BIOSHIELD: LESSONS FROM CURRENT EFFORTS TO DEVELOP BIO-WARFARE COUNTERMEASURES

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BIOSHIELD: LESSONS FROM CURRENT EFFORTS TO DEVELOP BIO-WARFARE COUNTERMEASURES

FRIDAY, JUNE 6, 2003

U.S. HOUSE OF REPRESENTATIVES,
SELECT COMMITTEE ON HOMELAND SECURITY,
Washington, D.C.

The committee met, pursuant to call, at 10:06 a.m., in Room 345, Cannon House Office Building, Hon. Christopher Cox [chairman of the committee] presiding.

Present: Representatives Cox, Dunn, Hunter, Sessions, Turner, Frank, Slaughter, Andrews, McCarthy, Jackson-Lee, Christensen, Etheridge, Langevin, and Meek.

Chairman COX. Good morning. A quorum being possibly present, the Select Committee on Homeland Security will come to order. The committee is meeting today to hear further testimony relating to Project BioShield. I would like to welcome the members in attendance this morning and thank our witnesses for agreeing to appear before this committee on such short notice. This initiative is moving quickly. I am grateful to be able to hear your testimony before we mark up the legislation next week.

The Secretary of Homeland Security is given a very important role in Project BioShield. This role is primarily one of threat assessment. Legislation requires the Secretary to assess existing and potential threats from chemical, biological, radiological and nuclear agents and to determine which of those threats presents a material threat against the United States population.

Countermeasures to agents so identified by the Secretary will be eligible for purchase for the strategic national stockpile using BioShield's special funding mechanism.

The Department's pivotal responsibilities under BioShield are part and parcel of its broader threat assessment responsibilities under the Homeland Security Act. There is a virtually infinite universe of potential threats, of course only a finite amount of resources to deal with them.

Conducting the kind of analysis and assessment that will allow us to set security priorities and focus our efforts on the most pressing threats is one of the most important functions of the Department of Homeland Security. Quality threat assessment is absolutely critical in order to prevent attacks on our homeland. This is nowhere more true than in the case of bioterrorism. To best protect against attacks on the U.S. population, our efforts must be con-

centrated fully on the agents that pose the greatest danger. Assuring this is the Department of Homeland Security's responsibility.

Yesterday, the Subcommittees on Emergency Preparedness and Response and Intelligence held a joint hearing examining the infrastructure already in place and the infrastructure that is now being built at DHS for performing the threat assessment required for the success of BioShield.

I want to thank Chairmen Shadegg and Gibbons for holding that hearing. This hearing is intended to bring the benefit of the valuable experience of other existing biothreat programs to our discussion of BioShield and the role of DHS. This hearing will help us understand the challenges the Department of Homeland Security will face and the capabilities that it must develop.

We have witnesses with us from the National Institutes of Health and the Center for Disease Control, both within the Department of Health and Human Services. HHS already performs threat assessment that is closely related to the kind of analysis that DHS will be required to perform for the BioShield legislation. The Secretary of Health and Human Services is required by the Bioterrorism Preparedness Act of 2002 to maintain a list of agents and toxins that could potentially pose a severe threat to the public health. This list is then used to set research and response priorities within the Federal Government

In order to be successful, DHS must perform these assessments and more. The Secretary must be able to combine a determination of which agents are most intrinsically dangerous with an intelligence assessment of terrorist capabilities. I hope this hearing gives us an idea of what this entails and whether there is anything that we in Congress must do as we consider this legislation to help the Department fully meet its mandate.

I look forward to hearing from our witnesses.

The Chair would now recognize the ranking member, Mr. Turner, for his opening statement.

Mr. TURNER. Thank you, Mr. Chairman. I want to thank you for your leadership on this issue of the biological threat that we face as a nation. I appreciate that this committee has been aggressive in trying to schedule hearings on this important piece of legislation and attempting to delve into some of the tougher issues that we all know exist.

Our hearing yesterday revealed to us information that I think all of us on both sides of the aisle consider to be quite disturbing with regard to the progress of the Department of Homeland Security, and its ability to carry out the responsibilities that we will be giving it under the BioShield legislation. And I am hopeful that we can move forward in urging the President and the Secretary of the Department to further strengthen that portion of the Department's function and responsibility.

Our hearings on Project BioShield have demonstrated, I think to all of us, that to solve the problem of bioterrorism, we are going to have to form a strong relationship between the public and the private sectors. The BioShield legislation is designed to give our pharmaceutical industry incentives to do what they do best, and that is, to take a potential medicine or vaccine against a biological agent and bring it to the stage where it can be mass produced.

But the difficult work of basic research and drug development is being done elsewhere. It is being done in government research laboratories, in the biotech industry and in our research universities. The seriousness of the bioterrorism threat and the sophistication required to develop adequate defenses requires, in my view, a sustained long-term and extremely focused research and development effort. We simply cannot leave this responsibility to the uncertainties of the market and sit back and hope that all the drugs and vaccines will be developed.

The federal government must play a role in funding the basic research and development work needed for an adequate biodefense. The administration has recognized this as well. That is why the proposed funding for biodefense at the National Institute for Allergies and Infectious Diseases has risen from $180 million since September 11th to the proposed $1.6 billion in next year's budget, an 800 percent increase. This funding increase is dramatic, and I wholeheartedly support it.

Still, the task of developing countermeasures is so difficult and so vitally important, there are many other issues besides the amount of resources that need to be addressed. First, the National Institute for Allergy and Infectious Diseases, commonly referred to as NIAID, has traditionally focused, as I understand it, on pure scientific research. Now it is being asked to become more involved in a related but distinct task of drug development. I will be interested to learn from our witness today what the leadership of NIAID is doing to implement this change of culture within your own organization, and I hope to hear assurances that we are making the proper investments to ensure that we get not only good research but also countermeasures that we can use to protect the American people.

Secondly, we have heard extensive testimony about the effectiveness of Project BioShield. There is a distinct possibility that the private sector may not participate in bringing promising drugs from the development stage toward final production, and I would like to know from our witnesses whether the government has or could build that capacity in the event the incentives in the BioShield legislation are insufficient.

I am particularly interested to learn more about NIAID's Vaccine Research Center as it relates to the biodefense effort. I am pleased that we have excellent witnesses from both the NIAID and CDC here today. You have a very important job to do. We want to support you in it, and be sure that you are successful.

I thank you, Mr. Chairman. I look forward to hearing from both of our witnesses.

Chairman COX. Thank you.

The Chair recognizes the vice chairman of the full committee, the gentlelady from Washington, Ms. Dunn, for her opening statement.

Ms. DUNN. Thank you, Mr. Chairman, and welcome, gentlemen. Thank you for being here with us today. As members of this committee will agree, the downside of serving on a brand new committee is that we don't have a space to call our own. This is just a temporary problem. We will find a space of our own very soon, but I am very happy that you were able to join us here in the Cannon Caucus Room today.

Providing the Department of Homeland Security the necessary resources to protect Americans from biological attacks is a very important goal for this committee, and I look forward to your input on implementing the BioShield Project.

As we found during the anthrax attacks in the fall of 2001, very small amounts of biological agents can wreck havoc on our livelihood, affecting our work, our home and the Nation's economy. All of us in Congress were affected by the discovery of anthrax in office buildings in the House and the Senate. As we will recall, all staff were exposed—there were some staff who opened the mail who were, in fact, exposed to anthrax, and we experienced and continue to experience today delays in receiving our mail, and of course many of our offices were quarantined during those days.

With the havoc the anthrax attacks caused, we all learned that we will need to be better prepared if a biological attack occurs to a greater population. Project BioShield will be a very important part of our homeland security efforts, yet its successes will not be dependent solely on how much money we are able, as Members of the Congress, to provide, but on developing the coordination, the infrastructure and the leadership within DHS and among other Federal agencies and our public health system.

Today we will hear about the role of the Centers for Disease Control and the National Center for Infectious Diseases in helping to prevent and respond to potential bioterrorism attacks. I look forward to hear how the CDC and the NIH will work together to ensure the safety of the American people.

BioShield, if implemented successfully, will have a profound effect on mitigating the effects of a biological attack as we are preparing to mark up this legislation toward the end of next week, I, too, look forward to hearing from you and to gleaning something from your experience today.

Thank you, Mr. Chairman.

Chairman COX. Thank you. The gentleman from the great State of New Jersey, whose Devils were successful last evening, Mr. Andrews, is recognized for his opening statement.

Mr. ANDREWS. Thank you, Mr. Chairman. I look forward to the testimony of the witnesses, and—the specific time measurements—and what I want to do on behalf of my constituents is know what benchmarks I should be evaluating. I am quite satisfied that you have laid the initial groundwork that you ought to lay, and I commend you for it. What I am interested in is learning ways that we can measure your progress in this very important mission. Thank you, Mr. Chairman.

Chairman COX. The gentleman from California, the chairman of the Committee on Armed Services, Mr. Hunter, is recognized for his opening statement.

Mr. HUNTER. Well, thank you, Mr. Chairman, and likewise I don't have a lengthy opening statement, but I want to thank my colleagues. Thank you and Mr. Turner and all my colleagues for the hearing, and simply say that in the end, we are going to have to translate these disparate agencies and all of the players in what I would call this maybe three-part chain, that is, detection, analysis and protection, into an apparatus that can move very quickly, meaning that if there is a disease or a substance that is threat-

ening, whether it is troops in theatre or civilians in this country, a single team that can move quickly to capture some of that substance or that disease, move it quickly to an analytical team, and from there, take it quickly to a team that can put together a defensive measure and then apply that, whether it—it has to be applied in inoculation to the civilian population or to the uniform services, and sometimes in this country, resolving fragmented and disparate agencies into a focused effort that involves action, and in this case, I think it is going to have to be action that can take place very rapidly is sometimes one of our biggest challenges.

So I am interested in knowing how we are going to put that team together, and how it is going to be integrated with the efforts that are already ongoing.

Obviously in the military, we have as the operation in Iraq has reflected, the capability of analyzing some of the obvious challenges and dangers and taking action to prevent those from becoming damaging to our troops, and so we have the—at least the embryonic apparatus of a BioShield in place with respect to the military already, but I am interested in knowing how we are going to be able to make this thing work together, the domestic and the military elements, and bring them—meld them into a single apparatus that can get the job done. So thanks for the hearing, and gentlemen, thanks for being with us

Chairman COX. The gentlelady from Missouri is recognized for her opening statement. Ms. McCarthy is recognized for 5 minutes.

Ms. MCCARTHY. Thank you, Mr. Chairman. My mike is having problems. I thank you for calling this meeting. I don't think—.

Chairman COX. If the gentlelady would suspend, it occurs to me that because we have so much space up here behind the dais, that if members would like to relocate, they would be welcome to do so, but at least you might want to relocate to a microphone that works.

Ms. MCCARTHY. Thank you very much, Mr. Chairman. I don't know of an issue more critical, more timely or more important than the biodefense of our country, and I am so grateful to you for calling this hearing. And ranking member Turner, thank you as well. And Dr. Khan and Dr. LaMontagne, I look forward very much to your input, and I know you look forward to our questioning and our thoughts as well as we work together as a team to address this very vital issue.

Thank you very much. I would yield back my time, and I look forward to continuing the hearing.

Chairman COX. The gentleman from Georgia wishes to waive his opening statement?

Mr. LINDER. I have no comment, Mr. Chairman.

Chairman COX. The gentleman from Texas is recognized for an opening statement.

Mr. SESSIONS. Thank you, Mr. Chairman. Dr. Khan, Dr. LaMontagne, we appreciate you being here before this committee today. I am particularly interested in your comments as they relate to the legislation that deals with the ability to take from what I would say in the lab ideas and serums or answers to problems and bringing them directly out on an expedited basis.

Now more than ever, this country and this world is faced with new viruses, new problems, new plagues that confront us, and I

don't know that it is necessarily bioterrorism, but it is certainly things that emanate as a result of people and animals and things all around the world. And so in particular, I would look today to hear from you about how we take those things as they are identified in the world as problems, threats to civilization, how we can mature that process very quickly in the laboratory and then make them generally available to people, and generally speaking, our process has been, I believe, slow. While I am satisfied that our pharmaceutical community does a very good job, I am concerned about rules and regulations that inhibit the introduction of those drugs on a more widely available and quicker basis.

So I will look forward to that testimony and hearing that from you today, and want to thank both of you for being before this great Select Committee today. I yield back, chairman.

Chairman COX. Thank you. The gentlelady from Texas, Ms. Jackson-Lee, is recognized for an opening statement.

Ms. JACKSON-LEE. Thank you very much, Mr. Chairman and the ranking member, for holding a very important hearing this morning, and I am pleased to join my colleagues on this committee. I would ask, Mr. Chairman, unanimous consent that my entire statement be allowed to be submitted into the record in it entirety.

Chairman COX. Without objection, and the chairman would note that all members will have the opportunity to submit further opening statements for the record.

Ms. JACKSON-LEE. Before their testimony even, I would like to thank the witnesses and just to make note that for a moment I have to testify in the Senate for a moment, but I will look forward to reviewing, as I have, their statements and look forward to participating in the questions.

We realize that terrorism is alive and well. In light of the tragic incidents in Riyadh, Saudi Arabia on May 12th, and of course, the tragedy in Morocco where 43 people were killed, it makes this hearing even more important, because we realize that the threat of bioterrorism remains with us, and the fact that biological weapons are highly portable and difficult to detect. Positive strides have been made in securing our borders and presenting unwanted materials from entering our country, but it is unrealistic to expect no biological weapons to enter the United States or maybe even to be created here.

Last year alone, 30 million tons of cocaine was smuggled into the United States. If we can't stop 30 million tons of cocaine, then we know the difficult charities, if you will, of dealing with the issue of bioweapons. Your position here or your testimony here will be helpful to us and insightful and encouraging as to how we might further enhance the security of America.

We are trying to educate our citizens with the color system. I believe now more and more they are sensitive to the fact that when we make note of the various levels of threat, that they will pay attention, but look, for example, to the worldwide SARS outbreak. No, it is not a biological terrorist effort, but we do know it has been difficult to deal with. The inability of many foreign countries to adequately deal with that outbreak raises questions about our own preparedness. What about other infectious diseases, like tuberculosis? Just last summer the country was faced with the West

Nile virus. Of course, that was not a biological threat or terrorist act, but I can tell you in my community, we faced real challenges in educating the community about how to protect themselves.

We must do better in the area of biological weapons and the threat that they pose.

The ease with which biological weapons can be manufactured is also a danger. The equipment and ingredients needed to manufacture many biological agents can be purchased over the Internet. Additionally, as our failure to apprehend those responsible for the 2001 anthrax attacks illustrates, biological terrorists can operate with more secrecy than traditional terrorists. We must be concerned. The provisions of Project BioShield provide a good start to protecting Americans from bioterrorist attack, but work remains.

It is important, of course, to realize the provisions in this legislation grants the National Institute of Health new powers, good powers through grants and contract awards to speed effective research and development efforts on bioterrorism countermeasures. I am interested in making sure that all of America, all of America's research specialists, all of America's universities, Hispanic serving universities, historically black universities, small universities and colleges understand this process so that those who have capacities, no matter where they are, will reach out and participate in the research and grant efforts.

In addition, I might want to raise a question, as I close, about the 40 million uninsured Americans who do not have health care. They do not have established relationships with physicians. How do we get them in the line of prevention, immunization? How do we work with some of the failures of this Nation so that we can ensure that every single person within our boundaries remains safe and secure as we fight collectively the war against terrorism. I am delighted that this hearing is proceeding, and I know that we will have good instructions that we should. And I yield back, Mr. Chairman.

[The information follows:]

PREPARED STATEMENT OF THE HONORABLE SHEILA JACKSON LEE, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF TEXAS

Mr. Chairman and Mr. Ranking Member, I thank you for convening this vital hearing to hear testimony from government experts on their efforts to assess the bioterror threat, develop countermeasure to bioterror attacks, and coordinate with Project BioShield.

The Al Qaeda terrorist network remains a threat to Americans and peaceful people worldwide. The recent suicide bombing attacks have confirmed that terrorist cells are still planning and executing deadly attacks. In Riyadh, Saudi Arabia, on May 12th, nine suicide bombers attacked three residential compounds. The attacks took the lives of 35 innocent people including 9 Americans. Another suicide bombing attack in Morocco killed 43 people. Despite Homeland Security Department Secretary Tom Ridge's decision to lower the terrorism threat on May 30th, American's are still at risk. Our nation's elevated level of vigilance may protect us from attacks like suicide bombing, but there are many other terrorist threats that put American lives at risk. Bioterror attacks are a perfect example.

The threat of bioterrorism must be one of our chief concerns as we continue our work of protecting our homelands from terrorist attacks. Biological weapons pose a particularly dangerous threat. Biological weapons are highly portable and difficult to detect. Positive strides have been made in securing our borders and preventing unwanted materials from entering our country, but it is unrealistic to expect no biological weapons to enter the United States. Last year alone 30 million tons of cocaine was smuggled into the United States. If we can't stop 30 million tons of co-

caine from crossing our borders, how can we expect to stop a vile filled with anthrax, botulism, or small pox? A vile that could kill hundreds or possibly thousands.

Bioterrorism attacks not only pose a danger to human lives, they also have the ability to cripple the operation of our society and severely harm our economy. We all recall the primary and secondary impact of the anthrax attacks in 2001. The attacks involved a series of letters mailed in pre-stamped envelopes to media outlets in Florida and New York and to the offices of Senators Thomas Daschle and Patrick J. Leahy (D–Vt.). The anthrax attacks killed five Americans and left 13 others severely ill. The five people who died from inhalation anthrax included two postal workers at the Brentwood postal facility in Washington, a Florida photojournalist, a New York hospital worker and a 94-year-old woman in Connecticut. Thousands more were exposed to the lethal bacteria. The letters passed through various post offices and postal distribution centers along the East Coast leaving a trail of contamination. Buildings from the Brentwood mail facility, to the Congressional office buildings, to NBC headquarters had to cease operations.

The threat of bioterrorism did not end in September of 2001. As recently as April 22nd of this year in Tacoma, Washington we had a bioterrorism scare. A white powder was found in two envelopes, and 94 people had to be evacuated from a mail distribution facility. Initial tests of the powder tested positive for biotoxins that cause bubonic plague or botulism. Four people at the facility had to be decontaminated. The same day, a suspicious powder was found in a Federal Express cargo area at Southwest Florida International Airport, in Fort Myers, Florida. Six people were taken to a hospital for possible decontamination, including one who suffered burning eyes and nose.

We are presently faced with the threat of a worldwide SARS outbreak. The inability of many foreign countries to adequately deal with that outbreak raises questions about our own preparedness. What about other infectious diseases like tuberculosis? There are many ailments that our medical professionals are struggling to control. We must do better in the area of biological weapons.

The ease with which biological weapons can be manufactured is also a danger. The equipment and ingredients needed to manufacture many biological agents can be purchased over the Internet. Additionally, as our failure to apprehend those responsible for the 2001 anthrax attacks illustrates, biological terrorists can operate with more secrecy than traditional terrorists.

