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BIODEFENSE AND PANDEMIC INFLUENZA

HEARING

BEFORE A

SUBCOMMITTEE OF THE

COMMITTEE ON APPROPRIATIONS

UNITED STATES SENATE

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BIODEFENSE AND PANDEMIC INFLUENZA

TUESDAY, MAY 23, 2006

U.S. SENATE,
SUBCOMMITTEE ON HOMELAND SECURITY,
COMMITTEE ON APPROPRIATIONS,
Washington, DC.

The subcommittee met at 10:28 a.m., in room SD–192, Dirksen Senate Office Building, Hon. Judd Gregg (chairman) presiding.

Present: Senators Gregg, Allard, and Kohl.

Also present: Senator Burr.

OPENING STATEMENT OF SENATOR JUDD GREGG

Senator GREGG. We will begin this hearing, which is an important hearing on bioterrorism and pandemic influenza and our preparation, our status of the government's preparation for either of these events, which we obviously hope will never occur. As a society, I think we recognize and as a culture I think we recognize that there are certain elements of threat which the government has a responsibility to prepare for even though we hope that they will never impact us.

Number one on that list, of course, is the use of a biological or nuclear or weapon of mass destruction used by an enemy of America, terrorists specifically, against us, and our preparation for that has been a major focus of this committee, myself and Senator Byrd. We have reoriented funds to address that.

Number two—not in that sense; they are equal in status—is the potential of a major outbreak of influenza along the lines of what happened in the early part of the last century, which would potentially harm and kill millions, potentially hundreds of thousands, of citizens across the world and in the United States and would obviously disrupt the entire world and the economy of the world, especially America, if it were not prepared for adequately. There has been a lot of talk about that because of the issues of bird flu and the possible mutation of that virus into a form that can be conveyed to humans and human-to-human conveyance from there.

So these are big issues that need to be constantly focused on and that we as a government need to be constantly addressing and talking about and making sure that the agencies in our government which are responsible are on top of these issues.

So what we have done today is convene a panel of experts from outside the government who have looked at the government response and will tell us, hopefully, where the weak points are, where the good points are, what we should be doing, what we should be strengthening, and what we are not doing that we should

be doing. That is the purpose of this hearing, to get critical assessment, constructive critical assessment of where the Federal Government is on the issue of preparing for these potentially horrific events, but events which, even though we do not want them to occur, we know we must be ready for.

We are joined today by Senator Burr. Senator Burr is the chairman of the subcommittee on the HELP Committee which has jurisdiction over bioterrorism. I have asked him to participate in this hearing. This was originally going to be structured as a joint hearing, but for logistical reasons we were not able to get that going. So I appreciate Senator Burr participating in this hearing. He is a leading expert on this.

Senator Byrd, who is equally an expert on this issue, unfortunately has other commitments today, so he is not going to be able to make this hearing. He has shown immense leadership and commitment to making sure that these areas of biological terrorism potential threat are prepared for, and I have greatly appreciated his help and support and leadership. More than help and support, he has shown the way in many instances in how we try to tool up for these issues.

So with that, we are going to go right to the panel. I have advised the panel that we have a vote at 11 o'clock and I unfortunately am going to have to stay after the vote in order to do a confirmation of Ambassador Portman to become OMB Director, as chairman of the Budget Committee. So I may not be able to make it back until about 11:20, 11:25. But we will continue the hearing. If I am not here somebody else will take the chair.

So why do we not begin going left to right and start with our witnesses. Let me begin with Dr. Offit. Why do I not introduce all the witnesses first and then we will begin. Dr. Offit is the Chief of Infectious Diseases at the Children's Hospital of Philadelphia and is a professor of pediatrics at the University of Pennsylvania School of Medicine. He is an internationally recognized expert in immunology. Dr. Offit has published over 130 scientific medical journal articles. He has also co-authored several books, including The Cutter Incident, which chronicles how the first polio vaccine led to the current vaccine crisis.

We have John Clerici, who is a partner with McKenna Long and Aldridge and specializes in homeland security and procurement of anti-terrorism technology. Mr. Clerici is a recognized expert on liability reform policies.

We have Dr. Lillibridge, who is professor of epidemiology and Director of the Center of Biosecurity and Public Health Preparedness at the University of Texas Health Science Center at Houston. Dr. Lillibridge recently served as Special Assistant for National Security and Emergency Management at HHS, where he oversaw the development of the National Bioterrorism Preparedness Program. He also established and directed the bioterrorist preparedness and response programs at CDC and was the lead physician during the Oklahoma City bombing and the 1995 sarin terrorist attack in Tokyo.

We have as our final witness Frank Cilluffo.

He is the Associate President of Homeland Security at George Washington University and the Director of the Homeland Security

Policy Institute. Prior to joining the faculty at GW he served as the Special Assistant to the President for Homeland Security at the White House. He also served in a senior policy position with the Center for Strategic and International Studies, with a focus on homeland security and counterterrorism.

Obviously an extraordinarily qualified panel and we look forward to their critique of where we are and where we are going.

We have written statements from Senator Craig and Byrd that will be entered into the hearing.

PREPARED STATEMENT OF SENATOR LARRY CRAIG

Thank you Mr. Chairman. I appreciate your holding this hearing today to focus our Subcommittee on the important topic of bioterrorism and pandemic flu preparedness.

Mr. Chairman, there has been no shortage of reviews of the Federal Government's capability to respond to another serious emergency across this country. Countless assessments have been done by non-governmental entities, such as the ones represented by our panel this morning. There have been dozens of hearings by multiple Committees in the House and Senate. And certainly the media has highlighted several areas that must be addressed.

I do not want to take a lot of the Subcommittee's time this morning outlining my thoughts on all of those assessments and where I think we need to move this government to respond to a bioterrorism attack or a pandemic flu. But, what I will say is that Congress must make some decisions about which agency of this government will be in charge during an emergency and who in that agency should direct all of our efforts. I know that Senator Burr and the HELP Committee have been working on a bill to answer some of these questions. Once we answer the questions though, I think this subcommittee must ensure that all of the Federal financing efforts necessary to carry out the Federal responsibilities will be available to the right agency for their part of the mission.

That may sound obvious to some. But, I say that Mr. Chairman because, as you know, I Chair the Veterans Affairs Committee. And many people in and out of government believe that VA's performance in response to the terrible storms that ravaged the Gulf Coast was so impressive that they should be given a larger role in the overall Federal response plan. Frankly, I think I agree with those who want to assign a larger role for VA. The agency has the medical infrastructure, the dedicated Federal employees, the purchasing power, and the logistics management system to do the job. But, I don't really want to argue the merits of the agency's role right now.

What I am concerned about is that VA, or other agencies like it, will be given an expanded role and then expected to find the financing within their current budget to carry out their new mission. I don't know if that is even possible in the case of VA, let alone how that would impact its other missions. But, what I do know is that such an approach—if applied government-wide—would have us relying on each subcommittee of the Appropriations Committee to separately fund the needs of each agency under its jurisdiction for a nationwide response plan. Then, we would be relying on appointed officials and bureaucrats to dedicate the proper amount of money to the preparedness and response missions of their agency. I sincerely hope we do not go down that road Mr. Chairman.

So, as we work through these issues and consider the HELP Committee's legislation on the floor later this year, I want to make certain that we identify what needs to be funded and for what efforts in each Federal agency for preparedness and responsiveness. We then have to weigh all of those needs in this subcommittee and provide preparedness and response funding from this subcommittee for that specific purpose.

There are many Federal agencies, like VA, that are well-suited to assist in the Federal response to a national emergency or a pandemic flu. But, the old adage is that we are only as strong as our weakest link. And it is incumbent on this subcommittee to make sure we are coordinating the funding for our response efforts in one bill so that we do not discover a weak link that cripples our response efforts right in the middle of the next emergency.

Mr. Chairman, again I want to thank you for holding this hearing. I look forward to the testimony and asking some questions of our witnesses.

PREPARED STATEMENT OF SENATOR ROBERT C. BYRD

A flu pandemic or bioterror event is a real threat to the United States. Medical experts warn that a global, cataclysmic pandemic is not a question of "if," but "when." Like any natural disaster, it could hit at anytime. And when it does, it could take the lives of millions of people.

Our current public health infrastructure and emergency management system are not equipped today to cope with a major flu pandemic or biological event. A coordinated, comprehensive, and aggressive national plan must be implemented for combating biological weapons or infectious diseases. This plan must serve to detect, identify, contain, and respond to threats abroad and to bolster domestic preparedness and response.

The September 11, 2001, terrorist attacks cost America many precious human lives. Hurricane Katrina's impact was devastating in its harsh impact over 93,000 square miles. A pandemic or biological attack will combine human toll and geographic dispersion with an added element of long duration that previous disasters have not yet demonstrated.

A pandemic or biological terrorist attack would likely overwhelm our medical capabilities. In the Twentieth Century, there were three influenza pandemics, killing over 600,000 people in the United States, including my beloved mother. The anthrax attacks of 2001 fell short of mass causalities, but five lives were lost, and the attack serves to illustrate the viability of a biological attack. We should be prepared, not scared.

Congress has appropriated over $4.1 billion for pandemic influenza prevention and preparedness and the Senate has approved another $2.3 billion on the supplemental. Since 9/11, Congress has appropriated over $10 billion for State and local government efforts to prepare for and respond to a bioterrorist attack, or other public health emergency. In addition, Congress has advance-appropriated $5.6 billion for Project BioShield to procure countermeasures for biological threats.

Our job here in the Congress is to write the law, appropriate funding, and provide oversight. I continue to be frustrated with this Administration's pace in getting the job done, and I have told the Administration as much. I am concerned that we have appropriated billions of dollars and, yet, we do not seem to be prepared for the wide range of threats facing us. I am particularly concerned that our public health system lacks the surge capacity to deal with mass casualties.

I thank our witnesses for being here today to discuss how we—as a nation—are doing in preparing for pandemic and biological threats. I look forward to hearing their frank comments and insights so that the Congress can continue to provide the leadership that the nation needs on this important topic.

I commend Chairman Gregg for his leadership on this important issue.

Senator GREGG. Dr. Offit.

STATEMENT OF PAUL A. OFFIT, M.D., CHIEF OF INFECTIOUS DISEASES, CHILDREN'S HOSPITAL OF PHILADELPHIA

Dr. OFFIT. Good morning, Senator. My name is Paul Offit. I am Chief of Infectious Diseases at Children's Hospital in Philadelphia and a former member of the Advisory Committee on Immunization Practices to the CDC.

I would like to talk briefly today about an event that occurred 50 years ago in 1957, the only time in our history that we have made influenza vaccine in advance of a pandemic, because I think there are several lessons that can be learned from that event. On April 17, 1957, Maurice Hilleman, a scientist working at the Walter Reed Army Medical Research Institute, read an article in the New York Times titled "Hong Kong Battling Influenza Epidemic." The article stated that 250,000 people, 10 percent of the entire population of Hong Kong, had suddenly come down with the flu.

Hilleman found that this outbreak signaled—feared that this outbreak signaled the start of the next pandemic. So the next day he sent a telex to the Army's 406th Medical General Laboratory in Zama, Japan, asking them to send him specimens from people in-

fected with the virus. The first specimens arrived 1 month later on May 17, 1957.

For 5 days and nights, Hilleman worked to determine whether the influenza virus circulating in Hong Kong could be a pandemic strain. He tested sera from members of the American military and adults in the general population, but could not find anyone whose immune systems had seen this virus before. Hilleman then sent the virus for testing to the United States Public Health Service, the Commission on Influenza of the Armed Forces Epidemiological Board, and the World Health Organization. They found that only a handful of people in the United States and the Netherlands had antibodies to the virus. Because few people in the world had antibodies to stop it, the influenza virus circulating in Hong Kong in 1957 could spread from one country to the next unchecked.

Hilleman then sent the virus, now called Asian flu, to six American-based companies. He figured that if he were to have any chance of saving lives companies would have to make and distribute tens of millions of doses in only 4 months. Hilleman sped up the process by ignoring the Division of Biologic Standards, the Federal agency responsible for regulating vaccines.

He also asked vaccine makers to advise chicken producers not to kill their roosters, even though it was late in the hatching season. He knew that production of tens of millions of doses of vaccine would require at least 200,000 eggs a day.

As predicted, in September 1957 Asian flu entered the United States from both coasts. The first laboratory-proven cases occurred aboard naval vessels in Newport, Rhode Island, and San Diego, California. The first outbreak was triggered by a San Diego girl who carried the virus to an international church conference in Grinnell, Iowa. The second occurred in Valley Forge, Pennsylvania.

Companies made the first lots of Asian influenza vaccine in June 1957 and vaccination began in July. By late fall, 40 million doses were distributed in the United States. Within a few months, influenza infected 20 million Americans. 70,000 died from the disease. Worldwide, the pandemic killed at least 4 million people.

The Surgeon General of the United States, Leonard Burney, later said, quote: "Many millions of persons we can be certain did not contact Asian flu because of the protection of the vaccine." For his efforts, Maurice Hilleman won the Distinguished Service Medal from the American military.

Several features of this outbreak and our response to it are instructive. First, Hilleman had to rely on reading an article in a newspaper to know what was happening in Southeast Asia and he had to wait 1 month before he received samples of the virus. Today the international community of scientists, clinicians, and public health officials, armed with sophisticated virological techniques, are much better at surveillance of outbreaks and characterization of possible pandemic strains.

Second, Hilleman called on six U.S.-based influenza vaccine makers. Today no U.S.-based companies make the inactivated vaccine. Sanofi Pasteur has a manufacturing facility in Swiftwater, Pennsylvania, but is not a U.S.-based company.

Third, Hilleman had to rely on eggs to produce vaccines. Recognizing that egg production is unreliable, the President's pandemic

flu plan has effectively encouraged vaccine makers to gear up facilities to grow influenza virus in mammalian rather than avian cells. For example, GlaxoSmithKline recently purchased a manufacturing facility in Marietta, Pennsylvania, and MedImmune, the makers of a live attenuated influenza vaccine, will manufacture vaccine in mammalian cells in Maryland. Given that the influenza vaccine is generic and inexpensive, it is unlikely that vaccine makers would have done this without financial encouragement.

Fourth, Hilleman completely ignored the Division of Biologic Standards, the Federal agency responsible for regulating vaccines. At the time vaccine regulation was in its infancy, regulated by a small division within the National Institutes of Health. Today vaccines are regulated by the Food and Drug Administration and they do an excellent job. Vaccine regulation I think has helped to make vaccines arguably the safest and best-tested products that we put into our bodies. But the process is slow and if we are to make vaccine quickly the regulatory process would have to be streamlined significantly.

Fifth, Hilleman was a committee of one. He took responsibility for shepherding each step of the process. It would be impossible for him to do that today, but it would certainly be of value for one central agency to be held accountable for making sure that vaccine was made, tested, and distributed quickly and efficiently.

Sixth, Hilleman never considered liability protection for vaccine makers. In 1957 pharmaceutical companies were not held liable if they were not negligent in the production or design of their product. Ironically, the birth of liability without negligence for pharmaceutical companies began with a jury verdict against a vaccine maker, Cutter Laboratories, only a few months later. However, it is clear that vaccine makers would not make a pandemic flu vaccine today without substantial protection from frivolous litigation.

Thanks for giving me an opportunity to speak before this committee.

[The statement follows:]

PREPARED STATEMENT OF PAUL A. OFFIT

My name is Paul Offit. I'm the Chief of Infectious Diseases at The Children's Hospital of Philadelphia, Professor of Pediatrics at the University of Pennsylvania School of Medicine, and a former member of the Advisory Committee on Immunization Practices to the CDC.

I'd like to talk briefly today about an event that occurred 50 years ago, in 1957: the only time in our history that we have made influenza vaccine in advance of a pandemic. Several lessons can be learned from that event.

On April 17, 1957, Maurice Hilleman, a scientist working at the Walter Reed Army Medical Research Institute, read an article in the New York Times titled Hong Kong Battling Influenza Epidemic. The article stated that 250,000 people—ten percent of the entire population of Hong Kong—had suddenly come down with the flu. Hilleman feared that this outbreak signaled the start of the next pandemic. So the next day he sent a Telex to the Army's 406th Medical Laboratory in Zama, Japan asking them to send him specimens from people infected with the virus. The first specimens arrived 1 month later, on May 17, 1957.

