S. HRG. 109–495

ENHANCING PUBLIC HEALTH AND MEDICAL PREPAREDNESS: REAUTHORIZATION OF THE PUBLIC HEALTH SECURITY AND BIOTERRORISM PREPAREDNESS AND RESPONSE ACT

HEARING

OF THE

COMMITTEE ON HEALTH, EDUCATION, LABOR, AND PENSIONS UNITED STATES SENATE

ONE HUNDRED NINTH CONGRESS

SECOND SESSION

ON

EXAMINING THE PROPOSED REAUTHORIZATION OF THE PUBLIC HEALTH SECURITY AND BIOTERRORISM PREPAREDNESS AND RESPONSE ACT RELATING TO ENHANCING PUBLIC HEALTH AND MEDICAL PREPAREDNESS

MARCH 16, 2006

Printed for the use of the Committee on Health, Education, Labor, and Pensions

Available via the World Wide Web: http://www.access.gpo.gov/congress/senate

U.S. GOVERNMENT PRINTING OFFICE

26–686 PDF WASHINGTON : 2006

For sale by the Superintendent of Documents, U.S. Government Printing Office
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C O N T E N T S

STATEMENTS

THURSDAY, MARCH 16, 2006

ADDITIONAL MATERIAL

ENHANCING PUBLIC HEALTH AND MEDICAL PREPAREDNESS: REAUTHORIZATION OF THE PUBLIC HEALTH SECURITY AND BIOTERRORISM PREPAREDNESS AND RESPONSE ACT

THURSDAY, MARCH 16, 2006

U.S. SENATE,
COMMITTEE ON HEALTH, EDUCATION, LABOR, AND PENSIONS,
Washington, DC.

The committee met, pursuant to notice, at 9:19 a.m., in room SD–430, Dirksen Senate Office Building, Hon. Mike Enzi, chairman of the committee, presiding.

Present: Senators Enzi, Burr, and Dodd.

OPENING STATEMENT OF SENATOR ENZI

The CHAIRMAN. Good morning. I will call the hearing to order.

I really appreciate the Secretary readjusting his schedule so that while we are debating this, the preparations can be made for doing some votes on it, on the floor of the Senate. We are really happy and honored to welcome Secretary Leavitt, and a distinguished panel of speakers today, as we formally begin the process of the reexamination of our bioterrorism and essential public health security. We need to get prepared for the bird flu, and toughen our defenses against bioterrorism. We do that by making sure all levels of Government are coordinated to face these threats.

When we last examined these critical issues, there was a tremendous cooperation between Democrats and Republicans to address the urgent concerns raised by the events of September 11th and the subsequent anthrax attacks. I know that we will work again in cooperative fashion, recognizing that as members of this committee, we are stewards of the public health system. The importance of working together cannot be overemphasized because the enemy we face already lies in wait on our horizon. Its presence cannot be ignored or denied.

We do not know when the threat will be realized and an attack will begin, and we cannot identify or categorize what danger we will face. It could be a natural disease like the bird flu, or it could be an orchestrated attack by a terrorist group. We cannot know for certain what it will be, but we do know full well that we must have a public system that is prepared for it.

The 9/11 attacks produced a phrase we all heard, and we should keep in mind during the consideration of this legislation. It has

been said that part of the problem was a "failure of imagination," an inability to predict in detail the kind of threats that we face. Needless to say, we cannot afford to have a failure to prepare for a threat to our national security.

The stewardship of the public health system is not a responsibility the Federal Government bears alone, but one that is shared with State and local health departments. The Federal Government cannot provide for all our public health needs. Rather, public health authority begins and ultimately lies with the States. Although we have developed and enhanced key Federal resources, the lion's share of public health authorities, even during an emergency, rests at the State level.

When we last examined this critical infrastructure, Congress understood the need to invest in modernizing our State public health system, and to enable them to respond to newly emerging threats.

As an accountant by training, I am very comfortable with evaluating a program by measuring the outcomes and effectiveness of past investments. Here, we need to do similar examinations. We have to determine if we are going to get enough bang for our buck. We have to make sure that States are using the Federal funds wisely, and they have the resources to make all Americans safe from bioterrorism or bird flu. This new reauthorization must provide better coordination, better preparation, a bigger and better supply of drugs, vaccines and other medical products, and better evaluations of each State's preparedness.

I would like to take a moment to commend the Bioterrorism Subcommittee and its chairman, Senator Burr, and the majority leader, Senator Frist, and their staffs, for their persistence and leadership on these issues. I also want to commend Senators Gregg, Hatch and Hagel for their attention to these issues.

In addition, I would like to express my deep appreciation to Senator Kennedy and the Democrats on this committee and their staffs, as well as Senators Lieberman and Obama for their continued hard work and leadership on these issues.

Senator Burr and I look forward to working with the entire HELP Committee in developing the legislation that will lead us to the next level of public health preparedness.

Again, thank you for coming here today to engage in a discussion of the threat that lies before us and how we can improve our preparedness. I look forward to working with this committee and our subcommittee to do what is needed to ensure a strong national health system, and to be sure that it is in place to protect and safeguard the health and well-being of all Americans.

When Senator Kennedy gets here, we will allow him to make an opening statement. He is a part of the discussion on the floor over there at the moment too, so his entire statement will be a part of the record.

[The prepared statement of Senator Kennedy follows:]

PREPARED STATEMENT OF SENATOR KENNEDY

I commend our Chairman, Senator Enzi, and our Subcommittee Chairman, Senator Burr, for holding today's hearing on an issue of extraordinary importance—preparing the Nation to meet the challenges of epidemics and public health disasters.

After our disagreements of yesterday on the small business health plan bill, I'm glad to return to a topic on which we agree so well. We've worked together on BioShield, on smallpox compensation, on the legislation enacted in 2002—on bioterrorism and outbreaks of infectious disease, and on many other issues related to health preparedness. Our challenge now is to reauthorize and strengthen the legislation enacted in 2002 and prepare for the public health threats we face.

An indispensable partner in that effort will be our distinguished witness, Secretary Leavitt. All of us on the committee are aware of his dedication to improving our readiness for pandemic flu. His commitment knows no bounds—he's even visited chicken coops across the world to see first hand the measures being taken in other countries to contain avian flu.

As commendable as Secretary Leavitt's efforts have been, every expert analysis has concluded that there are dangerous gaps in preparedness. In December, the Trust for America's Health gave the Federal Government a grade of only D+ for public health emergency preparedness. According to a recent GAO report, the administration is "still in the process of developing goals, requirements, and metrics" for assessing national preparedness.

The question is why—more than 4 years after the attacks of September 11th—we are still just in the planning stages of preparedness?

Most Americans probably assume that major investments are being made in our hospitals and health departments to see that they have the resources, the skilled personnel, and the information technology needed to respond adequately to a major epidemic.

Sadly, that assumption is mistaken. The programs to strengthen health agencies and to improve the readiness of hospitals do not receive enough funding even to keep pace with inflation. Other essential programs, such as anthrax research, pandemic planning, and emergency medical services for children, are being severely reduced or even eliminated.

But even those shortfalls tell only part of the story. The Nation's hospitals rely on Medicare and Medicaid for much of their funding—yet the President's budget cuts Medicare alone by over $100 billion in the next 10 years. In Massachusetts, hospitals will have to cut their budgets by more than $400 million. It's unrealistic to ask hospitals to invest in ventilators, positive pressure rooms, disaster preparedness exercises, and other actions to improve readiness—while cutting their budgets for basic services. We can't achieve preparedness by weakening the heart of our health care system.

Although the budget resolution we are debating now has wisely rejected these drastic cuts, we have seen time and again that conference agreements usually reflect the President's proposals, not the amendments of the Senate.

We must learn the lessons of the past and see that our health agencies can detect disease threats rapidly and accurately, that our hospitals and health professionals can treat the victims of disease, and that our communities have adequate plans to contain a disease outbreak.

I look forward to working with the members of this committee, with our colleagues in the Senate and with Secretary Leavitt and our other distinguished witnesses today to make more effective progress in meeting this basic responsibility.

The CHAIRMAN. So we will now hear from our first witness today. The Secretary of the Department of Health and Human Services joins us to discuss the Department's role in leading national efforts to protect the health of all Americans. Secretary Leavitt has a distinguished background in Government service, serving as the Governor of Utah, my neighboring State, and administrator of the Environmental Protection Agency, before coming to the Department of Health and Human Services in early 2005, and he has been really busy since then. He was even in Wyoming last week.

The Secretary will discuss the current initiatives in place to shore up America's defenses and the ability to respond to public health emergencies, as well as the next steps in preparing more effectively and efficiently for these threats at all levels of Government. I think you have made trips to 22 States already talking about this, and I appreciate that effort to inspire their preparedness. I look forward to your statement.

Mr. Secretary.

STATEMENT OF THE HON. MICHAEL O. LEAVITT, SECRETARY, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Secretary LEAVITT. Thank you, Senator. Mr. Chairman and Senator Burr, I am very pleased to be here to update you on the steps that the Department of Health and Human Services has taken to prepare for the threats of bioterrorism and other possible public health emergencies, including pandemic influenza.

The events of September and October of 2001 served as a continuing reminder that terrorism, indeed bioterrorism, is a serious threat to our Nation and to the world. The administration and Congress responded forcefully to this threat on a number of fronts, including the passage and implementation of Public Health Security and Bioterrorism Preparedness and Response Act of 2002, and the Project BioShield Act of 2004.

Together, the administration and Congress provided significant new funding to strengthen our medical and our public health capacities to protect the citizens of our Nation from future attacks. While public health remains chiefly at the local and State responsibility, HHS does play a pivotal leadership role, and I am very pleased to join you today to update the committee on our progress.

In the summer of 2003, HHS completed its first strategic plan to counter bioterrorism and other public health emergencies. Since then, HHS has worked diligently to work closely with State and local departments to implement this strategy. These experiences, in turn, have continued to yield important insights regarding our strategy and our implementation. HHS has updated the plan during the summer of 2005 to capture important lessons we have learned.

The updated plan continues to focus on the same major areas.

Rather than take time to go through all of those today in my opening statement, Mr. Chairman, I will submit it for the record, but I would like to comment briefly on Project BioShield.

It is a critical part of a broader strategy to defend America against the threat of weapons of mass destruction. It provides HHS with several new authorities to speed the research, the development, the acquisition and the availability of medical countermeasures to defend against chemical, biological, radiological and nuclear threats.

In exercising the procurement authorities under BioShield, HHS has launched an acquisition program to address each of the major four threats that we have deemed to be material threats to the United States population, that is to say, anthrax, smallpox, botulinum toxins and radiologic nuclear agents. HHS has used the special reserve fund to award two contracts for vaccines against anthrax, one contract for a liquid formulation of a drug to protect children from radiologic iodine exposure following a nuclear event, and one contract for agents for countering the effects of internal exposure to radioisotopes.

In addition, negotiations are under way for a series of other purchases that we will talk about, I am sure, in more detail.

Given the limits of my time, I would simply like to indicate to you that I am anxious to have a conversation about ways we can improve BioShield. I have been in this office now about a year. I was not here when the original act was put into place, but it is very clear to me we have to do some things to streamline this and to speed it up, and I look forward to working with the committee in devising those strategies. There are some things about the bill, the way it is written, that cause me pause and concern. I will be happy to talk about those in more detail as we get moving forward. We have suggestions, and I am anxious to sit down and work them out because this is a very important undertaking.

Thank you, Mr. Chairman.

The CHAIRMAN. Thank you, Mr. Secretary. We really appreciate you taking the time to come and visit with us today, and also to rearrange your schedule. Your comments on what we are doing are particularly critical because you are the one that has to put them into place.

I also want to thank Senator Burr for his diligence on all of these issues. He came from the House with a vast pool of knowledge, and he has put that to use here, as well as getting some real experts on his staff, and they are definitely making a difference. I would defer to him for any statement that he would like to make, and then any questions, as I know he needs to get back to the floor to do some defense of some things over there.

OPENING STATEMENT OF SENATOR BURR

Senator BURR. Thank you, Mr. Chairman.

Welcome, Mr. Secretary. Since we are discussing some avian flu issues on the floor, I will make my time as useful over there as we can, because we know the urgency of that.

Mr. Chairman, if I could, let me say that I think we are in one of the most crucial periods as it relates to the decisions we make about how well this country is prepared and our capabilities to respond to emergencies. We have gone through a lot in the last 4 years. Some has been intentional. Some has been natural. Some

has possibly been accidental. We have seen the gamut of things that can be thrown at us.

The biggest mistake we can make is not to look at those experiences and figure out what we learned from them that will enable us to be better prepared in the future. That is why I think there is a value in the natural disasters that struck the Gulf Coast, that we can look at our public health infrastructure, and, Mr. Chairman, we will announce a timeline when there will be a CODEL from this committee that goes specifically to the Gulf Coast to look at the public health infrasturcture and talk to the individuals involved in public health down there, and find what worked and what did not work, and how we might reflect those changes in conjunction with HHS in the reauthorization of the Public Health Security and Bioterrorism Preparedness and Response Act.

Making sure that somebody is in charge, Mr. Secretary, you have heard me say that numerous times. I believe it is absolutely essential, and I think that the Katrina after-action report suggests, from a response standpoint, that it clearly needs attention. Modernizing how our public health departments detect, investigate and contain health threats is absolutely essential. Protecting the public by more quickly and efficiently responding to national medical emergencies, we know there is no substitute. America will not let us off the hook for not being there.

We have a lot on our plate, and if it was not for the chairman's support and Senator Kennedy, the ranking member, quite frankly, we could not be as aggressive as we were last year. Mr. Secretary, I know that BARDA was a big bite. I will let you know today that I intend to reintroduce a bill that has been scrubbed, a week from Monday. I look forward to any further input that HHS would like to put in the bill. My hope is that, and my strong belief is, that we have done this in a way, not just with the administration, but with members of this committee, and more importantly, members throughout the Hill, where it has been, I think, one of the most transparent processes that we have gone through.

To some degree further in your testimony, you do say that the bill, as it is currently designed, would impose an organizational framework on HHS that impairs your ability to implement a strategic approach for medical countermeasure development and procurement. That disturbs me. It disturbs me because we are a year down the road of developing a bill that all of a sudden there is a new issue that arises in your testimony that we have not heard or maybe it is on the fringe of something that has been brought up before. But it seems somewhat new to me, so my hope is that within 9 days that we can work this out.

I was here when we did Project BioShield. I think it was communicated very clearly from the administration what their intent was. Like anything of this magnitude, I am not sure that we have necessarily structured it or implemented it in the way that I envisioned, and I think to some degree that is understandable, because I think that this is massive and it is a new creation, a new model, that did not exist. My hope is that with Senator Enzi, Senator Kennedy, Senator Dodd, you, and the Agency, that we can come up with legislation that complements what BioShield was set up to do, and I believe without a focused effort on advanced development of

countermeasures, it is impossible to believe that we are going to speed up the timelines on development of these countermeasures for current and future threats.

You have been a stalwart at carrying the message about avian flu. If it was not for you, America would not know about this. I understand next week North Carolinians are going to have you there, and we are delighted to hear that.

But we have a tremendous number of decisions to make about all of the other threats that we know about today, but more importantly, the ones that we do not know about, the ones that we are susceptible to for the same reason that we are to avian flu. They might be carried by a bird, so from a migratory standpoint they affect us. They may be carried on an airplane, where 10 years ago we did not have to worry about the mobility of a world population. We have to have a framework that is able to absorb what we do not know is going to be a threat in the future, because, quite honestly, we are not going to have the luxury of coming out and saying, let's take $7 billion and let's put it right here and let's create an infrastructure and let's develop a vaccine.

The reality is, to some degree we are a little bit behind the curve. This time, we have to do it this way. I think Congress agrees. But I am not sure it is a smart way, long-term. Short-term we have to, but I think we need to begin to think about what kind of framework we should set up to be able to handle what we do not know in the future for vaccine development. I know on this committee there is not consensus on what we did on liability, but I better sleep every night knowing that I think we are going to advance faster and further because we made a very tough decision as it related to liability, and Senator Dodd was very instrumental in the compensation piece. It is not perfect, but we have tried to address it.

It is my hope that we can go through this year with a dual-track of one bill on advanced development for countermeasures, and also the reauthorization of the Public Health Security and Bioterrorism Preparedness and Response Act.

I only want to ask you one question today, and it really does get at the heart of the pandemic flu issue. Last week it was carried in the news, I think, that HHS recommended—and I am not sure whether this is the case—that people go out and buy canned meat and canned milk and put it under your bed. I will let you address whether that was an official HHS suggestion.

But we are at a point where we do not have a vaccine. Even though we are not concerned tomorrow that we are going to have a mass of the population affected, I think it is time for us to begin to think about those things that the American people can have at home that might protect them. One of them is a mask. I raise this question because I am scared that we will come up with a decision that says, let's go buy 300 million masks and let's store them. And if we get to a point when we need them, we will distribute them to the American people. To me, that is extremely flawed because we have not figured out how to distribute anything to the American people, and I think we proved that with ice after Hurricane Katrina.

Has there been any out-of-the-box thinking at HHS relative to things that the American people probably should have in preparation for this new world of threats, and whether there is an ability for us to create a Federal Web site that allows us to negotiate a national price with manufacturers of certain products that meet the qualifications that we need, say, for protection against communicable disease, but that Americans could go online and purchase these products themselves and have them shipped directly to them, with the Government encouraging? I am not limiting that to masks or other products, and I am just curious as to your thoughts.

Secretary LEAVITT. Senator, we do feel, and have for an extended period of time, encouraged the American people to engage in activities that would amount to personal preparedness. We stockpile, as a Nation, certain commodities, not commodities, but certain medicines and medical supplies. As we have exercised our plans, it has become clear to me, as it has to you, that distribution is the challenge. It is not having a stockpile of medicines, it is being able to put pills into the palms of hands at the right moment to assure that it is doing what it needs to do. That is victory.

We have been working with the States, who have the burden primarily of distribution, to develop their plans. We have also begun to look at different alternatives. One of them, for example, would be to have supplies in smaller caches resident in States, or in some cases, to put it with first responders. We have also looked at the development of home kits that could have particular pieces of medication or other purposes that could be procured. We are in the active process of experimenting with those as delivery mechanisms. We have, as well, encouraged people that it is a good idea, whether it is a blizzard on the plains of Wyoming, or a hurricane, or a pandemic, or a bioterrorism event, that it is a good idea to have food in storage in case they cannot go to the grocery store. It is a good idea to have a first aid kit. It is a good idea to have some water in storage. That is just good common sense.

We are working with the Department of Homeland Security to provide information to people on what can be done and what should be done.

Senator BURR. Mr. Chairman, if I could, one more question. The White House Katrina Report suggests that the National Disaster Medical System, NDMS, should go back under HHS. Do you care to comment on that?

Secretary LEAVITT. It is a very good idea. As we went through Katrina one of the things that was evident is we were responsible under ESF-8 for the medical disaster, that unless we were—we were not able to deploy medical resources, and we are not always certain where they were being deployed. We have had a lot of discussion about this. The recommendation, in fact, was made that they transfer back. We are supportive of it, and we will be working with the Department of Homeland Security to develop legislation that can be presented to Congress soon.

Senator BURR. Are there other health response pieces that are currently housed at DHS that you feel are more appropriate to be at HHS?

Secretary LEAVITT. That was the primary one. There is a clear understanding, I believe, between the Department of Homeland Se-

curity and Department of Health and Human Services and the White House that the Department of Health and Human Services has primary responsibility on all medical disaster response.

Senator BURR. I do hope, Mr. Chairman, as we go through this, that HHS will work with us very closely if there are other areas, and that we might be able to handle all of them in this reauthorization bill and maneuver through any territorial battles that might or might not exist between agencies.

If I could, Mr. Chairman, as it relates to the bill that is currently being discussed on the Senate floor, in that budget resolution it assumes that the President's budget, which suggests that he will ask for $2.3 billion in additional avian flu money at some point for the 2007 budget, this budget resolution assumes that that will happen. We have accounted for it.

Can members of this committee feel confident that the administration has asked for the number that they need, that any attempt to raise that would necessarily not be needed from a standpoint of the development, procurement, preparation, and response relative to the 2007 timeframe?

Secretary LEAVITT. The $7.1 billion request that the President made for an emergency supplemental, we believe is responsive to the need.

Senator BURR. Mr. Secretary, I thank you. Again, I apologize for my time constraints.

Mr. Chairman, thank you for your leniency, and I thank my colleagues.

The CHAIRMAN. Thank you for all your effort on this.

Mr. Secretary, your full statement will be a part of the record, and I appreciate the timeliness you got it to us, and also all the information that is contained in there.

You did mention in your written statement, and mentioned it here briefly too in your oral statement, that HHS is working to more efficiently implement Project BioShield, and I applaud your efforts to work within the framework of that legislation. However, in your review of the bill's implementation, did you determine that any of the legislative authority hindered your efforts?

Secretary LEAVITT. Are you speaking about the current BioShield process?

The CHAIRMAN. Yes.

Secretary LEAVITT. Mr. Chairman, what I have found, after observing this for a year, is that we have just created, either legislatively or regulatorily—I am not sure which it is, it may be a combination of both—but a system that just takes too long.

I have experienced this firsthand. I mean it is basically a six-step process. The Department of Homeland Security determines what the threats are that we need to focus on. And then it comes to a subcommittee, the Weapons of Mass Destruction Medical Countermeasures Subcommittee. They determine what the options are. Then it goes on to HHS. As the Secretary, I determine whether we should do it or not. Then it goes from the Secretary of Health and Human Services to the Department of Homeland Security, and they have to make a decision to either endorse our recommendation or not. Then it goes on to the Office of Management and Budget,

where it has to be analyzed again, and then it goes all the way back to HHS for us to act on it.

At every point along that way there are delays, and it is a frustrating process that we just, frankly, need to improve, and we can. It is not something that we should not do and do quickly. I am looking forward to working with the committee to make whatever changes are necessary to accomplish that.

The CHAIRMAN. I appreciate that. One of the things that we run into is there is this formality of letters, and we expect that the formality will still continue, but we hope that there will be an informal process, where, as you notice things you can suggest them to us, so we understand them before we, perhaps, get to markup, and then run into the normal administration letter that sometimes is a surprise to us.

Secretary LEAVITT. We will do our best to be better at that.

The CHAIRMAN. I have not had that problem with you, and I just wanted to make sure that we would not.

I mentioned before your trips to the States. I really appreciate that. Wright, Wyoming had a tornado a couple of weeks before Katrina happened, and that is 38 miles south of my home in Wyoming, and it happened to be during a recess, and so I got to spend a lot of time in Wright seeing how the process worked, and I found out that what I thought FEMA did really was not what FEMA did. Consequently, I think there were some expectations with Katrina that really were not what FEMA does. The same could happen with all of HHS's efforts, and so I really appreciate your getting out and visiting the States. I think you have been to 22 now. Could you describe a little bit the difference in preparedness between—and you do not need to mention which States they are, but the difference between the well-prepared States and the States that need to work more on preparedness. What are the significant differences?

Secretary LEAVITT. Mr. Chairman, first of all, I do not believe anyone in the world is well prepared for a pandemic, and I am not sure anyone can claim to be well prepared for a broadly spread bioterrorism event, for example smallpox, that could spread across the country. We need to continue to improve our efforts. We are better prepared today than we were yesterday, and we will be better prepared tomorrow than we are today. It is a continuum of preparation.

One thing that is evident is that there is a substantial difference between having a plan and being prepared. The primary difference lies in exercising the plan and what is being learned from it. In a large section of the States now we are seeing preparedness exercises, and it is evident to me, when I see a State that has exercised, they are far more advanced in their thinking than those that have not. That is one of the things we are emphasizing in our cooperative agreements. It is not just having a plan on paper, but are you exercising it and being accountable for those exercises.

The CHAIRMAN. Thank you. The National Defense University has done some exercises for us, and involved some of the local groups which help them to understand what could happen under certain circumstances and what kind of preparations are necessary, and of course, I encourage all of my colleagues to be involved in that kind

of a process. It is stark and enlightening. I appreciate what you are doing to help enlighten the States.

Would it be helpful for the States to have more measures to determine if they are adequately prepared?

Secretary LEAVITT. I will make two points on this, Mr. Chairman. One is that every State is unique, but there are some overall metrics that help, should guide, and in fact, will inform their preparation and our knowledge that they are prepared. I have been, as you indicated, in 22 States. We have summits planned in every State.

One of the primary messages that I want to convey when I go to the States is this, that when it comes to a pandemic, or when it comes to a bioterrorism event that could spread disease across the country where there is a combination of terrorism and disease, that any community that has failed to prepare and to exercise their preparation in the anticipation that somehow the Federal Government will come to their rescue at the last minute, will be sadly disappointed, not because we lack the will, not because we lack the wallet, but because we lack a way to respond to 5,000 different communities at once. When we are dealing with widespread disease that is, essentially, communicable disease, that is essentially what we are dealing with.

So it is very important that local communities are preparing within their community, that every community has surge capacity in their hospitals, and figured out a way how they will deal with it if their hospital is overrun with demand and need, how they will set up additional facilities and what they will do. Senator Burr mentioned masks, and the gloves, and the kinds of things that need to be contemplated. Those are the decisions that need to be made within local communities, not just looking to the national Government. We have a role and we will play it, but every community needs to be prepared.

The CHAIRMAN. Thank you. My time has expired. I do not know what the American people would think of a quarantine these days, and how they would respond to that.

Senator Dodd.

Senator DODD. Thank you, Mr. Chairman.

Mr. Secretary, how are you?

Secretary LEAVITT. Good, Senator, thank you.

Senator DODD. I always tease the Secretary as the former Governor of Utah. My wife's family is from Utah, and I am considered the third Senator from Utah, and I represent those 10 Democrats in Utah that are out there.

[Laughter.]

