strong public health infrastructure at the state and local level has been a message consistently stated by the CDC and Institute of Medicine.

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 voluntarily isolated from others to prevent infection. Close contacts of infected persons have been asked to limit their exposure to others and engage 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 things 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 that 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,

[2] Associated Press, *Milwaukee: State Ready for SARS, Officials Say*, ST. PAUL PIONEER PRESS, 4/29/03, 1B.

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, although there have been administrative changes in New York City). 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 and 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 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) and the private sector (e.g., health care workers and institutions, pharmaceutical industry, NGO=s). Coordination among the various levels (e.g., federal, tribal, state, and local) and branches (e.g., legislative, executive, and 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 a 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 C 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 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 or the public health. 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 (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.

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 http://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. The Act has been introduced in whole or part through legislative bills or resolutions in 39 states, and passed in 22 states. The National Conference of State Legislators has developed a check list of powers based on the Model Act, which has been used in virtually all 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 multi-disciplinary 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 2002, the Act's provisions and structure are based on existing federal and state laws and public health practice. Existing state public health laws were used as model approaches for key areas in the Act.

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; and travel restrictions) that may infringe individual civil liberties (e.g., rights to due process, speech, assembly, travel, and 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 among persons who justifiably may pose risks to others because of their contagious conditions. In addition, the dignity of individuals is 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 create 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:

A. Sets a high threshold definition of what constitutes a "public health emergency" [Article I];

B. 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 [Article II];

C. Authorizes the collection of data and records and access to communications to facilitate the early detection of a health emergency [Article III];

D. Vests the power to declare a public health emergency in the state governor, subject to appropriate legislative and judicial checks and balances [Article IV];

E. 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 [Article V];

F. 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 [Article VI];

G. 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 [Article VII]; and

H. 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 [Article 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 or a highly fatal biological toxin or novel or infectious agent (that was previously controlled or eradicated) 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 in contact or 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. That is, the state must pay private owners for the use of their property. Correspondingly, the Act requires the state to pay just 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 public 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 the declaration of the 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 subject 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, respectively, 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 "the 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 promptly 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 HCW's 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 originally set forth in the *Model State Public Health Privacy Act* [www.critpath.org/msphpa/privacy.htm] and to be replicated in the comprehensive **Model State Public Health Act** supplement the provisions of MSEHPA.

Conclusion

Preparing for existing and future 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 authorize, or may even thwart, effective public health action. Law reform is needed to improve public health planning, detection, and response capabilities.

MSEHPA (and a 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 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.

Statement Of
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Ecolab Inc.
St. Paul, Minnesota

Good morning, Mr. Chairman and Members of the Committee. Thank you for the opportunity to speak to you regarding our company's response and challenges related to the global SARS crises.

My name is Bruce Cords. I am currently Vice President of Food Safety and Public Health for Ecolab, headquartered in St. Paul, Minnesota. I hold a Ph. D. in Microbiology and I am responsible for food safety and public health technology strategies across all Ecolab divisions. In this role, I have had the lead technical responsibility for the company's response to the SARS crises.

As a world leader in sales of premium commercial cleaning and sanitizing products, systems and services, Ecolab is in nearly 170 countries with global sales of $3.4 billion last year. Among other things, Ecolab's expertise is in the practical application of disinfection and cleaning technology to help manage and respond to exposures in the workplace and in a wide variety of community environments. They include healthcare facilities, schools, lodging, restaurants, food-processing facilities, military installations and public transportation.

Our customers, worldwide, depend on Ecolab to provide advice, products and systems to address problems with infectious diseases such as SARS. As the outbreak of SARS was peaking, in March and April, many international hotel chains asked for help to make sure that they had the latest training and information to deal with the SARS virus.

We continue to receive numerous information requests regarding SARS from both customers and industry officials. We have been closely monitoring the situation via the World Health Organization (WHO) and the Centers for Disease Control (CDC). There is still much to be learned and until many of the open questions have been answered we can only make recommendations based on the best available scientific information from sources such as the CDC and the World Health Organization. As an aside, Dr. Gerberding and her staff at the CDC have done an excellent job of regularly updating the public and health officials on the global status of outbreaks and any new information on the virus and its epidemiology

The SARS virus appears to spread primarily by close person-to-person contact. Most cases of SARS have involved people who cared for or lived with someone with SARS, or have direct contact with infectious material (for example,

respiratory secretions) from a person who has SARS. Potential ways in which SARS can be spread include touching the skin of other people or objects that are contaminated with infectious droplets and then touching the nose or mouth.

Initially, experts believed that the virus would survive for only a few hours on environmental surfaces. More recent information from the Chinese University of Hong Kong suggests that the virus may survive for days on environmental surfaces. Some examples include:

- Plastered Wall (24 - 36 hours)
- Plastic Surface (36 - 72 hours)
- Stainless Steel (36 - 72 hours)
- Paper File Cover (24 - 36 hours)

This possibility places more importance on cleaning and disinfection of potentially contaminated surfaces.

Examples of questions we are receiving include:

1. If we suspect a hotel room has been occupied by a SARS infected person, what cleaning and disinfection procedures should be followed?

2. What hand care products and procedures are effective against the SARS virus?

3. How do you inactivate SARS on carpet and upholstery?

4. What are recommended cleaning and disinfection procedures for an airplane that has arrived from a country with active SARS infections?

As you may know, the U.S. EPA has not approved any commercial product claims against the SARS virus. Consequently, we have followed the general recommendations provided by the CDC. To prevent the spread of the disease, the CDC specifically recommends:

1. Aggressive handwashing and the use of an alcohol gel hand sanitizer containing 60% – 95% denatured ethanol or isopropanol.

2. Disinfection of environmental surfaces such as faucets, handrails, restrooms, elevators and other surfaces touched by multiple individuals, with an EPA-registered Hospital Disinfectant.

We have provided our customers with this information through direct contact with our district managers and technical support staff and have also made the information available on our public website, www.ecolab.com. The information provided includes:

1. General information on how the virus may be spread

2. Ecolab hand care and disinfection products which are consistent with CDC recommendations

3. Specific decontamination procedures for different institutional settings.

I want to emphasize that simply identifying products does not provide the user with the "how to" guidance they need. For example, in response to the earlier referenced question "if we suspect a hotel room has been occupied by a SARS infected person, what cleaning and disinfection procedures should be followed?", our response was as follows:

- Cleaning personnel should wear a respirator or surgical mask rated by NIOSH at N95 or higher.

- Cleaning personnel should wear disposable gloves while cleaning the room.

- Frequently touched surfaces such as light and air control switches, faucets, toilet flush levers, door knobs, and TV and radio controls should be treated with an EPA-registered Hospital Disinfectant.

- All surfaces in the bathroom that may have contacted respiratory secretions, urine, or feces should also be disinfected.

- Laundry should be handled while masked and gloved, placed in a laundry bag, kept separate from other laundry, and laundered at a minimum temperature of 160°F (71°C) for a minimum of five (5) minutes.

- Gloves should be discarded after use.

- Hands should be washed with soap and water or an alcohol-based hand sanitizer after glove removal.

As mentioned earlier, no commercial products carry a claim of efficacy against this virus. Today, the CDC recommendations are based on extrapolation of data to other related viruses. Ultimately, products must be tested against the virus and products, which carry an efficacy claim against this virus, would provide the highest degree of confidence in performance.

For this to occur will require:

- A reliable method for enumeration of the virus must be developed. (It is my understanding that the CDC is working in this area);
- EPA must approve a protocol for testing commercial products against the virus or a surrogate virus;
- During the recent Foot and Mouth disease and Anthrax threats, Ecolab worked closely with EPA to expedite product approvals. Likewise, we look forward to EPA working to expedite approvals for products effective against SARS so that these products are available should the virus reappear in the United States.

In summary, based upon the latest scientific information, and working with appropriate government authorities, Ecolab will continue to provide our global customers with information on products and best practices to prevent the spread of this disease.

Thank you for your attention.

PREPARED TESTIMONY OF VICKI GRUNSETH
Chair, Metropolitan Airports Commission

SARS: HOW EFFECTIVE IS THE STATE AND LOCAL RESPONSE?

Hearing of the
Permanent Subcommittee on Investigations
Governmental Affairs Committee
United States Senate
May 21, 2003

Mr. Chairman and Members of the Subcommittee:

I'm Vicki Grunseth, Chair of the Metropolitan Airports Commission in Minneapolis. The Commission operates the Minneapolis-St. Paul International Airport and six reliever airports in a seven-county region of Minnesota. The size of our airport system is noteworthy. Minneapolis-St. Paul International is the 8th busiest airport in America and 12th largest in the world. In 2000, more than 37 million passengers traveled through the airport, and we accommodated more than a half million takeoffs and landings. Usage has declined slightly in the last couple of years but is beginning to increase again.

Thank you for the opportunity to appear today. Severe Acute Respiratory Syndrome (SARS) is obviously a major concern for airports as well as airlines. The aviation industry provides a vital link between people, businesses and economies worldwide. We want to make sure that link is not compromised by SARS or other communicable diseases. It is difficult to gauge the full impact of SARS on the aviation industry, given the timing of the outbreak amid war in the Middle East, recession at home, and the ongoing fallout of the 2001 terrorist attack on America. There can be no doubt, though, that the impact is severe.

The airport is like an artery through which people and things pass into the heart of the country. Most of the things that flow through that artery are good; many, in fact, are critical to our economic strength. But threatening things can also flow into Middle America through the airport artery, including potentially life-threatening viruses like SARS. If we don't act swiftly to stop them, they can wreak havoc in the Heartland and throughout our nation.

SARS is of particular concern to Minneapolis-St. Paul International, given our strong partnership with Northwest Airlines, a leading provider of air service to Asia. The Twin Cities are fortunate to be the headquarters of Northwest, the nation's fourth-largest carrier. MSP is one of three North American hubs for Northwest.