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First, Hilleman had to rely on reading an article in a newspaper to know what was happening in Southeast Asia and he had to wait 1 month before he received samples of the virus. Today, the international community of scientists, clinicians, and public-health officials, armed with sophisticated virological techniques, are much better at surveillance of outbreaks and characterization of possible pandemic strains.

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Thank you for giving me the opportunity to speak before this committee.

Senator GREGG. Thank you, Dr. Offit.

Mr. Clerici.

STATEMENT OF JOHN M. CLERICI, J.D., McKENNA LONG & ALDRIDGE, LLP

Mr. CLERICI. Chairman Gregg, Senator Burr, members of the committee: It is an honor for me to testify before you today regarding my views on the state of biodefense and pandemic planning in the United States. Just over a year ago I had the opportunity to testify before this same committee on these subjects and particularly the need for liability protection to promote participation in these markets. I am happy to report since that time significant progress has been made.

In the area of biodefense, the Department of Health and Human Services has recently acquired 10 million doses of a safe, effective, FDA-licensed anthrax vaccine. From a policy standpoint, Deputy Secretary Azar has recently announced that he and Secretary Leavitt have completed a revised implementation strategy for BioShield and intend to implement that policy. Of course, reintroduction of legislation by Senator Burr with the chairman's co-sponsorship creating the Biomedical Advanced Research Development Agency and the commitment of the President to fund advance development to almost $200 million in his budget is a very, very critical development and deserves strong industry support.

In the area of research and development of pandemic vaccines, recent events have also been very positive. On May 3 Secretary Leavitt announced the award of almost $1 billion in advanced development contracts for cell culture influenza vaccines. The committee should take heart in both the size and the diversity of the companies awarded these contracts. From the very large companies like GlaxoSmithKline to emerging innovative biotechs like MedImmune, which developed the first licensed innovation in flu vaccine in almost 50 years in its FluMist vaccine, it is clear that HHS has made substantial progress in attracting the best and brightest of industry over the last year.

But perhaps most importantly, under your leadership, Mr. Chairman, as well as the leadership of Majority Leader Frist and Senator Burr in the Senate and Speaker Hastert, Congressman Lewis, Congressman Issa in the House, the President has signed into law the Public Readiness and Emergency Preparedness Act of 2005. Through this legislation, the PREP Act, the Congress has provided a key tool to protect the Nation from infectious disease and other threats that could cripple the United States in a global economy.

As a result of the PREP Act, vaccine and countermeasure developers are now better protected from the massive lawsuits that could have eviscerated and have eviscerated the vaccine and countermeasure manufacturing base in the United States. With the implementation of these strategic and valuable protections, the United States is now in a far better position to revitalize the domestic capabilities and to produce the tools needed to secure the health and wellbeing of its citizens.

However, with all the outstanding progress we have made over the last year, both in the area of biodefense and pandemic, much more can and should be done. First, I would urge Congress to consider providing incentives to private entities to better prepare for a pandemic. A recent study by Mercer Human Resources Consulting has estimated that only 7 percent of U.S. companies have

established budgets for pandemic preparedness, with 12 percent of European companies and over 25 percent of Asian companies having such budgets. The private sector must take the lead in preparing for a pandemic, not only for their own businesses but also for the communities in which they operate. They cannot rely on the government to prepare the Nation on its own.

To that end, Congress should now consider changes in policy similar to those asked to prepare the Nation for the Y2K threat. This includes providing additional incentives such as expanded liability protection to those entities that have reasonable and prudent efforts to prepare for a pandemic. Congress should provide at a minimum the same level of protections provided by Congress on a bipartisan basis in the Y2K Act of 1998, signed by President Clinton.

Like Y2K, if a pandemic worst case scenario never happens, providing the legal certainty for businesses to upgrade their infrastructure and adequately prepare the Nation's fragile health care system, leading to better patient care, lower costs, fewer medical mistakes, and better patient privacy, is a win-win scenario.

Second, we must examine the supply chain delivery of clinical countermeasures that would be deployed in a pandemic. Congress should deal now with the policies to ensure protections from both counterfeiting of these critical countermeasures as well as theft. Congress should encourage private sector solutions to these problems. In fact, given the timing, the Federal Government should rely on the expertise and experience of the private sector in developing and executing supply chain management inventory controls.

Finally, Congress should act now to implement policies that will bolster our fragile public health infrastructure, especially the hospital systems. Should a pandemic strike the Nation, the surge in the hospitals nationwide from patients who are actually sick with influenza or other illnesses as well as the worried well could cripple our American health care system for years to come. Painfully hard triage decisions on who will receive care and when they will receive it are certain to lead to baseless lawsuits unless some protections from liability are provided to these health care providers. The trial lawyers are already lying in wait, planning their litigation strategies around the occurrence of these events. The last thing the Nation needs during a flood of illness is a flood of lawsuits, and Congress should act now to stem the tide of these events.

Turning briefly to implementation of BioShield, there were many challenges that we made to the Department last year when I had the opportunity to testify to you. Unfortunately, progress has not been made in certain areas. In particular, the regulations implementing Project BioShield required by the statute have yet to be promulgated. The material threat assessment process, which has come under criticism as slowing BioShield, still has not provided the clarity to industry that it needs.

I close by noting that none of the proposals I have suggested, Mr. Chairman, call for a single appropriation outside of what has been appropriated or within the chairman's budget—within the President's budget. I know that will appeal to your senses as chairman of the Budget Committee. There are real things that we can do

here today without taxing the American taxpayers any more than they are to prepare the country for a pandemic.

I welcome your questions and thank you for your support and the support of the President in this effort.

[The statement follows:]

PREPARED STATEMENT OF JOHN M. CLERICI

Chairman Gregg, Senator Byrd, and Members of the Committee, it is an honor for me to testify before you today regarding my views on the state of biodefense and pandemic planning in the United States.

Just over 1 year ago, I had the honor to testify before you and this Committee on the state of implementation of the Project BioShield Act of 2004 and the need for liability protections to promote participation in the biodefense market, but also to stimulate development of influenza pandemic countermeasures. Since that time, significant progress has been made.

In the area of biodefense, the Department of Health and Human Services (HHS) has acquired 10 million doses of a safe and effective FDA licensed anthrax vaccine from BioPort Corporation to better prepare the Nation against another anthrax attack like the one suffered by this body in October 2001. In addition, HHS has announced that the long-awaited purchase of anthrax therapeutics for postexposure treatment of anthrax victims will be completed very shortly.

From a policy standpoint, Deputy Secretary Alex Azar recently announced that he and Secretary Leavitt are about to complete a revised implementation strategy for Project BioShield to eliminate many of the delays that have been observed in the BioShield program. Given the substantial talents of Deputy Secretary Azar, his personal involvement in this effort is welcome and encouraging.

Of course, reintroduction of legislation by Senator Burr, with the Chairman's cosponsorship, creating the Biomedical Advanced Research and Development Agency (BARDA), and the commitment by the President in his fiscal year 2007 budget to fund such an effort with nearly $200 million, is a very positive development. Creation of BARDA will go a long way to address the "valley of death" in biodefense countermeasure development and merits the strong support of industry for passage this year.

In the area of research and development for pandemic vaccines, recent events have also been very positive. On May 3, 2006, Secretary Leavitt announced the award of almost $1 billion in advance development contracts for cell-culture influenza vaccines. These contracts are milestone driven, and support multiple companies pursuing diverse technologies. Given the recent challenges HHS has faced with its contractor, VaxGen, for an experimental anthrax vaccine being developed under BioShield, it is clear that HHS understands the need not put its eggs in one basket with influenza countermeasures.

We should also take heart in the size and diversity of the companies awarded the cell-culture contracts. From successfully engaging a large company like GlaxoSmithKline, to making awards to innovative biotechnology companies like MedImmune—which has developed the first licensed innovation in flu vaccine technology in over 50 years with its FluMist vaccine—it is clear that HHS has made substantial progress over the last year. HHS is now moving forward with development of adjuvant technology to improve the disappointing effectiveness of the H5N1 vaccine purchased last year, as well as to continue development of exciting new vaccine technologies such as DNA-based vaccines and novel antivirals. At the same time, HHS has recognized the need to accelerate the development of critical rapid diagnostics, and has announced plans to move forward with an advance development program for such technology in the coming weeks.

But perhaps most importantly, under your leadership, Mr. Chairman, as well as the leadership of Majority Leader Frist and Senator Burr in the Senate, and Speaker Hastert, Congressman Lewis, and Congressman Issa in the House, on December 30, 2005, President George W. Bush signed into law the "Public Readiness and Emergency Preparedness Act" (PREP Act).

Through this legislation, the United States Congress has provided a key tool to protect the nation from infectious disease and other threats that could potentially cripple the United States and the global economy. As a result of the PREP Act, vaccine and countermeasure developers are now better protected from the mass of lawsuits that have basically eviscerated the U.S. vaccine and countermeasure manufacturing base, leaving it ill prepared for threats such as avian influenza. With the implementation of these strategic and valuable protections, the United States is now

in a far better position to revitalize its domestic capability to produce the tools needed to secure the health and well-being of its citizens.

In short, the PREP Act offers targeted liability protections to those involved in the development, manufacturing and deployment of pandemic and epidemic products and security countermeasures. The Act creates a shield of immunity for claims arising out of, related to, or resulting from the administration or the use of a covered countermeasure (i.e., vaccines, countermeasures, devices and certain other products). This immunity covers a wide range of uses, including design, development, testing, manufacturing, distribution, administration, use and other activities so that the protections can be applied as broadly as possible.

This law dramatically improves the ability of the United States to develop the tools it needs to be prepared for a naturally occurring or terrorist-related public health emergency. However, it is absolutely critical for HHS take the necessary steps now to implement fully the PREP Act, as intended by Congress and the President, to prepare the Nation for a influenza pandemic. To that end, industry eagerly awaits the Secretary's declaration of a potential public health emergency for an influenza pandemic, thereby triggering the protections of the PREP Act for covered countermeasures. In addition, industry looks forward to the release of the 4 regulations required by the Act to provide further clarity on the scope of the Act and its protections.

However, will all the outstanding progress the United States has made over the last year, both in the area of biodefense and pandemic planning, more can, and must, be done.

First, I would urge Congress to consider providing incentives to private entities to better prepare for a pandemic. A recent study by Mercer Human Resource Consulting has estimated that only 7 percent of U.S. companies have established budgets for pandemic preparedness, compared with 12 percent for European companies and 25 percent for Asian businesses. The private sector must take the lead in properly preparing for a pandemic threat, not only for their own businesses, but also, for the communities where they operate, and not rely upon government to prepare the Nation on its own.

Pandemic preparedness is first and foremost an issue of public health. But it is also an issue of ensuring American competitiveness in the global markets. If we are less prepared than the rest of the World, not only will our Nation's health suffer more, but so will our economy and our path to recovery from such an event. Companies must plan now for the possibility that 40 percent or more of their work force may not be able to show up to work during a pandemic, including, according to a recent study by the Johns Hopkins Bloomberg School of Public Health, up to 67 percent of back office health care workers providing technical support, payroll and payment processing, and other administrative functions. Public companies, of course, have an even greater obligation to implement internal controls to address such an event to assure that shareholder assets are protected and their business recovers as quickly as possible.

To that end, Congress should act now to consider changes in policy similar to those passed to prepare the Nation for the Y2K threat. This includes providing additional incentives, such as expanded liability protections, to those entities that make reasonable and prudent efforts to prepare for a pandemic. Congress should provide, at a minimum, the same level of protections provided by Congress on a bipartisan basis in the Y2K Act of 1998, signed by President Clinton.

Policy changes to improve telework and increase high-speed internet access should also be part of this effort. The Administration's pandemic plan recommends that employers keep employees three feet apart in a pandemic event. Given that more and more companies are enabling employees to work remotely, perhaps Congress should provide incentives now to ensure that telework options are widely available. With sufficient bandwidth and data security to operate with large numbers at the same time, workers could work safely from home, thereby stemming spread of the pandemic while reducing the economic impact.

To the greatest degree possible, we must also ensure that certain critical functions for maintaining the operations of our health care infrastructure can be automated or operated remotely in those circumstances. Thus, Congress should expedite passage of legislation promoting electronic medical records as soon as possible.

The Y2K legislation served as a national wake up call to Americas businesses and gave them the comfort of liability protection to identify and correct the problems with their IT infrastructure. Many businesses then (like many hospitals, health insurers, and other businesses critical to our nation's health care infrastructure today), were afraid to even explore their vulnerabilities for fear of creating a paper trail for eager trial lawyers to launch baseless lawsuits in the future. U.S. businesses, particularly those critical to our health care infrastructure, need a similar

wakeup call—and equal liability protection—to upgrade, test, and retest our public health infrastructure to ensure pandemic readiness. Like with Y2K, even if a pandemic worst case scenario never happens, providing the legal certainty for businesses to upgrade their infrastructure and adequately prepare will improve our Nation's fragile health care system—leading to better patient care, lower costs, fewer medical mistakes, and better patient privacy. It is truly a winwin scenario.

Second, we must examine the supply chain for delivery of critical countermeasures that must be deployed during a pandemic, as well as the supply chain for delivery of good and services, as a whole, during a state of emergency caused by a pandemic. Most certainly, some—if not all borders—will close during a pandemic, thereby crippling food distribution and delivery of critical goods and component parts made outside of the United States. For critical countermeasures, Congress should deal now with policies to ensure protection from counterfeiting and theft of public health supplies. Congress should encourage the private sector to pursue implementation of workable, non-burdensome tracking mechanisms, while ensuring the protection of data and other information needed to allow the supply chain to function.

Because timing is essential, the Federal Government should rely on the expertise and experience of the private sector in developing and executing missioncritical functions like supply chain management and inventory control. We should ensure that policies encourage implementation of commercially tested systems—preferably those already in place in key parts of the health care infrastructure, that can be quickly and easily implemented. Effective supply chain management solutions for the strategic stockpiles must be proven and reliable, and be able to link thousands of stakeholders including pharmaceutical and medical supply companies, health care providers, distributors, shippers, security and customs organizations, and private and public local, State, Federal and international health care agencies.

Effective supply chain management may also require considerable automation, since significant numbers of personnel throughout the supply chain may be sick or fail to show up for work. Information must also, to the greatest degree possible, be readily accessible, but yet secure, among multiple jurisdictions. In addition, the communication channels must be easily interoperable with multiple existing systems using different levels of technical standards and training of operating personnel.

Finally, Congress must act now to implement policies that will bolster our fragile public health infrastructure, and especially, our hospital system. Should a pandemic strike the Nation, the surge on the hospitals, nationwide, both from patients who are actually sick with influenza or another illness, as well as the "worried well," will cripple our Nation's healthcare system unless we are fully prepared. Addressing a U.S. News & World Report meeting on health and preparedness, Secretary of Homeland Security Michael Chertoff noted that hospitals, nursing homes, and other health facilities "have a legal and moral obligation to develop evacuation plans and other emergency plans to ensure that people with special needs whose care has been entrusted to these caregivers will, in fact, be taken care of and will get the appropriate care in an emergency." We must give these entities the tools they need to meet this legal and moral obligation.

Under the best of circumstances, emergency response workers may receive a vaccine that provides some level of immunity prior to a pandemic, and thus, will have some small degree of protection. However, the hospital administrators, claims processors, and support personnel are unlikely to receive any vaccine in time. With hospital support staff either at home to avoid illness, or already sick, while the hospitals are being pummeled by acute care patients, no claims will be processed to insurers. Thus, hospitals will be under significant financial strain, potentially unable to recover, and likely will be taken over by the Federal Government, as has already occurred in some of the areas impacted by Katrina.

In addition, painfully hard triage decisions on who will receive care, and when they receive it, are certain to lead to baseless lawsuits unless some protections from liability are provided to health care providers. Trial lawyers are already lying in wait, planning their litigation strategies around the occurrence of such an event. The last thing the Nation will need during a flood of illness is a flood of lawsuits—Congress should act now to stem the tide of such an event.