Anyway, it is good to see you, Government, Secretary. Let me say at the outset that I have reached you in a number of forums, both publicly before the Congress, and I think you do a good job. You have your hands tied in some ways, which I am going to talk about here this morning, but you have a good demeanor. You are not an alarmist, but you are very direct and very honest. I listened to a number of interviews you have given and been asked some very tough questions, and have not ducked in terms of your concerns about the gaps we have to fill in here if we are going to be ready. That has been very helpful. I think it is really helpful to have peo-

ple in a public setting, who will look in a camera and answer an interviewer's question in a very direct way and be very candid with him, so I appreciate it.

Secretary LEAVITT. Thank you, Senator.

Senator DODD. I want to talk about a couple of issues with you, and my good friend from North Carolina, Richard Burr, we work pretty closely. Senator Kennedy, myself, Senator Burr, Senator Frist, Senator Enzi, a lot of hours we have sat trying to work through this issue of the bioterrorism bill. I was disappointed in a way that we did not complete the work, and I want to address a couple of concerns that I have about this, and you commented on them as well in the past, and I agree with your comments. I am just worried that we are not taking the comments and applying them in the law here.

It seems to me that any biodefense plan has to have two ingredients in terms of vaccines. One, you have to encourage manufacturers to produce the product, and to produce safe products and effective products. And to do that, it seems to me, while you want to get working on this stuff and you have to deal with some of the liability issues, I am concerned that we went so far over in the effort to get the products produced, that we got very lax on the effectiveness and safety issue, which relates to the second question, and that is the compensation issue.

I realize there are some compensation provisions in the bill, but we have the experience of the smallpox issue, you will recall, a few years ago, where clearly we had—we thought we did the right thing, and then we discovered first responders said, forget about it. I am not going to take this stuff because there is no compensation. Lord forbid, I have an adverse reaction to all of this.

I am trying to simplify this as tightly as I can. I am very worried that last December, when we sort of rushed this through in the Defense Appropriations Conference Report—and I realize there were time constraints in trying to get something done. But I am worried we did not seem to learn from previous lessons. When I look on the liability issues in terms of how we address them here, it was the bad actor decisions. Legal immunity, well, first of all, scope. the legal immunity to an incredibly broad range of products, which is very worrisome to me. All that needs to happen for the product to gain immunity is for the Secretary—and again, this is no indictment of you, Mr. Secretary—but any Secretary of HHS, to declare that it is necessary to respond to a pandemic or epidemic. I am just worried that is so loose.

And then the bad actor provisions, the legal immunity even applies to drug companies and health care providers that act with reckless or gross negligence. The only case where immunity does not apply is willful misconduct. That is a very low standard in my view, very low, and I am worried that with that standard out there we end up with a product that is not as safe, or maybe as effective, and then we have a compensation program that relies on an annual appropriation, which as you know, around here is very hard to get, instead of having a reliable funding source as we have done, for instance, we worked up here, a lot of us—I do not know, Mike, if you were involved—with the childhood vaccines, the compensation fund, which is tremendously well funded today. They have $2

billion in that fund. But it provides for an ongoing source of revenues to make sure we have an adequate amount of compensation, to assure families, when we say to them, "We hope nothing ever happens to your children when they get vaccinated, but if it does, you do not have to go through a long litigation process. We have a fund here to compensate you." Not that that is any great consolation if you have trouble, but nonetheless, it is there.

Here it is an annual appropriation process, and I think the combination of these things could pose some serious issues for us. You have made some wonderful statements about compensation. I have listened to them and heard them. I am trying to square your own views, I think, as I understand them, on the importance of a very good compensation problem so we do not have a smallpox problem with first responders and others.

And second, setting such a low bar on willful misconduct, as opposed to gross negligence, that combined with the compensation, can pose some real problems. And I would like you to address those concerns I have. And they are not my own. There are others up here that share them, but it seems to me they pose some real problems for us.

Secretary LEAVITT. Senator, it has been my observation that rarely is there a piece of legislation dealing with this subject, or many others in Congress, that comes out with perfect agreement. The circumstance I found myself in was, in terms of pandemic preparation, for example, that we have a need to get vaccines made, and we do not have a capacity as a Nation to do it. Vaccine manufacturers were clearly seeing liability as an obstacle, and we needed to get it removed, and there was a rigorous debate, and this bill came forward. I do not have the illusion that it will be the last time it is discussed. That discussion will go on.

What I can tell you is that the law that we have in place has now empowered me as Secretary of Health and Human Services to bring vaccine manufacturers to the table, and we are making very steady and important progress in being able to get vaccines made. I have made clear that I believe a compensation approach does need to be part of this, and I know that will be a conversation that will go forward, and we will be an active participant in it. We have to find the balance here, and there is always disagreement where the balance falls, but let me just say my appreciation for the fact that the Congress did act, because it was a clear barrier. I met with every vaccine manufacturer and said to them, "I have to get a vaccine made. We are facing the potential of a pandemic with no capacity for human immunity."

There were three barriers. The first was liability, which we are talking about. The second was the need for regulatory streamlining, and the third was to make certain that there was someone there to buy the vaccine.

We have solved the liability problem, at least for now. I recognize there will be ongoing conversations about it. We have worked with the FDA to take away those barriers. We are working with the FDA to assure that when we are developing new facilities, we are actually doing the regulation of them as we go, as opposed to waiting until it is finished, and that has helped. And then we are working with the companies on the market.

So I hear you about the debate. I think I understand the ramifications on both sides, but I can tell you how grateful I am that we are able to move, and we are moving rapidly to get this vaccine problem solved.

Senator DODD. I hear you saying that. And if we were sailing in uncharted waters, I might be more sympathetic to the answer, but we have known from previous experiences. I understand the manufacturers' side, they do not want to be sued. I do not know anybody that wants to be sued. And you want them to produce products. But it seems to me that we do not want to fall into the situation where we get vaccines produced that are not safe. And that is our responsibility collectively, both yours and ours up here, that it is not an easy path to go down, but it is one we have really got to try and insist upon.

I mean, you made a very good statement, I think you were on Meet the Press a few months ago, and you were asked about the limits on liability and adequate compensation. And there, I thought you gave a good answer. You said: adequate compensation needs to be made. In fact, your colleague, Dr. Gerberding, was very good was well. She testified before the Foreign Relations Committee on the general matter, and I asked her to comment about the compensation issue. She said at that time, and I am quoting her: "I certainly feel from the standpoint of the smallpox vaccination program, that an absence of a compensation program that was acceptable to the people we were hoping to vaccinate was a major barrier, and I think we've learned some lessons from that."

Are you satisfied that requiring an annual appropriation for the compensation fund is going to be adequate to maintain the strength of that compensation fund to encourage first responders and others to be able to take these vaccines?

Secretary LEAVITT. What is evident to me, Senator, is that we had to get vaccines made, and once we have them, we have time to deal with this issue. Once we can start putting vaccine into arms, that is when the compensation fund would in fact have to be in place. We have time to resolve that issue. We did not have time to do the vaccine, and I was deeply appreciative of the fact we were able to at least set a course for a compensation package, but at the same time, get the liability taken care of so I could start getting these companies started.

Senator DODD. My experience up here is we do not, once the doors are shut, it is awfully difficult to come back and relegislate again, and I realize, again, you have some power as Secretary here, which I appreciate, but this is law now, and where it succeeds you down the road, whatever, it will have the same authority, and whether or not they will be as judicious in the exercise of that authority is something we worry about. I just hope we are not sitting back here having a hearing and wondering why we did not do a better job on compensation requiring a consistent source of funding for this program.

Let me raise a second issue if I can, Mr. Chairman, here, and this has to do with the State efforts in emergency preparedness, and I listened to you talk about the number of visits to a variety of States you have made. The Connecticut Center for Public Health Preparedness at Yale New Haven Health System is leading the

State's emergency preparedness in my State. Interestingly, as we go through, it is the only hospital system in the country with a CDC and a Center for Public Health Preparedness designation, and the only CCHP with a primary focus on preparing the health care delivery workforce for disaster response.

They were asked the other day to come up and to develop some regional partnerships. In fact, 3 weeks ago, they were asked by the health agency here if they would be willing to develop a national standardized education and training program, but there is no financial commitments at all going along with this. I am worried this is the only place in the country that has this designation, both designations, and yet, we are not adequately funding their ability, or the ability of others. I am hearing from other hospitals in my State, and I am a small State, as you know, Connecticut, but you can imagine I am hearing from people in Hartford or other places in the eastern part of the State saying, that is great you are dealing with that New Haven area or lower part of the State, but we are all sitting up here and got a separate set of issues we have to address.

Give us some indication of how this is progressing, and whether or not the Yale experience—by the way, are pleased to be designated as such, and they are a very good facility, obviously, and pleased to have both designations. But I was sort of stunned to find it was the only place in the United States with both designations.

Secretary LEAVITT. Senator, I must tell you that that designation does not come to my memory quickly. I am not sure——

Senator DODD. Sure. I apologize on springing it on you.

Secretary LEAVITT. I can tell you that a primary part of our mission at the national Government is to assure that the States are providing for their communities, the deep community sense of training. In bioterrorism alone I am aware that over 230,000 people have been trained through those efforts. So I cannot respond directly. I would be happy to in writing, but I do not have a response for you immediately.

Senator DODD. Around the country, I presume other efforts are being made to see to it that we have facilities in these States that are designated by the CDC and the other centers for handling this kind of thing.

Secretary LEAVITT. We have a whole series, for example, of laboratories that—different categories of laboratories—and in every State now we have laboratories that have been certified to a certain extent and at a certain level. We have regional laboratories, we have national laboratories. We are working through a system to designate facilities in every State. One of the things that becomes quite evident, when you start dealing with bioterrorism and you deal with pandemics or any kind of an emergency involving disease, that will manifest itself first in a State. When a bird inevitably flies into the United States with the H5N1 virus on board, that bird will likely be presented at a State agricultural lab first. It will then go to a State agricultural commissioner. And then it will find its way to Washington.

So our first line of defense is at the State level.

Senator DODD. Thank you.

Mr. Chairman, going back to the first set of issues here, I am deeply concerned about the standards we are applying. Again, I have great respect. I probably represent more pharmaceutical companies in Connecticut than almost any other State in the country, and we are very proud of the work they do. They would be the first to tell you in some ways, because they worry. Their reputations suffer from time to time when competitor companies produce less than quality products, and they get a black eye. So those of us who sit on this side of the dais—and you have been on this side of the dais—know what that is like, when one or other people can do things that we all have to answer for to some extent. But they will tell you, Mr. Chairman, that this issue of making sure we have safe and effective products is a matter they are concerned with as well, and a compensation program that we do more than just the annual funding process for is something we have to look at, or I am fearful we will end up back in the smallpox situation. I raise those issues with you today, Mr. Chairman, and hopefully we can find some legislative vehicle to address those two concerns.

I thank you, Mr. Secretary.

Secretary LEAVITT. Thank you, Senator.

The CHAIRMAN. I thank the Senator for his questions, and also the intensity with which he worked with us on coming up with a solution, and it is my understanding that it is not the compensation package, it is the actual compensation that you are concerned about.

Senator DODD. More that than anything else. We just do not have the money there for it.

The CHAIRMAN. We will continue to work with you on that. I already knew that your State had the most insurance companies. Now I find that it has the most pharmaceutical companies too.

Senator DODD. Sort of the pinata here in politics.

[Laughter.]

The CHAIRMAN. Between Connecticut and Wyoming, we got a lot of stuff. Senator Dodd has one of the quickest minds that I have worked with, and some of the most intensity, but also some of the best institutional memory. So I appreciate your work on this.

I have several more questions. I will ask a couple more, and I will submit some in writing to you that will require a bit more detail, but we appreciate having all of this information for the record.

In S. 1873 we included an advance development agency to help spur late-state commercial development of Biodefense projects. Similarly, the administration's budget included money for advanced development at the National Institutes of Health. You said you thought it was desirable to have a new HHS agency to head up the advance development of bioterrorism inventions. Could you discuss that a little bit further?

Secretary LEAVITT. I would like one person at HHS to report to me and have responsibility for this entire area, and would be the Assistant Secretary of Public Health Preparedness. I have no reluctance, in fact, I have enthusiasm for having such an entity within HHS, but I would like it to fall underneath the purview of the Assistant Secretary for Public Health Preparation.

I have 27 direct reports at HHS. That is not an ideal organizational structure, and I would like not to perpetuate that. I think

it would not be just a matter of convenience to me, it would be better organization and we would get better work across the Agency. One of the dilemmas that often occurs in a department the size of HHS is that you get siloed work, and we have a number of different operating divisions within HHS that are working on matters related to this, and I need a person who can be the point. So my only request—not only request—but in terms of organization, I would like very much to see it organized underneath that one person.

The CHAIRMAN. I have gotten to watch you as Governor and at the EPA and HHS. I have always been inspired and impressed with your management skills and appreciate your suggestions on that.

In January of this year you announced a new proposal to revitalize the Commission Corps. Specifically, your new proposal would increase the number of officers by 10 percent to 6,600 members. It would improve response operations and team-oriented deployment and it would change the recruitment process so it includes stronger personal incentive programs and a better approach for assigning officers. Now, as you mentioned, Commission Corps officers are key to our national response to emergency by providing a ready reserve of health expertise. For instance, the Corps officers have been deeply involved in responding to recent public health emergencies. More than 2,000 Commission Corps officers were deployed to the Gulf region, before, during and after Katrina and Rita.

Given that, can you give me a few more details about this proposal? Will you need legislative changes to implement your new proposal?

Secretary LEAVITT. Senator, the Commission Corps of the United States Public Health Service, is a public service jewel in America, and it needs to be enhanced, expanded, and renewed. We have learned over time the importance of disease in the safety and health of our Nation. The Commission Corps basically represents a deployable force, or potentially a deployable force in a time of need and emergency.

So the reconfiguration basically is to expand it from 6,000 to 6,600. You mentioned that. It is to begin to organize it into deployable teams, so that if we need an epidemiology team that can be deployed to an event in the State of Washington, I have people who are ready to be deployed, and we do not have to search around through the various departments of HHS, assemble them together, and then move them off in a matter of a week instead of hours. I need them to be deployable in an hour. We need the capacity for what happened in Katrina, where we had 2,000 Commission Corps officers deployed throughout that entire region. It would be helpful to be able to do it more quickly and to have the teams designed in a way that they will not disrupt the operation of the places where they work.

This is an asset that is undervalued, under-appreciated, and in many respects, underfunded, and I intend to give it substantial attention during the time that I am Secretary, and the Nation will be a safer and healthier place as a result.

The CHAIRMAN. Thank you. I also want to ask you about the National Disaster Medical System that plays a crucial role in pro-

viding those emergency medical care, and ensuring patients are moved to the appropriate treatment setting. The National Disaster Medical System, which works jointly with a number of Federal agencies, was transferred from HHS to the Department of Homeland Security in 2002. Now FEMA and DHS direct its activation, administration and funding.

Given that HHS has been evaluating recent response efforts and developing policy proposals to bolster our medical response, have you been working with DHS to rethink the current structure of NDMS?

Secretary LEAVITT. We have, and I think it is fair to represent an agreement that we have with DHS, that it would be prudent to move the DMATs back to HHS so that we have the entirety of the medical disaster component there. We have responsibility for it in its entirety, and we need to have the capacity to deploy and manage the assets. And we will be preparing legislation to suggest that the Congress deal with that issue.

The CHAIRMAN. I appreciate that. We are going to have a vote shortly. I thank you for your testimony, and for being here today. We will leave the record open so that questions may be submitted, and as I said, I have a few more detailed ones, so your people can provide some numbers.

Secretary LEAVITT. Thank you. I will look forward to that.

The CHAIRMAN. I love numbers. We will continue to work with you on this. I really appreciate the job you are doing. Thank you for being here today.

Secretary LEAVITT. Thank you, Mr. Chairman.

[The prepared statement of Secretary Leavitt follows:]

PREPARED STATEMENT OF THE HON. MICHAEL O. LEAVITT

Good morning, Mr. Chairman, Senator Kennedy, and members of the committee. I am honored to be here today to update you on the steps the Department of Health and Human Services (HHS) has taken to prepare for the threats of bioterrorism and other possible public health emergencies, including pandemic influenza. The events of September and October 2001 served as a continuing reminder that terrorism—indeed bioterrorism—is a serious threat to our Nation and the world. The administration and Congress responded forcefully to this threat on a number of fronts, including through the passage and implementation of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 and the Project BioShield Act of 2004. Together, the administration and Congress provided significant new funding to strengthen our medical and public health capacities to protect our citizens from future attacks.

While public health remains chiefly a State and local responsibility, HHS plays a pivotal leadership role. I am pleased to join you today to update you on the progress we have made.

HHS STRATEGIC PLAN

In the summer of 2003, HHS completed its first strategic plan to counter bioterrorism and other public health emergencies. Since then, HHS has worked diligently and in close cooperation with State and local public health departments, to implement the strategy. These experiences, in turn, continue to yield improved insights regarding the strategy and its implementation.

HHS updated the strategic plan in the summer of 2005 to capture important lessons learned. The updated plan focuses on the following strategic foci, which compose the overall framework for HHS efforts:

1. Preventing Bioterrorism
2. Enhancing State, Local, and Tribal Preparedness for Bioterrorism and Other Public Health Threats and Emergencies

3. Enhancing HHS Preparedness for Bioterrorism and Other Public Health Threats and Emergencies
4. Acquiring New Knowledge Relevant to Bioterrorism and Other Public Health Threats and Emergencies
5. Developing, Acquiring, and Deploying Priority Medical Countermeasures for Chemical, Biological, Radiological and Nuclear (CBRN) Threats

In keeping with the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, the Plan emphasizes bioterrorism, while recognizing that public health threats and emergencies can ensue from myriad other causes, both naturally occurring and man-made. HHS and its partners therefore must prepare for and respond to all manner of mass casualty incidents. As a consequence, bioterrorism preparedness is not an insular activity for HHS but rather an integral critical component within an all-hazards readiness program. To ensure the synchronization of HHS' efforts in this area, the Office of Public Health Emergency Preparedness coordinates HHS-wide emergency preparedness activities and serves as the principal point of contact at HHS for other Federal agencies and Departments.

This year, we are proposing roughly $4.4 billion to prepare for possible bioterrorist and other public health emergencies. This includes:

• An additional $68 million in the Strategic National Stockpile to expand capabilities to operate, properly store, and deploy the rapidly increasing holdings of these critical repositories;
• Approximately $1.3 billion at CDC and HRSA to continue to improve State and local public health and hospital preparedness;
• $79 million to fund the Mass Casualty Initiative, which includes Federal Medical Stations, Medical Reserve Corps, Healthcare Provider Credentialing and the Commissioned Corps Transformation initiatives, and;
• $160 million to support advanced development of priority medical countermeasures.

This $4.4 billion is complemented by an additional $2.3 billion allowance for an emergency appropriation and $352 million in ongoing efforts in the fiscal year 2007 budget for pandemic influenza activities.

STATE AND LOCAL PUBLIC HEALTH AND HOSPITAL PREPAREDNESS

Under the President's National Response Plan, HHS leads Federal public health efforts to ensure an integrated and focused national effort to prepare for and respond to emerging biological and other CBRN threats. HHS is also the principal Federal agency responsible for coordinating all Federal-level assets activated to support and augment the State and local medical and public health response to mass casualty events.

HHS' leadership strategy begins with enhancing the capabilities of State and local public health departments and hospitals. This approach is consistent with experience of emergency responders everywhere; for all emergency incidents—whether naturally occurring, accidental, or terrorist-induced—begin as local matters.

Principally through HHS's Centers for Disease Control and Prevention (CDC) and Health Resources and Services Administration (HRSA), funds have been provided to States and localities to upgrade infectious disease surveillance and investigation, enhance the readiness of hospitals and the health care system to deal with large numbers of casualties, expand public health laboratory and communications capacities and improve connectivity between hospitals, and city, local and State health departments to enhance disease reporting. First, the Centers for Disease Control and Prevention (CDC) provides preparedness funding annually to public health departments of all the States, certain major metropolitan areas, and other eligible entities through cooperative agreements. Second, the Health Resources and Services Administration (HRSA) employs complementary cooperative agreements to provide preparedness funding annually within States for investment primarily in hospitals and other healthcare entities. HHS collaborates with DHS toward ensuring that the guidance associated with the CDC and HRSA awards is coordinated with the guidance associated with those DHS awards that address other aspects of State and local preparedness, such as emergency management and law enforcement. Including the funding we have requested for fiscal year 2007, CDC and HRSA's total investments in State and local preparedness since 2001 will total almost $8 billion.

PERFORMANCE MEASURES

HHS through the CDC and HRSA cooperative agreements has undertaken a conscious process to develop performance measures for public health and healthcare preparedness activities. HRSA conducted an expert panel of States and other stake-

holders (to include hospitals and hospital associations at the local and national level) in January 2006 to develop a core set of healthcare preparedness measures. These measures are being cross-walked with the public health measures developed by CDC and the Target Capabilities List (TCL) developed by the Department of Homeland Security (DHS). The measures will be undergoing a national vetting and review process in the near future and progress toward meeting these measures will be reported during the fiscal year 2006 funding year.

SURVEILLANCE

We are also taking important steps to expand and refine our disease surveillance capabilities. BioSense is a national program designed to advance a new type of biosurveillance at the national, State, and local levels. Using streams of health data and advanced algorithms for analyzing and visualizing these data streams, the new methods supported by BioSense address the needs of monitoring for infectious diseases, for biological and chemical attacks, and for naturally occurring public health emergencies. BioSense supports the situational awareness necessary to confirm and identify possible events, to track and manage their size and spread, and to provide public health and government decisionmakers the information needed to manage preparedness and response. Though data have been compiled through BioSense for the last few years, there has been a significant time lag in the transmittal and analysis of data. Starting January 1, 2006, CDC has been receiving near "real-time" data from over 30 hospitals in 10 cities. The goal is by the end of 2006 to have over 100 hospitals in all 31 BioWatch cities participating in BioSense.

In responding to the threat of pandemic influenza with the support of additional funding in fiscal year 2006, CDC plans to further accelerate implementation of the BioSense program in 2006 by increasing the number of participating cities, the number of healthcare systems and real-time clinical data sources within those cites, and incorporating other existing health data sources of importance in monitoring influenza activity and the effectiveness of emergency response.

HHS FOOD SAFETY EFFORTS

The Bioterrorism Act provided HHS with new authorities to protect the Nation's food supply against the threat of intentional contamination and other food-related emergencies. This legislation represents the most fundamental enhancement to our food safety authorities in many years. These additional authorities improve our ability to act quickly in responding to a threatened or actual terrorist attack, as well as other food-related emergencies.

In addition to implementation of the new authorities provided in the Bioterrorism Act, HHS has undertaken numerous other activities to ensure the safety and security of the Nation's food supply. We have enhanced coordination with our partners in Federal, State, and local governments, academia, and industry. As an example, FDA USDA, DHS, and the Federal Bureau of Investigation are collaborating with States and private industry to protect the Nation's food supply from terrorist threats through the Strategic Partnership Program Initiative. The Initiative involves using a vulnerability assessment tool to identify sectorwide vulnerabilities. It will also identify mitigation strategies and research needs.

TRAINING AND SURGE CAPACITY

An integral part of emergency response is the ability to provide surge capacity to undergird medical and public health systems that may be overwhelmed by mass casualties or displaced persons. A critical new program is the Federal Medical Stations (FMS), which was originally intended to provide a deployable medical capability (equipment, material, pharmaceuticals) to assist hospitals in meeting needed surge requirements. They are designed to be staffed by Federal personnel in support of regional, State, or local venues. Although still in the proof of concept phase, FMS capability was projected into the Gulf in response to Hurricanes Katrina and Rita. Ten 250-bed derivatives of the FMS were created within days of Hurricane Katrina. These units had pared down pharmaceutical lists and were used to support the medical needs of the evacuees, rather than providing hospital surge capacity. While the FMS was designed to be staffed by Federal personnel, they were also adapted during the hurricanes to support state-run medical needs shelters. Current plans are to expand the program to include FMSs that are specifically designed to support the States in providing care to evacuee populations with chronic medical conditions. As we further develop the FMS program we are considering how it can be used to support multiple capabilities. For example, with the growing concerns regarding pandemic influenza, the FMS program is exploring the possibility of using these mo-

bile medical units to support quarantine stations. Our fiscal year 2007 budget seeks $50 million for FMS.

In the mass casualty setting, the ability to quickly increase the number of health care workers available is a critical component of public health emergency response capacity. HHS' Health Resources and Services Administration (HRSA) has supported efforts to improve personnel surge capacity. Funds are used to allow jurisdictions to develop or enhance Emergency Systems for Advance Registration of Volunteer Health Professionals (ESAR-VHP), authorized under the Public Health Security and Bioterrorism Preparedness and Response Act. ESAR-VHP is designed to help States develop registries of volunteer health professionals whose credentials have been verified in advance of an emergency so that they can be quickly called on and utilized in an emergency. These systems are being developed according to national guidelines, standards and definitions so that States can easily exchange health professionals in an emergency. Once fully developed, these state-based volunteer registries will include up-to-date, verified information on health and medical volunteer identity licensure status, and professional credentials required for practice in hospitals and other facilities. These systems will include Medical Reserve Corps volunteers, State and local personnel, and health professionals working in the private sector.

Our fiscal year 2007 budget seeks $7.6 million for development of a web-based portal that would create the means for integrating the State ESAR-VHP systems into a national system, thereby promoting a more coordinated national deployment of personnel. The portal is intended to not only integrate existing State ESAR-VHP systems, but to also provide a credentialing service that could assist States with the development of their ESAR-VHP databases.

