

**THE DEPARTMENT OF HOMELAND SECURITY
SECOND STAGE REVIEW: THE ROLE OF THE
CHIEF MEDICAL OFFICER**

HEARING

BEFORE THE

**SUBCOMMITTEE ON MANAGEMENT,
INTEGRATION AND OVERSIGHT**

OF THE

**COMMITTEE ON HOMELAND SECURITY
HOUSE OF REPRESENTATIVES**

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**THE DEPARTMENT OF HOMELAND
SECURITY SECOND STAGE REVIEW:
THE ROLE OF THE CHIEF MEDICAL OFFICER**

Thursday, October 27, 2005

U.S. HOUSE OF REPRESENTATIVES,
COMMITTEE ON HOMELAND SECURITY,
SUBCOMMITTEE ON MANAGEMENT,
INTEGRATION, AND OVERSIGHT,
Washington, DC.

The Subcommittee met, pursuant to call, at 2:03 p.m., in Room 311, Cannon House Office Building, Hon. Mike Rogers [Chairman of the Subcommittee] presiding.

Present: Representatives Rogers, McCaul, Meek, and Thompson (ex officio).

Also Present: Representative Christensen

Mr. ROGERS. I would like to call the meeting of the Subcommittee on Management, Integration, and Oversight to order.

Before I do anything, I would like to ask unanimous consent that Dr. Christensen be allowed to sit on the dais and question the witnesses. Without objection.

We are holding this hearing today to examine the role of the new Chief Medical Officer in the Department of Homeland Security, and I would like to thank our witness for being here, taking time out of his full schedule to be with us, as well as the other witnesses we are going to have on the second panel.

Shortly after Department of Homeland Security Secretary Michael Chertoff assumed the office earlier this year, he launched a top-to-bottom review of the Department's policies, programs, and procedures. The review was referred to as the Second Stage Review, or 2SR. It was completed at the end of June. On July 13th, Secretary Chertoff sent his reorganization proposal to the Congress, as required by section 872 of the Homeland Security Act.

As part of the reorganization, Secretary Chertoff proposed a new position of Chief Medical Officer. In his letter of July 13th to Congress, Secretary Chertoff stated, quote, "The new Chief Medical Officer will be responsible for coordinating medical issues, including BioShield, throughout the Department, and working especially with officials at the Department of Health and Human Services and the Department of Agriculture to improve coordination of the Federal Government's medical preparedness efforts."

The following day, on July 14th, Secretary Chertoff announced the appointment of Dr. Jeffrey Runge to serve in this position. At that time the Department indicated, quote, "The new Chief Medical

Officer will provide the Federal Government with a much greater capacity to be prepared for, to respond to, and recover from catastrophic attack.” Also, as a part of the Second Stage Review, Secretary Chertoff proposed the creation of a new Preparedness Directorate, which will be headed by the Under Secretary for Preparedness. The office of Chief Medical Officer will be located in this Preparedness Directorate.

Congress provided \$2 million for the Office of Chief Medical Officer in the fiscal 2006 Department of Homeland Security Appropriations Act, which the President signed into law 9 days ago, on October 18th. As one can readily see, the Chief Medical Officer is a brand new position.

Therefore, we are pleased to have Dr. Runge here today in his first appearance before Congress in this role to share his vision with us. And from my perspective, there are three main issues that we would like to explore with Dr. Runge: first, a broad description of the role of Chief Medical Officer; second, the relationship between the Chief Medical Officer and the Department of Health and Human Services, the Centers for Disease Control and Prevention, the Department of Agriculture, and the Department of Defense, as well as State public health officials and local hospitals; and third, the timeline for fully staffing this office.

After September 11, 2001, and the anthrax attacks that immediately followed, the Congress and this Administration have made an unprecedented investment in building up the Federal, State, and local public health infrastructures to deal with potential public health emergencies to the tune of billions of dollars. It will be the job of the new Chief Medical Officer to work with his counterparts in the other Federal, State, and local public health agencies to ensure that this massive investment is achieving measurable success.

In addition, in my hometown of Anniston, Alabama, we have the Noble Training Center which is operated by the Department of Homeland Security. This Center is unique because it is the only hospital facility in the United States that is dedicated to training emergency managers and health care professionals to respond to natural disasters and acts of terrorism. Therefore, I am particularly interested to hear about the relationship between the Chief Medical Officer and the Noble Training Center. I am also interested in hearing what will be done to ensure the Center has the support it needs to provide the best training to medical professionals across the country.

On our second panel, we will hear from experts on what responsibilities the new Chief Medical Officer should undertake. We will also hear views on the role of the Department of Homeland Security in medical emergencies, and what steps the Department should take to help prepare the Nation for a public health emergency—whether it is the result of a bioterrorist attack or the naturally-occurring pandemic flu.

Once again, I want to thank the witness for joining us today and look forward to his testimony on this important and timely subject.

And I now recognize the Ranking Member, my friend and colleague from Florida, Mr. Meek, for any statement he may have.

Mr. MEEK. Thank you, Mr. Chairman. And I want to commend you on having the hearing I think it is very important as it relates to the country.

Dr. Runge, I want to thank you for coming before us here. I know you are very new in the job, but this is not your first time coming to the Hill, but under your new capacity, yes.

I think the Chairman has pretty much summed it up on what we need to know as a subcommittee, but I think that some of the issues that we are facing, to be able to truly understand your role as it relates to BioShield, as it relates to dealing with some of the other agencies like DHS. And I just wanted to tell you what folks in your profession say all the time, you know; this won't hurt a bit as it relates to us finding out what we need to know.

And the reason why this is important, as you know, many Members of Congress and folks throughout the medical emergency services community have been calling for the establishment of your office for some time now, and I was glad to hear that the Department saw fit, especially in the Second Stage Review, to find some of the findings that we have arrived at here in Congress of saying it is important.

At present, there are various administration policies and directives for biosurveillance and a few grant programs to help States and counties and local medical systems prepare for a response to an attack. The Department of Health and Human Services and the Center for Disease Control and DHS Science and Technology Directorate are the main players in this effort. Absent in this whole role is a central Federal official or leader who is responsible for making sure that all of the moving parts work together.

I will be interested in knowing whether you see yourself as filling that role; and, if so, how do you intend to accomplish the goals of making sure that everyone is working together within the Preparedness Directorate at DHS? Specifically, how do you see yourself commanding authority on biopreparedness issues in the Federal Government when you don't even have the line authority, like the head of DHS on the BioShield program? According to the Department of Homeland Security Policy Directive 10, DHS is the leading Federal agency when there is a massive casualty incident, like a BioShield—like a biological attack that requires parallel departments of Federal assets and other function areas like transportation or law enforcement. Do you need to have a seat at the table earlier than versus later? Like the DHS—like HHS's stated directive as it relates to directing an outbreak, how do you find yourself working with DHS? How do you find yourself working with the Center for Disease Control? Because I think this is very, very important.

To date, the Department has done a very good job in laying out what exactly you will be doing as a CMO. But as it relates to staff, direct line to the Secretary, those are the kinds of questions I think we need answered in this hearing. And it is not mainly a reflection upon you and your leadership; it is making sure that we can find ourselves in a situation that we know, A, who is in charge; B, that we are prepared because you have taken a command role in making sure that we are prepared, because we would hate to see you in a position like we have seen other DHS officials who the country

thought was in charge of overseeing the coordination, and we really don't have coordination.

Just as part of my opening statement, and this is like a question, but I want you thinking about this because I have read your statement—and I must say, Mr. Chairman, we have to really work on getting the statements of our witnesses. I received it 2 hours prior to this hearing, and I think it is not—it won't serve you good for us to be prepared of what you have to say here if we get them 2 hours in advance of the hearing when we knew the hearing was scheduled for some time. But you really need to address this issue of how do you think that you will be able to carry out your goals and objectives and making sure that departments outside of DHS understand that you are in charge as Chief Medical Officer of overseeing emergency—overseeing when we have a bioattack or overseeing the response and also coordination of EMS personnel. I think that is very important, and I would appreciate if you can try to answer that in your opening statement. I have read your opening statement as best I could, but those are questions that really need to be answered. And it is good to be able to answer them now versus in a time of an emergency.

Thank you, Mr. Chairman.

Mr. ROGERS. Thank you.

Dr. Christensen, did you want to make an opening statement?

Mrs. CHRISTENSEN. No.

PREPARED STATEMENT OF THE HONORABLE SHEILA JACKSON-LEE

Chairman Rogers and Ranking Member Meek, today's hearing affords this body the important opportunity to lay the foundation of ascertaining the gaps in responsibility that exist outside the scope of the authority to be assumed by the new Chief Medical Officer, to be established pursuant to Secretary Chertoff's Second Stage Review (2SR). According to 2SR, "The new Chief Medical Officer will provide the federal government with a much greater capacity to be prepared for, respond and recover from a catastrophic attack."

At the University of Houston, the "Tools for Ultraspecific Probe/Primer Design" project was awarded a \$500,000 grant for purpose of developing better methods of diagnosing bacteria or viruses that could be used in a bioterrorism attack.¹ These dollars came from an appropriation through the Homeland Security Advanced Research Projects Agency account. I would query the new Chief Medical Officer whether he would establish an entity or a body within your office to vet and assess this kind of research data for national use. It is critically important for this body to understand how this and other similar projects will be monitored and put to maximum use.

Our primary witness today, Dr. Runge, was cited in the Associated Press on September 24, 2005 as stating that he would "like to improve the government's medical response to disasters by creating a network of trained volunteers," and that he would "take advantage of volunteers and make it easy for them to volunteer their service, lowering barriers with liability issues and logistical issues to that kind of things could take place without further burden on the taxpayers."

Given my past ardent advocating of the use of local galvanization in the effort to keep our homeland safe, I will encourage a response to the question of whether he recommends utilizing the current volunteer groups such as the Citizen Corps in actuating this endeavor. In crafting an intelligent and efficient response to the threat of biological attack, it is critical that the people—the "second responders," play a significant role.

I hope that the new CMO and Secretary Chertoff will work closely with Members of this Committee to craft legislation to further define and delineate the role of this new post. Thank you, Messrs. Chairman and Ranking Member, for your effort and leadership in this matter. I yield back.

¹Matt Cooper, "U. Houston given \$500K grant for bioterror research," THE DAILY COUGAR, June 2, 2005.

Mr. ROGERS. Okay. I would like to call up Dr. Runge, and I would remind all of our witnesses on this panel and then in the second panel, that your full statement will be submitted for the record, so if you don't want to deliver the whole thing, try to keep it to 5 minutes and we will get to the questions and hopefully have some good interaction. But now I would like to call up Dr. Runge, the Chief Medical Officer from the Department of Homeland Security, for any statement he may have.

STATEMENT OF JEFFREY W. RUNGE, M.D., CHIEF MEDICAL OFFICER, DEPARTMENT OF HOMELAND SECURITY

Dr. RUNGE. Thank you, Chairman Rogers, Ranking Member Meek, Congressman Christensen, thank you very much for the chance to be with you this afternoon. I will just hit the highlights of my written statement, and hopefully I can address the Ranking Member's concerns; and if we haven't, we can do that in the question and answer time.

Secretary Chertoff did create the position of Chief Medical Officer in mid-July as part of the Second Stage Review process. Prior to that, DHS had no centralized medical structure to coordinate medical preparedness activities inside DHS or to be a coordinator with other departments of the administration. I joined DHS the day after Labor Day, last month. I am honored that Secretary Chertoff has picked me to be the first CMO for the Department.

As the Chief Medical Officer, I serve as the Secretary's principal adviser on medical issues, and the goal is to provide the Secretary with the best possible advice on medical issues to help ensure that he makes the best policy decisions. But this job entails full engagement with other Federal agencies, with State and local authorities, associations of medical professionals, hospitals, and a lot of other stakeholders that also deal with the medical consequences of natural disasters or terrorist attack. In fact, it is our Nation's local assets, first responders, emergency departments, trauma centers and local practitioners that really represent the front line for the health and security of our Nation in the event of a catastrophic event.

Secretary Chertoff has charged our office with filling the gaps in the Department's medical readiness, and so we are actively working to develop a strategic plan to do so. Also, under Second Stage Review, the DHS medical office is located in that Preparedness Directorate, as you mentioned earlier, and the CMO therefore reports to the new Under Secretary for Preparedness. But I also have a direct reporting relationship with the Secretary and the Deputy Secretary to provide them that direct and unfiltered medical advice and consultation.

Central to this mission is to support the Secretary and the Department's incident management needs. So I have the obligation to provide sound medical advice and policy counsel to help define risk and then mitigate risk.

My team will not replicate the deep knowledge base and the operational role of other Federal departments, but I will help the Secretary and his team have ready access to timely and complete medical data to help drive those core incident management decisions that he will make.

And under the Chief Medical Officer, we anticipate having a Deputy Chief Medical Officer with an appropriate doctoral degree in medicine or veterinary medicine, and expertise at the State and local level in emergency management, public health and other skills. Reporting to the CMO and the deputy would be some associate chief medical officers for science and policy, medical preparedness, operations and response, and mission support.

With respect to science and policy, we need to achieve a full integration of our available research and technology and our intelligence to formulate policies that will then drive our strategic plan and our actions. I intend for this office to be a data-driven, science-based organization which will provide the doctrine from which we coordinate our activities with HHS and Agriculture and other stakeholders. This plan will determine our success, and it would also drive future budget requests which you also alluded to earlier.

We do have strong interdepartmental alliances with the DOD, with HHS, and the intelligence community. Our Science and Policy Office will lay the foundation for those activities of our other offices to carry out Secretary Chertoff's vision for threat-based programs and countermeasures. Likewise, Preparedness will be policy driven; they will create initiatives to make sure that the Nation and its critical infrastructure are all medically prepared for catastrophic events.

Now, one of the great things about Second Stage Review is that it has given us access to all the other important elements of preparedness in this directorate. And in fact, Secretary Jackson calls this the Preparedness Board of Directors: The infrastructure protection and the State and local grants, the U.S. Fire Administration and so forth. And we really believe that we can leverage resources and apply programs of planning across that entire Preparedness Board of Directors.

Now, we have got many customers and stakeholders, and I intend to make sure that our partners understand that they have a vital role to play in national medical preparedness and a voice within DHS, and that is me. Our medical office will work very closely with State and local governments to help support that medical preparedness.

My time is running short, Mr. Chairman, I can probably answer much of this in the Q and A. We do believe that we have a role in operations and response to make sure that assets are in place to support the National Response Plan, including ESF-8, which is HHS's responsibility. Our goal is to ensure that our assets are aligned to support ESF-8 and the National Response Plan, the Interagency Incident Management Group, and the command centers both at HHS and at Homeland Security.

And just real quickly, the fourth area is mission support. I think I shared with you and your office that I think that one of our most important responsibilities is to care for our most valuable assets, and that is our workforce. We believe that our Nation will only be secure if those entrusted with its security are in fact cared for. And right now, every agency and directorate do not have equal access to workforce protection, I want to make sure that protocols and resources are in place to do so.

So thank you, Mr. Chairman. I can't emphasize enough how much I appreciate being here. And I want to remind everybody this is a brand new vision, we are in our formulative stages. Thank you. [The statement of Dr. Runge follows:]

PREPARED STATEMENT OF DR. JEFFREY W. RUNGE

Chairman Rogers, Ranking Member Meek, and Members of the Subcommittee. Thank you for the opportunity to be here with you this afternoon. I appreciate the opportunity to discuss the position of Chief Medical Officer (CMO) at the Department of Homeland Security (DHS or the Department) and the responsibilities of this new office.

Secretary Chertoff created the position of CMO in mid-July as part of the Second Stage Review process that he initiated at DHS. Prior to the Secretary's Second Stage Review, DHS had no centralized medical structure to coordinate medical preparedness activities inside DHS or with other Departments in the Administration. I joined DHS last month, and I am honored that Secretary Chertoff selected me to serve as the first CMO for the Department.

As the CMO, I serve as the principal advisor to the Secretary for medical issues within the Department. My goal is to provide the Secretary with the best possible advice on medical issues to help ensure that the best policy decisions are made. The DHS Medical Office is located within the new Preparedness Directorate, but my responsibility for medical issues stretches across the entire Department. I am also responsible for representing DHS when it comes to coordinating medical issues with other Departments in the executive branch and the Homeland Security Council.

As we have all seen in the aftermath of catastrophic events—whether natural or as a result of a terrorist incident—there will be significant medical issues for DHS that arise and must be addressed. Secretary Chertoff believes that a comprehensive approach to preparedness must include coordinated and highly skilled medical support. This preparation includes full engagement with other Federal agencies, state and local authorities, associations of medical professionals, hospitals, and other stakeholders that also deal with the medical consequences of natural disasters or terrorist attacks. It is our Nation's local assets—first-responders, emergency departments, and trauma centers and local practitioners—that represent the front lines for the health and security of our Nation.

Since I arrived last month, I have been focusing on preparation for the likelihood of an avian influenza pandemic. This is a public health and medical issue that many of us, both in and out of government, believe could have devastating effects in the United States and around the world. In this regard, I have been working very closely with my colleagues at the Department of Health and Human Services (HHS), the U.S. Department of Agriculture, and the Homeland Security Council to plan for the government's response to contain this disease and protect our Nation's critical infrastructure.

Secretary Chertoff has charged our Office with filling gaps in the Department's medical readiness, and we are actively working to develop a strategic plan for doing so. Under the Second Stage Review, the DHS Medical Office is located in the Preparedness Directorate, and the CMO reports to the Undersecretary for Preparedness. There is also a direct reporting relationship between the Chief Medical Officer and the Secretary and Deputy Secretary to provide direct and unfiltered medical advice and consultation. Central to our mission is to support the Secretary's and the Department's incident management needs. I have the obligation to provide sound medical advice and policy counsel to help define and mitigate risk. My team will not replicate the deep knowledge base and operational role of other Federal departments, but I will help the Secretary and his team access timely and complete medical data to help drive core incident management decisions.

To accomplish our mission, we will need talented, highly skilled leaders. Under the Chief Medical Officer, we anticipate a Deputy Chief Medical Officer with the appropriate doctoral degree in medicine and expertise at the state and local level in emergency management, public health, and other relevant skills. Reporting to the CMO and the Deputy CMO will be Associate Chief Medical Officers for science and policy, medical preparedness, operations and response, and mission support. Let me address each of these needs separately.

Rather than responding crisis-to-crisis, the DHS Medical Office needs to be a data-driven, science-based organization that brings cutting-edge science, technology, and intelligence to bear on the Department's policy-making. We anticipate that this function will be overseen by the Associate Chief Medical Officer for Science and Policy. Sound science-based policy will provide the doctrine from which we coordinate

our activities with other agencies such as HHS, The Department of Agriculture and the Department of Defense (DoD), interact with other stakeholders, and bring together resources within the Department. How we set our strategic plan, goals, and objectives will determine our success in carrying out our mission, and will also drive future budget requests.

For the last four years, I have run the National Highway Traffic Safety Administration as its Administrator, and I believe the Nation has reaped the benefits of having its highway safety programs completely data driven, its budget directed by programs that have proven to be effective—even to the exclusion of good ideas that have no basis in the data. I intend to run the DHS Medical Office based on the best information from the service elements of DHS, including our Science and Technology and Information Analysis Directorates. We also have strong interdepartmental alliances with the DOD, HHS and the intelligence community. It is vital that our preparedness, operations and response, and mission support functions carry out Secretary Chertoff's vision for threat-based programs and countermeasures, which can only be done through the integration of these various knowledge bases.

Our Associate Chief Medical Officer for Preparedness will be responsible for policy driven initiatives to ensure that the Nation and its critical infrastructures are medically prepared for catastrophic events, whether man-made or natural in origin. The Second Stage Review process has given us access to all the important elements of preparedness necessary to carry out this function. Full integration with the other offices in the Preparedness—Infrastructure Protection, the training assets of the U.S. Fire Administration, the relationships of the Office of State and Local Preparedness, and the financial assets of the Metropolitan Medical Response System—will allow our “Preparedness Board of Directors” to leverage resources and strategically apply programs and planning to meet our medical readiness needs. The Associate Chief Medical Officer for Preparedness will also be charged with examining *medically-related* grants and contracts from DHS to state and local governments and the private sector to ensure these resources are used strategically. Some of these grants and contracts are currently outside of the Preparedness Directorate, but the cross-cutting nature of my position dictates that this intradepartmental coordination takes place.