In terms of other policy changes that would benefit overall preparedness for a pandemic, the United States has the opportunity to build the infrastructure today to support improved access to influenza vaccine and better immunization for annual influenza—which kills over 30,000 American each year. Expanded immunization recommendations for influenza vaccine, particularly among the young who drive disease transmission, should be strongly considered. Congress should also challenge healthcare providers and the public health system to not squander the opportunity to begin building and testing the influenza vaccine infrastructure within the frame-

work of current immunization recommendations. Policymakers should act quickly to accelerate those recommendations, including universal pediatric vaccination up to 18 years of age, in order to build as much vaccine infrastructure capacity as possible to better prepare the Nation for a pandemic without the expenditure of any additional Federal dollars. The bottom line is that we should build out the vaccine infrastructure with a seasonal flu approach, which will, in turn, not only protect the population today for the annual flu strain, but also allow us to look for any leaks that might sink the ship under the wave of a pandemic flu crisis.

Turning briefly to the implementation of Project BioShield, while implementation has been improved, and according to HHS, additional improvements are under way, more can be done. When I last testified before you in April 2005, I noted that the regulations mandated under Project BioShield had yet to be promulgated. Unfortunately, that is still the case today. I also noted that the material threat assessment (MTA) process conducted by the Department of Homeland Security under BioShield provided neither the speed nor the clarity necessary to allow the full promise of BioShield to "build a market" to materialize. While some improvements have been announced in the MTA process, industry has seen little evidence that this problem has been adequately addressed. For example, when I testified last year, I noted that the market for badly needed countermeasures for cyanide—a well known and clearly established threat—was uncertain due to implementation issues with BioShield. Again, unfortunately, that remains the case today.

Finally, HHS must learn from the set back in the VaxGen anthrax contract and not allow itself, or industry, to be deterred from this apparent failure by a single contractor. It is clear from the recent statements by Secretary Leavitt that HHS appears to be doing just that, and that is very encouraging. However, additional clarity and greater speed in implementing BioShield, along with the fast passage and implementation of BARDA, will provide industry with greater confidence in the long-term viability of the overall effort.

I close by noting that the proposals I have suggested have one thing in common—they do not require the appropriation of any additional dollars other than those that have already been passed or are proposed in the President's budget. While that may not appeal to you, Mr. Chairman, in your role as an Appropriations Cardinal, I suspect it may appeal to your views as Chairman of the Budget Committee. Thus, through changes in policy alone, we can make substantial progress in improving the Nation's preparedness for a pandemic or bioterrorist attack, as well as enhancing and protecting public health as a whole.

I very much appreciate the opportunity to offer testimony on this very important public health and anti-terrorism issue. Again, I applaud your efforts, and the efforts of President Bush and his Administration, and look forward to continuing our work with Congress and the Administration in this critical area.

I am happy to respond to any questions you may have.

Senator GREGG. Thank you, Mr. Clerici. I would note that the supplemental there is an additional $2.3 billion for this effort relative to pandemic flu. So the commitment remains fairly strong from the administration.

Dr. Lillibridge.

STATEMENT OF SCOTT R. LILLIBRIDGE, M.D., DIRECTOR, CENTER FOR BIODIVERSITY AND PUBLIC HEALTH PREPAREDNESS, UNIVERSITY OF TEXAS HEALTH SCIENCE CENTER, HOUSTON SCHOOL OF PUBLIC HEALTH

Dr. LILLIBRIDGE. Thank you, sir. Good morning, Chairman Gregg, Senator Burr, other guests. I am Scott Lillibridge. I am a professor at the University of Texas School of Public Health. I am honored to be here today to talk about the important issue of bioterrorism preparedness and pandemic influenza preparedness.

Let me step back a little bit from when I used to be in my Federal role as CDC Director of Bioterrorism Preparedness and Response. As I survey the landscape over the past 5 years, I think we have had great strides in the area of stockpiling. I think we have a national laboratory response network in place and we have

bioterrorism coordinators at work in almost every State and major county in the United States. That is progress.

However, as we look forward there are things that need to happen to move to the next level of preparedness to face the new threats that we have, ranging from influenza to SARS to NEPA virus to any other emerging disease that we have around the corner, and we still have the specter of bioterrorism dogging us.

My comments really fall into six major areas: leadership, organization, accountability, surge capacity, stockpile, and training. Let me just from the grassroots level as an ex-administrator, a person who has been both in the private and public sector, kind of give you my overview of these things.

First of all, under the issue of leadership, I look at this as a complex of biomedical, clinical, hospital, health system endeavor preparedness activity. The feeling at the State and local level where I work is that this has not been under clear medical control associated with a clear agency responsible for this endeavor.

I will give you a case in point. If you look at the issue of the National Disaster Medical System, which was crafted to take care of mass care contingencies for civilian populations, we find that that resides in one Department, yet the lifesaving disease detection, epidemic control measures reside in another Department. Now, as a former administrator I will tell you that you can coordinate across and integrate, but you cannot develop in the Federal context a budget, personnel issues, when the responsibility for one program resides in one Department and the program resides in another Department. It just does not happen. I think that that is a setup for failure.

The issue of accountability has been on our desk for some time now. I think after $28 billion, nearly 7 years, as we look back some things are still on the to-do list. We looked at in 2003, when the GAO looked at DHS, HHS, and began to look at what the training doctrine was and how to coincide those things and bring those into harmony. That is still on the to-do list. I think that is an important accountability issue.

The second, on Trust for America. A number of things in 2005 really were left undone. Those were issues of having a common surveillance strategy, our surge capacity issues were not intact, and about half the States really did not have hospital preparedness fully in order. Those are still out there and I think we need to look at some solutions for those things.

Might I propose the following. We have been through benchmarks in 1999, performance capacities. We have been through capabilities and now we are looking at target capabilities, and we are on to the next measure of accountability, somehow to make sure this Federal money ends up in the right place, doing the right sorts of things. I think until we get the leadership and until we get the organizational framework, until we get a regional plan that is understandable to the States, I think getting more compliance and accountability at the State and local level simply will not happen.

Let me move to surge capacity, as I want to highlight that as probably the most undone part of emergency preparedness in the Nation. I think we have achieved a place where we can detect and warn people better than ever about bioterrorism and flu. We are

less able to take care of patients in surge and large meaningful capacity, to mobilize hospital level services or regional medical activities, than ever before. I think fixing and resourcing and getting the NDMS properly situated will go a long ways to addressing those issues.

The second thing is I think the medical services that we need and the health services really reside in private and public sector at the State and local level and HMO's, hospitals, academic health centers. Those things need to get mobilized to do the job at hand to a greater extent.

Let me talk briefly about stockpile and vaccine. I am really for a stockpile that is strategic, less things in the stockpile that can actually be moved into areas and implemented in harm's way.

The other thing that I think we have been dancing around with for a lot of years is the issue of whether we need Government capacity in vaccine production, and I say yes, we do. The Government will need all the tricks in its toolbox to respond to an epidemic. It needs both private and public capacity. The first thing that we did when we set about to develop the smallpox vaccine after the 2001 threats of anthrax was we had to contract with the private sector and build capacity internally.

Last, let me close with a few statements on training and exercise. I want to tell you that, after 7 years, I think this is an area that we really need to emphasize because it brings the issues of stockpile, vaccine implementation, surveillance, and leadership together. That is the training and education. Unfortunately, those who have most to offer, the academic health centers, academic sectors, our schools of medicine, nursing, and public health, so forth, have been the least involved in that effort when you look at the total amount of money spent and the amount of money that went into satisfying a national strategy.

I think getting those groups involved and those powerhouses, academic powerhouses, are going to do a great chore for us in getting our national strategy implemented and our health providers trained.

Let me close by saying just simply thank you for this opportunity to testify. We have made great progress, but I think those issues still require leadership, accountability, organizational changes, strategic orientation of our stockpile, and we have got to emphasize our training if we are going to be prepared.

Thank you very much.

[The statement follows:]

PREPARED STATEMENT OF SCOTT R. LILLIBRIDGE

INTRODUCTION

Good morning, Chairman Gregg, Senator Byrd and distinguished members of the Subcommittee. I am Dr. Scott Lillibridge of the University of Texas Health Science Center at Houston, where I serve as Director of the Center for Biosecurity and Public Health Preparedness, and am Professor of Epidemiology at the School of Public Health. It is an honor to appear before you today to discuss our Nation's preparedness for bioterrorism and pandemic influenza.

As a Nation, we have made steady improvements in medical and public health preparedness since the founding of the CDC Bioterrorism Preparedness and Response Program in fiscal year 1999. At that time, as the former Director of that program, I surveyed a landscape where CDC had no bioterrorism preparedness laboratory; few early detection disease surveillance programs were in place in our urban

areas; and no health department within the United States had a bioterrorism coordinator to foster preparedness or planning. Today, we have a National Laboratory Response Network and expanded biological detection systems in urban areas throughout the United States. Drills and exercises involving influenza and bioterrorism are common place in almost all municipal jurisdictions throughout the United States. However, there are several important issues to be addressed if we are to move forward with National preparedness for epidemics, pandemic influenza or other emerging infectious diseases.

CHALLENGES TO NATIONAL PREPAREDNESS

I believe the most important challenges related to National preparedness for bioterrorism and pandemic influenza fall into six major categories.

—Leadership
—Organization
—Accountability
—Medical and Public Health Surge Capacity
—Stockpiling
—Training and Education

Leadership

Bioterrorism and pandemic influenza preparedness are areas of great concern to the public because of their potential for catastrophic effects on our population's health. The policies that guide these programs are based on complex biomedical and life science decisions that must be crafted with the expertise of health professionals, hospital workers and public health guilds whose constituents provide the life-saving, "hands on" measures that these programs seek to provide. However, most health care providers and public health workers feel these programs reside outside clear medical control by health professional's, and that there is no clear Federal lead health agency (research or operational) guiding this endeavor.

Organization

Nearly 5 years after the anthrax attacks of 2001 and after spending $28 billion Federal, there is still confusion as to which organization within the Federal Government is directly responsible to address the medical and public health needs of citizens from these types of disasters. The most glaring example of this inconsistency relates to the National Disaster Medical System (NDMS), which was originally founded as a loose federation of DHHS, DOD, VA and FEMA. NDMS was designed to provide catastrophic health services to our populations following a disaster.

Currently, the responsibility for NDMS resides within DHS while the essential disease surveillance, control, medical personnel, and health authorities reside in an agency of another department (most notably DHHS). In the Federal Government this is a problem because proper budget and staffing decisions cannot be made for activities that reside outside of one's Agency or Department's authority. I believe the current organizational framework is a setup for failure and leaves our population's health at risk. Ironically, we are spending more money on public health preparedness than the rest of the world combined, and in my opinion we are getting less than we deserve, largely because the leadership and the organizational framework have yet to be connected effectively.

Accountability

After 7 years of funding for biodefense and recently pandemic influenza, there are still no common measures available to evaluate medical and public health readiness for States, hospitals, or health departments. The General Accounting Office recommended in a 2003 report that DHHS and DHS collaborate to develop specific benchmarks that define adequate preparedness for a bioterrorist attack that can be used by jurisdictions to guide their preparedness efforts. To date, DHHS and DHS have not finalized performance measures to guide these preparedness efforts. A recent report by Trust for America's Health published in 2005 revealed the following problems:

—The CDC recognized only 7 States as adequately prepared to administer and distribute vaccines and antidotes in the event of an emergency.
—Over one quarter of States do not have sufficient bioterrorism laboratory response capabilities.
—Almost half of the States do not use national standards to track disease outbreak information.
—Hospital Preparedness—Nearly one-third of States are not sufficiently prepared, through planning or coordination with local health agencies, to care for a surge of extra patients.

Medical and Public Health Surge Capacity

Much of the U.S. healthcare system operates at or near capacity on a daily basis. We have witnessed over the past several years an attrition of available hospital beds due to the downsizing of facilities and the rising costs of health care. In the United States, in every major city, on any day, is not uncommon for one of their medical centers to be in a position where the beds needed to receive emergency patients are full. Lack of health care access due to lack of health insurance adds to this strain. Consequently, I am worried that we have developed a system where we are better able to alert the health community to bioterrorism and pandemic influenza but less able to actually care for victims.

In developing our Nation's clinical and public health surge capacity strategy, we have not gone far enough to invest the private and non-Federal public sector into regional mass care strategies. In addition, we still continue to funnel preparedness dollars into mass care strategies on a "per capita" or formula basis. This results in a cycle of planning and "replanning" and adds little or no additional emergency bed capacity to deal with victims from such catastrophes.

Stockpiling

The strategic national stockpile has grown based on requests, passing threats, and amid confusion as to whether it is to supply all matters of medical equipment to victims or whether it is to be strategic in design, and focus on critical vaccines and medications that will be needed for victims affected by bioterrorism or other epidemic.

Currently, the stockpile resides within DHHS but has been moved twice in the past 3 years. The main problem with the growth of the stockpile has been disagreement on what its contents should be and how distribution should be implemented. In addition, States are being asked to determine their own risks and are in the process of making their own stockpile decisions and supplemental stockpiles. This has led to the development of a cumbersome collection of drugs for ailments, ranging from exotic radiation exposures to equipment caches for ventilators for patients suffering from respiratory distress. These activities may be undermining the strategic focus of stockpiling, drive up the costs and ultimately hurt the cause of preparedness.

Training, Education, and Exercises

The backbone of public health preparedness is not merely the purchase and storage of expensive equipment, but rather a continual cycle of education, training, exercises, and evaluation. Hospitals and healthcare delivery organizations, particularly those in the private sector have not been fully included in such a training cycle; therefore, they lag behind in the needed training to address community or regional planning goals. It is also important to mention the fact that there is also no consensus as to the needed core-level of training and education to achieve our Nation's public health and medical planning goals. Today, the menu of educational offerings is disparate and non-uniform. Specifically, there is no national training curricula to support NDMS capacities or our regional preparedness efforts. This deficiency is compounded by the fact that those who have the most to offer in terms of health training and education (our Nation's academic health centers) have been the least incorporated into our preparedness strategies.

ROAD MAP FORWARD

In summary, from a public health and medical standpoint there is no significant difference between epidemic preparedness for SARS, Pandemic Influenza, bioterrorism, or any other emerging infectious disease at the National level. The differences are only in the nuances of prevention, treatment, and public health disease control measures. The key to saving lives in epidemics resulting from new and unexpected threats is early detection and timely epidemic control. The areas which I would emphasize are as follows:

Leadership

Our National bioterrorism and influenza preparedness programs should move forward under clear medical and public health leadership by professionals experienced in emergency clinical and public health services. While the lessons of military medicine are extremely important, this preparedness task primarily involves the mobilization of the civilian public and private health care sectors.

Organization

Strengthening the public health infrastructure remains important. However, the ability to alert populations to danger via early disease detection or surveillance will

be meaningless if we are not able to ultimately address the medical and public health needs of victims in harms way. Consider the resulting anger and frustration citizens and victims will feel when health interventions do not occur on a timely basis, as in the recent case following Hurricane Katrina. I believe the most important priority for Federal preparedness at this time is to refine our notions for mass patient care involving the National Disaster Medical System (NDMS) and define how these capacities will support regional preparedness efforts. NDMS needs a clear organizational ownership and a better definition of its roles and responsibilities. It also must be resourced properly.

Accountability

The implementation of these programs will need more accountability if we are to achieve the bioterrorism and pandemic influenza preparedness goals of the Administration. First, I would start with better clarity concerning the leadership and organizational framework of these programs. Second, the Federal authorities in charge of these programs have already issued a series of benchmarks, performance measures and target capabilities, and are moving to the next oversight measure that attempts to ensure that grant money is spent appropriately at the State and local level. However, I seriously doubt that another accountability gimmick under a new label will stop the supplanting of funds, the presence of large carry-over monies, and the fragmentation of this National effort.

I believe the emphasis on accountability should start with a focus on the development of National capacities that result in the development of regional (multi-state) capabilities that are supported by strong central government reference laboratory and clinical capacities. In my opinion it will be easier for the State and local health preparedness programs to achieve measurable outcomes if they know how to link to the larger emergency response system.

Medical and Public Health Surge Capacity

We have made great strides in public health preparedness, but our clinical surge capacities have not been as well developed. These capacities cannot be developed without a fundamental shift in the emphasis of our clinical preparedness programs. First, the clinical capacities in the United States reside largely within the private sector and public sector at the State and local level. The Federal Government should look towards developing a collaborative preparedness program that allows Academic Health Centers, Large HMOs, and major hospital organizations to play key regional roles in addressing the medical needs of victims during disasters. In addition, given the limited clinical resources available in the Federal system when compared to what is available in the State private and public sector, a strategy that fully utilizes State-to-State mutual aid should be emphasized and supported.