Stopping SARS is important to us first and foremost from a public health consideration. It is also important to us from an economic standpoint. It's not enough that we stop SARS. We need to ensure that the traveling public has the information they need to feel safe while flying.

I want to speak for a few minutes about the Metropolitan Airports Commission's role in responding to SARS. Next, I want to highlight the airlines' efforts to combat the spread of the disease. And finally, I want to address the assistance the collective aviation community has received from the Federal Government.

In many respects, Minneapolis-St. Paul International Airport operates like a municipality. We have our own police, fire and 9-1-1 communications departments. Each of our firefighters is a trained emergency medical technician. Typically, airport fire and police personnel are the first to respond to health emergencies at the airport. When news of SARS emerged, therefore, we wanted to ensure we could protect our 'first responders' and all those who come to the airport for work or travel.

Consider the population of people potentially threatened by SARS at our airport. On average, 100,000 travelers pass through Minneapolis-St. Paul International each day. That's not counting all the colleagues, family members and other well-wishers who drop travelers off and pick them up at the facility. Then there the thousands of people who work at the airport and are potentially at risk: more than 17,000 airline employees, 3,500 food and retail workers, 2,200 ground transportation providers, 1,400 Federal agency staff, and 540 Airports Commission employees. Clearly, the potential for spread of infection is enormous if we don't respond effectively to diseases like SARS.

We had an existing protocol for dealing with infectious disease. That protocol includes all the normal precautions such as use of eye protection, surgical face masks and gloves when responding to calls in which infectious disease is suspected. We also called upon Dr. Tom Jetzer, a physician on contract to the Airports Commission. Dr. Jetzer provides ongoing medical training to airport firefighters and serves as a consultant for emergency health information. He acts as a local liaison with officials

from the Federal Centers for Disease Control and Prevention (CDC). And he reviews airline plans for responding to SARS.

Take, for example, Northwest Airlines. Northwest accounts for about 80 percent of all operations at MSP -- including service to Asia. Northwest screens passengers at ticketing and boarding areas in affected areas, such as Hong Kong, China, Singapore and Taiwan. Airline representatives ask passengers whether they have experienced SARS-like symptoms and whether they have been in contact with infected persons during the last 10 days. If travelers have, they are referred to a medical facility to be assessed as to their suitability to fly.

The same goes for passengers anywhere who appear obviously sick with SARS symptoms: if travelers are suspect, they must be checked. Otherwise, they don't get on a plane. The airline conducts additional cleaning of ticket and passenger counters in affected regions -- and of aircraft restrooms -- with a CDC-approved disinfectant.

If anyone exhibits SARS-like symptoms during flight, they are isolated from other passengers as much as possible. They are given a surgical mask to wear, and any flight attendants who help that traveler also wear masks and plastic gloves. Any aircraft that may have carried a possible SARS victim is subject to additional cleaning and disinfecting.

It is important to note that *not a single case* of SARS has been transmitted on airline flights since the World Health Organization recommended in late March that passengers from affected nations be screened. The World Health Organization's leadership, together with swift Federal action and cooperation from the aviation community, has effectively minimized the potential transmission of SARS on aircraft.

Working with international health officials, the Federal Government has provided valuable resources to help airlines like Northwest and airports like MSP prepare for and respond to suspected SARS incidents.

First, we benefit from information from the Centers for Disease Control and Prevention. Like most Americans, we first heard about SARS through stories in the news media. Within days, though, we had access to reliable, science-based information through the CDC. The CDC Web site, in particular, serves as a clearinghouse for reliable SARS-related information. The site specifically addresses issues regarding SARS and air travel. It advises travelers and provides information that enables airports to develop a higher awareness of the disease and its potential threat.

Many of you may have visited the site yourselves. Commission staff does so frequently to ensure we always have complete, accurate, up-to-date information on the disease. That information was particularly useful in verifying that the protocol we had in place for dealing with infectious disease was appropriate in the case of SARS.

We also found very useful information from the World Health Organization, which was communicated to us through the Transportation Security Administration and through our trade association, Airports Council International-North America (ACI-NA).

The second and perhaps most important resource is the Federal staff assigned to the airport specifically to respond to the SARS threat. Initially, when the disease was identified, Immigration officials provided information to travelers arriving from affected nations and screened arriving passengers for symptoms of the disease.

On April 16, the CDC assigned a staff member to MSP as a central resource for SARS information and planning. The CDC has maintained staff at MSP on a rotating basis since that time, and our understanding is that they will remain here for the duration of this crisis. Their presence has been pivotal to our SARS response efforts.

CDC representatives have worked with the Airports Commission, the airlines, Customs and Border Protection staff, and others from the Department of Homeland Security to standardize response procedures. In addition, the CDC has provided around-the-clock phone support from a quarantine supervisor based in Chicago.

Finally, the CDC has worked with our trade organization, Airports Council International - North America, to provide information. By working with ACI-NA through on-going teleconferences and information alerts, CDC helps ensure that airports across the United States receive uniform, consistent, aviation-specific information regarding SARS.

How has the process worked? Let me give you an example. Several weeks ago, an infant on a Northwest flight exhibited symptoms of SARS, including a fever, coughing and diarrhea. The infant was on its way from Beijing to Minneapolis. The CDC was contacted and requested that the infant be taken directly to a hospital upon landing. An ambulance was waiting at the airport to transport the child. Other travelers on the plane were ask to fill out contact cards so health officials could follow-up if physicians concluded the infant had SARS.

It turned out the infant had a common respiratory virus, not SARS. But officials were prepared. They acted in a coordinated fashion. And they took steps necessary to safeguard the traveling public.

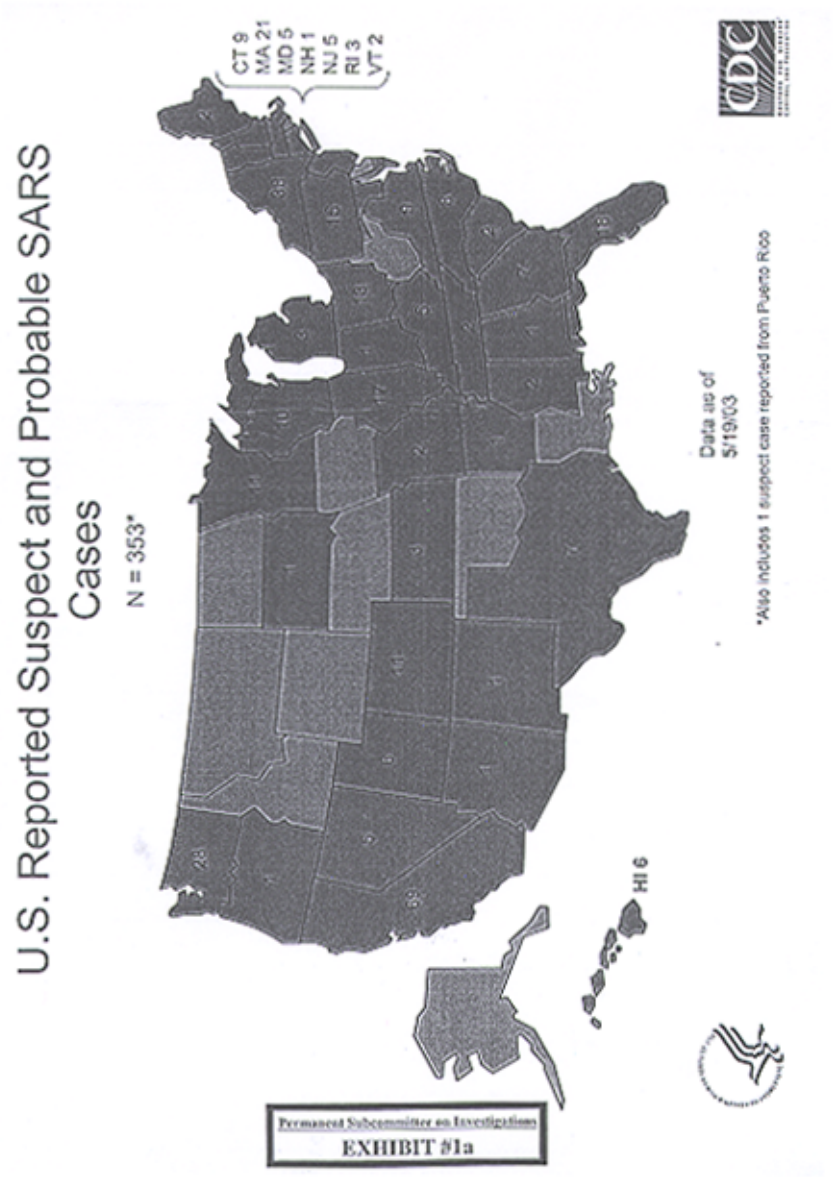
Our efforts are ongoing. Today, MSP's Airline Managers Council is meeting with Dr. Jetzer and a CDC representative to review the SARS protocol at our airport. We want to identify any remaining questions and concerns . . . and to ensure that the entire airport community *continues* to be vigilant, share information and act cooperatively.