These are but a few concerns we face as we consider Project BioShield. The provisions of Project BioShield provide a good start to protecting Americans from a bioterrorist attack but work remains. Presently Project BioShield's provisions grant the National Institute of Health new powers, through grants and contract awards, to speed effective research and development efforts on bioterrorism countermeasures. Project BioShield also creates a long-term funding mechanism for the development of medical counter measures, and empowers the government to purchase safe and effective vaccines. Finally, Project BioShield authorizes the Food and Drug Administration to use promising, yet uncertified, biological treatments in the case of emergencies.

Mr. Chairman and Ranking Member, I believe these are good first steps in protecting Americans from biological attacks. However, I feel that many questions remain. I look forward to the testimony of our witnesses today, and I hope that their guidance can help us make all Americans less vulnerable to bioterrorism.

Chairman COX. I thank the gentlelady. The gentleman from North Carolina, Mr. Etheridge, is recognized for purposes of an opening statement.

Mr. ETHERIDGE. Thank you, Mr. Chairman. Thank you for holding this hearing. I am going to be rather brief, but I do want to say based on the hearings we held yesterday and the information concerning—or the lack thereof, of information as it relates to biochemical weapons and others, I am somewhat disturbed, so I hope this morning you can—even though this is not part of your testimony, that your information will be more inclusive and helpful, because I think from what I heard yesterday, I am quite aware and concerned that the level of threat may be higher than we even think.

But I hope you will discuss or share with us, even though the responsibility is on a broader scope—you know, most people live in

local communities, you know, and the concern is what about the local community. Local health departments for a lot of people is where they receive their services. Depending on where you are in the United States, if you are in a rural area, that those departments are absolutely overloaded. We have people who aren't even taking smallpox shots now to be able to provide services if something should happen.

So I hope you will share some of that with us this morning and talk about two very critical issues to local folks. That is, the safety of water and the food. We have the safest food supply in the world, but I can see if there is an area where you would want to have some problems, you could create turmoil very quickly there. And I think that is important and as we look at the global movement of people. It may be, as has already been stated this morning, something someone intentionally puts in a system. It may be something that is started in nature that moves because we move so quickly from one part of the world to the other. Historically, you have dealt with those issues in a very positive way, and I would congratulate you on it, but I think as we look out into the 21st century, those challenges are going to increase even more. So I hope you will touch on that this morning.

Thank you, Mr. Chairman.

Chairman COX. Thank you. The gentleman from Rhode Island, Mr. Langevin, is recognized for his opening statement.

Mr. LANGEVIN. Thank you, Mr. Chairman, and I too will have a more formal statement to submit for the record, but, Mr. Chairman, I want to thank you and the ranking member for organizing this hearing, and I would like to thank the gentlemen for their presence and look forward to their testimony today.

I noticed in my briefing memo that we had attempted to get witnesses from DOD and DHS but were unable to do so. I would hope that DOD and DHS would follow the lead of CDC and NIH in being more forthcoming with this committee in the future.

The areas that I hope the gentleman will address and things that I am concerned with—and I agree with the gentlelady from Missouri that the bioterror threats that are facing this country are significant, and there is no greater a priority we should have than addressing and dealing with these issues.

I will be most concerned with knowing if you have adequate resources to do the job that you are facing. I would also be interested in hearing the degree to which you are coordinating efforts, both with nongovernmental and governmental agencies, particularly DOD and DHS, and also I am interested in knowing how you are setting priorities in terms of what types of bioterror threats we need to address, both terrorist threats or natural emerging pathogens that are antibiotic and drug resistent. But I thank you for your presence today and look forward to your testimony. Thank you, Mr. Chairman.

Chairman COX. Thank the gentleman. The gentleman from Florida, Mr. Meek, is recognized for an opening statement.

Mr. MEEK. Thank you, Mr. Chairman, and I would like to not only welcome our witnesses, but also thank the leaders in this committee, including yourself, for having this very important hearing. You heard some reference to yesterday. You had nothing to do with

yesterday. Today is today, and I am glad that you are here, and I am more interested in understanding more about our potential threat level and how y'all have worked with other agencies, both of your agencies work with other agencies to—the agencies abroad of efforts that they have to fight against as it relates to bioterrorism, will we be the leader in this effort, or are there other countries that are—taking countermeasures against bioterrorism?

What we are asked in this proposed legislation when we start to mark it up is to relax acquisition procedures, and we are going to be asked to do many things that we are not doing now, to give great discretion to members of the administration and future members of future administrations to be able to protect Americans in the future. I think that is so very, very important. We deal with bioterrorism from my reading and from what I have been briefed about, and something is going to be very difficult—I don't know if we can legislate the countermeasures totally, so what you do in the research community is going to be vital.

Intelligence will be vital also, and I know that, Mr. Chairman, as we go through this process, that we will discuss and iron out many of those issues, but I know that in this particular area, that preventive maintenance through discussion and also allowing many people within the field of helping us find countermeasures towards bioterrorism is going to be important. So I look forward to the discourse, and I want to thank both of you for being here this morning.

Chairman COX. I thank the gentleman.

The gentlelady from the Virgin Islands is recognized for an opening statement, Mrs. Christensen.

Mrs. CHRISTENSEN. I will submit my opening statement for the record, Mr. Chairman, and do we get 8 minutes if we don't do an opening statement?

Chairman COX. Yes. In fact, I think the Chair will be able to be very liberal today because of the good attendance of those who are here.

Does any other member wish to make an opening statement?

The gentleman from Massachusetts, Mr. Frank, is recognized for an opening statement.

Mr. FRANK. Thank you, Mr. Chairman. To begin, I want to thank you for the role the committee has been playing recently. I think yesterday's hearing, although painful was very useful, and this is exactly the role we should be playing and I am pleased to be part of it.

On this issue as I read Dr. Khan's statement, I was struck by his appropriate reference on several occasions to the role of State and local government, and we should be clear here. The role of the Federal Government in this situation is to direct the research to an overall coordinator, but the delivery of the service, whatever it is in terms of dealing with bioterrorism, is going to be overwhelmingly State and local. We don't have a core of Federal officials that we are going to dispatch.

And this is what troubles me about our current situation. While we are appropriately building up at the Federal level our capacity to deal with terrorism at that level, we are seeing an erosion at the State and local level of our capacity to carry out these policies. The

fact is that there are not two separate public health systems and two separate police departments and two separate fire departments, one of which at the State and local level exists to deal with terrorism outbreaks and another of which just exists to deal with ongoing activities, and what we have got, because of the fiscal policies being followed at the Federal and State level, is a serious erosion in many cases of the capacity of the State and local public safety people, public health, police, fire and others, to respond. And we are building up this structure at the same time that we are seeing the base weaken, and I do not think that it is a very sensible policy.

So I think it is important for us to go ahead with these preparations at the national level, but it is a mistake to think that we can do this. And as I said—read Dr. Khan's statement, he talks appropriately about working with State and local agencies. The actual execution of many of these plans is going to have to be carried out by local people, and as I said before, we were asked during anthrax whether the American public health system was ready for an outbreak of bioterrorism, and I can tell you from what I know of the cities, the American public health system isn't ready for Friday night.

I mean, by midnight tonight in many American cities, the emergency rooms are going to be closed. So to think we can then expect them in an emergency to take advantage of all this work that we hope we are going to be able to do is a mistake, and so I just urge that we treat—keeping the local public health, the local hospitals, the police, the fire and other responders in emergencies, keeping them in good shape overall is as important to this fight against any potential terrorism outbreak than anything else.

Chairman COX. I thank the gentleman.

Does the gentlelady from New York wish to make an opening statement?

Ms. SLAUGHTER. Thank you, Mr. Chairman. In the interest of time, I will withhold. I do have some questions, however, at the proper time. Thank you.

Chairman COX. Does any member wish to make a further opening statement?

PREPARED STATEMENT OF THE HONORABLE JIM LANGEVIN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF RHODE ISLAND

Thank you, Mr. Chairman. I would like to welcome our two witnesses, Dr. LaMontagne and Dr. Khan, for what I expect will be a very informative and productive hearing. I appreciate your willingness to come before us. I would also like to note that it is my understanding that the Committee sought witnesses from the Departments of Defense and Homeland Security to join you today, but none were forthcoming. It is my sincere hope that in the future, these agencies will show the same willingness as CDC and NIH to make their representatives available for participation in these important hearings.

Mr. Chairman, bioterrorism represents a major threat to our national security, and I believe it is our job as members of this Select Committee to instill confidence in the American people that a coordinated, concerted effort is being made to combat bioterror. Unfortunately, I do not think we have reached that point yet, but I do think that hearings like today' are important steps towards that goal.

I' very interested to hear from our witnesses about whether the resources they have are sufficient to handle the significant tasks for which they are responsible. In addition, I hope to learn what, if any, coordination exists between health-focused entities like CDC and NIH, and the Department of Homeland Security and Depart-

ment of Defense in identifying threats and directing efforts appropriately to address the most pressing dangers we face.

Specifically, I will be looking forward to hearing about what kind of formal procedures exist for information-sharing between members of the intelligence community and our federal medical researchers. If there is currently no formalized process, I would be interested to hear whether our witnesses think such a process would be helpful in determining where and how to direct their efforts, and how we on the Committee might be helpful in creating such a relationship.

I would also like to know whether our experts in the medical and public health areas of bioterror are working with peers in the intelligence community to determine threats and prioritize activities, or whether the intelligence agencies lack analysts with the appropriate medical expertise. Finally, I am interested in knowing whether DHS has sought the input of agencies like CDC and NIH as they set up their system for intelligence analysis of bioterror threats.

Again, Dr. Khan and Dr. LaMontagne, I greatly appreciate your presence here today. This is a vital issue, and I look forward to hearing from you both.

If not, I would like again to welcome our witnesses. We have two witnesses with us this morning, Dr. John Ring LaMontagne is the Deputy Director of the National Institute of Allergy and Infectious Diseases. And Dr. Ali Khan is the Chief Science Officer for parasitic diseases at the National Center for Infectious Diseases in the Center for Disease Control and Prevention.

Chairman COX. We have both of your written statements, and appreciate your submitting them. You are welcome to summarize and expand upon those statements in the 5 minutes that are dedicated to your formal testimony before we proceed to questions. I would like to begin, Dr. Khan, with you.

STATEMENT OF DR. ALI KHAN, CHIEF SCIENCE OFFICER, PARASITIC DISEASES, NATIONAL CENTER FOR INFECTIOUS DISEASES, CENTER FOR DISEASE CONTROL AND PREVENTION, DEPARTMENT OF HEALTH AND HUMAN SERVICES

Dr. KHAN. Good morning. Thank you.—se attention.

Chairman COX. Dr. Khan, I wonder if you could pull that microphone closer to you.

Dr. KHAN. Is that better? You have stated my current title. Let me start by saying that I was previously the scientific director for CDC's initial bioterrorism program and helped craft the framework for our national preparedness activities, including formulating our critical agent list to facilitate coordinated planning. Biologic agents on this list remain the basis for our State and local public health preparedness programs, formulary decisions for the national strategic stockpile, and the diagnostic reagents we distribute through our laboratory response network.

This list has also been—.

Mr. FRANK. Excuse me, Mr. Chairman. This room makes it hard to hear anything other than a horse, so if you could pull the mike closer and speak louder, I would appreciate it

Dr. KHAN. Is that better?

Chairman COX. Yes. Much better.

Dr. KHAN. The critical agent list has been embraced by the NIH for their research purposes and the medical community—.

Mr. FRANK. I hate to be picky, but a little too much—.

Dr. KHAN. I have been invited to discuss the process used to determine which biologic agents were selected for the list. However, let me state up front that my current activities center on global

emerging infectious diseases and malaria prevention activities worldwide.

However, I am joined by Mr. Joe Henderson, CDC's associate director for Terrorism Preparedness and Emergency Response, sitting on my right. He is the gentleman who is currently responsible for our bioterrorism preparedness program and is available for questions the committee may have about our current program.

I would like to go over two things briefly, first, how these certain biologic agents were selected and prioritized to make up the critical agent list and then the three categories of agents. In June of 1999, CDC convened a meeting of academic infectious disease experts, national, State and local public health authorities and civilian and military intelligence and law enforcement officials. They were asked to review and comment on the potential public health impact to civilian populations of various biologic agents. Four criteria were used to assess this public health impact. The first was the anticipated amount of illness and death do to an agent. The second was a delivery potential to a large population based on a combination of the stability of the agent, the ability to mass produce and distribute the agent and its potential for person-to-person spread.

The third criteria was the public perception of the agent in terms of arousing public fear and causing civil disruption. And the fourth criteria was the special public health preparedness needs relating to detecting and responding to the deliberate dissemination of a biologic agent in our communities based on their surveillance requirements, their diagnostic tools, stockpile needs, preparedness needs.

And these last two criteria are actually unique futures of the public health list, compared to many other lists that do occur for preparedness and other specific purposes.

Now, the participants I just discussed, they identified these four criteria and reviewed previously identified biological warfare agents in light of these four criteria. Once that was done, CDC personnel identified objective indicators in each of these categories, used a risk matrix analysis process to go ahead and further prioritize all of these agents that were initially discussed. The overall rating process in these four areas was used to assign agents to Category A, B and C, based on the priority of public health preparedness that would be required, and essentially the public health impact of these agents.

This risk matrix analysis in the final listing was subjected to an external peer review process and published for wide dissemination in the public health and medical communities. I believe all the members of the committee have a copy of that published paper that discussed the analysis and what agents eventually came out in that analysis.

And I will quickly go through those three categories. Agents in Category A have the greatest potential for adverse public health impact with mass casualties and essentially require the most broad-based public health preparedness efforts, be they be in surveillance, laboratory diagnosis, and again for the stockpile needs for specific medications. These agents have the most risk of dissemination to a large group of people, generally small particle aerosols in the air, and are most likely to cause civil disruption.

The diseases that these agents cause include smallpox, anthrax, plague, botulism, tularemia and some select biohemorrhagic fever such as Ebola hemorrhagic fever.

Now, it is because of this list and the presence of the anthrax on this list that we had Cipro and Doxi available in the national pharmaceutical stockpile. We had diagnostic tests for anthrax at all the local and State health departments in October of 2001 during the anthrax attacks. So it was because of that process that these preparedness measures were in place.

Now, the Category B agents have some potential for widespread dissemination, but do not pose the same threat potential or have the same degree of preparedness needs as Category A agents. Agents in this category required some focused improvements in surveillance and diagnostic, but generally the way these lists are structured, for the moment that you get to Category B, most of your stockpile and drug needs have already been met by Category A agents. So there is less need by the time you get to the second set of agents. And the agents on this list include brucellosis, typhus, various viruses that cause encephalitis and certain agents of concern for water and food safety issues, bioterrorism issues.

In the category C agents are not currently believed to present the high bioterrorism risk to public health, but they could emerge as future threats. Threat of these agents will be addressed by our general bioterrorism preparededness efforts and the ongoing development that is necessary for the public health infrastructure for detecting and responding to new diseases of unknown etiology or new emerging infectious diseases.

And the above category of agents should not be considered definitive. Agents in each category may change as we get new information or we obtain new assessment methods on how they may be used. However, fortunately, to date these lists—this list has not warranted being changed.

To meet the ever-changing response in preparedness challenges presented by bioterrorism, a standardized and reproducible evaluation process similar to the one I just outlined to you and is described in much more detail in the paper and the written testimony will continue to be used to evaluate and prioritize the current agents on the list and new agents that may emerge as threats to our civilian population and our national health security.

In conclusion, CDC is committed to working with other Federal agencies, academia and other partners, as well as State and local public health departments to ensure the health and medical care of our citizens. We have made substantial progress to date in enhancing the Nation's capacity to prepare for and respond to a bioterrorism event. The best strategy, however, that remains to protect the health of our civilians against a biological attack is the development, organization, and enhancement of our public health prevention systems, tools and research. Not only will this approach ensure that we are prepared for deliberate bioterrorist threats, but will also ensure that we are able to recognize and control naturally occurring and reemerging diseases such as West Nile a couple years ago, SARS this year, and pandemic influenza when it will reoccur.

A strong and flexible public health infrastructure is our best defense against any disease outbreak, and I believe many members have already mentioned this. Thank you very much for your attention. I will be happy to answer any questions you may have.

[The statement of Dr. Khan follows:]

PREPARED STATEMENT OF DR. ALI S. KHAN

Good morning, Mr. Chairman and Members of the Committee. I am Dr. Ali Khan, Associate Director for Medical Science, Division of Parasitic Diseases, National Center for Infectious Diseases, Centers for Disease Control and Prevention (CDC). I am accompanied today by Mr. Joseph M. Henderson, CDC's Associate Director of Terrorism Preparedness and Emergency Response. Thank you for the invitation to participate today in this hearing on the challenges and progress made in identifying agents that could be used as biological weapons. I will outline the overall selection and prioritization process used to determine the biological agents for CDC's public health preparedness activities.

As part of a Congressional initiative begun in 1999 to upgrade national public health capabilities for response to acts of biological terrorism, CDC was designated the lead agency for overall public health planning. An Office of Terrorism Preparedness and Emergency Response has been formed to help provide strategic direction across CDC, targeting areas to enhance preparedness activities, planning, improved surveillance and epidemiologic capabilities, rapid laboratory diagnostics, communications, and the delivery of medical therapeutics stockpiling. To focus these preparedness efforts, however, the biological agents toward which the efforts should be targeted had to be first formally identified and prioritized according to the level of threat posed. These agents make up CDC's critical agent list. This list is used as the framework for guidance to the state and local preparedness programs, determining the formulary for the Strategic National Stockpile, developing public health response plans and determining reagents and protocols for the Laboratory Response Network (LRN). The presence of anthrax on this list led to the focused preparedness efforts on drug stockpiles and diagnostic tests that were available during the 2001 anthrax attack.

A number of similar lists do exist such as the military's formal assessment of multiple agents for their strategic usefulness on the battlefield; an international list of agents for export control; a list of agents that have been processed for biowarfare; and classified lists. Most of these lists focused on biowarfare, but for public health preparedness purposes, CDC needed a list of agents that could have significant impact on the U.S. population. To guide the national public and medical health bioterrorism preparedness and response efforts, we devised a method for assessing potential biological threat agents that would provide a reviewable, reproducible means for standardized evaluations of these threats. Identifying these priority agents helps facilitate coordinated planning efforts among federal agencies, state and local emergency response and public health agencies, and the medical community.

Overview of Agent Selection and Prioritization Process

In June 1999, CDC convened a meeting of academic infectious disease experts, national public health experts, Department of Health and Human Services agency representatives, civilian and military intelligence experts, and law enforcement officials to review and comment on the threat potential of various agents to civilian populations. While biological agents can cause illness in humans, not all are capable of affecting public health and medical infrastructures on a large scale. The following four general criteria were used to assess this public health impact: 1) the anticipated amount of illness and death with an agent; 2) the delivery potential to large populations based on stability of the agent, ability to mass produce and distribute a virulent agent, and potential for person-to-person transmission; 3) the public perception as related to fear and potential civil disruption; and 4) the special public health preparedness needs based on stockpile requirements, enhanced surveillance, or diagnostic tools necessary to respond to a deliberate dissemination of an agent. These last two criteria were the unique features of the public health critical agent list.