Stockpiling

Stockpiling of medical equipment, vaccines or therapeutics should be strategic and based on medical and public health priorities linked to what we know about the risks confronting our population. The Strategic National Stockpile cannot be all things to all people without consideration for economic trade-offs. From a preparedness standpoint, I recommend developing the stockpile with fewer items, which have a greater likelihood of actually being used effectively at the time of crisis rather than expanding the program until it becomes a static warehouse enterprise.

Vaccines deserve special mention in the context of National preparedness for bioterrorism and pandemic influenza. The most pressing need at this time is to commit to the development of a Government Owned—Contract Operated (GOCO) vaccine production capacity. The Federal Government must use all the tools in the biotechnology tool box in both the private and the public sector to address biological threats to human health. Our government needs to have standby vaccine development capacity so it can quickly begin the production of life saving vaccines at the time of crisis. In addition, it must be able to produce vaccines that will never have a viable commercial market. Such a facility should meet FDA requirements for production and quality control. My preference would be to have such a facility tied closely to the academic research community and private sector expertise.

Training and Education

The cycle of preparedness is straightforward and involves the assessment of capacity, which is then followed by training to develop the desired proficiency. Subsequently, we exercise and evaluate the performance of those who were trained to ascertain a state of readiness. To the extent that our program fits into this model, it will be easier for DHHS to connect with the other partners in the Federal, State and local response.

One of the first priorities is to finally establish training standards that support field deployments and other emergency planning notions. The academic health community is well suited to this challenge. Once such a doctrine is clearly enunciated, educators in schools of medicine, public health, nursing, and allied health fields can then concentrate their training efforts to prepare our health care providers for the task at hand. I do not believe this training capacity currently resides (or will ever reside) within the Federal Government. DHHS should be required to immediately establish the core training and educational requirements for our health care providers and public health workers that address these important preparedness efforts. We need the powerhouses of health education in America squarely behind this training effort. To accomplish this task we need to finalize our Nation's training doctrine so we can better target of our vital training resources.

In conclusion, the threats of bioterrorism and pandemic influenza will always present challenges to our health and medical community, but we are making steady progress in preparing our Nation. It is time to refine and redirect this National effort if we are to advance the cause of preparedness.

Thank you for the opportunity to be here today. I would be happy to address any questions that you may have.

Senator GREGG. Thank you, Dr. Lillibridge.

Mr. Cilluffo.

STATEMENT OF FRANK J. CILLUFFO, ASSOCIATE VICE PRESIDENT FOR HOMELAND SECURITY, AND DIRECTOR, HOMELAND SECURITY POLICY INSTITUTE, GEORGE WASHINGTON UNIVERSITY

Mr. CILLUFFO. Chairman Gregg, Senator Burr. It is a privilege to join you today for this important dialogue. I will try to be brief, not my strong suit as I have rarely had an unspoken thought, but a lot of territory to cover. Five years ago, in testimony before the Senate Foreign Relations Committee on the threat of bioterrorism and infectious diseases I suggested that the country was at a crossroads and that the time had come for a cold-eyed assessment and evaluation. While much has been accomplished in the intervening period, our level of preparedness remains very much a work in progress and it is not yet where it needs to be.

Bioterrorism and infectious disease preparedness marks the convergence of public health and national security. The intersection gives rise to the pressing need for careful coordination on a range of matters, including budgets and resources, policies and programs, and organizations and structures. The cultural differences between these areas are significant. Not to be tongue in cheek, but historically the law enforcement community focused on stringing people up, the intelligence community on stringing people along, whereas the health community focused on treating the strung out.

Bioterrorism and pandemic influenza preparedness represents a challenge for the full spectrum of traditional and in this instance nontraditional first responders. Federal leadership requires that clear guidance be provided for those at the tip of the spear—State and local governments, hospitals and health care workers, businesses, families, and communities. It is at the State and local levels where the rubber truly meets the road, and it would be folly to try to micromanage from Washington. Expectations of all involved must be framed in realistic terms before something happens.

The good news—and I agree with Scott—is that important strides have been made. The United States is a global leader in terms of pandemic preparedness, leveraging international partnerships, and Secretary Leavitt's outreach and engagement of the States to foster jurisdiction-specific response efforts is laudable. At the end of the day it all comes down to implementation and execu-

tion. To this end, several pieces of Federal legislation already exist on the biodefense side, and with respect to pandemic flu the President issued his national strategy last November, followed up by an implementation plan earlier this month.

Collectively, these initiatives helped move the ball forward by defining parameters for action and serving as a catalyst. The danger is if we allow these measures to instill a false sense of security when we should be conducting an honest and rigorous assessment of whether we are truly prepared. On this front, I am sorry to say that we are currently experiencing a pandemic, a proliferation of plans. What we need now are the operating tenets that will marry up national and State strategies with implementation. Unless and until the focus shifts to competent execution, the Nation's preparedness posture will not be solidly grounded.

Despite this need, the various moving parts of the preparedness and response enterprise are not yet fully synchronized and harmonized. As Scott mentioned, the ongoing debate as to where we should situate NDMS suggests that we are still stuck to some extent in neutral and are not using our time and mind share to best advantage. What we should really be focusing on are the back end capacities and capabilities, irrespective of where NDMS is situated.

From plans to planning, and I believe we need to leverage an all-hazards approach. Where do we go from here? To shrink the delta to get to where we need to be, the most critical first step is to shift our focus from plans to planning and execution. To do so will require the development and elaboration of doctrine. Without significant doctrine, our best laid plans will never be translated into action. Being prepared means standing ready to exercise command and control through a fully integrated incident command system. Therefore it is crucial to align the National Response Plan, with the national pandemic influenza strategy and implementation plan. Unless the two fully mesh up operationally, we will have nothing more than a series of plans to plan.

The difficulty of this task should not be underestimated, as the NRP's focus tends to be on events that are geographically and temporally concentrated, not characteristics shared by pandemics. Underlying the NRP is an all-hazards approach which has consistently guided our preparedness efforts. Too often, to our detriment, we have allowed ourselves to be focused on the crisis de jure. Yes, there are important differences when it comes to preparedness for bad weather, bad people, and bad bugs. But we need to leverage the fact that many similarities exist.

Measures undertaken to prepare for a pandemic should not and will not constitute wholly sunken costs even if a pandemic does not materialize. Many of these steps have broader applicability and enable us to maximize secondary and tertiary returns on our investment beyond simply guards, guns, gates. This is an important concept since we simply cannot afford to protect everything, everywhere, all the time, from every perpetrator and every modality of attack. With finite resources, near infinite vulnerability, and a morphing threat, we simply must prioritize our actions based on solid risk management principles.

Public health capacity. This is clearly the touchstone and the foundation upon which everything else rests, and we need to have

nationwide public health infrastructures that make sure we can maintain and enhance the capacities across the board. Bioterrorism in particular merits greater attention, I think, in two areas. First, the strategic national stockpile. There must be a robust capacity not only to deliver needed items to affected communities, but also to rapidly distribute prophylaxis on site. Depending on the situation, I think we can also look to some unique ways to do that by leveraging UPS, the U.S. Postal Service, FedEx, DHL, WalMart and others, all of whom ran circles around the feds after the Katrina response, and I believe there is no shortage of ingenuity and creativity in our communities, but the time to do so is now, not after the balloon goes up.

Second, although our epidemiological investigation capabilities and supporting lab capacity are in much better shape than they were 5 years ago, our biosurveillance capacities still need work. An effective national bioterrorism surveillance system should allow public health and emergency managers to monitor the condition of human, livestock, and crop populations simultaneously, track outbreaks, and act as an alert in the event of an attack.

Nontraditional first responders such as agricultural services inspectors, entomologists, veterinarians, they need to be lashed up into this effort fully. A holistic approach also requires consideration of the pre-hospital piece of the puzzle, and that is EMS. Here again, surge capacity is an issue. The vast majority of EMS systems in this country operate at close too max capacity daily. A large-scale event, particularly a sustained one like pandemic flu, would tax most of our EMS systems beyond their ability to respond unless we are able to ramp up from the ordinary to the extraordinary. We should not be creating little black boxes that say "break glass when something bad happens." The trick should be to make sure we can ramp up from ordinary events to extraordinary events.

Clearly, when we're looking at these issues, vaccination policies and priorities, who gets vaccinated first, is a big issue. If people are afraid that their families are not protected, obviously they will have hesitancy going into harm's way.

I also believe, and in the interest of time, that we need to look at a Goldwater-Nichols Act, not only in the traditional sense, in the military sense, as it aligned budgets, priorities, and plans, but specifically with respect to homeland security and specifically with respect to the health and medical community. That will go a long way in driving unity and unifying plans, programs, policies, procedures, and exercises, where we should make the big mistakes on the practice field, not Main Street, USA.

Let me just touch really quickly performance metrics. What gets measured gets done, but we need to constantly ask ourselves if we are measuring what really matters. I think there is an awful lot more that can go on in terms of performance measures to make sure that there is an alignment between all the funds coming out from DHS and HHS and to make sure that the HRSA grants, the CDC grants, and the DHS grants are based on outcome, performance-driven objectives.

I think that the national planning guidance, the national planning goal, HSPD–8, will do a good job in the 15 scenarios to be able to look to how we can do that most effectively.

Regions. We have got to regionalize our approach, and I can get into that in much greater depth during question and answer. But I think, Senator Burr, North Carolina is the model we should be looking to, not only in terms of mobile hospitals, but also in terms of how they have aligned some of their grants to be able to get an outcome-driven perspective.

I also think there is an area that most people have not touched on and that is community shielding. This is a concept where it is shelter in place. Think of it as shelter in place on steroids, where most people will not shelter themselves even if they are being told to do so, but if they have the right vehicles and mechanisms to distribute food, prophylaxis, and the like, they will be much more likely to do so in the event of a crisis.

Let me just close with a couple of thoughts here. The subcommittee should clearly be commended for its determination to address the difficult issues before us today. Nothing short of a highly sophisticated, multifaceted, and integrated response will suffice. But I am confident that the creativity and the resolve demonstrated by the American people as they have done so often in our history will once again meet the bar, which has been set so high.

I thank you, Mr. Chairman, for the opportunity to share my thoughts.

[The statement follows:]

PREPARED STATEMENT OF FRANK J. CILLUFFO

Chairman Gregg, Senator Byrd, and distinguished members of the Homeland Security Subcommittee of the Senate Committee on Appropriations, it is a privilege to appear before you today to testify on this subject of national importance. Your leadership on preparedness issues related to bioterrorism and pandemic influenza in particular is both crucial and commendable. While our Federal, State and local governments as well as the private sector and healthcare community, have taken steps in the right direction, our level of preparedness remains a work in progress and it is not yet where it needs to be. Five years ago, the Senate Committee on Foreign Relations invited me to testify on the threat of bioterrorism and how we, as a Nation, might best organize and marshal our resources so as to meet that threat and combat the spread of infectious diseases. At the time, I suggested that the country was "at a crossroads" and that, "[w]hile credit must be given where it is due, the time has come for cold-eyed assessment and evaluation . . . ."[1] These words are equally apt today.

Neither bioterrorism nor pandemic influenza is a challenge for the Federal Government alone. It is at the State and local level that the rubber will truly meet the road, and it would be folly to try to micromanage these matters from Washington. What Federal leaders can and should offer, however, is clear guidance to their partners at the tip of the spear, including hospitals and healthcare providers, so that expectations are framed in realistic terms in advance of an event and preparedness plans are implemented effectively. To this end, several pieces of Federal legislation already exist on the bio-defense side, and with respect to pandemic flu, the President issued a National Strategy in November 2005, followed by an Implementation Plan earlier this month. Collectively, these initiatives and many others undertaken help move the ball forward by defining parameters for action and serving as a spur to it. The danger is if we allow these measures to instill a false sense of security, when we should be asking ourselves honestly whether we are truly prepared.

The good news is that important strides have been made. For instance, it is no exaggeration to say that we are a global leader in terms of pandemic preparedness (while recognizing that this is not an area where we can go it alone; to the contrary, international partnerships are, and will remain, crucial). Certainly Secretary Leavitt's national tour, reaching out to all U.S. States to foster tailored, jurisdiction-specific response efforts, is laudable. At the end of the day, though, it all comes

[1] Testimony of Frank J. Cilluffo, "The Threat of Bioterrorism and the Spread of Infectious Diseases," Before the U.S. Senate Committee on Foreign Relations, September 5, 2001.

down to implementation and execution. Yet currently we are experiencing a "plandemic"—a proliferation of plans. Unless and until the focus shifts to competent execution, the nation's preparedness posture will not be solidly grounded.

Similarly, extant legislation concerning bio-defense is in principle an important piece of the puzzle but, in practice, there have been difficulties with applying the law. While challenges including the financing of vaccines and countermeasures have been partly addressed by legislation such as the Project BioShield Act of 2004, delays have plagued the process and framework established by that law. By way of illustration, only a handful of the roughly sixty "material threat" assessments envisioned by BioShield have actually been completed. Further, while BioShield addressed the need for a guaranteed market for countermeasures, the so-called "valley of death" problem relating to investment in advanced development remains, and there is still a lack of clarity regarding who is in charge of the overall effort. This sends the wrong signal to industry and the manufacturing community, which are crucial components of the solution, and is at odds with the public interest.

These areas which could stand improvement highlight a broader issue, namely the convergence of public health and national security. This intersection gives rise to a pressing need for careful coordination of a range of matters including budgets and resources, policies and programs, and organizations and structures. Despite this need, the various moving parts of the preparedness and response enterprise are not yet as synchronized and harmonized as they ought to be. Indeed, ongoing debates such as that over where to situate the National Disaster Medical System (NDMS) suggest that we are still stuck in neutral, and not using our time and mindshare to best advantage. Focusing on where to place the NDMS is a distraction from the real issues, which are function and capacity—where NDMS sits is at best a subsidiary matter, so long as it gets the job done. To do so, the NDMS must be empowered with the authorities and resources required to effectively execute the mission, whether within the Department of Health and Human Services (HHS) or the Department of Homeland Security (DHS).

From Plans to Planning

To shrink the delta and get to where we need to be in terms of preparedness, the most critical first step is to shift our locus from plans to planning and execution. Doing so will require the development and elaboration of doctrine—something that has never been done in a meaningful way for bio-defense. Without significant doctrine, however, all of our best-laid plans will remain paper tigers, never translated into action or operationalized. As we transition squarely into the realm of implementation, moreover, it will be crucial to thoroughly align the National Response Plan (NRP) with, among other things, the National Pandemic Influenza Strategy and Implementation Plan. The potential for conflict clearly exists given the NRP's focus on events that are both geographically and temporally concentrated—characteristics not shared by the pandemic phenomenon. Being prepared means standing ready to exercise command and control through a fully integrated incident command system. Unless the NRP and the President's Implementation Plan fully mesh with each other in actual operational terms, we will have nothing more than a series of plans to plan.

Leveraging an All-Hazards Approach

Underlying the NRP is an all-hazards approach, which should consistently guide our planning and preparedness efforts. Too often, and to our detriment, we have allowed ourselves to become focused on the "crisis du jour." While recognizing that there are important differences when it comes to preparedness for bad weather, "bad guys," and "bad bugs," we should aim to leverage the fact that many similarities exist. Measures undertaken to prepare for a pandemic, for instance, will not constitute wholly sunk costs even if a pandemic does not materialize. Many of these steps will have broader applicability and we should bear that in mind while also seeking to maximize secondary and tertiary returns on our investments, beyond simply guns, guards, and gates.

Public Health Capacity—The Touchstone

Our medical and public health response structures are the foundation upon which all else rests. To meet the challenges posed by bioterrorism and pandemic influenza, these structures must be shored up and bolstered. A uniform system, whose hallmark is enhanced public health capacity, must be built nationwide. Every community must have surge capacity. Admittedly, this is an ambitious goal, especially when market forces press in the opposite direction, against the creation or maintenance of any excess capacity. It is also important to consider that the safety net that is the NDMS may be of limited value if there is a need to maintain those healthcare practitioners in their local communities. The challenge is not insurmountable

though, and Homeland Security Presidential Directive 8, which establishes the National Preparedness Goal (NPG) and accompanying scenarios, demands nothing less. Expanding the medical reserve corps would certainly be one step in the right direction.