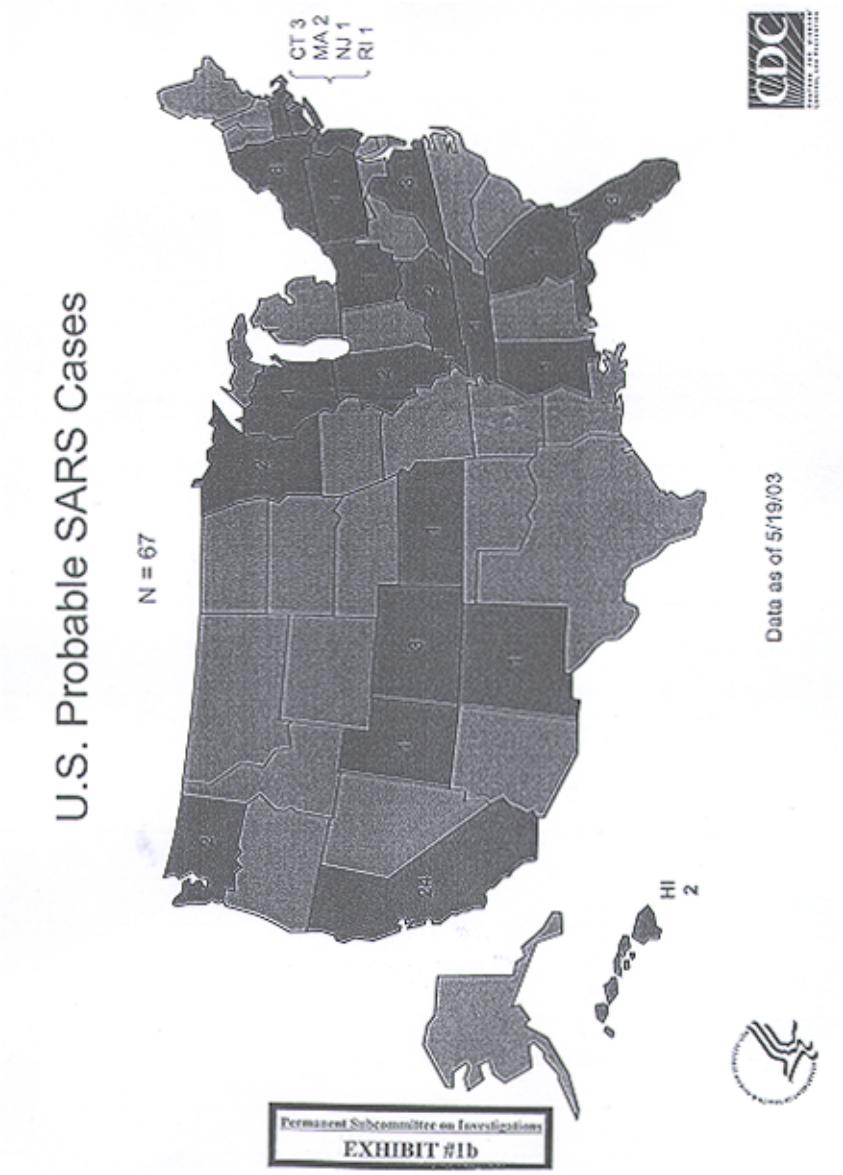
The Metropolitan Airports Commission is very grateful for the assistance provided by the CDC. Health officials are still learning about SARS, and the aviation community must be prepared to modify our procedures swiftly and collectively as new information becomes available. Federal interaction and coordination is key to our ability to respond effectively.

Can the process be improved? Internally, the threat of SARS has served as a reminder for airport police and firefighters to be prepared and to follow the protocol: have gloves, masks and goggles on hand at all times both for emergency workers themselves and for their patients. We don't know what's going to flow into the airport artery but, whenever possible, we want to stop harmful things from flowing out of it.

It's possible the CDC or other Federal health officials could have communicated directly with airports sooner, instead of several days after news of SARS appeared the media. It certainly would have be helpful if information had been immediately available. Generally, though, we are very pleased with the level of assistance received to date. We hope we can count on a similar level of service in the future.

Again, thank you for the opportunity to address you today. I'd be pleased to answer any questions you may have.


U.S. Reported Suspect and Probable SARS Cases
N = 353*
CT 9
MA 21
MD 5
NH 1
NJ 5
RI 3
VT 2
HI 6
Data as of 5/19/03
*Also includes 1 suspect case reported from Puerto Rico
CDC
Permanent Subcommittee on Investigations
EXHIBIT #1a


U.S. Probable SARS Cases
N = 67
CT 3
MA 2
NJ 1
RI 1
HI
2
Data as of 5/19/03
CDC
Permanent Subcommittee on Investigations
EXHIBIT #1b

Health Alert Notice

건강 경보 공지사항

KHUYẾN CÁO Y TẾ

健康に関する注意喚起

紧急保健通告

紧急保健通告

DEPARTMENT OF HEALTH AND HUMAN SERVICES

CDC
CENTERS FOR DISEASE CONTROL AND PREVENTION

Permanent Subcommittee on Investigations
EXHIBIT #2

HEALTH ALERT NOTICE

건강 경보 공지사항

KHUYẾN CÁO Y TẾ

健康に関する注意喚起

AVIS D'ALERTE MÉDICALE

AVISO DE ALERTA DE SALUD

紧急保健通告

紧急保健通告

DEPARTMENT OF HEALTH AND HUMAN SERVICES

CDC
CENTERS FOR DISEASE CONTROL AND PREVENTION

HEALTH ALERT NOTICE
Health Alert Notice for International Travelers Arriving in the United States from China, Vietnam, and Singapore

TO THE TRAVELER: During your recent travel, you may have been exposed to cases of severe acute respiratory disease syndrome. You should monitor your health for at least 10 days. If you become ill with fever accompanied by cough, or difficulty in breathing, you should consult a physician. To help your physician make a diagnosis, tell him or her about your recent travel to these regions and whether you were in contact with someone who had these symptoms. Please save this card and give it to your physician if you become ill.

TO THE PHYSICIAN: The patient presenting this card may have recently traveled to China, Vietnam, or Singapore where cases of severe acute respiratory syndrome (SARS) have been identified. If you suspect that this patient may have SARS, please contact your city, county, or state health officer (see http://www.cdc.gov or call the CDC Emergency Operations Center 770-488-7100).

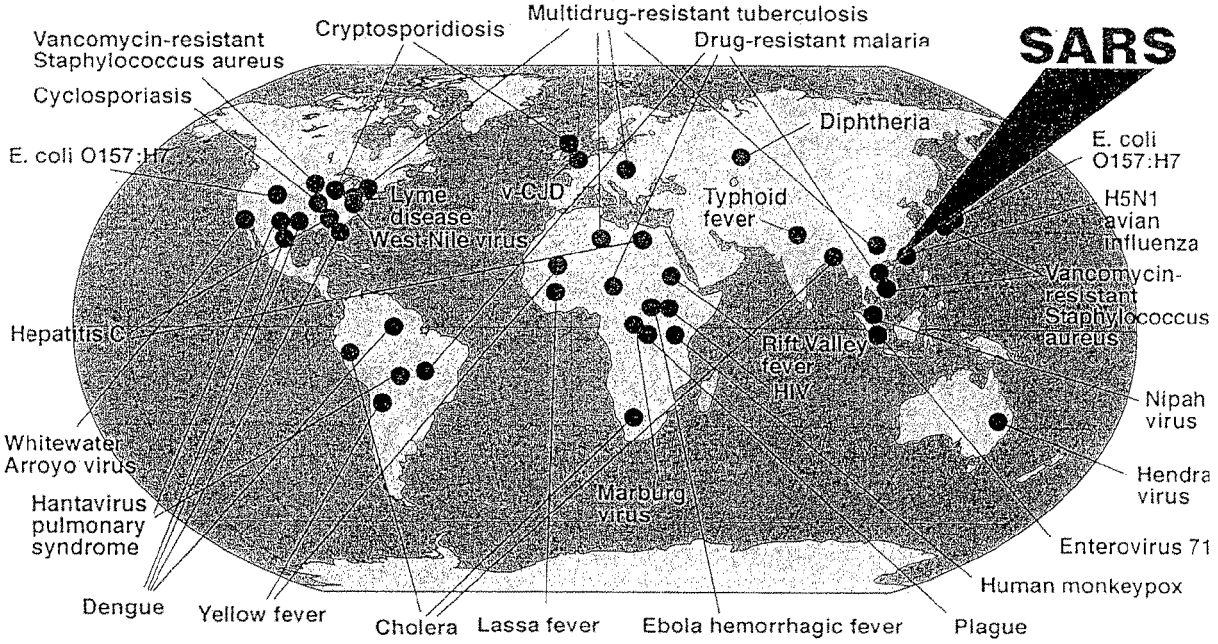
HEALTH ALERT NOTICE
For International Travelers Arriving in the United States from Toronto, Ontario, Canada

TO THE TRAVELER: During your recent travel to areas affected by severe acute respiratory disease syndrome (SARS), including Toronto, you may have been exposed to cases of SARS. You should monitor your health for at least 10 days. If you become ill with fever, cough, or difficulty in breathing, you should consult a physician. In advance of your visit to the physician, tell him or her about your recent travel to these regions and whether you were in contact with someone who had these symptoms. Please save this card and give it to your physician if you become ill.

TO THE PHYSICIAN: The patient presenting this card may have recently traveled to SARS-affected areas, including Toronto, where cases of SARS have been identified. If you suspect that this patient may have SARS, please contact your city, county, or state health officer (see http://www.cdc.gov or call the CDC Emergency Operations Center at 770-488-7100).