HRSA also continues to support the Bioterrorism Training and Curriculum Development Program (BTCDP). This program provides support to health professions schools, health care systems, and other educational entities to equip a workforce of health care professionals to address emergency preparedness and response issues. It is estimated that nearly 225,000 health care professionals have received training to enable them to recognize indications of a terrorist event, treat patients and communities in a safe and appropriate manner, participate in a coordinated multidisciplinary community response, and alert the public health system rapidly and effectively. HRSA is promoting consistency, collaboration and coordination in healthcare preparedness training through the alignment of curriculum with the National Preparedness goal, adoption and promulgation of competency-based training, evaluation of training and healthcare preparedness through exercises and drills, and establishing a system for disseminating tested materials.

PHS COMMISSIONED CORPS

The Commissioned Corps provides a unique source of well-trained and highly qualified, dedicated public health professionals who are available to respond rapidly to urgent public health challenges and health care emergencies. The Corps' response to Hurricane Katrina is a powerful example of what the Corps can do. In response to Katrina, we deployed more than 2,000 Corps officers—the largest deployment in the history of the Corps—and we still have personnel in the field providing care in Louisiana today. Transformation is intended to make the force management improvements that are necessary for the Corps to function even more efficiently and effectively. We are now in the process of organizing our officers into teams, providing more training and supplying more equipment so that they can deploy more rapidly and with more capability than is the case presently. All of our officers will be required to meet readiness standards. The President's fiscal year 2007 budget request reflects the importance that has been given to the transformation of the Corps, including an additional $10 million for strengthening the systems that will allow us to better manage the force.

DEVELOPING, ACQUIRING AND DEPLOYING PRIORITY MEDICAL COUNTERMEASURES

CDC also operates HHS's Strategic National Stockpile (SNS), which contains large quantities of medicine and medical supplies to protect the American public if there is a public health emergency severe enough to cause local supplies to run out. Once Federal and local authorities agree that the SNS is needed, medicines and medical supplies can be delivered to any State in the United States within 12 hours. Consequently, each State is now required to develop plans to receive and distribute SNS medicine and medical supplies to local communities as quickly as possible in the event of a deployment.

HHS's National Institutes of Health (NIH) is assigned the lead role in the research and early development of medical countermeasures to prepare for and re-

spond to a biological, chemical, radiological, or nuclear threat agents, and in the conduct of research that will expand our understanding of the human health impact of these agents. The National Institute of Allergy and Infectious Diseases (NIAID) is the NIH institute with primary responsibility for carrying out this assignment.

Thus far, NIAID has used Project BioShield authorities to award $35.6 million in grants and contracts. The activities supported by these awards will advance development of countermeasures toward possible future procurement with Project BioShield funds. Twelve grants and two contracts have been awarded to support research for therapeutics and a vaccine candidate directed against the CDC Category A agents that cause anthrax, smallpox, tularemia, plague, botulism, and viral hemorrhagic fevers. NIAID has awarded 4 grants and 3 contracts to support research on medical countermeasures against radiological or nuclear terrorist attacks, including countermeasures to protect the immune system against radiation and improved treatments for the elimination of internal radionuclide contamination that can be given by mouth rather than intravenously.

Pandemic Influenza Activities

As you know, last year, the President requested $7.1 billion in emergency funding for the *National Strategy for Pandemic Influenza*, of which $6.7 billion was requested for HHS. Congress appropriated $3.8 billion as the first installment of the President's request to begin these priority activities, and of this amount, $3.3 billion was provided to HHS. We appreciate the action of Congress on this appropriation as it takes us an essential step forward to become the first generation in history to be prepared for a possible pandemic.

Using the first $3.3 billion we received in December, we are planning by the end of this year to procure approximately 22–24 million regimens of antivirals at the Federal level. The funding we propose for fiscal year 2007 will help us come closer to our goal of covering 25 percent of the American population. This year we will expand our pre-pandemic stockpile of H5N1 vaccine by 1.7 million courses, and will be investing significantly in the domestic development of cell-based technology for influenza vaccine. This, and the proposed fiscal year 2007 funding, is necessary to add additional manufacturers to have the domestic capacity to produce enough vaccine for the U.S. population within 6 months of the first sign of a pandemic.

In March 2006, HHS, through CDC, started allocating $100 million to help States and other eligible entities enhance preparedness for pandemic influenza. Later this year, we will allocate an additional $250 million for further State and local preparedness. The Congress has specified that the bulk of funding in this area should be based on performance. In the near future, HHS will apprise the States as to the contractual arrangement whereby they may purchase additional antiviral drugs, if they so choose, at a 25 percent subsidy.

As the next step in these efforts, this year's budget includes a $2.3 billion allowance for the second year of the president's Pandemic Influenza plan. These funds will enable us to meet several important goals, including providing pandemic influenza vaccine to every man, woman and child within 6 months of detection of sustained human-to-human transmission of a bird flu virus; ensuring access to enough antiviral treatment courses sufficient for 25 percent of the U.S. population; and enhancing Federal, State and local as well as international public health infrastructure and preparedness.

Project BioShield

The Project BioShield Act of 2004 (P.L. 108–276) ("Project BioShield") is a critical part of a broader strategy to defend America against the threat of weapons of mass destruction. It provides HHS with several new authorities to speed the research, development, acquisition, and availability of medical countermeasures to defend against chemical, biological, radiological and nuclear (CBRN) threats.

In exercising the procurement authorities under Project BioShield, HHS has launched acquisition programs to address each of the four threat agents deemed to be Material Threats to the U.S. population by DHS [*Bacillus anthracis* (anthrax), smallpox virus, Botulinum toxins, and radiological/nuclear agents]. HHS has used the Special Reserve Fund (SRF) to award two contracts for vaccines against anthrax, one contract for a liquid formulation of a drug to protect children from radioactive iodine exposure following nuclear events, and one contract for chelating agents for countering the effects of internal exposure to transuranic radioisotopes.

In addition, negotiations are underway for the acquisition of anthrax therapeutics. With respect to smallpox vaccines, an award will be made for the manufacture and delivery of up to 20 million doses of a next generation attenuated smallpox vaccine, modified vaccinia Ankara (MVA). Additionally, negotiations are underway for procuring 200,000 doses of botulinum antitoxin.

These countermeasures are being added to the SNS that currently includes vaccines, antibiotics to counter infections caused by anthrax, plague, and tularemia, antitoxins, chemical antidotes and radiation emergency medical countermeasures.

However, we recognize that more can and must be done to aggressively and efficiently implement Project BioShield. To this end, I intend to establish a dedicated strategic planning function in HHS that more efficiently integrates biodefense requirements, across the full range of threat agents, with the execution of advanced development and procurement of medical countermeasures. I will reorganize the Office of Public Health Emergency Preparedness (OPHEP) and assign and empower it as the responsible office to develop and implement a strategic plan for this purpose, and I will ensure that HHS component programs and functions are properly aligned, and that their respective strengths are leveraged, to support OPHEP's efforts. I will also work closely with other departments and agencies to streamline and make more effective the current BioShield interagency governance process. We will make this process more transparent and work to educate the public and industry about our priorities and opportunities. As part of this, HHS will convene an outreach meeting with these external stakeholders later this year.

I applaud the committee's efforts to support and promote innovation for medical countermeasures, as reflected in S. 1873, the Biodefense and Pandemic Vaccine and Drug Development Act of 2006. However, as presently drafted, I am concerned that S. 1873 would impose an organizational framework on HHS that impairs my ability to implement the strategic approach for medical countermeasures development and procurement that I have outlined, including the functions to be executed by a reorganized OPHEP and a more efficient BioShield interagency governance process. I am committed to ensuring that advanced development of medical countermeasures is properly supported and conducted, and that the procurement and medical countermeasures is timely and efficacious. I would therefore appreciate the opportunity to work with the committee to further refine S. 1873 to ensure that it achieves our mutual objectives of improving processes that expedite the availability of promising treatments to naturally-occurring infectious diseases or to a chemical, biological, radiological, or nuclear attack.

As part of this, the administration will work with the committee on funding for this effort, while preserving the BioShield Special Reserve Fund for medical countermeasures against known and emerging terrorist threats. I also note that the administration is requesting $160 million in fiscal year 2007 for advanced development.

CONCLUSION

Thank you once again for inviting me to testify on this important issue. Maintaining a robust national public health infrastructure to effectively prepare for all emerging threats requires sound collaboration, communication, and clear lines of command and control. Although preparedness depends on plans at the local, State, and Federal levels, without the exercise of these plans, we will not be able to know if we are truly prepared. HHS will continue to lead the way toward public health emergency preparedness. As the threat of a pandemic influenza clearly shows however, the scope of the Federal Government in responding to pervasive public health emergencies such as a pandemic is limited. States and localities must be prepared to rise to the challenge as well.

I would be happy to take any questions.

The CHAIRMAN. As to the next panel, Senator Burr wants to chair that in its entirety, so he will be here right after the vote. So we will have a recess until the vote is completed. We will stand at recess.

[Recess.]

Senator BURR. [presiding]. The hearing will come to order.

Let me thank our witnesses for their patience and flexibility. We do know that we are going to start a series of votes sometime between 10:30 and 10:45. My hope is that we can get all of your testimony in, and potentially give you a short break of about an hour and have more members participate in the questioning. I hope that works for everybody's timeline. If it doesn't, certainly we will try to accommodate. But as has been the last 48 hours up here, we

could get to 10:45 and have not had a vote yet, so we might be able to get the completion of the hearing in.

At this time I would like to recognize Dr. Richard Falkenrath, national security expert, a senior fellow at the Brookings Institution, the former Deputy Homeland Security Adviser to the President. He holds a Ph.D. from the Department of War Studies at Kings College in London, as well as degrees in economics and international relations.

Mr. Falkenrath, the mike is yours.

STATEMENTS OF RICHARD A. FALKENRATH, SENIOR FELLOW, THE BROOKINGS INSTITUTION; LEAH DEVLIN, D.D.S., PRESIDENT, ASSOCIATION OF STATE AND TERRITORIAL HEALTH OFFICIALS, AND DIRECTOR, NORTH CAROLINA DEPARTMENT OF PUBLIC HEALTH; DAN HANFLING, M.D., DIRECTOR, EMERGENCY MANAGEMENT AND DISASTER MEDICINE, INOVA HEALTH SYSTEM; AND A. RICHARD MELTON, DEPUTY DIRECTOR, UTAH DEPARTMENT OF HEALTH

Mr. FALKENRATH. Thank you very much, Senator, for the invitation to appear today. I will be very brief and ask that my prepared statement be——

Senator BURR. Without objection, everybody's testimony will be made a part of the record.

Mr. FALKENRATH. I was in the White House when the first bioterrorism bill was worked on by the Congress and was involved in that. I think it made sense at the time, and it still makes sense. I think there are certain aspects of it which should be modified, and I am going to lay those out.

First just a general point about the subject you are working on. I am concerned with national security. I have worked on terrorism for most of the last 5 years of one form or another. I will say this, though: that when viewed in comparison to all other conceivable threats to U.S. national security, in my opinion catastrophic disease is now and for the foreseeable future the greatest danger we face. And so I could elaborate on that in questions, if you are interested, but let me just say that I have looked at this in comparison to lots of other threats, and I think it presents the worst combination of likelihood, severity of consequences, and poor countermeasures and defenses on our part.

Now, since we are short on time and we need to be brief in our opening statement, I am just going to focus on the shortcomings that I see in the U.S. response to this threat rather than all the things that we have done right, of which there are many.

I believe that we are better prepared for biodefense threats than any other country in the world and that we have made enormous strides. I think there is no area of national security in which we have come further since 9/11, but also no area where we have further to go. And so that is the context when I now offer some criticisms about how we are doing as a Nation.

I am going to focus on four areas: first, countermeasure availability; second, the National Response Plan; third, State and local roles in the National Response Plan; and, fourth, the Federal organization.

On countermeasure availability, this is obviously critical. These attacks and diseases, pandemics, are in principle treatable. So if we have the right countermeasures, we can make an enormous difference.

Two areas I think are working right. We have a very good R&D program for fundamental discovery at NIH. I also think we have an appropriately sized effort at HHS to purchase countermeasures to known pathogen threats. Everyone agrees, including Secretary Leavitt, that that is moving too slowly, and I am talking about the BioShield Program, but we do have a program to buy countermeasures to known threats, things that are already on the CDC list.

There are four areas where we are not doing so well in countermeasure availability:

First, the pharmaceutical industry has not yet been effectively mobilized to this task. Everyone understands that. Big PHRMA, the largest pharmaceutical companies with enormous resources, are really not involved in the way that we would like them to be as a country. We can understand why that is economically. It is still an outcome we would like to change.

Second, the clinical trial process just takes too long. It takes too long to get a drug from discovery to manufacturing. Everyone is aware of that. I don't have a quick solution to it, but it is the sort of thing that we need to keep paying attention to.

Third, we do not have a program to deal with novel pathogens. These are pathogens that either emerge newly in nature or that are genetically modified by some adversary. We have a program to buy countermeasures to known pathogens, but not to look over the horizon and figure out how we can fight against novel pathogens that come along.

I would note that the Department of Defense, without prompting by Congress or the White House, elected to dedicate $1.5 billion over 5 years to this threat. I think that is good. I am glad Secretary Rumsfeld decided to do that. But we need a program, and I don't really care where it is in the U.S. Government, but we need a program, and it should be separate from our program to buy countermeasures to known threats. It is a fundamentally different task, and they should be organizationally distinct.

A final point on countermeasure availability. As Secretary Leavitt said, we need domestic influenza vaccine production capacity. We need it here in the country, and we need it now. And this is taking a very long time to deal with the vaccine manufacturers, but we are trying to bring them along so that they will voluntarily build this capacity, which everyone who studies this problem knows that we need.

I am starting to wonder whether they will ever do it and whether we need a different approach, whether we should go for some sort of Government-owned contract or -operated approach, which is a radical departure. But, you know, the definition of insanity is to keep repeating the same behavior and expect a different outcome, and I am really wondering whether we are ever going to bring these companies around to build a plant which economically they have yet to feel like is in their interest to build. No matter how much incentives, how much tax breaks, how much liability relief,

they haven't done it in the last 5 years. I am not sure they are ever going to do it, certainly not in the timetable that we want.

I would say here as a parenthetical, given the extra—we have an enormous foreign dependency on foreign producers of vaccine for a pandemic. The relative lack of attention to that foreign dependency for a pandemic is, I think, striking when you contrast it to the enormous outcry that we had over the transfer of six port terminal operators to another company. Just think about the security implications of these two things. There is no doubt the vaccine production capacity is a far more significant security issue.

The NRP. In my judgment, the NRP is not adequate for catastrophic disease contingencies. I was involved in writing the NRP. I was involved in writing the Presidential directives that called for the NRP. I am very familiar with it. It assigns responsibility to HHS for ESF-8, Medical Support, and assigns responsibility for implementing the Biological Annex of the NRP.

There are two big problems. This works fine for routine disasters, for routine health problems, for providing discrete assistance in the midst of a major disaster. It is, in my judgment, completely inadequate and unrealistic for a genuinely catastrophic disease contingency—a pandemic or a wide-area bioterrorist attack—when you need to distribute life-saving medicines to a fearful population over a very large area, potentially the entire country, in a very short period of time and in which we have reason to believe that the State and local agencies will not be able to perform what the Federal Government implicitly expected them to do. And we know this from exercise after exercise after exercise. We know this.

So what do you do about it? I think HHS is fine for leading ESF-8 routine matters, including medical support in something like Katrina. I do not think they are capable of doing what the country and the President and the Congress will expect of them in a pandemic or a wide-area bioterrorist attack. And, therefore, I think that we need to amend the NRP, amend the Presidential directives that relate to the NRP, and a number of different internal administration documents to allow the President to transfer ESF-8 to the Department of Defense when he decides it is necessary, and to direct the Department of Defense to prepare to assume that responsibility and to assume for the incapacitation of State and local and public health agencies. This is a major change, but we know from exercise after exercise that the current arrangement is not working.

I am almost out of time. I will say further on State and local responsibilities, I think that we give a lot of grants to State and local agencies. I think it is very important to build this capacity. I supported them before I even entered into Government. I think we need to start conditioning them. We need to make them powerfully conditional on meeting the certain requirements for plans and capabilities that the Federal Government expects of State and local agencies in the midst of a crisis. This would be a radical change, and this would require amendment of Title I of the bioterrorism bill, which right now gives the grants out more or less as an entitlement. I think they need to be conditioned.

A final point on organization of the Federal Government. There is no one in charge in this area, there is no one person in charge

beneath the President. It is widely distributed across the U.S. Government. That is frustrating. It was frustrating when I was on the White House staff. There is no single solution to it. You can't just decree that one person is in charge. It doesn't work the way our Government is organized. I think the only answer is to augment the White House coordination staff on which I used to work and also to augment the HHS staff. Secretary Leavitt needs a robust and large staff under him to coordinate his highly stovepiped agency at HHS, which has huge responsibilities. Right now the Assistant Secretary for Emergency Health Preparedness has far too small a staff for the expectations that we have of it.

Senator BURR. Thank you very much. You have certainly laid on the table in a very short period of time some very meaty things for us to weigh, especially a transfer to DOD, which I am probably in total agreement with you that that debate needs to begin to happen because that is not a transfer that happens easily or quickly. And it is time we learn from what we have seen.

[The prepared statement of Mr. Falkenrath follows:]

PREPARED STATEMENT OF RICHARD A. FALKENRATH

Introduction

Good morning, Mister Chairman, Senator Kennedy, and members of the committee. I am grateful for the opportunity to be here today to provide my views on the reauthorization of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (P.L. 107–188), and biodefense and public health preparedness more generally. I am honored to be asked to assist your committee as you discharge your vital oversight responsibilities.

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 was an extremely important bill. It was the first of several important steps taken by the United States in the area of biodefense after the terrorist attacks of September 11, 2001. The direction and authorizations contained with Title I of the Bioterrorism Act made sense at the time. Most of them still make sense today, but there are certain aspects in which I believe modifications are in order. I describe these recommendations in the testimony that follows.

I would like to commend the members of this committee for holding a hearing at this time. Biodefense and public health preparedness is not the crisis de jour. Yet biodefense and public health preparedness are profoundly important subjects: more important, in my judgment, than many of the security issues that have dominated the public debate in the last few months. As I know from first-hand experience, it is difficult for senior policymakers to devote their time and energy to matters of great importance but no immediate urgency.

I would also like to commend the American and international public health community. I am continually impressed by the beneficence and selfless dedication of the countless doctors, nurses, scientists, technicians, and other public servants who have devoted themselves to the fight against infectious disease. Here in the United States, we are particularly fortunate to have two individuals of highest possible caliber serving as our Director of the Centers for Disease Control (CDC) and our Director of the National Institute for Allergy and Infectious Disease (NIAID). I have some sense of the enormity of the challenges they and others still serving in government face. The testimony I have to offer today should in no way be taken as a critique of the performance of any individual government official at any level. Rather, the criticism I offer today is meant to be constructive and is directed at the overall U.S. strategy for dealing with catastrophic disease events.

For the record, my name is Richard A. Falkenrath and I am presently a senior fellow in Foreign Policy Studies at the Brookings Institution. I am also Managing Director of the Civitas Group LLC, a strategic advisory and investment services firm serving the homeland security market, and a security analyst for the Cable News Network (CNN). Until May 2004, I was Deputy Assistant to the President and Deputy Homeland Security Advisor on the White House staff. Previously, I served as Special Assistant to the President and Senior Director for Policy and Plans within the Office of Homeland Security, and as Director for Proliferation Strategy on the National Security Council staff. Prior to government service, I was an Assistant Pro-

fessor of Public Policy at the John F. Kennedy School of Government at Harvard University.

The Threat of Catastrophic Disease

I have studied many different threats to U.S. national security. As an undergraduate, I studied the Soviet maritime threat to the United States and its European allies. As a graduate student, I studied the Soviet conventional forces threat in central Europe. As a postdoctoral researcher, I co-authored a book on the threat of fissile material and nuclear weapons leaking out of the former Soviet Union's sprawling nuclear complex. As a Kennedy School professor, I co-authored another book on the threat of mass-casualty terrorism involving nuclear, biological, and chemical weapons. As a member of the National Security Council staff, I was a voracious consumer of intelligence on the extraordinarily wide variety of threats to the United States. After the terrorist attacks of September 11, 2001, I became one of the President's homeland security advisors; in this capacity, I scrutinized not only the never-ending stream of intelligence related to terrorist threats against U.S. interests, but also the less accessible body of information related to America's underlying vulnerabilities—that is, to the plausible scenarios which present the greatest likelihood of the greatest harm to the Nation. In previous testimony before the Senate Homeland Security and Government Affairs Committee, I have drawn attention to some of those vulnerabilities, notably those presented by toxic industrial chemicals.

My years of study and government service have led me to the following conclusion. As the prospect of global thermonuclear war has faded away, the greatest remaining source of danger to U.S. national security in the 21st century—and to mankind as a whole—is disease.

I reach this conclusion in part because I define the catastrophic disease threat broadly, to include both natural and manmade disease outbreaks. The pathogens that cause disease range from the viruses that cause influenza, smallpox, West Nile, and SARS—to the bacteria that cause anthrax, cholera, plague, and tuberculosis—to the parasites that cause malaria and sleeping sickness. Some, like smallpox, are recorded in earliest human history; others, like the virus that causes SARS, have only recently become known to science. Like all living organisms, pathogens evolve to adapt to changes in their environment, which in most causes is another living organism—a human, a bird, a pig, or a mosquito, for instance—with an immune system that seeks to manage the host's microbial infections.

There are three basic categories of the catastrophic disease threat. The first are naturally occurring infectious diseases, such as influenza, yellow fever, and tuberculosis. Naturally occurring disease has profoundly influenced human history, as the scholar William McNeill explained in his brilliant 1976 book, *Plagues and Peoples*, and retains the capacity to do so again today despite revolutionary advances in public health methods and biomedical science. In the words of Nobel Laureate Joshua Lederberg:

> We are engaged in a type of race, enmeshing our ecologic circumstances with evolutionary changes in our predatory competitors. To our advantage, we have wonderful new technology; we have rising life expectancy curves. To our disadvantage, we have crowding; we have social, political, economic, and hygienic stratification. We have crowded together a hotbed of opportunity for infectious agents to spread over a significant part of the population. Affluent and mobile people are ready, willing, and able to carry afflictions all over the world within 24 hours' notice. This condensation, stratification, and mobility is unique, defining us as a very different species from what we were 100 years ago. We are enabled by a different set of technologies. But despite many potential defenses—vaccines, antibiotics, diagnostic tools—we are *intrinsically more vulnerable* than before, at least in terms of pandemic and communicable diseases.[1]

The greatest danger seems to develop when a pathogen shifts suddenly from an animal reservoir into an immunologically naive human environment (a process called zoonosis), as has happened in Asia and Turkey with the H5N1 influenza strain (and happened with the human immunodeficiency virus (HIV) in the late 1970s or early 1980s).

The second category of the catastrophic disease threat are naturally occurring disease-causing microorganisms that some State, nonstate actor, or individual has deliberately acquired, produced, and then somehow disseminated against a susceptible

[1] Joshua Lederberg, "Infectious Disease as an Evolutionary Paradigm," *Emerging Infectious Diseases*, Vol. 3, No. 4 (October–December 1997), at http://www.cdc.gov/ncidod/eid/vol3no4/lederber.htm [emphasis added].

population in order to cause harm; this is bioterrorism. In principle, virtually any disease-causing agent can be used as a weapon, but in practice certain characteristics—communicability, lethality, resistance to countermeasures, environmental resilience—make some agents far more attractive than others.[2] An essential element of the bioterrorism threat is what Richard Danzig, the former Secretary of the Navy and noted thinker on bioterrorism and biodefense, calls the "reload" problem.[3] Once a State or a terrorist has established an effective production process for a biological weapon, there are very few inherent limitations on the amount of biological weapon agent that can be produced. This is because microbes in proper settings reproduce and multiply on their own; time, therefore, is the main constrain on the amount of pathogenic agent a terrorist can deploy. The implications of this fact are profound and are responsible for putting bioterrorism in an altogether separate category from, for instance, nuclear terrorism. As Danzig warns us, bioterrorism needs to be thought of not as one or more discrete attacks but as a *campaign* that will continue until the attacker calls it off or its production process has been located and destroyed. (Nuclear terrorism, on the other hand, is far more likely to consist of only one or a few nuclear detonations due to limits established by the availability of fissile material).

The third are disease-causing microorganisms that a State, nonstate actor, or individual has genetically manipulated (or, conceivably, produced from scratch) for the purposes of improving their utility as a weapon, and then produced and disseminated against a susceptible population; this is bioterrorism involving a novel pathogen. As a result of revolutionary advances in genomics and microbiology, scientists can create new microorganisms that are more communicable, lethal, resistant to countermeasures, and/or resilient to the environment than naturally occurring pathogens. There is debate about the severity of the novel pathogen threat, but the potential dangers were graphically revealed in late 2000, when a team of Australian scientists inadvertently discovered that they could significantly increase the lethality (in rodents) of a relatively benign pox-virus by splicing the interleukin-4 gene into the virus. This relatively simple genetic modification of an animal pathogen raised serious questions about the ease with which a bioterrorist could create novel pathogens that would be more dangerous than the likely naturally occurring biowarfare agents for use against human beings.[4]

Infectious disease is, of course, a chronic problem throughout the world with particularly devastating manifestations in the developing world. My particular focus in this testimony is *catastrophic* disease events in any of the three categories outlined above. A catastrophic disease event in an extreme scenario may result when one or more of the following three criteria apply.