Concerning bioterrorism in particular, two areas merit heightened attention and focus. First, with respect to the Strategic National Stockpile (SNS), it is crucial that there be a robust capability not only to deliver needed items to affected communities, but also to rapidly distribute prophylaxes once they have arrived on-site. Depending on the situation, it may be possible to convey the relevant items directly to affected residents. When a healthcare provider is not required in order to administer the treatment, it may be possible to draw on existing distribution and delivery systems, such as that of the U.S. Postal Service or other private sector entities like FedEx, DHL, UPS, and Wal-Mart. There is no shortage of ingenuity and creativity in communities across the country, but the generation of ideas should take place now, in advance of an event, and feed into planning efforts that should also be ongoing currently, at the local level.

Second, although our epidemiological investigation capabilities (and supporting laboratory capacity) are in better shape than they were 5 years ago, our bio-surveillance capabilities still need work. An effective national bioterrorism surveillance system would: allow public health and emergency managers to monitor the condition of human, livestock, and crop populations; track outbreaks; and act as an alert in the event of an attack. (This list is merely illustrative, not exhaustive). Non-traditional first responders, such as agricultural services inspectors, entomologists, and veterinarians, must have a seat at the national security table, and their expertise must be lashed up and fed into the broader surveillance effort. Moreover, since "bugs" know no borders, partnerships at the international level are important, and the United States should continue to work with the World Health Organization (WHO) to monitor infectious disease trends and outbreaks. Similarly, with U.S. military services deployed around the globe, our military medical organizations may provide us with a sentinel system to monitor a multitude of health environments and serve as an early warning system.

A holistic perspective on preparedness for bio-terrorism and pandemic flu also requires consideration of the pre-hospital piece of the puzzle, that is, emergency medical services (EMS).[2] Here again, surge capacity is an issue. More often than not, EMS systems in this country operate at close to capacity on a day-to-day basis. A large-scale event, particularly a sustained one, would tax the majority of our EMS systems beyond their ability to respond unless we commit now to focusing, with unprecedented determination, on the ramp-up from the ordinary to the extraordinary. In connection with such efforts, perhaps we should examine the merits of creating an equivalent to the Emergency Management Assistance Compact (EMAC), not only for EMS but also for the public health system more generally. In any case, expansion of operational capabilities should not take place in a vacuum—supporting policy and doctrine must be developed concurrently. Continuity of EMS operations may not be assured if EMS providers fear that their own families may not be taken care of during extraordinary times. This issue resonates across the board with all first responders, and highlights the need to think through carefully the implications of allocating and prioritizing the distribution of finite amounts of vaccines, antidotes, and the like.

A Goldwater-Nichols Equivalent for Public Health

Honing our technical capacities alone will not be enough. Intangibles are an equally important element of the equation. Specifically, a culture of preparedness that is common to the health sector and the national security sector alike, as well as beyond, is the glue that will hold together the sprawling enterprise that is our national preparedness and response system. Cultural change is notoriously difficult to bring about, but it is absolutely essential that we cultivate the mindset that will support the convergence that has taken place on the ground, between public health and national security. The two are now inextricably and indisputably intertwined, and only if a genuine culture of "jointness" prevails will we be able to achieve in practice the requisite reforms to our system, be they structural, procedural, budgetary, programmatic, or policy-related. Notably, this is a two-way street: the national security community needs to be well versed in public health matters where the two domains intersect, just as healthcare providers and medical experts need to be fluent in the language and practice of national security.

[2] For a more detailed examination of EMS issues, see: Homeland Security Policy Institute (HSPI) Issue Brief, Back to the Future: An Agenda for Federal Leadership of Emergency Medical Services, May 2, 2005.

Put another way, perhaps a Goldwater-Nichols equivalent is needed for the homeland context and for the public health and medical arena in particular. In recent testimony before the Senate Homeland Security and Government Affairs Committee, during their after-action hearings on Hurricane Katrina, I emphasized that the challenge of successfully executing interagency coordination is age-old and that, although we probably should never transpose wholesale a military model into the civilian context, there is substantial merit in looking to the military context given its success in institutionalizing the concept of jointness.[3] As you know, the 1986 Goldwater-Nichols Act unified and streamlined the defense structure, and realigned budgets accordingly. Over time, greater cohesion has resulted in heightened effectiveness. A Goldwater-Nichols equivalent for the homeland should not be limited to the Federal level, but should apply also between and among the States themselves.

Performance Metrics, End-States, and Budget Realignment

As a starting point, better and sustained coordination (at all levels) between the Departments of Health and Human Services, and Homeland Security, is sorely needed. By way of illustration, both HHS (the Centers for Disease Control and Prevention, the Health Resources and Services Administration, and the National Institutes of Health) and DHS are directing substantial funds towards bio-terror and pandemic preparedness and response initiatives. Yet, these monies are not being distributed or allocated according to a streamlined and well-coordinated process. Instead, there is a multiplicity of funding sources and the left hand does not always know what the right hand is doing at least in so far as grants are concerned. An outcomes-based system, with built-in performance measures and metrics, would go a long way towards remedying the present situation. By focusing on end-States and capabilities, just as the outcome-oriented NPG scenarios guide us to do, and by giving life to the adage "what gets measured gets done," both our goals and the paths to achieving them would be clarified. Realignment of budgets, and coordination of the various departmental and agency funding streams would follow, as a logical corollary. This level of organizational rigor would promote an efficient and effective use of our limited resources. It would, after all, break the bank if we were to try to fight each "bug of the day" with vaccines, antidotes, and prophylactics.

A more harmonized approach at the Federal level would also serve the nation well. As things now stand, no common threat assessment exists in the form that is truly needed. This is a disservice to us all. At the very least, the various departments concerned should be looking to one another to remain informed, and relevant information should be disseminated to the frontlines, where it may be acted upon.

A Regional Approach

It is on the frontlines that the bulk of decisions during an event will, and should be, made. For this reason, we need to build capacity in the field, and regionalizing our national preparedness system—the linchpin that connects all of the elements of our preparedness and response—is, to my mind, perhaps the best way to build the robust capabilities that we seek to achieve on the ground. Co-locating Regional Health Administrators with regional components of DHS and field components of DOD as well as other stakeholders, including representation from the private sector, would foster synergies and forge strong partnerships before disease or disaster strikes. In turn, these bonds would (among other things) facilitate the management and deployment of the SNS and the NDMS. Encouragingly, it appears that DHS is, in fact, expecting to establish a planning mechanism through joint field offices that would serve as a framework for coordinating response for all levels of government (including any military joint task forces that may be established), non-governmental organizations, and the private sector.

A muscular regionalized system serves the best interests of the States and their governors by providing the latter with an all-purpose Federal point of contact that is well-versed in the particularities of a relevant area. Conversely, from a national perspective, regionalization offers a means of unifying planning, training, and exercising efforts—a prerequisite for identifying and developing needed Federal, State, and local capabilities and capacities. Looking forward, HHS and its regional coordinators should be consistently plugged into DHS' exercise schedule, and future exercises should specifically focus on bioterrorism and pandemic influenza scenarios. At a time when the convergence of public health and national security is plain, it is at our peril that we allow any disconnect to persist. It should also go without saying that after-action "hotwashes" should be conducted to identify lessons learned during exercises, and that such lessons should then be fed back into the system in order

[3] Testimony of Frank J. Cilluffo, "Hurricane Katrina: Recommendations for Reform," Before the Senate Homeland Security and Government Affairs Committee, March 8, 2006.

to prevent the same mistakes from being made once again as well as to benefit those who were not party to the actual exercise.

Taking a regional approach to hospital preparedness would also be valuable, though most hospitals are not now regionally oriented in their planning, activities, and outlook. Exceptions to the rule include the National Capital Region (NCR) and North Carolina, where real regional medical capabilities exist in the form of mobile hospital capacity. The lessons learned from these experiences should serve as a model for the country as a whole, demonstrating the benefits of joint planning and exercising between and among hospitals at the regional level.

Although limited regional surge capacity remains a significant problem, it is undeniably mitigated by surge protection—a strategic solution known as "community shielding." A recent study of the NCR revealed that many area residents would abandon their protected home and work environments during a contagious epidemic, despite government instructions to shelter-in-place. However, if there is an effective mechanism for community shielding through distribution of food, water, medication, and information to those who need it, those potential evacuees would in fact follow instructions, thereby enhancing community resilience by remaining safely in their homes and localities until the regional threat has abated.[4]

Key Partners

In our zeal to "get it right" when it comes to preparedness for bioterrorism and pandemic influenza, we should take care not to stretch too thin those assets that have proven their worth time and again in many and varied contexts. Our military forces proved to be able and responsive in the aftermath of Katrina and, as the saying goes, "no good deed goes unpunished." This month alone, the National Guard has been assigned a significant role in furthering border security as well as implementation of the National Strategy for Pandemic Influenza. While the National Guard brings valuable skill sets to domestic needs, the Guard has a dual character and mission, and its war-fighting aspect should be respected and retained. Moving forward, it will be important to bear this bigger picture in mind, and exercise caution and balance accordingly, when drawing and planning to draw on such treasured and proven national resources.

The nature of the challenges before us dictate that everyone be involved in preparing for them. It is no exaggeration to suggest that this is not only a community-wide responsibility, but also an individual one. Families, schools, places of worship, and business—all have an important role to play in containment of infectious disease, and all must be well integrated into the operationalization of relevant strategies and plans. Personal preparedness will take on a much greater importance in pandemic influenza than even natural disaster. Ultimately, it will be up to individuals to take personal responsibility for their own support, namely enough food and water should they be required to stay at home. Framing expectations in advance will be necessary to avoid hysteria. Just last week, Buncombe County, North Carolina, provided an excellent example of a local physician and the local media partnering to manage expectations and to let people know that they will not be able to rely on State and local governments, in particular health departments. There, a small newspaper in Asheville published an editorial piece written by the doctor in question, stating that the Federal and State governments have outlined what they will need to do to respond to pandemic flu, but in the final analysis, "[o]ur job as citizens is to be informed and prepared."[5]

Preparing for bioterrorism and pandemic influenza also requires robust partnerships between the private and public sectors. At the same time, each sector must do its utmost to put its own house in order. While a majority of U.S. businesses have expressed their concern about pandemic flu, only a much smaller fraction have actually done robust continuity of operations planning, which is crucial to maintaining critical infrastructure operations and services in a crisis.[6] During and after Hurricane Katrina, however, the private sector was a tremendous source of both mate-

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[4] M.T. Williams, G.B. Saathoff, T.M. Guterbock, A. MacIntosh, and R. Bebel, Community Shielding in the National Capital Region: A Survey of Citizen Response to Potential Critical Incidents (Final Report, Volume 16), September 2005, http://cipp.gmu.edu/archive/Vol-16-%20Community%20Shielding%20in%20the%20NCR.pdf.

[5] Marilyn A. Roderick, "As threat of the avian flu looms, one question remains: Will we be ready?" Asheville Citizen-Times (May 16, 2006). See also David Heyman, Model Operational Guidelines for Disease Exposure Control (Center for Strategic & International Studies, 2005), at http://www.csis.org/media/csis/pubs/051102_dec_guidelines.pdf [offering detailed guidance on non-pharmacological measures that public officials and individuals could take for protective purposes].

[6] David Brown, "Business Plan for a Pandemic? Most Firms Haven't Prepared for Possibility of a Global Outbreak," Washington Post (May 2, 2006), p. D1.

riel and expertise, including logistical support. Industry, and particularly "Big Pharma," offers a wealth of knowledge that must be thoroughly tapped for present purposes. With proper incentives, the private sector's research and development capacity, and production capability, could be fully marshaled and harnessed for national ends, with striking results. Incentives offered by Project BioShield have been insufficient to garner the full support of investors, whose support of the fledgling countermeasure industry is critical. To the extent that prevailing legislation and frameworks come up short in their incentive structure, it is crucial to complement those measures with needed new ones, and to re-structure and redesign existing mechanisms in a more rational, market-oriented manner that effectively addresses potential deterrents such as liability issues, and profit and cost factors. The "DARPA-like" proposed Biomedical Advanced Research and Development Authority, contained in bill S. 2564, could serve to assist companies in crossing crucial thresholds and allow relatively advanced products to actually reach the marketplace. In order to make progress on this front, it is imperative that industry perceive the Federal Government to be a reliable partner in this endeavor.

Conclusion

As we strive to create a performance-based, outcomes-driven preparedness system that is responsive to all hazards but also to the unique needs under study at this hearing, it must be remembered that policy without resources is rhetoric. Though redressing a number of the gaps and shortfalls in our preparedness posture identified herein will turn less on matters of financing than on other issues, in some cases funding will be essential to realizing requisite unique capabilities. The SNS is but one area which would benefit strongly from an injection of new monies, specifically to "plus up" its contents. Not only are the caches for that "very bad day" insufficiently supplied, but our current stock of basic but fundamental items such as facemasks and ventilators is simply not adequate, and the same is true of certain drugs and countermeasures. Dual-use elements that are also instrumental to the provision of "ordinary" or day-to-day medical care should be viewed as sound investments that will yield significant rates of return—an important fact and a feature that is consistent with a system founded on accountability and on end-State capabilities and capacities. Throughout, it bears remembering that what gets measured gets done, though we need to make sure that we are always measuring what matters.

The Subcommittee should be commended for its determination to study the difficult issues before us today. Tempting as it might be to alter focus, and direct time, money, and energy exclusively to other less complex challenges that might be easier to master, it would be a mistake to do so. The scale of the challenges under examination today is undoubtedly large, and even an entity the size of the Federal Government cannot tackle these issues alone. Northing short of a highly sophisticated, multifaceted, and integrated response will suffice—but I am confident that the creativity and resolve demonstrated by the American people so often in our history will once again serve as a solid foundation upon which to build as we endeavor to meet that bar which has been set so high. Thank you and I would be pleased to try to answer any questions you may have.

The George Washington University Homeland Security Policy Institute (HSPI) is a unique, nonpartisan "think and do tank" that builds bridges between theory and practice to advance homeland security, through a multi and interdisciplinary approach. By convening policymakers and practitioners at all levels of government and the private sector, HSPI creates innovative strategies and solutions to current and future threats to the Nation.

Senator GREGG. Thank you very much.

Those were excellent presentations and I appreciate that you were under time restraints.

What I am going to do now I think is recess this, and then Senator Burr is going to come back and chair as soon as he votes. I will have to do this and then I want to come back. I have got a whole series of thoughts and questions I want to engage with you on.

So this is a typical Senate situation. They always call votes in the middle of hearings that are interesting and important and we have to rush off and vote and then come back. So if you do have the time, we hope you will be able to stay and indulge us for this

vote, and then I suspect Senator Burr will be back about quarter after, and I will try to get back here by 11:30. Thank you.

We will recess until Senator Burr returns.

Senator BURR [presiding]: I call the hearing back to order. I will take whatever time that we need to until Senator Gregg comes back. Let me thank all of you again for your willingness to be here.

I asked the question last week of my committee staff, should we take the fact that we have not heard anything publicly about pandemic flu as publicly as we did for literally the entire first part of this year as a sign that the concern is over with. I was very quickly pointed to an article of May 18, with an additional seven cases of human infections in Indonesia, six members of an extended family all dead, at this point no sign of human to human transmission. This is the largest cluster of cases closely related in time and place reported to date in any country and is being carefully investigated.

I put that into the record for the purposes of suggesting to other Members of the United States Senate that might not have seen it prominently placed on the evening news or the front page of the morning paper that pandemic threats are not something that are here today and gone tomorrow. Until the scientific community and health community looks at it and says, this particular strain is no longer a threat, there has to be a very concerted effort on the part of the United States, on the part of the world, to prepare for.

I draw that distinction because I think somebody's testimony talked about plans and preparation and we are at the point that we need to be in the preparation stage.

Mr. Offit, let me turn to you for just a second. Are children more susceptible to becoming ill from pandemic flu? And do you know of any special considerations that would impact our planning as it relates specifically to treating children for pandemic?