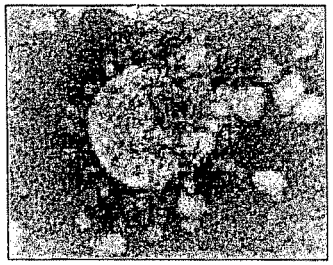
English

Examples of Emerging and Re-Emerging Diseases



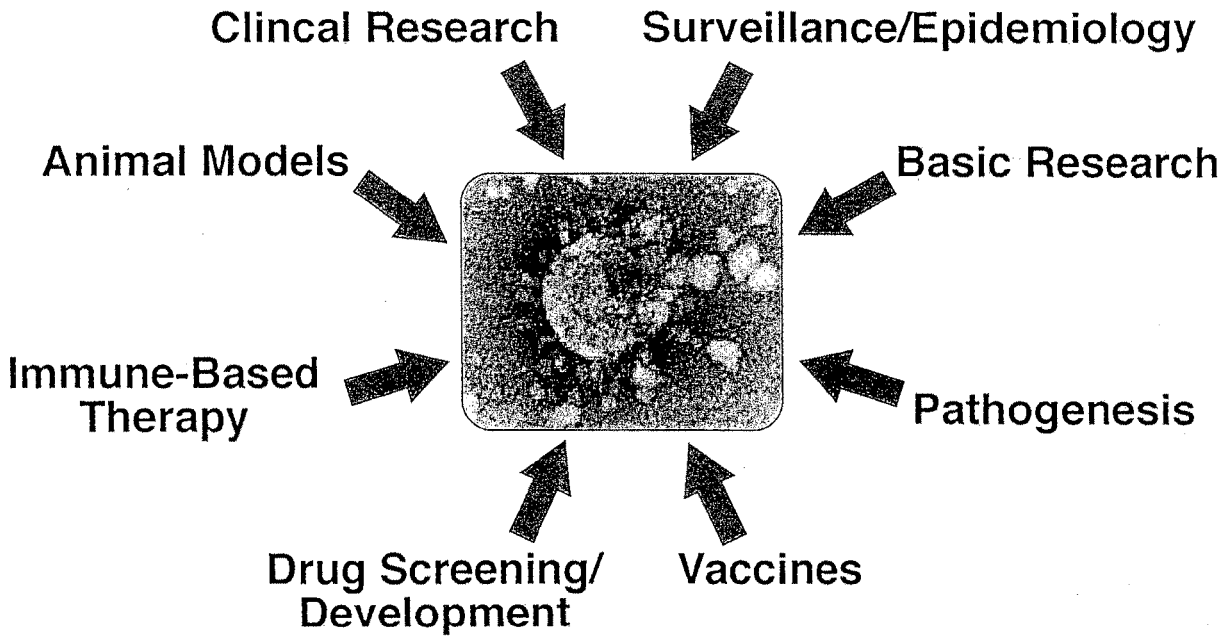
Permanent Subcommittee on Investigations
EXHIBIT #3a

Coronaviruses



- 3 known groups
- Infect humans and domesticated animals, e.g. pigs, cows, dogs, cats, fowl, rodents
- Cause colds, pneumonia, enteric disease
- No specific therapies or human vaccines; vaccines for veterinary use
- >20 NIH grants on coronaviruses

NIH Research on Coronaviruses/SARS



Department of Health and Human Services

Fiscal Year 2003
Public Health Emergency Preparedness and

Hospital Preparedness Funding
by State, Selected Municipalities, Territory

State	Ranking	CDC Award	CDC Funding per capita	HRSA Award	HRSA Funding per capita	Total to Jurisdiction	Total per capita	Population
Alabama	30	$14,056,645	$3.15	$7,762,315	$1.74	$21,818,960	$4.88	4,468,912
Alaska	4	$6,284,107	$9.92	$1,958,803	$3.09	$8,242,910	$13.01	633,630
Arizona	33	$15,755,935	$2.97	$9,030,450	$1.70	$24,786,485	$4.67	5,306,966
Arkansas	20	$10,461,043	$3.88	$5,077,591	$1.88	$15,538,634	$5.77	2,694,698
California (minus LA County)	54	$55,589,662	$2.23	$38,773,726	$1.56	$94,363,388	$3.79	24,923,243
LA County	48	$24,531,232	$2.53	$15,583,354	$1.61	$40,114,596	$4.15	9,677,220
Colorado	29	$13,979,790	$3.16	$7,704,930	$1.74	$21,684,720	$4.89	4,430,989
Connecticut	24	$11,960,524	$3.48	$6,197,237	$1.80	$18,157,731	$5.29	3,434,602
Delaware	7	$6,614,378	$8.30	$2,205,436	$2.77	$8,819,784	$11.07	796,599
District of Columbia	1	$11,162,901	$19.45	$2,868,332	$5.00	$14,031,203	$24.45	573,822
Florida	52	$38,181,999	$2.33	$25,775,957	$1.57	$63,957,966	$3.91	16,373,330
Georgia	43	$22,034,847	$2.62	$13,719,390	$1.63	$35,754,237	$4.25	8,405,677
Hawaii	10	$7,486,672	$6.10	$2,856,721	$2.33	$10,343,393	$8.43	1,227,024
Idaho	13	$7,676,282	$5.81	$2,998,297	$2.27	$10,674,579	$8.08	1,320,585
Illinois (minus Chicago)	47	$24,923,148	$2.54	$15,875,935	$1.61	$40,799,143	$4.15	9,830,881
Chicago	19	$10,450,197	$3.89	$5,069,493	$1.89	$15,519,690	$5.77	2,689,346
Indiana	39	$17,416,386	$2.84	$10,270,929	$1.68	$27,687,315	$4.52	6,126,743
Iowa	23	$10,941,890	$3.73	$5,436,624	$1.85	$16,378,514	$5.59	2,931,967
Kansas	21	$10,476,095	$3.88	$5,088,830	$1.88	$15,564,926	$5.76	2,702,125
Kentucky	28	$13,245,815	$3.26	$7,156,894	$1.76	$20,402,709	$5.01	4,068,816
Louisiana	31	$14,059,595	$3.15	$7,764,518	$1.74	$21,824,113	$4.88	4,470,368
Maine	12	$7,603,092	$5.92	$2,943,648	$2.29	$10,546,740	$8.21	1,284,470
Maryland	34	$15,915,365	$2.95	$9,150,163	$1.70	$25,065,528	$4.65	5,386,079
Massachusetts	40	$17,972,524	$2.81	$10,686,180	$1.67	$28,658,704	$4.48	6,401,164
Michigan	49	$25,278,581	$2.53	$16,141,386	$1.61	$41,419,967	$4.14	10,006,266
Minnesota	32	$15,101,600	$3.03	$8,542,551	$1.71	$23,644,151	$4.74	4,984,535
Mississippi	22	$10,795,501	$3.78	$5,327,321	$1.86	$16,122,822	$5.64	2,859,733
Missouri	36	$16,424,504	$2.91	$9,530,322	$1.69	$25,954,826	$4.60	5,637,309
Montana	8	$6,834,837	$7.55	$2,370,015	$2.62	$9,204,852	$10.17	905,382
Nebraska	14	$8,485,811	$4.93	$3,602,747	$2.09	$12,088,558	$7.03	1,720,039
Nevada	17	$9,251,219	$4.41	$4,174,253	$1.99	$13,425,472	$6.40	2,099,722
New Hampshire	11	$7,552,202	$6.00	$2,905,650	$2.31	$10,457,852	$8.30	1,259,359
New Jersey	44	$22,248,528	$2.61	$13,878,940	$1.63	$36,127,468	$4.26	8,511,116
New Mexico	16	$8,710,551	$4.76	$3,770,553	$2.06	$12,481,104	$6.82	1,830,935
New York (minus NYC)	46	$22,794,404	$2.52	$18,019,873	$1.63	$45,814,277	$4.16	11,022,323
New York City	***45***	**$20,881,716**	**$2.59**	**$12,858,383**	**$1.59**	**$33,740,099**	**$4.19**	**8,062,027**
North Carolina	42	$21,630,396	$2.64	$13,417,400	$1.64	$35,047,796	$4.27	8,206,105
North Dakota	5	$6,290,025	$9.88	$1,963,221	$3.08	$8,253,246	$12.97	636,550
Ohio	50	$28,082,405	$2.47	$18,234,514	$1.60	$46,317,319	$4.07	11,389,785
Oklahoma	25	$12,031,404	$3.47	$6,250,131	$1.80	$18,281,535	$5.27	3,469,577
Oregon	26	$10,039,235	$3.47	$6,255,978	$1.80	$16,295,213	$5.27	3,473,441
Pennsylvania	51	$29,933,326	$2.43	$19,616,940	$1.59	$49,550,266	$4.03	12,303,104
Rhode Island	9	$7,147,493	$6.75	$2,603,466	$2.46	$9,750,959	$9.20	1,059,659
South Carolina	27	$13,232,255	$3.26	$7,146,769	$1.76	$20,379,024	$5.02	4,062,125
South Dakota	6	$6,536,811	$8.62	$2,147,489	$2.83	$8,684,300	$11.45	758,324
Tennessee	37	$16,651,663	$2.90	$9,699,534	$1.69	$26,351,597	$4.58	5,749,398
Texas	53	$48,310,184	$2.26	$33,338,368	$1.56	$81,648,552	$3.82	21,370,983
Utah	18	$9,618,011	$4.22	$4,448,125	$1.95	$14,066,136	$6.17	2,278,712
Vermont	3	$6,242,254	$10.18	$1,927,552	$3.14	$8,169,806	$13.33	612,978
Virginia	41	$19,584,849	$2.72	$11,890,053	$1.65	$31,474,902	$4.37	7,196,750
Washington	38	$17,146,134	$2.86	$10,069,141	$1.68	$27,215,275	$4.54	5,993,390
West Virginia	15	$8,649,835	$4.80	$3,725,218	$2.07	$12,375,053	$6.87	1,800,975
Wisconsin	35	$15,955,629	$2.95	$9,180,227	$1.70	$25,135,856	$4.65	5,405,947
Wyoming	2	$6,000,636	$12.15	$1,747,144	$3.54	$7,747,780	$15.69	493,754
TOTAL U.S.		$853,221,223	$2.99	$486,739,807	$1.71	$1,339,961,030	$4.70	285,317,559

