TAKING MEASURE OF COUNTERMEASURES PARTS I & II

HEARING

BEFORE THE

SUBCOMMITTEE ON EMERGENCY PREPAREDNESS, RESPONSE, AND COMMUNICATIONS

OF THE

COMMITTEE ON HOMELAND SECURITY HOUSE OF REPRESENTATIVES

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TAKING MEASURE OF COUNTERMEASURES (PART I): A REVIEW OF GOVERNMENT AND INDUSTRY EFFORTS TO PROTECT THE HOMELAND THROUGH ACCELERATED RESEARCH, DEVELOPMENT, AND ACQUISITION OF CHEMICAL, BIOLOGICAL, RADIOLOGICAL, AND NUCLEAR MEDICAL COUNTERMEASURES

Wednesday, April 13, 2011

U.S. HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON EMERGENCY PREPAREDNESS,
RESPONSE, AND COMMUNICATIONS,
COMMITTEE ON HOMELAND SECURITY,
Washington, DC.

The subcommittee met, pursuant to call, at 2:10 p.m., in Room 311, Cannon House Office Building, Hon. Gus M. Bilirakis [Chairman of the subcommittee] presiding.

Present: Representatives Bilirakis, Marino, and Richardson.

Mr. BILIRAKIS [presiding]. The Subcommittee on Emergency Preparedness, Response, and Communications will come to order. The subcommittee is meeting today to receive testimony on the efforts of Federal agencies to work with each other and with industry to research, develop, and procure vital medical countermeasures.

I now recognize myself for an opening statement.

I would like to welcome all of our witnesses here today and thank you for your dedication to making our Nation more secure from terrorist threats. The events of October 2001, when our Nation was attacked through the mail with anthrax letters, changed the face of medical preparedness. These tragic events instilled an urgency to prepare for bioterror threats in a way that we had never done before.

The 2009 H1N1 influenza pandemic similarly caused us to turn inward and review the successes of our public health response as well as our failures. The catastrophic events in Japan—two natural disasters and a subsequent industrial disaster, an entirely unforeseen combination of events—once again force us to assess our preparedness capacity, this time for radiological and nuclear threats.

This hearing was planned well before Japan was hit with an unimaginable crisis. We are here today to discuss the ways we can and must be proactive, not just reactive, to chemical, biological, radiological, and nuclear threats, both nature and manmade.

The responsibility begins with the Department of Homeland Security. The threats must be recognized, defined, and prioritized.

The DHS threat and risk assessments are central to this effort. These tools have become instrumental in providing an awareness of the threat. They are designed not to instill fear, but rather to provide a healthy recognition of reality and an effective means by which to prioritize limited resources.

I look forward to hearing from our DHS witnesses today on how these assessments have grown, surpassed criticism, and are providing their customers with an indispensible tool.

One of those customers is the Department of Health and Human Services and its Biomedical Advanced Research and Development Authority. BARDA is responsible for advanced development and procurement of CBRN medical countermeasures. We look forward to learning from the witnesses about BARDA successes that must be supported as well as continued challenges to forging an effective and fruitful relationship with the private sector.

We know that BARDA has the authorities it needs to develop and acquire countermeasures. What is less clear is why it has not made use of those authorities.

Of particular concern are the contracting delays. These delays seem to have increased in the past, since the contracting and procurement functions were taken out of BARDA and placed under the assistant secretary for preparedness and response.

What is the strategic direction that BARDA is looking to take to allow development and procurement of the best countermeasures and in the most expedient, transparent, and industry-friendly way possible? What are the countermeasures that are missing from our stockpile? Do we need vaccines for hemorrhagic fevers or rapid diagnostics to know who has been exposed? How the material threat determinations are informing HHS investments and meeting the needs laid out by DHS is a central question.

The contributions of the Department of Defense to the health of our Nation through medical countermeasure development go back decades. DOD was a pioneer in this area. I look forward to hearing today how DOD's program has matured and how its best practices and expertise are leveraged by DHS and HHS.

DOD and HHS have a unique relationship—that of a shared stockpile. The shared anthrax stockpile, for example, allows fewer vaccines to expire and therefore better resource efficiencies.

Of course, we would also like to see a next-generation anthrax vaccine developed, and I am aware of considerable delays on the part of BARDA to procure that, pushing this until at least 2018, from what I understand. I look forward to hearing from DOD and HHS on how we can meet these and other pressing countermeasure needs.

So once again, I thank our witnesses for being here and for working to protect our health, protect our homeland, and foster more jobs and a healthier economy in the process.

I now recognize the Ranking Minority Member, Ms. Richardson, from California, for any statement she may have.

Ms. RICHARDSON. That timing wasn't planned.

[Laughter.]

Ms. RICHARDSON. Good afternoon to all of you. Actually, I am going to hold most of my comments since I just walked in, but it would suffice to say that I am glad we have the witnesses before us. I am very concerned in light of some of the things that have occurred.

I concur with Mr. Bilirakis in terms of my concern with the timing of the anthrax. I think that all the delegates probably have some questions about that.

Then I would also like to talk about this potassium iodide. I have some concerns in those areas, so I will hold the rest of my comments and submit my full statement into the record. Thank you.

Mr. BILIRAKIS. Thank you. Appreciate it.

Other Members of the subcommittee are reminded that opening statements may be submitted for the record. Before I introduce our first panel I would ask unanimous consent to insert in the record a statement from Mr. Morris, of Anbex, Inc. If there are no objections, so ordered.