- First, is the disease characterized by efficient human-to-human communicability and serious expected health effects due to inadequate immunological or likely medical response? The SARS outbreak did not meet this criterion because the disease was not particularly communicable. Efficient human-to-human transmission is most likely to be airborne, involving an invisible respiration of infectious aerosol, since the other possible modes of transmission can more effectively countered through behavior change. Pandemic influenza is the disease most likely to satisfy this criterion in the near term.
- Second, is the outbreak the result of a wide-area release of a pathogenic agent deliberately and competently selected for the seriousness of its health effects, its resistance to available medical treatment, and/or its environmental resilience? The anthrax attacks of October 2001, as serious as they were, did not meet this criterion because of the relatively small amount of pathogenic agent used. A line- or point-release of 100 times as much agent of the same quality in a densely populated area would, however, in all likelihood satisfy this criterion and qualify as a catastrophic disease scenario.
- Third, is the fear created by the outbreak likely to trigger a public response of such scale or character that it damages the authorities' ability to manage the initial outbreak and/or its follow-on waves, provokes civic unrest, impedes the provision of essential services, undermines public trust in government, damages the economy, or

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[2] The Centers for Disease Control list of "Category A" agents include anthrax (Bacillus anthracis); botulism (which is an acute intoxication rather than infectious disease, caused by clostridium botulinum); plague (Yersinia pestis); smallpox (variola major, which no longer exists in nature); tularemia (Francisella tularensis); and various viral hemorrhagic fevers (e.g., Ebola, Marburg], Lassa, Machupo). See http://www.bt.cdc.gov/agent/agentlist-category.asp#a.

[3] Richard Danzig, Towards a Long-Term Strategy for Coping with the Risk of Bioterrorism. Washington, DC.: The Defense Science Office, October 2005.

[4] Elizabeth Finkel, "Engineered Mouse Virus Spurs Bioweapon Fears," Science, Vol. 291, No. 5504 (January 26, 2001), p. 585.

impairs the Nation's ability to protect its strategic interests or fulfill its global responsibilities? These effects seem most likely to result from shortages in vital, lifesaving medical countermeasures to the disease in question. For instance, because of the "reload" problem noted above, an effective aerosolized anthrax attack in a confined area of the country is likely to create enormous demand for antibiotic prophylaxis across the entire country (until the perpetrator is identified and the anthrax production and weaponization facility destroyed). If this demand for antibiotic prophylaxis is satisfied, hundreds of thousands, if not millions, of healthy people could quickly consume the Nation's entire available supply of effective antibiotic—leaving the country acutely vulnerable to a follow-on attack.

A catastrophic disease event is admittedly an extreme scenario, residing at the very highest end of the threat spectrum. With respect to manmade threats—bioterrorism—I am not suggesting that such a scenario can be easily effectuated or is imminent. Nonetheless, I do not believe that the trends are in our favor. With every passing year, the latent technological potential of States and nonstate actors to use disease effectively as a weapon rises inexorably. With respect to naturally occurring disease threats, no one can estimate precisely the likelihood, timing, or consequence of the appearance of a new human pathogen.[5] However, for at least one potentially catastrophic disease, even the conservative World Health Organization concludes that "the world may be on the brink of another pandemic."[6] According to the WHO, a pandemic along the lines of the relatively mild pandemic of 1957 would result in 2 million to 7.4 million deaths worldwide. A pandemic with the death rate of the 1918 Spanish flu—perhaps the most extreme human disease event in history—could result in several million fatalities in the United States and perhaps over 100 million abroad.

In sum, when viewed in comparison to all other conceivable threats to U.S. national security, the catastrophic disease threat is and for the foreseeable future will remain the gravest danger we face. No State, no terrorist group, no ideology or system of government, no other tactic or target or category of weapons, no technological accident, and no other natural phenomenon, presents as terrifying a combination of likelihood, poor defenses and countermeasures, and consequence.

Achievements, Shortcomings, and Recommendations

Since the terrorist attacks of September 11, 2001, there is no area of national or homeland security in which the United States has made more progress than civilian biodefense, and no area in which the Nation has further to go.

We have launched an extraordinary biodefense research program at the National Institutes of Health; improved our domestic and international epidemiological surveillance systems, including through the deployment of an effective atmospheric sampling system called BioWatch; and stockpiled enough smallpox vaccine for every American, as well as vast quantities of other pharmaceutical and emergency medical supplies that give us dramatically better ability to manage the consequences of certain categories of bioterrorist attack. No country in the world has attacked the challenges for biodefense more aggressively or effectively as the United States, and in my opinion, no country in the world is better prepared for a bioterrorist attack.

There are, however, a number of serious shortcomings in our Nation's current and likely future capacity to cope with most catastrophic disease scenarios. I will focus on four general areas: countermeasure availability; the National Response Plan; local, State, and Federal responsibilities in response plan execution; and Federal organization for biodefense and public health preparedness.

I. Medical Countermeasure Availability

The critical difference between pathogens and most other threats facing the United States is that disease is, in principal, treatable. The right vaccine administered with enough lead time can make a person immune to particular pathogen threats. Antibiotics administered quickly enough can cure a person of most bacterial threats, or at least those which have not acquired antibiotic resistance. Intensive care—respirators and other methods of treating the acute symptoms of a disease—can improve a person's chance of survival dramatically.

The availability of appropriate medical countermeasures is, therefore, a critical element of the Nation's overall biodefense and public-health preparedness. As noted earlier, the U.S. Government has made some extraordinary strides in acquiring

[5] Again, in the words of Joshua Lederberg, "the outcome of encounters between mutually antagonistic organisms is intrinsically unpredictable. . . . Infectious agent outcomes range from mutual annihilation to mutual integration and resynthesis of a new species." Ibid.

[6] http://www.who.int/csr/disease/influenza/pandemic10things/en/index.html.

large stocks of certain medical countermeasures that, in the certain disease contingency, will dramatically improve the Nation's ability to cope with the crisis.

Two aspects of the U.S. strategy for acquiring biomedical countermeasures to pathogen threats seem to me to be essentially sound. The first is the multibillion dollar NIAID biodefense research program. I believe this program is adequately funded, excellently led, has already yielded many important discoveries for reducing the catastrophic disease threat, and will continue to do so in the future. The second is the Department of Health and Human Service's program for procuring proven biomedical countermeasures against *known pathogen threats*, such as ordinary anthrax and smallpox. This effort has been funded through the $5.6 billion BioShield advance appropriation as well as the annual discretionary budget of the Department of Health and Human Services. Most observers would like to see this HHS procurement program move more swiftly, but in my estimation it is reasonably sized and directionally sound.

Nonetheless, I see four general problems in the area of pathogen countermeasure availability.

First, I do not believe that the pharmaceutical industry has been effectively mobilized to the task. From the perspective of the largest pharmaceutical firms, their relatively modest commitment to anti-infective research, development, and production is economically understandable. There is in general less money to be made, and more risk incurred, from developing treatments for infectious disease than treatments of chronic disease and other ailments. Governments, however, cannot shoulder the burden of countering pathogen threats alone, and so we must find a way to more effectively marshal the resources of the world's leading pharmaceutical firms.

Second, the clinical trial process for new biomedical countermeasures takes too long, often 5 years or more. It is, of course, necessary for drug researchers and manufacturers to demonstrate the efficacy as well as the safety of new drugs, and for the Federal Government to regulate this process. The finalization of the Food and Drug Administration's "animal rule" for clinical trials of countermeasures that cannot be tested on humans was a step in the right direction, as was the emergency use authority conferred to the Secretary of Health and Human Services in the Bioterrorism Act of 2002 and BioShield Act of 2004. Even so, the revolutionary advances in the biological and computer sciences over the past decade should make it possible for the U.S. Government to reduce significantly the length of time, and perhaps even the expense, of proving the efficacy and safety of all new disease countermeasures.

Third, the United States needs a discrete program dedicated to understanding and, to the extent possible, developing and acquiring countermeasures to novel pathogens. As noted earlier, the HHS procurement program for the Strategic National Stockpile focuses on countermeasures against *known pathogen threats*—that is, the threat agents that appear on one of several official lists maintained by the Centers for Disease Control. At the moment, there is no government program focused on developing and acquiring countermeasures that will be effective against the threat agents that do not exist or are not yet known. Given the long-term potential for the genetic manipulation of pathogens, the United States should invest in such a capability as part of the Nation's overall biodefense effort. In its 2006 Quadrennial Defense Review, the Department of Defense has announced its plan to reallocate "more than $1.5 billion over the next 5 years to develop broad-spectrum medical countermeasures against advanced bio-terror threats, including genetically engineered intracellular bacterial pathogens and hemorrhagic fevers."[7] This important initiative, which has not yet begun, should be strongly supported by the Congress, authorized by statute (perhaps in the reauthorization of Title I of the Bioterrorism Act), and fully involve all other agencies with biodefense responsibilities. The location of the novel pathogen countermeasures program within the U.S. Government matters less than that it exists in the first place and that it is organizationally separate from the government's program to procure countermeasures against known pathogens. This separation is important because novel pathogens are an over-the-horizon threat requiring innovative, advanced, high-risk countermeasure strategies that are not likely to prosper within a more conventional procurement bureaucracy.

Finally, the United States requires a domestic influenza vaccine production capacity to produce sufficient vaccine for the entire U.S. population within at most 1 year of the onset of a global pandemic. According to the estimates of the University of Minnesota's Center for Infectious Disease Research & Policy, the current domestic vaccine production capacity would allow only 37.5 million U.S. citizens, out of a total

[7] Quadrennial Defense Review 2006, pp. 52–53.

population of 295 million, to be vaccinated during the first year of a pandemic.[8] The United States has plans to acquire 20 million doses of "pre-pandemic" vaccine—that is, a vaccine that was developed against the H5N1 strain that is currently endemic in avian populations but not yet communicable between humans. This pre-pandemic vaccine stockpile is clearly one critical strategy for ameliorating the expected vaccine shortage in the short run. Stockpiling "pre-pandemic" vaccine is not, however, a viable long-term strategy due to the uncertain efficacy of pre-pandemic vaccines against pandemic strains of the virus.

Currently, most of the world's vaccine production capacity located abroad, mainly in Europe, and relies on a relatively unreliable egg-based production technique with a rigid production timetable that can lead to months of unnecessary delay. CDC Director Julie Gerberding has testified that the "pandemic influenza vaccines produced in other countries will likely not be available to the U.S. market as those governments may prohibit export of the vaccines produced in their countries until their domestic needs are met."[9] The implications are obvious: in the event of a global pandemic, thousands to hundreds of thousands of U.S. citizens will contract the disease, and some fraction of them will die, while the citizens of countries with more robust domestic vaccine production capacities—Australia, Canada, France, Germany, Italy, the Netherlands, Switzerland, and the United Kingdom—will acquire an effective vaccine and survive. Given the extreme public and political concern expressed over the security implications of Dubai Port World's intended acquisition of operating contacts for six container terminal facilities at six U.S. ports, the relative lack of concern over this far more significant foreign dependency is astonishing. As a matter of great national urgency, therefore, the United States should develop a large-scale, domestic based vaccine production facility. I urge the Congress to include this mandate in its reauthorization of Title I of the Bioterrorism Act. If private-sector financing is unavailable or only partially available for this project, then it should be paid for from the general revenue. The total cost would be a small and an entirely justifiable fraction of total U.S. national security expenditures.

II. The National Response Plan

The National Response Plan (NRP) is not adequate for catastrophic disease contingencies. The plan assigns responsibility for Emergency Support Function #8, "Public Health and Medical Services," to the Department of Health and Human Services. The Biological Incident Annex to the NRP similarly assigns lead responsibility to the Department of Health and Human Services. The NRP's premise is that "State, local, and tribal governments are primarily responsible for detecting and responding to disease outbreaks and implementing measures to minimize the health, social, and economic consequences of such an outbreak,"[10] and that HHS's role is to coordinate "the provision of Federal health and medical assistance to fulfill the requirements identified by the affected State, local, and tribal authorities."[11] This is a perfectly appropriate arrangement for ordinary emergencies, routine public health problems, and noncatastrophic disease contingencies. It is completely inappropriate and unrealistic for genuinely catastrophic disease contingencies, particularly those which will require the effective distribution of life-saving medicines to a fearful population over very large areas in very short periods of time. In such circumstances, we must assume that State, local, and private-sector health care capabilities become fully or partially incapacitated, and that the Federal Government

[8] "In the United States, domestic production was estimated at 50 million doses of trivalent vaccine during 2004. This would be equivalent to about 150 million doses of monovalent standard-dose, assuming 15 mcg HA per dose. . . . Two critical caveats need to be considered with these types of estimates: (1) it is not clear how many micrograms of antigen will be necessary to elicit an immune response to a pandemic strain and (2) two doses of vaccine will likely be needed to confer adequate protection. For example, recent data from a clinical trial of a candidate H5N1 vaccine demonstrated that volunteers required two doses of a 30-mcg vaccine to mount an adequate immune response to H5N1. If this is the case for a pandemic vaccine, then 60 mcg of antigen would be needed per person, which is four times higher than that needed per dose to confer protection with current annual influenza vaccines. An extrapolation of the current production capacity to this antigen requirement per person suggests that only 37.5 million people in the United States could be vaccinated during the first year of a pandemic (roughly 10 percent of the country's population)." See <http://www.cidrap.umn.edu/cidrap/content/influenza/panflu/biofacts/panflu.html#—Surveillance—Considerations>.

[9] Testimony of Julie L. Gerberding, MD, MPH, before the Subcommittee on Health, Committee on Energy and Commerce U.S. House of Representatives, May 26, 2005 <http://www.cdc.gov/washington/testimony/in05262005.htm>.

[10] National Response Plan, p. 332.

[11] National Response Plan, p. 160.

will need to step in forcefully. A variety of recent full-field and tabletop exercises have supported this assumption.

The Department of Health and Human Services is the locus of most of the Federal Government's expertise on the science of disease and bioterrorism and should remain so. But HHS does not possess much capacity to conduct field operations. The Centers for Disease Control (CDC), an agency within HHS, has various operational capabilities at its headquarters in Atlanta and in the field, but these are, for the most part, optimized for routine public-health matters and epidemiological investigations. With its limited organic operational capabilities, the Department of Health and Human Services is simply not going to be able to meet the American people's expectation of the Federal Government in a truly catastrophic disease contingency such as a high lethal pandemic or major bioterrorist attack.

To address this problem, I believe that Homeland Security Presidential Directive 5 (HSPD-5 on "Management of Domestic Incidents"), HSPD-10 ("Biodefense for the 21st Century"), the National Response Plan, the National Strategy for Pandemic Influenza, the HHS Pandemic Influenza Plan, the CDC Smallpox Response Plan, the Defense Planning Guidance, and the DOD Contingency Planning Guidance should be amended to permit and, indeed, anticipate the assignment of ESF #8 to the Department of Defense in a catastrophic disease incident at the order of the President. The Department of Defense should be directed to plan and prepare for the assumption of the ESF #8 responsibilities—to include the provision of essential health care, distribution of medical countermeasures, rationing of scarce essential supplies—and to anticipate the inability of State, local, and private-sector entities to perform the medical and logistical functions expected of them in the National Response Plan. In such a circumstance, the Department of Health and Human Services should be assigned responsibility for supporting the Department of Defense by providing necessary medical advice and personnel, thus essentially reversing the roles of the two departments in catastrophic disease situations. In ordinary emergencies, noncatastrophic disease scenarios, and catastrophic scenarios without a significant medical dimension, the Department of Health and Human Services should retain responsibility for ESF #8. This can all be effectuated by Executive Order but given the significance of this change it would probably be prudent to authorize expressly in a statute such as the reauthorization of Title I of the Bioterrorism Act of 2002.

My reason for this recommended change is simple. Only the Department of Defense has the planning, logistics, and personnel resources needed to conduct nationwide medical relief operations in a full-scale catastrophic disease scenario.

III. Local, State, and Federal Responsibilities in Response Plan Execution

When Hurricane Katrina hit metropolitan New Orleans, we saw what could happen when State and local authorities lack appropriately robust contingency plans as well as the operational capability to implement those plans (which in some cases they did not even follow); when Federal authorities assume incorrectly that State and local authorities will perform vital operational tasks in the early stages of the crisis; and when the Federal authorities lack real-time situation awareness and effective mechanisms for interagency command, control, and coordination.

I believe that many, if not most, of the problems in the national response to Hurricane Katrina were unique to metropolitan New Orleans. Most other cities in the hurricane belt are above sea-level, and most other cities and States in this region have over the years demonstrated an ability to respond to major hurricanes more effectively than New Orleans and Louisiana did before, during, and after Katrina. This is not to excuse the many failures at the Federal level, but instead to make a broader point about the Nation's preparedness for the disease equivalent of a Category 5 hurricane—namely, to a catastrophic disease scenario such as the onset of pandemic influenza in the United States or a major, fully effective bioterrorist attack.

The Federal Government's strategy for responding to catastrophic disease scenarios relies very heavily on State and local authorities. The Federal Government expects States and localities to receive supplies from the vast Federal stockpile of medical countermeasures—antibiotics, vaccines, and other pharmaceuticals as well as respirators and other essential medical supplies—for use at whatever treatment centers the State and local authorities plan to utilize or establish. The Federal Government expects State and local authorities to communicate with their citizens about when, where, and how they can receive necessary treatment. The Federal Government expects State and local authorities to ration scarce medicines.[12] The

[12] On November 20, 2005, Secretary Leavitt even said on Meet the Press that, in the event of pandemic, the Federal Government will distribute its vital supplies of antiviral medicines and

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Federal Government expects State and local authorities to develop plans for crowd control and security at medical treatment facilities and distribution centers, and to execute those plans in a crisis. The Federal Government expects State and local authorities to develop plans for "surge capacity"—that is, for the treatment of hundreds, thousands, or tens of thousands of people who may require medical attention and to execute those plans in a crisis. The Federal Government expects State and local authorities to work out appropriate operational, legal, and financial arrangements to support all these plans with private health-care and logistics providers.

I am not sure that anyone in the country has an authoritative document that lays out all of these expectations. I do not think that any senior Federal official has bluntly stated them in a public setting. In fact, I suspect that many responsible officials at the Federal, State, and local level are not even aware that these are the expectations of State and local performance in the Federal Government's catastrophic disease response plans. I think that many people assume that, in the aftermath of a catastrophic disease outbreak, the Federal Government will come to the rescue of the affected communities, setting up its own treatment, isolation, and pharmaceutical or vaccine distribution system. This is not, so far as I am aware, the Federal Government's plan, and even if the Federal Government could perform this function (realistically, only the Department of Defense has capacity to perform such a task on a large scale, and even the Department of Defense could not undertake such an effort across the entire country), it would take weeks, if not months, to get up and running.

So far as I am aware, there is not a single State or city in the entire United States that is currently equipped to fulfill the Federal Government's expectations in the event of a catastrophic disease scenario.[13] The implications of this fact are deeply troubling.

This extraordinary national deficiency was first revealed during the first TOPOFF exercise in May 2000 at which I was an observer. It was revealed again during the May 2003 TOPOFF II exercise, in which I played a central role. And, in April 2005, it was revealed again in the TOPOFF III exercise at which I was again an observer. It has been revealed in a wide variety of smaller scale tabletop exercises and simulations. It has been candidly discussed at countless interagency meetings, some of which I participated in during my government service. The Federal Government, in other words, is fully on notice that a series of critical assumptions in its plans for responding to a major disease scenario—namely, those related to the effective and timely performance of a series of specific actions by State and local agencies and their associated private health-care and logistics providers—are incorrect. The implication is inescapable: the plans, if put to the severe test of a catastrophic disease scenario in the near future, will fail.

To deal with this problem, I believe that all Federal homeland security assistance—that provided by DHS as well as HHS in the form of public health grants pursuant to Title I of the Bioterrorism Act of 2002—should be made powerfully conditional. In particular, I believe that Congress should by statute give the President or his designee the authority and mandate to establish baseline requirements for State and local governments to conduct emergency medical operations and other essential homeland security functions. Every 6 months, Congress should require the secretaries of homeland security and health and human services to jointly certify to the President and the Congress that their requirements are or are not likely, with a high level of confidence, to be met by the State and local agencies in question. With respect to any State or local agency that the two secretaries certify as unlikely to fulfill their requirements in a crisis, the two secretaries shall be required to notify the President and the Congress of this fact. In addition, they should request that the Director of the Office of Management and Budget freeze up to 100 percent of all Federal grants, financial transfers, reimbursements, or in-kind assistance provided to the agencies in question indefinitely and until such time as the two secretaries determine the entity to be likely, with a high level of confidence, to meet the appropriate requirements. At this time, the Director of the Office of Management and Budget will release the funds to the entity in question. Each freeze

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pre-pandemic vaccines—supplies which for the next few years will be insufficient for the entire U.S. population—to the States for further distribution to the citizens. This was also the approach employed by the Department of Health and Human Services during the unexpected shortfall of season influenza vaccine in 2004–2005 (see Monica Schoch-Spana, et al., "Influenza Vaccine Scarcity 2004–05: Implications for Biosecurity and Public Health Preparedness," Biosecurity and Bioterrorism, Vol. 3, No. 3, 2005.

[13] This is despite the fact that the Federal Government has dispersed roughly $14.5 billion in biodefense spending through HHS between 2002 and 2005 (allocating about $5.5 billion to CDC specifically).

shall be individually reported to the Congress, which may at any time pass an act requiring the release of the funds and resources in question.

The original public health-grant authorization in Title I, Section E, of the Bioterrorism Act of 2002 needs to be amended to impose some strong form of conditionality along the lines suggested here. Federal homeland security and public health grants should not be an entitlement but a part of a bargain that requires State and local agencies to fulfill their responsibilities under the Constitution, law, and national response plans.

IV. Federal Organization for Biodefense and Public Health Preparedness

During my service on the White House staff, I found biodefense and public health preparedness to be one of the most difficult areas in which to coordinate interagency policy and operations. The number of different departments, agencies, and offices within departments involved in biodefense and public health preparedness is astounding. The plain fact is that there is no executive branch official beneath the President "in charge" of all relevant aspects of the Federal Government's biodefense and public health preparedness program.

The President and most of the Federal Government look to the Department of Health and Human Services for intellectual leadership on biodefense and public health preparedness. But HHS is not a tightly integrated department and it pays attention only to certain aspects of the biodefense and public health preparedness challenge. Its three key agencies—CDC, NIAID, and FDA—are highly autonomous entities with their own appropriations and separate lines into the Congress and into the White House. These agencies possess deep subject matter expertise but, in my experience, have relatively limited interaction with other elements of the Federal Government and, at the working level, relatively little exposure to national security affairs. The Secretary of HHS has a very small staff, led by the Assistant Secretary for Public Health Emergency Preparedness established by Section 102 of the Bioterrorism Act of 2002, to advise and assist him on biodefense and public health preparedness, to run countermeasure procurement programs, and to manage the public health grants. I do not believe that the staffing and funding of this HHS staff element is commensurate with the expectations placed upon it.

The President's original legislative proposal for the Department of Homeland Security sought to give it a substantial role in biodefense and public health preparedness. This proposal was essentially rejected by the Congress, though the Homeland Security Act of 2002 did transfer a few biodefense-related assets and responsibilities to the new department. One of these was the Strategic National Stockpile, but this was transferred back to HHS in 2004 after much difficulty. Another was the Metropolitan Medical Response System (MMRS), which oversees and helps support a variety of specialized medical response teams around the country. The MMRS is now located within FEMA; the advantages and disadvantages of this arrangement are not clear. DHS also runs the National Biodefense Analysis and Countermeasures Center at Fort Dietrich, Maryland. The most significant DHS responsibility for biodefense and public health preparedness relate to the Secretary of Homeland Security's role as the principal Federal official in the management of all domestic incidents of national significance.

The Department of Defense also plays an important role in biodefense. There are three assistant secretary-level officials within the Office of the Secretary of Defense with significant biodefense responsibilities: the Assistant to the Secretary for Nuclear, Chemical, and Biological Defense Programs; the Assistant Secretary for Homeland Defense; and the Assistant Secretary for Health Affairs. There are countless research, development, and procurement programs in the Department of Defense related to biodefense, and the Northern Command engages in extensive planning and exercise related to domestic biodefense contingencies.

Most interagency policy and operational matters are managed out of the White House, mainly the biodefense directorate of the Homeland Security Council. Given the fragmentation of agency responsibilities, this White House staff function is indispensable.

Within this interagency setting, there are both substantially overlapping responsibilities and significant omissions. For instance, the Department of Homeland Security and the Department of Health and Human Services both make grants to State and local agencies to help improve their preparedness; there is little if any real coordination of these separately authorized, appropriated, and managed grant processes. HHS, DHS, and DOD all conduct research and development on a wide variety of biodefense technologies, with only the loosest coordination. Each of the three main departments tends to conduct exercises and develop plans in relative isolation from the others, leaving it to the White House staff to pull them together. A variety of different expectations and responsibilities apply to each of the three main depart-

ments in a crisis, which leads to both unnecessary duplication of some efforts and omission of others.

I have given a great deal of thought to how to improve the interagency coordination of biodefense policy and operations. It is tempting to simply declare one official to be "in charge." This, in my opinion, is unrealistic given the complex and interdisciplinary nature of the biodefense challenge and the distribution of statutory authorities and operational capabilities across multiple executive branch agencies and officers.

The only realistic option, in my judgment, is to strengthen the White House staff element in charge of interagency integration. Accordingly, I believe that the President should establish a Deputy National Security Advisor for Health Security, with appropriate support personnel, within the National Security Council staff, building on the existing biodefense directorate within the Homeland Security Council. I do not believe, however, that this should be legislated as it pertains to the President's personal staff. At most, the reauthorization of Title I of the Bioterrorism Act of 2002 should offer a sense of the Congress that strong, continuous interagency leadership from the White House staff is essential given the statutorily grounded fragmentation of biodefense and public health preparedness across the executive branch.

I also believe that the Secretary of Health and Human Services requires a robust, large, and high qualified staff element to support him in discharging the extensive biodefense and public health preparedness responsibilities and to conduct intra-agency coordination and oversight. I do not have a precise number of the appropriate size of this staff, but I know it should be substantially larger than it is today. I further believe that it should be led by an Under Secretary, not an Assistant Secretary, and thus that Section 102 of the Bioterrorism Act of 2002 should be amended accordingly.