Dr. OFFIT. It depends on the virus that is causing the pandemic. So for example, the 1918 pandemic, which has certainly gotten a lot of play following John Barry's book, that virus caused a very interesting problem, which is that when it infected people it actually turned their immune systems against them. So it would infect these specific kind of cells that actually present foreign proteins, including viruses, to the immune system and it would cause those cells to make large quantities of a protein, proteins called cytokines. It would induce this phenomenon of cytokine storm. So just paradoxically what happened in 1918 is it was the healthiest people among us, the sort of 20 to 40 year olds, who died disproportionately of that disease because they had the healthiest immune systems, therefore they made the largest quantities of this protein.

So I think, so there is an example where children were especially at risk for death. Now, traditionally children are actually the reservoir of flu. So if you look at the way flu spreads across our country or other countries, it usually goes from children, and that is why the 1957 pandemic that I talked about started in schools. It started in church congresses and schools. It started in September because that is when schools got, all those kids got together.

So they are often the reservoir of infection, and so that is why I think they are a perfect group to target because you target the reservoir.

I think in terms of treatment, if you are talking about agents like Tamiflu, ossiltamavir, it again depends on the virus. I think, for example, if you took Tamiflu back to 1918 I honestly do not think it would have made much difference, the reason being that what Tamiflu does is it prevents the virus from reproducing itself, from replicating. I am not sure it would have done anything for a cytokine storm.

Senator BURR. If in fact we were exposed to a strain like 1919, that healthy community that you talked about that was most susceptible died how quickly?

Dr. OFFIT. Very quickly, within 36, 48 hours. I will say this. Children still die of that kind of phenomenon. I tell you, we had a child last year in our hospital who came in, a healthy 11-year-old, no risk factors, boy, who within 36 hours died of flu, and came into our hospital laughing and making jokes. So it can be overwhelming. That child was treated with ossiltamavir very early in its course; it made no difference.

I got the feeling from watching this child go from face mask oxygen to a ventilator to an oscillator to a heart-lung machine to his death that if we had taken our entire intensive care unit and transported it back in time to 1918 we would have had the same effect, which is no effect.

One thing I just wanted to pick up on, the business about whether our interest in pandemic flu is maybe fading a little bit, is that I think the one, it is not a mistake necessarily, but I personally, as do many scientists, do not believe that this particular bird flu, this H5N1 strain, is going to be the next pandemic strain. It just, it is not transmitted easily from person to person, and H5 viruses never have been and they have been around for 100 years. This virus has been around for about 9 years.

So I do not think this is going to be the pandemic strain. But the good of all this preparedness is that there will be a pandemic. There are three pandemics a century. There is no reason to believe this century is spared, will be spared. So I think getting things in place to get ready for that is all a good thing.

Senator BURR. Well, we all hope that in fact you are right and those that have suggested that this strain may not be the one—and I think that supports the reason that anything that we do and everything that we do should be an all-hazards approach, that we should use this opportunity to make sure, not knowing what that threat is or what that strain is, but knowing that it is down the road, or that new biologic threat or chemical threat, or in fact something else that Mother Nature throws at us, that we have got an infrastructure that is able to adapt to whatever in fact we throw at it.

Let me just ask you one more question about children, because I think you reference to the fact that historically they are the source of spreading this infection. Who decides when to close the schools? If H5N1 becomes the pandemic or if next year there is a pandemic with a different strain, is it the local community, is it the State, or is it the Federal Government that triggers that?

Dr. OFFIT. I am not sure I am the one to answer that question. But I will say just this one thing. There was a study done in Japan a number of years ago, just to sort of amplify your point, where

they immunized all children below 5 years of age. What they found was that not only did they decrease hospitalizations and the less common deaths in that group, they decreased hospitalizations and deaths in the elderly.

So when you attack the reservoir, in this case children, you really have an impact on all people who come in contact with children. When the elderly die of this disease, they die often because they are coming in contact with children. But in terms of the logistics of who closes schools, I am not the one to answer that question.

Senator BURR. So if the health professionals that are tasked with the job of determining who is vaccinated first, given that you have a delay in full production—where would you tell them children fit?

Dr. OFFIT. You are asking a pediatrician, but I would obviously put children first on the list.

Senator BURR. Yes, but I truly believe that you look at it from an overall perspective.

Dr. OFFIT. That is true. I think that is true. I think if you are trying to—the disease invariably starts in children. They are commonly hospitalized. They do not die as commonly, obviously, as the elderly, but they are typically the source. That is true of many viral infections. This is sort of the opposite of whooping cough, where adults and adolescents give the disease to children. This is the opposite of that.

Senator BURR. Dr. Lillibridge, you talked about an all-hazards approach, but you also mentioned something really important that I would like you to expand on. Clearly, your prior life gives you some degree of expertise on this. How important is the structure of our logistics plan, from a standpoint of how we respond to this or any threat?

Dr. LILLIBRIDGE. Senator, I think our logistics plan in support of regional planning or our preparedness strategy is extremely important. Let me emphasize that health care organizations are typically weak or absent in their capacity to have logistics mobilization, staff, support, field units, or even expanded units in warehouses, hotels, and so forth, if you need supernumerary beds in a major epidemic.

We have looked at that. We think that there are probably two ways to begin to look at that. One is partner with the private sector; second, deal with larger organizations that have internal logistics. For example, when expanding health and medical services during Hurricane Katrina, Houston had somewhere between 100,000 to 200,000 people come into our town. We put them in the Dome, in the Coliseum activity, and we supported them with two field hospitals.

Now, that worked because each of those field hospitals were supported in turn by health care organizations that had multiple hospitals and logistics capacities in place to nurse, resource, and to service those things. I think it is those kinds of arrangements as you begin looking through HMOs, academic health centers, large hospital organizations, that are going to be extremely important.

The second part is that there may be a security element with the logistics support or a rugged field element of airplane transportation, security, and so forth. We have always thought and made a decision to do this in the private sector, but always thought at

CDC early in the inception of this program that maybe the Department of Defense or an organization like that needed to be intimately involved when you needed to have a no-fail transport in a security context, as in a bioterrorism attack or an event like Katrina, where law and order were clearly at a premium.

Senator BURR. Let me ask the same question in a slightly different way. Does the Federal Government understand the importance logistics will play in our ability to meet the threat?

Dr. LILLIBRIDGE. Sir, I think they understand the issue of logistics when it comes to standard emergency management. I think we have yet to learn the lessons of resourcing and providing logistics support to health and medical operations in the field.

Senator BURR. I look at the national stockpile and question whether today we could move the stockpile to the place that we need it in a timely fashion to meet the current threat. It is a concern that many on the Hill have engaged, not just this administration but past administrations, and will future administrations, the importance to plan and to prepare.

I know that we have looked at all sorts of options on logistics. But I am not sure in the Federal plan that a determination has been made on this piece and whether we are going to hand it over to DOD, or use UPS, or use the Postal Service. To me, that seems like one of the most important things for us to get an answer to, because if it were to happen tomorrow we would not be prepared to execute that piece. I see that as a vital piece and a necessary component.

Agree, disagree?

Dr. LILLIBRIDGE. Senator, I agree. Let me frame it how I see this. One is we cannot get to those kinds of decisions and cooperative engagement unless we can fix the sort of medical high ground and make the decision what really needs to be in the stockpile and then organizationally frame it in an organization to make those decisions.

Senator BURR. I agree totally.

Mr. CILLUFFO. Senator Burr, if I could just expand on that, because I think you are hitting the crux of much of the operational side of the issues here. There is an old Marine adage: Amateurs talk strategy, professionals talk logistics. Quite honestly, it does come down to logistics, logistics, logistics, supply chain, and to make sure that you have a requirements-driven process put in place.

One of the take-aways after Katrina was you do not necessarily want to say, we need 5,000 MREs. What you ultimately want to have is a system or a requirements system in place that says, we need to be able to feed 5,000 people for 3 days, and then you find the best way to be able to meet those needs. The military has done that well and they have got the scar tissue and learned the lessons the hard way to be able to do that most appropriately.

I do not think that that has been translated as robustly as we need it in the domestic context. So I do think you are hitting a key issue.

Mr. CLERICI. Senator, if I may just add one comment. There is a commonality between your question to Dr. Offit and your question to Dr. Lillibridge. At least in the area of influenza and the

area of influenza vaccines, we run a war game every year. We vaccinate people every year for annual influenza, and we need to do that in order to keep public health.

That is a good thing because at least there is a system in place to get, depending on what kind of year it is, 70 million doses of vaccine out to the American people. With respect to pediatrics, if we can increase that penetration up to 18 years old, then that war game, if you will, is going to be run in the event of a pandemic, all the better. And when you are dealing about annual vaccine, if we look at the supply chain distribution, there is only a handful of providers of licensed vaccine right now. We can look at the way that they are doing things and try to emulate that, and also drive that demand up because there is no down side to vaccinating more people annually. That is only a good thing. If we get that demand up to where the market can sustain it, the manufacturing base could sustain it, the logistic transport can sustain it, and we have enough vaccine for kids all the way up to the elderly, then when the pandemic hits all we just do is turn the system around, secure it, make sure that there is security surrounding it, make sure that there is authenticity measures surrounding it, and we are off and running. That is a great opportunity that we have with the annual flu vaccine program, to build from that and learn from it.

Senator BURR. Let me throw one last question out to anybody that would like to address it. Can we address a pandemic threat or any other potential threat that we will face in the future without redefining the face of public health in America?

Be brave, Dr. Lillibridge.

Dr. LILLIBRIDGE. Okay, Senator, I will take that one. One of the things I think is refining and developing the public health infrastructure is extremely important. We have put an effort that largely concentrated on that with our first $28 billion that we put in the last 6 or 7 years. I think there are some things we need to redirect, to think about how we get more value out of that money in the future in terms of building preparedness, that looks the same or has an all-hazards approach, whether you are dealing with radiation exposure or a pandemic influenza.

The kinds of things that we talked about with leadership organization are important. The surge capacity, building the clinical element, needs to get under the tent this time, and we need to galvanize our academic health centers. I think we need a better training doctrine, and get those solidified.

But I think you are going to have to make a shift from infrastructure and public health building into national preparedness around health and security if you are going to get more value out of these dollars in the future.

Senator BURR. Can you have a Federal response plan or a State response plan without public health having a uniform consistancy of services that are provided everywhere in the country?

Mr. CLERICI. I think you are absolutely right. I think you need the bedrock of surveillance, laboratory detection, and a basic public health infrastructure. But you also must have an honest purchase on the preparedness measures that you need in place to build those capacities. I honestly believe North Carolina is the model. I have worked there extensively lately and they have what I think is a

good tradeoff between infrastructure, training, capacity-building from the public health base out there to the critical capacities they need to respond regionally. And they have built a system that can respond nationally.

The North Carolina system responded admirably to bring hospitals into Mississippi and provide health care on a State emergency management compact. That is a real model.

Senator BURR. Dr. Offit.

Dr. OFFIT. Just to extend what Dr. Lillibridge said, it has started to happen. It is interesting, the CDC has started to sing a different tune regarding influenza, epidemic influenza preparedness. So a couple of years ago they increased their recommended group to include the healthy 6 to 23 month old, and in the last year the healthy 6 month to 5 year old. That has really for the most part exceeded the capacity of physicians' offices to give vaccine. You are talking about giving a yearly seasonal vaccine to basically your entire group, meaning less than 5 year olds.

My wife is in private practice pediatrics and so what they have done, what she has started doing, I think what many people are starting to do, is they are trying to sort of expand out so that, for example, you have school-based programs. So that has changed things a little bit. So now, because we are expanding the vaccine recommendation in children with hopefully a goal toward a universal recommendation, I think you have to get it at some level out of the physician's office into the community, and that all works toward pandemic preparedness.

Mr. CILLUFFO. Senator Burr, could you briefly expand on that? I do think that it is the cultural things as well. I think Scott touched it at the end. It is the health and security. Right now the two are treated to some extent as if they are mutually exclusive, short some of the implementation plans and the national strategy that came out recently. These take time, though. This is not something that instantaneously can merge and converge.

But I do think that unless you look at it through the full, not a particular lens, but a prism that reflects both those perspectives, it will not occur. You cannot expect the public health infrastructure to suddenly have all the transportation assets that perhaps Department of Transportation or DOD or some of the other entities do. They are going to have to leverage and ramp up from the extraordinary to the extraordinary, to certain capacities and capabilities that reside through the country.

The way I look at it, it is Federal, Federal-State-local, Federal-State-local-community, Federal-State-local-community down to the individual. In this case, unlike most natural disasters, the role of the individual is very significant in terms of what they can do to better protect themselves, their families, and their communities from the spread of infectious disease.

Senator BURR. Once again, I thank the witnesses. I thank the chairman for allowing me to participate in this hearing, and I turn everything back over to the chairman.

Senator GREGG [presiding]. Well, it is great to have you here. You are leading the efforts here in the Senate and we very much appreciate your leadership on this, Senator.

Senator Kohl.

Senator KOHL. Thank you very much, Senator Gregg.

As ranking member on the Aging Committee, I chaired a hearing last week on emergency preparedness for seniors. As you know, seniors are particularly vulnerable during emergencies, a point made clear during Hurricane Katrina, where 71 percent of the people killed were older than 60, and our hearing witnesses told us that seniors need more information to prepare for emergencies, first responders need better training to help seniors, and communities need better plans to locate seniors who live alone during and after an emergency like the pandemic flu.

Do programs exist to train first responders and medical professionals to meet seniors' needs in the event of a pandemic flu outbreak? Should the Federal Government provide funding for programs such as these at the State and at the local level? Do we have programs that particularly focus on seniors? Should the Federal Government take an active role in developing these programs? Do first responders have the resources to do this?

What is the role of the Federal Government in this whole area as it relates particularly to seniors?

Dr. LILLIBRIDGE. Sir, I will take a stab at that, Senator Kohl. There are two things. One is that there are programs in HRSA, the Health Resources and Services Administration, to deal with preparedness for seniors and for that segment of the population. It is not one of our biggest programs and certainly could be expanded. One of the two things that I think would be a good direction to go was educating the health providers that interface with seniors. That was a powerful way to provide training. The second was community outreach to assist them at the time of crisis with the things they needed to do to help make themselves safe. Those have been the thrust of these programs in the past.

My impression is they could certainly be expanded and better integrated if we had a larger and more robust educational program targeting our health providers.

Mr. CLERICI. Senator, I am aware that at least HHS has categorized and looked at special populations, and I would imagine that both seniors living alone as well as seniors living in retirement homes or collective areas are a targeted population, much like students living in a dorm room. Any time you have a collective living situation, the planning needs to go into that.

So I would hope that HHS has taken into account the types of resources as well as the type of surge capacity that might be required or taps on other resources that seniors might be living with that might get redirected in the event of a pandemic perhaps to other areas. So I believe that is part of their plan, but I do not have any great clarity into how much that has risen through the ranks.

Mr. CILLUFFO. Senator Kohl, just to expand on that and to lead back to a previous point. I do think there are special needs populations in general, not just seniors but many others, that we need to be able to target, different languages, different cultures, different perspectives, so we can actually induce changes of behavior or initiate action; that we have got to continually improve our capacities.

But I do not think that we should look at it in isolation of our other plans, programs, and procedures. Quite honestly, it is going

to be the EMS, it is going to be those that deal with these sorts of situations every day, that need to build in and build the capacity to surge, not to create a separate program per se targeted, obviously, to meet the special needs, but ultimately it is going to be the people who act and respond. You need to make sure that they are up to date.

There are some programs within EMS, the EMS community, to deal specifically with seniors and geriatric programs that I think could potentially deserve a boost. I do not know what the budget numbers are here and I know policy without resources is rhetoric, so I am coming out of this a little blind.

But I just want to underscore that it needs to be part of a holistic approach. I do not think we should bifurcate some of those responses, but rather enhance capacities of those who respond to crises on a daily basis.

Senator KOHL. Well, generally speaking I would not disagree with you, but we need to, I think, learn from Katrina, where again 71 percent of the people who were killed were over 60. So it does, I think, dramatically illustrate that the seniors population is not like all the other segments of our population, for all the reasons we can understand.

Mr. CILLUFFO. You are right, Senator.

Senator KOHL. Another question. Many seniors live alone and rely on others for transportation, supplies, and information. One Florida county that we heard from last week set up a voluntary registry so that first responders will know where to find seniors who need help during or after an emergency. Do you think that the Federal Government should participate in helping to set up such registries as part of national preparation for an outbreak of pandemic flu?