For the last month I have been meeting with representatives of many organizations in our Nation that are key players in our medical preparedness. I have been asking for “to do lists” from organizations that will be our key partners for us in the future, including the Association of State Health Directors, the American College of Emergency Physicians, the American Hospital Association, the American Ambulance Association, and the Federation of State Licensing Boards. Our Department has many customers and stakeholders, and I intend to make sure that our partners understand that they have a vital role to play in national medical preparedness. The Medical Office will work very closely with state and local governments to help support their medical preparedness.

The Associate Chief Medical Officer for Operations and Response will help ensure that assets are in place to support medical response under the National Response Plan. This part of our operation requires close collaboration with our Federal partners, most notably HHS. Our goal is to ensure that our assets are aligned to support Emergency Support Function 8 under the National Response Plan, the Interagency Incident Management Group, and the command centers of both Homeland Security and HHS. This office will also support the DHS Continuity of Operations (COOP) function when medical advice and consultation are needed. We are now receiving comments from our stakeholders about the best way to approach this operations-and-response function, and our goal is to make it a fully coordinated effort. We believe that the Secretary needs a medical response element under his control to ensure a medical support function for the Nation. It is clear that state and local medical resources make up the “front lines” of national medical response, and they must be fully integrated into preparedness planning.

The fourth element of our mission in the Medical Office is to support the mission of the Department in terms of its most valuable assets—its workforce. As the various operating elements of DHS were put together two years ago, they brought with them existing legacy workforce protection and occupational health programs. Some operating elements, such as the Coast Guard, have very sophisticated programs with a long legacy of workforce safety and security programs. Others have none at all or rely on contracted entities to provide some preventive health care. I believe that our Nation will only be secure if those who are entrusted with its security are likewise cared for. We will recruit an Associate Chief Medical Officer for Mission Support to ensure that every agency and directorate in the Department has appropriate workforce protection, protocols, and resources in place whether they are pro-

tecting our Nation's borders, ensuring that our airlines are secure, or engaged in critical planning activities. We also intend, through this office, to build a network of all DHS medical assets to ensure that they are likewise supported with training and education, and that we have access to the various specialized skills available from the medical workforce within DHS.

In conclusion, Mr. Chairman, although we have a strong vision of what we would like to accomplish through our Office, we are in the very early stages of trying to realize that vision. We look forward to working with the Committee to incorporate your suggestions and advice into how we can better serve our Nation. I am confident that with my experience as a clinician, researcher, and as a Federal manager, my team and I can bring this vision into reality if we have the necessary support to do so. Our support from senior management in the Department has been excellent, and I look forward to working with you closely to ensure similar support from our leaders in the Congress.

Thank you, again, for this opportunity to introduce my office to you and your colleagues.

Mr. ROGERS. Thank you. I would like to ask some questions now.

I noted in my opening statement that you currently are starting off with a \$2 million budget. And, as I understand, you currently—including yourself—have 3 people in your office, and I think you are budgeted to have 10 or 11. My question is: Do you expect, since this is so new, do you expect when you are fashioning the next fiscal year's budget, to play an active role in formulating what that budget should be, or do you expect to be total what it would be?

Dr. RUNGE. Well, we are already involved in 2007 budget planning. Unfortunately, in the 2006 budget planning time, I was planning the budget for the National Highway Traffic Safety Administration. I did a really good job of that.

Mr. ROGERS. Which is not helping you now.

Dr. RUNGE. That is correct. So we are grateful for what we have got and I think it is a good building point.

Mr. ROGERS. What is the exact number of people that you are budgeted for now under your \$2 million?

Dr. RUNGE. Well, the FTE numbers are cited at 10. The executive-level slots have not yet been allocated, but I think the bottom line is that we can't spend more than what we have got this year. And I do think we will be able to leverage some resources across the other offices in the Preparedness Directorate, and I have been assured by the acting Under Secretary he is going to do everything he can to get that done.

Mr. ROGERS. Given that statement, do you think your staffing allocation for this year is going to be sufficient?

Dr. RUNGE. We will be able to accomplish a lot. We will not achieve the vision completely for the office until we have an opportunity to present justifications for these positions, what the mission requirements are, and present them to the Secretary in the budgeting process.

Mr. ROGERS. Could you share with the Committee, who fills the current three positions and what would you expect the remainder of positions to be filled with, what titles?

Dr. RUNGE. Well, I have brought over my office manager with me to do logistics. That is sort of an essential function. And my chief of staff joins us as the guy who is trying to get us staff and working on our budget. I did bring one technical person, Laura McClure, who is behind me. I was able to steal her away from DOT, where she served the Secretary as his security adviser, and has lots of tentacles out in the security parts of the Federal Government.

Mr. ROGERS. What about the remainder of positions that you have budgeted?

Dr. RUNGE. In my written statement I talked about four main buckets of activity. Each of those I would anticipate being headed by an Associate Chief Medical Officer, although I have not yet gotten sign-off for the executive-level slots necessary to do that.

Mr. ROGERS. Do you plan to have a veterinarian on your staff?

Dr. RUNGE. We have two veterinarians that we work with very closely. You know, one of the beauties of DHS is that resources abound, and we just have to be smart about how we access those. I have got two of the finest veterinarians who have been working with us on the Avian Flu Task Force, who are also readily available for consultation for just about anything that we ask. We have not ruled out or ruled in having a vet actually as part of the CMO.

Mr. ROGERS. Also, as I represented in my opening statement, the Noble facility is in my hometown, and it is near and dear to my heart, and is the only hospital in the country that serves that mission. Can you tell us a little bit about your relationship with that facility?

Dr. RUNGE. Well, as you know, Mr. Chairman, it is under the auspices of the U.S. Fire Administrator, and one of the first things—actually, before I came to DHS I met with Dave Paulison before he—obviously before acting FEMA administrator—and we talked about that and how to better utilize Noble.

I also did some research since I met with you and looked at the inventory of activities going on down there. They are quite busy, but I think we can—my interest is in making sure that everybody who touches a patient out there, whether they are a paramedic, an EMT, an emergency position, a trauma surgeon, an infectious disease doc, is adequately prepared. And I think that we can use Noble in a bit smarter way to help accomplish that. And I intend to work with the USFA and the U.S. preparedness effort to coordinate all of our training efforts to make sure they are strategically applied.

Mr. ROGERS. You mentioned it is under Fire Services; is that going to be a problem for you?

Dr. RUNGE. I don't think so.

Mr. ROGERS. Or is it positioned where it should be? Do you anticipate making some recommendations that may change that?

Dr. RUNGE. I don't believe so. If it is not broken, don't fix it is one of my mottos. And I do believe that with the collegiality that we have developed across this Preparedness Board, these six people, the Office of Domestic Preparedness is now State and local grants and training, and it is sort of all on the same level and it is all in the same basket. So I understand already that the Center for Domestic Preparedness and Noble are sharing some administrative assets, and those are the kind of efficiencies we need to look for.

Mr. ROGERS. Well, thank you, I see my time is up. I would now like to recognize the Ranking Member of the Subcommittee for any questions he may have.

Mr. MEEK. Dr. Runge, I know that you are new to the Department, but you are aware of the Chief Information Officer that is also there at the Department. We have been having quite—a very

difficult time with the Chief Information Officer working with the 22 legacy agencies within the Department. It is all thank you and please. You have a great title, Chief Medical Officer, but the question is, chief of what? And who is going to listen?

You know, when it comes down to the whole issue of the incident of national significance, are you the person that says, Mr. Secretary, you need to designate that; or is that Department of—Secretary of HHS? That is the reason why I am asking these questions, because either we need to legislate that authority of who is in charge, because the last thing that we want to find ourselves is in a situation where we have Homeland Security saying one thing—and it has happened before—Department of Justice; it was an event once before when Justice Department said something, Homeland Security said something, first responders were confused and States. You are going to be working with States, HHS is going to be working with states, Center for Disease Control are going to be working with States. So how are you—what do you envision in your capacity as Chief Medical Officer in the Department of Homeland Security that, you know, in one place you read the overall authority on this, what kind of role, how do you see yourself playing a role there as Chief Medical Officer? And do you feel that your office needs more authority to be able to at least put forth that recommendation to the Secretary and the Secretary can make that decision?

Dr. RUNGE. Congressman, I really appreciate that insight. And as a former administrator of an agency with 700 people instead of 3, I have a great appreciation for organizational charts. And I reorganized NITSA partially because there were too many direct reports.

I am very sympathetic. If you look at the DHS work chart, I am very sympathetic with the conundrum of needing direct access to the top-level staff and with the inability to direct and oversee the activities of more than 20 people at one time.

It doesn't hurt my feelings at all to be in the Preparedness Directorate. And already there have been a couple of occasions in which Secretary Chertoff has told me you are the guy on this, and I need you to address this issue.

And let me just say one other thing, too. With respect to roles—and I want to make sure this is very, very clear—there is no ambiguity with me about who does what. I think that is very well laid out in the National Response Plan. We will be there to support and help the various agencies that are responsible for taking the lead in the various emergency support functions; for instance, HHS with ESF-8, and Agriculture with their emergency support function, and Transportation and so forth.

In the event of an incident of national significance, the DHS Secretary has overall authority for making sure those assets are coordinated. And I believe that the genesis of my—

Mr. MEEK. I am sorry, Doctor, because my time is—I am sorry, I know that you are trying to—and that is the heart of it; how will be it coordinated? I mean, you are the person, quote unquote, that will either be talking to the Under Secretary or directly to the Secretary about this, and how do we coordinate within the agency of Homeland Security and the Chief Information Officer. I am just

taking that position, just as an example, they get an F year after year because they can't get the agencies within the agency—departments within the agency to respond to the Chief Information Officer. And so I am trying to get down to the bottom of it because really that, if we are going to do something, let's do it for real, especially as it relates to your position, to be able to give either you or someone authority who is going to be the person that is in charge of that. We have conflicting views here.

And if I get an opportunity later on I will, you know, as it relates to the National Preparedness Plan versus some statutory language that is out there, of who is going to coordinate that. And that is pretty much the question that it comes down to. If you are going to be talking to the Secretary, you have no authority over these other departments. And also, you are parallel on the third tier of the Department chart as it relates to the Department of Homeland Security. How is your office going to command that with 10 employees and a limited budget?

Dr. RUNGE. That is a very pregnant question, and I hope that over time I can satisfy you, Congressman, with being able to do those support functions with diplomacy. I spent a lot of time in the last month making a lot of house calls. I have been with the CDC. I met with Dr. Besser, who is the Bioterrorism and Emergency Response Director; with Dr. Gerberding; with Stu Simonson and his staff; Jerry Parker at HHS. And, in fact, if you look at my e-mails, there are a lot of them coming from HHS in collaboration with what we are trying to do.

Mr. MEEK. Doctor, let me say this. I am well over 10 seconds over my time. I just want to tell you, it is not to satisfy me, it is to make sure that we are doing what we are supposed to do. And it is not a criticism of you either. It is, legislatively, we are going to respond to some of this and we want to respond to it in an appropriate way, especially with your consultation, and also realize that we don't want folks pointing in two different directions when it comes down to lights, cameras, action, because one day very soon it may be the case. And we want to know that you have what you need to carry out your duties and the Department of Homeland Security has what it needs.

Dr. RUNGE. Thanks. I look forward to working with you, Congressman. I appreciate it.

Mr. ROGERS. Thank you. The Chair now recognizes the gentleman from Texas, Mr. McCaul, for any questions he may have.

Mr. MCCAUL. Thank you, Mr. Chairman. And Dr. Runge, thank you for being here today.

As you know, DHS has been tasked with the responsibility to do material threat assessments and determinations. It is the 1-year anniversary of BioShield, and we have issued, I believe, 4 of the 60 of these hot agents. And I wanted to know—and I know you are relatively new to the job—have you thought about how you want to try to speed up that process? That is my first question.

And my second one is with respect to the Avian Flu Task Force. When we go back home, that is an issue of great concern to our constituents. Now that it has jumped from bird to the human species, I believe in Europe and in Indonesia, it is of great concern to us. How are we going to handle that situation? And God forbid it

breaks out in the United States; what is our level of preparedness and strategy to deal with that type of situation?

Dr. RUNGE. Thank you, Mr. McCaul. Let me just address the first part of this first.

These material threat assessments and determination, there is a very fixed protocol for how that is done. The material threat assessment is managed by the Science and Technology Directorate, using intelligence functions as well as the best possible science. I believe that we have five, now, material threat determinations done, and I have been talking to them about the process. I do not expect to insert myself into the material threat assessments. That is very much of a scientific and intelligence function; however, when it comes to a determination, we will be there in the consultative process, and I will advise the Secretary accordingly.

With respect to the speed, I believe that a report is due in January for another sort of omnibus bunch of the assessments. I was told that by the Director of R&D a couple days ago, and we will be following up on that with you.

Mr. MCCAUL. Would it be helpful if we provided some limited form of immunity from lawsuits? I know a lot of the major pharmaceutical companies are not involved because they are concerned about lawsuits.

Dr. RUNGE. I really can't speak to that, Congressman. We would be happy to reply back to you in writing. I can tell you as a physician I love the idea in general. But with respect to this particular thing, I can't answer that question, sir.

Mr. MCCAUL. As to the Avian Flu Task Force.

Dr. RUNGE. When I walked in the door, I was given responsibility to come up with a DHS plan. The first call was to HHS because they have the lead in avian flu, wanting to make sure that whatever planning function we did would dovetail with the HHS plan so that they could give a national plan for avian flu. That work is ongoing.

We also completed a memorandum of understanding with HHS with regarding border protection for infectious diseases—it would specifically apply in this case—which took a little bit of doing. That involves quarantine and data sharing, passenger information. It is important to know where someone is sitting on a plane if someone actually shows to be positive. So work is going on. This has gotten attention throughout the executive branch at the very highest levels, and we are working diligently to make sure that our plans are in place.

Mr. MCCAUL. I know we have antiviral medication to treat the symptoms, but where are we with the vaccine for avian flu?

Dr. RUNGE. HHS, of course, has the lead for vaccines. You know, the vaccine makers all came and met with the President a few weeks ago, and I think the results of that meeting have been reported in the press. There is no question that we as a country need to ramp up our vaccine research, our vaccine production. And frankly, Americans need to take flu vaccines. It is very hard to generate a profit if you are a company, if you can't sell your product. So one of the public health messages that I think should be incumbent upon all physicians is to make sure that everybody who is supposed to get a flu shot should get a flu shot.

Mr. MCCAUL. It is very timely; I just took mine today, actually. Do we have a vaccine for the avian flu is, I guess, is my—

Dr. RUNGE. That is under study. And again, HHS is all over that. Secretary Leavitt personally has become engaged with the vaccine makers themselves and Deputy Secretary Azar. I am confident that they are on the case.

Mr. MCCAUL. Okay. Thank you, Mr. Chairman.

Mr. ROGERS. Thank you. And the Chair now is proud to welcome and recognize the Ranking Member of the full committee, my friend and colleague from Mississippi, Mr. Thompson, for any questions he may have.

Mr. THOMPSON. Thank you very much, Mr. Chairman. Welcome Dr. Runge. We are happy to see you, glad you are on board.

I want to take off on some of the other comments that I have heard. You are looking to the Department to have 10 employees—

Dr. RUNGE. Yes, sir, that is the current configuration.

Mr. THOMPSON. Now your testimony talks about hiring, I would assume, four senior people that you have presented to us today. And, I would assume, somewhere around 150,000 annual salary or something like that for them?

Dr. RUNGE. That would be correct.

Mr. THOMPSON. And your budget is \$2 million.

Dr. RUNGE. Your arithmetic is bearing right down on it, sir.

Mr. THOMPSON. Do you think you can do your job, hiring that many people with just \$2 million?

Dr. RUNGE. Well, as I told the Chairman, I believe before you walked in, sir, I was not here during the 2006 budget planning process, and this was the number that I was given when I came in. And we will have a transition team in place with that amount of money. Meanwhile, we are diligently working on the 2007 budget planning. We have been given a little bit of a grace period to provide some numbers and some rationale. And we will be talking with the powers that be over there, including the Secretary, on making sure that we are staffed up to an appropriate level.

Mr. THOMPSON. So what is your staffing expectations if you had your druthers?

Dr. RUNGE. Well, I haven't got a number for you right now. I would be happy to come back and we can sit down and go through the functions. Part of the problem is that having just received sign-off on the organizational plan, we really need to develop personnel requirements for the jobs necessary, and we have not yet done that.

Mr. THOMPSON. Do you plan to use any contract employees?

Dr. RUNGE. Yes, sir, we do.

Mr. THOMPSON. Why would you want to use contract employees rather than full-time people?

Dr. RUNGE. Well, for one reason, we can get them quicker; they are a little bit more nimble, mobile. We can select them for jobs that require a kind of a quick hit. And the other process actually is going to take some more time, and time is my enemy right now.

Mr. THOMPSON. One of the things some of us are concerned about is the inordinate price tag that we pay for contract employees. Do you anticipate paying more for contract employees than you would for full-time employees?

Dr. RUNGE. I would think not. Our objective, the one contract we have got pending right now for our next person to bring in is right in line with a senior-level salary.

Mr. THOMPSON. That is a full-time contract person?

Dr. RUNGE. Yes, sir.

Mr. THOMPSON. For 12 months?

Dr. RUNGE. Yes, sir.

Mr. THOMPSON. What kind of conflict of interest form, or anything that you would have a contract employee or a full-time employee sign if they come work with your agency?

Dr. RUNGE. I hadn't really given that any thought. Can you elaborate more on this issue?

Mr. THOMPSON. Well, I would assume that if you are going out hiring contract people, they may or may not be in a position to make a decision that would be favorable to the company they work for. And if that is the case—

Dr. RUNGE. I see. Okay, I understand. The individual that we bring on next is through an IPA with a university. And, absolutely, they would be recused from any sort of financial gain going back to that university.

Mr. THOMPSON. Can you provide the committee with whatever document those individuals would be required to sign?

Dr. RUNGE. I would be happy to do that.

Mr. THOMPSON. So that we could know? The other thing I would like is for you to provide the committee, if in fact the contract employees cost more than a salaried employee, that information.

Dr. RUNGE. We will be happy to give you the full rundown as soon as we have it.

Mr. THOMPSON. Thank you. Mr. Chairman, I have one other question.

Dr. Runge, you know, just before I guess you came, we received notice that some information was for official use only and that you couldn't testify to it. But I guess my problem is, if I can get most of what you say off the Internet, off the AP wires, off MSNBC, why would the Department prevent this committee—prevent you from giving it to us?

Dr. RUNGE. Congressman Thompson, I don't set the classification of documents. As they say, I just work there. And I take my classification literally. And obviously—I think the document you are referring to is Dr. Lowell's report to Secretary Ridge, which has been in the press. And I think the contents of that are certainly for official use only, but the issues are fair game.

Mr. THOMPSON. But you know, it is the worst-kept secret in town—

Dr. RUNGE. There are a lot worse ones than that, Congressman Thompson.

Mr. THOMPSON. Well, it might be worse, but my question is, I am concerned that the Department would label something "for official use only" when we can get it off the Internet or off the wire service already. And it appears to be a practice of the Department to keep certain information hostage. And if it was produced at public expense, I am convinced the public has a right to know.

Dr. RUNGE. I will be happy to convey that sentiment to my bosses. Thanks.

Mr. THOMPSON. Thank you.

Mr. ROGERS. I thank the gentleman.

The Chair now recognizes my favorite physician on the Homeland Security Committee, Dr. Christensen, for any questions you have.

Mrs. CHRISTENSEN. It has nothing to do with the fact that I am the only one, but thank you, Mr. Chairman. And I would like to welcome you.