Participants discussed and identified these four criteria and reviewed available lists to subjectively place agents they felt had the potential for high impact. Participants with appropriate clearance levels also reviewed intelligence information regarding classified suspected biological agent threats to civilian populations. Genetically engineered or recombinant biological agents were considered but not included for final

prioritization because of the inability to predict the nature of these agents and thus identify specific preparedness activities for public health and medical response to them. In addition, no information was available about the likelihood for use of one biological agent over another. This aspect, therefore, could not be considered in the final evaluation of the potential biological threat agents.

After the meeting, CDC personnel then attempted to identify objective indicators in each category that could be used to further define and prioritize the identified high impact agents and provide a framework for an objective risk-matrix analysis process for any potential agent. The agents were evaluated in each of the general areas according to the objective parameters. Final category assignments (A, B, or C) of agents for public health preparedness efforts were then based on an overall evaluation of the ratings the agents received in each of the four areas.

Categories of Agents

Based on the overall criteria and weighting, agents were placed in one of three priority categories for initial public health preparedness efforts: A, B, or C. Agents in Category A have the greatest potential for adverse public health impact with mass casualties, and most require broad-based public health preparedness efforts (e.g., improved surveillance and laboratory diagnosis and stockpiling of specific medications). Category A agents also have a moderate to high potential for large-scale dissemination or a heightened general public awareness that could cause mass public fear and civil disruption.

Most Category B agents also have some potential for large-scale dissemination with resultant illness, but generally cause less illness and death and therefore would be expected to have lower medical and public health impact. These agents also have lower general public awareness than Category A agents and require fewer special public health preparedness efforts. Agents in this category require some improvement in public health and medical awareness, surveillance, or laboratory diagnostic capabilities, but presented limited additional requirements for stockpiled therapeutics beyond those identified for Category A agents. Biological agents that have undergone some development for widespread dissemination but do not otherwise meet the criteria for Category A, as well as several biological agents of concern for food and water safety, are included in this category.

Biological agents that are currently not believed to present a high bioterrorism risk to public health but which could emerge as future threats (as scientific understanding of these agents improves) were placed in Category C. These agents will be addressed nonspecifically through overall bioterrorism preparedness efforts to improve the detection of unexplained illnesses and ongoing public health infrastructure development for detecting and addressing emerging infectious diseases.

Agents were categorized based on the overall evaluation of the different areas considered. For example, smallpox would rank higher than brucellosis in the public health impact criterion because of its higher untreated mortality (approximately 30 percent for smallpox and less than or equal to 2 percent for brucellosis); smallpox has a higher dissemination potential because of its capability for person-to-person transmission. Smallpox also ranks higher for special public health preparedness needs, as additional vaccine must be manufactured and enhanced surveillance, educational, and diagnostic efforts must be undertaken. Inhalational anthrax and plague also have higher public health impact ratings than brucellosis because of their higher morbidity and mortality. Although mass production of Vibrio cholerae (which causes cholera) and Shigella species (which cause shigellosis) would be easier than the mass production of anthrax spores, the public health impact of widespread dissemination would be less because of the lower morbidity and mortality associated with these agents and because of some of the preparedness efforts implemented for other agents such as drug stockpiles.

The above categories of agents should not be considered definitive. Agents in each category may change as new information is obtained or new assessment methods are established. To date, changes to these lists have not been warranted. Disease elimination and eradication efforts may result in new agents being added to the list as populations lose their natural or vaccine-induced immunity to these agents. Conversely, the priority status of certain agents may be reduced as the identified public health and medical deficiencies related to these agents are addressed (e.g., once adequate stores of smallpox vaccine and improved diagnostic capabilities are established, its overall rating within the risk-matrix evaluation process might be reduced). To meet the ever-changing response and preparedness challenges presented by bioterrorism, a standardized and reproducible evaluation process similar to the one outlined above will continue to be used to evaluate and prioritize currently iden-

tified biological critical agents, as well as new agents that may emerge as threats to civilian populations or national security.

Conclusion

In conclusion, CDC is committed to working with other Federal agencies, academia, and other partners, as well as State and local public health departments, to ensure the health and medical care of our citizens. We have made substantial progress to date in enhancing the Nation's capability to prepare for and respond to a bioterrorist event. The best public health strategy to protect the health of civilians against a biological attack is the development, organization, and enhancement of public health prevention systems and tools. Priorities include strengthened public health laboratory capacity; increased surveillance and outbreak investigation capacity; and health communications, education, and training at the Federal, State, and local levels. Not only will this approach ensure that we are prepared for deliberate bioterrorist threats, but it will also ensure that we will be able to recognize and control naturally occurring new or re-emerging infectious diseases such as SARS or pandemic influenza. A strong and flexible public health infrastructure is the best defense against any disease outbreak.

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

Ms. DUNN. [Presiding.] Thank you very much, Dr. Khan. And next we will hear from Dr. LaMontagne, who is the deputy director of the National Institute of Allergy and Infectious Diseases for the National Institutes of Health. May I just suggest to you, Dr. LaLantagne, the speakers are not aimed in our direction, and if you could speak slowly and precisely, we will give you the extra time you need, but it is very difficult to hear. The acoustics in this room are terrible. Go ahead, Dr. LaMontagne.

STATEMENT OF JOHN RING LaMONTAGNE, PH.D., DEPUTY DIRECTOR, NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES, NATIONAL INSTITUTES OF HEALTH, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Dr. LAMONTAGNE. Thank you very much, Madam Chair and members of the Committee. Thank you for giving me the opportunity to discuss the comprehensive and accelerated process for developing medical countermeasures against bioterrorist threats. As you know, the National Institutes of Health, particularly the National Institute of Allergy and Infectious Diseases, of which I am Deputy Director, is engaged in a vigorous effort to ensure homeland security and protect the American people against potential agents of bioterrorism, as well as emerging and reemerging infectious diseases.

Integral to this effort is the enactment of Project BioShield which will increase the authority and flexibility of the NIH to expedite research towards the development of critical medical countermeasures for biodefense.

Today I will describe for you, one, how the NIAID has set up its research priorities to develop vaccines and therapeutics against bioterrorist threats; two, why NIAID has identified certain biological agents as its top research priorities and, third, what NIAID is doing to ensure that medical countermeasures, particularly vaccines and therapeutics, are developed as rapidly as possible to protect homeland security.

The NIAID set its research priorities for defense against bioterrorism through a comprehensive and systematic process. Since February of 2002, we have convened four multi-institutional panels of scientific experts and developed a strategic plan and a strategic re-

search agenda based on their recommendations. For example, based on advice of the Blue Ribbon Panel on Bioterrorism and Its Implications for Biomedical Research, we developed the NIAID Strategic Plan for Biodefense Research and the NIAID Research Agenda for CDC Category A Agents.

Strategic plan emphasizes, first of all, basic research on microbes and host defenses; second, targeted milestone-driven development of drugs, vaccines, other interventions and diagnostics.

The NIAID defense research agenda emphasizes the short-term, intermediate, and long-term goals for research in Category A agents, a group of microbes and toxins that you have just heard about identified by the CDC as the most dangerous. These include anthrax, smallpox, plague, botulinum toxin, tularemia, and hemorrhagic fevers caused by viruses such as Ebola.

Thus, the initial focus of our biodefense research effort has been to develop new and improved vaccines, therapeutics and diagnostic tests against Category A agents. An essential component of this program is enhancing the Nation's capability to conduct research on these agents. This requires that additional high-containment research facilities known as BSL 3, or biosafety level 3, and BSL 4 laboratories be constructed and made accessible to government-supported scientists. Also required to fulfill the goals of our research program are other specialized research resources such as centers for sequencing the genomes of these microbes and skilled scientists and technicians who are trained to handle dangerous microbes and toxins.

In addition to research on Category A agents, NIAID is also spearheading efforts to develop new and improved vaccines, therapeutics, and diagnostics for Category B and C agents as well.

Again, based on the recommendations of a blue ribbon panel, we developed the NIAID biodefense Research Agenda for Category B and C Priority Pathogens. These agents include a diverse array of viruses, bacteria and bacterial toxins that are carried by insects, livestock, and other vectors; can be inhaled; or are spread through contaminated food and water.

I have indicated that the NIAID biodefense program emphasizes research on Category A agents: anthrax, smallpox, plague, botulinum, tularemia, and Ebola and other hemorrhagic fever viruses. Why are these viruses, bacteria and toxins considered the more dangerous potential agents of bioterrorism? Many of the microbes, such as those that cause measles, mumps or even AIDS cause serious illness that are not in a Category A list.

Simply put, the high priority Category A agents include organisms that can pose a risk to national security, because they, first of all, can be easily disseminated and transmitted from person to person. They result in higher mortality rates and have a potential for major public health impact. They might cause public panic and social disruption. They require special action for public health preparedness.

In Category B agents are considered to have the second highest priority in terms of the bioterrorist threat potential. These agents are moderately easy to disseminate, result in moderate morbidity rates and low mortality rates and require specific enhancements of our diagnostic capacity and enhanced disease surveillance.

Category C agents, the next highest priority, include emerging microbes that could be engineered for mass dissemination in the future because of their availability, ease of production and dissemination and potential for high morbidity and mortality rates, and obviously a major health impact.

In general, the NIAID has three broad goals in vaccine research. The first is to identify new vaccine candidates to prevent disease for which no vaccines currently exist, improve the safety and efficacy of existing vaccines and, third, to design novel vaccine approaches such as the use of new vectors or adjuvants.

To achieve these goals, NIAID supports basic research to understand the biology of the microbes that cause disease and to determine how humans and other animals respond to infection with these microbes. Key to our understanding of microbial biology is identification of the nucleic acid sequence of their genomes. With this information in hand, we will be better poised to identify molecular targets to use in the design of vaccines and therapeutics.

Another primary objective of the NIAID biodefense research program is to attract the long-term interest and support of academia and industry in the efforts needed to develop effective bioterrorism countermeasures.

NIAID's biodefense research program facilitates the involvement of academic scientists through the use of all available funding mechanisms including the development of a network of Regional Centers of Excellence for research on bioterrorism and emerging and reemerging infectious diseases.

Our biodefense strategic plan and research agenda has required an expansion of investigator-initiated and institute-initiated grants and contracts. In Fiscal Year 2002 and 2003, NIAID developed a total of 46 different biodefense initiatives to stimulate research in this area. Thirty are totally new, and 16 are significant expansion. During this time, NIAID has also seen a 30 percent increase in the number of grant applications. The vast majority of these are in response to our biodefense initiatives.

In closing, thank you again for giving me opportunity to testify today before you about NIAID's biodefense research agenda. I would be pleased to answer any questions you might have.

Ms. DUNN. Thank you very much, Dr. LaMontagne.

[The statement of Dr. LaMontagne follows:]

PREPARED STATEMENT OF DR. JOHN R. LAMONTAGNE

Mr. Chairman and Members of the Committee, thank you for giving me the opportunity to discuss the comprehensive and accelerated process for developing medical countermeasures against bioterrorist threats. As you know, the National Institutes of Health (NIH), particularly the National Institute of Allergy and Infectious Diseases (NIAID), of which I am Deputy Director, is engaged in a vigorous effort to ensure homeland security and protect the American people against potential agents of bioterrorism as well as emerging and re-emerging infectious diseases.

The destruction of the World Trade Center, the attack on the Pentagon, and the anthrax attacks in the fall of 2001 starkly exposed the vulnerability of the United States to acts of terrorism. At the NIH, and particularly at the NIAID, these events triggered the development of an aggressive, broadly based research program designed to provide the American people with vaccines and therapeutics against a range of bioterrorist threats.

Integral to this effort is the enactment of Project BioShield, which will increase the authority and flexibility of NIH to expedite research toward the development of crit-

ical medical countermeasures for biodefense. Project BioShield would also establish a secure funding source for the purchase of critical medical countermeasures, and would give the Food and Drug Administration (FDA) an Emergency Use Authorization for these countermeasures. Thus, the accelerated research and development program of the NIH, and the NIAID in particular, would work in concert with Project BioShield to provide the American people with safe and effective vaccines and therapeutics to protect them against a range of biological threats.

Today, I will describe to you: (1) how the NIAID has set its research priorities to develop vaccines and therapeutics against bioterrorist threats; (2) why NIAID has identified certain biological agents as its top research priorities; and (3) what NIAID is doing to ensure that medical countermeasures—particularly vaccines and therapeutics—are developed as rapidly as possible to protect homeland security.

Overview

For years, civilian agencies such as the NIH, the FDA, the Centers for Disease Control and Prevention (CDC), as well as the U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID) in the Department of Defense (DoD), have addressed the threat of bioterrorism. The research has been directed at viruses, bacteria, and bacterial toxins that could emerge or re-emerge spontaneously in nature, or that could be intentionally released as biological weapons into human populations. However, the anthrax attacks of 2001 revealed significant gaps in our overall preparedness against bioterrorism, and gave a new sense of urgency to our biodefense research efforts.

We realized quickly that it was no longer adequate to do business as usual. A primary goal of the NIH has always been to support research efforts that generate new knowledge about disease and to translate these findings into vaccines, therapeutics, and diagnostics that protect public health. But, to develop safe and effective products for biodefense as quickly as possible, we needed to intensify and accelerate this process. Thus, we sought creative ways in which to modify NIH's traditional process of research and development, while continuing to preserve the excellence that is a hallmark of NIH research. The NIAID biodefense research program is directed primarily toward the needs of civilian populations, although interventions emerging from it may logically also have application in military settings.

How has NIAID set its research priorities to develop vaccines and therapeutics against bioterrorist threats?

Bioterrorism is defined as the intentional use of microorganisms that cause human disease, or of toxins derived from them, to harm individual people or to elicit widespread fear or intimidation of society.

The NIAID set its research priorities for defense against bioterrorism through a comprehensive and systematic process. Since February of 2002, we have convened four multi-institutional panels of scientific experts, and developed a strategic plan and strategic research agendas based on their recommendations. Based on advice from the Blue Ribbon Panel on Bioterrorism and Its Implications for Biomedical Research, we developed the NIAID Strategic Plan for Biodefense Research and the NIAID Research Agenda for CDC Category A Agents. The Strategic Plan emphasizes: 1) basic research on microbes and host defenses; and 2) targeted, milestone-driven development of drugs, vaccines, other interventions, and diagnostics. The NIAID Biodefense Research Agenda emphasizes the short-term, intermediate, and long-term goals for research on Category A agents, a group of microbes and toxins identified by the CDC as the most dangerous. These include anthrax, smallpox, plague, botulism, tularemia, and hemorrhagic fevers caused by viruses such as Ebola.

Thus, the initial focus of our biodefense research effort has been to develop new and improved vaccines, therapeutics, and diagnostics against Category A agents. An essential component of this program is enhancing the Nation's capability to conduct research on these agents. This requires that additional high-containment research facilities, known as BioSafety Level-3 (BSL–3) and BSL–4 laboratories, be constructed and made accessible to government-supported scientists. Also required to fulfill the goals of our research program are other specialized research resources such as centers for sequencing the genomes of these microbes, and skilled scientists and technicians who are trained to handle dangerous microbes and toxins.

In addition to research on Category A agents, NIAID is also spearheading efforts to develop new and improved vaccines, therapeutics, and diagnostics for Category B and C agents. Again, based on the recommendations of a blue ribbon panel, we developed the NIAID Biodefense Research Agenda for Category B and C Priority

Pathogens. These agents include a diverse array of viruses, bacteria, and bacterial toxins that are carried by insects, livestock, or other vectors; can be inhaled; or are spread through contaminated food and water. They include the bacteria that cause typhus and cholera, and viruses such as West Nile virus, which is carried by mosquitoes, and tick-borne encephalitis virus. As is the case for the Category A agents, NIAID research on Category B and C agents is designed to understand the biology of the microbe and the host response to the microbe, and to use that knowledge as the basis for developing safe and effective vaccines and other medical countermeasures.

Why has NIAID identified certain biological agents as its top research priorities?

I have already indicated that the NIAID biodefense program emphasizes research on Category A agents: anthrax, smallpox, plague, botulism, tularemia, Ebola and other hemorrhagic fever viruses. Why are these viruses, bacteria, and toxins considered the most dangerous potential agents of bioterrorism? Many other microbes, such as those that cause measles, mumps, or even AIDS, cause serious illness but are not on the Category A list. Simply put, the high-priority Category A agents include organisms that pose a risk to national security because they:

- Can be easily disseminated or transmitted from person to person
- Result in high mortality rates and have the potential for major public health impact
- Might cause public panic and social disruption
- Require special action for public health preparedness

Category B agents are considered to have the second highest priority in terms of their bioterrorist threat potential. These agents are moderately easy to disseminate, result in moderate morbidity rates and low mortality rates, and require specific enhancements of our diagnostic capacity and enhanced disease surveillance. Category C agents have the next highest priority. They include emerging pathogens that could be engineered for mass dissemination in the future because of their availability, ease of production and dissemination, and potential for high morbidity and mortality rates and major health impact.

What is NIAID doing to ensure that vaccines and therapeutics are developed as rapidly as possible to protect homeland security?

The process by which NIAID is developing safe and effective countermeasures for biodefense is complex and multifaceted. I would like to describe, in general terms, how we develop vaccines. I will relate this process to the specific development of vaccines and therapeutics for biodefense.

In general, the NIAID has three broad goals in vaccine research:

- Identifying new vaccine candidates to prevent diseases for which no vaccines currently exist.
- Improving the safety and efficacy of existing vaccines. (NIAID researchers are collaborating with colleagues at USAMRIID, and with private industry, to develop and test safer, next-generation vaccines for smallpox and anthrax.)
- Designing novel vaccine approaches, such as new vectors and adjuvants (Scientists at the NIAID Vaccine Research Center are working to develop gene-based vaccines for Ebola and related viruses.)

To achieve these goals, NIAID supports basic research to understand the biology of the microbes that cause disease and to determine how humans and other animals respond to infection with these microbes. Key to our understanding of microbial biology is identifying the nucleic acid sequence of their genomes. With this information in hand, we will be better poised to identify molecular targets to use in the design of vaccines or therapeutics. Recently, for example, two teams of NIAID-funded researchers at The Institute for Genomic Research in Rockville, MD, reported the complete genetic sequence of the strain of Bacillus anthracis used in the 2001 anthrax mail attacks, and the complete genomic sequence of the Q-fever pathogen and Category B agent, Coxiella burnetii.

In addition to understanding how a microbe causes disease, it is also important to understand how animals and humans respond to microbial infection. NIAID supports research on innate and adaptive immune responses in a range of animal models and in humans. We also are working to understand how certain pathogens evade immune surveillance and use this information to design ways to trigger a protective immune response. We are investigating new immunostimulatory agents that boost the effectiveness of vaccines. Additionally, we need to understand how immune re-

sponses vary in different individuals according to age, general health status, genetic makeup, and treatment with immunosuppressive drugs.

Developing new and improved vaccines and therapeutics also requires a strong clinical infrastructure. NIAID supports Vaccine and Treatment Evaluation Units, which conduct human clinical trials to determine the safety and efficacy of candidate vaccines for infectious diseases, including several caused by Category A, B, and C agents. This network has served as a national resource for the independent evaluation of vaccines since 1992.