Permanent Subcommittee on Investigations
EXHIBIT #4

Department of Health and Human Services

Fiscal Year 2003
Public Health Emergency Preparedness and

Hospital Preparedness Funding
by State, Selected Municipalities, Territory

State	Ranking	CDC Award	CDC Funding per capita	HRSA Award	HRSA Funding per capita	Total to Jurisdiction	Total per capita	Population
District of Columbia	1	$11,162,901	$19.45	$2,868,302	$5.00	$14,031,203	$24.45	573,822
Wyoming	2	$6,000,636	$12.15	$1,747,144	$3.54	$7,747,780	$15.69	493,754
Vermont	3	$6,242,254	$10.19	$1,927,552	$3.14	$8,169,806	$13.33	612,978
Alaska	4	$6,284,107	$9.97	$1,958,803	$3.09	$8,242,910	$13.01	633,630
North Dakota	5	$6,290,025	$9.88	$1,963,221	$3.08	$8,253,246	$12.97	636,550
South Dakota	6	$6,516,811	$8.62	$2,147,489	$2.83	$8,684,300	$11.45	758,324
Delaware	7	$5,614,378	$8.30	$2,205,406	$2.77	$8,819,784	$13.07	296,599
Montana	8	$6,834,837	$7.55	$2,370,015	$2.62	$9,204,852	$10.17	905,382
Rhode Island	9	$7,147,493	$6.75	$2,603,466	$2.46	$9,750,959	$9.20	1,059,659
Hawaii	10	$7,486,672	$6.10	$2,856,721	$2.33	$10,343,393	$8.43	1,227,024
New Hampshire	11	$7,552,202	$6.00	$2,905,650	$2.31	$10,457,852	$8.30	1,259,359
Maine	12	$7,603,092	$5.92	$2,943,648	$2.29	$10,546,740	$8.21	1,284,470
Idaho	13	$7,676,282	$5.81	$2,998,297	$2.27	$10,674,579	$8.08	1,320,585
Nebraska	14	$8,485,811	$4.93	$3,602,747	$2.09	$12,088,558	$7.03	1,720,039
West Virginia	15	$8,649,835	$4.80	$3,725,218	$2.07	$12,375,053	$6.87	1,800,975
New Mexico	16	$8,710,551	$4.76	$3,770,553	$2.06	$12,481,104	$6.82	1,830,933
Nevada	17	$9,251,219	$4.41	$4,174,253	$1.99	$13,425,472	$6.40	2,097,727
Utah	18	$9,618,011	$4.22	$4,448,125	$1.95	$14,066,136	$6.17	2,278,712
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Kansas	21	$10,476,095	$3.88	$5,088,830	$1.88	$15,564,925	$5.76	2,702,125
Mississippi	22	$10,795,501	$3.78	$5,327,321	$1.86	$16,122,822	$5.64	2,859,733
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Connecticut	24	$11,960,524	$3.48	$6,197,207	$1.80	$18,157,731	$5.29	3,434,602
Oklahoma	25	$12,031,404	$3.47	$6,250,131	$1.80	$18,281,535	$5.27	3,469,577
Oregon	26	$12,039,235	$3.47	$6,255,978	$1.80	$18,295,213	$5.27	3,473,441
South Carolina	27	$13,232,255	$3.26	$7,146,769	$1.76	$20,379,024	$5.02	4,062,125
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Minnesota	32	$15,101,600	$3.03	$8,542,551	$1.71	$23,644,151	$4.74	4,984,535
Arizona	33	$15,755,035	$2.97	$9,030,450	$1.70	$24,785,485	$4.67	5,306,966
Maryland	34	$15,915,365	$2.95	$9,150,163	$1.70	$25,065,528	$4.65	5,386,075
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Missouri	36	$16,424,504	$2.91	$9,530,322	$1.69	$25,954,826	$4.60	5,637,309
Tennessee	37	$16,651,663	$2.80	$9,699,934	$1.69	$26,351,597	$4.58	5,749,398
Washington	38	$17,146,134	$2.86	$10,069,141	$1.68	$27,215,275	$4.54	5,993,390
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Virginia	41	$19,584,849	$2.72	$11,890,053	$1.65	$31,474,902	$4.37	7,196,750
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New York City	***45***	**$20,881,716**	**$2.59**	**$12,858,383**	**$1.59**	**$33,740,099**	**$4.19**	**8,062,027**
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Illinois (minus Chicago)	47	$24,923,148	$2.54	$15,875,995	$1.61	$40,799,143	$4.15	9,830,881
LA County	48	$24,531,232	$2.53	$15,583,364	$1.61	$40,114,596	$4.15	9,677,220
Michigan	49	$25,278,581	$2.53	$16,141,386	$1.61	$41,419,967	$4.14	10,006,266
Ohio	50	$28,082,405	$2.47	$18,234,914	$1.60	$46,317,319	$4.07	11,389,785
Pennsylvania	51	$29,933,326	$2.43	$19,616,940	$1.59	$49,550,266	$4.03	12,303,104
Florida	52	$38,181,999	$2.33	$25,775,967	$1.57	$63,957,966	$3.91	16,373,330
Texas	53	$48,310,184	$2.26	$33,338,368	$1.56	$81,648,552	$3.82	21,370,983
California (minus LA County)	54	$55,589,662	$2.23	$38,773,726	$1.56	$94,363,388	$3.79	24,923,243
TOTAL U.S.		$853,221,223	$2.99	$486,739,807	$1.71	$1,339,961,030	$4.70	285,317,559

Institute for HOMELAND Security

Institute Commentary 020, April 2003

Now to Confront A Greater Enemy

Dr. Elin Gursky is Senior Fellow for Biodefense and Public Health at the ANSER Institute for Homeland Security

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Operation Iraqi Freedom demonstrated once again the unparalleled organizational and technological strengths of the American military and that of its coalition partners to eliminate a threat to international stability. Ironically, in the reopening of a second front--humanity's most enduring struggle against disease--similar strengths are clearly lacking, though the threat is as equally menacing. As allied efforts in Iraq shift from fighting to rebuilding, indicating a successful campaign moving towards a conclusion, the efforts to prevent Severe Acute Respiratory Syndrome (SARS) may be far from over. Operation Iraqi Freedom resulted in 162 deaths, both combat-and accident-related. According to the World Health Organization (WHO), the SARS virus has resulted in 251 deaths - all noncombatants. SARS (Severe Acute Respiratory Syndrome) has now resulted in 4288 probable cases across 27 countries and six continents.[1] Ironically, the advantages seen in the Iraqi conflict are not necessarily replicated in the fight against the virus, which Nobel Laureate and microbiologist Dr. Joshua Lederburg refers to as, "The single biggest threat to man's dominance on the planet."

These two battles reveal rather glaring inequities in preparedness, training and resources between two sectors designated to defend America - the military and public health. A myriad of federal defense agencies perform continual surveillance of the trafficking of technology for Weapons of Mass Destruction, military build-ups and movements of known terrorists. Yet our national security efforts against microbial threats are dependent upon comparatively rudimentary, technologically unsophisticated and frequently disconnected platforms of disease intelligence gathering and sharing at the local and state levels. Globally, our international disease surveillance depends upon voluntary rather than compulsory reporting to the WHO. In the case of SARS, the Chinese government deliberately delayed reporting cases that occurred as far back as November - and continues to obfuscate the facts regarding disease incidence - increasing the level of difficulty in projecting and preparing for the global impact of this

disease.

The US military was praised for its flexibility and rapid accommodation to an evolving military situation on the battlefield of Iraq. The public health system writ large - the complex and nonsystematized aggregate of government public health agencies, hospitals, medical professionals, laboratories, emergency responders and others that daily fight the wars against illness and disease - lacks a similarly robust strategic planning and implementation process to support an immediate response to a unique and evolving health threat - one that ultimately can impact global populations in large numbers.

The three-week "Gulf War II" saw significant debate regarding the numbers of troops deployed to the Iraqi theater. Comparatively few work within the ranks of public health - the mean number of employees across approximately 3,000 local agencies nationwide is only thirteen. Hardly a force sufficient to sustain a prolonged response involving tracking and investigating suspected cases of disease associated with the growing threat of microbes that, through global climatic and ecological changes; increasing population density; overuse of antibiotics; mass international migration; and natural genetic microbial shifts have contributed to the emergence of at least thirty new diseases in the past two decades.

We witnessed the success of many joint missions across the multiple US branches of service and with coalition forces. However, our public health agencies have had woefully little interaction, planning and practice with other critical community-based emergency responders. As we learned through the anthrax attacks, the abundance of response plans (hospital plans, health department plans, fire department plans and so forth) and the proprietary culture of the various responder groups, contribute to the challenge of mounting an integrated and efficient response to a WMD attack or mass casualty event.

No military operation commences without clearly articulating the rules of engagement. The public health equivalent often has relied upon a nationally uneven mix of federal guidance and local practices. But, in the absence of medical countermeasures and vaccines, the efficacy of isolation, self-confinement and quarantine to contain the SARS epidemic- now multiple generations of disease later- must wrestle beyond theoretical models towards readily implementable strategies to reduce active viral transmission.

The conclusion of a military mission is followed by an after-action analysis. This review contributes to the success of subsequent missions, supports the justification for acquiring additional tools and resources, and provides insight into expanded training requirements. The public health community rarely has embraced post-outbreak assessment and review. The battles against current and future disease threats demand that we illuminate our shortcomings and so that we may build our capacities wisely.

Many have written about the Iraqi conflict as a pivotal point in US foreign relations. Our response to SARS will be no less a defining moment in history. We have a well-trained and well-equipped military to defeat nation states with the capability of producing and deploying biological agents as weapons against humanity. Our response to naturally occurring biological threats can be no less resourced, no less equipped with tools of detection, surveillance and early intelligence, and no less practiced in decision-support and the implementation of actions. This nation's ability to meet the threat of terrorists as well as newly emerging diseases is now clearly a matter of 21st century national security.