We had some concerns about when we heard there was going to be a Chief Medical Officer for the Department, but you come with good credentials. We still have many concerns of how the job is going to really work and what exactly your role will be.

But I have a specific question related to Katrina, because you did come in after Katrina, but now in recovery. And I just came from a meeting of AIDS advocates, People Living with AIDS, and organizations, some of whom are in New Orleans, and some from Mississippi, Texas, et cetera. And one of the concerns that they raise is one that I have as well: What is being done to restore the services? There are a lot of physicians and other health providers who are working in New Orleans and some of the other impacted areas in the gulf, and at least I am not hearing that anything is being done to restore their practices and help them to provide services to the people who are remaining there, some of whom who are in desperate need.

Dr. RUNGE. I can probably best respond to that by recounting a vignette. I was actually asked by Deputy Secretary Azar to come over to HHS my first or second day on the job, to sit around a table with a group of people about 6 o'clock at night to talk about medical issues in Mississippi and Louisiana. I was very, very impressed with the level of strategy and response that the Health and Human Services folks were putting into this challenge. And that was a question that came up around the table: What are we going to do now to try to ensure that physicians will come back after the initial exodus is over? And number two, is it an opportunity to improve a community health system that really wasn't working very well in many parts of that region?

I know it is on HHS's radar screen. We have, through our office in helping them facilitate, we have gotten FEMA funds for some of those purposes to which you refer. And we would be happy to give you an inventory of those. But that really does fall under HHS' bailiwick.

Mrs. CHRISTENSEN. See, we are still not clear. Hopefully as we go through this, it will be clearer where you are.

You mentioned that you have been spending some time on avian flu, and you don't seem to have much of a direct responsibility for BioShield, but yet we are now looking at BioShield, too. And I wanted to ask you a question about another bill. I think we still call it Safe Cures bill, which focuses more on shortening the time from the identification of a bug to a cure or a vaccine. And we constantly hear about the length of time it will take when it mutates and we know that we have to develop a specific countermeasure.

Don't you think that we ought to be spending more time on research that shortens the time to get from identification to cure or vaccine?

Dr. RUNGE. I doubt that there is any disagreement about that, Dr. Christensen. I think that that is a sentiment that is shared everywhere. There is, I think they call it the “valley of death” between initial drug or countermeasure development and actual deployment, at which time it takes off and has commercial viability. And I do know that there is some energy over here, particularly in the Senate, about stimulating—providing a catalyst between that initial point and the time that it zips through until the time it is commercially viable.

We have had an opportunity to review a couple of bills, and I am not sure they have been introduced, and I will be happy to check that and make sure that you have access to that information.

Mrs. CHRISTENSEN. You said that you have been meeting with representatives of organizations that are key players in medical preparedness. Are you finding that the health providers, doctors, public health people, emergency medical services, are fully integrated into the first responder systems?

Dr. RUNGE. That is a great question. I asked each of those organizations to give me a “to do” list, and some of them have come back right away, and I can tell you that answer varies from organization to organization.

Mrs. CHRISTENSEN. Can you do something about that; is that your role?

Dr. RUNGE. I believe it is. And certainly we will coordinate with HHS as much as we possibly can to make sure—my interest in getting out there and making all these house calls is to make sure they know they have a voice in DHS, and if something is happening that they don’t like, they have got a place to call and we can circle back and try to fix the problem.

Mrs. CHRISTENSEN. But do you set standards and certain criteria that have to be met—

Dr. RUNGE. I do think that is our role at DHS. And our coordinating role for all the support functions is to make sure we have a set of system requirements that will actually get the job done. You know, with an office of 3 or 10, obviously I can’t operationalize that; but I think through the power of the Secretary of DHS, we will in fact get those requirements accomplished.

Mrs. CHRISTENSEN. Thank you, Mr. Chairman.

Mr. ROGERS. Thank you. I would like to ask a couple more questions, and it has to do with BioShield. You heard in my opening statement, I made reference to Secretary Chertoff’s announcement of the creation of the Chief Medical Officer. And in that letter he said the chief medical officer would be, quote, responsible for coordinating medical issues, including BioShield, throughout the Department. Could you tell us about this relationship with BioShield, what your role will be?

Dr. RUNGE. The Secretary and I have not discussed that. In trying to get smart on BioShield, I have studied both the material threat—first of all, the CDC’s list and working its way down through the material threat assessments and determinations, trying my best to understand the process and all the inputs. I really am still gearing up my knowledge on this.

The expenditure of funds is, I think, really sort of where the rubber hits the road. I believe \$6 billion was initially appropriated

over 10 years for the acquisition of countermeasures, and much of that has been spent, over half of it has been spent; and I think that the next round of purchases will put another dent in it. And I think the Secretary is very interested in my—

Mr. ROGERS. By the way, when do you expect that next round of expenditures?

Dr. RUNGE. Let me withhold an answer on that. I know that there is an agreement that is in process right now.

Mr. ROGERS. But if you would follow up as soon as you can let us know and get that to us, I would appreciate it.

Dr. RUNGE. There is some fiduciary responsibility here as well as a prioritization that has to take place. And I think that my role is basically one of overseeing and consulting. I have no role in intelligence, and I certainly have not been in a lab to look at the viability of countermeasures. I have talked with the folks who do make those assessments and determinations, and I think that the Secretary wants somebody just to put the information all together for him in a package that is all rolled up, and that he has confidence that when he signs that memo that this in fact is a material threat, and sends it to Secretary Leavitt that he has confidence that it is.

Mr. ROGERS. Can you tell us how you can ensure in your capacity, if you can, ensure that our Nation has an adequate supply of vaccines and other medication in the event that we do have a bioterrorist attack or a pandemic in this country?

Dr. RUNGE. Well, I believe I will again just try to be very clear about roles and responsibilities. This is an area that HHS has complete jurisdiction over. And Secretary Leavitt and the Deputy Secretary over there—in fact the whole team, Dr. Fauci, they are very focused on getting that job done. It clearly is an issue of national security as well as health, and we are working together. They keep us abreast of what they are doing. The need for investment, the need for a coordinated approach has been shared with us. But they have the lead on it.

Mr. ROGERS. See, that is—there is some confusion from my perspective on that. I have read in some of the documents in preparation for this hearing that DHS had envisioned your position would be the lead in those situations with pandemic outbreak, but you are telling us that is not the case.

Dr. RUNGE. Well, regarding vaccines, that is not the case. There is a point at which in a pandemic—

Mr. ROGERS. Who is in charge? In the event we have a pandemic outbreak next year—

Dr. RUNGE. When critical infrastructures are threatened, the Secretary of DHS is responsible for the preservation of critical infrastructures. HHS will continue to have the lead in prevention, containment, and treatment of avian flu, but if the government surges and if the ESFs stand up and so forth, the Secretary of DHS will be responsible for each of those emergency support function's discharging of their duty. One of the duties of HHS is containment, prevention and treatment of Avian Flu.

Mr. ROGERS. Well, as everybody knows, this is a very real threat that our country faces, perhaps as early as next year, and we need to make sure everybody understands who has got which responsibility, and that is of some concern to me.

As we saw last year, the United States had difficulty acquiring this sufficient supply of flu vaccines from foreign providers. Do you think it is preferable to have domestic providers of flu vaccines to ensure that Americans who want treatment can get access and vaccines?

Dr. RUNGE. My opinion is that any time we can acquire something domestically, it would be preferable to having it acquired overseas; yes, sir.

Mr. ROGERS. Are you at all concerned about the current suppliers being foreign suppliers?

Dr. RUNGE. I do share Secretary Leavitt's concern with that, and I do believe he has worked very hard on remedying that situation.

Mr. ROGERS. Thank you.

The Chairman recognizes the Ranking Member to see if he has any additional questions.

Mr. MEEK. Thank you, Mr. Chairman.

Dr. Runge, I want to pretty much—I know almost on the heels of the Chairman's question, right now the military is the only branch of government with the operational capacity to respond to a large medical outbreak. And I want to know what steps are you taking, the necessary steps to coordinate in such an emergency, a time of emergency. Because when it comes down to, quote unquote, the chain of command or when it comes down to the chain of making sure that we are all—well, when it comes down to operational issues in the time of an emergency, I don't need to explain that. I mean, you just left the Highway Safety, you know—like you said, operationally as a professional and as a doctor, you know it is important to know who is really coordinating here. And I see all the questions kind of swarming around that question because this is a serious question. I mean, we are in a committee hearing now and we don't find ourselves under, quote unquote, the gun. But if we are, are you coordinating with the military? Are you having discussions with the military as it relates to the outbreak, Northern Command?

Dr. RUNGE. Yes, sir.

Yes, sir, thus far, I have met with General Kelly in medical affairs at the Pentagon and some of his staff as well as his policy people. I have also met with the medical director of NORTHCOM basically just to assess where we are. I have the same questions that you have. And I want to make sure that I understand what their capacity is, what their mission is, and how they can contribute in the event that they are needed domestically.

The President asked a very important question a few weeks ago and it was a question. And he sort of threw it over to Congress saying, you know, we need to talk about the role of the Department of Defense in these domestic activities. I think that the folks at Defense are working on solutions to that question, as well. I do think it is worth our pondering.

I am sort of at the assessment stage. There is a quote that sticks in my mind and that is: We are not as vast and fast as people think we are. You know, they are a lean Department of Defense with a mission to defend our country externally. And I think it would be unfair of us to assume that they have capacity to jump in domestically and save us. I don't think that is fair.

So I think this coordination is extremely important. That we have to understand our roles and our responsibilities and our capacity.

Mr. MEEK. Well, we need to know that ASAP. And I am glad you have that concern already planted in your head of the capabilities of the military, especially when it comes down to bioterrorism. During Hurricane Katrina, speaking with a two-star general in the 82nd Airborne, when they got on the ground, they jumped right in the water and started carrying out their rescue missions and found that his troops were getting a rash here, a sore there. They had to go out and through a commercial vendor with a credit card go out and buy—what is the thing you wear—you know what I am talking about?

Dr. RUNGE. Waders.

Mr. MEEK. Waders.

Dr. RUNGE. I am from North Carolina; I know what they are.

Mr. MEEK. Very good. We do not wear too many of those on South Beach. But they had to go out and buy those. And then the discussion started with the Centers for Disease Control of what the 82nd Airborne was going through.

I think it is important as we start talking about a military response, because everything can't be the military will handle it. There is more to that than just bodies out there up front. I see your position, tell me if I am wrong. Quote, unquote, as the Surgeon General for the Department of Homeland Security, and also the public in terms of how they can protect themselves in terms of a bioterrorism or biochemical attack.

And I think it is also important what you have share with them is almost identical of what the way HHS sees it, and the way that the Centers for Disease Control sees it also. But you are going to be the person that is designated for that. Have you had a discussion with them about that role?

I do have some reports—you were talking about the issue of getting volunteers involved, especially in the EMS field. That is one question. But EMS field of looking at the issue of lowering the barriers of liability issues that they may face. And that is a real discussion, something that this committee, subcommittee just passing this news report. I just got off the Web on some statements that you have made, that is something is that we need to talk about, because during Katrina, you had folks from other States, docs that wanted to come down, EMS personnel that wanted to come down, and there were some issues as it relates to licensing and issues as it relates to foreign countries that wanted to send doctors, Mexico, Pakistan of all places, they are needing docs over there, but they wanted to send doctors. But because of licensing issues, they could not address those issues.

I think as it relates to your public information officer role that you play, and also as it relates to foreign doctors coming into the United States and helping us in our time of need, is there some thinking going on there as it relates to your office and how are you going to accomplish that?

Dr. RUNGE. I am a believer that public information and public education is one of the three legs of the three-legged stool, and without it, you can't sit up. I am also the guy that took Click It

Or Ticket nationwide. I believe in branding. And Only You Can Prevent Forest Fires. We do not have a Smokey the Bear for biologicals. We need that. And I have talked to our marketing folks about that who are configured right now less for marketing and more for handling press.

The head of our public affairs is well aware of that. And he is actually hiring somebody who is going to be a health specialist to start to coordinate these messages with HHS and with others to make sure that we are saying the same thing in government. That there is not an HHS message or a DHS message or an ag message, but that all of our messaging is consistent and coherent and it actually tells people what to do and what to expect. Surprise is not a good thing for people. They want to know—they can handle bad news if they know what is coming.

So I take your advice to heart. And I will do everything I can to make sure that we do have a coherent message across government for these issues.

Mr. MEEK. The issue of these docs or EMS personnel that are in other States that may run into licensing issues and going to a State like Florida, someone coming from Illinois, medical boards they do not recognize the Illinois license. You are going to address that as you try to get volunteers in the medical response?

Dr. RUNGE. Yes, sir, there are some systems out there in place, there is something called ESAVIP. And I can't ever remember what this stands for, but it is a precredentialing mechanism. There is also MDMS credentialing. One of the problems after Katrina hit, and there was such devastation, people who are helpers by nature wanted to help. They had not done their work ahead of time to make sure they were trained, they were not going to get in the way as volunteers, that they had credentialing issues. That is what I was talking about in that article.

I would like to see every physician—and some States actually have a place where you can—on your license application, where you can be contacted about how you can volunteer and be part of the Medical Reserve Corps that the Surgeon General has stood up. And I met with the Federation of State Licensing Boards, this is a group in Dallas that coordinates every State medical licensing board in the country. They think they have a solution to this. It is a matter of me getting the right people together.

Again, talking about public information, to educate our physicians, nurses, and paramedics, and how is it that they do this ahead of time.

Mr. MEEK. I am over my time. As someone who just left south Florida yesterday, that we have issues from the top to the bottom, getting ice and water to people, leave alone dealing with the very technical issue that we are dealing with right now. And the things that we have to work out as it relates to authorization for docs to come in from other States and they know from a liability standpoint they do not have to end up sitting in a trial because they were sued because they were not licensed in a particular State. I think it is something that we need to work out more sooner rather than later.

I am a cheerleader for the Department, but I honestly feel overall that a lot of places where we are saying we are ready, we really

are not. We really are not. And we do not want to scare the public by saying that we are not. But I think we need to start seeing it as leaders that we have a lot of work to do to get us where we need to be so that the folks who are listening to us, the folks under your command and the folks in HHS, and the folks in the Centers for Disease Control and in the military, we say that so that we can, number one, see that we have a problem and then we can start working towards the solution.

I would like to know more about that cross-State licensing, because we do have, with the emergency compacts, with the emergency management, with States, State emergency compacts. I sponsored that bill on the floor of the legislature in Florida making sure that you have a compact with the State and automatically there are some things that come along with that. We can use your National Guard, we can use your Department of Transportation trucks, Bobcats or what have you.

We need that as it relates to the medical issue. And I am going to tell you, as it relates to these medical boards, take it from me in Florida, it is tough to get into a medical board or barred in certain States. So we want to make sure that folks recognize one another in a time of emergency and we want to work with you on that.

Thank you for coming before the committee. We look forward to seeing your role stronger and given the ability to coordinate with other agencies and within the Department of Homeland Security. So thank you.

Dr. RUNGE. Thank you very much.

Mr. ROGERS. And I want to echo that sentiment. We very much appreciate you taking time to be here, but we also look forward to helping you and your employees fulfill the mission that is set out by the Secretary and creating this Department.

We are now going to excuse this panel. I have just been informed by staff that we are about to be called for a series of four votes which will keep us away for about 40 minutes, I would expect. The second panel, oh, and Dr. Runge, and I will tell the second panel, too, the record will be kept open for 10 days. There may be some Members—there are a lot of markups going on so members are having conflicts about coming over here—but they may have questions that they want to submit, and I would ask you, too, in writing, respond to those.

And the second panel will be the same deal, some members may want to get questions in for a record, and I ask you to respond to those in a timely manner in writing. Thank you, Dr. Runge, and your panel is discharged.

Let's do this, the second panel, let's go ahead and seat the second panel and try to get your opening statements in before we break for votes then we will do questions after that.

Mr. ROGERS. We turn now to Mr. Timothy Moore for any statement that he may have.

STATEMENT OF TIMOTHY MOORE, DIRECTOR, FEDERAL PROGRAMS, NATIONAL AGRICULTURAL BIOSECURITY CENTER, KANSAS STATE UNIVERSITY

Mr. MOORE. Mr. Chairman, thank you. Mr. Meek, thank you for allowing me to be here today to testify before this committee. I think that the work you are doing is very important. The role of the chief medical officer, as you have noted in your earlier panel, is evolving. One of the things I would like to make sure that, in my role as a private citizen before this committee today is this: the importance of the connection between the chief medical officer's position and that of animal health, veterinary health issues, because they are intertwined. As the avian influenza issue is looming about, it is an animal issue, it is human issue and they will have to be closely coordinated. I would tell you today that I don't believe that that issue is being as well addressed as it should be between DHS, USDA and the Centers for Disease Control, HHS. There are some issues there that I think this committee can lend some guidance to.

Sir, today we are vulnerable to issues involving animal diseases, emerging diseases, one of which is avian influenza. While the potential for a human pandemic is obviously of grave concern, I ask this committee to consider the fact that even in its current configuration, the H5N1 strain, if it were to arrive in this country, it would have catastrophic effects upon our poultry and agricultural sectors such that we may have a cascade of economic events that would cause great harm to States such as Alabama, Arkansas, North Carolina and Georgia where we rely on these industries for a mainstay of our agricultural sectors.

The chief medical officer's role needs to be clearly defined, in my estimation, so that the veterinary issues are front and center from the Homeland Security Department, because there is a lot of confusion, Mr. Chairman, as to who will have control. One of the issues of great concern is the issue of quarantine. Agricultural quarantine, animal quarantine, human quarantine issues are not one and the same. So if you have an animal event break out and you have a human quarantine event that follows on behind that, who exactly is in charge at what time, what tripwires have to be initiated for these things to occur to my mind have not been addressed.

As I stated, the agricultural sector is vulnerable to emerging animal diseases. One of the reasons for this, Mr. Chairman, is the fact that within the Federal sector we have less than 3,000 Federal veterinarians in employment across all Federal agencies. Within the next 18 months we will lose approximately 50 percent of those individuals. With those individuals going out, we will lose decades of hard-fought experience that we will not be able to readily capture and transfer to the next generation of Federal veterinarians.

What does that mean? That means that that experience will dissipate and that means that States and industries and regions will have to bear a greater burden in the response to any kind of agricultural disease incident.

I want you to consider, for example, the paucity with which we have Federal resources to respond. In 2002 and 2003, the United States experienced an exotic new castle disease in California. It only affected poultry. At the height of the outbreak, the U.S. De-

partment of Agriculture was only able to mobilize 1,800 personnel for the response. If we look at these numbers in light of the 50 percent reduction due to retirement, that means the pandemic flu that we are worried about, avian flu, coming to this country we may have less than a thousand individuals to respond at a given time. If it breaks out in multiple States, we may find that we do not have the resources to respond. As one Federal veterinarian said to me, avian flu has the potential to be the Hurricane Katrina for the agricultural sector.

Sir, one of the things I have tried to stress in the last 2 years of working in the agricultural response community is that this is a blended response requirement. We have had these two communicates operating in silos. They do not normally interact and we need to make sure that they do so.

Things I would recommend this committee to consider, sir: I would recommend that we credential graduating veterinarians from the 28 veterinary schools in this Nation to be accredited in the areas of incident command response, emergency preparedness skills, so they are capable of helping this Nation from the moment they graduate. At present no college does that.

Second of all, we need to reinforce within the Federal agencies that preparedness for agricultural diseases is not an unfunded mandate, it is not a "nice to have," it is something that is front and center in their primary mission.

Lastly, I think through the chief medical officer, Dr. Runge, is what you can achieve is one medical voice for the Federal Government as to what is going to happen in an agricultural disease incident or heaven forbid a pandemic flu incident.

The last thing I would have this committee consider is the fact that the agricultural sector accounts for \$1.25 trillion of our annual U.S. economy. I would ask this committee to think about the investment we put forth protecting that sector and what will happen to our citizens is if we do not do that.