Another primary objective of the NIAID biodefense research program is to attract the long-term interest and support of academia and industry in the efforts needed to develop effective bioterrorism countermeasures. NIAID's biodefense research program facilitates the involvement of academic scientists through the use of all available funding mechanisms, including the development of a network of Regional Centers of Excellence for research on bioterrorism and emerging and re-emerging infectious diseases.

Key to the development of safe and effective medical countermeasures for biodefense are collaborations with private industry. Since the Fall of 2001, we have strengthened and expanded our interactions with the private sector, including biotechnology companies and pharmaceutical manufacturers. Many biodefense products will not provide sufficient incentives for industry to develop on their own, because a profitable market for these products cannot be guaranteed. Therefore, NIAID has developed public-private partnerships to overcome these obstacles. Also, the passage of Project BioShield, which would authorize the purchase of biodefense countermeasures, would provide a much-needed incentive to participate in this effort.

Our biodefense strategic plan and research agenda has required an expansion of investigator-initiated and Institute-initiated grants and contracts. In Fiscal Years 2002 and 2003, NIAID developed a total of 46 biodefense initiatives to stimulate research: 30 are new initiatives and 16 are significant expansions. During this same time period, NIAID has seen a 30 percent increase in the number of grant applications; the vast majority of these are in response to our biodefense initiatives.

Still another important element in our biodefense research program is an enhancement of Intramural research. Of note, the NIAID Vaccine Research Center, is working on the development of new and improved vaccines against a range of bioterrorist threats, including the Ebola virus, as well as a next-generation vaccine against smallpox.

Related to our biodefense preparedness research program is a more recent, NIH-wide effort to develop effective countermeasures against chemical and nuclear/radiological weapons. We recognize the NIH may not necessarily have a predominant role in developing countermeasures for these threats, although we must still be prepared for any eventuality. Dr. Elias Zerhouni, the director of NIH, has established the NIH Biodefense Research Coordinating Committee to facilitate and coordinate the development of a research agenda and to implement R&D programs that address relevant aspects of chemical and nuclear/radiological threats. Dr. Anthony S. Fauci, the director of NIAID, serves as committee chairman.

That concludes my testimony. I would be happy to answer any questions you may have.

Ms. DUNN. It was a little difficult to hear, and so I would like to know from you, both you gentlemen, the list that we talked about, the categories A, B and C that are current priorities, how will they compare, do you believe, over what you expect to recommend to the Secretary as your bioterrorism threat prioritizations as we move into the future?

Dr. LAMONTAGNE. Well, I would say that we strongly believe the Category A agents represent the major threats, and within that list three major targets, I think, for which there is probably unanimous agreement is smallpox, anthrax and botulism, but all of the agents on that list—all seven of the category A agents, I think, are considered to be important targets.

Dr. KHAN. Let me state that the list that we are talking about are the identical lists, so NIH at least has coordination between

CDC and NIH on these same lists. And, again, our State and local health departments and the medical community agree on the nature of those lists and how they were put together. The criteria to put together those lists and the agent remain valid currently, and the agents within them and the way they were prioritized also appear to remain valid. The Agency already reevaluates this process on a yearly basis as they provide new guidance to State and local health departments to verify that the lists are valid.

Ms. DUNN. Thank you. Yesterday we had a hearing in which we discussed these issues with the man in charge for the Department of Homeland Security, and I think we all had some question that over the next 10 years we are going to be spending $5.6 billion on this program. We want to make sure that DHS can handle it. A few months ago, the SARS epidemic struck North America and the rest of the world. Not knowing at the beginning whether this was a biological attack, how did the Department of Homeland Security work with both of your organizations in responding to the outbreak? What organizational structure was established? And were you effectively able to work through that problem?

Dr. LAMONTAGNE. Well, I think in response to the question about interaction or communication with homeland security, I think that given the youth of the organization and the idea of homeland security, that is, I think that our interactions have been actually quite good. We do have frequent meetings with them. There are meetings at the departmental level as well, but I am not perceiving that there is an inability to communicate with them pretty effectively on these issues. I think we do.

Dr. KHAN. Let me make a comment about SARS. I just came back from 5 weeks in Singapore assisting them with the SARS outbreak, and I asked for consultation with Mr. Joe Henderson about this question in preparation for this question, and, yes, CDC did work with DHS to discuss the SARS outbreak.

Let me state that we have been doing this for a number of years. We did it for the West Nile outbreak when it was originally identified in the United States to verify that it was not bioterrorism. There are also published guidelines on how we evaluate epidemics, coauthored by CDC and the FBI to go through the epidemiologic and laboratory criteria on how to investigate an outbreak and say whether or not you think it is bioterrorism.

For specific comments about our current relationships and structure with DHS, if you would allow me, I believed defer to Mr. Henderson who can talk about our specific relationships.

Mr. HENDERSON. Thank you for the opportunity to make a few additional comments on what Dr. Khan had mentioned regarding our work with homeland security. It is a new forming organization, and we are working with them closely. When SARS first appeared, of course the first thing we were concerned with was that it was, in fact, potentially a terrorism event. Since September 11th, that is the way our thinking has been in relation to emerging diseases and outbreaks globally. We have, I think, additional room to work with homeland security to make sure that we have a process in place to rapidly analyze information regarding potential terrorist threats, but we do have a routine communication with homeland security on these issues.

Ms. DUNN. Thank you, gentlemen. Dr. Khan, you mentioned in your statement that both civilian and military intelligence experts were parts of the panel that the CDC established in 1999 to help formalize and prioritize the categories A, B, and C biological agents and you also mentioned that participants with appropriate clearance levels also reviewed the intelligence information regarding classified suspected biological agent threats to civilian populations.

Can you tell us what agencies within the Intelligence Community participated on your panel generically and at an unclassified level can you explain how this information was analyzed? For example, is the information a product or raw or analyzed information. Is this collaboration still ongoing?

Dr. KHAN. We can submit to the committee a complete list of agencies and individuals who were present at that briefing if they would request. As far as putting the list together, the purpose of the list was actually to try to develop something that would not be classified and be available for the whole public health and medical community. So we took the information that was available on the biowarfare agents and extrapolated that to what would happen in specific categories if they were used on civilian populations. That allowed us to go from what would essentially be considered some sort of classified information to unclassified public use information that would be used for preparedness purposes.

Ms. DUNN. Looking forward to that list. Thank you very much, gentlemen. And now, Congressman Turner, would you like to ask your questions for 5 minutes?

[The information follows:]

Participants in CDC Critical Biological Agents for Public Health Preparedness Meeting, June 3–4, 1999

Donald A. Henderson, M.D., M.P.H.
Director,
Johns Hopkins Center for Civilian Biodefense Studies

Thomas Inglesby, M.D.
Johns Hopkins Center for Civilian Biodefense Studies

Dennis Perrotta, Ph.D.
Chief, Bureau of Epidemiology,
Texas Department of Health

Mike Osterholm, M.D., M.P.H.
Chair and CEO
Infection Control and Advisory Network, Inc.

Kenneth Bernard, M.D.
Special Advisor to the Assistant to the
President of the United States on National Security

Kathy Zoon, Ph.D.
Director, Center for Biologics Evaluation and Research
Food and Drug Administration

Mark Elengold
Deputy Director, Center for Biologics
Evaluation and Research
Food and Drug Administration

Participants in CDC Critical Biological Agents for Public Health Preparedness Meeting, June 3–4, 1999—Continued

George Hughes
Special Agent
Office of Criminal Investigations
Office of Regional Affairs
Food and Drug Administration

John Taylor
Senior Advisor for Regulatory Policy
Office of the Commissioner
Food and Drug Administration

Martha Girdany
Biological and Chemical Group
DCI Nonproliferation Center

Kathleen Kuker
Director, Weapons of Mass Destruction Operations
Federal Bureau of Investigations

Howard Stirne, M.D.
Consultant, Medical Coordinator, SWAT EOD
Federal Bureau ofInvestigations

Jeff Mazanec
Supervisory Special Agent,
Joint Terrorism Task Force
Federal Bureau ofInvestigations

Arlene Reidy
Department of Justice

Ted Plasse, M.S.
Defense Intelligence Agency
Biological Warfare Group

LTC Ted Cieslak, M.D.
US Army Medical Research
Institute of Infectious Diseases

William Raub, Ph.D.
Deputy Assistant Secretary for Science Policy
Department of Health and Human Services

Amandeep Matharu

Scott Lillibridge, M.D.
Director, Bioterrorism Preparedness and Response Program
National Center for Infectious Diseases
Centers for Disease Control and Prevention

Steve Ostroff, M.D.
Associate Director for Epidemiologic Science
National Center for Infectious Diseases
Centers for Disease Control and Prevention

James LeDuc, Ph.D.
Associate Director for Global Health
National Center for Infectious Diseases
Centers for Disease Control and Prevention

Ali Khan, M.D.
Deputy Director, Epidemiology and Surveillance
Bioterrorism Preparedness and Response Program
Centers for Disease Control and Prevention

C.J. Peters, M.D.
Chief, Special Pathogens Branch
Division of Viral and Rickettsial Diseases
National Center for Infectious Diseases

Participants in CDC Critical Biological Agents for Public Health Preparedness Meeting, June 3–4, 1999—Continued

Budget Examiner for Bioterrorism and Food Safety
Office of Management and Budget
Department of Health and Human Services

RADM Robert Knouss, M.D.
Director, Office of Emergency Preparedness
Department of Health and Human Services

CDR Kevin Tonat, Dr.P.H., M.P.H.
Special Assistant to the Director
Office of Emergency Preparedness
Department of Health and Human Services

John La Montagne, Ph.D.
Deputy Director, National Institute of
Allergy and Infectious Diseases
National Institutes of Health

James Hughes, M.D.
Director
National Center for Infectious Diseases
Centers for Disease Control and Prevention

Centers for Disease Control and Prevention

Robert Craven, M.D.
Chief, Epidemiology Section,
Arbovirus Diseases Branch
Division of Vector-Borne Infectious Diseases
National Center for Infectious Diseases

Joseph Esposito, Ph.D.
Chief, Poxvirus Section, Viral Exanthems and
Herpesvirus Branch
Division of Viral and Rickettsial Diseases
National Center for Infectious Diseases
Centers for Disease Control and Prevention

David Ashford, D.V.M., M.P.H.
Meningitis and Special Pathogens Branch
Division of Bacterial and Mycotic Diseases
National Center for Infectious Diseases
Centers for Disease Control and Prevention

David Swerdlow, MD
Foodborne and Diarrheal Diseases Branch
Division of Bacterial and Mycotic Diseases

National Center for Infectious Diseases
Centers for Disease Control and Prevention

Steve Bice
Chief, National Phannaceutical Stockpile Branch
Division of Emergency and Environmental
Health Services
National Center for Environmental Health
Centers for Disease Control and Prevention

Lisa Rotz, M.D.
Bioterrorism Preparedness and Response Program
National Center for Infectious Diseases
Centers for Disease Control and Prevention

Peg Tipple, M.D.
Assistant Director of Medical Science,
Office of Health and Safety
Office of the Director
Centers for Disease Control and Prevention

Participants in CDC Critical Biological Agents for Public Health Preparedness Meeting, June 3–4, 1999—Continued

Bryan Hardin, Ph.D.
Deputy Director
National Institute for Occupational Safety and Health
Centers for Disease Control and Prevention

Scott Deitchman, M.D.
National Institute for Occupational Safety and Health
Centers for Disease Control and Prevention

Arnold Kaufmann, Ph.D.
Emergency Response and Coordination Group
National Center for Environmental Health
Centers for Disease Control and Prevention

DDonald Shriber, M.P.H.
Associate Director/Washington
Centers for Disease Control and Prevention

Martha Katz
Deputy Director for Policy and Legislation
Office of the Director
Centers for Disease Control and Prevention

Mr. TURNER. Thank you, Madam Chairman. Dr. LaMontagne, I want to start with you and ask a couple of questions.

Under the BioShield legislation that is before this committee, the funding that has been talked about so much and has been modified as it has moved forward through the process of congressional hearings, is dedicated to "security countermeasures" which are defined under the bill as "approved drugs or drugs that have sufficient clinical experience or research data to qualify for approval or licensing at a later date." Now, one of the concerns that I have had about BioShield is that the much talked about funding is limited to that stage at the end of the process after the vaccine has been discovered, after it has been tested at an applied research level, after all that is done. Only then is the BioShield funding available to contract with the private company to go through the final stages of clinical trials and production of the vaccine. That is what is referred to oftentimes by Dr. Fauci as the pull side of the equation. I am more interested in, because of the area that you work in, understanding the push side of this process. And I know that the creation of the Center for Vaccine Research deals with a broad category of potential threats. I think it was originally created to try to deal with AIDS. But you obviously have expanded it and it is now the entity that would deal with the basic research, the applied research, and developing the vaccines necessary to meet these biological threats that we have talked about.

I am very interested in how you view the capability that you currently have, even with the expanded funding, to provide the leadership that is necessary to do the basic research and the applied research to come up with the vaccines that can be moved to the final stages, develop as and produced the private sector. Could you give us some feel for your capacity to accomplish that task?

Dr. LAMONTAGNE. Well, I will try. That is a complicated set of questions. But let me begin by clarifying something about the Vac-

cine Research Center, which, as you said, is the unit which is on the NIH campus which is part of our Institute dedicated to the development of vaccines. And it was created 4 years ago or so with the express notion that it would focus on AIDS vaccines. It has expanded its agenda in a clear reflection of the pressures and priorities that the Nation is facing to add to its activities some very important work in other vaccines, particularly Ebola virus and West Nile, which are two very interesting projects that it has currently underway.

The process of vaccine development or countermeasure development, however you want to phrase it, particularly for biodefense agents, is a very complex one because for one thing the marketability of these products at the end of the process is limited. Secondly, the ability to test these materials in the traditional randomized clinical trial settings that we have become accustomed to, for example, for AIDS drugs or for other vaccines is simply not available. There are not enough anthrax cases, for example—anthrax, fortunately is not a common disease, plague is not a common disease, Ebola is not a common disease. To satisfy the standards for efficacy and safety that one might require under normal circumstances, we have had to adapt to what the FDA is now referring to as the two-animal rule. In other words, we will seek to gain evidence of the efficacy of these materials by testing them in a very rigorous manner. There is not going to be any compromises here in terms of their ability to elicit protective responses in at least two different animal model systems. We will then use that information in addition to information obtained in clinical trials of the antigenicity of these or the immunogenicity, the ability of these vaccines, for example, to elicit protective immune responses in humans and compare those to what we see in the animal model systems. Based on that information we should be able to assess whether or not a particular vaccine is of the quality that will provide the kinds of protection that are needed to prevent disease following a challenge from whatever source.

I should just conclude my remarks by saying there is another very difficult aspect to this, and that is what you can do in a laboratory; for example, the Vaccine Research Center can make candidate vaccines in the 10,000 to 20,000 dose range. When you are talking about vaccines that are going to be required in the millions or tens of millions of dose ranges, you require an amplification of production capacity that really only exists in the private sector. So we have to develop methods or ways of attracting and bringing the private sector into this process early on so that they can then take the handoff when it is appropriate and move those vaccines into the level of production that is going to be required to meet a national challenge such as the one we are facing.

I hope that answers your question.

Mr. TURNER. I will follow up with you on my next round of questioning. Thank you, Doctor.

Chairman COX. [Presiding.] Thank you. The Chair recognizes himself for 5 minutes. What we are interested in here today, in particular, is to propose the role for the Department of Homeland Security because nothing that gets funded under Project BioShield for ultimate stockpiling and use can go forward unless there is a

materiality determination by the Secretary of Homeland Security under the terms of the proposed statute; that is, the statutory scheme, so very literally the determination, responsibility exercised by the Secretary of Homeland Security is the linchpin of all of the scientific work that proceeds and all the monies that get spent in support of it and in support of the stockpile.

I have every confidence that CDC, NIAID, are competent to determine the relative lethality of the different agents that might be used against our human population, against American people as the result of a terrorist attack or military threat. But the job of Homeland Security encompasses more than that. We have to have some notion of what are the capabilities of terrorist groups, what are the capabilities of states or other individuals or organizations; second, what are the means that these states or terrorist groups or individuals might use to deploy those weapons; and, third, perhaps most important, what is the probability of that happening given their capabilities and given the means of deploying the weapons. Ultimately, of course we have to go back then to the science and say if they are going to deploy in this fashion, given their capabilities what would be the relative lethality, what would be the effect and, summing it all up, is that material?

I first want to ask you whether or not either of your organizations has any analytical capability with respect to identifying terrorist groups, states, individuals or organizations who possess these agents or the capacity to manufacture and deploy them and, second, whether or not you believe that that is something that if you can't do, that Homeland Security will be able to get its arms around and interface with you so that you can do the crosswalk because you have information that their analysis is dependent upon and vice versa?

Dr. Khan and Dr. LaMontagne, in either order.

Dr. KHAN. Let me start by saying that as we devise these critical agents lists, it was—the criteria that were put together were more than the lethality and the mortality of the agent. We tried to integrate in what was known about whether these agents had been weaponized and previously used potentially and how these agents would be transmitted.

Chairman COX. What is the source, Dr. Khan, for that information? Is that an input for you or is that something that you can develop yourself based on resources that you possess?

Dr. KHAN. A lot of it was from input from our intelligence experts. Some of it is from—.

Chairman COX. You say our intelligence experts, you mean?

Dr. KHAN. Our civilian and military intelligence experts who provided input into the process of putting together the list. I promised a copy of all the individuals who participated in the—.

Chairman COX. Does "our" refer to CDC?

Dr. KHAN. No, I am sorry, the United States.

Chairman COX. So those are outside inputs for CDC? Is the same true for NIAID?

Dr. LAMONTAGNE. Absolutely. We don't have any internal ability to do that kind of analysis

Chairman COX. And then once you have those inputs and you are taking that information and running with it, do you then go back

to those sources with the question of how might these agents be weaponized and dispersed?

Dr. KHAN. That information was used in deriving the list. And we took into account the worst case scenario, which would be that these agents would be well produced and distributed by large particle aerosols. And then when you integrate that in with what we know about the morbidity and mortality, then you get a set of agents, the seven that we have mentioned, that would likely cause the most public health impact given all the right conditions for how the agent is manufactured, produced and distributed.

So that list is not just the most lethal diseases because if you put a list together of what the most lethal diseases is you would start with rabies potentially at the top and Ebola and HIV and other diseases before you would get down to the seven that we are talking about. So it is more than just what is likely to kill you, it is what is likely to be produced and manufactured, what is their data and that if it is disseminated deliberately would cause a lot of public health damage.

Chairman COX. Dr. LaMontagne.

Dr. LAMONTAGNE. I would agree with what Ali has said but I also would comment that, yes, if we need additional information about whether some agent can be weaponized and how, we would have to ask for advice or information or input from the intelligence agencies. That is the only way we would know how to get that information. We have done that. I mean, they do communicate with us on these issues as well.

Chairman COX. I think that my time has expired and I look forward to pursuing this line of questioning further. I believe that the gentleman from New Jersey, Mr. Andrews, is next to ask questions.