1. WHO 23 Apr 2003

(*Dr. Elin Gursky is Senior Fellow for Biodefense and Public Health at the ANSER Institute for Homeland Security.*)

Description of Institute

The ANSER Institute for Homeland Security is a nonprofit public-service research organization dedicated to examining a new set of national security challenges. Initiated and funded by ANSER's Board of Trustees in October 1999, and formally established in April 2001, the Institute believes preparing for these new challenges will require a determined, integrated effort at every stage of the process: deterrence, prevention, preemption, crisis management, consequence management, attribution and response.

ISSUE REPORT

Trust for America's Health

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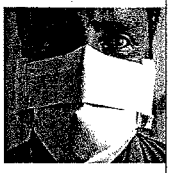

TRUST FOR AMERICA'S HEALTH IS A NON-PROFIT, NON-PARTISAN ORGANIZATION DEDICATED TO SAVING LIVES BY PROTECTING THE HEALTH OF EVERY COMMUNITY AND WORKING TO MAKE DISEASE PREVENTION A NATIONAL PRIORITY.

ACKNOWLEDGEMENTS:
This report is supported by a grant from The Pew Charitable Trusts.

The opinions expressed in this report are those of the authors and do not necessarily reflect the views of the Trusts.

MAY 2003

SARS AND ITS IMPLICATIONS FOR U.S. PUBLIC HEALTH POLICY – "We've Been Lucky."

Severe acute respiratory syndrome (SARS) is a new and serious public health threat. Much like the anthrax attacks of 2001 or the current national asthma epidemic, the recent SARS outbreak provides a "real time" example of the complex challenges facing the U.S. public health system – the network of local, state and federal health agencies that collectively are responsible for disease prevention, response and control in America.

What is SARS?

SARS is a life-threatening respiratory illness that has been reported in Asia, North America, Europe, South America and Africa and has already infected thousands of people worldwide and has caused hundreds of deaths. In fact, on May 7, 2003, the World Health Organization (WHO) concluded that approximately 15% of those infected with SARS will die.[1]

SARS is puzzling government officials and scientists around the globe, constraining travel, producing economic chaos, and creating widespread fear. The health community still has many unanswered questions about the progression and recovery of the virus.[2] Presently, there is no known effective treatment.

SARS symptoms generally begin with a fever greater than 100.4F (>38.0° C) and may include headache, body aches and a generalized feeling of discomfort. Some people also experience mild respiratory symptoms. After two to seven days, SARS patients may develop a dry, nonproductive cough and worsened respiratory symptoms that may progress to the point where insufficient oxygen is getting to the blood. In 10% to 20% of cases, patients will require mechanical ventilation. The most severe cases end in death.[3]

Transmission of the disease appears to involve close human-to-human contact, predominately through aerosol droplets (e.g. coughing or sneezing). Although not yet confirmed by scientists, it is possible that SARS may be spread more broadly through the air or by contact with infected surfaces. At this point, no one can predict how far the disease will spread and how much higher the human toll will be. Health professionals are unsure if this outbreak will be contained or is likely to become the next global pandemic.

The Public Health Response

THE LOW NUMBER OF SARS CASES IN THE U.S. SEEMS TO BE "THE GOOD LUCK THAT WE HAVE NOT HAD THE RIGHT COMBINATION OF SOMEONE WHO IS HIGHLY INFECTIOUS AND INADEQUATELY PROTECTED PUBLIC HEALTH PERSONNEL."[1]

– CDC Director Julie Gerberding as reported in *The New York Times*

U.S. and international public health officials are working urgently and collaboratively to address the SARS outbreak. Consulting with the World Health Organization (WHO), the Centers for Disease Control and Prevention (CDC) has been the lead government agency responsible for coordinating the U.S. response.

To date, the response of the CDC to the global SARS epidemic is testament to why a coordinated public health game plan can and will save lives. At the same time, however, it is important to note that SARS has barely touched U.S. shores, so the preparedness of the entire public health system – local and state health departments, hospitals, and laboratories – remains largely untested.

Yet, the SARS outbreak also has demonstrated just how easily health care systems can be overwhelmed by the demands for patient screening and care, particularly with the specialized infection control requirements that come with an infectious respiratory illness. Similarly, the disease has resulted in troubling questions about how and when travel and commerce should be constrained in the context of communicable disease. On both the domestic and international level, a great deal more work must be undertaken to develop appropriate policies, define authorities and design strategies for containing a global epidemic.

While scientists are rapidly working to develop vaccines, pharmaceutical treatments, and other medical interventions, our best hope today is a vigilant public health system that rapidly detects, responds and isolates SARS cases, thereby stopping the epidemic dead in its tracks.

In the past, the U.S. public health system served as the world leader in stamping out diseases like yellow fever, typhoid, influenza, and cholera. It is again time for the U.S. to be at the forefront of fighting the newest global epidemic. But, are our national public health defenses up to the task?

Sadly, the answer is "no."

The Public Health System is Sick Itself

The 2001 CDC report on public health infrastructure found that the current U.S. public health infrastructure "is still structurally weak in nearly every area." The report calls for a system of "public health armaments," including a "skilled professional workforce, robust information and data systems and strong health departments and laboratories."[6]

"OVER THE PAST TWO DECADES, THE [NATION'S PUBLIC HEALTH] INFRASTRUCTURE HAS GREATLY DETERIORATED. A LACK OF FOCUS, FUNDING, AND NATIONAL ATTENTION HAVE COMBINED TO REDUCE THE PHYSICAL STRUCTURES (SUCH AS LABORATORIES) AND WORKFORCE CAPABILITIES NECESSARY TO COLLECT AND ANALYZE DATA, CONDUCT EPIDEMIOLOGY AND DISEASE SURVEILLANCE, COMMUNICATE EFFECTIVELY, AND IMPLEMENT INTERVENTIONS TO RESPOND TO THREATS TO THE HEALTH OF THE ENTIRE COMMUNITY."[5]

— U.S. Senate Majority Leader, Bill Frist, MD

In a separate report, the General Accounting Office (GAO) found that "the 1999 West Nile Virus outbreak, which was relatively small, taxed the federal, state and local laboratory resources to the point that officials told us that the CDC would not have been able to respond to another outbreak had one occurred at the same time." According to the GAO report, coordination between state, local and federal authorities, communication systems, disease tracking, staffing and laboratory capacity are areas that require immediate improvement.

SARS highlights the gaping holes in systems designed to prevent disease, and to respond and control outbreaks when they do occur. Despite the recent targeted federal support for bioterrorism preparedness, America's public health infrastructure remains fragile, due to years of "perceived irrelevance, underfunding and Congressional mistrust," which in turn has led to limited federal funding, says CDC Director Gerberding.[7] In testimony before the House of Representatives on the SARS outbreak, GAO's Director of Health Care — Public Health Policy, Janet Heinrich, summarized that, "...there are significant gaps in public health surveillance systems and laboratory capacity, and the number of personnel trained for disease detection is insufficient."[8]

SARS reminds us too that public health officials must always be ready today for the unexpected health threat of tomorrow. While it will never be possible to fully anticipate and prepare for every potential threat — occurring in nature or perpetrated by terrorists — there is a great deal that can and should be done.

Revitalizing Public Health Can Not Be Achieved on a Piecemeal Basis

The prevention, containment and treatment of SARS cannot be considered in isolation. Today, the U.S. public faces a broad spectrum of potential, emerging and existing health threats, including:

- **Infectious diseases:** SARS is but one of a series of new and deadly infectious diseases, including West Nile Virus — not to mention longstanding diseases like tuberculosis that have resurged, often in new and more virulent forms due to drug-resistance;
- **Chronic diseases:** The rates of these diseases that include cancer and diabetes and are responsible for 70% of American deaths, continue to rise; and
- **Biological, chemical, and radiological terrorism:** In the post-September 11, 2001 era, we must be prepared for the potential use of biological, chemical, and radiological agents as weapons used by terrorists intent on causing mass casualties.

The public health response to SARS cannot be viewed as a one shot deal. Preventing epidemics and protecting people means making strategic investments in revitalizing and modernizing America's entire public health system.

The good news is that the public health community knows what works — improving early warning systems, enhancing communications plans, creating nationwide disease tracking networks, assuring quality laboratories, and recruiting a new generation of public health professionals. Now, we have to generate the national resolve to do it right.

HOW THE PIECES OF AN EFFECTIVE PUBLIC HEALTH RESPONSE FIT TOGETHER

In order to be adequately prepared for a major infectious disease outbreak like SARS, the GAO finds that:

- *Public health departments need to have disease tracking 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.*
- *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 exercises at the state, local, and regional levels.**

Components of a "Well-Prepared" Public Health System

The Institute of Medicine (IOM) released a major report in November 2002 on the future of the public's health in the 21st century. As part of its recommendations for repairing "a neglected [public health] system," the IOM called for an "overhaul of its components" which include legal authorities, workforce, communications and information technology, disease surveillance, and public health laboratories, among other elements. [10]

The following is a brief analysis of the key public health infrastructure components in the context of the SARS epidemic and TFAH's recommendations for strengthening them.

HEALTH TRACKING

A strong public health defense begins with disease surveillance, also known as health tracking. It not only helps us monitor and mitigate potential chemical and bioterrorist attacks, but also is crucial to unlocking the mysteries behind chronic and infectious diseases. Tracking disease is one of the most vital weapons public health officials have in the fight to prevent and control threats to the nation's health.

A comprehensive disease tracking system monitors the occurrence of disease and can inform the rapid identification of outbreaks or "clusters" of cases, which leads to analysis of geographic variations and temporal trends. With this information in hand, public health investigators can search for the sources and routes of exposure to determine why the outbreak occurred, how to prevent similar outbreaks in the future, and, if the outbreak is ongoing, how to prevent others from being exposed. Concurrently, action must be taken to control the spread of the disease and minimize further illness and death, even when clear cause and effect have not been fully identified.