Dr. Offit.

Dr. OFFIT. I do not think I am the one who is best to answer that question. I would turn it over to Dr. Lillibridge.

Dr. LILLIBRIDGE. Senator, I will tell you that at the State and local level we are increasingly in the planning of preparedness activities related to flu and so forth, beginning to look at which community outreach things can we do to better identify and get services to the elderly population at the time of crisis. So whether it is a registry or a better planning function or a block captain, how that unfolds at the State and local level is unclear to me which is best. But I know that greater emphasis in that area is needed.

We had the tremendous evacuation activity post-Katrina, just before Hurricane Rita, when we thought when a level 5 hurricane was going to hit Houston. It veered to the east and missed us. But we lost a lot of people on freeways, on transportation, and we learned that our vulnerable population is going to have a lot of trouble mobilizing, getting cared for, without preplanning.

So those are now part of our routine planning elements in Texas as well as in other States.

Mr. CLERICI. Senator, without commenting on whether it is a State, local, Federal, or family responsibility, I do think that, as Mr. Cilluffo said, we need to kind of think one step deeper. It is not just EMS care if we are in a pandemic. It is whether they can get food, whether they have the ability to transport, to get to a gro-

cery store, and whether the shelves of the grocery store are full when they get there.

So the whole supply chain issue as it impacts not only the distribution of critical countermeasures, not only vaccines and therapeutics and respirators, but also food, water, clothing, medicine, typical medicine, not just the medicine to treat a flu. What happens when 40 percent of the workforce is sitting home in the event of a pandemic and how those populations are impacted?

So those are the issues, I think, that are probably the next level of penetration in the Nation's thinking and preparedness. To Frank's point, those do not only necessarily hit just pandemic. That is any natural disaster.

Dr. OFFIT. One point just regarding vaccines. As compared to say 50 years ago, the demographics of our population as the baby boomers get older has gotten older. Traditionally, what the CDC has done, and I think in retrospect maybe not best, is to target the greater than 65 year olds: Here is a person who is most likely to die; let us make sure this person gets the vaccine.

But the fact of the matter is that people at greater than 65 years old do not make a great immune response to the vaccine, they do not. Their immune response in general is not what it was when they were 18 or up to 30. So therefore it becomes all the more important, I think, to try and immunize those people to whom they are most likely to be exposed. In this case, young children, that is certainly true.

I think the Japanese experience, where they immunized children less than 5 and had a dramatic decrease in the number of deaths in the elderly, I think was instructive. Just a point. The greater than 65 year old is not great at responding to flue vaccines.

Similarly, the other difference between 1957 and now is that we have a lot more people who are immune compromised. We use steroids a lot more than we did, we do solid organ transplants and bone marrow transplants. So we have a much greater population that are immune compromised. Now, that came up I think with the smallpox vaccine, fears associated with contact spread of smallpox.

Mr. CILLUFFO. Senator Kohl, and this may suggest asking a little more from some of the NGOs as well as the Medical Reserve Corps and some of these other entities that can perhaps plan a more active role in that special needs community, because, unlike in the Katrina event, in most cases we are going to want to shelter in place. The last thing you want to do is evacuate and put everyone in a common place where it could spread that much more quickly.

So I think that perhaps this could be a mission area for the Medical Reserve Corps to play a more active role, not to mention many seniors are very active in the Medical Reserve Corps, playing an active role in protecting one another, and that should not be lost in this, is that there is so much talent that we want to be able to tap into that may not be in the traditional way tapped into, and to be able to do that.

Senator KOHL. I thank you for your comments, gentlemen. It has been very helpful.

Thank you, Senator Gregg.

Senator GREGG. Thank you. Thank you, Senator.

Senator Allard.

Senator ALLARD. Thank you, Mr. Chairman.

My question I guess I would direct to Dr. Lillibridge or Dr. Offit. How do you assess risk with a disease that, according to the last time I looked at the CDC web page, we have only had one documented case of human to human transmission? We have lost thousands of birds, but just a few people have actually contracted influenza relatively speaking to the bird population, and it does not occur yet in this country.

So how do we assess risk to the population in America?

Dr. LILLIBRIDGE. Do you want to go first?

Dr. OFFIT. I think that traditionally with typical epidemic influenza those most likely to die are those greater than 65, those who have chronic medical conditions such as problems, chronic conditions of the lung, heart, kidneys, etcetera. That has traditionally always been true.

Senator ALLARD. Based on an individual basis. That is an individual basis, is it not? I am looking at a public health assessment for the total population.

Dr. OFFIT. Sir, I think it depends on what the nature of the strain is. For example, you knew in 1957—you were not here to hear my initial comments, but in 1957 you knew it was going to be a pandemic because very quickly one-tenth of Hong Kong's entire population was infected. Tens of thousands of people were in line trying to get medical care. Then you know, so now it has started. It is clearly spreading easily from person to person. That has to happen in order for a pandemic to exist. And not only do you know that it is now a likely pandemic because it is easily spread and it is a novel virus, but you know who it is infecting and who is getting hospitalized and who is dying, which is to say what kind of strain it is.

I think the 1918 experience was an unusual experience. That particular virus, the surface protein of that virus, which is called the hemagglutinin, which is where the "H" comes from, was a very unusual hemagglutinin. It had the unique capacity, frankly, to stimulate the body's immune system to react against itself, which put that 20 to 40 year old or even younger person at great risk.

But you would know that early on, I think, in a pandemic.

Senator ALLARD. But early on in those outbreaks that you described, we recognized early on that there was a pandemic there because, like you said, the cases showed up and all of a sudden you noticed. But even though we have had people get ill now, we have no indication of a pandemic other than the fact that we know that influenza virus has a tendency to mutate.

Dr. OFFIT. No, I think personally we have every indication that the H5 virus is not going to be a pandemic strain. But that does not mean there will not be a pandemic. There will be a pandemic.

Senator ALLARD. Okay, so what is all the excitement about?

Dr. OFFIT. Well, the excitement is about the fact that there are three pandemics every century, that this century will not be spared, that you have what has clearly been a crumbling in the infrastructure to make and produce vaccines.

Senator ALLARD. But should not our efforts be, instead of thinking so much about this influenza attack and getting everybody all hyped and everything, should we not be looking generally at our

public health procedures, on how we handle public health infectious diseases generally, and whether—maybe it is influenza this time, but it could be some other virus or bacterial infection in some other aspect.

Would we not be better off to look at just the total public health approach and how you handle infectious disease with a very virulent organism, no matter what that is?

Dr. OFFIT. Well, keep in mind—good point. I think one has to keep in mind that if you take the inter-pandemic periods and just add up the number of deaths from epidemics, they dwarf the amount of deaths that come during a pandemic. So I think we are not very good, frankly, at taking care of the infectious disease influenza, which kills 35,000 to 40,000 people in the United States every year. Can we avoid a lot of that death by expanding influenza immunization programs? Absolutely. But somehow we seem to grandfather in that 35,000 to 40,000 deaths, that is okay, because it is the pandemic that we focus on.

But as I said earlier, I think that the degree to which we take the epidemic threat seriously, that we make vaccine and educate the public that they need to get this vaccine, is the degree to which we will have an infrastructure in place for when the pandemic does come, and it will come. There will be a pandemic. When the pandemic comes, it may be a pandemic like 1957 or 1968, when maybe 100,000 people in the United States die or 150,000 die. But remember, 35,000 to 40,000 die every year.

Senator ALLARD. My time is expiring, Mr. Chairman.

Senator GREGG. Do you have other questions?

Senator ALLARD. Yes, I could follow more.

Yes, go ahead.

Dr. LILLIBRIDGE. Senator, I think we are singing from the same page. I agree with you that I think the issue at hand on pandemic flue preparedness is that epidemic preparedness as a Nation is an important issue. I do not see any difference from bioterrorism preparedness, pandemic flu preparedness, SARS pandemic, or preparedness for other emerging diseases.

I think we are right to focus on the detection and the disease control measures of the system and the leadership, organization, and methods by which we control disease, is much more important to me than each individual widget or new vaccine or new lab test.

Mr. CLERICI. Senator.

Senator ALLARD. Yes?

Mr. CLERICI. Senator, if I could follow up on that point. I think your message is exactly correct. It is not just pandemic or Avian flu or whatever it might be. It is the global preparedness of public health. But if you look at what we have done with Avian influenza in preparing, we passed liability protection not just for Avian flu, for any pandemic, epidemic or bioterrorist event. There are currently eight licensed vaccine makers of any type of vaccine in the United States versus the 30, 20 to 30, there were several years ago. That problem hopefully is along the way to being fixed.

We make our annual flu vaccine, as Dr. Offit pointed out, which kills 30,000 people every year, from chicken eggs. Last month we ordered a contract for a billion dollars to multiple companies, some very large companies, to go to cell-based manufacturing.

So all of that progress—and the bird flu has been analogized already by the New York Times to Y2K, as all about nothing. I actually take a good heart in that because if Y2K caused us to upgrade our IT infrastructure from 1980 to 2000, led to a lot of increase in American efficiency, and nothing happened, we are all the better. If we spend $7 billion here, raise the awareness of public health preparedness, and a pandemic does not happen to the degree that we think it will, but yet we are better prepared as a society and our public health infrastructure are upgraded, I think that is a win.

Senator ALLARD. But I think risk assessment is really critical, because the treatment, there is a risk assessment, too. So you need to know what are the risks. If you do not have any risk on treatment, then that is mute. But I have yet to see treatment that does not have at least a little bit of risk in it, I think. Then you have got the other risk of the disease or the virus, in this case the Avian influenza variety H5N2, and that virus shows from what I can tell very little tendency right now to spread from human to human.

But if you are going to go on to a vaccination program and you have two people die out of every 100 vaccines you give, that is not a very good—see, this is where risk assessment is so very important, and I do not see many people talking about how we get about doing risk. They are talking about, well, what if. But we need to look at the degree of risk that we have there, and that is what I am trying to get at.

Mr. Cilluffo, you had something.

Mr. CILLUFFO. Senator Allard, not to speak lightly about a very serious matter, but I think it is fair to say since the end of the cold war to some extent threat forecasting has made astrology look respectable. So I do not know what the future will bring.

I do think that there are some back end capacities and capabilities that will maximize and we need to be very diligent to make sure our finite resources, our infinite vulnerability, is based on a risk management, solid risk management principles, where you can maximize those secondary and tertiary returns on investment that will be beneficial, not only for the bad bug, but also for the bad weather and also for bad people, because the other component that I think is not being discussed here is bioterrorism.

With respect to bioterrorism, that can be a transforming sort of an event to the United States. Unfortunately, our adversaries have made clear that if they could build the capacity and disseminate and deliver the capacity to do so they would. So I think that we want to look to what are the resources that could be spread across the board that will get that return on investment and maximize our efficiency.

I do think you are underscoring another important point. I am not sure we have really built the business case yet for homeland security, not just pandemic influenza, not just—because I agree with you, if we were to chase every bad bug we will break not only our bank but every bank. But we need to be able to look to what is that business case across the board, and I think it is incumbent upon us to look at it from an all-hazards perspective, where we will yield return irrespective of whether or not we see H5N1 or it morphs into H5N7 or whatever it may be.

So I think you raise some very good points, but I do not think the panel here—at least agrees with your points, but recognize that, as President—or as Benjamin Franklin, not President—they did not promote him yet—once said, failing to prepare is preparing to fail. So I think we need to be able to act.

Senator ALLARD. Thank you, Mr. Chairman.

Senator GREGG. Thank you. You have covered a lot of really important topics and given us some interesting ideas.

Let me ask, to try to filter this off a little bit, if you can each give a grade to where we are as a government in our preparations for an all-hazards event and our preparations specifically for influenza? Do you have a grade you would give the Government at this point?

Dr. OFFIT. I think I can best answer the question, the grade I would give the Government for influenza preparedness is a B-plus, because I think the two things that have happened that have been really important is a recognition that the vaccine manufacturing infrastructure has crumpled and that it needs to be bolstered; two, that we need to get away from what is a fairly archaic, egg-based technology to mammalian cell technologies. I think that is really important. So a solid B-plus.

Senator GREGG. That is good news. I presume you think we have got the vaccine issue moving in the right direction, in part because we have addressed the liability issue?

Dr. OFFIT. So you want to talk about liability. I think that liability—I guess I do not completely agree with the way that we have done liability. Do you want me to talk about that?

Senator GREGG. Absolutely. That is why we are here. We want to know your thoughts.

Dr. OFFIT. I guess the program that I think works is the vaccine injury compensation program, because at the heart of that program is essentially a Federal excise tax on every dose of vaccine, that then creates a poll of money and then if there is a problem following a vaccine, as occasionally happens, as Senator Allard said, then the way that works in the vaccine injury compensation program is essentially a group of epidemiologists and clinicians and people who understand the data look at the data and say, okay, this is a problem. Rotashield, the rotavirus vaccine that was on the market for a year, caused intestinal blockage. Influenza vaccine can—was, at least for the swine flu, it was a rare cause of Guyon-Baret syndrome. And influenza vaccine currently has egg proteins, so it can be a rare cause of severe and occasionally allergic responses.

Those things are real. What you worry about is—and this is why it should never go to a jury, frankly—is the fact of all these unreal things that vaccines are blamed for. That was what was great about vaccine court. Essentially, the vaccine injury compensation program is vaccine court.

So I think when you ask a populace, for example, to get a vaccine en masse, if it does cause unanticipated side effects, I think that it is fair to compensate those people who were hurt by that, I do. I think my concern about the current plan is that I think it sets too high of a bar for that. In other words, it does not—other than, I think my understanding is it is—I am not a lawyer, but I will

pretend I am because they pretend that they are doctors, so why not.

The notion of the bad actor provision, the knowingly negligent provision, I think is a bit much. Believe me, I am a big fan of tort reform. I just think it is not fair, if it really was found to cause harm, harm that was not due to negligence, harm that had nothing to do with design or production, but was found to cause a negative effect—I think it would be fair to compensate those who are being asked to get that vaccine, but not like the $253 million you get if you have an arrhythmia with Vioxx in east Texas, but something like what the vaccine injury compensation program does, which is in the sort of $250,000.

So I think that is fair.

Senator GREGG. I will move on in a second. I just want to respond with the public policy reasons why we went the way we did, which was because I presume and I think most of the people who worked on the decision presume that if we had a national epidemic and we had the vaccine, we had a huge national vaccine program that was brought on line very quickly, that any sort of personal harm that was caused by that vaccine would inevitably—the responsibility would inevitably be picked up by the Government for compensation. But to try to guess where that was going with a prevaccine program, like we did with polio where we had a predictable number or with smallpox where you have a predictable number, was probably counterproductive to bringing vaccines on line.

Everybody is presuming that there is going to be a compensation event if, or at least I am, if there is a national vaccination event which involves a vaccine that is rushed to market or rushed to the population, simply because we had the event and we had to respond and this was the only thing we had available in our toolbox.

So I think it is almost a moot point. It is going to be done. It is just to do it on an estimate that has no relevance at all because nobody knows what the harm is going to be, as compared with smallpox where we know the harm because you know the percentage. That was why that decision was made on purpose, to get the vaccine industry functioning.

I think the fact that you think we may have accomplished that, that is good news. That is very good news if it is true.

Mr. Clerici, what would be your rating of where we are in this exercise? A grade, you have got to start with a grade here. We have got to keep this simple. We are simple people.

Mr. CLERICI. In terms of flu preparedness, I would definitely put it at a B. The good news is a year ago when I sat at this table I would have put it at a D-minus to an F. So I think the last year, both with liability protections as well as the resources and focus that the Federal Government has put into pandemic planning, has been very positive.

I would say, with respect to annual flu vaccine, we are probably back at a C and, ironically, if we can get that annual flu program up to an A, then that is going to make the stronger grade for pandemics. So there is more that can be done in messaging in terms of——

Senator GREGG. Well, what is it that gives us a B? Give me a thumbnail. What are we doing right right now and what do we still need to do, in a thumbnail?

Mr. CLERICI. I think with respect to vaccination we are well along our way there. I think the fact that the liability leash has been removed from the neck of the industry to actually participate, and that is all they want to do is participate, has proven out with the billion dollars in contracts that were given to big companies that were never in the United States market before, which is very, very positive.