Mr. ANDREWS. Thank you, Mr. Chairman. I would like to thank the witnesses and follow up on the chairman's line of questions about inputs from intelligence sources and then outputs from your research work and management work to other groups. I assume that if they have not already done so, that terrorist organizations and enemy states are going to gain some knowledge of our vaccine potential or treatment potential and begin efforts to alter bacterial agents in a way that would defeat those vaccine efforts. I think it is a fair assumption that someone is going to try to do that.

How would you find out that such an effort to alter had taken place? Would you have to ask the intelligence agencies or is it your experience that they would volunteer that information to you?

Dr. KHAN. If I could defer this question to our current director of the CDC program who deals with these agents.

Mr. HENDERSON. Thank you. Basically we do have some—.

Chairman COX. I am sorry. Excuse me, sir. As you prepare to answer this question could you identify yourself for the record?

Mr. HENDERSON. My name is Joe Henderson. I am the Associate Director for CDC's Terrorism Preparedness and Emergency Response Program. We do have a scientific capability to look at organisms that we fear may have been genetically manipulated. One of the first tests we did with the anthrax events of 2001 was determine its antibiotic susceptibility. If we see that the organism is not susceptible to those antibiotics that it normally would be susceptible to, we would be suspicious. Then we have other laboratory

tests working with the NIH and the military to determine if in fact we could tell with some certainty that an organism has in fact been manipulated.

Mr. ANDREWS. Let me use this example. Let's assume that our Intelligence Community discovered research being done on a new strain of synthetic anthrax and they had some information about that. It was taking place somewhere else in the world. What procedure exists for them to brief and notify you about that so you can begin to reassess your matrix of threats that you have to address?

Mr. HENDERSON. I would say that prior to September 11th, 2001 it virtually didn't exist. Since then I think our ability to work with the Intelligence Community has improved considerably. For example, if we were to hear about—if there was in fact known intelligence that either the CIA or the FBI or the National Security Council or even DOD's intelligence arm found to be credible they clearly would work through the Department of Health and Human Services through—the structure we use is through the Secretary's command center to communicate to CDC this known threat. This has happened several times, most recently prior to the war with Iraq where we were concerned about retaliation.

Mr. ANDREWS. I appreciate the answer. Mr. Chairman, what I find instructive about the answer, which is entirely candid and accurate, is that the Department of Homeland Security never emerged anywhere in the answer to the question, which I think tells us something about the intelligence problem that we have, not you.

Second question is about outputs from research. I assume that if you are successful in identifying the—I may not pronounce this correctly—nucleic acid sequences of some of the biological agents, that that research might also have some usefulness or viability in the technology of detection. I assume right now it is impossible to know that someone is bringing in a vial of smallpox in a suitcase through an airport. It would be impossible to screen and identify that in any kind of technological way. I assume, though, that the more you learn about the makeup of these biological agents the more possibilities there are for research to detect the presence of the particular characteristics of these agents so they could be screened, they could be detected, they could be prevented from being brought into the country.

What mechanism exists for to you share the research that you have done at NIH about the makeup of these agents with others that might use that research for purposes other than creating vaccines but, for example, for purposes of creating detection technology that might detect the presence of such agents?

Dr. LAMONTAGNE. Well, I think we use a lot of traditional methods for that kind of transmission of information. Meetings, workshops, publications, are very commonly used for that purpose, and I think we would exploit all of them to try to get that moving into that direction.

Mr. ANDREWS. Here again I think it is interesting that what we need is some kind of institutionalized connection between your agency and the Department of Homeland Security since if such a technological gain were possible, and it isn't today, but if it became possible we would want to see an institutionalized mechanism

where you would report that information to the DHS so they could begin the practical application research to do something with it. I offer no fault or criticism of you. I think it shows a disconnect in the structure that we have created that could fully exploit the research that you are doing.

I see my time is up, Mr. Chairman. Thank you.

Chairman COX. Thank the gentleman. The gentleman from California, Chairman of the Armed Services Committee, Mr. Hunter, is recognized for 5 minutes.

Mr. HUNTER. Thank you, Mr. Chairman. I want to thank my colleague from Texas here for letting me take the next question. Gentlemen, it looks to me like we have been looking at this from the defense aspect. At some point we have to have in place a mechanism that would have maybe four parts to it: First, the ability to detect bad stuff quickly; secondly, the ability to analyze that stuff; thirdly, the abilities to quickly fabricate vaccines; and lastly, the ability to vaccinate the people who might be victims of that, whether it is uniform folks or folks in the population. And bringing into focus or focusing all this weight of talent that we have spread out across our institutes, our educational system, our private sector and the elements that are in DOD, bringing them, the weight of that talent into focus against those four elements that I just laid out looks like is a major challenge. And so maybe we are going to have two types of programs that we have to run. One is for what I would call anticipated problems and those are the major threats that you have listed in your categorization from A in descending order, things that we know are out there and that we are going to have to deal with but, secondly, the ability to deal with unanticipated stuff.

So I would like to ask you your thoughts on whether you think we can do this, knit together a mechanism that can rapidly—and I think the key here is time is going to be of the essence—rapidly detect, analyze, fabricate inoculation or a medicine that will handle this particular problem and, lastly, protect our folks; that is, get the inoculations to them. You think we are going to be able to draw together from all these disparate elements this capability?

Dr. KHAN. Let me talk to the first two elements of that.

Mr. HUNTER. Pull that thing up close because I have trouble hearing. I would rather have you louder than softer in here.

Dr. KHAN. The detection and analysis part is very much a function of what we do domestically with our State and local health departments working with CDC to try to figure out what new diseases or emerging diseases may be out there, quickly figure out that that disease is out there, find the agent, characterize the agent, and then move to step three, which is your step about fabricating vaccines, et cetera. That also works in the international arena.

Let me just use SARS as an example of how that worked. Working with WHO, we discovered that there was a new disease out there which had never previously seemed to have been described as causing a lot of infection among health care workers who were dying. It was mainly focused in the health care setting. Working with our partners in WHO, and that meant putting staff out there in countries, we got hold of this agent, uncharacterized, brought it

into the agency, quickly were able to isolate it and identify that this was a brand-new virus which was a type of corona virus, sequence the agent within weeks to help develop diagnostic tests.

Now part of that process was that we shared what materials we got with NIH and other members in the private community and academic community and said, look, this is what we have, this looks like it may be a new corona virus. Can you help us develop diagnostic tests, can you help us develop new countermeasures against these agents? That happened extremely fast in this case. We would like that to be a model of how we look at not just new and emerging infectious diseases, but BT is part of that broader pallet of emerging infectious diseases that if somebody did release something like anthrax or plague that quickly that identification would occur in the local and public health departments, that agent would be very quickly characterized to say we have looked at the genes, none of these genes have been swapped, it doesn't look like it is abnormal or it does look like it is abnormal, there seems to be new genetic markers in there, it seems to be resistant to everything, why is that, that shouldn't happen naturally, and then move it to the next step with NIH to get us forward from there.

Dr. LAMONTAGNE. I think I would add to what Ali has said, Mr. Hunter, that actually in the field of infectious diseases there is actually a lot of communication among investigators out there. There has also been historically—I have been at the NIH for 27 years—a lot of very positive interactions between DOD agencies and CDC and NIH on many, many of these issues. So we have a track record of really sorting through these problems, I think, pretty effectively.

The latter two points that you made in terms of developing the vaccines or countermeasures and actually deploying them effectively are really formidable challenges though that require considerable amount of investment in research and in infrastructure to accomplish successfully. I think that that is one of the areas that we really need to work most actively on because it is the most difficult.

Dr. KHAN. If I could pick up from number 3 and 4 from John to go to 4, which is you get the vaccine but that is only partway there. You have to get it into people's arms or the drug, you have to get it into somebody's body. Then you have to monitor for the side effects, you have to maintain registries of those people. And that applied public health research is where CDC comes back into the picture to say, okay, there is actually some public health research involved in that part of the process. There was obviously research involved in the first part, the surveillance methodologies. The diagnostic methods we have out there didn't come de novo. It took a lot of work and research to say these are the best strategies to find out what is going on, these are the best diagnostic tests. So research infuses the whole process.

Chairman COX. Does the gentleman have further questions?

Mr. HUNTER. No, Mr. Chairman. I appreciate it.

Chairman COX. The gentlelady from Missouri, Ms. McCarthy, is recognized for 5 minutes.

Ms. MCCARTHY. Thank you, Mr. Chairman. Thank you for your thoughtful presentation as well as your thoughtful responses to the committee's questions. I would like you to elaborate a little bit.

When Ms. Dunn was inquiring you talked with us about how the agencies have been coming together to work with you. But I wonder if you would expand a little bit on how the Intelligence Community is helping you assess what biological issues are priorities for us so that we can further direct you not only in your research but in your ability to help our local responders and communities all over America be adequately prepared.

When I visit with my local responders out in the heart of America, their biggest fear is that they do not have the means to both coordinate with the hospitals and emergency centers in the case of a biological incidence but that even if there are drugs or other materials available that they won't have them or the ability to disseminate them. While I know that you are primarily involved in the research end of this, please know that whatever comfort you can bring in your work to those on the front line 24/7 would be of great help to us and to our work and how we might better serve you in accomplishing that goal.

Dr. KHAN. If you would permit, let me ask that question of the current Director of our CDC Bioterrorism Program, who deals with these local and State preparedness needs all the time.

Mr. HENDERSON. Thank you, Dr. Khan. Excellent question, two parts of your question I see. One is how do we take the intelligence that we are currently getting at CDC and then translating that down to our State and local colleagues. I do want to mention a bit about our grant program from CDC that as at the end of August of this year we will have funded $2 billion to State and local health agencies, which has been a huge infusion into the public health system to assure they can in fact respond to these terrorism events. The intel piece, the challenge for us at CDC and the Department of Health and Human Services is the fact that our method of looking at information and data to determine how it might trigger an outbreak of an infectious disease or some other type of public health emergency is different than what the Intelligence Community does to analyze intel that comes in. We basically in public health like to investigate every possible event that could lead towards some type of illness, injury, death, even if it only affects one person. Intel we are finding out and becoming more knowledgeable about this process and gathering information from the Intelligence Community is a bit more of an art than a science we are finding, and it is difficult for us to really weed through all that to find out what in fact is credible information that needs to be relayed to the State and local law enforcement officials and public health so we can have a unified response in addressing the threat.

So we continue to work on that to try to improve that. But again since September 11th we have done a lot with our health alert network to disseminate information to State and local health colleagues and through governors' offices and State emergency management officials so that they are constantly aware of what we find throughout the Nation and globally that they need to know about that could potentially impact and affect their populations.

The grant program we always say at CDC and with our colleagues at the National Association of County and City Health Officials that all response is local. We know that. For a terrorism event we know that regardless of the event the first 48 hours is going to

fall on the backs of State and local, really the local public health officials to respond effectively to mitigate the consequences and recover from that event.

We are building capacities at all levels. We know we need to continue to focus on the local level. Our grant program looks for meaningful collaboration between State and local health officials to ensure they have that capacity. We will continue to improve this program to assure we see that local response capacity.

Ms. MCCARTHY. I thank you for that information and would like to suggest that if we on this committee can be of further assistance to you in reaching that goal you just described of adequately preparing our local first responders you must make us aware of that so we can be your advocates in the Congress. I know that my community—I have the greater Kansas City area on the Missouri side and suburbs—did receive a homeland security grant recently for training and equipment for our local emergency responders. For example, in Independence, Missouri, Harry Truman's hometown, my police chief, my fire chief can't communicate with each other. Equipment doesn't talk to each other. When we had the tornado incidents recently they used their cell phones for as long as they could before those went out in order to meet the needs of the community and the surrounding communities. So you know, that grant money is helpful but still not enough. And I am thinking $2 billion, I applaud you for that on the efforts to help our first responders on the bioterrorism aspect of it, but I would like to say that that is not enough money either for what is needed locally all over this country. And we need to be sure we educate everyone to the fact that you know we aren't going to leave them out there with great expectations but without the means to carry out their work. They want to do what is right. They are training and preparing to do so and we at the Federal level must be willing to help be that partner.

So to the degree you can continue to advocate among the executive branch for better funding, for full funding, for adequate funding to carry out the goals you have established through your research and your intelligence and your work, then we can all be partners in seeing that the people's needs are met in a crisis anywhere in America. Let's hope that we never need to, but I do know that it is a very real concern out there in the heart of America, I would expect in all the communities represented here today on the committee.

And I want to, Dr. Khan, thank you for your work with the intel officials that you have been meeting with and continue to do so, please, because it is critical that we all have the best information possible and to the degree that we can anticipate and be prepared the public will be better served.

Mr. Chairman, I would like to yield back the rest of my time. I thank the witnesses and experts here today for responding to my questions.

Chairman COX. Thank the gentlelady. The gentleman from Texas, Mr. Sessions, is recognized for 5 minutes.

Mr. SESSIONS. Thank you, Mr. Chairman. I don't know who to direct this to on the panel, but I am sure each of you would have an opportunity to make a comment. I believe as a result of precaution in the last few months we have gone about inoculating first re-

sponders, nurses, doctors, other people in the community who would come upon a potential of smallpox. A lot of people were given the inoculation. And I am interested in hearing from you about how that worked, lessons learned, things about not only giving the vaccination but people receiving it, whether it was based upon a threat, whether it was based upon, you know, just the best information that we had. I am interested in an evaluation of how that process went and has taken place because—and whether it was an actual threat or whether it was just something we did as a precaution.

Mr. HENDERSON. Sir, I will take that question since at CDC it is my primary responsibility to manage the National Smallpox Program. It has been since August of last year. We have been very involved with working with our State and local colleagues on this issue. So I can touch on several aspects of your question.

One, I want to mention the smallpox preparedness activity. You seem to indicate in your question as though we have done something and we are done with it and now we are looking back to see whether or not we have actually succeeded. I have to say that from CDC's perspective we have done an awful lot in the past 8 to 10 months in improving overall focus on smallpox preparedness, which is more than just offering the opportunity to vaccinate individuals. It is also a focus on assuring there are plans and employees that should you see a case of smallpox in your emergency department you can mobilize your resources to investigate that case, confirm that it is in fact smallpox disease, isolate that patient, hopefully minimize the spread. Those plans a year ago today, 10 months ago today, frankly weren't in place. They are in place now.

Also having plans in place to assure you can protect your population that hadn't really been exposed yet if you see disease in your community through mass vaccination campaigns. Those are extremely labor intensive plans that require a lot of thinking, a lot of partnering at the State and local level with a whole variety of stakeholders. Those plans are in place now. They weren't a year ago today.

So even though there has been this focus on smallpox vaccination there has been a much more broader focus on smallpox preparedness in general.

I have to say that the vaccine program itself has been relatively successful because we have people vaccinated now that we will call upon to evaluate those first cases of disease in the emergency department and to be called upon to investigate cases of disease in the community through our public health system. It is not the numbers that we had planned for initially but it doesn't make the program a failure. We think it still makes the program a success because we have over 270,000 doses of vaccine forward deployed that should we see a case of smallpox we have people who are trained to vaccinate, we have clinics set up to vaccinate people, to screen them appropriately to assure we are not putting people in harm's way who may be contraindicated.

So overall we see this program as being a success. It is a success today and will continue to be a success as our State and local colleagues are now developing plans to focus on their supporting and maintaining smallpox preparedness into the future.

Mr. SESSIONS. Well, I am glad to hear that it was a success. I think what you are saying to me was it was necessary to make sure we had a cadre of people who received the inoculation so that if they do come into contact or once it is recognized as smallpox is that, as Duncan Hunter said, that thing that is out there, that we are able to then have a group of people who are able to come into contact with those, and I think that is wise management.

Secondly, I heard you say that you think it is at least reasonably successful, and that makes me happy. I think this is part of the preparedness that we are looking to CDC and this administration to be in those sorts of positions.

I see my time is nearing an end. I would hope that at some point also we are able to have some discussion about—Dr. LaMontagne, you began to speak about it—but allowing the private sector once whatever this thing is that is identified but getting it to private sector companies, I am interested in knowing how we can more effectively unleash them so that bureaucratic rules, regulations do not hinder their ability to properly function.

Dr. LAMONTAGNE. If I could comment briefly on this in relationship to the question on smallpox. We have actually been managing an effort that involves various agencies of the government, including CDC, FDA, USAMRIID and others, on the development of a next generation smallpox vaccine that is expected to be much safer. And that is a process that does engage the private sector and our approach in that process has been to generate milestone-driven initiatives where we will evaluate over a period of time how the private sector that we are providing resources to is actually performing against some standards.

Mr. SESSIONS. Thank you. I thank our great chairman for his leadership in today's wonderful meeting.

Chairman COX. I thank the gentleman from Texas. The great gentlelady from Texas, Ms. Jackson-Lee, is recognized for 5 minutes.

Ms. JACKSON-LEE. Thank you, Mr. Chairman. I will work with this microphone this morning again. I thank the witnesses very much and I appreciate the testimony that I had a chance to review and would like to raise several questions following the line of some of my colleagues, but specifically I want to acknowledge that all of us deal with the national security question but certainly must deal with the securing of our respective constituencies and the boundaries thereof. And in particular, I serve an urban area, Houston, Harris County, Harris County, one of the largest counties in the Nation, Houston, the fourth largest city in the Nation, extremely diverse, many individuals coming through for trade and other reasons and as well coming from all parts of the world to live in that community. So we have our respective challenge, but we have a very strong base of resources because we have the Texas Medical Center present, but also we have stakeholders like Riverside Hospital, which is a historically black hospital and we have the Lyndon Baines Johnson Public Hospital in the public hospital system that has a very large clientele, patient base, if you will, but not large enough.

So I want to raise the question that I raised earlier in my opening statement and that has to do with the 40 million uninsured in-

dividuals in America, those that don't have health coverage. I raise that because individuals who have health coverage are used to going to facilities, either have a physician relationship, used to knowing where a health facility or they know where a hospital is because they have a relationship there. What is the planned response if a situation arises where millions of people in an area need to go in for consultation, then inoculation, then follow-up and there are so many people without this good working relationship? How are aspects of your agencies looking at the questions of facilities to be in place for distribution that are not necessarily health facilities? Would be the follow-up with these facilities then continue or would you expect the normal public health system to assist? How will the resources be distributed to take this extra burden of people who don't have a standing relationship and how will they know where to go?

One of the questions that I have been raising with the—I have a homeland security task force in my community that I convene and I include institutions of learning, public school systems, as well as community groups because the question always becomes how will they be secure, how will they be apprised of the threat. So that is one question.

The other question comes with accountability. Six billion dollar, part of the responsibility is of course to—I think the language is push and pull, push for vaccines to expedite research and pull by providing a market. What is the accountability of the pharmaceutical companies in terms of whether they will create the research, whether they will provide for the actual creation of the drug, what oversight do we have in doing that?

My last question involves this whole issue. I think your testimony noted that there were certain bioterrorist entities or drugs—not drugs but creations that we are aware of for at least diseases rather, smallpox, anthrax, plague and botulism as the top ones. What are we doing with respect to getting ahead of that? And how soon do we think, for example, smallpox will be available for everyone in the United States of America?