DISEASE TRACKING DOUBLE DUTY

The good news is that the system for tracking an infectious disease like SARS could also be used to track chronic diseases conditions if designed properly. For example, SARS and asthma are both respiratory conditions. Today, between 14-15 million Americans have asthma, including 5 million children.[11] Asthma rates in the U.S. climbed over 58% from 1979 to 1992, and the death rate from asthma for children under the age of 19 escalated 78% from 1980 to 1993. It is the leading cause of school absences from a chronic disease for children ages 5 to 17 and is estimated to cost the country over $11.3 billion annually.[12] Advances that help us track and contain SARS can be used to do "double duty" to help us understand and prevent asthma. This will require a strategic plan for health tracking, not the piecemeal, "disease de jour" approach that presently exists.

TFAH IS CALLING ON CONGRESS TO ALLOCATE $100 MILLION IN FY 2004 AS THE NEXT STEP FORWARD IN CREATING A ROBUST, INTEGRATED NATIONWIDE HEALTH TRACKING NETWORK.

ALSO, CONGRESS SHOULD SUBSTANTIALLY INCREASE FUNDING TO ENHANCE THE INFORMATION AND COMMUNICATIONS SYSTEMS RELATED TO PUBLIC HEALTH SURVEILLANCE.

For the first time, in FY 2002 and again in FY 2003, with bi-partisan support, Congress allocated initial funds to begin a program to establish a nationwide disease tracking network at CDC.[13] The Administration's FY 2004 budget request also recognizes the importance of health tracking, calling it a "major focus" of its environmental health program. It is now time to take this critical surveillance tool to scale. TFAH is calling on Congress to allocate $100 million in FY 2004 as the next step forward in creating a robust, integrated nationwide health tracking network.

Also, Congress should substantially increase funding to enhance the information and communications systems related to public health surveillance. Specifically, Congress should provide full funding for the National Electronic Disease Surveillance System (NEDSS), which serves as CDC's architectural backbone of surveillance. Former CDC Director, Dr. Jeffery P. Koplan wrote in 2002, "As the initiative [NEDSS] proceeds, it will reshape the way public health is practiced with unprecedented access to high-quality and timely surveillance data."[14]

Finally, SARS illustrates the need for global public health tracking. Failures to initially track this unusual respiratory syndrome last fall in China's Guangdong Province likely represents a missed opportunity for rapid investigation of the outbreak and disease control. Time lags in getting samples to the best laboratories around the world for evaluation no doubt added further significant delays to an already difficult diagnostic challenge. To make matters worse, the U.S. is not alone in lacking a comprehensive, coordinated nationwide health tracking network; there is not an adequate system for global disease surveillance either. Nor is there a coordinated system worldwide to assure appropriate action and response when cases appear.

LEGAL AUTHORITY

CDC does not have a command and control mentality with respect to disease surveillance. The most recent example is the agency's unwillingness to require that SARS be considered a reportable disease in every state. In fact, most of the nation's disease tracking systems suffer from the lack of national standards and uniform structures, resulting in a patchwork approach to disease tracking. Often, the CDC is in the unenviable position of having to cajole state health departments to provide important data about cancer, birth defects, and many other chronic diseases and conditions.

In many other cases, CDC and the states lack the legal authority to respond to emerging health threats, although since September 11, 2001, 35 states and the District of Columbia have considered legislation to clarify the health powers of state and local public health authorities to ensure a strong, effective, and timely responses to public health emergencies, while also respecting individual rights.[15]

Isolation and quarantine are two common public health strategies which aim to protect the public by preventing exposure to infected or potentially infected individuals.

Generally, isolation refers to the separation of people who have a specific infectious illness from healthy people and the restriction of their movement to stop the spread of that illness. Isolation is a standard procedure used in hospitals today for patients with tuberculosis and certain other infectious diseases.

In contrast, quarantine usually refers to the separation and restriction of movement of people who are not yet ill, but who have been exposed to an infectious agent and are

therefore potentially infectious. Quarantine of exposed individuals is a public health strategy, like isolation, that is intended to stop the spread of infectious disease. Both isolation and quarantine may be conducted on a voluntary basis or compelled on a mandatory basis through legal authority.

On April 4, 2003 the President signed an executive order adding SARS to the list of quarantinable communicable diseases under the Public Health Service Act. By amending the list to include SARS, the U.S government took the pragmatic step of readying all options as the public community continues to tackle this disease. This authority would only be used if someone posed a threat to public health and refused to cooperate with a voluntary request.[16] Canada, Singapore and Hong Kong have taken similar measures.

SARS patients in the United States are being isolated until they are no longer infectious. Patients with the most severe cases are being cared for in hospitals. Those with milder cases are being cared for at home. Individuals being cared for at home have been asked to avoid contact with other people and to remain at home until 10 days after the resolution of fever, provided that respiratory symptoms are absent or improving. To date, the CDC has recommended isolation of individuals with SARS, but has not compelled quarantine or isolation of these individuals.[17]

REPAIRING STATE PUBLIC HEALTH LABORATORIES

The public relies on state public health laboratories to deliver reliable and rapid results to communities and individuals. The Association of Public Health Laboratories (APHL) identifies the core functions of labs as: monitoring food and water safety, emergency response, specialized testing, disease prevention and control, and training and education. Unfortunately, state budget cuts and stagnant federal funding have left these state public laboratories in disrepair.

Even before the SARS outbreak, the nation's public health laboratories were stretched to their limits working on biological and chemical terrorism preparedness, other emerging infectious diseases like West Nile Virus and environmental health issues, in addition to the everyday demands of routine public health testing and new federal regulatory requirements.

The APHL reports a myriad of problems confronting public health laboratories, including outdated facilities, equipment, and communications systems in addition to inadequate training and staffing.[18]

The APHL recently asked Congress for an immediate infusion of $10 million to help state public health laboratories deal with SARS, including funds for the following needs:

- ***Instrumentation;***
- ***Personnel;***
- ***Laboratory testing for respiratory illnesses; and***
- ***Packing and shipping of specimens.***

APHL also recommends that the CDC be provided with additional resources to assist with its SARS-related activities including the production of reagents for SARS testing. These funding requests should be considered immediately to ensure public health capacity if a broader SARS outbreak hits the U.S.

The Need for Qualified Public Health Professionals

Public health professionals have traditionally been guardians of the health of communities. They are charged with preventing health epidemics. These professionals perform the detective work necessary to provide proper treatment and prevent the spread of problems in emergency events, such as a chemical spill or food-borne illness outbreak, and are responsible for finding ways to manage ongoing health threats through measures like mammography screenings, childhood immunizations, and tobacco cessation programs.

According to the Health Resources and Services Administration (HRSA), fewer than 50% of the current 500,000 public health professionals have had formal, academic training in public health. Recent CDC data shows that 78% of all local health department executives do not have graduate degrees in public health. Further, their average tenure is less that two years, which dilutes their ability to handle a public health crisis with authority.

THE PRESIDENT'S FY 2004 BUDGET CUTS THIS CRITICAL EFFORT BY 2.3%, OR $1.8 MILLION, COMPARED TO CURRENT YEAR FUNDING LEVELS. THESE FUNDS MUST BE RESTORED.

The results are painfully clear: without trained and capable staff, our communities are vulnerable to unforeseen health threats and hamstrung in efforts to prevent illness. Public health officials, working together with private clinicians, can be the face of a healthier America. A January 2003 GAO report stated that "increasing staffing of public health departments and laboratories is a top priority for enhancing preparedness in many areas."[19]

The CDC has recommended that one trained epidemiologist be available for every 500,000 people; this investment in the public health workforce will provide communities with the scientific knowledge necessary to create a healthier U.S. population. Public health laboratories are also facing insufficient training opportunities and staffing, which is negatively affecting the capabilities, particularly to respond to surge in service demands that occur in times of crises.[20] State laboratories need adequate levels of PhD-level microbiologist and PhD-level chemists to ensure effective biological, chemical, and environmental testing capabilities.

CDC's Epidemic Services and Response Program trains public health professionals to respond to emergencies, develop accurate public health information, and provide resources for surveillance systems. The President's FY 2004 budget cuts this critical effort by 2.3%, or $1.8 million, compared to current year funding levels. These funds must be restored.

Upgrading Communications Capability

Chronic under-funding has led to a network of agencies that have trouble communicating with each other, let alone with the public. CDC data illustrates that public health departments lack basic infrastructure necessary to keep the public informed and as we have learned with SARS, communicating with a shaken public is key to alleviating natural fears that arise with an emerging illness.

The Health Alert Network (HAN), a federally coordinated system between the CDC and state/local health departments, has the potential to fill this current communications gap. By using advanced technological tools, this network will allow for real-time coordination in situations where even seconds matter. Currently, all 50 states in addition to the District of Columbia and Guam receive funding and technical assistance.

The HAN plays a vital role in the nation's state of readiness and timetables to completion and activation must be accelerated and linked directly to state and major metropolitan health departments.

THE HAN PLAYS A VITAL ROLE IN THE NATION'S STATE OF READINESS AND TIMETABLES TO COMPLETION AND ACTIVATION MUST BE ACCELERATED AND LINKED DIRECTLY TO STATE AND MAJOR METROPOLITAN HEALTH DEPARTMENTS.

WHY ARE NEW EPIDEMICS EMERGING OR REEMERGING?

Infectious illnesses unknown in the United States only a few years ago, like West Nile encephalitis and hantavirus pulmonary syndrome, have emerged to kill hundreds of Americans. Meanwhile, infectious diseases such as measles, tuberculosis, and malaria—which were thought to be a thing of the past in the United States—have reappeared.