With respect to other countermeasures, including antivirals, more needs to be done there, which is probably why the grade is lower than even Dr. Offit gives, in terms of finding next generation antivirals and promoting those resources. As I understand it, stockpiling—I am a lawyer, not a doctor, to take Dr. Offit's point. Tamiflu may not be the solution, so perhaps we need to be putting that same type of focus in finding those next areas.

Areas such as rapid diagnostics have not gotten the attention they deserve. We need to know what we are dealing with when these people show up at a hospital so we can treat them appropriately and also triage the very few resources that we have. As I understand it, HHS is moving toward that. They have not yet. There is a lot of dysfunction between the CDC and HHS in what sort of processes are in place for rapid diagnostics.

Then with respect to annual vaccination, which is also dragging down the grade with pandemic, until we get our messaging right on who should take the vaccine—unfortunately, things were moving along very nicely towards a very strong message from the CDC up until October 2004, when we had to take back that message and say: Okay, no one get a flu vaccine, because one of the suppliers collapsed.

That set us back in terms of messaging. For the good of the Nation, it was a very mild flu season that winter, which means that people did not take a vaccine and did not get sick to the extent that they had in the past, which was good for the country. It was bad for the message to get people back on track saying you really do need to take a vaccine, and to make sure that we have the capacity to get that universal recommendation where it needs to be as very, very important.

With respect to bioterrorism, I think we are still in the C range. BioShield is still moving too slow in order to generate the type of market interest that we need it to. As I said in my testimony, Secretary Leavitt and Deputy Secretary Azar have committed to fixing that, and they are both incredibly able and capable of doing that.

We had a setback in the last few weeks, with the first BioShield contract well on its way to failure. I think that we cannot take that as a bad message. We need to learn from it, build from it, as they have with flu, quite frankly, in implementing the flu program, and not take the failure of VaxGen to drag down all of BioShield.

There are good signs: the fact that they purchased another vaccine, the fact that the anthrax therapeutic awards should be made relatively shortly, according to HHS, and that new RFPs are going to be hitting the streets for things we have not dealt with—plague,

botulism, antitoxin. But until that happens, I think we need to keep the grade probably at a C to encourage them to do better.

Senator GREGG. Dr. Lillibridge.

Dr. LILLIBRIDGE. Senator Gregg, I think I would give us a respectable C. I think preparedness in my book is an ongoing process. You do not just achieve an end result and then rest on your laurels. The things that I think need to happen to move that up over the next year or two—and I am pleased with the progress of Julie Gerberding at CDC and Secretary Leavitt at HHS and the other partners, DHS. But here is what I think I would like to see happen or what I would like to focus on.

First of all, disease detection and epidemic control are not an all-hazards enterprise. Those are complex biomedic disease control activities. They require an infrastructure, a leadership, and an organization that is a little different. I believe they can work in an all-hazards framework, but I think they are different than all-hazards preparedness because of the science, the laboratory, the medical components, the health, and so forth that have to be tickled, nurtured, and developed. That is one.

The second thing, as I alluded to earlier in testimony, is the issue of leadership and agency organization. I would fix, and I would have high on my emphasis list to fix, the National Disaster Medical System such that we really do have the surge capacity and can get our academic health centers, HMOs, and large hospital organizations better involved in supporting our national strategies.

Senator GREGG. Thank you.

Mr. CILLUFFO. Senator Gregg, let me preface my answer with the fact that I believe anything short of an A-plus is unacceptable. So with that as sort of a backdrop, I think at the Federal level we are actually doing quite well in terms of the strategies, in terms of the policies, in terms of the plans, and in terms of the laws. I think we would be that much further if we were to actually legislate and pick up your bill in particular, Senator Gregg, Senate Bill 2792, which I think would enhance our capacities that much more, and I think Senator Burr's bill, S. 2564, in terms of bridging the so-called valley of death from basic research to advanced research to actual, would take us to an A-plus at the plans level.

But this really is not about what we are doing here in Washington. It is ultimately about execution and implementation at the State and local level, where the rubber hits the road. There I do not know what to grade because you cannot give a one size fits all. Some communities, some States, are much better prepared than others. Some are further along than others. Others are doing great work. So I do not know how you would give a fair grade because you would have to actually grade a whole lot of people.

Then you have got to look at the private sector, the continuity of operations planning. I think there is an awful lot of work we need to do here, and maybe even in terms of prioritizing vaccines. You are going to have the owners and operators of our critical infrastructure who are going to be absolutely instrumental and critical to maintaining our continuity of government and our day to day issues.

So here you have a majority of the companies recognizing it as a problem, yet only one-third have actually put in robust continuity

of operations plans. So there is a delta between the verbiage and the action.

I would say the same with the American public. We should stop asking how afraid we should be, but what is it we can honestly do to better protect ourselves and our families? Here I am not sure we have hit saturation, and that is a risk communication sort of issue which is a tough balance.

So I think it is the interface between Federal, State, and local where there is an awful lot of work that needs to be done and it is ultimately operationalizing. As General Eisenhower said when he was then General: "In preparation for battle I have often found plans to be useless, but planning to be indispensable." I am not suggesting plans are useless. They are very important. But we need to get the operational tenets that can bring the plans and the strategies together with operations.

Senator GREGG. The subcommittee has received a statement from Steven D. Brice, Battelle's Health and Life Sciences Division which will be intered into the record.

[The statement follows:]

PREPARED STATEMENT OF STEVEN D. RICE, SENIOR MANAGER, BATTELLE'S HEALTH AND LIFE SCIENCES DIVISION

Thank you, Mr. Chairman and Members of the Subcommittee on Homeland Security, for receiving my written testimony for the record. It is my privilege to provide my opinion concerning our Nation's preparedness and capabilities to respond to the kinds of cataclysmic events that could face our Nation in the near future. Both natural and technological disasters as well as terrorist-perpetrated incidents loom on the horizon, and it is vital that we honestly and forthrightly assess our capabilities, our strengths, and our weaknesses. Until January of this year, I was a Federal employee working at the Centers for Disease Control and Prevention (CDC). I directed the Strategic National Stockpile from its inception in fiscal year 1999 until January 2006. Post-September 11, I was asked by CDC Director Dr. Julie Gerberding to direct emergency response at that agency, as well.

I retired from CDC in January and joined Battelle's Health and Life Sciences Division where I am responsible for development of strategic plans for emerging infectious diseases and for overall emergency response. Battelle is a non-profit 501C(3) organization with a long history of dealing with a wide range of critical issues in the health and life sciences. Battelle has substantial contract research experience with various parts of the Department of Health and Human Services (DHHS), including NIH and CDC. Battelle also has a long history of support for bio-defense programs for a variety of Federal agencies. In addition, Battelle has significant long-term relationships with various pharmaceutical companies, primarily in clinical trial support and vaccine development for defense and civilian applications.

My comments today are intended to emphasize and underscore the need for proper prior planning, proper resourcing, proper coordination, and the absolute necessity of establishing new partnerships. I will discuss three examples to support my observations. Specifically, I will discuss aspects of the Strategic National Stockpile; Federal, State, and local preparedness; and the urgent need to develop and exercise public-private partnerships.

The Strategic National Stockpile

My comments on this subject reflect only my knowledge of events prior to January of this year. I have not worked either at CDC or in the Strategic National Stockpile (SNS) since January 3, 2006. No doubt, many changes have since occurred at DHHS, at CDC, and within the Stockpile.

I believe the SNS is overburdened by missions for which it is not adequately resourced and by missions that were not well thought out or not properly planned. These shortcomings have made it very difficult for CDC and its staff to operate at top effectiveness. Two examples will, I hope, be helpful.

My first example comes from DHHS's implementation of project BioShield, a multi-billion dollar program to acquire medical countermeasures should our Nation be attacked by biological, chemical, or radiological weapons of mass destruction. As originally conceived, CDC's Strategic National Stockpile was not designed to handle

drugs, vaccines, or anti-toxins in its formulary that were not licensed by the Food and Drug Adminstration (FDA). SNS's warehouses met the highest industry standards for storage of pharmaceuticals and medical equipment after the product had been licensed. However, the standards for products prior to licensure are much more costly to adhere to. The cost is due in good part to the labor-intensive documentation required by the FDA (for its licensure application package). The general purpose for adhering to these extra measures when handling products prior to licensure is to ensure that nothing in the "handling" of the unlicensed product could be responsible either for jeopardizing licensure or for the product's failure to be licensed by the FDA.

Even though the SNS was not designed to handle unlicensed product, the fact is that it has had to handle such product. Specifically, licensure of a medical countermeasure may take several years and may not be accomplished until well after the millions of doses of the countermeasure are produced and stored in the SNS warehouses. It became necessary for the SNS to stand up (that is, plan, staff, and implement) a quality assurance/quality control unit similar to those of private pharmaceutical manufacturers. The SNS was now considered by the FDA as part of the manufacturing chain of events. The transport and storage records of the SNS would be reviewed by the FDA as it assessed whether or not to license a given product. The manufacturer and the SNS had to assure, through meticulous record keeping, that the product was transported and stored under good manufacturing practice (GMP) standards. The record keeping is much more burdensome if one is dealing with an unlicensed product, even though the transport and storage standards for cleanliness, temperature control, etc. are virtually the same for medical products stored at local pharmacy, hospital, or prime vendor warehouses. Let us use as an illustration the moving of an unlicensed product requiring refrigeration. A refrigerated truck that transports a licensed product need only ensure the product was kept at, let us say, 20 degrees Celsius, whereas a truck transporting an unlicensed product must be certified as meeting GMP standards. This requires many dozens of temperature probes to ensure that every place in the trailer's storage unit is within exact tolerances—and documentation of that fact becomes part of the licensure package submitted to FDA for review.

This added burden was taken on willingly by CDC in order to have the medical countermeasure on hand (even before final licensure) should our Nation be attacked. Additional staff was required with expertise that essentially came only from the private sector. The CDC/SNS budget had never accounted for such hiring and program implementation. CDC was told to take the costs and the program burden for standing up such a unit out of current operating expenses. Equally debilitating, CDC was told to have the unit operational in 3 months' time. While this was indeed accomplished, it placed hardships on both CDC staff and budget and is one example of an inadequately resourced requirement.

Another example occurred in 2003, when the DHHS Office of the Assistant Secretary for Public Health Preparedness began exploring the possibility of adding primary care, public health contingency beds to the SNS inventory. Referred to at the time as Federal Medical Contingency Stations (FMCS) or Federal Medical Stations, the beds, bedding, and limited ancillary support items were to be shipped by CDC to the site of an emergency and were to be used by local personnel. The purpose of these beds was to provide the Nation with an additional resource when responding both to the aftermath of natural disasters (hurricane-displaced persons, for example) and/or to terrorism events. Unfortunately, as of December 2005, the concept of operation and the exact use of these beds remained unclear both to CDC staff and to state and local emergency responders and public health personnel. Thousands of beds were purchased, but very few were used in the 2004 hurricane season in Florida and in response to hurricanes Katrina and Rita. Their effectiveness was blunted because state and local responders were not acquainted with the equipment; and further because state and local responders did not know they had to provide power, water, food, linen changes, laundry, and most importantly, health care providers to support the patients who might occupy those beds. Thus, instead of viewing the beds as an added asset, many state and local response coordinators considered the beds to be a burden.

CDC was not given the human resources to train and exercise the use of these beds with state and local responders; CDC was not given the human resources to adequately store and kit the beds for use in the field. Yet, despite not being properly resourced to accomplish this mission, CDC once again did its best to purchase, kit (i.e., put everything together so that when the "beds' were transported they arrived with as much supporting gear as CDC could afford given the inadequate budget), transport, and set up this medical/public health asset. Unfortunately, however, because the original concept of operation was never well articulated to either CDC or

to state and local responders, this potential asset was rendered a liability during disaster response.

Nor was the FMCS concept ever fully coordinated with the Department of Homeland Security's National Disaster Medical System staff or their primary response element, the Disaster Medical Response Teams (who would, it could be assumed, be called upon to staff and use these assets). The lack of a clear mission, the lack of a clear concept of operation, and the lack of coordination with Department of Homeland Security further reduced the potential effectiveness of these medical and public health assets.

Before I leave this portion of my testimony, allow me to underscore that I cannot think of a better place than CDC to carry out the missions and assignments in the examples I provided. My point is that CDC must be adequately resourced when they are given future missions and that each assignment needs to be accompanied by a clear, well-articulated concept of the operation that is vetted and fully coordinated at all appropriate levels of government, at DHHS and the Department of Homeland Security, down through the local level.

State and Local Preparedness

CDC has a long and fine record working with state and local public health departments as the agency assists in the fight against illness and injury. In recent years, CDC has also taken on the fight against terrorism by working closely with state and local governments, not just public health departments, but police, fire, public safety, and emergency response elements as well. Within the past 2 years, CDC and DHHS began planning for the worst-case scenarios of a clandestine release of a biological agent that would require extremely close coordination between agencies at all levels. When I left Federal Service in January, I had not yet seen the kind of coordination, planning, and exercising required in one critical arena: namely coordination between the Department of Homeland Security's National Disaster Medical System component and the various DHHS response elements, including CDC's emergency responders and the SNS. The interface between the National Disaster Medical System units, CDC, and other DHHS assets such as the DHHS Secretary's Emergency Response Team is necessary if we as a Nation are to be able to respond to catastrophic natural disasters such as Katrina or to terrorists' use of weapons of mass destruction. My hope is that in recent months, DHHS and the Department of Homeland Security have undertaken such planning and coordination and, ultimately, have exercised together. This should ensure that, when they respond to the scene, they know how to communicate with one another; their formularies are similar, if not identical; their routes of supply and re-supply are well known to one another; and their trust in mutual capabilities is well established. Anything less is not good enough.

Partnerships

In the aftermath of Katrina, much has been said about partnerships. I endorse and support each of the various recommendations that would facilitate all entities working more closely together. I would like to concentrate today on one aspect and in one area of partnership that I believe is essential to the success of a national emergency response: namely, partnership in the discipline of logistics, both medical logistics and general emergency response logistics. I define medical logistics' as getting medical supplies and equipment where needed, when needed.

In Katrina, we failed as a Nation to move critical medical supplies for the chronically ill, for the aged, and for children into New Orleans rapidly enough. We should have known better. After every catastrophic natural disaster, the people who suffer most quickly in the hours post event are our elderly, our infants, and our chronically ill who have lost their medications. Diabetics, heart and hypertension patients, those with breathing difficulties, infants, and the elderly can become critically ill very quickly. In New Orleans many of these individuals survived the hurricane itself only to succumb to dehydration or to a chronic disease that went unmanaged for days.

Keeping this example in mind, it would seem to me that the Federal Government must do a better job in partnering with pharmaceutical manufacturers, prime vendors, local suppliers, and transportation businesses prior to such disasters. Specifically, I believe agreements can be established between private corporations and public entities such as state and local public health agencies and DHHS and the Department of Homeland Security at the Federal level to ensure an immediate supply of medications for the chronically ill, the aged, and the children in an affected area.

Yet partnerships with medical suppliers and transportation corporations are only one side of the partnership triangle I wish you to consider. Both DHHS and the Department of Homeland Security require help in establishing a well-functioning logis-

tics response. There are many private firms (both profit and non-profit) that have discussed the need for a more robust logistics (and medical logistics) capability in our Nation. Speaking as a representative of a private non-profit organization, I urge Congress to call upon the private sector to create meaningful long-term partnerships with our Federal, State, and local counterparts to design, implement, and exercise a civilian logistics capability. This can complement Department of Defense efforts when it comes to responding to a natural disaster or a terrorism event, both within the United States and internationally when necessary.

Thank you again for allowing me to submit my statement for the record for your consideration.

CONCLUSION OF HEARING

Senator GREGG. Thank you.

Well, you folks have been very generous with your time and this has been an excellent presentation, given us a lot to work with, and ideas and thoughts, which we hopefully can convert to action. We appreciate your courtesy in coming here to inform us. It is very important. As you say, Dr. Lillibridge, this is not a static event; it is a moving event. So as you have thoughts and ideas as we go forward, please do not hesitate to communicate them to our staffs or ourselves because we need that information.

Thank you very much. I appreciate your time. The hearing is recessed.

[Whereupon, at 12:10 p.m., Tuesday, May 23, the hearing was concluded, and the subcommittee was recessed, to reconvene subject to the call of the Chair.]

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