Dr. LAMONTAGNE. Let me try to answer the question on the accountability issue, which I think is an important concern. I think there are a number of safeguards in the process that are nested in the regulatory process that we go through for drugs and vaccines that will ensure that whatever is available at the end of the day is satisfactory and meets the highest standards that we can achieve for a product to prevent or treat a disease. I don't think there is any compromise in that at all. So we will—I am pretty sure that—that is an important safeguard. In addition, I think the—as I mentioned, there is more of an attempt to use milestones, performance milestones in the award of these kinds of contracts to make sure that progress is at an appropriate level with the investment being made.

Ms. JACKSON-LEE. The uninsured?

Dr. KHAN. Let me answer that from the aspect of local preparedness. Your point is well taken and was actually one of the foundations of the Bioterrorism Program when it was laid out a couple years ago. All response, all detection occurs locally. Nobody from the Federal Government is going to come into your community and

say, okay, I know where your hospitals are, I know where your gyms are, I know where your facilities are. This is where these people need to go. This is how this needs to get set up. All that preparedness has to occur locally. It is the local communities that will have to identify where their hospitals will be, where their facilities will be, what will be put up, what will be put down, and how they will try to integrate in the national resources as they come in for a response. And essentially the essence of our local preparedness and response program is to get those communities up and running with some guidance from the agency.

So, again, it is the local response that we are all dependent on, all the Federal agencies that the local community is ready and knows if this pharmaceutical stockpile comes with 100 billion doses of X, how do we move it from this gigantic pallet into people's mouths. It is again the local community.

Ms. JACKSON-LEE. On the smallpox immunization, what efforts are we making to be able to immunize everyone in the United States?

Mr. HENDERSON. Our plans right now are from the Department of Health and Human Services, looking at where we are in the clinical trials from the AKM products. First of all, I should mention we do have enough vaccine right now that should we have to vaccinate the entire population we can dilute existing quantities of vaccine to do that. But we are looking for the new product to be available in probably early to mid-2004.

Ms. JACKSON-LEE. Let me just say thank you very much. Let me say, Mr. Chairman, I thank these witnesses very much. I want to make sure that the program of BioShield does not overlook small hospitals, small research centers, historically black colleges, Hispanic serving colleges where there are research elements, native American institutions. I just simply in closing would like to say that I would like someone to get with my office in particular about exposing these other, maybe other level entities about the research opportunities.

Can I just conclude by saying is there any foreclosure precluding any of those kind of entities, smaller entities being involved in the research of research grants that are under your jurisdiction?

Dr. LAMONTAGNE. Not at all. Actually we encourage that and are trying hard to reach out to that community as well.

Dr. KHAN. Same at our agency.

Ms. JACKSON-LEE. If I could encourage that and also, as was noted, these small and the local government areas, county health clinics and city health clinics, that we can work together to make sure that they are well informed and well involved.

Thank you, Mr. Chairman.

Chairman COX. The gentleman from North Carolina, Mr. Etheridge, is recognized for 5 minutes.

Mr. ETHERIDGE. Thank you, Mr. Chairman. And again thank you for being here. Let me, Dr. Khan, go to you first if I may, please, sir. Obviously all of us are concerned as we talk the BioShield and the funds available here and it has been alluded to already and several have asked questions, but let me follow the question a little bit as it relates to districts because all of us represent different districts. Mine is one that has urban, suburban, rural, one large mili-

tary base and a small one. So it is a little unique and we have some of the large institutions. Most of our responders, first responders are volunteer, many of the areas as you can appreciate.

You said in your prepared testimony that a strong and flexible public health infrastructure is the best defense against any disease outbreak. That being said, the four areas that I have talked about, the cities, the suburban areas, rural areas and the military, which one is the weakest link in our public health infrastructure and why? And what is the best way to address these weaknesses as we see them and, finally, which of these four areas is most vulnerable to attack?

Dr. KHAN. They all, sir, have their own unique weaknesses from a public health standpoint. I can't comment on the military, but we do know based on the anthrax attacks in 2001 that our civilian population, and a previous attack using a food borne agent, that our civilian populations are vulnerable to attack using biological agents. And I will go back to your comment about, I guess, what I originally started as my comment, is our agency's comment about the public health system requiring to be flexible.

Marcy Layton, who is the health director up in New York, is the first person to admit that her response to West Nile virus was better and was a more focused response because of her activities for bioterrorism preparedness. That is very much true if you look today at our response for SARS. Our response to this international outbreak is a lot better than it would have been based on our response to anthrax in 2001.

So, again, the bioterrorism preparedness activities are helping to improve basic public health infrastructure. But we need to remember that the broader pallet of what we need to be doing is improving the ability not just for anthrax, which may or may not happen again, or smallpox, but there continues to be routine infectious diseases every day that need attention at the domestic level and also many diseases that need attention at the international level that we need to stay engaged in. And within that milieu we will then find out about these new diseases. But if we don't stay engaged in what is going on every day, we will never fine anything new because we are having trouble finding the old stuff and taking care of it.

Mr. ETHERIDGE. You don't want to identify the weakest link in each one, because each one has their weak links. The reason I raise that question is because a lot of our States right now are really pressed, a lot of our health facilities are woefully inadequate and, to be very candid, because of the number of years we haven't done the funding. I think as we look at this whole issue of BioShield the weakest link is where we have the greatest problem and we have to be prepared for that.

Mr. HENDERSON. Can I just follow up on that and add a couple of things? You hit on a very important question, one that drives us in looking at our State and local program, as far as people ask us all the time are we prepared, who is prepared, who is not prepared, et cetera. It is a really difficult question to answer. There are three things that we see that impact the success criteria. One is political will. The second is leadership. And the third is resources. We have seen local jurisdictions with very little resources but strong leader-

ship and political will that have done amazing things. We have seen some jurisdictions with a lot of resources, but don't have the political will, are struggling with leadership and they are probably not as far along as their citizens would like them to be.

It is trying to find ways to combine those three strengths so we can assure we have a network of systems across the country that can in fact prepare and respond to these events. That is what we are doing in developing our evaluation criteria for our State and local cooperative agreements, is to provide the standards to assure we can develop those three success criteria so we can improve preparedness.

Mr. ETHERIDGE. Thank you. Let me go very quickly to the next question because you testified, Dr. LaMontagne, about the 30 percent increase in the number of grant applications to develop bioterrorism countermeasures. With the existing personnel you now have and the resources, are you able to keep up with the application in grants and are most of them applications for basic research or are they actually for development of vaccines and other countermeasures? And, finally, do you believe that the BioShield funding is absolutely critical to the development of the most dangerous countermeasures?

Dr. LAMONTAGNE. The question is a very important one, Mr. Etheridge. I think that—just to give you an analysis of the response that we have received—it is across the board. It is not only basic research which we have encouraged, but also we encouraged programs in very targeted and focused initiatives to try to generate the kind of vaccine or drug that we would like to have for a particular disease. One can always use more resources. That is always true, as you know. But I think it is moving along pretty well. So we will see how this evens up in the next year or so, I think. We will have a better indication of how well we have titrated our own resources with what is coming in.

Chairman COX. Thank the gentleman.

The gentleman from Rhode Island, Mr. Langevin, is recognized for 5 minutes.

Mr. LANGEVIN. Thank you, Mr. Chairman. Again thank you for your testimony today, gentlemen. It has been very enlightening and informative. I guess I would start off by saying that clearly what we need to do and various aspects of government need to do is inspire confidence in this question and, more importantly, inspire confidence in the minds of the public that there is a coordinated and comprehensive process and effort that exists with respect to dealing with bioterrorism and the threat of bioterrorism. I don't think that we are there yet. I don't think that in the mind of the public that we can say that we have inspired that level of confidence. I think CDC and NIH are off to a very good start. I think that is one of the bright spots in this whole effort. But we clearly have more work to do.

I would like to turn to the line of questioning that the chairman had started with in dealing with how you are getting your information and intelligence. Clearly identifying the pathogens, for example, that NIAID should be working on depends on assessments of the bioterrorism threat. And I am curious to know, in exploring again the chairman's line of questioning, the level of interaction

that you are having with the intelligence communities. In particular, it sounds like this is more of an informal process than a formal process. So I would like to you explain that interaction a little more thoroughly if you could.

And also, I would like to know where the Intelligence Community is deriving its data set; for example, where are they getting their intelligence? And are you dealing with peers within the Intelligence Community when you are talking to these individuals or are they lay people?

And also, since DHS is going to have a major role in this process, I would like to know if DHS has contacted either CDC or NIH to ask for your input as they are setting up their internal structure for dealing with the bioterror threat?

Dr. KHAN. That question, sir, let me turn that again to Mr. Henderson, who deals with our current day-to-day programming.

Mr. HENDERSON. Just again reflects on the intelligence and formalizing the process. I should say that for my particular agency, just to be selfish for a moment, we would love to have a one-stop shop where all the intel is coming in, they are analyzing it and they are handing us stuff and they find it to be credible that they are looking for us and our State and local colleagues to respond to. Right now, that is in fact the concept of homeland security and we are working with them in trying to decide how best to do that. We still though have our peer relationships and contacts in the agencies I mentioned earlier, the NFC and the CIA and the FBI. We actually at CDC have an FBI analyst who is stationed at CDC to help us with any potential threats that may be coming into CDC as a facility since we managed to secure select agents, and so that is a sea change in thinking in how we dealt with this prior to September 11. The only way that happened was through a coordinated approach working with the Department of Homeland Security.

I also want to mention that in formalizing this arrangement with Homeland Security to understand how we will take this intelligence and respond appropriately, and accurately, it played out pretty well in the TOPOFF II exercise where we were looking at plague in Chicago and a dirty bomb scenario in Seattle. We saw through that exercise scenario how the future will look as far as how CDC will get information that we will act upon, and we liked what we saw. It made sense to us. It was logical. We could react faster and we had a higher degree of confidence in the information that was coming to us. Again that was a scenario that was artificial. But it showed us what the future held and I have to say that Homeland Security played a strong role in that activity.

Mr. LANGEVIN. And they are reaching out to you and asking for your input as to how they should set up their internal infrastructure with respect to bioterrorism?

Mr. HENDERSON. Yes, they have asked us because you have to remember it's not a one-way street. As much as they are going to give us intelligence information they are looking for CDC to also provide them intelligence information. And SARS is a good example. We have people over the globe we are working with and as we collect all the information the only way for them to get it is through CDC. So it does open a two-way channel of sharing of information.

Dr. LAMONTAGNE. I would completely agree with what Joe has said. I mean I think we have experienced a sea change in our ability to interact and work with the intelligence agencies not only at the NIH, but obviously, as Joe has pointed out, with CDC, and I think the Department of Homeland Security and before it the Office of Homeland Security have been very helpful in making sure that that conversation takes place.

Mr. LANGEVIN. I see my time has expired, so I thank you for your—.

Chairman COX. The gentleman from Florida, Mr. Meek, is recognized for 5 minutes.

Mr. MEEK. Thank you, Mr. Chairman. I want to go back to some of the statements I made in the opening dealing with working with other countries, and I know that the Dutch have worked in many areas of research and have found, been discoverers of vaccines. I know that both agencies work with the international community as it relates to finding vaccines and sharing research information. I believe bioterrorism here—and there are three categories, A, B and C—is something that could be a reality in any city or small town. How are we working with those other countries that are out there that may be facing some of the same threats that we are facing? And the reason why I am asking the question, the fact that I think that we would see some activity abroad maybe not here in the homeland, but we would see activity abroad first and then we can pretty much expect that that is just a test or the training area, just to bring a homeland attack here in the United States.

Dr. KHAN. Thank you very much for that question, sir, and actually it is a major focus of what I do on a day-to-day basis these days. We have a number of activities in place internationally. So I am working with the World Health Organization directly and their smaller subsets of WHO. We have relationships with regions. We have relationships with specific countries to do various projects and systems. We have also set up something called international emerging infectious disease programs. We have one such program we would be delighted to expand that worldwide. These are areas where there are a couple of CDC specific people in country who help build up their surveillance capacities and their response capacities and it would allow the country to find what is going on, be it bioterrorism, other emerging diseases, a lot faster because that is truly what the delay is.

You know, once the countries recognize it we generally have good relationships to get those agents to the United States and other countries for development of vaccines and diagnostics, but often the countries don't have the ability to recognize what is going on in their own country, and that delay is deadly, especially for bioterrorism, because you may only have a couple of days to actually treat patients or get your set of countermeasures ready before the agent comes to you. So we would like to expand that international emerging infection program and it has been—let me give SARS as an example.

Again this was not bioterrorism, but we had one of these programs in Thailand that provided us the opportunity to help Thailand, Taiwan, Cambodia and Laos based on this handful of people

who were based out in Thailand, and it would have been nice to have done that in additional countries.

Mr. MEEK. And, Dr. Khan, one of the other concerns or things that I think that we need to know if it is something that is going on somewhere in the globe that any of you on the panel may be very concerned about, that could potentially happen here in the United States as it relates to bioterrorism. And I can tell you right now, since 9/11 everyone is trying to focus on issues that you have been working on your entire careers. Now, all of a sudden you are front stage. Everyone wants to pay attention. But still when we start looking at local communities, States, they are also fighting for funding. They are fighting for the flexibility that is being asked for in this piece of legislation, and I think Americans as we look at legislation that has been passed through this Congress, PATRIOT Act I, with the potential PATRIOT Act II, and the misallocation or appropriation of that legislation, it set us back. And one, do you see an area in the country or in the—not in the country but in this world that because of your individuals that are out there from the CDC, something that potentially that is raising your eyebrows, something that we need to pay close attention in, something that you are right working with—what you have now to work with that you are moving in that direction to find a vaccine to make sure that it doesn't become a problem for Americans? That is one.

Two, as it relates to dissemination of a vaccine, if something was to happen here in the United States, do we have better functions in being able to get that vaccine and being able to make sure that we have enough of it to deal with a wide-scale bioterrorism activity? We have had several exercises or two or three recently. How did things turn out there as it relates to the response?

Dr. LAMONTAGNE. I could start on one aspect of your question, Mr. Meek. I think that, yes, there are diseases that we are quite concerned about overseas that might come here. The one that I might mention that I have had a professional interest in for a long time is influenza. And as a matter of fact, we have a considerable interest in looking at influenza in many parts of the world, including the Far East, Hong Kong and China in particular, through projects that we have supported for surveillance of animal influenza viruses in the Hong Kong, area in particular. I think that was, as it turned out, that group, because of its enhanced capacities, I think it was quite helpful in dealing with the SARS outbreak that occurred recently.

So, yes, we do have groups out there doing that kind of work all the time.

Dr. KHAN. Let me follow up on those comments that we do have a number of people stationed overseas who look at emerging infectious diseases, and pandemic influenza is a major concern for us. Again the influenza outbreak of 1918 was the largest epidemic in the world, killed probably over three-quarters of a million Americans based on that population. And we know without a doubt pandemic influenza will happen again and we need to be prepared and the only way to be prepared is to have a presence overseas.

So it is important and I think, Mr. Meek, this is where your question was coming from, it is important to maintain our focus internationally as we think about bioterrorism also. Because people

may practice potentially outside the U.S. first, or for a disease that is spread by person-to-person transmission, there is no reason to start in the U.S. If it is spread by person-to-person transmission you put it anywhere in the world it will make it is way to the U.S., and there is numerous diseases that are examples of that. West Nile is an example of that. Wasn't in the United States. SARS is an example of that. Wasn't in the United States. We continue to get imported cases, 1,500 cases of malaria every year into the United States.

So importations, translocations of disease are a common process. Another reason why we can't forget the international arena for bioterrorism is you know John said they are trying to develop countermeasures, anthrax, plague, tularemia. There aren't that many cases in the U.S.; however, there are such cases abroad and if we have good relationships with countries where these are still problems we would have a place to use our countermeasures. You know as we develop new smallpox vaccines if we have good relationships with countries where monkey pox is still an issue, potentially that could be a model that could be used for vaccines and therapeutics that would then prepare us domestically and help our counterparts internationally.

Dr. LAMONTAGNE. Just to add to what Ali has said, in terms of the availability of the vaccine or the intervention that might be desired, I think there is still much work to do to make sure that we have adequate supplies of these vaccines, and I think that is where the complementarity associated with BioShield could be very helpful.

Mr. MEEK. Mr. Chairman, I believe that when we start to move forth this legislation, not only communications, not only statutory direction to the departments, because we have a number of agencies and departments working together, what we find in the law enforcement community everyone talks about, oh, we are working together and they come here and they walk in the room hand in hand and hugging each other and then after they walk out the room, they don't talk to one another. I call it bleacher democracy. I mean, they would be together only in a time that they need to be there. But communications is very, very important. And in the area that y'all are working in, this is front seat. To get vaccines, to be able to get preventive measures countermeasures out there in a timely manner with local health agencies, working with them, making them feel a part of what is going on is going to be key. I don't know if we can legislate that. That is something that I think that works within the professional community of making sure that that happens. Anything to the end of helping us, well, anything to helping us in this legislation work with other nations that are ally nations that share a common threat, a common loss, it is very, very important and I think that we reflect that, and I am pleased to hear that you are out sharing and looking and trying to detect that information. Hopefully that is going across to the law enforcement segment of this effort against terrorism.

Chairman COX. The distinguished gentlelady from the Virgin Islands, Dr. Christensen, is recognized for 5 minutes.

Mrs. CHRISTENSEN. Thank you, Mr. Chairman, and I just want to start out by saying how much we appreciate both, all three of

you being here and the work that you have been doing, as evidenced I am sure only in small part by your testimony and your responses. We want to make sure that you have the resources and the support to continue to do it and to improve upon it.

I want to ask—my first question kind of piggybacks on the last one my colleague Mr. Langevin was asking, and it is one that has been asked before. There are coordinating councils, there seems to be a very good but informal working relationship between the different parts of the Department of Health and Human Services and the other agencies. Would it, as we look at the act and look towards some possible amendments, is there something that we ought to be doing to put all of this into one umbrella agency with one director? Would that improve, would that be an improvement over the relationship we have now? Would it be easier? Would the communication be better or do you feel that the way it is working now is working at its best, all of the research and development of countermeasure?

Dr. LAMONTAGNE. Well, I think considering the fact that for many of us it is a new role, this I think actually works pretty well. And I am not sure that a new entity as such is really required. I think the big challenge for us, which is a comment that I think Joe alluded to in one of his responses a little while ago is that you are dealing with different cultural aspects to these different agencies, and I think developing ways in which we can communicate is going to be something that is perhaps iterative and takes a while. But I actually think that it is quite positive from my perspective. I don't really have any reasons to complain.

Mr. HENDERSON. I agree, John. One of the things I think that you are probably hearing on this particular committee, you probably heard it yesterday, you may be getting a sense of it today, is that it has only been 7 months since they passed the Homeland Security Act, and so 7 months employing this large organization, and we are working very hard with Homeland Security because we want to develop the right relationships.

What are the right relationships? And you know where are we seeing the true leadership? Where are we seeing the resources in the political world that I mentioned before? What we are asking State and local health colleagues to consider we need to consider at the Federal level. I think if we give the current situation a chance and a little bit more time we will pull it together. But in the meantime there should be some confidence that we are engaging and we are developing these relationships. We can continue to improve communication, but we are working at doing that. I think hearings like this are very helpful to bring this to light for us to just remind us that we need to continue to make this investment in time and building relationships.