Conclusion

The Bioterrorism Act of 2002 has served the country well. It established the basic framework for the country's first serious effort to prepare itself for catastrophic disease contingencies. But, in the past 4 years, we have learned a great deal about this threat, as well as about how the department and agencies of the Federal Government are likely to respond to a catastrophic disease contingency. A great deal has been accomplished, but there is much more to do. In my opinion, our future efforts will be even more successful and efficient if we modify certain core elements of our strategy for dealing with the catastrophic disease threat, as I have outlined in this testimony.

Thank you again for the privilege of appearing before you. I will try to answer any questions you may have.

Senator BURR. At this time let me introduce Dr. Leah Devlin, who is the State Health Director of my State of North Carolina, Department of Health and Human Services. Dr. Devlin also pulls double duty as the President of the Association for State and Territorial Health Officials. She holds a dental degree and a master's degree in public health administration from the University of North Carolina at Chapel Hill—one of the 64 teams playing in the NCAA, I might add, but only three ACC teams, and I think that will take a legislative remedy to make sure that never happens again. There should be more. Dr. Devlin has led a distinguished 20-year career in public health serving in both local and State public health departments since 1986.

Leah, it is awfully good to have you. You are recognized.

Dr. DEVLIN. Thank you, Senator Burr, for having me here today. We are very grateful and proud of your leadership role here on public health preparedness and response and bioterrorism. Thank you, Senator Burr.

We also want to thank you for the investments that have been made in the public health infrastructure since 2002 to protect the health of the people of this country from terrorism and other public health emergencies. This is essential that you continue to make this investment, and here are a few key points as to why.

First, the State and local public health system has made enormous progress in strengthening our preparedness capabilities. If you boil it all down, it is about early detection and rapid response.

Let me give you a few examples that are concrete from my own State, your State. We have knitted all of our hospitals together, the emergency departments, to public health and we have reduced our opportunity for early detection from 1 month to 12 hours. We have created seven regional strike teams that provide surge capacity, expertise to all of the counties in our State in epidemiology, veterinary medicine, pharmacy, lab, environmental. We have embedded public health epidemiologists in our 12 largest hospitals, doubled our laboratory capacity. Every health department has a full-time person dedicated to preparedness. It is their full-time job, planning, exercising, reiterating what we learn, train, train, train. And we have developed a tiered medical response surge capacity. Our 100-bed statewide asset mobile hospital was deployed, as you know, Senator, to Mississippi during the Katrina response, served over 7,400 people in a 7-week deployment of over 500 professionals. These are just some concrete examples about what we are doing to make progress in our States. Again, our goal, early detection and rapid response.

The role of the State agency in coordinating that whole statewide effort is unique, and we also are responsible for supporting at the local level the communities, the health departments, and knitting together and developing their plans and exercising and training, their relationships. So much progress is being made.

Point two, we have established essential partnerships with law enforcement, with other first responders, emergency medical services, agriculture. These partners expect public health to pull their weight, as you have just heard our first speaker say. And we are pulling our weight in the States in public health thanks to the investments that you have been making in public health.

Point three, many challenges remain, so we have had progress, we have the strong partnerships, but we have challenges, and these are the challenges very quickly.

First of all, no community can say they are fully prepared.

Second, the threats are not going away. We are preparing for all hazards every day. We are using this capacity in the States, and this work does prepare us for an event that would be intentionally delivered as well.

The biggest challenge probably is sustaining the Federal investment that you are making in State and local preparedness. I cannot overemphasize how important this is because early detection, rapid response will save lives in our communities across the State. That investment has eroded over the past 4 years. We have had a redirection of funds in 2004 of $39 million into the Strategic National Stockpile. We had another year $95 million redirected for the Cities Readiness Initiative. The 2007 budget proposes to redirect hospital preparedness funds that would normally go locally to other initiatives. Now is not the time to be backing up on the preparedness investments in State and local health departments. And these investments are never—almost never one time. Even laboratory equipment requires maintenance; it requires reagents; it requires replacement.

Preparedness at the State and local level is a people business. It is an expertise business. Yes, we need countermeasures, vaccines, antivirals, equipment, but it takes a workforce that will deploy them, and as the Secretary says, to put the pill in the palm of the people, that requires a workforce. And that is your State and local infrastructure.

Speaking of the workforce, our workforce is aging. We have some States where 45 percent of the workforce in public health will be retiring within the next 5 years. We do not see the young people coming in to take their places, and we would ask and urge you strongly to include in your reauthorization bill the Public Health Preparedness Workforce Development Act of 2005 that is a loan repayment and scholarship program.

So this is the progress, the challenges that we face. I was asked to address two specific issues. One I think we have already heard spoken to today, which is how clear are the lines of authority, and we do understand what the National Response Plan requires of DHHS and Homeland Security. We operate that way in North Carolina where public health has the lead for the health issues, but very quickly moves into an overarching response by our homeland security chief in the States. But certainly if there are things that you need to do differently here at the Federal level so that the Federal Government is clear on how they are going to work together, we would support that.

And, yes, we are accountable and we look forward to continuing to work with CDC and our Federal partners to make sure that we have performance measures that document the progress being made in States in order to come into compliance with the national goals and objectives.

In closing, let me just reiterate that early detection and rapid response is the core goal of our public health preparedness, and that will save lives back home. And we ask that in this reauthorization you continue to sustain the Federal investment that you have made in the State and local infrastructure.

Thank you very much, Senator Burr.

Senator BURR. Thank you, Dr. Devlin.

[The prepared statement of Dr. Devlin follows:]

PREPARED STATEMENT OF LEAH DEVLIN, DDS, MPH

Mr. Chairman and members of the committee, I am Dr. Leah Devlin, Director of the North Carolina Division of Public Health and President of the Association of State and Territorial Health Officials (ASTHO). ASTHO represents the State and territorial public health agencies of the United States, the U.S. Territories, and the District of Columbia. Our members are the chief health officials of these agencies. It is a pleasure to appear before you today to discuss the critical reauthorization of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (P.L. 107–188).

First, let me begin by thanking you for recognizing the need in 2002 to invest in building our Nation's public health infrastructure to deal with terrorism and other public health emergencies and emerging threats. In responding to the events of September 11, 2001 and the subsequent national anthrax crisis, we realized that many public health agencies, a critical piece of our front line of defense, were not fully prepared to deal with such threats. We thank you for creating a program that has strengthened our laboratory, surveillance and epidemiologic capacities, and improved our communications and information technology systems. Critically important attention and funding were also provided for preparedness planning, readiness assessment, and the education and training for public health professionals to respond to bioterrorism and other public health threats and emergencies. Public

health agencies are now recognized as key partners with law enforcement, emergency management and health care in preparedness and response.

My remarks will focus on: (1) what State and local health agencies have done to increase their level of preparedness, (2) what challenges remain that must be addressed, and (3) what resources are needed to sustain a high level of public health security.

In North Carolina, our new Hospital Emergency Surveillance System has dramatically improved our ability to rapidly detect bioterrorism attacks, pandemic influenza, and other disease outbreaks. Today, the North Carolina Division of Public Health receives real-time electronic reports from more than 100 hospital emergency rooms so that we can rapidly identify potential disease outbreaks. We now have seven disease investigation strike teams that respond immediately to suspicious disease reports anywhere in the State. Our three-tiered State Medical Assistance Team (SMAT) system provides medical care during emergencies and augments our hospital capacity. Investments in our public health laboratories have tripled our capacity to test suspicious substances and confirm the presence of select biologic and chemical agents. None of this existed prior to 2002.

Real life emergencies such as Hurricane Isabel in 2003 tested our ability to protect our citizens. During that hurricane, our regional disease investigation strike teams assessed community health needs and helped redirect critical resources such as food and water to the most vulnerable households. Last fall, following Hurricane Katrina, we sent our mobile hospital, ambulatory care clinic, and more than 500 public health and medical professionals from our SMAT to Mississippi to provide care for more than 7,400 patients over 7 weeks. An effort of this magnitude would not have been possible prior to 2002.

Since passage of the Public Health Security and Bioterrorism Preparedness and Response Act, State and local health agencies have made real progress in their ability to respond to bioterrorism and other threats and emergencies. No single State, and no community within any State, has reached a full level of preparedness. The act has made a tremendous difference, but the safety of the American public requires us to do more.

The ability of the public health system to respond adequately to potential terrorist events, emerging infectious diseases, and other public health threats and emergencies depends on a well-trained, diverse, and adequately staffed public health workforce at the Federal, State and local levels. Recruiting, training and sustaining the public health workforce is the preparedness crisis. Some States are experiencing retirement rates of up to 45 percent over the next 5 years. The average age of a State public health professional is 47. The current scenario is a rapidly aging workforce that will experience high rates of retirement over the next 5 years with no clearly identified source of qualified public health professionals to fill the void.

ASTHO urges you, in the strongest way possible, to include the provisions of the Public Health Preparedness Workforce Development Act of 2005 (S. 506) in your reauthorization legislation. This bill would provide incentives for health professionals to enter the practice of governmental public health, ensure these individuals commit to a designated number of years of service in public health agencies, and help to retain current employees in the field of public health.

We continue to face new challenges each year, from anthrax to smallpox to SARS to pandemic influenza. One of the lessons of Hurricane Katrina is that we cannot focus too narrowly on specific threats. Instead, an all-hazards approach is needed. We must ensure that essential public health resources—personnel, laboratories, surveillance systems, communications, well thought out response plans—are available to address ongoing and new public health threats.

I cannot emphasize enough how important it is that Federal bioterrorism funding to State and local health agencies be predictable and sustainable. Recruitment and retention of qualified public health professionals is not possible in an environment where there are concerns about the future of program funding. There are very few examples of one-time preparedness needs. Even expensive laboratory equipment must be replaced every few years and requires costly maintenance contracts and continuous replenishment of reagents. Antibiotics, antidotes and other medical supplies acquired to prepare for mass casualty events must be rotated, replaced or replenished.

Over the past few years, portions of existing preparedness funding for State and local programs have been redirected to support other Federal preparedness needs. For example, last year the Centers for Disease Control and Prevention's (CDC) State and local public health preparedness cooperative agreement funds were cut by $95 million to pay for an expansion of the Strategic National Stockpile (SNS). Prior to that, CDC's State and local public health preparedness cooperative agreement funds were redirected to launch the Cities Readiness Initiative (CRI). The adminis-

tration's fiscal year 2007 budget doubles the Emergency System for Advance Registration of Volunteer Health Professionals (ESAR-VHP) funding. This new funding would again be redirected from the Health Resources and Services Administration (HRSA) hospital preparedness cooperative agreement.

While SNS, CRI and ESAR-VHP are all important programs for improving our public health and medical response to catastrophic events, funding them by redirecting resources from existing State and local public health preparedness efforts is wrong. Worthy new initiatives and expanded activities should be worthy of their own funding. Funding cuts may result in layoffs of highly skilled public health professionals, reductions in the number of exercises planned and implemented, and delays in upgrading laboratory equipment, surveillance technology and surge capacity. We must ensure that all State and local health agencies sustain and improve existing public health preparedness activities, not cut back on them.

In your letter of invitation, you asked if the lines of authority within the Federal Government are clear during medical and public health emergencies. Yes, the National Response Plan (NRP) correctly assigns coordination of emergency health and medical functions to the U.S. Department of Health and Human Services (HHS) under Emergency Support Function 8. It also makes clear that the U.S. Department of Homeland Security is the overall coordinating agency for issues including and transcending those addressed in ESF-8.

You also asked if HHS should require more State and local accountability and Federal oversight for developing medical surge capacity. ASTHO supports the development and implementation of performance measures to assess progress in preparedness. Accountability is essential and best measured against a limited set of performance measures that are evaluated over time and flexible enough to allow States to match their individualized strategic plans to national goals.

In closing, I want to again thank the members of this committee for your past commitment to improving public health preparedness. While we applaud the accomplishments that this committee has permitted the public health community to make, we know that so much more can be and must be done to improve our Nation's security. We welcome the opportunity to continue to work with you in pursuit of that goal.

Thank you for your attention. I will be pleased to answer any questions you may have.

MAJOR INFRASTRUCTURE DEVELOPMENT IN NORTH CAROLINA PUBLIC HEALTH PREPAREDNESS AND RESPONSE SINCE 9/11/2001

Strengthening Local Preparedness Statewide

- Established seven Public Health Regional Surveillance Teams.
- Provided local funding and guidance to 85 local health departments and the Eastern Band of the Cherokee Indians.

Providing State Level Leadership and Expertise

- Established a State level Office of Public Health Preparedness and Response.
- Appointed the Public Health Preparedness and Response Advisory Committee.
- Created the Public Health Command Center.

Creating Necessary Legal Authorities

- Sought passage of two new laws (1) reporting by hospitals of Emergency Department data (2) extended isolation and quarantine authority.
- Sought passage of major legislation to require reporting of zoonotic diseases from the State veterinarian and improved reporting requirements for suspected bioterrorism events.
- Added smallpox, pandemic flu, west nile virus, and monkeypox to the NC list of required communicable diseases reports.

Developing and Exercising the Plans

- Developed numerous plans as a part of the NC Emergency Operations Plan.
- Developed the first FEMA approved mitigation plan for infectious diseases.
- Routinely conducted State, regional and local field exercises.
- Established the Avian Influenza & Human Health Task Force.

Assuring Earliest Detection: Surveillance

- Initiated the development of the North Carolina Public Health Information Network which includes the NC-Health Alert Network (NC-HAN), the National Electronic Disease Surveillance System (NEDSS), the NC Hospital Emergency Surveillance System (NCHESS), a pre-hospital emergency medical services data system

called PreMIS, the Laboratory Information Management System (LIMS), and the NC Immunization Registry.

• Developed the Mobile Data Entry Project—a system for collecting electronic data in the field including geocoding for GIS applications.

• Created the NC Hospital Emergency Surveillance System (NCHESS).

• Embedded Public Health Epidemiologists (PHEs) at the 12 largest hospitals in NC.

• Established NC-DETECT (North Carolina Disease Event Tracking and Epidemiology Collection Tool).

Improving Communications

• Established the North Carolina—Health Alert Network (HAN).

• Enhanced the existing NC Medical Communications Network.

• Participated in the development of statewide telecommunications partnerships with State and local first responders.

• Established system of communications with the private healthcare providers.

Identifying the Agent Early

• Developed the NC Laboratory Response Network (LRN) in the State Laboratory of Public Health.

• Created the first statewide registry of biological agents in the Nation.

• Developed the white powder protocol used by all first responders and law enforcement.

Getting Health Information on Risk to the Public

• Distributed to 1.5 million people an insert into all major newspaper publications.

• Provided additional staffing and technology support to the Department of Health and Human Services Care Line to answer citizen inquiries.

• Established new public information officers in the Division and the Department including bilingual (Spanish) expertise.

Implementing Training to Maintain Readiness

• Partnered with the North Carolina Community College System and the University of North Carolina to develop educational modules that will enhance statewide preparedness and response efforts.

• Developed the first training program in the country for how law enforcement and public health work together—Forensic Epidemiology.

• Implemented the NC National Incident Management System (NIMS) Training Program.

• Implemented numerous preparedness trainings of the public health workforce.

• Conducted in partnership with UNC School of Public Health a workforce development survey and learning management system.

Building Surge Capacity for Mass Care

• Partnered with the Office of Emergency Medical Services (OEMS) to plan and implement a statewide Hospital Preparedness Program.

• Established the 3-tiered State Medical Assistance Teams (SMAT).

• Strengthened capabilities at the State Medical Examiners Office.

Learning From Real Life Experiences

• Established and operated shelters in Wake and Mecklenburg counties for hundreds of Hurricane Katrina and Rita evacuees in NC.

• Investigated and contained one of the eight laboratory confirmed cases of SARS in the country in 2003.

• Managed the distribution of limited flu vaccine available during the 2004 flu season.

Senator BURR. Dr. Melton, I am going to skip over you, if I can. I will give Senator Hatch, who really wants to introduce you, every opportunity, but given that I see that the bell is going to go off, I doubt he is going to make it. But let me go to Dr. Dan Hanfling, the Chairman of the Disaster Preparedness Committee of Inova Fairfax Hospital in Falls Church, Virginia. He has an extensive background in emergency response. Dr. Hanfling is involved with FEMA, USAID, Urban Search and Rescue Response, and serves as

the operational medical director of the Fairfax County Fire and Rescue Department.

Doctor, it is great to have you here.

Dr. HANFLING. Thank you, Senator Burr. I am pleased to be here this morning on behalf of the American Hospital Association's 4,800 hospitals, health systems, and other health care organization members, and I appreciate the chance to share some thoughts with you.

This morning I want to talk to you specifically about two things related to the reauthorization of this important legislation: the need to create health care delivery surge capacity and the critical importance of hospital preparedness funding.

We are doing perilously little to achieve real surge capacity. The goal of any medical response to disaster must be to save as many lives as possible and to reduce as much suffering as possible. And while the term "surge capacity" has been used to explain a variety of health care-related needs to a variety of constituencies, the way I suggest that we ought to define surge capacity is to ask this question: How many lives are we going to allow to hang in the balance?

A natural disaster or a terrorist-related attack may result in hundreds, thousands, or more critically ill or injured victims, and it goes without saying that the timely provision of appropriate medical care will play a key role in decreasing morbidity and mortality after such events or, simply stated, the delivery of care is going to lessen the burden of pain and suffering for those in need.

A response to surge demand and care cannot be provided without substantial planning, and experience has shown that hospitals in these situations have limited ability to divert or transfer patients to other hospitals in the immediate aftermath of such events. The experiences of Katrina and Rita also show that a deployable medical team or medical teams of the Federal Government will have a limited role in increasing a hospital's immediate ability to provide critical care to large numbers of victims. As a result, hospitals will need to depend on local and State sources and reserves of medications and equipment necessary to provide appropriate care for the first 48 or more hours following the onset of a catastrophic event.

Currently, there are significant deficiencies, particularly in the ability to provide critical care to those patients who may be most severely affected. The HRSA National Hospital Preparedness Program and the Department of Homeland Security's Urban Area Security Initiative grant program have helped fund initial purchases of some basic medical supplies and equipment, and they have provided for some health care worker training. However, funding has been inadequate to establish the necessary all-hazards acute care surge capacity that is really required.

As a result, only piecemeal solutions have been developed to address the problem, meaning the ability to provide acute and extended health care delivery in the setting of a surge and demand for care remains significantly far behind other elements of the Nation's tactical response to creating a secure homeland. Consider preparedness efforts underway for the avian flu, for example. The amount of available funding for supplies and equipment has not been adequate to support the purchase and use of items of signifi-

cant cost. The New York times recently reported that the national supply of ventilators, which would be critical for caring for patients in a pandemic influenza outbreak, falls far short of the estimated need, and even considering the number of ventilators that are currently being stockpiled by the Federal Government.

Second, the goal for preparedness funding should be to allocate sufficient resources so as to maximize the number of lives saved. It is worth noting that the ability to meet these added challenges is occurring in a larger context, a context in which hospitals face significant increasing financial pressures. Today, a third of hospitals lose money on operations, with Medicare and Medicaid underfunding being a key driver. Hospitals also face other financial pressures, such as rising labor costs, uninsured patients, skyrocketing medical liability insurance costs, and rising pharmaceutical and medical supply costs.

Hospitals receiving funding under the first Bioterrorism Act through the National Bioterrorism Hospital Preparedness Program were able to take big steps forward toward increasing hospital readiness, and at the time the bill was passed, preliminary estimates suggested that hospitals would require approximately $11 billion to obtain the necessary levels of preparedness. To date, hospitals have been appropriated and received approximately $2.1 billion, minus the administrative costs taken by HHS and the State governments. While we have become smarter and somewhat better prepared with time and experience, we still have a long way to go.

The Federal Government must help to protect the Nation by providing greater resources to hospitals to meet the challenges of emergency readiness and ensuring that those resources are made available in a timely manner.

So, in conclusion, we urge you to:

No. 1—reauthorize the Hospital Preparedness Program with substantial funding for the next 5 years.

No. 2—direct program funds primarily to acute care hospitals rather than being inappropriately siphoned off.

No. 3—improve coordination between all Federal preparedness programs to avoid confusion and waste.

And, No. 4—require that State health departments consult hospital groups in developing their funding plans.

Mr. Chairman, thank you for your time, and we look forward to working with you and your staff on sharing a goal of improving the emergency preparedness of America's hospitals and communities.

Senator BURR. Thank you, Dr. Hanfling.

[The prepared statement of Dr. Hanfling follows:]

PREPARED STATEMENT OF THE AMERICAN HOSPITAL ASSOCIATION

Good morning, Mr. Chairman. I am Dan Hanfling, M.D., a board certified emergency physician practicing in the Department of Emergency Medicine at Inova Health System (Inova) in Falls Church, Va. On behalf of the American Hospital Association's 4,800 hospitals, health systems and other health care organization members, and our 33,000 individual members, we appreciate this opportunity to present our views on medical preparedness as you consider reauthorization of the *Public Health Security and Bioterrorism Preparedness and Response Act of 2002*.

I am Director of Emergency Management and Disaster Medicine at Inova, a six-hospital health system with over 1,500 licensed beds in suburban Northern Virginia. In addition, I currently serve as State Medical Director for PHI AIR Medical Group—Virginia, the largest private rotor-wing air medevac service in the States,

and as a Medical Team Manager for Virginia Task Force One, a FEMA- and USAID-sanctioned international urban search and rescue team. I have extensive experience in the delivery of out-of-hospital emergency medical care, including disaster scene response, most notably at the Pentagon on September 11, 2001 and the recent responses to Hurricanes Katrina and Rita. I was also intricately involved in the response to the anthrax bioterror mailings in the fall of 2001, when two cases of inhalational anthrax were successfully diagnosed at Inova Fairfax Hospital.

Hospitals have long had emergency management plans in place that have been carefully developed and tested. These plans are multipurpose and flexible in nature because, as we have recently witnessed, the number of potential disaster scenarios is large. As a result, hospitals maintain "all-hazards" plans that provide the framework for managing the consequences of a range of events, including natural and man-made disasters. The funding provided to hospitals through the National Bioterrorism Hospital Preparedness Program (NBHPP), a program authorized by the *Public Health Security and Bioterrorism Preparedness and Response Act of 2002*, has been a good first step toward increasing the readiness of the Nation's hospitals and their communities and developing improved strategies for dealing with all kinds of threats facing our communities. At the time preliminary estimates suggested that hospitals would require approximately $11 billion to obtain a basic level of "all hazard preparedness." To date, Congress has appropriated approximately $2.1 billion over 5 years for the program. The amount that hospitals have actually received is significantly less due to dollars taken off the top for the Federal Government's administration of the program and overhead allotments that the State grantees have retained. As you will hear, we have become smarter with time and experience, but we still have a long way to go before we can say we are fully prepared to handle disasters that will surely occur in the future.

Defining Surge Capacity

The public looks to hospitals to play a critical role in the event of a disaster. As such, hospitals must be able to accommodate the surge in demand for care in order to screen, stabilize and provide definitive care for affected persons. Traditional disaster planning has largely concentrated on "fixed occurrence" events, such as those created by transportation accidents or the terrorist attacks of September 11, 2001, in which there are a finite, and usually relatively small, number of victims requiring hospitalization. However, the swiftly changing and sophisticated nature of terrorism, the growing threat of natural disasters such as Hurricanes Katrina and Rita, and emerging infectious diseases such as "avian flu," require that hospitals update their emergency management plans. Hospitals must be able to effectively extend their ability to deliver uninterrupted medical care in the face of a prolonged event involving large numbers of victims, such as an attack utilizing chemical, biological or radiological (CBR) weapons or a pandemic disease.

Because of the dual nature of disasters—fixed versus prolonged events—hospitals and their communities must plan to create surge capacity for each of these two distinct types of events. Hospitals can increase their patient care capacity in relatively short periods of time by "surging in place." This involves rapidly discharging existing patients, cancelling scheduled procedures, and taking steps to increase the number of patient care staff in the facility in order to make additional staffed hospital beds available for incoming disaster event patients. In addition, "surge in place" includes the creative reconfiguration of available space by a health care facility for use in the initial management of disaster victims. Many hospitals, in addition to creating inpatient availability, have plans to extend emergency department capability by using lobby and waiting room areas, as well as other patient care areas typically reserved for specialty patients undergoing gastroenterology, pulmonary and cardiac procedures, to accommodate additional patients.

Examples of the creation of internal surge capacity abound from the experiences of the health care systems most impacted by the attacks in New York City and Northern Virginia on September 11, 2001. Upon learning of the events that transpired at the Pentagon that day, Inova, which has facilities within mere miles of the Pentagon, implemented its facility emergency management plan. Patients already designated to go home sometime that day and those deemed stable enough for continued management of their medical conditions at home were discharged as quickly as safely possible. Elective surgeries were canceled, and all ongoing surgical cases were completed. As a result, an additional 343 hospital beds (out of approximately 1500 beds across the health system) and 43 operating rooms were made available within 3 hours of the attack on the Pentagon.

While this type of strategy can provide for a temporary ability to increase patient care capacity, most hospitals cannot sustain such a surge for extended periods of

time. Individual facilities would quickly become overwhelmed if the disaster involved large numbers of victims presenting over a prolonged period of time.

Prolonged disasters involving large numbers of victims that overwhelm the health care system in a community, such as would be seen in pandemic influenza, would require the development of "community surge capacity," involving the development of alternative care facilities. This type of community surge capacity is complicated and costly to achieve and involves advance planning for logistical support, the development of protocols, and the determination of specific mission goals. Communities must plan for this contingency using the advanced designation of facilities that can be used to accommodate patients, perhaps under more austere circumstances than would be faced in everyday medical care.