The 1918 pandemic was an avian strain as we have now learned. At that time, America was much more compartmentalized. We bought our bread, we bought our milk, we bought our meat from local markets that were grown and harvested locally. Today we are a global economy. If things begin to go awry, our transportation sectors may collapse to the point where we may not be able to feed our citizens and exacerbating the problems and fears and concerns that Dr. Runge talked about.

That concludes my formal statement and I will yield to any questions you may have, sir, thank you.

[The statement of Mr. Moore follows:]

PREPARED STATEMENT OF TIMOTHY MOORE

Introduction

Mr. Chairman and distinguished Committee members, it is indeed my pleasure to testify before you today regarding the clear need for disease incident response training as it relates to the veterinary and agricultural communities. I come before you today as a private citizen with broad experience and knowledge of the threats against our agricultural sector and the current status of preparedness and response training efforts to mitigate these threats.

Background Information

This distinguished Committee has received previous testimony regarding emerging and re-emerging diseases that threaten our nation's agricultural sector. Current

headlines are replete with information, warnings and concerns over “Avian Influenza.” Yet, Avian Influenza is but one of multitude of diseases that our nation must be prepared to recognize, detect, respond to and, if necessary, recover from in the coming years. Avian Influenza is particularly troublesome among diseases due its unpredictability—its ability to “jump species” or exhibit zoonotic tendencies and due to the fact that there are multiple environmental or animal reservoirs that hinder our ability to eradicate it. Currently Avian Influenza is concentrated within the poultry and wild fowl populations in select areas/nations around the globe. Unfortunately, we have no assurance that the disease will remain in these areas. The combination of the unpredictable nature of the virus coupled with the pressures associated with globalization of the agricultural sector and the speed-to-market required to compete on the international level have all strongly contributed to the conditions that will most likely result in the continued spread of this disease. Therefore, as a nation, we must be prepared to deal with this and other emerging disease threats. In order to reduce the likelihood of the emergence of Avian Influenza in our country we are fortunate to have a group of dedicated professionals who work at our federal, state and local levels to protect us from and respond to these diseases: Veterinarians.

As one measure of our veterinary population, let us examine the current status of our federal veterinary community. At present, we have fewer than 3,000 veterinarians spread amongst all agencies within the federal sector. Across the nation we have roughly 100,000 veterinarians. By contrast, the state of New York has more than 70,000 MDs. The nation generates fewer than 4,000 new Veterinarians from our 28 Colleges of Veterinary Medicine a each year. These numbers are troubling, but they tell only part of the story.

At present, approximately 85% of all Veterinary graduates are electing to enter exclusively into small animal practice with only 15% electing to enter service within the food animal or mixed practice (i.e. treatment of small and large animals). This represents an abrupt change from 25 years ago when we witnessed approximately 50% of all Veterinary graduates electing to enter into food animal or mixed animal practice. The changes over the past 25 years reflect the economic changes within the animal care sector of our country. Companion animals represent the largest growth area within veterinary medicine. As we move further away from individual farms and family agriculture we can expect to see these trends continue. This is troubling because food animal veterinarians have played a key role in securing the health of our nation’s animal populations for the past 100 years.

As vexing as these data are, they are only an indicator of the challenges we will face in the future. Within the federal sector we are witnessing a precipitous decline in the numbers of federal veterinarians with direct experience in responding animal disease incidents. This is not a trivial matter. For example within USDA’s Animal and Plant Health Inspection Service (APHIS), we find a federal veterinary population that has done a magnificent job in preserving the health of our pre-harvest animal population. However, we have fewer than 500 USDA-APHIS veterinarians who are in the field conducting important disease surveillance and response missions. This same group of federal veterinarians serves as the backbone of our animal disease incident response infrastructure - they led the 2002-2003 Exotic Newcastle Disease response in California, Nevada and Arizona. Currently, more than 50% of these veterinarians are scheduled to retire from federal service before 2007. These retirees will, in effect, remove hundreds of years of combined experience at the very moment that we are witnessing the appearance of new and re-emerging diseases which threaten our agricultural sector, our economy and perhaps our health. As these key personnel retire, their replacements will be required to master not only basic veterinary skills, but they will they will need to master those skills required to effectively respond to disease incidents. These emergency response skills may have to be learned largely through trial and error. The nation’s 28 Colleges of Veterinary Medicine offer few, if any, programs of instruction geared toward the role of veterinarians in disasters or emergency response. There is no standard for instructing veterinary students in the art and craft associated with the Incident Command System or in the proper selection of personal protective equipment or how to properly don or doff this equipment. Further there is limited discussion of the relevant points of self, equipment or structural decontamination procedures and limited guidance on proper animal carcass disposal techniques that will be needed to reduce the spread of infectious agents. As important as our federal veterinary population is, we have little if any structured process in place at the present time for the recruitment and training of their replacements or any developed strategy to “collect” relevant skills and best practices to “pass” on to the next generation of federal veterinarians. Our current federal response strategy is predicated on working closely with our state and industrial partners to effect the eradication of a detected dis-

ease. This may become more problematic in the coming years unless we have an aggressive and successful strategy to replace these individuals. If we are slow or ineffectual in our attempts to replace these losses, we can anticipate that each state will bear a greater burden in the surveillance of and response to animal infectious diseases.

In the past, animal disease response was largely handled within the federal, state and local veterinary populations. However, Avian Influenza presents a complication to this traditional response strategy. Avian Influenza and other zoonotic diseases, regardless of origin (natural, accidental or deliberate) will require a coordinated response by federal, state, and local veterinary AND non-veterinary (i.e. traditional 1st responders) response personnel. Veterinary responders and traditional 1st responders have limited experience in working together—in many cases they do not know that the other exists. This limited interaction could pose significant problems if the H5N1 strain of Avian Influenza is detected in the US. The detection of this strain could cause significant disruption to our poultry production regions of the country and necessitate a close interaction between local and state law enforcement for quarantine enforcement and local fire departments to support individual and equipment decontamination needs. Further, an animal only Avian Influenza strain will prompt close involvement and surveillance by local, state and national public health entities—something that has not occurred in the past nor has it been a standard component of public health or veterinary training. Ultimately any Avian Influenza disease response will require agricultural and traditional 1st responders to work together in ways that they have never done so in the past. Due to the rapidly diminishing numbers of experienced veterinarians at the federal level we must anticipate that state and local authorities must be prepared to address wide spread animal disease incidents largely on their own for an extended period of time.

Presented below are some of the several activities underway to help improve our readiness to combat agricultural disease incidents:

The first step in addressing any type of incident is achieved with greater awareness on the part of veterinarians and traditional responders alike of the various diseases, how they are manifested and what must be done to contain and result in its eradication. Toward this end, USDA-APHIS assembled and began distributing a CD entitled “The Threat to American Agriculture—Livestock Disease Awareness” to the nation’s 28 Colleges of Veterinary Medicine, all 56 field offices of the FBI, all state veterinarians and have made the CD available to traditional responders. Furthermore, USDA-APHIS is working closely with the Office for Domestic Preparedness in the development and validation of didactic program regarding agricultural foreign animal disease recognition that will capitalize upon the nation’s community college network to effectively spread this information. USDA-APHIS in concert with the Department of Homeland Security has embarked on a cooperative program to develop and deliver a *beta version* of an emergency response training course (Individual performance—Defensive by the ODP guideline) designed for federal, state and local veterinary AND traditional 1st responders to train side-by-side to recognize and respond to agricultural disease incidents. This new course is entitled the Agricultural Emergency Response Training (AgERT) course and is currently undergoing pilot delivery at the Center for Domestic Preparedness located in Anniston, Alabama. The AgERT course teaches agricultural responders the proper skills required to safely respond to “all hazards” incidents and provides traditional 1st responders with basic animal disease information (e.g. introduction to epidemiology principles; overview of animal diseases; carcass disposal considerations, etc.) This course offers promise and path forward as to how the nation can train veterinarians and 1st responders to work together during a disease incident. Upon completing the pilot phase, discussions will begin as to how best to distribute this training across the nation to meet the broader training audience. Lastly, discussions are underway for the development of an advanced veterinary response training course that will better prepare federal, state and select local veterinarians to handle the difficult issues associated with leading animal disease incident response.

Issues to Consider

The Committee is well aware of the looming potential for a pandemic version of Avian Influenza to strike in the United States. The Committee may not recognize that Avian Influenza is just one of multitude of emerging or re-emerging diseases which either may exclusively affect the agricultural sector or have the potential to impact both animal and human health. Disease threats, regardless of origin are a “new normalcy” that we must expect, plan for and react to. If we are fortunate enough to “dodge” a pandemic involving this particular strain of Avian Influenza, then we must be ready to deal the next strain or the next disease that will almost

assuredly come during our lifetime. In short threats from new or re-emerging diseases will not fade away.

The Committee must understand that steps must be taken to assure Americans that we will have a sufficient number of properly trained Veterinarians at the federal, state and local levels to meet the response requirements associated with either an animal disease incident or a zoonotic disease incident. Programs need to be considered to reinforce and fund Veterinary Public Health Service-related positions within the Agricultural and Public Health sectors. Without such funding, the possibility of attracting our best and brightest into the service of their country is remote. These positions would assist states and regions in the conduct of general and targeted disease surveillance efforts.

An issue of concern surrounds the ambiguity of the issue of Quarantine. The Committee understands that Agricultural/Animal Quarantine and Human Quarantine measures are neither identical nor are they imposed in similar fashion. Without a clear and concise understanding within the federal, state and local levels as to how these types of quarantine procedures should and must work together, we can be assured of general confusion and increased apprehension regarding these issues within the ranks of our fellow citizens. As such we must work together as a community to identify where and how these types of Quarantine procedures will interact and who is ultimately responsible for Quarantine during a zoonotic disease event.

Suggested Next Steps for Consideration

Listed below are a few suggested next steps for the Committee to consider when addressing the issues surrounding agricultural sector preparedness.

The Committee has been instrumental in the creation of new position within the Department of Homeland Security entitled the Chief Medical Officer (CMO). I applaud this action as an important first step. I urge the Committee to consider designating one of the CMO's permanent staff positions for a Assistant CMO—Veterinary Emergency Response (VER). This position would answer to the CMO on all issues pertaining to effective and proper preparedness, to include the measurement and validation of readiness as it relates to the directives contained in HSPD 9 (Food and Agricultural Security). In this way, the nation will have a veterinarian “in the loop” when it comes to all matters pertaining to agricultural disease incident readiness and response within the Department of Homeland Security who will coordinate with USDA, CDC and any other relevant federal agencies.

Secondly, I urge the Committee to consider implementing a series of federal, state and local, as well as “joint” assessment exercises, of a similar nature to the “Crimson Sky” to clearly identify our gaps, voids and needs so that our limited funding and staff time can be put to best use. Further, the data arising from these exercises must be placed into actionable formats so that key issues are identified and coupled with a plan arising from the CMO's level to support preparedness strategies.

Thirdly, I urge the Committee to direct DHS, USDA and HHS/CDC to form a working group to examine the consequences of a pandemic influenza. There are a number of issues related to who is in charge at precisely what moment during a potential “species jumping” disease incident that we have yet to work through at the national level. This will be important to the security of our nation during any significant disease outbreak.

Fourthly, I urge the Committee to explore mechanisms by which we can train, certify and mobilize veterinarians on a national basis to react to disease incidents. Currently within DHS we have the Veterinary Medical Assistance Teams (VMAT) which have performed well in the response to companion animal crises (e.g. Katrina) and we have the Veterinary Services component of the USDA to deal with pre-harvest animal disease events. While these groups are important, we must consider methods to support their actions with greater numbers of federally trained veterinarians so that we create some type of veterinary surge capacity.

Lastly, I urge the Committee to consider its role in spelling out specific national mandates with regard to animal disease incidents. We live in a world at the federal, state and local levels with limited personnel resources and funding. However, we are entering a period in our nation's history in which we simply cannot afford to conduct our activities in the manner which we have grown accustomed. Preparation to effectively, swiftly and accurately respond to agricultural or zoonotic disease events is too important to allow it to be mixed with other “routine” agency activities. Emergency response must emerge as a “top of the list” issue for our agency and program personnel and it cannot be allowed to viewed as an “optional issue” or as an “unfunded mandate.” Disease surveillance, detection, response and recovery need to be at the top of our priorities to ensure that we have the staff and with the proper training to ensure the continuity of our agricultural sector.

Conclusions

Mr. Chairman, I want to take this opportunity to thank you and the members of the Committee for allowing me the opportunity to testify today. I hope that I have clearly conveyed that we have diseases that are looming and which could potentially alter our agricultural sector, our economy and even our health.

I would like to leave the Committee with two quotes to consider. The first quote is from Alex Thierman, Office of International Epizootics (i.e. the World Health Organization for Animals) who stated in 2001 that "Governments will no longer be judged on whether or not they have incursions of [new] diseases, rather they will be judged on how well they respond to them." The second quote was recently conveyed to me by a veterinarian who stated that "Avian Influenza has the potential to become the agricultural sector's Hurricane Katrina." It is my hope that we can avert disaster through our dedication to being prepared. Thank you.

Mr. ROGERS. What I would like to do, and I neglected to cite your title—you are the Director of Federal Programs at the National Agricultural Biosecurity Center at Kansas State University. I thank you for that statement.

I am hoping that we can get Dr. Lowell's and Mr. Heyman's statements in. Dr. Jeffrey Lowell is Professor of Surgery and Pediatrics at Washington State University School of Medicine, and you are recognized for any statement you might have.

STATEMENT OF JEFFREY A. LOWELL

Dr. LOWELL. Thank you, Chairman Rogers, Ranking Member Meek, and distinguished members, for the opportunity to testify today. My name is Jeffrey Lowell. I am a surgeon at Washington University School of Medicine, where I am a professor of surgery and pediatrics and direct the transplant surgery programs at St. Louis Children's Hospital. I am a liver and kidney transplant surgeon and have held the position of assistant vice chancellor in the School of Medicine. I have also served as the police surgeon for the St. Louis Police Department, I also served on the hostage response team and senior advisor to the mayor for medical affairs and chief of the St. Louis medical response system.

I am here to today to discuss medical readiness responsibilities and capabilities in the Department of Homeland Security and the role of the chief medical officer in relying and strengthening the Federal medical response.

In September 2004, I was appointed by then-Secretary of Homeland Security, Tom Ridge, to serve as the senior advisor to the Secretary for medical affairs. In that capacity, I was the principal advisor to the Secretary on medical issues relevant to the Department, including medical response to disaster, distribution and utilization of medical assets within the Department, coordination with other departments and agencies on medical issues and occupational health and safety issues regarding DHS employees and support personnel.

Secretary Ridge, and now Secretary Chertoff, have recognized that medical preparedness and response are critical elements of the DHS mission. One of my tasks as senior advisor to the secretary for medical affairs was to assess the Department's capability to carry out its medical mission as part of that task, I examined DHS's medical readiness requirements and capabilities for addressing these requirements. I reviewed the medical and health assets activities resources and capabilities located in DHS and how these assets and responsibilities are related to other Federal depart-

ments or agencies at the executive branch with a focus on mass casualty care.

I found that DHS lacked a clearly defined and unified medical capability to support its mission of preventing protecting responding to and recovering from major terrorist attacks or natural disasters. The primary consequences of most events of national significance are the impact on human health. People get injured or they die. If we do not save lives, little else matters.

Americans expect DHS to pass the readiness test. I found the Department's medical readiness responsibilities, capabilities, assets, personnel, and fiscal resources needed to be realigned and consolidated in order for the Department to pass the medical readiness test and I make recommendations on how to do so.

In recognition of the importance of the medical mission, Secretary Chertoff, after conducting the second stage review of the department, established the position of DHS Chief Medical Officer. And I applaud Secretary Chertoff for this decision. Secretary Chertoff has stated that the CMO position is to be housed within the proposed Preparedness Directorate; however, I would respectfully suggest an alternative.

Instead, I recommended establishing an Office of Medical Readiness in the Department of Homeland Security and would like to provide a brief overview of the configuration responsibilities and benefits of such an office. I would like to discuss the role of the chief medical officer in leading this office.

The DHS Chief Medical Officer should be charged to protect the public, emergency responders, and affiliated medical personnel from the range of manmade and naturally occurring biological and environmental diseases, injuries and threats that the Department will face and to serve as an information and communication channel with the public, emergency responders, and the medical profession regarding all aspects of these issues.

The CMO should lead a centralized, coordinated organizational structure within DHS and serve as the central medical point of contact to coordinate with other Federal and State and local agencies, and to provide the core architecture for managing and coordinating the delivery of Federal emergency medical support; deliver medical risk communications; and provide medical and health support to DHS employees in the workplace and on deployments.

The CMO should have the following responsibilities: To act as the principal advisor to the Secretary on medically-related issues. To direct the operational elements of the Federal medical health threat response to a national critical incident. To integrate relevant agencies and programs within DHS and within the U.S. Government, such as CDC, Office of Public Health and Emergency Preparedness of HHS, the Public Health Service, Army Air National Guard Medical Corps, and the VA Hospital System.

To act as a spokesperson for the Secretary on medically-related issues, including threat risk assessment, preparation and responses. To focus Federal resources on developing a national medical surge capacity, including the integration and coordination of existing Federal assets, including the National Guard, NORTHCOM, and VA with civilian response systems. To ensure effective integration among civilian medical providers and facilities

including developing systems to ensure intra/inter regional coordination, interoperable equipment, standardized practices and procedures including electronic systems to track patients that may be transported from one location to another, and robust intra—and inter-regional exercises. And to coordinate relevant research and development programs across agencies.

I would recommend that the CMO, in the immediate period, address four critical problems in the Federal medical response to an event of national significance.

First, people. There must be a trained, equipped mobile medical workforce composed of the appropriate medical and surgical disciplines capable of providing medical care in the event of catastrophic threats or events. There are weaknesses in the Federal medical response currently led by the national disaster medical system, the NDMS. NDMS is currently assigned to the Emergency Preparedness and Response Directorate in DHS, where there are few qualified medical personnel available to develop the requisite medical doctrine, policies and procedures.

I would recommend that NDMS be moved to the proposed Office of Medical Readiness and be substantially transformed to include full-time Federal medical teams and a uniformed Reserve corps supplemented by volunteer teams to satisfy casualty requirements from existing planning scenarios.

A full-time and uniformed reserve medical corps led by the CMO would need to be recruited and supported as part of the medical element of either the U.S. Coast Guard in DHS, the National Guard or a new clinical readiness component of the independent DHS medical corps. Just as our nation expects other components of its emergency response systems, police, fire and EMS, to be solely committed to its singular commission and responsibility, the medical health components must be comprised of solely committed specialized personnel. We do not expect our Nation's largest estates to rely disproportionately on volunteer firefighters and auxiliary police officers. There needs to be a thorough analysis and transformation of NDMS by the DHS CMO.

I think I am over my time here.

[The statement of Dr. Lowell follows:]

PREPARED STATEMENT OF JEFFREY A. LOWELL, MD, FACS

Good afternoon. Thank you Chairman Rogers, Ranking Member Meek, and distinguished Members of the House Committee on Homeland Security, for the opportunity to testify before the Committee.

My name is Jeffrey Lowell. I am a surgeon at Washington University School of Medicine, where I am Professor of Surgery and Pediatrics and direct the Transplant Surgery program at St. Louis Children's Hospital. I am a liver and kidney transplant surgeon, and have held the position of Assistant Vice Chancellor in the School of Medicine. I have also served as the Police Surgeon for the St. Louis Metropolitan Police Department (where I served on the Hostage Response Team), as Senior Advisor to the Mayor for Medical Affairs, and Chief of the St. Louis Metropolitan Medical Response System.

I'm here today to discuss medical readiness responsibilities and capabilities in the Department of Homeland Security and the role of the Chief Medical Officer in realigning and strengthening the Federal Medical Response.

In the Summer of 2004, I was appointed by then Secretary of Homeland Security Tom Ridge to serve as Senior Advisor to the Secretary for Medical Affairs. In that capacity, I was the principal advisor to the Secretary on medical issues relevant to the Department, including medical response to disaster, distribution and utilization of medical assets within the Department, coordination with other Departments and

agencies on medical issues, and occupational health and safety issues affecting DHS employees and support personnel. Secretary Ridge, and now Secretary Chertoff, have recognized that medical preparedness and medical response are critical elements of the DHS mission.