Mrs. CHRISTENSEN. And apropos of the issue of time and the time it takes to do this right, and to get it where it needs to be, the Institute of Medicine has been asked to look at Project Bioscience to assess, investigate it and come up with some recommendations which won't come out until later on this year. The recent interim report says that they really need more time because this is a very complex, bioscience is a very complex initiative and with far reaching implications. And I heard, and I read in your statement, Dr.

Khan, something that I have asked many questions about in previous hearings, the importance of focusing on the public health system. We hear that there are laboratories still to be built, B–3, B–4 laboratories still to be built. What is the danger in waiting until we—and especially given the fact that many of our hearings have not been as informative as this one. What is the danger in waiting until we get a very informed assessment of bioscience before moving ahead? Can't we be doing more with our public health system, doing more with basic research, putting the facilities in place that we know need to be in place now? And wait until we get a report and do it right?

Dr. LAMONTAGNE. Well, I think one danger would be—in my mind the fact that there are lots of things that are going on right now in the research arena, the sort of push thing that Dr. Fauci refers to. There is a big investment being made in this field. We are pushing research very aggressively to develop the vaccines and the drugs we need. We need to get the pull components. So that pull component is I think very important. It is a complement to the push. So the sooner that we can do that I think the more effective the program will be in its total capability.

Mrs. CHRISTENSEN. That was the shortest 5 minutes I have ever seen, Mr. Chairman.

Chairman COX. The gentlelady is recognized for an additional 2 minutes.

Mrs. CHRISTENSEN. Okay. Thank you. Thank you. Project BioShield—thank you, Mr. Chairman—presumes basic research being done, promising countermeasures being identified and then incentives being given as you just described. What is the status of the basic research? Do we have a lot of basic research done ready to go to the private sector to be taken to the final product?

Dr. LAMONTAGNE. I think the short answer to that question is that it depends on the agent. In some cases we have very good basic information, for example, in anthrax. But for a lot of the other diseases that are in the Category A list, basic research has not been—they haven't been easy to study so we don't have a lot of basic information. We do need it in order to get the kinds of things that we will need at the end of the day.

Mrs. CHRISTENSEN. And for those that you have the basic research ready to go, how—can it be done under the current processes? Even with the incentives, the private sector has some concern that they will spend significant amounts of their own money and not be able to put this on the private market. So can it be done now with what we have?

Dr. LA MONTAGNE. Well, I think that is the dilemma. We can take it through the basic research and I am going to include in that some developmental research. We can do clinical trials perhaps and learn how to produce something in large amounts, and so forth, and have a very mature product. But the risk is that there won't be anything, any entity, a corporate entity which—and they are really the ones where the expertise exists to produce vaccines and medications at high quality reliably in large amounts. And unless you have the capacity to basically hand it over to them in some effective way, you are not going to be able to get the material that you need in the amount you need. That is the risk.

Mrs. CHRISTENSEN. Thank you, Mr. Chairman. I appreciate the extra time.

Chairman COX. I thank the gentlelady. Our witnesses, we do have additional questions for the panel. We'd like to let you go before noon if that is at all possible. You have been at the witness table for nearly 2.5 hours, and so I would invite you, unless you want to just press on, to stretch your legs and take a recess. But it is up to the panel.

Dr. KHAN. We will press on, sir.

Chairman COX. We could adjourn for 5 minutes and come back at 11:30 if that would work for you. We will recess for 5 minutes, and that I think would put us at 11:25. At 11:25 we will resume.

[Recess.]

Chairman COX. I would like to welcome our members and our witnesses back. Dr. Khan and Dr. LaMontagne, I hope you are ready for the second round of questions. We have four members present. We hope to be sparing of your time. You have been very generous with your time. I want to thank you once again, as I did at the outset, for being with us here today and for your outstanding assistance to this committee as we prepare to mark up legislation perhaps as early as next week to create the Project BioShield, a multibillion dollar program.

The Chair would recognize himself for 5 minutes. Right off the bat, let me ask whether either of you have familiar with the program of the former Soviet Union, Biopreparat. Is either of you familiar with that?

Dr. LAMONTAGNE. Yes, somewhat.

Chairman COX. Dr. LaMontagne, Scott Becker, who is the Executive Director of the Association of Public Health Laboratories has stated, quote, we do not have a national plan or a lead agency for many of the laboratory activities. Did the U.S. have such a thing as Biopreparat?

Dr. LAMONTAGNE. Well, I mean my understanding of the genesis and the purpose of Biopreparat was as an organization that was designed for the production of basically biological munitions, so I don't see any need for us to be in that business necessarily.

Chairman COX. But I am sorry. I mean only organizationally, a lead agency with overarching responsibility. I don't mean to draw the analogy beyond that.

Dr. LAMONTAGNE. I am really not sure whether we would need something quite like that. As I tried to illustrate in my responses to various questions through the morning, I think there is actually very good interaction and communication within the agencies that are responsible with this activity. There are entities such as the Homeland Security Council and other groups that are, I think, bringing together these agencies in a coordinated manner. So I am not sure that it is needed at this point.

Chairman COX. Dr. Khan.

Dr. KHAN. Let me specifically talk about Scott's comments. There actually is a laboratory response network in the United States working with APHL, which is how we get diagnostic reagents out to all States and local health departments. And if you expand that laboratory response network one more step, you realize why it is difficult to take all terrorism response activities into a single entity

from a public health standpoint because you can't separate out the routine public health responsibilities from what potentially could be terrorism. Terrorism doesn't wave a red flag saying hi, I happen to be anthrax. It is somebody walking in the emergency room short of breath who has a large middle of his chest on his chest x-ray and you look at the chest x-ray, you look at the symptoms and you go, okay, this may potentially be anthrax. Or somebody walking in with a rash and you need a clinician to say, no, I don't think this is chicken pox, I actually think this potentially could be smallpox.

So you can't separate out those pieces of the public health response. They are an integrated public health response. And going back to the APHL and the relationship with the laboratory response network, this laboratory response network, it was originally set up specifically for bioterrorism purposes. It was set up to say these are the critical agents, these are the reagents and the tools you will be using to monitor for these agents. We just sent SARS reagents through that network. We have sent West Nile reagents through that network. It is too interconnected, it is extremely interconnected.

Chairman COX. I want next to go to the report that you submitted with your testimony. Dr. Khan, you were one of the authors of this report which is summarized for us, titled "Public Health Assessment of Potential Biological Terrorism Agents."[1] It describes how in June of 1999 experts got together to review general criteria for selecting the biological agents that pose the greatest threat to the population.

Reading this, and then reading testimony that you provided today covering some of the same ground, it is not clear to me just how much classified information went into the preparation of this evaluation of this review. In the CDC report summary, it stated that the following unclassified documents containing potential biological threat agents were reviewed. The Select Agent Rule List, the Australian Group List, the Unclassified Military List, the Biological Weapons Convention List and the WHO Biological Weapons List. Participants with appropriate clearance levels reviewed intelligence information regarding classified suspected biological agent threats to civilian populations. No information was available about the likelihood for use of one biological agent over another. Because this assessment that we are after is meant to rank the threats according to materiality, I am in the dark about what classified information, if any, was directed towards the likelihood of these threats.

Dr. KHAN. Sir, the list in the acknowledgment section are some of the participants and we have promised to provide the committee the specific names and the agencies CIA, FBI, National Security Council, et cetera, who participated in developing the list and did provide classified information in terms of what agents had been weaponized and mechanized for potential use. So that data was integrated into the final risk analysis matrix.

Please recognize that the reason for the matrix was that we needed to try to get some of the information that may have been classified into an unclassified setting because that is the only way

[1] Rotz, Lisa D., Khan, Ali S., Lillibridge, Scott R., Ostroff, Stephen M., and Hughes, James M., "Public health assessment of potential biological terrorism agents" *Emerging Infectious Diseases,* Volume 8, No.2, 225–230, February 2002, Centers for Disease Control and Prevention.

to prepare a public health and medical community. You can't tell them there is something I can't tell you that may be a problem. You have to tell them we think based on the risk matrix there are six or seven diseases we need to pay lots of attention to. Make sure you know their clinical signs. Make sure you have surveillance, make sure you have diagnostic tests.

Chairman COX. I am just trying to understand the representation in both the testimony and the report summary that no information was available about the likelihood for use of one biological agent over another. So I am inferring from this that classified, unclassified or otherwise, there was no information, is that right?

Dr. KHAN. At the time of that meeting we were not specifically provided information that said agent X is the likely agent. And the list, the way it is structured, is not a probability list.

Chairman COX. Right. Now, June of 1999, that is when this was done, is that right? There was no information. Has this analysis, this ranking, or the composition of the list, been updated since 1999?

Dr. KHAN. Let me take that from one aspect and then I am going to turn it over to our current Director who deals with this on a day-to-day basis. The list, the set of the criteria was peer reviewed after 1999 before publication in 2001 and to make sure those criteria were stable.

Chairman COX. And does the peer review include the Intelligence Community?

Dr. KHAN. No, sir. It includes the process to say that this is the right way to put together the list.

Chairman COX. That is, the scientific community?

Dr. KHAN. The scientific process to put together the list. And then since that time, and, Joe, maybe you can take the question from this point of our ongoing interactions with the Intelligence Community.

Mr. HENDERSON. At this point we at CDC have to consider that this list is still viable and it is still a useful tool to provide our framework based upon the criteria.

Chairman COX. Well, just pause right there. My question was whether it has been updated since 1999 and what I am hearing you say is that we have to still consider that it is applicable.

Mr. HENDERSON. Yes, sir. It has not been changed since 1999.

SUBMITTED FOR THE RECORD BY THE HONORABLE CHRISTOPHER COX

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CIA says al Qaeda ready to use nukes

By Bill Gertz

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Al Qaeda terrorists and related groups are set to use chemical, biological and nuclear weapons in deadly strikes, according to a new CIA report.

"Al Qaeda's goal is the use of[chemical, biological, radiological or nuclear weapons] to cause mass casualties," the CIA stated in an internal report produced last month.

"However, most attacks by the group—and especially by associated extremists probably will be small-scale, incorporating relatively crude delivery means and easily produced or obtained chemicals, toxins or radiological substances," the report said.

Islamist extremists linked to al Qaeda leader Osama bin Laden "have a wide variety of potential agents and delivery means to choose from for chemical, biological and radiological or nuclear (CBRN) attacks," said the four-page report titled "Terrorist CBRN: Materials and Effects."

The unclassified report was produced by the CIA's intelligence directorate, and a copy of it was obtained by The Washington Times.

The report identifies several deadly toxins and chemicals that al Qaeda could use to conduct the attacks, including nerve gases, germ and toxin weapons anthrax and ricin, and radiological dispersal devices, also known as "dirty bombs."

Disclosure of the CIA report comes as the agency is under fire over its reports on Iraq's chemical, biological and nuclear weapons, none of which has been uncovered. Several lawmakers from both parties, including Sens. John W. Warner, Virginia Republican, and John McCain, Arizona Republican, have called for hearings into the intelligence about Iraq that the Bush administration received.

In the latest report, the CIA said terrorist success would depend on planners' technical expertise. However, one likely goal of any attempted attack would be "panic and disruption," the agency stated.

Several groups of al Qaeda tried to conduct "poison plot" attacks in Europe using chemicals and toxins in assassinations and small-scale attacks, the CIA said.

"These agents could cause hundreds of casualties and widespread panic if used in multiple, simultaneous attacks," the report said.

Also, al Qaeda is developing bombs with radioactive material from industrial or medical facilities, and an al Qaeda document obtained in Afghanistan revealed that the group had sketched out a crude device capable of causing a nuclear blast, the report said.

"Osama bin Laden's operatives may try to launch conventional attacks against the nuclear industrial infrastructure of the United States in a bid to cause contamination, disruption and terror," the report stated.

Al Qaeda's plans for chemical arms were revealed in a document obtained in summer 2002 that "indicates the group has crude procedures for making mustard agent, sarin and VX," the report said.

Mustard is a blistering agent, and sarin and VX are nerve agents that can kill humans in small amounts.

The report also states that Mohamed Atta, ringleader of the September II attacks, and Zacarias Moussaoui, who is on trial in Virginia on charges related to the attacks on the World Trade Center and Pentagon, studied methods of delivering biological weapons.

Both men "expressed interest in crop dusters, raising our concern that al Qaeda has considered using aircraft to disseminate [biological warfare] agents," the report said.

According to the report, al Qaeda and other terrorists also could produce what the CIA calls an "improvised nuclear device" capable of causing a nuclear blast.

Such a bomb is "intended to cause a yield-producing nuclear explosion," the report said.

Terrorists could produce a nuclear device in three ways, including a bomb made trom "diverted nuclear-weapons components," a nuclear weapon that had been modified, or a new, indigenously designed device, the report said.

A homemade nuclear bomb would be one of two types: either an implosion device that uses conventional explosives to create a nuclear blast, or a "gun-assembled" device. Making a nuclear bomb would require that terrorists first obtain fissile material such as enriched uranium or plutonium as fuel for creating a nuclear blast.

A more likely type of terrorist attack is the use of such nuclear material with conventional explosives to create a "dirty," or radiological, bomb, the report said.

"Use of a [radiological dispersal device] by terrorists could result in health, environmental and economic effects as well as political and social effects," the report said. "It will cause fear, injury, and possibly lead to levels of contamination requiring costly and time-consuming cleanup efforts."

Among the materials that are available to terrorists for this type of bomb are cesium–137, strontium–90 and cobalt–60—materials used in hospitals, universities, factories, construction companies and laboratories.

A security notice made public by the State Department yesterday stated that "al Qaeda and sympathetic terrorists groups continue to demonstrate their interest in mass-casualty attacks using chemical, biological, radiological, and nuclear (CBRN) weapons."

The notice said no information proves the group now is planning an attack in the United States with a weapon of mass destruction, but noted that "such an attack cannot be ruled out."

The FBI also distributed a bulletin recently to law-enforcement agencies identifying the chemical, biological and nuclear weapons available to al Qaeda and other terrorists.

The CIA report contains photographs of a training video obtained in Afghanistan from an al Qaeda training camp showing chemical agents being tested on dogs.

Agents available to the group include toxic cyanides that can kill in high doses and less lethal industrial chemicals such as chlorine and phosgene.

Biological agents al Qaeda could use include anthrax, a bacteria that can cause mass casualties, and botulinum toxin. The CIA stated that methods for producing botulinum have been found in terrorist training manuals.

Another toxin weapon, ricin, "is readily available by extraction from common castor beans," the report said.

"There is no treatment for ricin poisoning after [the toxin] has entered the bloodstream," the report said. "Terrorists have looked at delivering ricin in foods and as a contact poison, although we have no scientific data to indicate that ricin can penetrate intact skin."

Chairman COX. It has not been changed since 1999. There is a report that was referenced in the newspaper on June 3 from the CIA titled "Terrorist CBRN Materials and Effects. " That includes a report that al Qaeda terrorist and related groups are said to use chemical, biological and nuclear weapons in deadly strikes. Quote, Biological agents al Qaeda could use include, and then they are listed. Now this is obviously more recent. The list that you are working off of dates 2 years before 9/11. Is that right?

Mr. HENDERSON. Yes, sir.

Chairman COX. And even then at the time it did not include information concerning the likelihood for use of one biological agent over another. The reason I ask this question and I am pursuing this line of inquiry is that in the legislation that we are considering right now the Secretary of Homeland Security is going to be responsible for making this ranking. He is going to be responsible for doing it on an ongoing basis and a current basis and we are trying to understand what facility, what resources are available to the Department and to the Secretary to accomplish this. Based on our joint subcommittee hearings of yesterday, I think it is very clear that this capacity does not exist in the Information Analysis Directorate and that we have to go outside for it, and so we are becoming intensely interested in how this process is working with you and the Intelligence Community and in any way that we can we want to make sure that you have opportunities to be current, to get the intelligence that you need, and to adjust the science accordingly.

So since my time has expired I will just leave you with this question. We are in fact moving forward on marking up this legislation. What could we do in this legislation to improve your life, to improve your capacity to do these things? So, for example, you are no longer working off a 1999 list. I would address that to any of the three of you.

Mr. HENDERSON. I will start and I am sure John has a comment. One thing I would recommend is that when we make a decision to include something on the list, whatever the disease is and how the disease is transmitted, understand that provides a framework for a whole variety of other decisions that then have to be made at the State and local level, the Federal level, et cetera, including for us and the Department of Homeland Security the formulary for the strategic national stockpile. We know we need to have a routine re-

view, whether it is annual or every 2 years, of the formulary for the stockpile and that is all based upon what we consider to be those agents where there is a higher likelihood that they could potentially be used by terrorist organizations. There is nothing right now that mandates the review by any form of a committee. So if you were to recommend something that could be seen as very helpful for us in pulling together all the resources that we would look at as being our scientific and law enforcement advisory body that could help advise on what we need to do with our programs to stockpile, et cetera.

Chairman COX. Well, the legislation does mandate an ongoing review, and it places that responsibility with the Secretary of Homeland Security. But it is very abstract about how in the world this is going to be accomplished and since it is going to be apparently accomplished with a great deal of outside resources, I think we need to think through in a little more detail how we can make this work.

Mr. HENDERSON. I should mention that even in the absence of the legislation we at CDC are still, we will drive ahead and try ro pull this together for our own purposes.

Chairman COX. The other members have been very generous with the chairman, and the Chair recognizes the ranking member from Texas, Mr. Turner.

Mr. TURNER. I thank you, Mr. Chairman. Dr. LaMontagne, I want to follow up on our earlier line of questioning. As I had shared with you, and I know you are aware, the statute that is being proposed, the so-called BioShield legislation, deals not with the development of the drug, but with the production phase of a vaccine. And in your testimony earlier you said that the most difficult area in the development of a vaccine is the research and development and infrastructure piece. Can you expand upon what that is briefly?

Dr. LAMONTAGNE. Well, what I was alluding to was that for many of the drugs and vaccines that we use in everyday use today, you need to have basically, fundamentally a dedicated facility almost that can produce these things in the quality and the quantity that is needed. That is not something that occurs in the context of a research entity necessarily. But let me give you an example.

For many years the NIH and CDC and other agencies worked on the development of a meningitis vaccine for children called Haemophilus influenzae type B. This vaccine has been so successful it has eliminated the disease in the United States. But to produce it in the quantities that were required to deliver it to every child in the United States required a huge investment in the manufacturing sector. That is what I am talking about, that there is a need at the pull end of the process to have the resources available that can facilitate that translation from the basic clinical research finding to broader use in the population.

Mr. TURNER. If you had a promising vaccine and you brought it through the basic research and applied research stage, I believe you testified that in your center you could actually produce about 10 to 20,000 doses of some vaccine?

Dr. LAMONTAGNE. Yes, we can. That facility, however, I should emphasize is a research facility. It is not a manufacturing facility and there is an important difference between the two.

Mr. TURNER. All I was trying to determine is if you are in a position where you have developed a vaccine through the centers of excellence that are being created through the university research centers, and you have a vaccine that has produced 10—or 20,000 doses currently, you could actually go out, if you had the dollars appropriated to you, and you could contract with a pharmaceutical manufacturer to produce that vaccine?

Dr. LAMONTAGNE. I suppose we could, yes, sir. We could contract it if we had the resources to do that. I should caution that many of the amounts I have seen would be quite huge. You are talking hundreds of millions of dollars to do that.