A Demonstrated Need

Like the attacks of September 11, 2001, a number of recent man-made and natural disasters have also demonstrated the necessity of hospital surge capacity. The evacuation of hospitals and nursing homes in Louisiana and Mississippi due to Hurricanes Katrina and Rita, and the illnesses and injuries resulting from the hurricanes, required that thousands of acutely ill and fragile patients be admitted to hospitals in surrounding communities and States. Here in the Washington area, the delivery of anthrax spores to the Hart Senate Office Building in 2001 caused a surge in demand for care at Inova. The emergency department of Inova Fairfax Hospital diagnosed two confirmed inhalational anthrax cases and screened over 1,127 patients with influenza-like symptoms or concerns of "anthrax exposure" over a 2-week period of time.

Key Assumptions Validated

Review of these, and other recent disaster events that generated definable surges in demand for care, validates a number of important assumptions regarding the development of acute care surge capacity. First and foremost, the rate limiting step in mounting any coordinated response to a surge in demand for care will be the sustained availability of medical and nursing staff. Whether the disaster results from the use of weapons of mass exposure (WME)—including biological, chemical or radiological attacks—a contagious, infectious disease, or the widespread disruption in civil order, it must be assumed that staffing will be a problem. With the use of WME in particular, workforce attitudinal survey suggest that one-quarter to one-third of the workforce may be deliberately absent for some period of time. The experience of several hospitals, including the Ochsner Clinic in New Orleans, during and after Katrina give further credence to the importance of adequate planning for workforce reductions in a prolonged event. Infectious disease outbreaks would also reduce the workforce if caregivers or their family members succumb to the very illnesses they treat.

It is also important to note that in planning for surge demand for care due to a disaster, decisionmakers must also consider the ongoing need to continue to deliver basic health care services. Hospital services will be required to maintain routine delivery of emergency care, such as delivering babies, dealing with traumatic injuries and sudden acute illness. In fact, some researchers have noted that certain conditions, particularly those related to cardiovascular events, may even increase in times of great stress related to disaster.

In addition, last year's response to Hurricanes Katrina and Rita emphasize the key assumption that the initial forward movement of patients is not likely to occur, and that Federal resources could be unavailable for up to 3 days following the onset of any disaster event. A surge in demand for care is going to have to be handled locally, with locally available resources.

Lack of Funding Hindering Readiness

Emergency readiness requires a significant investment in staff and resources. But the ability to meet these investment challenges is compromised by the significant financial pressures facing hospitals. Today, a third of hospitals lose money on operations—with Medicare and Medicaid under-funding being a key driver. On top of under-funding by government payors, hospitals face other financial pressures: labor costs continue to rise as hospitals increase wages to attract scarce workers; the number of uninsured patients also continues to grow, contributing to greater levels of uncompensated care; and hospitals face skyrocketing costs for medical liability insurance, pharmaceuticals and medical supplies.

A hospital's ability to deliver optimal medical care in the setting of any disaster event, regardless of its cause, is in large part contingent upon an immediately available supply of key medical equipment, supplies and pharmaceuticals, as well as adequate staffing. However, due to financial pressures, hospitals have adopted just-in-time supply chains for their equipment and supplies. As a result, in a disaster hos-

pitals would face an almost immediate shortage of critical supplies such as ventilators, personal protective equipment for staff, drugs and other supplies. In addition, most hospitals routinely operate at or near full capacity and have only limited ability to rapidly increase their workforce.

The NBHPP, administered through HRSA, and the Department of Homeland Security's (DHS) Urban Area Security Initiative (UASI) grant program have helped to fund initial purchases of some basic medical supplies and equipment, as well as some health care worker training. However, these programs have not provided the level of funding required to establish adequate "all-hazards" acute care surge capacity. As a result of the relative paucity of funding, only piecemeal solutions have been developed to address the problem of developing surge capacity. The amount of available funding for supplies and equipment has not been adequate to support the purchase and use of items of significant cost, such as ventilators, intravenous pumps, or cardiac monitoring equipment. For example, *The New York Times* recently reported that the national supply of ventilators, which would be critical for caring for patients in a pandemic influenza outbreak, falls far short of their estimated need, even considering the numbers that are being stockpiled by the Federal Government. In addition, the rate limiting step in surge capacity planning, namely the ability to recruit, retain and deploy staff to the bedside during any given crisis, has not been fully and comprehensively addressed, despite some progress in the development of systems to identify and register in advance health professionals willing to volunteer for service in a disaster.

As a result, the ability to provide acute and extended health care delivery in the setting of a surge in demand remains significantly limited. Furthermore, planning and funding for medical surge capacity remain far behind the other elements of the Nation's tactical response to creating a secure homeland. And given the very real concerns regarding an impending influenza pandemic, communities must focus on priorities for building such capacity that goes beyond the purchasing of beds, a metric which is too simplistic, and of little use, in creating the sort of capacity that is truly needed.

The Federal Government must help protect the Nation by providing greater resources to hospitals to meet the challenges of emergency readiness and ensuring that those resources are made available in a timely manner. In addition, given what Americans need from our Nation's hospitals, today is a time for investment, not cutbacks.

Key Principles to Consider Moving Forward

As Congress prepares to reauthorize the NBHPP, I would like to share with you eight key principles the AHA has developed after carefully analyzing the program's successes and shortcomings since its inception in 2002. We hope that you will take these principles, along with the information I have just shared with you on the challenges of creating adequate surge capacity, to heart during the reauthorization process.

Ensuring Program Sustainability

First, the AHA supports reauthorizing the program for a full 5, or more, years. We urge Congress to continue to include "such sums as may be necessary" for ensuring consideration of needs during the appropriations process. Disaster readiness is an investment that is well worth its cost. However, hospitals simply do not have the extra funds to pay for what is needed to ensure their readiness to respond. As noted previously, hospitals' ability to adequately respond in a disaster will depend in large part on the availability of key medical equipment, supplies and pharmaceuticals, as well as optimum staffing levels. Simply put, to adequately meet the most basic needs of our communities in the event of a disaster, more money is needed.

Funding Acute Care Hospitals

Many in the field believe that too large a proportion of the hospital readiness funds have been funneled to nonhospital providers. Given the challenges hospitals face in responding to the threats such as pandemic influenza and catastrophic natural disasters and the significant gaps remaining in hospital preparedness for these threats, program funding should be primarily directed to acute care hospitals.

Improving Coordination Between all Federal Preparedness Programs

Over the last several years, various Federal departments and agencies, including HRSA, the Centers for Diseases Control and Prevention (CDC) and DHS, have administered funding to enhance health care, public health and first responder preparedness. These streams of funding have often worked at cross-purposes, including inconsistent requirements and redundant purchases. The law must ensure that Fed-

eral agencies plan in a coordinated way to enhance national preparedness and avoid confusion and waste.

Broadening State and Metropolitan Hospital Associations' Roles

State health departments should continue to be the "grantees of record" for preparedness funds. However, the AHA strongly recommends that State and metropolitan hospital associations be given a more substantial role in disbursing funds to the proper recipients. While many of these hospital associations have had some level of involvement with their State departments of health with regards to this program, we are concerned that States have not often permitted their hospital associations to have real input into decisionmaking. Therefore, we recommend that each State's grantee agencies be required to work with the State hospital association (or metropolitan hospital associations for city-specific funding) to develop the State's preparedness plan and to determine how funds will be disbursed.

Greater Flexibility in Approved Use of Funds

Under the current legislation, hospitals have been subject to myriad Federal and State requirements in order to receive preparedness funding. The AHA recommends minimizing the number of Federal/State requirements imposed on hospitals as a condition of funding to reduce the potential for unfunded mandates. As stated previously, ensuring adequate supplies, equipment and staff in the event of a disaster is very costly. Placing additional unfunded mandates on hospitals in the form of numerous Federal and State requirements further stretches hospitals' already scarce resources, limiting their capacity to not only respond in the event of an emergency, but to deliver the care their communities need every day.

We also recommend expanding the "allowed uses" of NBHPP preparedness funds in appropriate areas. For instance, funds should be allowed to be used for making facility/security enhancements (i.e., allow construction for enhancing ventilation systems, window enhancements, etc.). These upgrades are a vital part of ensuring hospitals' response capabilities and should be eligible to receive funding. The AHA also recommends more comprehensive funding for education for hospital preparedness. For instance, permit funds to be used to pay for staff to attend education sessions and as "backfill" for staff who are attending educational sessions.

Reduce Ability to Use Funds to Build State Health Department Infrastructure

The AHA recommends Congress take steps to minimize the use of hospital preparedness grant funds by health departments for internal operations and hiring. While we understand the need for the State to have adequate staff and resources to administer their hospital preparedness program, we are concerned about reports that some States are inappropriately using hospital preparedness money for purposes that are more appropriately funded under the CDC's public health infrastructure stream of funds. Congress should also make States accountable for how they expend funds. Specifically, we recommend the creation of ongoing State progress reports.

Maintain HRSA Program Administration

While we recommend greater coordination between Federal preparedness programs, we believe the National Bioterrorism Hospital Preparedness Program should continue to be administered by HRSA.

Conclusion

Hospitals face new and emerging threats—both man-made and natural—every day. We have always been ready for the foreseeable. Now we must plan for the previously inconceivable.

Hospitals are upgrading existing disaster plans, and continue to tailor their disaster plans to suit the individual needs of their communities in the face of new threats. America's caregivers perform heroic, lifesaving acts every day. And, in the face of the unexpected, they can be depended on to rise to the needs of their communities.

We look forward to working with this committee and staff to forge ahead toward a shared goal of improving the overall preparedness of America's hospitals and communities.

Senator BURR. Clearly, Senator Hatch is probably headed to the floor. Let me call on Dr. Richard Melton, the Deputy Director of the Utah Department of Public Health. He holds a master's degree in public health and laboratory medicine and a Ph.D. in public health. While serving as Director of the Division of Laboratory Services at

South Dakota Department of Public Health, Dr. Melton developed a collaborative statewide approach to disease outbreak investigation and has been an avid proponent of health information technology. Dr. Melton also played a vital role in the preparations for the 2002 Salt Lake Winter Olympic Games.

On behalf of Senator Hatch, especially, Dr. Melton, welcome.

Mr. MELTON. Thank you. Good morning, Senator Burr. I am grateful for the opportunity to be here. It is hard for me to add too much to what has already been said. My specific task was to talk a little bit about how preparations for the Olympics helped us in using the funds and preparing for what we have been talking about today.

One of the greatest things that we got out of preparation for the Olympics was our ability to work with other agencies, particularly with Federal and State law enforcement. One of the most interesting things we developed was with the Department of Energy wherein we started using the instrumentation that is now utilized for BioWatch. We are not a BioWatch State, but we gained a lot of experience out of that, including one of the most exciting times Secretary Leavitt talks about when a sample returned a positive result from the airport and we considered closing the airport for a while until we finally got a confirmatory report that said that was negative. But the interesting thing that we got from that was that the plans that we had prepared, while they did not exactly work—and no plan ever exactly works—was able to get us through what was then an exciting time.

We developed during the Olympics a coalition of hospitals in the Olympic footprint where we talked about surge capacity particularly, in that we arranged for some long-term care facilities in the area who were not utilizing all of their beds, we would be able to utilize those in case of a disaster. Since then, those beds are no longer available to us, and we continue to work with a statewide coalition of hospitals on surge capacity, which is, as mentioned, a vital element.

We still do not have, very frankly, a very good surge capacity plan. It is very difficult. Staffing is one of the biggest concerns that we have with surge.

Disease surveillance, as Dr. Devlin has talked about, is one of the main things that we were concerned about during the Olympics as well. We decided to utilize a real-time outbreak detection system that the University of Pittsburgh was utilizing at the time, and we tied together three emergency rooms in the Salt Lake area at that point and were able to look at the major complaints that were coming into those facilities and were able to look at the disease. We currently are looking at trying to expand this from emergency rooms to primary care physicians as an extension of our monitoring of disease in the State.

We had a contingent of the Strategic National Stockpile that was stationed in Salt Lake City during the Olympics and developed for the footprint of the Olympics a very good distribution system for the Strategic National Stockpile. It has been far more difficult to develop distribution systems statewide, however, and that still is an ongoing task for us.

We worked with the Denver regional office of the Department of Health and Human Services, and they were very beneficial. We believe that Health and Human Services is the correct place for medical response.

Let me share with you in the last minute that I have a couple of concerns. In the past few years, we have seen a reduction in the amount of funding that is coming to State and local government for preparedness, and in Utah, in the 2007 year, we will see about 50 percent of the funds that were originally put in Utah. And while it will allow us to continue to make progress, progress will be significantly slower.

Another issue that I would like to address is disease reporting, and I have in my testimony a couple of instances that point out that response is, in fact, a local issue. One of those was a smallpox scare where we had a hospital that had smallpox. And we were able, with our current ability, to resolve that within a few hours. But it is a local issue, and disease reporting and surveillance should be at the local level.

We also support the Public Health Preparedness Workforce Development Act language. We believe that that is essential.

We also believe, as Senator Dodd was talking about, that we do need a regional training program for disaster preparedness. Right now in Utah, if we need good training, we must go to the East Coast, and we believe that we need to develop that. The University of Alabama, Yale University, and University of Utah are working on developing a regional plan. We would like to see that kind of language placed in this reauthorization as well.

With that, I thank you very much for your time and attention.

[The prepared statement of Mr. Melton follows:]

PREPARED STATEMENT OF A. RICHARD MELTON, DR.P.H.

Mr. Chairman and distinguished committee members, it is an honor for me to address you today. I hope you will find the information I share both interesting and informative. My name is Dr. A. Richard Melton. I served as the laboratory director for the State of South Dakota for about 12 years followed by about 5 in Utah before being appointed as the Deputy Director for the Utah Department of Health (UDOH) about 14 years ago. One of my assignments as Deputy Director is to administer the Public Health Security and Bioterrorism Preparedness and Response Act funds from both HRSA and CDC. I was also involved along with Dr. Scott Williams as we prepared for the Salt Lake 2002 Winter Olympics. I have been asked to share with you how these Olympic preparations influenced our use of funds provided under this act.

Salt Lake City was named as the host city for the 2002 Olympics in June of 1995. We watched with interest as the 1996 Atlanta games unfolded, but had no real understanding of what preparations we would need to make for our upcoming event. We finally started to consider seriously what was involved during the 1998 Nagano games. It was at that time we started to develop the coalition of partners we felt would be necessary to assure the public's health during the 2 months surrounding the 17 days of the 2002 games. While these considerations provided a strong base for cooperation and planning, and an alliance was formed around public health issues, it was not until we sent a representative to the 2000 Sidney games that we fully understood the extent of the challenge that lay ahead. I have provided the staff with some documentation of what was done and what we learned. Time only permits me to touch briefly on our experiences which provided an extraordinary foundation for what we have been able to accomplish with the funds provided by this act.

One of the foremost benefits the preparation and games provided was the close working relationship that we developed not only with agencies with whom we normally work such as local and Federal public health partners, but we developed such relationships with local, State and Federal law enforcement agencies, fire agencies and interestingly the Department of Energy (DOE).

The DOE approached us early in our preparations about testing some experimental equipment that could sample air in selected Olympic venues for the presence of biological agents. We agreed to work with them and began our introduction to the technology now used in BioWatch. We are now able to use the analysis part of the system daily in our surveillance activities. The actual instrumentation provided by the DOE was removed after the games and Utah is not a BioWatch State, but our laboratory staff developed expertise using this technology and since have been able to easily implement the testing procedures now used for biological agents. The DOE instrumentation monitored such locations as the airport and the medals plaza. The one exciting experience we had with the system is one to which then Governor Leavitt often refers. A sample from the airport returned a presumptive positive result. On confirmatory testing, the sample was not a bioagent. The experience provided a live, real time test of our plan and processes. Frankly, the plan did not work as outlined, but the underlying process did. The key to the effective use of this technology, either as used by DOE during the Olympics or as implemented in BioWatch, and the most difficult to get right, is a well thought through and well defined response when a positive result is reported.

It was important as we prepared for the Olympics that we take an all-hazards approach, for there is no way of predicting whether a disaster will be from a terrorist or if it will be a natural disaster, whether an incident will be an explosion in a single location, or a disease across the entire population or within a selected group. Our preparation following the Olympics has continued to address all aspects of preparedness—all-hazards.

Our Olympic planning concentrated on five areas of preparedness that represent this all-hazards approach.

1. EMS and Hospital Preparedness (Surge Capacity)
2. Environmental and Food Safety Regulation
3. Disease Surveillance and Outbreak Response
4. Public Information and Health Promotion
5. Event Operations and Disaster Preparedness

We did make statutory and regulatory changes, during Olympic preparation that gave the UDOH clearer authority for all aspects of medical and public health response. I could speak at some length on each of these issues, but I will just mention an item or two for each area.

1. EMS

In order to increase the number of ambulances available for the venues, vehicle replacement was planned for 2 to 3 years in advance and staged to create a period of service overlap where both new and aging vehicles were used. Additional emergency technicians were recruited from other areas to staff the needed response capacity.

To provide surge capacity for major hospitals, arrangements were made with large long-term care facilities nearby that had a low occupancy rate and thus beds available for use. We developed a coalition of all of the hospitals in the Olympic footprint to plan with us all aspects of medical response outside the actual Olympic medical responsibility. The Olympic medical service was awarded to the Intermountain Health Care system. They were, of course, also a part of our planning coalition.

2. Environmental and Food Regulation

An estimated 150,000 meals per day were prepared and served in the Olympic venues. The safety and security of these meals had to be assured. Also drinking water and solid and sanitary waste disposal was a problem especially for the mountain venues. Processes and staffing were developed and implemented with the cooperation of the local health departments, the Utah Departments of Environmental Quality and Agriculture as well as the USDA.

3. Disease Surveillance and Outbreak Response

Traditional disease surveillance for this event was clearly not sufficient. The typical disease report often takes 2 weeks to make it to public health. The need to see potential terrorism agents or natural disease outbreaks for the games demanded real time monitoring. The DOE system provided one real time detection system. Collaboration with the University of Pittsburgh using a system called Realtime Outbreak Detection System (RODS) reported and evaluated major complaints in the emergency room of LDS hospital or what is referred to as syndromic surveillance. Collaboration with the University of Utah reported syndromic information from the University of Utah Medical Center emergency room and the Olympic village. These systems were effective in monitoring dis-

ease in the population. It is unclear if they really would have detected a bioagent because seasonal influenza peaked in Utah during the games. I have included, on the following pages, 3 charts outlining the data which was produced over the 17 day period of the games. We continue to use the RODS system and are working to expand the number of health care providers report through it.

4. Public Information and Health Promotion

It is not uncommon in the Salt Lake Valley to have temperature inversions that increase air pollution. The UDOH along with the Utah Department of Environmental Quality developed pre-written statements that were used when levels of pollutants were high. These included recommendations for at-risk populations. Many other pre-written press statements were prepared for issues that might present during the games. All of the public information processes were coordinated across all agencies.

5. Olympic Operations and Disaster Preparedness

Table top training and exercises in public health were conducted in the 2 years preceding the games. These covered almost 20 topics and included in excess of 40 agencies and organizations. The topics ranged from mass gathering issues through medical management to fatality management. During the games we did experience incidents that tested the system. These included the airport incident mentioned earlier and a chemical incident in downtown Salt Lake. Because of the preparation, these were handled "without incident."

I would comment that while we had good cooperation from the Salt Lake Organizing Committee command system and other partners on general public health issues such as sanitation and health preparedness, with the exception of the Department of Energy, no one took our concern for bioterrorism seriously until after the 2001 Anthrax attacks. Following those attacks, HHS agreed to station a contingent of the National Pharmaceutical Stockpile (NPS) (now called the Strategic National Stockpile) in Utah during the games and other assistance became more generous. Our preparations during the Olympics had included our Federal partners at the regional level (Denver Regional Office), and they were very good at responding to our needs where they had the resources. Since the NPS was not something they could just call in for us in the absence of a declared disaster we made the request to the Secretary. Our current planning assumes that in a disaster, we could make requests through the Denver Office and it would be forthcoming. Following the Salt Lake City tornado of 1999, our requests through Denver brought the needed response. We have no reason to believe, even in light of the experience of Katrina, that this processes would not continue to work.

The attacks of September 11 and the following Anthrax attacks focused our Olympic preparations. As stated previously, our planning took an all-hazard approach. We had planned for bioagents. With the attacks of late 2001 our focus on terrorism became more intense. We also finally had the attention of all of our partner agencies, both State and Federal. There were discussions of canceling the Olympic games entirely. After reviewing our preparations, we all concluded the games should go on. By the time the games started, Federal resources on the ground included; the DOE detection system, National Guard Civil Support Hazmat Teams, Urban Search and Rescue Teams, Disaster Medical Assistance Teams, National Medical Response Teams, Disaster Mortuary Assistance Teams and the National Pharmaceutical Stockpile. IOC president Jacques Rogge summarized the impact that these attacks had on the games when he said "No major sporting event will ever be the same because of heightened security concerns following the terrorist attack in the United States . . . because, of course, when it comes to security, everything has changed since Tuesday."

Let me move to the impact this experience had on our use of the HRSA and CDC funding provided by this act. We had, of course, received a small amount of preparedness funding through CDC prior to the Olympics which were very helpful in our preparations. During the preparation and games, many of our staff along with those of the other agencies involved assumed double duties, preparing for the games as well as whatever duties were normal. There was little funding provided by the SLOC, the State or Federal Government. We could accomplish what we did only because it was seen as a short, 2 year, defined period. This also highlights the advantage of having to meet a set preparedness deadline. We knew when this disaster would occur. We recognized that we could not maintain this level of expectation after the games. Following the games then we searched for ways to take advantage of what we had accomplished. With the funds that became available later in the

year through this act we were not only able to maintain but to build on our experience.

One challenge that the Olympic experience did present early in our use of the CDC funds surrounded the limited footprint of the Olympic games. The Olympic preparations had included only 7 counties and 6 local health departments of the 29 counties and 12 local health departments that make up Utah. I have included a map on following pages that shows the Olympic footprint. The challenge we faced was how to continue the progress with the 6 LHOs who had worked closely with us for 4 years and yet bring the other 6 up to the same level of preparedness. Does one distribute the funds disproportionately to those who have not been involved or equally to all based on some formula. There was no choice but to spend some additional resource on the nonOlympic venue departments. That then caused concerns from those who had been working with us so long that they were being "punished" for having already done so much. Over time we have resolved the issue, though the nonOlympic venue departments are still not quite to the level of those who experienced the Olympics. We also had to bring the nonOlympic hospitals (mostly rural) our medical response coalition hospitals. We had somewhat the same dilemma with hospitals and our expenditure of the HRSA funds.

Let me share with you in the limited time left to me, just two of many recent experiences that demonstrate how much these funds have changed how public health operates in Utah and how preparedness is a local issue.

At 6:00 one morning, a long haul truck driver who had just arrived in Salt Lake Valley from Seattle, having stopped at a number of truck stops along the way, presented at an emergency room with skin lesions and fever. The attending ER physician determined that the appearance of the lesions were compatible with smallpox. She immediately recognized the complexity of the situation and called the Salt Lake Valley Health Department. The emergency room was also immediately closed and all of those who were there were isolated and not allowed to leave. After consulting with the UDOH and CDC a sample was taken to the UDOH laboratory and tested. It was quickly determined that the man had atypical chicken pox and not smallpox. Everything went, well not quite like clockwork, but within about 7 hours the people in the emergency room were released and the emergency room was reopened. What really made this happen was that the people were trained to communicate with the local health department and the Utah laboratory had the technology to do the diagnosis within a couple of hours. Had this happened 1 year before, the sample would have been sent to CDC for testing and would have taken at least a couple of days if not more. In Utah we can now test, within a few hours, for all of the BT agents and our local health departments have a working relationship with the hospitals in their area.

Another recent event took place in a remote part of Utah near one of our beautiful national parks. A lodge—Ruby's Inn—had a chemical irritant intentionally introduced into the air handling system, exposing a large number of visitors. These guests were quickly transported to the small local hospital not far away. The hospital had a decontamination tent, provided with HRSA funds, and were trained in its use. Though, as it turned out, the agent was not life threatening, the visitors were all appropriately decontaminated and treated. Interestingly, just 2 weeks prior to this event, the hospital administrator had complained that he didn't know why he had to store one of those tents, no one would ever use it in such a remote area. The fallacy of course is that the risk of such events is limited to large metropolitan areas.

I could detail for you many such incidents we now manage, in Utah, almost daily, which we would or could not easily have managed before. A SARS case in Saint George, a chemical explosion at Thiakol in remote northern Utah, a meningitis outbreak at a Job Corps site, and last summer we efficiently received and cared for 600 evacuees from Katrina.

Each year we continue to build our level of preparedness. We have recently implemented a radio system we believe to be unequaled anywhere in the Nation. We do not have statewide coverage of 800 mhz radio service. However, through a system called Omnilink, we can set up radio communication with all emergency providers in the State, regardless of the frequency they use, and make on-the-fly bridges to connect groups as required by the situation. All local health departments, ambulances and emergency rooms, fire and law enforcement agencies and the national guard are a part of this system so we can link to them as needed. We are now working on adding wireless data service to this same system. This system was tested during a recent military exercise when one of the coordinating 800mhz towers was struck by lightning. Radio dispatch saw the tower service go down and used Omnilink to reroute the signals to another tower and no one on the ground knew the tower was lost. We also have a notification system, called UNIS (Utah Notifica-

tion and Information System) that is statewide and can be used to send automated notifications to all emergency personnel, including primary care physicians who sign up for the service. This also includes reverse 911 capacity across the State. We hope to add primary care physician disease reporting to the syndromic surveillance system within a year or two.