One of my tasks as Senior Advisor to the Secretary for Medical Affairs was to assess the Department's capability to carry out its medical mission. As part of that task, I examined the Department of Homeland Security's medical readiness requirements and its capabilities for addressing these requirements.

I reviewed the medical and health assets, activities, resources and capabilities, located in the Department of Homeland Security, and how these assets and responsibilities related to other federal departments or agencies of the executive branch, with a focus on mass casualty care.

I found that the Department of Homeland Security lacked a clearly-defined and unified medical capability to support its mission of preventing, protecting, responding to, and recovering from major terrorist attacks or natural disasters.

The primary consequences of most Events of National Significance are the impact on human health—people get injured or die. If you don't save lives, little else matters. Americans expect the Department of Homeland Security to pass the medical readiness test. I found that the Department's medical readiness responsibilities, capabilities, assets, personnel, and fiscal resources need to be realigned and consolidated in order for the Department to pass the medical readiness test, and I made recommendations on how to do so.

In recognition of the importance of the medical mission, Secretary Chertoff, after concluding the Second Stage Review of the Department, has established the position of DHS Chief Medical Officer. I applaud Secretary Chertoff for this decision. Among other issues, Secretary Chertoff has recommended that the CMO position be housed within the new proposed Preparedness Directorate. However, I respectfully suggest an alternative.

Instead, I recommend establishing an Office of Medical Readiness in the Department of Homeland Security, and would like to provide a brief overview of the configuration, responsibilities, and benefits of such an office. I would like to discuss the role of the Chief Medical Officer in leading this Office.

The DHS Chief Medical Officer should be charged:

- to protect the public, emergency responders, and affiliated medical personnel from the range of manmade and naturally occurring biological and environmental diseases, injuries, and threats that the Department will face
- to serve as an information and communication channel with the public, emergency responders and the medical profession regarding all medical aspects of these issues

The CMO should lead a centralized, coordinated medical organizational structure within DHS, and serve as the central medical point of contact to coordinate with other Federal, State, and local agencies and to provide the core architecture for managing and coordinating the delivery of Federal emergency medical support; deliver medical risk communications; and, provide medical and health support to DHS employees in the workplace and on deployments.

The CMO should have the responsibilities:

- To act as the principal advisor to the Secretary on medically related issues
- To direct the operational elements of the federal medical/health threat response to a national critical incident
- To integrate relevant agencies and programs within DHS and within USG (e.g., Centers for Disease Control and Prevention (CDC)—Office of Public Health and Emergency Preparedness (HHS), U.S. Public Health Service (HHS), Air/Army National Guard Medical Corps (DOD), and VA Hospital System (Department of Veterans' Affairs)).
- To act as the spokesperson for the Secretary on medically related issues, including threat/risk assessment, preparation and responses
- To focus federal resources on developing a national medical surge capacity—including the integration and coordination of existing federal assets (including the National Guard, NORTHCOM, VA Hospital System) with civilian response
- To ensure effective integration amongst civilian medical providers and facilities, including developing systems to ensure intra/inter regional coordination, interoperable equipment, standardized practices and procedures (including electronic systems to track patients that may be transported from one location to another), and robust intra/inter regional exercises
- To coordinate relevant research and development programs across federal agencies

I would recommend that the CMO, in the immediate period, address four critical problems in the federal medical response to an event of national significance.

First, people. There must be a trained, equipped, mobile, medical work force composed of the appropriate medical and surgical disciplines, capable of providing medical care in the event of catastrophic threats or events. There are weaknesses in the federal medical response to mass casualty events, which is currently led by the National Disaster Medical System (NDMS). NDMS is currently assigned to the Emergency Preparedness and Response Directorate in DHS, where there are few qualified medical personnel available to develop the requisite medical doctrine, policies, and procedures. I would recommend that NDMS be moved to the proposed Office of Medical Readiness and be substantially transformed to include full-time federal medical teams and a uniformed reserve corps, supplemented by volunteer teams, to satisfy casualty requirements from existing planning scenarios. A full-time and uniformed reserve medical corps, led by the CMO, would need to be recruited and supported as part of the medical element of either the U.S. Coast Guard, the National Guard, as a new clinical readiness component of the U.S. Public Health Service, or as an independent DHS medical corps. Just as our Nation expects other components of its emergency (first) response (e.g., police, fire, EMS) system to be solely committed to its singular mission and responsibility, the medical/health components must also be comprised of solely committed, specialized personnel. We do not expect our Nation's largest cities to rely disproportionately on volunteer fire fighters and auxiliary police officers. There needs to be a thorough analysis and transformation of NDMS by the DHS CMO.

Second, surge capacity. There is little surge capacity in U.S. hospitals for catastrophic events. The surge capacity of a health care system includes more than an accounting of staffed vs. licensed hospital beds. Most hospitals in the U.S. function at or near capacity on a daily basis. After action reviews of Hurricanes Katrina and Rita will undoubtedly identify large gaps in the plans and systems to redistribute, and track, patients regionally and nationally. DHS should establish a standard for temporary, mobile medical facilities, and staff requirements to support these facilities, that can serve as alternative care sites or potentially sites for quarantine, to supplement the already strained U.S. Hospitals.

Third, interagency coordination and leadership. There must be a solution to the lack of interagency coordination. There are apparent conflicts in the requirements of the Homeland Security Act of 2002 and Emergency Support Function—8 of the National Response Plan and Homeland Security Presidential Directive 10 that should be clarified and resolved. There is a lack of a clear and effective public education strategy for medical/health response to a critical incident, termed "risk communication" and a lack of an understanding of who (from which USG Department and position) should be the risk communications spokesperson.

Fourth, manage and coordinate the current medical/health programs that reside within DHS, within the proposed Office of Medical Readiness.

DHS was created to prevent, protect, respond to, and recover from natural and man made disasters. Meeting the health and medical needs of the nation at times of disaster is a core requirement in the mission of DHS. Accordingly, to efficiently and effectively complete this mission, DHS must re-evaluate and refine the medical component of its mission; design, develop, and realign medical response capabilities within the Department, under the direction of its Chief Medical Officer, and collaborate with HHS and other Federal partners to ensure the seamless integration of medical preparedness and response capabilities at the Federal, Regional, State, and local levels.

Thank you again Mr. Chairman and Ranking Member Meek, as well as the other Members of this distinguished Subcommittee for your continued leadership and for the chance to appear before you today to discuss medical readiness responsibilities and capabilities in DHS and the role of its Chief Medical Officer in realigning and strengthening the Federal Medical Response. I will be happy to answer any questions that you have.

Mr. ROGERS. Your full statement is in the record, that is good. We will go to Mr. Heyman. And Mr. Heyman is a Senior Fellow and Director of the Homeland Security Program Center for Strategic and International Studies. The floor is yours.

STATEMENT OF DAVID HEYMAN

Mr. HEYMAN. Thank you, Mr. Chairman, and members of the committee. I do have a full statement which I would like to be included in the record.

First, I want to discuss the new context that shapes the catastrophic health emergencies today so that I can set the recommendations in context. Second, I want to touch on some recommendations from a report we wrote on DHS 2.0, which looked at the CMO function. And third, I am going to highlight four areas of greater leadership we need in the Federal Government that the CMO might be able to adopt. And finally, I have some recommendations specifically for the CMO in light of the possible pandemic flu.

To understand the challenges we face today in public health, we must also appreciate the changes that evolved over the past 50 or 70 years in terms of health risk or health care. In the 20th century, we saw two important health care trends and two health care risks evolve. We saw the rise of the era of preventive medicine in which a number of techniques, including vaccines and antibiotics, could employ not only to prevent disease, but to reduce the lethal effects.

We also saw beginning in the 1980s the just-in-time manufacturing principles applied in health care and hospitals to reduce costs and increase revenue. This led to the reduction in overall number on average of available beds and hospital services. It also helped create a health infrastructure that thrives on efficiency at the expensive surge capacity.

In terms of risks, we began witnessing the emergence of novel infectious disease causing pathogens and increased microbial resistance to antibiotics in some known pathogens. This meant diseases that are now cropping up that are not necessarily amenable to our sort of standard 20th century interventions.

And finally, more recently, we have experienced the advent of catastrophic terrorism, of deliberate release of *Bacillus anthracis*, and the fear that the world's deadliest weapons, nuclear, biological and chemical, may be acquired and used by terrorists.

The implication of all of these developments is that whereas preventive medicine and its aspirations to eliminate infectious disease was the focus of the 20th century, responsive health care may be increasingly required at the beginning of the 21st century to manage new health risks.

What I mean by that is the ability to develop new vaccines or medicine to apply to newly emerging diseases or, in particular, rapidly deliver health care services to possibly large populations in short order.

These trends are important to the preparedness and response activities that may fall under the purview of the new chief medical officer at DHS. Greater national leadership in biodefense was one of the principal recommendations of our task force report, DHS 2.0. And today I believe, despite a new presidential directive and a preparedness directive describing the administration's approach to biodefense, the need for leadership is still great and confused.

There are four areas in particular where clear leadership is needed today:

One, leadership in providing scientific, medical, and public health advice at DHS. Two, leadership in developing greater situational awareness of biotreats and health preparedness. Those are threats and vulnerabilities that go together. Three, leadership in integrating Federal, State, local, and private sector preparedness

and response functions. We have had a number of comments on that today. And four, leadership supporting public education through public preparedness. They are really at the first line of response.

Let me conclude by turning to avian flu. The increased concern and possible risk of pandemic flu provides a special case that urgently needs leadership in preparing for biological events. By any standard, we are not prepared should a pandemic emerge today. Vaccines needed to protect us would take a minimum of 6 months and might take longer to develop. Small stockpiles of antiviral medication exist but not in sufficient quantities. And without vaccines or medical countermeasures the next best option—perhaps the only best option—is to put in place disease exposure controls to reduce as much as possible the likelihood that individuals will pass the disease from one to another.

Disease exposure control is a process by which the spread of disease is minimized by limiting contact between uninfected individuals and other individuals who are potential spreaders of disease. To be sure we do need medical supplies, vaccines and antiviral drugs. We also need enhanced disease surveillance networks for early warning and we need to put plans in place to prioritize, move, and dispense medical countermeasures as well.

But in their absence, which is where we are today, with a possible pandemic on the horizon, the chief medical officer's yet to be defined role could be vital in helping delineate these additional tools to limit exposure to disease and help protect public health should a pandemic materialize. National leadership is needed now. And I am happy to answer your questions.

If I hadn't stumbled, I would have been right on 5 minutes.

[The statement of Mr. Heyman follows:]

PREPARED STATEMENT OF DAVID HEYMAN, SENIOR FELLOW AND DIRECTOR, HOMELAND SECURITY PROGRAM, THE CENTER FOR STRATEGIC AND INTERNATIONAL STUDIES (CSIS)¹

Mr. Chairman and other distinguished Members of the committee,

Thank you for the opportunity to testify before the committee today to discuss improving the national response to catastrophic health emergencies and, specifically, the role of the new chief medical officer at the Department of Homeland Security.

I also want to thank Ambassador Bob Stuart who had the foresight and has generously helped support much of CSIS's work in this area.

Greater national leadership in biodefense was one of the recommendations of the task force co-chaired by myself, on behalf of The Center for Strategic and International Studies, and Jim Carafano, of The Heritage Foundation. The task force's report, DHS 2.0: *Rethinking the Department of Homeland Security*, evaluated the department's capacity to fulfill its mandate as set out in the Homeland Security Act of 2002.

In evaluating the new role of chief medical officer, I would like to first discuss the new context that shapes catastrophic medical emergencies today. Second, I will review the recommendations the task force made related to the chief medical officer and our nation's ability to respond to these type of emergencies. Third, I would like to discuss the areas in which greater leadership in the federal government would enhance our nation's ability to prepare for and respond to catastrophic medical

¹The Center for Strategic and International Studies provides strategic insights and practical policy solutions to decision makers committed to advancing global security and prosperity. Founded in 1962 by David M. Abshire and Admiral Arleigh Burke, CSIS is a bipartisan, non-profit organization headquartered in Washington, D.C with more than 220 employees. Former U.S. Senator Sam Nunn became chairman of the CSIS Board of Trustees in 1999, and John J. Hamre has led CSIS as its president and chief executive officer since April 2000. More information is available at www.csis.org.

emergencies. Fourth, and finally, I would like to recommend actions the Chief Medical Officer at DHS might consider in regard to the possibility of a pandemic flu outbreak.

A New Context—Catastrophic Medical Emergencies

To understand the challenges we face protecting public health today, we must appreciate some of the changes that have evolved over the past fifty to seventy years in terms of health risks and health care.

First, the 20th century was a period that ushered in the era of *preventive medicine*. In this period, we saw the development of a number of techniques and medicines including vaccines, antibiotics and other medical interventions that could be employed not only to prevent disease, but also to reduce its lethal effects. Preventive medicine has become the dominant model within which health care is delivered today.

Second, beginning in the 1980s, we saw principles of “just-in-time” manufacturing applied to health care and hospitals, to reduce costs and increase revenue in increasingly privatized health care systems. This led to a reduction in the overall number on average of available beds and health care services. It also created a health infrastructure that thrives on efficiency, at the expense however, of surge capacity.

Coincidentally, at the same time, we began witnessing the emergence of nearly two dozen novel infectious disease-causing pathogens, and increased microbial resistance to antibiotics in some known pathogens. This meant diseases are cropping up that are not necessarily amenable to our standard twentieth-century interventions.

And finally, more recently, we have experienced the advent of catastrophic terrorism, the deliberate release of *Bacillus anthracis*, and the fear that the world’s deadliest weapons—nuclear, biological, and chemical—may be acquired and used by terrorists.

The implication of all of these developments is that whereas preventive medicine and its aspirations to eliminate infectious disease was the focus of the 20th century, *responsive health care* may be increasingly required at the beginning of the 21st century to manage new health risks.

What I mean by and what I am calling “responsive health care” is the ability to quickly develop new vaccines or medicine to apply to newly emerging diseases, combined with rapidly delivering health care services to possibly large populations in short order. In a world of newly emerging and possibly deliberately spread biological threats, we may no longer aspire to eliminate these threats, we will have to manage them.

We saw the seeds of responsive health care applied in New York in September 2001; we see the need for it in large-scale hurricanes and natural disasters; and we saw it in Washington DC when the city government had to dispatch antibiotics to 40,000 individuals who were potentially at risk of contracting anthrax. We may yet see the greatest need for responsive health care if the H5N1 avian influenza virus mutates to become transmissible among humans around the world.

Why DHS 2.0?

Before I discuss our recommendation for greater national leadership in biodefense, I would like to share with the committee our rationale for undertaking the CSIS/Heritage study where this recommendation comes from, and why the task force urged Congress and the department’s new leadership to consider adopting the recommendations of the report.

When we wrote the DHS2.0 report last year, we had learned much over the intervening three years since the 9/11 attacks. We had come to understand that the age when only great powers can bring great powers to their knees is over and that the specter of catastrophic terrorism that could threaten tens-of-thousands of lives and hundreds-of-billions of dollars in destruction will be an enduring concern.

Our review of the initial conception for the DHS in the Homeland Security Act suggested that the department’s original organization did not reflect these realities well. Additionally, since its creation, whether one looks at the department’s capacity to organize and mobilize a response to a catastrophic terrorist attack or at the international dimension of DHS programs, the department had been slow to overcome the obstacles it faced in becoming an effective 21st century national security instrument.

Fundamentally, a new threat environment requires a new approach to security. A nimble, highly adaptive adversary necessitates a bureaucracy that must also be flexible and responsive to a constantly changing threat. Experience with the creation of the Department of Defense reminds us that it takes only a few years for

bureaucracies to become entrenched. And thus we must attempt to correctly structure them at the beginning or live with the mistakes for a long time.

The proposals related to biodefense were developed by a task force with members from academia, research centers, the private sector, and Congress and chaired by homeland security experts at The Center for Strategic and International Studies and The Heritage Foundation. Based on analysis, seminars, an extensive literature search, and interviews, the task force developed 40 major recommendations for improving the oversight, organization, and operation of DHS.

The findings and recommendations of the task force can be found on CSIS' web site at: http://www.csis.org/media/csis/pubs/041213_dhsv2.pdf

The Need for National Leadership on Biopreparedness and Biodefense

One of the taskforce recommendations was for the government to clarify authorities and national leadership roles for biodefense by establishing and empowering a lead executive.

Today that need is still great. Despite a presidential directive² that provides a comprehensive framework³ to forge a national system to protect us against future biological attacks; and despite specific descriptions of roles and responsibilities for the multitude of federal agencies involved in bio-defense, the directive fails to resolve the largest shortcoming in our bio-defense strategy—lack of a single authoritative federal entity to ensure national leadership and coordination for biopreparedness and biodefense.

None of the federal entities discussed in the directive have overall responsibility across all aspects of bio-defense, and none has the mandate or authority to reconcile competing agendas and capabilities across the entire spectrum of federal resources or national interests. Without coordinated federal leadership, states lack measures to assess their own readiness plans, our national surveillance system devolves into a patchwork of state systems, surge capacity is limited and international coordination becomes ad hoc, agency by agency.

A key—and unique—mission of the Department of Homeland Security is leading national—not just federal—efforts to protect, prepare for and respond to possible attacks and other emergencies like the 9/11 terrorist attacks. National biodefense preparedness and response includes naturally occurring and deliberate attacks and requires the involvement of a wide range of Federal departments and agencies—the Department of Health and Human Services (HHS, which includes the Public Health Service, the Centers for Disease Control, and the National Institutes of Health), the U.S. Department of Agriculture (USDA), and the Department of Defense (DoD).

Until the recent adoption of a new Preparedness Directorate at the DHS, even within just the Department of Homeland Security, the range of departmental elements with some role in preparing for and responding to biological attacks is widespread. Referring in some cases below to their pre-Preparedness Directorate names, they include:

- (1) The DHS Emergency Preparedness & Response (EP&R) Directorate. This Directorate is primarily the Federal Emergency Management Agency (FEMA), but it also includes within it certain efforts to coordinate with state, local, and private entities on preparing for disasters, including terrorist attacks.
- (2) The Infrastructure Protection (IP) piece of the DHS Information Analysis and Infrastructure Protection (IAIP) Directorate. The job of IP is to identify critical infrastructure warranting protection, prioritize efforts, and work with state, local, and private entities to secure this infrastructure.
- (3) The DHS Office of State and Local Government Coordination and Preparedness (OSLGCP). This entity—the product of merging the Office of State and Local Coordination, and the Office of Domestic Preparedness—works with state and local governments on identifying needs, coordinating efforts, and doling out DHS grant money for critical infrastructure protection and preparedness.
- (4) The Office of Private Sector Liaison. This office has primarily been an ombudsman for private efforts to influence DHS policy in various areas, but it con-

²See “Biodefense for the 21st Century” at <http://www.whitehouse.gov/homeland/20040430.html>

³HSPD-10 describes four key elements of the president's strategy: bolstering our nation's threat awareness, which includes biological weapons-related intelligence, vulnerability assessments and anticipation of future threats; strengthening prevention and protection capabilities, which includes interdiction and critical-infrastructure protection; improving surveillance and detection, which includes attack warning and attribution; and expanding response and recovery capacity, which includes response planning, mass casualty care, risk communication, medical countermeasures and decontamination.

ceivably could be a forum for working with the private sector on critical infrastructure protection and preparedness for attacks.

(5) The Science and Technology Directorate Office of WMD Operations and Incident Management (WMDO-IM). This new office, within the S&T Directorate, is intended to provide rapid scientific and technical expertise and decision-making in response to WMD attacks and incidents.

(6) The Assistant Secretary for Plans, Programs, and Budgets develops the R&D agenda for biodefense countermeasures, which is executed by the Office of Research and Development and the Homeland Security Advanced Research Projects Agency.