Several decades ago, there was enormous optimism that the threat of infectious diseases was receding. Scientific and technologic advances, including the development of antibiotics and vaccines, along with improved sanitation and vector control enabled the control and prevention of many infectious diseases, particularly in the industrialized world. However, we know today that such optimism was premature. It did not take into account many critical factors like:

- *Extraordinary increases in international travel, immigration and trade;*
- *Movement of people into urban settings where opportunities for the spread of disease are amplified through crowding, and possibly poor sanitation and hygiene;*
- *Changing agricultural practices and environmental manipulations that alter disease vectors as well as opportunities for exposure;*
- *Continuing difficulties of translating existing medical knowledge and tools into action for all who need it, whether because of inadequate resources, ignorance or complacency; and*
- *The extraordinary resilience and adaptability of the microbes themselves.*

"Whether naturally occurring or intentionally inflicted, microbial agents [infectious diseases] can cause illness, disability, and death in individuals while disrupting entire populations, economies, and governments. In the highly interconnected and readily traversed 'global village' of our time, one nation's problem soon becomes every nation's problem as geographical and political boundaries offer trivial impediments to such threats."[1]

—2003 Institute of Medicine report: *Microbial Threats to Health: Emergence, Detection, Response*

CONCLUSION:
Urgent Care and Leadership Needed Now

Until now, the federal government has neither addressed the current comprehensive public health crisis at a sufficiently high level, nor provided adequate resources.

The experience with SARS reinforces the need for improved disease surveillance and reporting, linked to a rapid investigation and response capability, including adequate and appropriate diagnostic laboratory capacity. The response to SARS underscores the importance of strong public health systems, from the global to the local, as well as integrated and well-functioning systems for health care delivery. Future preparedness will also depend on a well-educated and trained clinical and public health workforce. In addition, the nation needs a sound research agenda addressing near and long-term requirements for new insights into the nature of infectious disease threats, human host responses, and the opportunities to develop new diagnostics, drugs and vaccines.

As stated in the IOM's Microbial Threats to Health: Emergence, Detection, and Response report, "the prevention and control of infectious diseases are fundamental to individual, national, and global security; failure to recognize – and act on – this essential truth will surely lead to disaster."[22] The magnitude and urgency of the problem demand renewed concern and commitment.

To this end, the Department of Health and Human Services should convene a national summit on the future of the American public health system and the resources needed to build a robust, integrated 21st century infrastructure that can play a "double duty" role by enhancing preparedness for the full spectrum of health threats from chemical terrorism to cancer and from biological attacks to birth defects.

As the SARS epidemic illustrates, the United States needs to devise strategic solutions for revitalizing and bolstering our public health defenses, while avoiding the "piecemeal fixes" of the past. The goal of the summit should be to produce a blue print for the future, wherein the public health system is re-designed in light of this century's current and emerging health threats. At the same time, there should be a national dialog on the resources needed to implement the requisite changes and the need for accountability at every level of the public health system.

As we take stock of our prospects with respect to microbial threats in the years ahead, public health leaders and national policy makers must recognize the need for a new level of attention, dedication, and sustained resources to ensure the health and safety of this nation – and of the world.

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Dr. Margaret A. Hamburg is a physician and a public health professional, currently serving as Vice President for Biological Programs at NTI, a private foundation, co-chaired by Ted Turner and Sam Nunn, whose mission is to reduce the global threat from weapons of mass destruction. Previously, Dr. Hamburg served as Assistant Secretary for Planning and Evaluation in the Department of Health and Human Services; as New York City Health Commissioner; and as Assistant Director of the National Institute of Allergy and Infectious Diseases, National Institutes of Health. She also recently co-chaired, along with Dr. Joshua Lederberg, a report from the Institute of Medicine (IOM), National Academy of Sciences, entitled Microbial Threats To Health: Emergence, Detection and Response which examined a set of critical issues concerning microbial threats to health in the 21st century. Dr. Hamburg is a member of Trust for America's Health's Board of Directors.

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TESTIMONY OF THE AMERICAN PUBLIC HEALTH ASSOCIATION
SARS: How Effective Is The State And Local Response?

Statement by Georges C. Benjamin, MD, FACP
Executive Director

Submitted to the Senate Government Affairs Committee
Permanent Subcommittee on Investigations

Wednesday, May 21, 2003

The American Public Health Association (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. We are pleased to submit a statement for the record on the state and local response to the Severe Acute Respiratory Syndrome (SARS) epidemic.

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 submit this statement 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.

PERMANENT SUBCOMMITTEE ON INVESTIGATIONS
Hearing On
SARS: HOW EFFECTIVE IS THE STATE AND LOCAL RESPONSE?
May 21, 2003

STATEMENT FOR THE RECORD

of

Robert J. Capetola, Ph.D.
President and Chief Executive Officer
Discovery Laboratories, Inc.

SUMMARY

SARS is an acute respiratory illness in which patients have difficulty breathing. SARS can progress to life-threatening **ARDS**. A prominent characteristic of ARDS is the destruction of a patient's lung surfactant. Surfactants are produced naturally in the lungs and are essential for breathing. Should these surfactants degrade or be destroyed, the air sacs in the lungs collapse, airflow becomes constricted and the lungs do not absorb sufficient oxygen.

World health authorities have employed intense efforts to contain the spread of Emerging Infectious Diseases (EID), like SARS, in which proper lung function is implicated -- exploring numerous medical treatments, focusing on antivirals, vaccines, and mechanical ventilation. The next logical step is for world health authorities to fully evaluate pulmonary therapies aimed at restoring or maintaining proper lung function in SARS and other patients suffering from similar EID.

Surfactant Replacement Therapy has the potential to play an important role in addressing EID including the SARS crisis. Surfactant Replacement Therapy is intended to maintain or restore proper lung function. Discovery's surfactant technology is the only surfactant technology that could play this role. There is significant scientific literature and clinical data establishing the safety and pharmacological activity of Discovery's surfactant technology.

Discovery's lead Surfactant Replacement Therapy, Surfaxin®, is in three Phase 3 and two Phase 2 clinical trials addressing critical respiratory indications, including ARDS. *Surfactant Replacement Therapy could be evaluated for the most severe SARS patients on mechanical ventilation as early as mid-to late-summer of 2003.*

Discovery's lung surfactant can also be prepared as an inhalable aerosol formulation that retains the critical therapeutic properties of fully-functioning surfactant. *Inhalable surfactant aerosol formulations now have the potential to treat respiratory diseases that have been unable to benefit from Surfactant Replacement Therapy and could be evaluated for maintaining lung function in SARS patients by early-fall of 2003.*

U.S. Senate
Permanent Subcommittee on Investigations Committee on Governmental Affairs
May 21, 2003 hearing entitled "SARS: How Effective is the State and Local Response?"

Written statement of Robert J. Capetola, Ph.D., President and Chief Executive Officer of Discovery Laboratories, Inc., a specialty pharmaceutical company developing its proprietary surfactant technology as Surfactant Replacement Therapies for respiratory diseases including Respiratory Distress Syndromes (RDS and ARDS), Acute Lung Injury (ALI), asthma, Chronic Obstructive Pulmonary Disease (COPD), and upper airway disorders. Discovery Labs is currently in five late-stage clinical trials of its engineered lung surfactant as a treatment for severe respiratory diseases including Part B of a Phase 2 trial for the treatment of ARDS, the life-threatening respiratory condition that severe SARS sufferers deteriorate to.

Certain **E**merging **I**nfectious **D**iseases (**EID**), like **S**evere **A**cute **R**espiratory **S**yndrome (***SARS***), cause 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 Acute Lung Injury (referred to as ALI), the most serious manifestation of which is **A**cute **R**espiratory **D**istress **S**yndrome (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.

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 EID and 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 EID, including 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 EID including 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 and other patients suffering from similar EID. 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 alveolar 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.

Pulmonary surfactants have additional properties such as:

(i) Physical barrier to inhaled particles and noxious agents;
(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 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:

			Clinical Results	
Patient Group	***Number of Patients***	***Surfaxin Dosage****	***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 EID and 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 EID including 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 EID and 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.

[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.

[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.

[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.

ECOLAB

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Bruce R. Cords, Ph.D.
Vice President Food Safety & Public Health

July 1 2003

Senator Norm Coleman
United States Senate
Permanent Committee on Investigation
Washington, DC 20510-6250

Dear Senator Coleman:

This letter is in response to your request for input on how the U.S. can be better prepared should an outbreak of SARS reoccur in the United States. Some specific recommendations/observations are as follows:

1. We need to better educate state and local public health officials on how to recognize the disease. As we discussed at your hearing, we were very fortunate the early cases in the U.S. happened to present themselves to hospitals that had the expertise to recognize the disease.

2. We need **easy to use** rapid diagnostic tools that have the sensitivity and specificity to detect levels of infection in individuals that might lead to transmission of the disease. These diagnostic tools must be readily available even at the local level.

3. We need to develop an emergency response plan for isolation/quarantine of large numbers (up to 100?) of people at the regional/state level.

4. We need to define specific procedures to be used by healthcare workers who are caring for suspected or confirmed SARS patients. We must avoid the transmission of the disease to the healthcare worker and prevent them from being a vector for spread of the disease.

5. We need better scientific data on how long the virus can survive outside the host on environmental surfaces.

6. We need to determine the effectiveness of disinfectants/virucides against the SARS virus or designated surrogates.

Ecolab would be willing to provide technical support for developing answers to items 4, 5, and 6. Please let us know how we can be of further assistance.

Sincerely,

Bruce R. Cords

C: A. L. Schuman, Ecolab Inc.
Joe Kennedy, General Counsel, United States Senate

Permanent Subcommittee on Investigations
EXHIBIT #9