Mr. TURNER. Right. So it would be a large sum of money. But you could currently, under current law you could contract for that if you were appropriated the funds to do it. Assuming you have the resources available to you and the appropriations, then basically if there is a vaccine that your efforts, grants program and centers of excellence developed, and you were at that stage where you know it is ready to go into the final stages of development and production, we could get those vaccines done.

Now, under Project BioShield we are envisioning some kind of guaranteed level of funding. Based on your knowledge of where we are in the development of vaccines for these category A pathogens—and I think you mentioned there are three that really are uppermost on your mind: anthrax, smallpox and botulism—if we pass this legislation tomorrow, what contract would you suggest to Dr. Fauci and Tommy Thompson that we enter into immediately? And with what company?

Dr. LAMONTAGNE. Well, I think that the vaccines that are currently being developed are not at the stage, unfortunately, where one could expand them into large production at the present time. But I think the ones that you have cited, anthrax, a new smallpox vaccine, perhaps, antitoxin for botulism, other vaccines in that general category, even an Ebola vaccine, these are all viable candidates for this expansion process if one had it available.

Mr. TURNER. Is there anybody out there right now at the door that you are aware of?

Dr. LAMONTAGNE. There is no large vaccine manufacturer at the door saying that they are ready to produce any of these vaccines in large amounts.

Mr. TURNER. I just wanted to be sure we shouldn't continue to meet through the weekend here to be sure we don't delay this at all. One other question that I have before my time expires: When we talk about the biological threat, we have got all these possibilities of different strains of anthrax and we have been told that you may develop a vaccine and then find out somebody has altered the strain and it is not effective. How are we going to deal with that kind of threat? Because once you contract for the production of some particular vaccine it seems to me that if somebody is smart enough to alter the strain, then the contract you just entered into is basically useless and you have to go back and do another one. Is that the reality of the bioterrorist threat that we face?

Dr. LAMONTAGNE. Well, I think there is an element of that reality in all the decisions that we are facing, but I am not sure I would paint it quite that starkly. I mean, I think that there is utility to these vaccines from a biological, technical perspective. I think a vaccine that induces antibodies to the protective antigen, which is in the case of anthrax the most important constituent that can first protect, would be useful no matter what kind of interventions or changes one might make in the organism itself. I am not aware that one can develop a vaccine that would escape the neutralizing capacity of the immune response generated by that antigen. That may be possible, but I think it is a very difficult technical problem for someone to do. But you are right. There is a risk in all of these. This is not the same thing as a vaccine for a traditional public health problem like measles or rubella. We are dealing with a problem where a manipulation by some external forces might actually influence the outcome quite dramatically. So we do have to have a nimble response if we can.

Mr. TURNER. My time has expired. I have a couple of other questions. I will reserve them. Thank you.

Chairman COX. The gentlelady from Texas, Ms. Jackson-Lee, is recognized.

Ms. JACKSON-LEE. Thank you, Mr. Chairman. Thank you very much. And again the witnesses should be certainly acknowledged for their willingness to continue with us in what I think is a very important hearing. On 9/11, we saw the utilization of common, if you will, vehicles and an accelerated utilization of entities that we are comfortable with. Airplanes filled with fuel. Prior to 9/11 most Americans would not be threatened by an airplane that lifts off to the destination of which they choose. We saw those now vehicles and fuel source be turned into a terrorist act that was devastating. One of the aspects of your testimony included the listing of smallpox, anthrax I think most of us had not heard of prior to the time that was used as a terrorist threat and vehicle as well. The plague and botulism many of us have read about.

What about tuberculosis, which is highly infectious? And if utilized by the infected person to be a terrorist vehicle, if you will, where are we in terms of either providing for that under the bioscience effort, doing greater research, and preventing that infectious person from becoming a threat from a terrorist perspective. I assume it is like going into a crowded theater and being infected possibly. And if tuberculosis is a wrong example, if you could utilize any other example, and how are we prepared for that kind of threat? Also, if you would expand on the response you gave to Chairman Cox about how we could be helpful. Did I hear you say that an advisory committee or a group that would provide insight, greater insight to how you can use your resources would be helpful? If that is the case I would like that expanded on.

And I have two specific questions, one to Dr. LaMontagne. You are used to—in NIAID I would be interested in how you define biodefense work, but more particularly how do you balance the work that is going to be necessary between basic research which traditionally has concentrated on an applied research which can find more directly, which can lead more directly to the production of a specific vaccine or other countermeasure? The question is how are

you going to balance the work that you already do with new work that will be required by this legislation? I think that would be more clear.

And to Dr. Khan, the FDA has used the two animal route for testing. We are going to be moving fast and furious, I hope. I hope our pharmaceuticals who may be engaged will pierce the issue of transparency or will make sure it is transparent and they will in fact be accountable, which is one of the things I would like you to further respond to. But will we have the capacity as we are moving fast and furiously to be able to test these drugs so that they can be utilized as quickly as possible? We have a rule against using humans and we understand that. But will we have the capacity to meet the test, the challenge that we are going to face when we are truly trying to secure the homeland?

Dr. LAMONTAGNE. Well, let me start first of all with the issue of how the institute is trying to balance its biodefense with non-biodefense research responsibilities and then talk a little bit about TB in response to your question. I think we have tried very hard to maintain our focus, not only on the new responsibility of biodefense, but also we haven't lost, I believe, any momentum in our research activities related to AIDS, particularly AIDS vaccine development and other activities in the non-biodefense area, and we are very strongly committed to maintaining that kind of balanced portfolio. The basic research that you refer to is fundamentally—I just want to clarify that the way we look at it and what we are trying to achieve is we think basic research is essential to gain fundamental information about these bioterrorist agents. That basic information is critical for us to be able to move into the next step, which is the development of the drugs, the vaccines and the diagnostic tests that can be used just generally. I think in closing the consensus on the utility of tuberculosis as a bioterrorist agent is that it is probably very remote. This is a disease that, while certainly an important focus of our attentions in the non-biodefense area, is not something that occurs in an acute manner. It is a long-term, chronic, lifelong infection, as you know, and there are effective approaches to try to control it.

Dr. KHAN. Let me expand on those comments and go back to sort of how the list was derived. Tuberculosis is a severe public health—it remains a severe public health problem. It is also a severe disease if you are unfortunate to get it, and there are numerous such diseases besides tuberculosis, rabies, HIV, ehrlichiosis, toxoplasmosis, et cetera, that didn't make it on the list, at least A and B. Those would generally be covered under the category C agents, and the reason is that to derive these priority lists wasn't just a function of whether or not it was a public health problem or whether or not the disease was severe but it was additional information on whether or not this agent could be spread to a large group of people, what percentage of those, what proportion of those people would become sick, and how effective that spreading process would be, and then what special preparedness needs would be required, and that is why a number of agents remained in this emerging infectious category C. But that I think goes back to the broader thing that these bioterrorism agents are just part of this bigger issue of emerging infectious diseases and we are always

looking for the flexibility to be able to deal with all of this as a group because you do not know what tomorrow's threat may potentially be or what may show up that you didn't think about 2 or 3 years ago.

Mr. HENDERSON. Just to follow up on your question about the advisory body. Because you are talking about several Federal agencies that are involved in some decision model here, there is three things that I think we would benefit from and again we will pursue this regardless. And one is informing. You know, this is an advisory body of government nongovernmental officials. Inform us of the threats. Then help us prioritize our decision making around the type of research that we would do, and the development of the appropriate countermeasures. I think that would be helpful. And the third thing is just having an advisory body that can enable effective communication between and among the Federal agency. That, I think, would be something that we would find to be extremely valuable and we are pushing that now.

Ms. JACKSON-LEE. I got your two. You said inform us of the threat and then an advisory body, but what was the other?

Mr. HENDERSON. Enable the communication between and among Federal agencies.

Ms. JACKSON-LEE. Thank you. The question about the capacity, the two animal capacity in terms of keeping up with the fast pace of research, the testing. Anyone have a comment on whether we do have that adequate capacity? There is a two animal test I understand, and as we are trying to move as quickly as possible and efficiently as possible, do we have the capacity in that kind of process to keep up with the kinds of drugs that are being discovered that we are pushing to be discovered?

Dr. LAMONTAGNE. I think that we don't have the capacity yet, but we are rapidly building it. In the next couple of years I think we will have expanded our research laboratory capacity to be able to do many of the two animal test protocols that would be required. One thing to keep in mind is that these studies by their nature will require containment facilities for many of these agents. So as soon as that capability is expanded, which is part of our plan currently, then we expect we will have sufficient capacity to do much of this.

Ms. JACKSON-LEE. I thank you very much. In my earlier questions, as I close on this one, I indicated the interest of stakeholders like small hospitals and I indicated in my community Riverside Hospital and other public hospitals, other institutions. I mentioned Texas Southern University, Prairie View A&M only because they are in my area, but there are others. I imagine that research can be done if you do it in partnership offsite from your respective locations and that you can have collaborative partnerships with institutions like that that may be helpful in some of the testing in other areas that you are working in particularly basic research.

Dr. LAMONTAGNE. That is absolutely correct and we would encourage that.

Ms. JACKSON-LEE. Thank you. I hear a loud yes. All right. Thank you very much. Thank you very much, Mr. Chairman.

Chairman COX. Mrs. Christensen is recognized once again.

Mrs. CHRISTENSEN. Thank you, Mr. Chairman. My first question is a relatively simple one I think. How long does it take—and I

hope it wasn't asked before—how long does is take to develop a vaccine to a not seen before agent? Because the bioscience has a 5-year bring to completion time frame and there was some concern raised about that limit, that time limit.

Dr. LAMONTAGNE. That is a very hard question to answer, but a very important question. I think it depends entirely on the agent in question. I mean, some vaccines have moved actually very rapidly through the developmental process in the absence of the current pressures we are feeling in terms of biodefense. But I think depending on where you stand, let's say you have the essential components of the vaccine identified, you can probably do it in that 3 to 5-year confine. If you have to start at a fundamental level without identifying what will work as a vaccine, it will take much longer, perhaps 2 or 3 years beyond that.

Mrs. CHRISTENSEN. And Dr. LaMontagne, back to you again, too. You responded to a question about safeguards in the process a while back. And Project Bioscience uses a lot of expedited procedures and really puts a lot of authority in one person, the Secretary of Health and Human Services. There are already expedited procedures I believe at NIH and the Food and Drug Administration that can be used. Do you see the—can existing expedited procedures be used to better protect the public especially since some of the approvals can be extended if needed and we still have some questions about how best to provide compensation for injury?

Dr. LAMONTAGNE. Well, I think that in response to your question, that most of the—or virtually all of the expedited capabilities that we have have been engaged. I think that what we are talking about is a need for an enhancement of that capability. The safeguards that I mentioned earlier on have to do as much with the safeguards that currently exist in the system, which are actually quite robust, to ensure that the vaccines and the medications and the drugs that we are providing are produced consistently at high quality and do what we intend them to do.

Mrs. CHRISTENSEN. And one last question. We have had three or four hearings on Project Bioscience. There hasn't really been brought to us a Project Public Health. And I know $2 billion, and that is just part of it. Let me ask the CDC, how is that—if you were asked to—knowing the state of local and State public health agencies, areas where high disparities exist and perhaps what that 2 billion is going to be used for now, how much more should we be providing or did you ask for when you put together a proposed budget? Where was it?

Mr. HENDERSON. Just one second. We would like to provide a more comprehensive response back for the record if that is okay because the public health system is a complicated situation and it really requires a more detailed response.

Mrs. CHRISTENSEN. Yeah. And we really want to be assured that the public health system that is going to deliver the services, the vaccines, all these wonderful medicines that we are going to develop, countermeasures, is going to be in place and it is going to be in place everywhere. And so we would really appreciate your response, what the needs really are.

Thank you, Mr. Chairman.

Chairman COX. The gentleman from Texas, Mr. Turner.

Mr. TURNER. Thank you, Mr. Chairman. Dr. LaMontagne, let's follow up again on my earlier thoughts. Recognizing the limitation in the BioShield bill, dealing with the tail-end of the process—that is the final stages of its development, production—would you have any objection to making the BioShield legislation and its funding mechanism available for basic and applied research even perhaps just in the event of a national emergency where there was a determination made that there was a material threat to the U.S. population?

Dr. LAMONTAGNE. Well, that is an interesting and provocative question, Mr. Turner. I am not sure if, in the current situation, that is necessarily needed. That is my own opinion. I mean, I think that there is a quite healthy funding stream going into the basic research elements of the research agenda for all of these countermeasures. What is really needed is that pull component that we have talked about. However, is that going to be an absolute? Should there never be a circumstance in which we might—which I think is at the heart of your question—where one might want to do this. I really can't predict that. I don't foresee it currently. But it is certainly possible that one might want to entertain that prospect sometime in the future.

Mr. TURNER. Well, as you know, the BioShield legislation itself says that the funding is not triggered until there is a finding that there is a material threat to the U.S. population. So I wouldn't really be suggesting that what you are doing now is not likely to be sufficient. I am talking about that circumstance where we are confronted with a biological threat, where the determination is made as provided for under the legislation. If there is a material threat to the United States population, would you have any objection to giving the authority to the President or to the Secretary of HHS or DHS the power to make the determination that the funding that is there could be applied on an emergency basis through the applied research to finding a vaccine that we need to address?

Dr. LAMONTAGNE. In the scenario you are asking about it would be a situation—I just want to make sure I understand what exactly you are asking me. And as I understand the scenario, you are talking about a situation in which a new and novel agent appears as a validated threat to the citizens of the United States. Under those circumstances I think we should take all options available to us. So I suppose in a sense the answer might be yes, but I am not sure that that is the wisest use of those resources. I think the intention of them, as I understand the bill, is to provide that kind of pull component to engage the private sector in some of this research activity as well as the developmental activity. So to the extent that it could be covered under that kind of a rubric I think it is probably acceptable.

Mr. TURNER. Well, I would hope that if we did determine that there was a material threat to the U.S. population that we would be in a position of doing everything we possibly could to address it. And as you know, under the legislation there is no funding going to be made available to any of these private sector companies for the production of a vaccine unless there is a finding that there is a material threat to the U.S. population. I think it is a pretty high

standard that is in the bill already unless I misunderstand the intent of the language of a finding of a material threat.

Dr. LAMONTAGNE. I would have to get back to you on that, sir. I am not exactly sure what the standards are because I have not been that engaged in those discussions frankly.

Mr. TURNER. The budget request from NIH is for $1.6 billion for the various research, basic research, applied research activities, both internal, external grants that you may give to universities and others. Could you tell me how those funding streams will break down in actual practice, assuming that $1.6 billion is appropriated by the Congress, among the grants or the research by universities and others versus the monies that you will apply internally on this activity?

Dr. LAMONTAGNE. I don't have those figures in front of me, Mr. Turner, but I will be happy to provide that for the record in writing. But we do have an organized plan to address those issues.

Mr. TURNER. I don't mean to confuse you by my line of questioning. I am just one who believes we need to do more and we need to do it faster than we are doing. I want to be sure you are equipped to the extent to which you need to be to accomplish the task of discovering the vaccines, which currently the BioShield legislation, in my understanding, has little to do with. I think that side of the equation also deserves the attention of this committee and of this Congress.

Thank you very much for your testimony today.

Chairman COX. I want to thank the panel very much. You have been exceptionally generous with your time, your knowledge and your expertise, very helpful to this committee as we move forward to mark up the BioShield legislation.

I want to ask one question as we wrap up. It is by inference from what I have listened to throughout the morning that both of you, for NIAID, for CDC, it would be helpful to have as much information from the Intelligence Community as possible for you to continue to prioritize your work. Is that correct?

Dr. LAMONTAGNE. Absolutely. Yes, Mr. Chairman.

Chairman COX. That the more information that you have, respectively, about the actual capabilities of terrorists and states, the better; the more information that you have about the modalities that might be employed to disperse microorganisms the better off we will be; and the more information that you have about the relative likelihood of the use of one biological agent over another the better, is that correct?

Dr. LAMONTAGNE. Yes, sir.

Dr. KHAN. Yes, sir.

Chairman COX. It is my reading of the draft legislation that would create the bioscience program that the responsibility for seeing to it that that happens would rest with the Department of Homeland Security and the Secretary of Homeland Security. I think we need, as we move forward, to make sure that this legislation and that other authorities of the Department are adequate so that this actually happens. I don't think we want to find ourselves perpetually in a circumstance where you are relying on a 1999 list or the communication with the Intelligence Community is episodic. Assure that is an ongoing responsibility that would be placed in

law for the Secretary of Homeland Security and that the Secretary's exercise of these authorities would be enormously consequential for you, for the funding that bioscience would make available and none of it would be made available without the Secretary's prior determination. So making sure that those determinations are based on good information both good science and good intelligence is of vital importance.

So I know you are going to be partnering with other parts of the government in this as we go forward. I want to compliment you on what you have achieved already over the years and have mercy and let you go without continuing to praise you so long that you can't have lunch. Thank you very much for being with us.

The hearing is adjourned.

[Whereupon, at 12:10 p.m., the committee was adjourned.]

APPENDIX

Materials Submitted for the Record

QUESTIONS FOR THE RECORD—FOR NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES (NIAID)

(NIAID)—BioDefense Research

• How does NIAID's biodefense research compare to what takes place within other government agencies, such as the Centers for Disease Control, the Department of Defense, and the private sector?

• How should NIAID balance its work between basic research, which it traditionally has concentrated on, and applied research which can lead more directly to the production of a specific vaccine or other countermeasure?

• Should NIAID be more actively involved in such applied research? If so, how should it transition to a better balance between basic and applied research?

NIAID's Vaccine Research Center (VRC)

• How successful has the Vaccine Research Center been in developing needed vaccines? How many vaccines has the Center been responsible for producing since it was first created?

• Does the Vaccine Research Center partner with the private sector to accomplish its work? If so, who does what? What is the division of labor between NIAID and the private sector?

• How does the work to be carried out by the private sector under Project BioShield compare to the work already being done by the Vaccine Research Center?

• What is the capacity of the Vaccine Research Center? Is it—or can it be—the government's alternate to Project BioShield if Project BioShield does not result in procuring needed vaccines and other medical countermeasures?

Should the Government Do More to Produce Vaccines?

• If Project BioShield does not succeed in procuring needed vaccines, should the government do more—apart from the pharmaceutical or biotechnology industry—to develop vaccines and other medical countermeasures?

• If government efforts should be expanded, how should we go about doing so? Should NIAID or another government entity be in charge of such work? What resources will be required?

NIAID Lessons Learned

• What, in your view, are the principal lessons learned from ongoing government efforts to research and produce countermeasures against the highest priority biological agents? What has worked well, and what hasn't?

• How important is the private sector been in researching and developing medical countermeasures against biological threats? How do the private sector's efforts complement similar efforts underway within the government?

Testing of vaccines

• Is there sufficient capacity—either in the government or in the private sector—to test vaccines using the Food and Drug Administration's "two animal rule?"

• If not, what plans exist, or what efforts are currently underway, to boost testing capacity? Will NIAID's "facilities improvement" initiative for this fiscal year help in alleviating any problems?