The Secretary of Homeland Security, as the principal Federal official for domestic incident management, is responsible for coordinating domestic Federal operations to prepare for, respond to, and recover from biological weapons attacks and natural disasters. Nonetheless, the task force concluded that the ability of the DHS Secretary to lead in this regard was hampered not only by the absence of clear leadership in biodefense, but also by the fragmentation of key responsibilities both within and outside DHS, among a number of entities.

The task force recommended both a greater consolidation of authorities for biodefense and medical response to catastrophic terrorism to support a more efficient and coordinated federal response, and also consolidation of a number of preparedness functions that were fragmented across the department into one directorate. (These recommendations have now been adopted by the Department and supported by Congress.)

The Role of the New Chief Medical Officer

Following his second stage review,⁴ DHS Secretary Michael Chertoff consolidated all the Department's existing preparedness efforts—including planning, training, exercising and funding—into a single directorate led by an under secretary for preparedness. Further, as part of his consolidated preparedness team, he created the position of a chief medical officer within the preparedness directorate to be his principal advisor on medical preparedness and lead representative to coordinate with DHS federal partners and state governments.

The chief medical officer and his team, the Secretary has said, will have primary responsibility for working with HHS, Agriculture, and other departments in completing comprehensive plans for executing our responsibilities to prevent and mitigate biologically-based attacks on human health or on our food supply.

First, let me commend Secretary Chertoff and the Department for creating the position and those in Congress for supporting it. This is clearly much-needed and well-founded.

The question is what specific roles will the CMO play.

As I have described earlier, the new chief medical officer faces a number of challenges that will require urgent attention. I believe if you consider the breath of responsibilities, however, that his role should be more one of a *Chief Health Officer* than a medical officer, as he must help guide the Department in far more than medical advice, to include for example navigating health care systems, understanding disease surveillance, or advising on waste disposal, sanitation and decontamination.

As described by Secretary Chertoff, the role of Chief Medical Officer is primarily to provide much-needed leadership at the Department—and perhaps even more so across the federal government—to prepare for catastrophic health emergencies, and to provide guidance to leadership in times of crisis.

In particular, there are four specific areas where clear leadership is needed today:

1. *Leadership in Providing Sound Scientific, Medical, and Public Health Advice*
The chief medical officer should be the principle advisor to the secretary, providing scientific, public health, and medical advice.

While DHS has responsibility for preparedness and response to natural disasters, as well as biological, chemical, radiological, or nuclear weapon attacks—all of which would require a health care response—biological outbreaks, whether naturally occurring or deliberate, present a special case. Occurrences of outbreaks are highly variable and often unpredictable. They can originate from a diversity of pathogens; they can be naturally occurring or deliberate; they can crop up in cities of any size; and they can occur among peoples with wide-ranging customs, social habits and lifestyles. Each of these factors affect how a disease spreads, and thus, to the extent possible, must also figure into strategies to detect and halt the transmission of a disease.

⁴ See Secretary Chertoff remarks on second stage review at: http://www.dhs.gov/dhspublic/interapp/speech/speech_0255.xml

Similarly, strategies for controlling the spread of disease must rely on the medical countermeasures available, on the ability of our health care systems to provide services, and on the coordinated support of a number of federal, state, local, and private sector actors.

Decisions at DHS regarding preparedness and emergency response programs must be based at a minimum on expert scientific advice; the epidemiologic features of the disease; and knowledge of resources available for deployment.

2. Leadership in Developing Greater Situational Awareness

The chief medical officer should be the principle architect for providing the secretary with greater situational awareness of both biological threats (threats) and health care preparedness (vulnerabilities).

The speed at which a public health threat can be detected and characterized, and health care services and/ or medical countermeasures deployed is critically important. The faster and more effectively this is accomplished, the quicker response and containment efforts can be employed, resulting in fewer casualties.

Situational awareness, both of emerging biological threats and of health care readiness, requires timely, complete actionable information—both of our national and the international health disposition, and of the state of health care preparedness (e.g., countermeasure inventories, protective gear, medical and isolation services available, plans, etc). Greater situational awareness will allow for better operational decision-making that is critical for providing early-warning, deploying assets and protecting public health.

This capability, which largely does not exist even within a public health community, will be critical to effective management of a terrorist biological attack or a natural disease outbreak whose spread, taking advantage of modern transportation systems, can be much more rapid than previously in the past.

3. Leadership in Integrating Federal, State, Local, and Private Sector Elements.

The chief medical officer should provide a focal point in the federal government for development and implementation of a national strategy to protect against biological events.

Homeland Security Presidential Directive-10 (HSPD-10) rightly says that “defending against biological weapons attacks requires us to further sharpen our policy, coordination, and planning to integrate the bio-defense capabilities that reside at the Federal, state, local, and private sector levels.” Who today is ultimately in charge of developing and implementing the national strategy? Who makes sure that all of the diverse components of bio-defense—from threat analysis to research and development of countermeasures, to crisis detection, response and recovery—are fully integrated? A clearly empowered federal authority to provide national leadership and a focal point on the spectrum of issues related to securing America against biological events is needed today.

4. Leadership Supporting Public Education/Public Preparedness

The chief medical officer, in close coordination with HHS officials, should establish and lead outreach efforts to educate citizens on steps to prepare for and protect their health during catastrophic health emergencies.

Public action in anticipation of and in response to a health crisis can help mitigate casualties and speed recovery, or it can cause panic and hasten the spread of disease. Today, the public has little to no knowledge of when it is appropriate to shelter-in-place versus evacuate. They have equally little knowledge of the steps they can take to reduce the likelihood of exposure to disease. The public must be engaged as a partner, particularly when it comes to protecting the public health. Individuals empowered with the knowledge to enhance their safety and help limit the spread of disease, can reduce the need for admittedly scarce resources to be required for providing health care to them, when and if an outbreak occurs.

The Special Case of Avian Flu

The increased concern and possible risk of a pandemic flu provides a special case that urgently calls for leadership in preparing for biological events.

We have witnessed three pandemic flu epidemics over the last century, with the 1918 Spanish flu pandemic being the most severe, causing over 500,000 deaths in the United States and more than 20,000,000 deaths worldwide. Given the disease patterns, historical data indicate that a new pandemic is likely in the near term.

Recent studies suggest that a rapidly spreading strain of avian influenza, which has become endemic in wild birds and poultry populations in some countries, holds great potential of mutating to cause severe disease in humans and possibly the next pandemic flu outbreak.

In the past year, 8 nations—the Republic of Korea, Thailand, China, Vietnam, Laos, Indonesia, and Japan—experienced outbreaks of avian flu (H5N1) among

poultry flocks. More recently Croatia, Russia, and Greece have also started to see cases of avian flu in birds and poultry.

There have also been over 100 confirmed human cases reported of this strain of avian influenza (also H5N1), 60 of which resulted in death. Of these cases, 91 were in Vietnam, 17 in Thailand (including one possible human-to-human infection), 4 in Cambodia, and 4 in Indonesia. With no natural immunity to this strain of influenza, which differs from seasonal strains of influenza that have traditionally infected human populations, humans are vulnerable to a possible-mutated version of this virus that would be capable of human-to-human transmission.

By any standard, we are not prepared should a pandemic flu emerge today.

Vaccines needed to protect Americans would take a minimum of six months—and likely longer—to develop. Small stockpiles of anti-viral medication exist, but not in sufficient quantities to protect the vast numbers of people likely to get sick; and we lack a way of urgently increasing production in a timely manner. Moreover, our cities, states, our nation's healthcare delivery systems, hospitals, and managed care organizations have yet to put together the plans for handling the dramatic increase in patients, for determining priorities for scarce resources and augmenting those for which demand will vastly exceed supply, or for ensuring the delivery of services to the vast numbers of individuals who may be affected.

Without vaccines or medical countermeasures, the next best option—perhaps the only option—is to put in place disease exposure controls, to reduce as much as possible the likelihood that individuals will pass the disease from one to another.

Disease Exposure Control (DEC) is the process by which the spread of disease is minimized by limiting contact between uninfected individuals and other individuals who are potential spreaders⁵ of a contagious disease. DEC programs could help confront possible large-scale outbreaks of contagious diseases, in particular when vaccines or antivirals do not exist, are unavailable, or are insufficient to halt a fast-spreading disease.

DEC programs rely on the use of a number of tools—including infection control, isolation, community restrictions, sheltering-in-place, and even quarantine—that can slow down or perhaps stop the spread of a fast-moving, contagious and potentially deadly disease, in the absence of sufficient medical countermeasures.

Although vaccines and medical countermeasures are much needed, to date, unfortunately, too large a fraction of our national attention has been placed on developing them, and too little on putting into place those disease exposure control programs that might be our only recourse for slowing a pandemic flu.

To be sure, we do need medical supplies, vaccines, and antiviral drugs. We also need to enhance disease surveillance networks for early warning. And we need plans to prioritize, move, and dispense medical countermeasures as well.

But in their absence, and with a possible pandemic on the horizon, the chief medical officer's yet-to-be defined role could be vital in helping delineate these additional tools and protecting public health should a pandemic materialize.

National leadership is needed now.

CSIS is continuing to explore these important issues including how to operationalize disease exposure controls.⁶ We would be happy to work with the Committee as we go forward.

Thank you.

Mr. ROGERS. That is great. All three of those were very interesting, thoughtful, and provocative statements, and I am looking forward to the Q&A interchange after we go vote.

My expectation is that it will be approximately 4:15 when we come back. At this time we will stand in recess subject to the call of the Chair.

[Recess.]

Mr. ROGERS. I would like to call the hearing back to order and start off with the questions.

I really was impressed with those statements. They are better than usual, but particularly provocative. Dr. Lowell, in particular,

⁵The term “potential spreaders” refers to individuals who either may have been exposed, are incubating, subclinically affected, or are a carrier of a disease. It also includes individuals with active disease.

⁶For more information, see CSIS Homeland Security Program, Current and Ongoing Projects, Disease Exposure Control at http://csis.org/index.php?option=com_csis_progj&task=view&id=294

when you were describing this new position of readiness, as opposed to a CMO, tell me more about how you see that being structured. Just kind of help me get a mental picture of what you are—the leadership structure of that.

Dr. LOWELL. Thank you, Mr. Chairman.

I had proposed four divisions within this readiness office, one dealing with intelligence, to make sure that we are consolidating all of the intelligence products from the different intelligence agencies that deal with medical intelligence, so that we can both develop policy and plans—

Mr. ROGERS. Where is that intelligence component currently?

Dr. LOWELL. It is spread out in a variety of different places, in U.S. Government. It is in DAA. DHS has some at Fort Detrick and MPACT. It is CIA. There are a variety of different components to it. DHS also has, at least when I was there, it was in the DIA IPNIA, but it was disjointed.

Mr. ROGERS. Okay. In addition to the intelligence component, what else? What would be the other three? And then tell me, would they answer to the CMO?

Dr. LOWELL. Yes. All of the medical and health assets, in my opinion, in DHS should be consolidated in one office, reporting to one person.

Mr. ROGERS. Would anything be pulled from HHS?

Dr. LOWELL. That is a good question. I think one thing I would probably recommend is the stockpile—right now it is in the CDC, and I am not sure that is necessarily the best place for it. It probably deserves a separate answer. But right now that would be the main thing I would move from HHS to DHS is the stockpile and have that associated with the person who I think should run the Federal medical response, which would be the DHS Chief Medical Officer.

The second division in DHS I think the CMO should be responsible for is preparedness, and that would include—medical preparedness—that would include a variety of different programs that currently organically exist in DHS now, such as MRRS, Noble—you talked about before, the program called CONTOMS, which is the Tactical Medical Training Center for the United States, which used to be at DOD; now it is in BTS in Immigration and Customs Enforcement is where it is located now—and also to provide the reachback to State and local to make sure that the Federal medical response is integrated as part of the response to medical events of national significance.

Mr. ROGERS. Now, as I understand it, before you go to the third and fourth components, what you are describing is a readiness department that would answer directly to the Secretary and would not be under the Preparedness Directorate.

Dr. LOWELL. Yes, sir. To me that makes the most sense. I mean, part of the—the primary mission I think for DHS is to protect people. And in an event, whether it is from a bad guy or Mother Nature, people are going to get hurt or they may die, so I think that the medical and health primacy has to have the appropriate place in the organizational structure.

The third piece is perhaps the most important. That is the Federal medical response. Right now the Federal medical response is

the Natural Disaster Medical System, which is a 20-year old system that was originally designed for natural disasters, essentially all volunteer. Very few full-time people work at NDMS. And the people that have been involved in NDMS, the doctors, nurses and paramedics, and people who have been volunteering their time for all these years, are incredibly dedicated Americans and I think deserve a huge amount of praise. However, it is not enough; it is nowhere near enough. The size of it really is based on the number of people that have volunteered to date. I mean, it is not how I think we should be building our Federal medical response. And it shouldn't be all volunteer. I mean the size of the Federal medical response should be based on what missions we are asking it to do.

So if the goal is to be able to take care of, as some of the scenarios have been developed, 100,000 people concomitantly hurt in four different geographic areas for a month, 2 months, or 3 months, that is the mission. And then we have our planners say this is what we need to accomplish that mission. We need this number of doctors, nurses, paramedics, this number of equipment, this number of logistics, people to get stuff to and from the place, and that has to be a guarantee that it works, it can't—we cannot just rely on a volunteer force. No other piece in the U.S. Government that is so important relies solely on volunteers.

And then the fourth division is the occupational health and safety piece. DHS has 180,000 people in it. It doesn't really have a unified occupational health and safety core in one office. And there are a lot of people operating, some tactically operating in a variety of different conditions where they need or may need medical and health support, whether they are deployed in a foreign country, they are working at the borders, or trying to get a flu vaccine. Which is what I was dealing with last year. I mean, all 180,000 people are very important to the country, and all needed a flu vaccine, but we didn't have enough flu vaccine. So we had no real single point of contact to say this is what the 180,000 people that are protecting our country need to have in order to get their job done.

Mr. ROGERS. My time is up, but I am looking forward to coming back around.

The Chair recognizes the Ranking Member, Mr. Meek.

Mr. MEEK. I want to thank all of you for your testimony, and we do have it, and I had an opportunity to take a look at it. And you got your testimony in before the Department, so if there is anything to commend you on, that is one of them.

We have had three top-off exercises that have been sponsored by the Department of Homeland Security. One simulated an airborne release of the plague in Denver. Another top-off took place, a dirty bomb in Seattle Washington. There was a plague attack also in Chicago. And I can tell you that what these top-off programs, they are sponsored by the Department of Homeland Security, of course. They ask the Center for Disease Control to participate, they ask HHS to participate. But this is when we rehearse how we are going to respond.

But better yet, when you look at the National Response Program and also a plan, and you look at some statutory language, it is not necessarily putting the Department of Homeland Security in the lead. And I don't know if you all have any recommendations on

what we should do legislatively to clear some of this up, quote unquote, streamline some real line of responsibility. Because I believe it is going to be like the baseball game last night; the ball pops up in the air and the catcher thinks that the infielder has—you understand it, the short stop has it. And we can't afford that, especially with these threats that are out there as it relates to bioterrorism.

Dr. LOWELL. I will take the first crack at that one.

I agree 100 percent. I think we have—at least my view of it, there is conflict as to who is in charge, at least with regard to the medical and health component.

The Homeland Security Act of 2002 transferred over the Natural Disaster Medical System, the stockpile MMRS programs, and all of the responsibilities and authorities related to mass casualty care from the Office of the Assistant Secretary for Public Health and Emergency Preparedness from HHS to DHS. So I think in my view, the sense of Congress was that DHS was supposed to drive the medical and health response to the events of national significance. That is why the law said stuff was supposed to move, and the authorities and responsibilities were supposed to move. I am not sure that everything that was supposed to move did move, and I don't know if Congress has ever taken a look at that. But that might be something that would be worth doing, to make sure that all of the things that were supposed to transfer over in the Homeland Security Act of 2002 did.

Mr. MEEK. Doctor, do you have any recommendations on what was left that should come over to the Department of Homeland Security? And it can be the same expertise. I mean, obviously you are changing the letterhead, but if it comes down to responding to a Homeland Security bioterrorism attack, folks don't—we need to not only know who to call, but know who is responsible.

Dr. LOWELL. Well, I agree 100 percent. I think there is conflict because EFS-8 of the National Response Plan says that HHS is responsible. So I think there is conflict between the responsibilities and authorities that transferred over in the Homeland Security Act of 2002 and ESF-8 of the National Response Plan.

Also, HS PD-10, Homeland Security Presidential Directive 10, also says that HHS is responsible or has the lead for medical and health response of mass care. That also I think is in conflict with the Homeland Security Act of 2002, at least the spirit of what Congress—at least my interpretation of what the spirit of Congress wanted. So that I think those need to get reconciled.

I think getting back to your original question, I think a very important thing to do is figure out who is in charge, because you have asked several times in this hearing—it is not in my mind at least, and I think in many others, clear who is in charge. And if it was to me, I would make the CMO in charge. I would make that person the Operational Surgeon General of the United States and leave public health issues to the Public Health Surgeon General: Lead paint, stop smoking, lose weight; and have the medical response to events of national significance the responsibility of the DHS CMO.

Mr. HEYMAN. Just a couple of points to follow up on that question. One is that the CMO has got to be broader than just medical. It is health—as you heard from the testimony this morning, you have got health care systems involved, you have got disease sur-

veillance, you have got agriculture and food concerns. When we are talking about crisis in America and homeland security and all things bio, it is much broader—waste disposal, sanitation, decontamination—all of those things need to be factored into it, so it is not just medical. And maybe he or she should be responsible for operational management during a crisis.

I would recommend that—if you look at HSPD–10, it distributes the responsibilities and roles across the government, but it doesn't tell you who is in charge of managing strategy, reiterating strategy or making sure it is being implemented, and I think you need a higher role for that. And I am not sure it is CMO, but if it could be anybody, perhaps him.

Finally, I will just make a recommendation to Congress, this committee, other committees, Homeland Security and health committees could join together, perhaps Agriculture, and have a joint hearing with USDA, HHS, DHS and ask those questions about who is in charge and walk them through the different scenarios you are concerned about. I would like to see those witnesses clarify that in front of you.

Mr. MOORE. Mr. Meek, my position on this is simply that I echo my copanelists here. It is unclear, it is ambiguous I guess is the way I would put it. And the expectation is things will happen, and when the expectations aren't met, aren't managed, in essence chaos ensues.

One of my recommendations is that you form or compel these agencies to sit down and work through when are you in charge, what are the specific timelines and trip wires that will have to be navigated for these things to occur.

You run the risk, of course, if you lump everything into DHS, you have one Federal agency and that's all you have got. You have to go through some type of unified command structure like you have in an incident command system when you roll up to one organization being in charge, how do the other organizations statutorily roll in and what their roles and responsibilities are.

One of the difficulties you have I think before you, one of the challenges—I guess I better say it—is this: Homeland Security understands that it has got a mission to protect America from terrorism and bad things. Agriculture has a mission to regulate and ensure safety of food and all these other kinds of things, and terrorism as well. So you have to, I believe, establish a clear mandate of what is the anticipation, what are the expectations, what is the guidance from Congress as to how they are supposed to apply funds and what results you want.

The saying in science is the less the data, the more it is speculation. If you give them money and expect them to do good things, you need to have a way to check that. One of the ways I think is—and one of my complaints, I guess, with the top-off process, it is very valuable but the frequency was too infrequent. It happens episodically every 2 years. We need to be measuring more effectively on a smaller scale, more rapidly, so that you have the ability to adjust course more often to meet the needs. Otherwise, what it turns into is, in essence, a large dog-and-pony show, that everybody doesn't want to look bad and they try to massage the answer, as opposed to what is exactly going on and where do we need to step

in to fix the problems. More non-attributional and more action-oriented, that would be my point.

Dr. LOWELL. Thank you, sir. There are, I think, two other things that I think should be discussed on the topic of who is in charge. When you have two different agencies that are in charge, parallel systems will be built. And right now parallel systems are being built both at DHS and HHS, and I think we run the risk of creating interoperability issues within U.S. Government on our watch, which I think would not be a good thing and certainly would not be in the best interest of our country.