Our legal review of the Utah health statutes recently found that our quarantine and isolation laws still would not allow us to deal with large groups of ill or exposed populations such as one might have with terrorism in a large office building or an airplane landing at one of our airports, and certainly not the numbers expected if we have an influenza pandemic similar to 1918. Our legislature just passed and the Governor signed a revision to our enabling statute that now allows us to address such situations. It is clear that the Executive Director of the UDOH has the legal authority as well as the networks to deal with all medical and public health situations that may arise.

I am sure that most States can give you similar information about how much the CDC and HRSA funding has helped and how wisely we have expended the funds—how many epidemiologists and laboratorians have been added and how much training has been provided to health and public health professionals. They will also assure you that continuation of this funding is vital to our continued preparedness and to test those preparations. They will tell you that Biosurveillance should include all levels of government and that disease reporting should be through the local and State health agencies and not directly to Federal Agencies. They will also encourage you that it is vital that we begin training a new generation of public health leaders by enacting language proposed for the Public Health Preparedness Workforce Development Act. All of these things are true for us to continue strengthening the local and State health response and should be included in the reauthorization.

I appreciate the opportunity to share with you these thoughts and our thanks for the vital funds that have allowed us to become more prepared. I have listed for you, on the last couple of pages some of the many things we accomplished with these funds in just the last year. I also want to emphatically State that we are far from fully prepared. I could give you another list of the things that we yet need to do and I assume others who address you will do so. I would like only to say that it is vital that these funds continue to come to us to maintain what we have and to assist us in making further progress toward preparedness. Thank you for your time and attention.

HEALTH AND PUBLIC HEALTH PLANNING ORGANIZATIONS FOR THE 2002 OLYMPICS

Utah Olympic Public Safety Command (UOPSC)

Unified command of local, State and Federal public safety agencies involved in Olympic security.

Environmental & Public Health Alliance (EPHA)

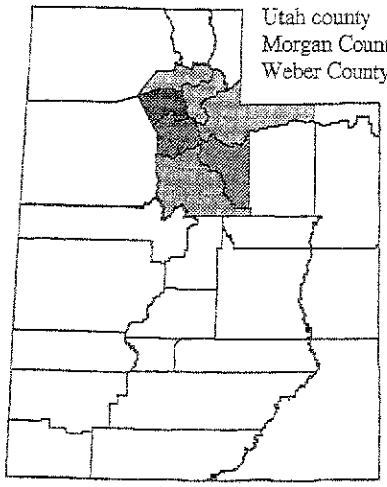
3 State agencies (UDOH, UDEQ, UDAF)
6 local health departments
Coordination with Federal agencies (EPA, FDA, CDC, HHS)

Salt Lake Organizing Committee (SLOC)

SLOC Medical Services

SLC 2002Olympic Footprint

Counties	Local Health Departments
Davis County	Davis County Health Department
Salt Lake County	Salt Lake Valley Health Department
Summit County	Summit County Health Department
Wasatch County	Wasatch City-County Health Department
Utah county	Utah County Health Department
Morgan County	Weber-Morgan Health Department
Weber County	

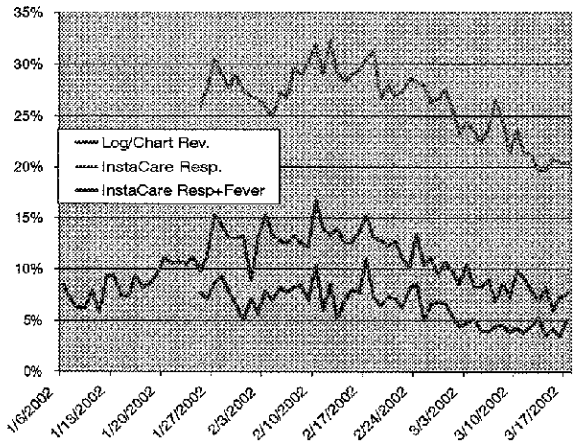


Urgent Care Visits by Syndrome

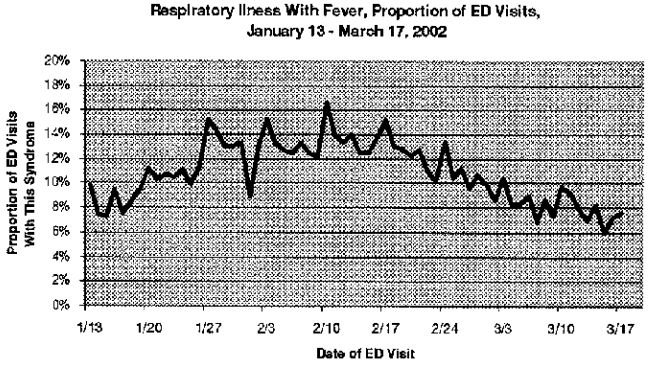
Jan 6 – Mar 17

Non-syndrome visit	133,577		86.0%
Respiratory illness	14,910		9.6%
Gastroenteritis	5,203		3.3%
Central nervous system	688	follow -up on 772 of these cases	0.4%
Rash with fever	429		0.3%
Bloody diarrhea	184		0.1%
Botulism -like	156		0.1%
Lymphadenitis	89	65 notifiable diseases	0.1%
Sepsis	84		0.1%
Suspected hepatitis	41		<0.1%
Unexplained death	3		<0.1%
Total visits	155,364		100.0%

Respiratory Illness Syndromes
Jan 6 through March 17, 2002



2002 Olympic Winter Games
Daily Surveillance Report
Respiratory Illness with Fever



Utah's Public Health Preparedness & Response Grant

Accomplishments: Grant Year 2004

• A major response exercise conducted by the University of Utah and 10 of the major Salt Lake County hospitals allowed SNS and notification systems to be further tested. The exercise was held May 11, 2005.

• SNS training has been provided to UDOH and local health department staff members. Training has included attendance to SNS courses in Atlanta, Georgia for local health emergency response coordinators.

• Pandemic Response Plan has been developed and includes information about immunization.

• Pediatric considerations in emergency response were developed and presented at the Health Resources Services Administration (HRSA) trainings throughout Utah.
• The Utah Smallpox Response Plan was revised to include the National Response Plan and the National Incident Response Plan as well as updated information.
• Development and implementation of the Adult Immunization Management System (AIMS) is continuing. Significant progress was made this year.
• Lessons learned from participation in mass vaccination clinic exercises or real events were included in the mass vaccination and medication plans.
• UDOH has implemented two data management tools called: SERPH (Surveillance and Epidemiological Response for Public Health), which provides a single web-based tool supporting surveillance and outbreak investigation, linking UDOH and the 12 local health departments; and RODS (Real-time Outbreak and Disease Surveillance), which provides early warning of outbreaks or bioterrorism through monitoring emergency department visits and sales of over-the-counter medicine.
• UDOH has hired four skilled epidemiologists (disease experts) to work in different parts of the State. The epidemiologists strengthen Utah's ability to detect and respond to diseases.
• In partnership with Utah's local health departments, a workgroup has been formed to coordinate and improve laboratory testing and disease outbreak detection and response.
• A system has been established to assure 24/7 response to urgent reports of diseases or outbreaks across Utah, including procedures for testing and improving the system.
• The UDOH State public health laboratories had developed testing capabilities for most of the bioterrorism agents and other emerging infectious disease agents. They train weekly to stay current in running the tests.
• This past year, the laboratory developed testing capability for avian influenza, a disease of concern around the world. The laboratory's ability to test for this particular disease will allow for rapid public health intervention to stop the spread of the infection.
• The lab began the implementation of a new Laboratory Information Management System. This new system allows the laboratory to collect, manage and report data used for making rapid and informed public health decisions by local, State and Federal public health workers. The laboratory had been using a data management system that is over 15 years old.
• The microbiology laboratory purchased leading edge equipment that significantly decreases the time needed to identify the organisms that cause infectious diseases.
• Microbiologists from the public health laboratory provided regular training to community and hospital clinical laboratory staff, emergency first responders, local health departments and other interested parties on bioterrorism organisms, diseases, and how to handle and pack specimens safely for delivery to the lab for testing.
• The UDOH public health laboratory has achieved proficiency to detect and confirm 12 heavy metals in urine and cyanide in blood samples. The laboratory is one of 37 laboratories in the country deemed proficient by the CDC for detecting these chemicals in response to a chemical emergency incident.
• UDOH took the lead in identifying various problems with the cyanide analytical method. The experience reported to CDC was made available by CDC to all 50 States to raise awareness of data quality and of potential problems that could arise with cyanide testing.
• A Round Robin study to test the efficiency of field testing equipment was conducted. Findings of the study will help Utah better characterize contaminants of concern in a bio/chem-terrorism emergency.
• Training was provided to hospitals and clinics to ensure safe packaging and shipping of samples to the State health lab. Training included how to safely package and ship blood and urine samples exposed to chemical agents.
• A laboratory response plan for a chemical terrorism incident is in place. Follow-up training is planned.
• The Utah Notification and Information System (UNIS) is being used on a regular basis. UNIS is a statewide, integrated, web-based information and communications system serving as a platform for distribution of alerts, dissemination of guidelines and other information to local, State and Federal partners. Various enhancements to improve the system have been developed and implemented during the past year. Numerous additional users statewide have been enrolled in the system.

• The UDOH has partnered with other State agencies to purchase and implement the Utah Wireless Integrated Network (UWIN)—OmniLink. This system allows agencies in the State to patch together various communication channels on one frequency. Various types of radios as well as cell and land lines can be connected to facilitate emergency communications.
• Application, Database, and Web servers have been added to increase the redundancy, efficiency and capacity of the network. This will also allow bioterrorism applications and databases to be integrated with each other. In some cases, data can be reused instead of gathered multiple times.
• New server room chillers have been purchased and installed. These chillers maintain a constant, safe operating temperature for all bio-terrorism and UDOH systems.
• The UDOH developed a public service campaign that encouraged action from the public. The campaign's primary goal was to provide Utahns with the tools needed to develop emergency plans and emergency kits. The highly successful campaign focused its efforts on two primary tools to reach Utahns: a video documentary and an emergency planning guide brochure. Research performed after the campaign showed that the UDOH was successful in reaching its audience and prompting action.
• From July 2004 to July 2005 approximately 3,208 public health and health care professionals and emergency response partners were reached through the implementation of a Statewide Public Health Preparedness Training Plan. A wide range of delivery methods were used to implement training and exercises in areas across the public health preparedness spectrum. Some highlights were a Suicide Bombing Conference (471 people trained), Bioterrorism Track at the Utah Public Health Association Conference 2005: Making Public Health Visible! (203 people trained) and ongoing distance learning outreach (837 people trained).
• Emergency Preparedness in the Healthcare Setting: Bioterrorism and other WMDs (weapons of mass destruction). From May to September 2005, hospitals and clinics were provided with a 2-day train-the-trainer course in hospital bioterrorism preparedness. Eight locations throughout the State received this training, with a total attendance of 247 people. The target audience was primarily the healthcare setting. Additionally, key partners from the community, such as emergency management services (EMS), military medical centers, surgery centers, emergency management, local health departments, convalescent care managers/staff and public health officials, were also encouraged to attend.
• Local Health Department partnerships and reporting. The UDOH worked closely with 12 local health departments to implement and report on the status of the Statewide Public Health Preparedness Training Plan. Utah has put a major focus on training partnerships, guidance, and reporting tools with local health departments. Each local health department was very responsive with their reporting and coordination with UDOH. This mutual effort has made reaching our preparedness goals attainable.
• Countering Bioterrorism 2005: Breaking New Ground. UDOH sponsored and facilitated the implementation of a regional conference titled Countering Bioterrorism 2005: Breaking New Ground. This year we partnered with the Department of Public Safety and presented both the Public Officials Conference and the Countering Bioterrorism Conference. Over 400 people attended this conference and learned from many national experts in preparedness. The combination of these two conferences strengthened ties and coordination between all parties involved in emergency response.
• Utah expanded bioterrorism response capabilities through the stockpiling of N95 Masks, gloves, gowns, and 500,000 3-day antibiotics to prevent the spread of disease. This is a solid beginning, with plans to expand the medication cache to include antidotes for Acute Radiation Sickness and increased personal protection equipment.
• A comprehensive Emergency Operations Plan for the UDOH was developed and implemented. The plan includes the National Incident Management System. This plan has been exercised, and continued exercises will need to be conducted to assess for shortfalls.
• Legislation was passed to allow hospitals to expand beds 20 percent beyond licensure without seeking permission from UDOH, and to protect medical volunteers from lawsuits through expansion of the Good Samaritan Act. These actions will enhance the ability of healthcare facilities to meet surge needs during a Mass Casualty Incident.

Senator BURR. Dr. Melton, thank you so much. As one who had the great fortune or misfortune to be involved in the Russell Build-

ing nerve gas evacuation of several weeks ago, I understand how vital detection is, but more importantly, the distinction between a positive and a negative detection. But it taught us firsthand up here the progress we have made, when you compare it to the anthrax evacuation of several years ago, where the response was to run, and there was never any thought process to figure out who was in the building before it was evacuated, and potentially who might have been contaminated. It made the back end of it, the response end, very difficult in that case. Though it was inconvenient, all individuals who might have been affected were accounted for, and more importantly, they were not released until we knew exactly whether it was negative or positive. So we have learned from past experiences.

It is unfortunate that we are going to have to break at this time for votes on the floor. My intention is to reconvene this hearing at 11:45. That would be 55 minutes from now, a great opportunity to take a break or grab some lunch. I am going to ask my staff to get with all of you. If there are inconveniences, we understand. My hope is that all of you will be able to come back for a short period of time for questions from members.

At this time we stand in recess until 11:45.

[Recess.]

Senator BURR. Let me once again thank all four of you for your patience, your flexibility and your willingness to share with us your information.

Dr. Melton, Senator Hatch sends his regrets that he is already scheduled to be somewhere else, but did want me to, on his behalf, welcome you here.

Richard, I have to go to your comment on DOD, which I think probably should already be a debate in this country. Probably framed from the standpoint of when does a disaster, a catastrophe, reach a level where potentially you would automatically go to Federal assets because you know that it has now reached a level that is overwhelming to a State and locality. How do we define what that level of catastrophe is?

Mr. FALKENRATH. I do not think you can define it for the whole country all the time. I think it will vary with the contingency, the type of scenario it is, the scale of it, the severity, and also the capabilities that we find at the State and local level, wherever it happens to happen.

Looking at that, then you can decide, are the local assets going to be overwhelmed to the point that a Federal assumption of responsibility is necessary? Take hurricanes, for instance. As far as I can tell, many States in the government are perfectly capable of dealing with major hurricanes hitting their cities, and there is no need for the Federal Government to step in in a more forceful way. What we saw in New Orleans was a city below sea level, a Cat 5 hurricane direct hit, and where the municipal authorities really were overwhelmed very quickly. And that, I think, in hindsight, shows us the Federal Government should have been stepping in.

On bioterrorism——

Senator BURR. Let me stop you if I can though, and Dr. Hanfling referred to this, that we are sort of geared at the local and regional level today to be prepared for the first 48 hours. The difficulty

comes from the length of time that it takes, and it took in the Gulf Coast case, for all three parties, local, State, Feds, to come to a conclusion that Federal assets were needed. Unfortunately, that decision was made after the 48 hours. Then it took an additional 48 hours minimum to accumulate all the assets, aircraft, pilots, maintenance crews, fuel, food, because we knew enough by then to know that to move people in, they had to be self-sufficient. And to some degree, I think it was miraculous that within 48 hours, and at the far end of it, 72 hours, all those assets were on the ground.

But what I am hearing the local folks say is that that is a decision that has to be made at the beginning, not after 48 hours, because 48 hours becomes 96, and at 72 we have chaos that breaks out, if in fact the local resources are overwhelmed. How do we establish some criteria?

Mr. FALKENRATH. Well, on the timeline issue, and the lag time, let me first offer this comment. I actually think the decision to prepare for this has to be made long in advance. And at the Federal level, you want to have planning assumptions that are realistic, given your contingency, so you can get ready, and so it does not take you 48 hours or 72 or 96 to come in in the way that you will, in fact, be expected to come in in the contingency at hand.

To my point in my testimony was, we need to tell some competent agency of the Federal Government to be ready to do this if necessary, if called upon. And by "do this" I mean something very, very specific, which is to prepare to distribute life-saving medicines to extremely large populations, very, very quickly, when they are afraid, because there is a communicable disease out there that they do not know how to deal with. And this is something that we have never asked our State and local agencies to do for real. We have only done it in exercises, and we have had a lot of these exercises in the Federal Government, and the exact same thing happens every time, which is they cannot do it fast enough. They cannot do it in the way that the President and the people will expect them to do it in the sort of extreme contingencies that we are talking about, and I am talking about the very high end, the most extreme contingencies, not the routine ones.

Therefore, what is our approach as a Federal Government? Is it just to keep replaying this situation again and again and again in exercise until it happens in reality, and we experience in reality what we know will happen in a simulated way, or do we adopt a different approach?

Senator BURR. I think we have some constitutional issues with those Federal assets and how quickly they could trump, for the lack of a better word, a State request, but clearly, the Governors in this country could have a compact with the Federal Government that triggers something. I think the key thing is figuring out how to stimulate that debate, and establishing what that criteria is for the trigger.

You talked about research and development of countermeasures, the lack of big pharma participation. I think to a large degree, in the current world of vaccines and antivirals, academia is cut out of it. There is some basic research that goes on that is funded from numerous different Federal sources and some private.

What does it take for us to have the level of advanced development of countermeasures that would create a framework that could address the threats we know of today, but also could serve as a sufficient blueprint for threats that are going to come that we do not know about today?

Mr. FALKENRATH. It is going to take a lot of things, and some of them are already in place. I mean I think we have a pretty sound fundamental R&D effort in the country now for basic discovery. The harder part is development, to take a discovery and actually do all the work needed to bring a drug online. There, there is no one single answer, but what you do need is a very well-staffed, professionally led program at the Federal level, and probably located in HHS, to take care of every little detail that needs to be dealt with as you bring countermeasures along.

As I said, I think the effort to deal with countermeasures to known pathogens, the ones that are out there today, like ebola or anthrax or smallpox, should be separate from the ones that do not exist yet, or that we do not know about, because I think they require a very different approach, a different mindset, as it were.

But you need a well-funded, well-staffed program at the Federal level that has responsibility for this effort from soup to nuts to bring these things along. I think the embryo of it exists at HHS today, but I think as Secretary Leavitt acknowledged this morning, even it, there is not enough people with not enough resources and not enough flexibility to do all the things they need to do.

Senator BURR. As I shared with the Secretary before I left, BioShield really has become a procurement tool for countermeasures. We have played with advance development, but usually it involved a request to another agency that happened to have some available money, and they became a venture capital fund almost for whoever reached that advanced research stage and needed further development. This might work, but I think you alluded to the fact, if I remember, that we have a problem with the length of clinical trials.

I guess my question is this: is it not impossible for us to layer clinical trials, if in fact, we do not have some third party group that can see the data in real time? It is really unacceptable to believe that we cannot shorten that clinical trial period?

Mr. FALKENRATH. I think that is probably right, Senator, and I speak as a sort of former policy official and expert, not as a technician. I have never done this. I am not a scientist. But there is no question that we have for clinical trials, a process which is largely sequential, one step follows another, follows another, and we need to make it massively simultaneous and to find a way to do all the different things we need to do in as great a degree simultaneously as we can.

I think it is good that we have emergency use authority already conferred through the first bioterrorism bill and then the BioShield bill to the Secretary of HHS. We need that. But we need the ability, somehow, to more quickly find out if the countermeasure will be effective and safe for use in a general population.

I will say on BioShield, I was involved in this in the White House. There is a theory behind BioShield, which is, if you create an advance appropriation, a pot of money that is out there and available, they will come. The industry will come and say, "We see

the money to buy the stuff in the end, and therefore, we are going to produce it." That assumption probably is not, as I think we have learned, is not entirely right. They are not going to come. They need a lot of hand-holding and bringing along, and it tends to be the small and mid-cap companies, not the largest ones, that are willing to do this.

Senator BURR. I think to some degree that period between identification and development might also share additional information where one, in hindsight, might look and say, "Well, I am not really sure this is necessarily a stockpile item," but you have already got the commitment out there to purchase it, and that is a troubling thing, not necessarily for what we know today and what we are after as far as the countermeasure, but for tomorrow, not knowing what to develop in time, not knowing the specificity of the countermeasure that we are looking for, and not knowing how long that threat might exist. It could be that the threat is gone by the time you get the countermeasure, but you are still obligated to the purchase for the stockpile.

As I have just raised on the Senate floor, we have a fiduciary responsibility to the taxpayers to make sure that what we do is not throwing money down a black hole, but is truly an expenditure on behalf of their protection.

I am going to ask you one last question, and then I would open that up to anybody else that would like to comment as well. I asked the Secretary, while he was here, specifically as it related to masks, because HHS made a proposal or suggestion to the American people this week that canned meat, canned milk were probably good things to store. I think the comments were targeted at avian flu. The Secretary, wisely, this morning, expanded that to any potential disaster or threat that might be out there, and certainly it is appropriate for us to suggest to the American people, and remind them that there are preparations they can make on their own.

But there is an issue on masks, and there may be other products that go into the category of, you know, it would be good for the American people to have this from a standpoint of prevention. The marketplace will be flooded with them. Not all of them will necessarily be ones that will be sufficient to protect somebody from contracting the flu.

Is it possible for us to negotiate with the appropriate manufacturers to approve the appropriate masks, and either directly from that manufacturer or through somebody they choose to use as a marketer of their product, have an official Government Web site that would suggest to people, here are the masks that are approved for avian flu. Here is the price that the Federal Government negotiated for every person that would like to purchase. All you need to do is go on the Internet and purchase those for yourself. Is that reasonable?

Mr. FALKENRATH. Yes. It is. They should be able to do that. But I would probably take it one step further, which says, if the Department of Health and Human Services is not capable of protecting the population medically from a particular disease, like pandemic, or we just do not have the vaccines or the antivirals to

do it, they better have another answer, and masks are suboptimal. They are not ideal. It would be much better to vaccinate everyone.

But if you have no vaccine and you have insufficient antivirals and you expect every single hospital to be flooded with sick people, and so you are not going to be able to get proper medical care, you need an alternative idea about how you are going to protect people and slow the velocity of viral transmission among each other. And that say, you are going to have to do something to protect the respiratory system.

I came back from Asia 2 days ago. In Asia people routinely walk around and take subways with masks on. It looks kind of odd, but in every Asian country I have been to, you see people walking around with masks on. I am not an expert on which mask would be effective against which particular pathogen, but science should be able to figure that out, and in addition to making that information available and allowing people to purchase them on their own, if I were HHS or whatever responsible agency in the Federal Government, I would think about stockpiling them myself to distribute if we do not have a medicine to distribute.

Senator BURR. I do not disagree with you on that, but at some point you and I are going to have a discussion then about how you distribute them to the American people, because ultimately, they need to make it to people across the country. I will get to you, Dr. Melton. You said we pre-positioned the national stockpile in Utah, and still today you are sitting there going, if we had needed it, how would we have gotten it to the population of Utah? The distribution link is something that has been way down on our list of things to think about in a realistic way. I know from a modeling way, we have looked at it.

Mr. MELTON. We had plans for a six-county area. Beyond that, it would have been far more difficult. In the rural areas, it is a different issue in rural Utah than it is urban Utah, to develop plans for distribution. We are still working on some of the rural areas as we speak, how to get a distribution system we feel is comfortable in the rural area. Urban Utah, we believe we could distribute most anything in the urban areas of Utah with the organizations that we currently have developed within a 24-hour period.

Senator BURR. Leah, let me ask. You talked about the partnership with local law enforcement. Why is that so important?

Dr. DEVLIN. Well, we found out in 2001 when the first anthrax person actually got sick in North Carolina, and we ultimately knew he contracted his infection in Florida. But right away, this was a partnership then with law enforcement because we knew that if this was pulmonary anthrax, which it turned out to be, that it was intentionally delivered. So we moved from there into the white powder incidences, and we are front-line first responders with law enforcement in North Carolina on a consistent basis since then. We are part of the national security.

If I might go back and talk just a little bit about some of the all-hazards approach, would that be acceptable to you, Senator Burr?

Senator BURR. Yes, ma'am.

Dr. DEVLIN. Thank you. You can be very proud that in North Carolina, the first hurricane to come ashore after Katrina was Ophelia, and in planning for a hurricane, there is a lot you can do

ahead of time. And we had forward placement of Federal assets. We had over 400 people from FEMA positioned in North Carolina, and we were ready. We had a U.S. Coast Guard, the highest level official in our emergency operations center, and he stayed there from Sunday to Thursday, ready to assume responsibility if the State and local response was not adequate in his judgment. And when he left Thursday night, he said in his 32 years of service, this was the best run operation that he had seen.

Now, luckily, Ophelia was not a category 5, but the pre-positioning of assets in that kind of situation works. In a communicable disease outbreak or an act of terrorism, all communities have to be prepared on an ongoing basis, and we have to have the capacity in the State and local level to be responsive at early detection and rapid response. We have never been resourced until 2002 to really step up to the plate and be partners with law enforcement, agriculture and first responders.

So we have this all-hazards approach. It is every day in North Carolina, and it is real. So something big, we will all have to be ready, is the point that I wanted to make.

Senator BURR. I remember in the months after 9/11, on the House side on the Commerce Committee, as we began to look at our public health infrastructure, the amazement of Congress to find that a third of our public health infrastructure in this country was only connected to CDC via telephone. It was not the Internet, it was not a fax, but it was a telephone. For a health threat, in order to notify that public health entity, CDC had to rely on somebody actually answering a telephone. And I think the initiative at that time was to make sure that 100 percent of our public health infrastructure was electronically connected so that in real time we could transmit information. I am still not sure that we are at 100 percent yet, and that is something that we are going to look at as we get ready for this reauthorization.