And the second point is, I think it is very important to decide up front who is going to talk to our country, who is going to be the person that does the risk communication, both before the event, as well as during and after the event; because I think adlibbing that also would be a bad thing. Having three or four different spokespersons in various departments in the U.S. Government, which may or may not be giving the same message, I think could be disastrous.

Mr. ROGERS. I would like to go back and talk about who is in charge of vaccines. You made reference to it a few minutes ago. Who do you think should be—I would ask each one of you to give me your answer to this—who should be in charge of making sure that we have adequate stockpiles of vaccines and other medications that would be necessary in the event of a pandemic outbreak? Should that person be over at HHS, should that person be at DHS or at the White House, or some other place? Dr. Heyman, if you will start.

Mr. HEYMAN. The question of what to stockpile should be a decision that is made amongst a number of agencies, so there should be a Federal task force of sorts that is responsible for making that judgment.

Who owns and operates the stockpile, in my opinion, should be at this point now DHS. The Department, because the stockpile would be used for dealing with catastrophic events perhaps or response to large-scale events like a hurricane, stockpiles today can include things like bandages and such. And since that is largely a DHS or FEMA response requirement, I think it should reside there.

Mr. ROGERS. Dr. Lowell.

Dr. LOWELL. I would advocate consolidating all this in one department and putting it in the same place that has the intelligence, just figure out what we should buy, and then having the detectors out there to tell us where in real time we should be.

Mr. ROGERS. I am interested in who should own it. Who should be the person that is responsible for making sure that if we do have a task force that decides we need X, Y, and Z vaccines or medications, that it is done, and that person is who you roll up to and say where are they at this time?

Dr. LOWELL. I am not sure of the answer to that. I think it makes good sense to put it in the same department that is making—that owns the primacy for the determination piece. And I think that would be DHS, but I am not exactly sure.

Mr. ROGERS. Okay. Mr. Moore.

Mr. MOORE. Mr. Chairman, I would advocate that you have, in essence, a single belly button inside of DHS that would probably have to be, as we talked about today, the CMO. But the CMO can't be buried down the organization. That individual has to have the ability to have the authority and carry the weight and execute.

Mr. ROGERS. I was surprised to hear it from Dr. Runge, but you may not have been surprised, when he said he has nothing to do with whether or not we have enough vaccines or what we buy. Were you already aware of that, and if not—

Mr. MOORE. I was aware of it, sir. It is disconcerting is the way I would put it, because we all have a role in this, and we need to determine how this is going to function. I mean, obviously it affects everyone in this room because if we have a pandemic, this individual is going to have enormous responsibilities. And to use Mr. Meek's analogy, we don't want the pop-up to be dropped because we are assuming the other fellow or other individual has the beat on it.

The other thing I would like to point out about strategic stockpiles, the concern that I found following Katrina is the stockpile isn't a stockpile. I assumed there were warehouses of trucks ready to roll with materials available at a moment's notice. Apparently there have been decisions made, as I understand it—perhaps Dr. Lowell will have better information than I—but the understanding that I have is the stockpile is basically 10 percent loading and the rest of it is vendor inventory management, we-will-get-to-you-when-we-get-to-you kind of thing, as opposed to being at a moment's notice.

In response to Hurricane Katrina, there were calls for the strategic stockpile to be released, and they were preparing for warehouse loads of materials showing up, and what they got were two trucks, and the rest of it was coming days later.

I would argue, sir, that having a single person involved and then you go exercise and hold that person accountable for the results of those exercises is probably the easiest way to understand if we are prepared or not. Right now it is so spread out that you are not going to get any leverage. One person will say it is Dr. Lowell's, the other will say it is so-and-so's responsibility. It needs to be unified in one location, sir, if we are going to have any kind of positive reaction in a rapid manner.

Mr. ROGERS. And your initial thought is that that person should be in DHS and may or may not be the CMO?

Mr. MOORE. Yes, sir. That is something this committee will have to discuss. You need a body, whether that is a CMO, or something above the CMO or Assistant Secretary or Deputy Secretary, I don't know. That is going to require some good thought. However, it needs to be a single body.

In the military sense, where I came from, sir, you had to know that you work for one individual. You had to know that when he told you to do something or when she told you to do something, it was an order, it would be carried out. What concerns me, quite frankly, is if the stockpile is in one agency's arms and they are responsible for preparing and maintaining it, and yet I have got the ability over here to pull the trigger to deploy it, what I am anticipating they have done may not have occurred, and yet I have no

control over their actions. And so that is to me, that is a recipe for heartbreak.

Mr. ROGERS. One of my concerns after this morning's testimony or—early afternoon's testimony—when I was talking with Dr. Runge about it—which is why I was particularly interested in Dr. Lowell's suggestion—I was talking to him about who is responsible for coordinating or who has authority over these different department heads and functions because in Secretary Chertoff's letter, it says that the CMO would be responsible for coordinating these responsibilities. And when I read all these directives that outline these different responsibilities, it was my impression that the CMO would be the head guy that would be pulling resources within HHS, but from hearing Dr. Runge, that is not the case. And it leads to what you referenced, which is this ambiguity out there.

And what I can't stand about many of the circumstances we find ourselves in, in Washington is when there is one guy saying oh, you have to go to HHS for that, and then you go to HHS and they say, you have to go to DHS for that. It always allows finger-pointing, and that is why I am so interested in seeing a single individual. When it comes to this purview, we have got one person who is in charge and there is no finger-pointing. The finger is pointed at that person.

So what you have suggested I think has some merit, and I know we will be paying some more attention to it.

But before I let you all go, I wanted to go back to something that Mr. Moore mentioned earlier, and that is this issue of losing 50 percent of our veterinarians. Over what time period was that?

Mr. MOORE. Sir, within the next—before fiscal year 2007, you are scheduled to lose—well, 50 percent of the Federal workforce in total, sir, is eligible to retire. And most of your veterinary population is older than the minimum retirement age. And the forecasts that I have seen range anywhere from 50 to 60 percent of your field veterinary force that is out there on the preharvest side—that is the Animal Health Inspection Service component—is scheduled to go away. It is alarming because of the skill.

You know, avian flu is new to a lot of members of this committee perhaps because of its topical nature in the news, but avian influenza is something that the agricultural community has dealt with for 25 years on a recurring basis because it occurs naturally in fowl and poultry. It becomes alarming from the health standpoint because it can sometimes jump over to humans and mutate. And yet our youngest foreign animal disease diagnostician, those that are specially trained to deal with these things, is 11 months and change away from retiring. And that is hard thought experience, sir. If you want to ask me what keeps me up at night, that is what scares me.

Mr. ROGERS. What is your proposed remedy?

Mr. MOORE. Sir, I think there are two or three things that need to be done. One is we need to engage the—there are a couple of levers that this committee may have some ability to influence. One is that all veterinarians that graduate from veterinarian school, approximately 3,500 to 4,000 each year from the 28 veterinary schools, almost 95 percent of them obtain a Federal health accreditation certification, basically the ability to write health certificates

to move animals across country, across State lines around the world. Right now, that is a lifetime accreditation. I know the USDA is looking very diligently at how to restructure that to make it a recurring or a renewable kind of a process.

One of the things that needs to happen is these schools need to be brought into the training focus to prepare these veterinarians to deal with all sorts of calamity. So that is one way you can do it. You can tie it to their ability to get a health certificate, ability to write that health certificate; they have to have these kinds of training. That is one.

Two, there needs to be a dedicated program to capture best practices from these individuals. We have learned a lot. Why reinvent the wheel and have a steep learning curve every time we go to resolve the problem?

The third thing, sir, is we need to look at how we are going to incentivize and try to attract the best and brightest. Right now statistically within the veterinary community, 85 to 89 percent of all veterinary graduates go into small animal practice. It is lucrative, it is a business, we all understand that. Therefore, public health or public service kinds of roles are diminishing.

We are requiring these people—we need these people, so we are going to have to come up with a way to incentivize or absolve a school debt or something to try to get them into these roles that we need them to be in.

Quite frankly, Mr. Chairman, my concern is that the window of vulnerability is open. With these retirement waves, that sash will rise higher and the actions, I think, of this committee are going to determine whether that sash remains in an elevated state for 2 or 5 or 10 years. And with that, sir, will go our vulnerability to basically all infectious disease agents.

If you look at the category A, B, and C agents that the CDC worries about, 75 percent of those are zoonotic, meaning they can reside in animals and humans. We have to look at this as one medicine. That is why I really endorse what Dr. Lowell has espoused here today, because the way to do that is to unify the command structure, the command structure that must respond. And that is DHS, as this committee and Congress has mandated.

So that is what keeps me awake at night. So those would be the off-the-cuff suggestions that I would recommend.

Mr. ROGERS. Okay. And I appreciate that. What I would ask is, is there something that I didn't ask about or one of the Members didn't ask about that you really want to make sure is on the record before we adjourn? Any of you?

Dr. LOWELL.

Dr. LOWELL. I think as a country we need to come to grips with the fact that we do not have a rigorous, robust Federal medical response to events of national significance, and our reliance on volunteers isn't going to get us where we need to get. And I think we need to rapidly look at building one, building a professional medical Federal response system. It could be mirrored after one of the existing ones that DOD has, the Medical National Guard or Air Medical National Guard. But we need to have organic medical assets that are under contract to the government, and when we call them we know that they will come, and that they are not volun-

teers. And this is going to take a substantial amount of resources to get us there. But we are so far away from where we need to be.

And we deployed, in Katrina, all of our assets. And the actual number of people that were significantly hurt in Katrina—while many, many people were taken care of—but the number of actual people that were hurt by the storm, relatively small compared to some of the scenarios that have been planned. And it is likely—

Mr. ROGERS. When you say scenarios that have been planned, are you talking about pandemic or bioterrorist attack?

Dr. LOWELL. I am talking about the planning scenarios that came out of the White House Security Council, the 15 planning scenarios.

And the number of people that were hurt and taken care of in Katrina would likely also have to be dealt with in many of those planning scenarios. But the delta of people that are hurt either in an explosion or nuclear device or some sort of fire, earthquake or something, would be substantial. And we threw everything we had as a country at Katrina, so there is nothing left.

So that what I would propose is some sort of uniformed medical corps, a weekend a month, 2 weeks a year, which would include both full-time as well as Reservists as well as volunteers. But we cannot as a country rely solely on the volunteer system that was designed 20 years ago to deal only with natural disasters. Now we deploy for national special security events, and we have all kinds of technological things. And we are now starting to recognize that Mother Nature may be a lot worse in terms of its ability to injure people than we had originally planned 20 years ago.

Mr. ROGERS. Thank you. Mr. Heyman, Mr. Moore.

Mr. MOORE. Mr. Chairman, one thing I think that Dr. Runge talked about was the ability for public information, what the public should do.

One of the things I think that has to be broached, and I don't know what branch of the government will do that, what leader will do that, but the Federal Government is not a panacea. We are not going to have instantaneous response to disasters, particularly if they are bicoastal; and burning like wildfire, we are going to have a lag period. My advice to local responders has been plan; plan on the fact that you will not have Federal assets available to you. You must be able to respond with what you have for an extended period of time.

Subsequently, American citizens need to understand it is their responsibility as well to be prepared, not alarming, but be prepared. We have to do a better job at communicating that. Telling somebody on the eve of the storm that they need to have 3 or 4 days' worth of food and water. It checks the box, but it doesn't meet the moral requirement of leadership in my opinion. If we have something that erupts within our agriculture sector, our leadership of this country may be faced with the fact we may have to shut down large portions of interstate commerce just to get our arms around some diseases that are burning.

As a result, sir, you know the average city in the United States has less than 5 days' food supply on hand. The world's largest purchaser of food right now is Wal-Mart. If we are relying on this system to be effective and have continuity of operations at every com-

ponent of our civilized society, we need to tie our citizens into this and give them the no-kidding advice of what they need to do, not just duct tape, but here is how you build a kit, this is why you need a kit, this is how you keep an inventory; because otherwise we are going to see chaos ensue if we have a problem. And we have seen parts of that. And probably the meltdown point, Dr. Lowell has probably seen it better than anybody else, is probably 48 hours before we see society become unglued.

So we need to have this whole piece tied together. So that, I think, is the public campaign message that needs to get out while we are busily trying to repair and fix and build what we need to have, what we would like to have from the Federal response side.

Mr. ROGERS. Well, I thank all of you. This have been some very informative presentations and Q and A, and I really appreciate that.

I do want to remind you that the record is kept open for 10 days. Because of all the markups going on, Members are going to have questions I know they will submit to you. I would ask you to respond to those in writing in a timely manner.

Also, I would like—I am going to ask for unanimous consent—I know I am going to get it—to include in the record a statement from Auburn University that discusses Auburn's work on a computer program model to do what you were just talking about: to allow people to go through exercises, real-time exercises to find out if we have the ability to respond medically and in other ways to whatever the disaster might be.

So, since I did get unanimous consent, that is now in the record. [The information follows:]

FOR THE RECORD

PREPARED STATEMENT OF DR. MICHAEL MORIARTY, VICE PRESIDENT OF RESEARCH AUBURN UNIVERSITY

Mr. Chairman, Members of the Committee, thank you for the opportunity to present testimony on vaccine technology that can prevent the spread of avian influenza in birds and the potential impact of avian influenza on public health and the U.S. economy.

Vaxin Inc, with Auburn University, has developed vaccine technology that allows it to produce influenza vaccines in large-scale cell culture and can rapidly address genetic shifts in influenza viruses including avian influenza. Working with Auburn University, this technology has been shown to elicit specific antibody responses to chickens *in ovo* and other routes, with the development of very high serological titers. Once this vaccine has been demonstrated to be safe and efficacious, it can be used to prevent avian influenza in the poultry industry. Such a vaccine can be expected to interfere with the potential spread of avian influenza strains into man, having a significant impact on public health. The effect on the U.S. Poultry industry would preserve both domestic and foreign markets.

Introduction

Recent reports from Southeast Asia concerning the transmission of avian influenza from birds to man have caused alarm in both the public health circles and in the poultry industry. Although the transmission rate of avian influenza is very low, the virus is highly pathogenic in man. The number of deaths has been few (108) while the mortality is extremely high at over 50%. There is a public health concern that through genetic reassortment between avian and human influenza strains, this virus may acquire the genetic potential of infectivity (spreading) from man to man, raising concerns about a potential pandemic that would equal or exceed the flu pandemic of 1917-18 that killed from 50 to 100 million people world wide.

In 1997, an outbreak of H5N1 avian influenza in people in Hong Kong caused alarm because people did not have immunity to this virus and appropriate vaccines were not available. This outbreak led to fears that the control of an H5N1 influenza

virus pandemic would be difficult to maintain by quarantine if the virus evolved to be transmitted from chickens to man and from man to man. Prevention of infection by immunization with vaccines prior to virus exposure is highly desirable—for both man and chickens. Current methods of preparing conventional inactivated vaccines against infections in man have serious limitations. Both live and killed vaccines for chickens also have significant drawbacks.

This avian influenza virus (H5N1) strain has long plagued the poultry industry in various countries. In the USA, outbreaks in chickens have been traditionally addressed by test and slaughter methods. Once the disease avian influenza was diagnosed, federal officials moved in, quarantined the area, and slaughtered all of the poultry within a given radius of the initial infection. This eradication procedure has cost U.S. taxpayers hundreds of millions of dollars in the past two decades.

Vaccination has not been attempted in large measure because use of existing killed avian influenza vaccines makes diagnosis of infected birds difficult. This lack of differentiation interferes with eradication efforts. The vaccine contains the same antigens as the infective virus so that an infected bird cannot be differentiated serologically from a vaccinated bird. Live recombinant vaccines are based on a natural vector (fowl pox) to which the egg laying chickens are immune and maternal antibodies interfere with this vaccine in newly hatched chicks.

Almost all birds are susceptible to avian influenza. Migratory birds are the chief carriers and spreaders of the infection. It is imperative that all reasonable means of preventing the establishment of this disease or its spread in the USA be pursued.

Significant Issues

Homeland Security has the charge to protect the United States against unwanted foreign invaders—and that includes biological invasion. The economic power of the poultry industry is based in the Southeastern United States. This industry addresses domestic production, use, and broiler export markets. According to the Economic Research Service of the USDA (current web-site, updated Oct. 18, 2005) the retail equivalent of the broiler industry in the US was \$43 billion in 2004. The top five producing States are all in the Southeast; these are Georgia, Arkansas, Alabama, Mississippi and North Carolina.

Without proper control or prevention, an outbreak of avian influenza in these States would be an economic disaster to the broiler industry, while raising the possibility of transmission to man causing pandemic influenza.

The Technology

Conventional flu vaccine technology: Most influenza vaccines require that the influenza virus be adapted to grow in eggs. Once that adaptation has occurred, the virus is propagated in embryonated eggs. Fertile eggs are incubated for about 10 days, then the virus is injected into the egg. The virus is allowed to propagate for 3 days, after which the embryos are killed and the virus harvested. One dose of vaccine requires approximately one egg. Sometimes the virus is too pathogenic and virulent and cannot be adapted to eggs. It kills the embryonating eggs before the virus can be propagated. Outbreaks of avian influenza in the chickens producing the eggs for vaccine production could significantly limit the availability of influenza vaccine for humans in any given year.

Vaxin's technology: This technology has all the features needed for rapid production of a safe and efficacious avian influenza vaccine. The vaccines produced are non-replicating; impart an immune profile that allows the vaccinated bird to be differentiated from an infected bird; manufactured in tissue culture in 3 days; and can be administered by various routes. Vaxin has developed a rapid method of making recombinant constructs using a proprietary technology that allow recombination of the selected gene(s) taken from the influenza virus. To produce non-replicating vectored vaccines usually takes several months of selective recombination to obtain the recombinant virus that can be used as the vaccine. Vaxin can do this in one month.

The novel aspect of this application to birds is that the vector is a human viral strain of adenovirus. The tissue culture cells upon which the virus is replicated during manufacturing are genetically engineered human cells that allow the virus to replicate in a defective manner so that it cannot be transmitted among vaccinates nor can it contaminate the environment. The gene inserted into the vector is a single gene, the hemagglutinin gene (HA) from the avian influenza strain H5N1.

Auburn University has demonstrated that this non-replicating adenovirus vaccine can be administered to chickens via a variety of routes, resulting in antibody titers. The data presented in this paper focus on the injection of the vaccine into the embryonating eggs, resulting in immunity to the newly hatched bird. Serological data obtained from birds vaccinated *in ovo* were derived by the USDA Southeastern Poultry Laboratory in Athens, Georgia from serum submitted by Auburn University.

Experimental Techniques and Results

Adenovirus Recombinant Construction was performed in the Vaxin Laboratory using rapid methods for adenovirus recombination.

Techniques

Summary of Results: Preliminary results using the replication-defective adenoviral-vectored influenza vaccine containing the human influenza virus hemagglutinin gene by topical delivery have demonstrated protection against a lethal influenza virus challenge in mice, and antibody response in chickens, rabbits, monkeys and man.

Advantages of this novel replication defective adenovirus influenza vaccine containing the avian influenza hemagglutinin in chickens include the feasibility for large-scale administration; the fact that vaccinal immunity can be differentiated from that of an infected bird; and that the vaccine will not replicate in the bird.

Results—Preliminary Studies—Using Vectored Influenza Vaccine Designed for Man

Trial 1: 100 μ l of the construct (1.3 x 10⁷ pfu/ml) including the H1 hemagglutinin gene of the human influenza strain (A/PR/8/34) (H1N1) was administered into nine 2-year-old hens via the nasal and ocular route.

Sera obtained at 13 days post inoculation showed two hens with hemagglutination inhibition (HI) titers of 1:16 and 1:8 against human influenza strain A/PR/8/34. Remaining hens maintained an antibody negative status.

Trial 2: A construct containing the H3 gene of human influenza strain A/Panama/2007/99 (H3N2) was inoculated into three 4-week-old chickens via the intramuscular route.

All three chickens seroconverted achieving HI titers of **1:512**.

Trial 3: The same Ad-H3 construct was inoculated *in ovo* at days 10 and 18 of incubation. Hatched chicks were bled at day 15 of age and tested for seroconversion.

All chickens showed HI titers between **1:8 and 1:16** against A/Panama/2007/99.

Results—Avian Influenza Studies

The HA gene of avian influenza strain A/Turkey/Wisconsin68 (H5N9) (TK/WI/68) (genes kindly provided by Dr. D. Suarez, USDA SPRL) was inserted into the adenovirus vector. The recombinant vaccine was manufactured at Vaxin and sent to Auburn University for testing.

The following inoculation or vaccinations were administered into eggs that were being incubated. Serological titers were determined 28 days after the chickens had hatched.

Group 1—in *ovo* vaccination at day 10 of incubation

In this group of newly hatched chickens, a single vaccination *in ovo* resulted in seroconversion in all of the birds (12) with 11 of the 12 showing high titers. The mean titer for this group was between 4 and 5 log 2. The sera from which this data was obtained were sent to the USDA Southeastern Poultry Laboratory for analysis in order to obtain impartial results. It was surprising that a single inoculation of a recombinant human adenovirus containing the gene encoding the hemagglutinin gene from the avian influenza strain H5N9 could transfect the tissues of the chicken, producing sufficient antigen to elicit such a strong immune response, especially when inoculated at such an early stage of embryonation.

Group 2—in *ovo* vaccination at 18 days of incubation

In this group of newly hatched chickens, a single vaccination *in ovo* resulted in seroconversion of all sixteen (16) of the birds with 15 of the 16 demonstrating high titers. The mean HI titer for this group was above 5 log 2. Again, the sera from these birds were sent to the USDA Southeastern Poultry Laboratory to obtain impartial results. The titers from the birds in this group were higher than those in Group 1, suggesting that the positive serological response to the same vaccine is stronger as the length of embryonation increases prior to vaccination.

Conclusions

It is generally accepted in the avian influenza vaccine community that high HI titer against the HA antigen will protect birds against infection. The titers presented in these studies suggest outstanding flock immunity. These data are exciting in that they demonstrate the potential of using vaccination *in ovo* to protect the US poultry industry against infection with this troublesome virus. By vaccinating in the egg, those who handle the birds in all levels of processing will also be protected against exposure to these potentially lethal viruses. The mechanism to administer egg vaccination robotically already is in use in the poultry industry.

The NIH has awarded Vaxin Inc. a \$3 million grant to develop a non-invasive vaccine against the avian influenza. The collaboration between Vaxin and Auburn University has produced data that must be assessed further in challenge studies using

secure facilities and by manufacturing the vaccine in large volumes for widespread administration to poultry. This endeavor should be funded at a level to allow our important collaboration to implement its findings. We believe that all reasonable means should be undertaken to get the next important and critical steps funded to complete initial challenge studies in a high level secured containment environment, and simultaneously to make proposals for the next levels of funding necessary to prepare the vaccine for proliferation in America.

Thank you for the opportunity to present this testimony.

Mr. ROGERS. And I want to thank you for your time. I know you all are busy, and it was very generous of you to come here and share your thoughts with us. And at this time this hearing is adjourned.

[Whereupon, at 5:02 p.m., the Subcommittee was adjourned.]

APPENDIX

QUESTIONS AND RESPONSES FOR THE RECORD

FOR THE RECORD

COMMITTEE'S ADDITIONAL QUESTIONS TO JEFFREY A. LOWELL, MD, FACS

1. Domestic Surge Production Capacity for Modern Smallpox Vaccine

Given the stated purpose of the CMO, how should the CMO coordinate with HHS to ensure the timely implementation of domestic surge capacity programs for necessary biodefense countermeasures?

The DHS CMO responsibilities for nation biodefense programs should be to provide the leadership and coordination of the relevant federal partner agencies (Department of Health and Human Services, Defense, Veterans Affairs, Agriculture, State and Justice, the Intelligence Community, etc.) in developing and executing the essential pillars of the national biodefense program—assessments, critical infrastructure protection, attack warning, attribution, response and recovery, and risk communication (Homeland Security Presidential Directive-10). The Secretary of DHS is the Principal Federal Official for domestic incident management and is responsible for coordinating domestic Federal operations to prepare for, respond to, and recover from biological weapons attacks or disease outbreaks. The CMO is the senior advisor to the secretary for medical and health affairs, and as such should lead the effort to coordinate with the respective heads of the other Federal departments and agencies to effectively accomplish this mission.

The role of the CMO should be to lead and coordinate the USG multi-agency effort to create policy and guidance that assures the nation has a clearly articulated mission and executable biodefense plan. Each participating USG department and agency should have clearly defined roles/responsibilities and performance metrics which are defined in the operational plan.

2. Development of Next Generation Technologies for Pandemic Flu Preparedness

Is the Federal Government considering new technologies—such as biotechnologies—that can cover a broad spectrum of flu strains and enable mass production, on demand?

Numerous programs and agencies are currently engaged in addressing this issue which includes: NIH/NIAID; DARPA/DSO Unconventional Pathogen Countermeasures Program (<http://www.darpa.mil/dso/thrust/biosci/upathcm.htm>); other offices in DOD, coordinated by the Deputy Assistant to the Secretary of Defense for Chemical and Biological Defense; and USDA.

What should be the role of the CMO in working with HHS to identify and support the development of such new technologies?

The CMO should chair a multi-agency panel, which includes participants from the Departments of Defense, Energy, Agriculture, Veterans Affairs and Health and Human Services (NIH/NIAID and CDC) to address these issues—both materiel and doctrinal.

3. Noble Training Center

1. (A) Do you believe the Noble Training Center is currently being utilized effectively? If not, how would you increase its usage and expand its programs?

Noble Training Center is a tremendous national asset that has most recently been utilized primarily for training of emergency managers and healthcare professionals. The Noble Center portfolio should also be expanded to serve as a test bed for developing new technologies (applied research and beta testing), new techniques (injury treatment, protection of health care personnel and facility protection, communica-

tions, HVAC operations and decontamination systems) and new doctrine. Going beyond teaching current dogma, Noble should also have the role of the Nation's learning lab—developing and testing new and novel materiel and response techniques. To enhance these efforts, the Noble Center should work closely with HSARPA and the Department of Defense. In addition, the Noble Center should work with national healthcare governing and licensing agencies (e.g., JCAHO, American Hospital Association, American Medical Association, etc. . .) to establish national training and response standards. In addition, the Noble Campus might be considered for expansion as the primary base and headquarters for the National Disaster Medical System. This could significantly strength both programs. This campus might also be considered as a home for national Emergency Medical Services (air and ground transportation) programs—technologies, techniques and doctrine. Though should also be given to evaluating whether Noble could be used as an actual, functioning medical care facility, in the vent of a national critical event, in which hospital surge capacity is needed.

(b) What training needs in the emergency medical community can you identify that the Noble Training Center currently is meeting and could meet if its programs were expanded?

Noble currently provides training for a cooperative local response to a disaster in a medical facility. There are substantial opportunities to expand the role of Noble to include: evaluating and testing new technologies, techniques and doctrines; providing training for the integration of the local, state and federal response; serving as a home for national EMS programs; and, serving as a home for the National Disaster Medical System, and the federal medical response programs.

(c) How do you think this {the location of the CMO and Noble in the new Preparedness Directorate} will impact the functions and coordination of these entities with other medical preparedness programs and resources in the Department.

As I have testified before the committee, I believe that all DHS medical/health programs—Intelligence (e.g., National Biodefense Analysis and Countermeasures Center (NBACC), BioWatch, etc. . .), NDMS, Preparedness (Metropolitan Medical Response System (MMRS), Counter Narcotics and Terrorism Programs (CONTOMS), etc. . .) and Mission Support (e.g., medical logistics, communications, information technology, facilities and resource management and force health protection (occupational health and safety), and risk communication) should be consolidated into one Office, under the direction of the CMO. The primary reason for this is to ensure, at a policy level, that these various programs, as well as other complimentary ones in other agencies and Departments, function in concert and in a coordinated manner.

TIMOTHY E. MOORE RESPONSES TO THE HONORABLE MIKE ROGERS QUESTIONS

1: Domestic Surge Production Capacity for Modern Smallpox Vaccine

“Given the stated purpose of the CMO, how should the CMO coordinate with HHS to ensure the timely implementation of domestic surge capacity programs for necessary biodefense countermeasures?”

At present, I am not entirely certain as to the specific role of the CMO. I am aware that the Department of Health and Human Services serves as the primary lead agency on matters pertaining to domestic surge production and capacity. Furthermore, with the advent of the “Bioshield Program,” which was developed in a coordinated manner through Centers for Disease Control (CDC) and through the HRSA grant process by which funding was supplied to state and local entities to perform wide-spread vaccinations and delivery of prophylactic medications in times of need, there appears to be a strong center of gravity within HHS regarding this matter. Thus it would seem most appropriate that the CMO meet with the leaders of these programs and serve as a coordinator to ensure that DHS is fully aware of all developments involving surge vaccine development, as well as surge medical support. This should be done with the intent of seamless interaction between these agencies in a time of crisis so that the federal government speaks with one voice. I believe that one area that the CMO can directly influence is in regards to development and evaluation of major training exercises involving medical surge capacity and the ability to project medical resources at a given time and place. In this manner, the CMO can serve as an “external” evaluator of the condition of readiness for large scale incidents requiring medical surge. Other suggested roles for the CMO would include:

- Assist in the development of the partnership of DHS and HHS utilizing the Exercise division of Grants and Exercises under the new DHS Preparedness Directorate. Incorporation of field exercises by DHS HSEEP guidelines would

allow local and state authorities to test the plans to ensure their viability. The role of the CMO would be to facilitate that interaction.

- Work to coordinate DHS medical assets such as the National Disaster Medical System and the Metropolitan Medical Response System into the planning and execution of these plans.

2: Development of Next Generation Technologies for Pandemic Flu Preparedness

I respectfully defer this matter to HHS/NIH, as well as to the CMO and Secretary Chertoff.

3: Noble Training Center

1. A. Do you believe the Noble Training Center is currently being utilized effectively? B. If not, how would you increase its usage and expand its programs?

A. NO. As you stated in your question, the Noble Training Center (referred to as "Noble") is truly a unique facility in the nation and with the possible exception of the ER 1 facility (formerly D.C. General Hospital), it is an intact hospital facility which can be utilized as a field test site for training and technology development pertaining to healthcare response to catastrophic, all-hazards events. It is unique in its setting and physical location in close proximity to the US Department of Homeland Security's Center for Domestic Preparedness and the abundant unencroached property opportunities the old Fort McClellan affords.

Response: B. I believe that there is a glaring need for curricula to be developed or revised for healthcare and public health personnel as it pertains to the medical response to mass casualties, terrorism, WMD and naturally occurring events (e.g. Hurricane Katrina) which prepares both those in the practice of healthcare delivery and those professionals and paraprofessionals in training to meet the demands of response.

I understand that currently work is in progress by the Office of Grants and Exercises spearheaded by one of its training partners, The University of Texas Health Science Center-Houston's Center for Biosecurity and Public Health Preparedness, that is based upon a training matrix and needs assessment which was begun earlier this year in the revision of the Target Capability List (TCL). The Senior Medical Advisor to the Center for Domestic Preparedness (Dr. Mike Proctor) is assigned to this position from the University of Texas HSC and works very closely with the Office of Grants and Exercises who provide his direct taskings.

A concept paper is currently in preparation which outlines a program and process to revise current training offerings and develop new training and educational offerings which will meet the needs of healthcare delivery as well as augment the offerings of HHS / CDC/ HRSA in preparing the Public Health sector to respond in all-hazards events. Plans are to further utilize current DHS training partners and enlist the assistance of new partners as needed as well as the healthcare and public health professional organizations and entities. This program would well benefit the merger of the Noble facility with the CDP to fully encompass First Responder training as outlined in HSPD 8.

2. What training needs in the emergency medical community can you identify that the Noble Center is meeting and could meet if its programs were expanded?

A: The current Noble Training Center healthcare educational offerings are follows:

- B960—HEALTHCARE LEADERSHIP COURSE
- FEMA Health Care (HC) MEPP Series—NEW FOR FISCAL 2006
- B461—Hospital Emergency Response Training (HERT) for Mass Casualty Incidents (MCI) Train-the-Trainer Course

Of the three courses listed above only the Healthcare Leadership Course has been offered more than once. The remaining two courses are to be offered in December 2005 and on into calendar year 2006. I have found limited information on the new courses with regard to the course content, course design, or authors other than the brief outline contained on the NTC web site <http://training.fema.gov/emiweb/NTC/>

Further discussion of the needs and requirements for future courses will be discussed in the concept paper mentioned under question number 1 above.

3. "A. As part of Secretary Chertoff's Second Stage Review, the office of the Chief Medical Officer and the Noble Training Center are located in the new Preparedness Directorate.

B. How do you think this will impact the functions and coordination of these entities with other medical preparedness programs and resources in the Department?

Response: A. I believe that this issue will need to be evaluated as more details of the structure and organization of the new Preparedness Directorate become available. There is still question of the specific job functions of the CMO and where, within the new Preparedness Directorate Noble Training Center will reside. There is pronounced concern among the healthcare community that have been deeply involved in disaster preparedness, weapons of mass effect and mass casualty response by the lack of experience of the current CMO in these areas. The current CMO is a capable administrator but his background lies almost totally in motor vehicle related trauma and in the seat belt initiative for the DOT with very little to no experience in WMD, mass casualty events or disaster preparedness.

Response: B. I believe that is a wise decision to place both the CMO and the NTC under the Preparedness Directorate, as it will serve to place greater focus directly on the training and response to any mass casualty event. All hazards and mass casualty response training for the Healthcare Community has been to say the least, disorganized, with no continuity or central theme or oversight. Some efforts have been accomplished by HHS in the form of the CDC and HRSA grants process but these efforts have dealt more with public health preparedness and not actual healthcare delivery. As I understand it, further hampering this educational and training effort is the lack of recognition that the overwhelming majority of healthcare providers and the response community actually reside in private industry and as such enjoy no single entity that speaks for the healthcare delivery system or its professional components. The single best example of a more unified healthcare preparation, training and response can be found in the nation's Chemical Stockpile Communities where unified efforts to standardize training and response have been employed since the mid 1980's in preparation for the destruction of the unitary chemical weapons (e.g. Sarin, VX, Distilled Mustard, etc.) via the Chemical Stockpile Emergency Preparedness Program (CSEPP).

Another issue that I recommend that the Subcommittee consider involves where the National Disaster Medical System (NDMS) and the Metropolitan Medical Response System (MMRS) will reside and what role they are to play in regards to response to catastrophic events. The NDMS contains the Disaster Medical Assistance Teams (DMATs), Veterinary Medical Assistance Teams (VMATs) and Mortuary Assistance Teams (DMORTs) has fallen into disarray and in my opinion is in need of a major restructuring and reorganization. I believe that one manner in which this may be accomplished will be through the Noble Training Center which could serve as the National Headquarters for this vital system. The Noble Training Center could serve as the nexus for training and retraining of the NDMS team members with the surrounding facilities of the old Fort McClellan base being utilized house stockpiles of equipment and supplies as well as utilize the expertise of the Center for Domestic Preparedness (CDP).

I believe that the nation's healthcare response to the major disasters has performed well due to the willingness and sacrifice of the professionals involved and their humanitarian spirit. I believe that we as a nation owe these professionals and their attendant systems the same level of training opportunities we have afforded the traditional responders of law enforcement and fire service. All hazards, weapons of mass destruction / effect and mass casualties are areas that the healthcare community is not familiar or comfortable with as compared to their routine daily duties.

QUESTIONS FROM CHAIRMAN MIKE ROGERS FOR JEFFREY W. RUNGE, M.D.
RESPONSES

(1) Domestic Surge Production Capacity for Modern Smallpox Vaccine

According to the Department of Homeland Security, the Chief Medical Officer should "provide the federal government with a much greater capacity to be prepared for, respond and recover from a catastrophic biological attack." One way to ensure biodefense preparedness is to establish and maintain domestic surge production capacity for biodefense countermeasures.

Given the stated purpose of the CMO, how should the CMO coordinate with HHS to ensure the timely implementation of domestic surge capacity programs for necessary biodefense countermeasures?

Response: "Domestic surge capacity" with respect to biological attacks may refer to issues of capacity of hospitals, physicians, and Emergency Medical Services (EMS), as well as provision of countermeasures such as vaccines and antibiotics. Responsibility for health care surge capacity falls within the responsibility of the Office of Public Health Emergency Preparedness in the Department of Health and Human

Services (HHS). The Homeland Security Chief Medical Officer (CMO) works with HHS in accordance with DHS' role as coordinator of Federal assets. The CMO will work with his counterparts in various agencies, including HHS, Agriculture, Department of Defense, and Veterans Affairs to define the requirements and definitions for medical preparedness in biological attacks. The CMO also has responsibility for coordinating DHS medical assets, and is building a network of all DHS medical assets to ensure that their activities are strategically aligned, that they have necessary training and education, and that the Secretary and his management team have ready access to the various specialized skills available from the Department's medical workforce. The CMO will also work with the Office of Grants & Training and the US Fire Administration within DHS, as well as the Department of Transportation, to ensure that EMS first responders have access to training in response to biological attacks.

With respect to biological countermeasures, the CMO will support processes already in place to perform material threat determinations and assessments, and to advise the Secretary on issues necessary to fulfill the Department's statutory role under the Project BioShield Act of 2004. The CMO acts on behalf of the Department to inform the procurement of BioShield funded countermeasures intended for additions to the Strategic National Stockpile.

During a biological attack, the Department would operate as directed by the National Response Plan. In addition to serving as the DHS Secretary's principal medical advisor, the CMO and his staff will assist with the Interagency Incident Management Group and support HHS' role in the execution of Emergency Support Function #8, which coordinates Public Health and Medical Services.

(2) Development of Next Generation Technologies for Pandemic Flu Preparedness

The CMO's primary responsibility is to work with the Department of Health and Human Services and other departments to prevent and mitigate biological based attacks on our Nation's human health and food supply. Pandemic flu, which poses a natural threat to our human population and food supply, can also be weaponized by terrorists.

Whether in nature or in a bioterrorist attack, our Nation's level of pandemic flu preparedness is hampered by the fact that the pandemic strain spread from human to human is unknown. Even once the pandemic strain is identified, both egg-derived and cell-culture-based vaccine production methods may not be able to satisfy mass orders on demand.

Therefore, is the Federal Government considering new technologies—such as biotechnologies—that can cover a broad spectrum of flu strains and enable mass production, on demand?

Response: The broad issues of biotechnologies for influenza should be addressed by HHS.

DHS also has research activity underway. The Science & Technology Directorate funds development of biothreat agent assays at the Lawrence Livermore National Laboratory for Avian Influenza/Flu strains and research through a University Center of Excellence at Texas A&M's National Center for Foreign-Animal and Zoonotic Disease Defense.

What should be the role of the CMO in working with HHS to identify and support the development of such new technologies?

Response: The CMO would provide consultation on the clinical and policy issues of any new technologies advanced by the Department. Vaccine development, production, and administration protocols are the responsibility of HHS.

QUESTIONS FROM REPRESENTATIVE STEVE PEARCE FOR JEFFREY W. RUNGE, M.D.
RESPONSES

(1) I understand that HHS has Title 42 authority, which allows them to pay physicians above the normal GS pay schedule in order to recruit and retain experienced medical clinicians.

Is there a need for a similar type of authority for your office in order to attract and retain qualified doctors who are experts in emergency medicine, preparedness and response?

Response: The Department of Health and Human Services (HHS) informally advises that some HHS doctors are paid under Title 38 authority delegated by the Office of Personnel Management. The Title 38 authority, pertaining to the compensation of physicians, has recently been expanded and offers attractive features. Presently, the Department of Homeland Security (DHS) is exploring a range of options

for compensating physicians, including the use of the Title 38 authority under an OPM delegation, the physicians' comparability allowance under Title 5, United States Code, and, of course, the basic pay and pay flexibilities that will be offered under DHS' own system, which is currently being developed.