How important is it that we exhaust every possibility from a surveillance standpoint to understand what is going on across this country? We have some Federal programs that are specifically designed to detect some of the chemical, biological, and radiological threats that exist. We have had available for quite some time, the ability as the Federal Government, via CDC and a connection to the public health entities, regardless of what community they were in, to plug in prescriptions that were written the day before across this country because we have the capabilities now to look at about 95 percent of all the scrips that were filled. Yet today, we still do not plug into that, and were CDC to contract for that, every public health entity across the country could plug into their area of jurisdiction and look at the scrips.

Now that would not be specifically just things limited to anthrax or just things limited to our host of chemical, biological or natural threats, but the communicable diseases that public health is really charged with being on the front line, how valuable would that be to a local public health entity?

Dr. DEVLIN. Thank you, Senator Burr. I do think that we have to take advantage of existing systems that are already electronically capturing data that can be of use to public health. I think we have to get as near real time data as we can so that we have ongo-

ing situational awareness, and certainly, plugging into hospital emergency departments, moving from there to urgent care centers and primary care centers, bringing those into contact with the public health system to get as near real time as we can is important, and certainly, the data that you are talking about from the pharmacies, is data that is not quite as real time, but it is low-hanging fruit, if you will, and it does add value. So I think we have to get clear on what our priorities should be as we roll out, and what can we get in a timely fashion that will move us forward.

Senator BURR. I think it is safe to say we do not mine that data very well today, in part because we do not have all the pieces electronically connected, but that has to be a goal, and I think our answer is we have to do it all, and that anything short of that would be a mistake.

As we look at the progression of avian flu around the world, I think it is safe to look at this morbidity rate of 50 percent, and say, you know, this is probably not accurate. It is 50 percent of the people who are actually walking in so sick that they are staying in a hospital. And when we look back at 1918, the morbidity rate was 2 percent, huge difference. So I think we have to look at avian flu and ask ourselves, do we have only a gap in surveillance? Or do we have a problem with the ability to identify everyone who is ill? Do we have a gap in the surveillance just simply because of the multiple places that people are going such as drug stores and clinics, and we do not identify it as bird flu?

Dr. Hanfling, you talked about medical surge. You talked about the specific needs for surge in ventilators and other supplies. I do not disagree with you. The difficulty that I have is that we could bring 10 times the number of ventilators online that are currently available across the country. All it would take is appropriations.

Dr. HANFLING. Good to hear it is that simple.

Senator BURR. But we do not have the medical staff available today or in the foreseeable future to actually take care of the patients on the ventilators.

Dr. HANFLING. It is an important point, and I am glad to hear that it is as simple as just asking for an appropriation and getting it, and I urge you and your colleagues to consider doing that, because I think it will make a huge difference in terms of providing for the care, the availability and the resources that will be required to care for the American people should something as drastic as avian influenza come across our shores.

But it speaks to a broader point that I think you alluded to in the Secretary's comments about how the American people can be prepared and take preparations under their own wing so to speak, and I would suggest that that conversation needs to be broadened out to include the recognition that there may be—there may come a time in the most catastrophic of situations where we are discussing and need to discuss and need to put in place and legislate altered standards of care that allow for what we call the graceful degradation of care, that we will not be delivering health care in the context or to the level that we are used to delivering it today.

And in that setting then, begin to also recognize that there will be a need to train health care workforce and nonhealth care workforce to take a role in the delivery of some degree of care, and we

have looked at the issue of the shortfall in the way of trained critical care intensivists and respiratory therapists and so on, and, you know, have some recommendations in terms of providing for a real training capability that will identify a cohort of folks who could step into those roles, either under direct supervision—in other words, I would be responsible for the three others at this table, to show them things to look out for. And then beyond that, really to go back to the family side and to give the families some role in the provision of health care.

Senator BURR. I think it certainly gets back to Mr. Falkenrath's comments about, you know, there needs to be a Plan B. If you have not got the vaccine, if you have not got the antiviral, then at some point we are going to know what the right morbidity rate is, and if it is a full-scale pandemic, we are going to know what we are dealing with from the standpoint of the affected population, what percentage of those likely will not make it through, and what percentage we are going to, to some degree, have in some type of medical care.

I think the challenging thing for me is the reality that every week when I go back to North Carolina, and we are spitting out nurses just as fast as we can educate them, and we are doing it in 4-year programs and 2-year programs, and 6 months before they graduate, they have got a work contract for twice as much money as they made before they went in the nursing program. They are excited. They are interested, and we cannot even fill North Carolina's needs.

And the problem is, not that we cannot increase the size of the class, we could do that tomorrow. The problem is we do not have the clinical space to take them through the program, and in some cases, we are running three nursing programs where they are doing clinical work at some point 24 hours a day in the hospitals, but you just do not have enough capacity to jet them out—we can do it much faster on teachers than we can on nurses because of the clinical side of it.

So there are some realities out there that I hope you understand. I would expect you to say exactly what you did. I hope you would expect me to say there are some limitations where you have to be realistic about this that we cannot do.

Dr. HANFLING. Just to follow up on that though, I think that there is, somewhere between the sun and the shadow lies the middle ground, and in that middle ground is not the worst, worst, worst case scenario, which we just discussed, but there are many, many other scenarios and many, many communities right now that cannot even mount a basic response to what I would consider to be a small to moderate size scale disaster. In other words, in Northern Virginia, in our health care system, where we have about 250 ventilators spread amongst our hospitals, you know, 80 to 85 percent of them are already in use. I mean they are in place already. So there is a role to supporting some degree, I think, of local cache capability.

I would go back to Dr. Falkenrath's point that, yes, there is some threshold at which with preplanning you will call in the cavalry, but even in calling in the cavalry, it will take some time, and that is why I go back to the point that I made, which is that how are

we going to answer to the American people when lives are hanging in the balance? I think that that is the question that I suggest we put ahead of us as we discuss surge capacity, and then in the context of staffing, surge capability, which is the complement to capacity.

Senator BURR. Richard.

Mr. FALKENRATH. Senator, on this question of surge capacity, I think it is very important, and we need some manner of surge capacity in this country. I would just say though, I think it is very multidimensional. It is not just about equipment. It is also about plans, personnel, physical space, communication systems, and it is multiyear, so it is not a matter of a single appropriations. You can spend the appropriations 1 year, and it might get you something that is useful in some circumstance, but it does not give you across-the-board surge capacity.

The dilemma we face at a national level, as you well know from your committee, health care is incredibly expensive. I do not know what part of the economy is devoted to health care, very high percentage, and it is rising very fast. The implicit policy direction of both Republican and Democratic administrations, for quite a while, has been to reduce health care costs, to keep it in check and to squeeze out excess capacity. So you have a collision of the national economic imperative of squeezing out excess capacity for the purpose of saving money, versus the homeland security imperative of preparing for calamity, in which case you need the excess capacity. So that is a real dilemma that we in the White House wrestled with and I know you in the Congress still have to wrestle with.

On grants, I will say, when I was in the White House, in the beginning I was a very strong proponent of both the homeland security and the public health grants. I supported them very strongly. I have come to be very concerned about the value that we are getting for those investments for catastrophes, for the highest-end scenarios, not for the middle tier and lower-end scenarios, where I know they are very useful out there in America, but for the highest end, I am not sure that we are getting a whole lot of additional capacity, a delta, to deal with the extreme sorts of contingencies that we could have.

I think—and this is not an indictment of any particular entity—my understanding is that every agency—we have a problem nationwide with the recipients of grant assistance of essentially sort of defraying other operating costs with them. So we are not getting a delta, we are not getting a bump up so much as budgetary support for the grant recipients. I know the recipients of the grants do not like to hear that, but I will say, as someone who reviewed the sort of audits of what we were getting for the grants, no agency was able to come to the White House and say with great certainty that they knew the money that they were handing out was being used only for new and additional capabilities, as opposed to paying for things that already were planned for.

Senator BURR. I might say that in a meeting that we had last week on the reauthorization, it made me stop and think that for the last several years, in an effort to try to lower the health care costs overall, we have suggested, to some degree, national policy. You know, you get a cold, go to the drugstore, do not go to the doc-

tor, go to your cold medicine. Now, all of a sudden, we are sitting here going into a period where there may be bird flu. Do we still continue the policy of, if you get the sniffles, if you get the fever, if you feel like you are getting the flu, go to the drugstore, get this, or is it go to the hospital?

We have to figure out what our message is going to be, because if not, we either overreact one way or we under react, and the consequences are much greater as are the challenges.

Leah, did you have something you wanted to say?

Dr. DEVLIN. Well, I have a couple of things I would like to say. Thank you very much, Senator Burr.

Just in response to your thinking, and yours about workforce issues related to surge capacity, that is there for that IT question that you asked also. We have to have people in public health that can bring that data in, make sense of it, get the medical record, read it, and still put the medical epidemiologist, the nurse, the environmental specialist out there in the field. So I just wanted to hold that thought too, that with these new technology systems, that is also a workforce issue, as is true of many other aspects of public health.

An interesting twist on the issue of supplanting that has been raised, actually, what we have seen in our State is that the Federal investment in public health preparedness, which really is central to our mission if you know the history of public health, we have been about the business of communicable disease control since the inception. Strengthening that function—and we have led a road for the past 30 years—has actually resulted in our State, and probably is true in other States, of strengthening other parts of the public health infrastructure as well because we are visible now for the first time, and people understand more what the role of the local, State health department, the Federal role is as well.

So actually it has not been supplanting, but it has been a strengthening that has brought additional opportunities to public health, which gets to that larger issue of controlling health care cost, because we really need to invest in prevention in many ways, not just in preparedness, but in all aspects of our health behaviors and health policies if we are going to be able to control cost.

Senator BURR. Should every public health entity in America, regardless of the jurisdiction that they are in, be exactly the same?

Dr. DEVLIN. Well, we have a local system and a State system and a Federal system, but we all work together toward the same end. And the needs of the communities are different. We have the rural parts of our State. We have some urban area. We have the mountains with their separate air quality issues, and so each State is different.

Senator BURR. Let me explain why I asked the question. Today you can go into a community where the primary care provider for an at-risk income group could be the health department, could be public health. You could go 30 miles down the road and go to the public health department there, and find that the extent of what they offer is vaccinations for low-income children. There is a problem with that, in my estimation.

I guess my question is, as we go through this reauthorization, I think it is vitally important that we define what our expectations

are from public health entities. How much flexibility, if any, should exist from one to the other, based upon the State they are in, based upon urban versus rural? How much of it needs to be really a uniformity from place to place to place to place?

Dr. DEVLIN. We are working for our performance indicators from CDC, and we welcome these performance measures, and we have been—they have been changing on us since 2002, when the funding first started to come. So we would like to get clear on that with the Federal Government on what is expected county to county to county, and we want to meet those deliverables.

Senator BURR. Dr. Melton.

Mr. MELTON. We need to be careful though not to mix function. We are talking here about preparedness for disaster and for communicable disease. At least in Utah, most of the local health departments that provide primary care are not doing so with the dollars that we are talking about here. They are doing so with either local dollars provided by their government to provide primary care for their citizens, or they are getting it through third-party payers as the only primary care provider in the area, because we also do not standardize our health care system. So in some areas public health is the only health care system available, and in those, we cannot say you cannot do that because you are public health.

So we cannot function. Public health has an assurance function. In some areas they do not need to assure health care, primary health care.

Senator BURR. So we need to possibly legislate a floor but not a ceiling?

Mr. MELTON. That may be correct, yes. There is a minimum number of things that we need to do for public health, and those are the kinds of things that Dr. Devlin has been talking about and that we need to talk about here. What should we do with the Federal dollars we are getting? There should be a floor on that, and there should be a thing required. And there probably should be a set of things that we should not expend our money for. I cannot talk about other States, where they may have put some money into primary care, but we in Utah have not used any of these funds for things that we had otherwise planned to do.

Senator BURR. Dr. Devlin addressed some of the things that I think North Carolina does well. We do them well for two reasons. One, we have a plan. Two, every year, multiple times, we get an opportunity to execute that plan, and we are just fortunate location-wise, that like Florida, we get an opportunity to play it out.

Utah is one of the few, if not the only other place, where you have an opportunity to actually create a plan, bring the assets in, and have to think about it from a standpoint of how do we actually implement it?

One of the things you said was the importance of coordination with other agencies. I am just curious if you would comment how easy it was or how difficult it was to seek the level of coordination of different agencies that you had to achieve.

Mr. MELTON. Utah has, I think, a culture that makes it a little easier for us to coordinate. That may be an underlying statement. However, it was not easy for public health to insert itself in a lot of the planning. Other than food, sanitation and some medical co-

ordination, it was not easy for us to get across the idea that there were other things that they needed to be thinking about as well, until the anthrax attacks. And then all of a sudden the surveillance activities that we had been talking about previously became very important subjects. Until that, it was not easy to get them to think about surveillance as one of the underlying pieces that had to be done for the Olympics.

Let me add one other thing that is true about the Olympics that is not true about what we are talking about here. We knew when that disaster would occur and what we were expecting. What we are talking about here, with the exception of a few days, perhaps, with a hurricane, we do not know when an earthquake is going to take place, and that is one of the things we prepare for, earthquakes. We do not know when a terrorist might attack, so it is a little harder for us as a Nation to maintain the level of preparedness that Utah was able to get to when we knew when the disaster would take place.

Senator BURR. I thought during the days and weeks and now months after Katrina, that—Dr. Devlin, correct me if I am wrong—this year we will put the last individuals who were displaced in the eastern North Carolina floods from a hurricane into permanent housing. This year, I think 5 years later, the last group of individuals will be moved from temporary housing to permanent housing. We had flooding on a geographical area that exceeded the city of New Orleans, certainly not a population the size of New Orleans that was affected, but in some ways, a greater challenge from a standpoint of rebuilding. It is a reminder that the challenge in front of us is not one that is going to be done overnight. We have lived it firsthand.

What I think, in many cases, is that it was the level of our plan that was written, and our ability to respond even to something we never dreamed could happen in North Carolina, that enabled us to get by that particular catastrophe, disaster. We were able to do it. New Orleans was not. I think to some degree, the difference is the fact that we actually got the opportunity to implement our plan so often, that even though it was not perfect and we learned from it, our ability to respond to it when it did happen enabled us to have a little different result.

Richard, if I could ask you just one last thing. The White House after-action report on Katrina recommends NDMS to move to HHS. Do you have any comments on that? And if I could, let me expand that as well to say, are there other areas of health care response that still are at DHS that you would say, you know, you ought to look at moving this over?

Mr. FALKENRATH. I think it makes sense to move it back. The history of this is that in the President's initial proposal for DHS, there was a whole bunch of biodefense capability that he wanted to move in, not just NDMS, also the stockpile, also the R&D stream at NIH, also the public health grants. Congress at the time did not go along with that. That was the one area of the proposal actually they rejected. And so only a few things were moved in. Plum Island was moved from USDA, NDMS into FEMA, and the stockpile into FEMA. The stockpile was transferred back in 2004. That did not work. It was the legislative language that authorized the transfer

divided up responsibilities where it was just too complicated. And so Secretary Ridge and Secretary Thompson agreed to move it back, and Congress concurred in that in the appropriations rider.

I think this will be the sort of same arrangement. You know, the two secretaries are in agreement, the White House is in agreement. If all relevant interested Members of Congress are okay with it, I think it should be pretty easy to effect a transfer back.

Senator BURR. You know as well as I do how difficult it is sometimes to move things from one agency to the other, because there is a budget that follows it. I hope it is as easy as maybe what you have suggested.

Mr. FALKENRATH. I hope so. I guess it is true, I did spend a lot of time on the stockpile issue, but once the decision was made, it moved pretty easily.

I think it does not make sense to—it made sense to move the biodefense capabilities from HHS to DHS when DHS was getting them all. But that did not work. Congress did not concur, and maybe the idea was not well conceived enough, and so there ended up being a division, where a lot of responsibilities stayed at HHS and a little bit went to DHS, and so it was sort of complicated.

DHS does not have a whole lot of medical expertise, frankly, and the ability to manage things, and HHS retains responsibility for ESF-8 under the NRP. So if they have ESF-8 under the NRP, why not have the NDMS, which is one instrument for executing the responsibilities in ESF-8?

Senator BURR. Dr. Hanfling, Secretary Leavitt said earlier that significant moneys, 27 million per year, have been spent on medical preparedness. Do you think we have sufficiently established the national standards for a variety of the health care workers to establish a floor for medical preparedness?

Dr. HANFLING. Let me answer that question, and then if I may, I would like to go back to address on of the other issues that was on the table.

Senator BURR. Absolutely.

Dr. HANFLING. You know, this is a marathon, and so we are talking about being in the front end of a long race toward getting a degree of competency-based training in place amongst the full spectrum of health care workforce staff, and I would go so far as to tell you that it is not just doctors and nurses anymore, we need our housekeeping staff, we need our cafeteria staff, we need our clerical staff and so on. We are a complex community, if you will, all of whom have to receive some training, and I think that there has been a lot of work, particularly put forth by a number of academic institutions to really begin to shed light on what those competencies ought to be.

And I think that one of the problems that we faced in the first go-around of the HRSA grant funds was that we could not pay for our staff to attend training, so there was a mandate to receive training, but we could not actually pay them to do that, and I think that that is something that has to be looked at in the reauthorization.

If I may, sir, I would like to just go back to address the issue about the role of public health vis-a-vis the hospitals in delivery of basic care needs, because the public health community does a tre-

mendous job, in some places better than others, but the emergency departments and our hospitals are the safety net for delivery of heath care to those who are disenfranchised or underprivileged or have no place else to go. And I can tell you that from firsthand experience because I take care of the public health patients on the weekends and at night when there is no place else for them to turn.

So I think it is important, again, for the discussion about the delivery of care, to come back, not to the public health community, but to the hospitals and the health care community. And in that context, I would also remind you, as I am sure you are well aware, that in this year's budget that the President submitted for review, there is an elimination of a number of programs that have been funding key elements of the delivery of health care, particularly as it relates to trauma care. The trauma and EMS program, budgeted for no dollars in fiscal year 2007. The children's EMS program, budgeted for no dollars. The Preventative Health and Health Services Block Grant, budgeted for zero dollars.

So here we are on the one hand talking about how we are going to create surge capacity and surge capability, but on the other hand, we are taking it away. I think that you and your colleagues have to give strong consideration to the successes of those programs and the importance that they plan.

Another one, the traumatic brain injury program, I mean here is a place where we have made tremendous strides in the last few years, and now we are taking moneys away from these programs. Are they important? Sure, they are important, because whether it is a low, moderate or large-scale disaster event, all of those elements are going to need to come together to provide for a response.

Senator BURR. I appreciate that input, and Congress, in its own way has an ability to sort of shrug off budget resolutions and presidential budgets, because we know that at the end of the day under the umbrella, under the cap, we are the ones charged with making sure that we put the money where it serves the most good for the population, and I think we will do that again, and the likelihood is that many of those areas that you just talked about will receive funding, so I am fairly confident we will see some things that we have seen in the past.

Having said that, I think it was stated earlier that we are challenged every year with a larger share of the GDP going to health care, and the question is, when does it pop? To me, I look at Medicaid in the United States, and I seriously do go to bed at night and wonder why is it not mandatory that every Medicaid beneficiary be assigned a primary care provider? How do you educate a population on taking care of their health if they do not have a relationship with a health care professional? And this is an explosion of the Federal Government's budget, an explosion of State budget, regardless of which State it is. Medicaid is out of control. We are doing some very creative things in North Carolina. I actually think more about how we take that population and set a precedent that if it is not an emergency, the last place you are coming to is the hospital. Why is it the primary care provider today? Because we have not forced a relationship with a primary care entity, be that a doctor, be it a rural health clinic, be it a community health center.

And until we do that there is no way for us to have that educational link for disease management or for prevention.

I think at the end of the day, putting aside the subject matter that we are here to talk about today, if we cannot find a way to build wellness and prevention into the health care model in America, Richard, we do not have a prayer turning around the percentage. At some point, the difference is, we are going to choose between children's health insurance for low-income children and seniors' participation in Medicare, and then you start ratcheting it down, and every choice is winners and losers versus trying to figure out a strategy where everybody wins.

Now, there is one thing that I can promise you, if that day comes, I will not be up here. You may still be in your profession, but I will not be up here making the choices. I think that is one of the reasons that as we go through the choices that we have on making, creating the availability of countermeasures, and how we restructure or reauthorize the bioterrorism bill, that we do not do it in a way that picks winners and losers. The objective here is to create an infrastructure that can withstand anything that is thrown at it, and to some degree, when you get behind the eight-ball, like we are in avian flu, where there is a time constraint that you are dealing with, you are forced to pick winners and losers. It may solve that one problem, but the problem down the road is how you have an infrastructure that can handle it all, and that is truly what we are trying to grapple with as we do both of these bills. I think there is a way to do it. It is not going to be easy, as I learned last year, but I also have learned that big things do not happen up here in Washington quickly.

Dr. HANFLING. And your point about accountability, which is really what we are talking about in sort of the broadest terms, is a very good one, because what we are saying and what I think the Secretary said and what others on the panel have said, is we need our citizens to take some accountability. Well, you know, that goes so far as to if you are a Medicaid signatory, figure out who your doctor is going to be. Do not always come to the emergency room in the middle of the night, because, yes, I will be there, but let's build systems, I think is really what we are talking about.

And I would agree with you that this bill, although focusing on disaster preparedness and the sorts of things that we have been discussing, really is the opportunity to continue to build this platform upon which we are looking at the delivery of health care at all times, and the kinds of communications and linkages that we have to build amongst the communities.

Senator BURR. Every step in the right direction enables us to achieve a higher level of preparation and response. I am not sure when we get to the ultimate plateau at the top where we can all look back and say we are there. I am not sure we ever will be. This will be a process that will continually challenge us to figure out where it is we need to be.

I cannot thank all of you enough for your flexibility today. I have kept you 30 minutes past what Bob told me your timelines accommodated, but, literally, this is invaluable to us as we start this process.

I would ask unanimous consent—and since I am the only member here, I am going to get it.

[Laughter.]

That the record be left open for 10 days to accommodate the other members who might have questions or statements for the record. As well, I would ask all of you that if you have additional information that might have been stimulated in this hearing, if you would share it with us in writing. It will certainly be useful to us as we begin to craft this legislation.

Once again I thank you for the input, thank you for the wisdom, and thank you for the flexibility.

This hearing is adjourned.

ADDITIONAL MATERIAL

QUESTIONS OF SENATOR CLINTON TO SECRETARY MICHAEL LEAVITT

Question 1. We cannot respond to any public health emergencies—biological attacks, pandemic influenza, and naturally occurring disasters like Hurricane Katrina—unless we have a strong public health infrastructure that is effective in day to day operations. It is particularly important to invest in "dual use" mechanisms—such as the vaccine tracking system proposed in the *Influenza Vaccine Security Act*, legislation I introduced with Senator Pat Roberts—that can be used to address the public health needs that we face every year, but can also be used in emergency situations. The benefit of "dual use" systems is that they allow our public health professionals to become comfortable with something they're using every day, so that it's second nature to them in times of emergency, and I believe that the mechanisms set up in our legislation are ones that HHS should support.

How will you ensure that the steps we take in preparing for pandemic flu are "dual use," and can help strengthen both our traditional public health infrastructure and our ability to respond to bioterrorism or other public health emergencies? I am particularly interested to learn of any efforts to establish tracking and distribution systems for vaccines, antivirals, medical supplies, and other items that are needed during our annual flu season and will be necessary for pandemic influenza or other emergencies.

Question 2. Stewart Simonson, Assistant Secretary for Public Health Preparedness at HHS, submitted his resignation to the President last week. As the *Associated Press* reported, ". . . [he] told the president . . . that he had accomplished what he had set out to do, and it was time to move on." Yet the hearing before the HELP Committee highlighted multiple concerns—lack of coordination, no clear authority, the need for additional resources and guidance—with our Federal response to bioterrorism preparedness. Could you please elaborate how the Department will address these remaining concerns? What is the timeline for doing so?

Question 3. In your testimony, you noted that you are considering a reorganization of the role of the Assistant Secretary for Public Health Preparedness. Could you please explain how your plans for reorganization would take into account the need to increase coordination both within HHS and with other Federal agencies like the Department of Homeland Security? How would the Assistant Secretary of Public Health Preparedness coordinate with the Assistant Secretary of Health, and what roles would be assigned to each individual?

Question 4. In an appearance on CNN earlier this year, you said:

> "**Don't count on Washington, D.C. to manage your pandemic because it will be about your schools, it will be about your parades, it will be about your businesses. And you need to have the ability to be knowledgeable and to respond when—if your hospital were to surge and need to have three to four or five times the capacity that it currently has. You need a plan**."

Could you please explain in greater detail how HHS is taking responsibility to ensure that States, local public health departments, local governments, and health care have adequate resources to plan and prepare for an all-hazards response to all emergencies, not just pandemic influenza?

Question 5. States, local health departments, and hospitals have raised significant concerns over the use of CDC's and HRSA's critical benchmarks in evaluation of funding allocations. Specifically, there are concerns that these benchmarks do not adequately measure bioterror preparedness. How does HHS plan to address these concerns in the revision of these indicators? How will HHS take these comments into account when developing indicators to measure use of the $350 million in pandemic flu funding that will be given to States and localities?

Question 6. We are aware of multiple exercises to help both health officials and other Government agencies prepare for emergencies. The Department of Homeland Security has engaged in its TOPOFF exercises in cooperation with several States. High-level officials within the administration have engaged in both pandemic influenza and smallpox planning scenarios, and in your recent pandemic flu update, you have indicated the intent of HHS to assist with both State exercises and spearhead a national pandemic exercise. Could you explain how these drills are being evaluated and used to inform both your agency and State and local preparedness efforts?

What changes have occurred in operations as a result of the lessons learned through these exercises?

[Editor's Note—The repsonses to the above questions were not available at time of print.]

[Whereupon, at 12:50 p.m., the committee was adjourned.]

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