I am pleased to welcome our witnesses. I will note, however, that I am disappointed that Dr. O'Toole, Dr. Lurie, and Mr. Weber declined to attend today's hearing. I certainly hope their failure to attend does not indicate a lack of attention or commitment to this very important issue.

That being said, I look forward to hearing from our witnesses. Our first witness is Ms. Cynthia Bascetta. Ms. Bascetta is the managing director of the Government Accountability's Office, GAO, health care team. She has led the programs designed to protect and enhance public health.

She is currently leading GAO's public health work with its focus on quality of care and disaster preparedness and response. Ms. Bascetta joined GAO in 1983 after conducting regulatory impact analysis of major occupational health rules at the U.S. Department of Labor.

In 2008 Ms. Bascetta was a finalist for the Service to America Medical for career achievement. She has a Bachelor's Degree in government from Smith College, a Master's in applied economics from the University of Michigan, a Master's in public health from the University of Michigan.

Our next witness is Dr. Segaran Pillai. Dr. Pillai serves as the chief medical and scientific officer in the division of chem bio and Department of Homeland Security's science and technology directorate. In this role he serves as an advisor for all DHS S&T initiatives to deter, detect, or mitigate a biological attack on the Nation.

Prior to joining S&T, Dr. Pillai served as director of the Florida Department of Health State Public Health Laboratory in Miami and as the clinical services director for the Miami-Dade County Health Department. Dr. Pillai is board certified by the American Academy of Microbiology and the American Society for Clinical Pathology.

He received a Bachelor's Degree with honors in microbiology and a Master's of Science Degree with honors in medical physiology from the Pittsburgh State University. He also received his Ph.D. in molecular genetics and biochemistry from the University of Kansas.

Following Dr. Pillai, we will hear from Dr. Richard Hatchett. Dr. Hatchett is chief medical officer and deputy director for strategic sciences and management at the Biomedical Advanced Research and Development Authority, of course, BARDA, within the Department of Health and Human Services office of the assistant secretary for preparedness and response.

Prior to joining BARDA, Dr. Hatchett served as director for medical preparedness policy on the White House National security staff, where he worked on issues related to the development of medical countermeasures. Dr. Hatchett received his undergraduate and medical degrees from Vanderbilt University.

Finally, we will hear testimony from Dr. Gerald Parker. Dr. Parker serves as the deputy assistant to the Secretary of defense for chemical and biological defense. In this role Dr. Parker is responsible for chemical and biological defense program oversight throughout the Department of Defense and integration with interagencies and international partners.

Prior to joining DOD, Dr. Parker served as the principal deputy assistant secretary in the office of the assistant secretary for preparedness and response at the Department of Health and Human Services. Dr. Parker also served in the United States Army for 26 years.

Dr. Parker graduated from Texas A&M University with a Bachelor's of Science in veterinary medicine and with a degree of Doctor of Veterinarian Medicine. He holds a Doctorate in psychology from Baylor College of Medicine in Houston, Texas, and a Master's of Science in resourcing the National strategy from the Industrial College of the Armed Forces.

I want to welcome all our witnesses. Your entire written statements will appear in the record. I ask that you each summarize your testimony for 5 minutes, and we will begin with Ms. Bascetta.

Welcome.

STATEMENT OF CYNTHIA A. BASCETTA, MANAGING DIRECTOR, HEALTH CARE, GOVERNMENT ACCOUNTABILITY OFFICE

Ms. BASCETTA. Thank you very much.

Mr. BILIRAKIS. Thank you. Is the microphone on?

Ms. BASCETTA. Now it is.

Mr. Chairman, Ranking Member Richardson, and Representative Marino, I am pleased to be here to discuss the acquisition and development of medical countermeasures to protect the public health in the event of exposure to chemical, radiological, biological, and nuclear threats, whether intentional or accidental. The 2001 anthrax attacks and the on-going nuclear disaster in Japan are just two reminders of the need for CBRN countermeasures to mitigate the potentially devastating effects of exposure. Members of Congress, Federal commissions, and other experts have all noted the need for acquiring available countermeasures as well as developing new ones.

Today my remarks will focus on HHS, which leads Federal efforts to determine countermeasure priorities as well as to develop and acquire them. HHS coordinates these efforts through the interagency public health emergency medical countermeasures enter-

prise, known as PHEMCE, which is responsible for all hazards, from bioterrorism to naturally occurring epidemics.

PHEMCE was established in 2006 and it includes several HHS components as well as DHS, DOD, VA, Department of Agriculture, and the Executive Office of the President. Through PHEMCE, DOD and HHS also coordinate an integrated portfolio to identify common civilian and military medical countermeasure priorities.

HHS's acquisition strategy is based on a four-step process, as shown on the dark blue side of our graphic, shown overhead. With input from HHS in Step No. 1, DHS identifies and assesses CBRN agents to determine which ones pose a material threat to National security, as required by the Project BioShield Act.

DHS develops material threat assessments using plausible, high-consequence scenarios to provide estimates of the number of people likely to be exposed to an agent. Since 2004 DHS has determined that 13 CBRN agents pose a material threat.

In Step No. 2, PHEMCE assesses medical and public health consequences of attacks with CBRN agents. HHS and its PHEMCE partners use the DHS material threat assessment scenarios along with other scientific data and expert consultation to model the public health and medical consequences of a CBRN event. This modeling estimates the number of individuals who may become ill, be hospitalized, or die after exposure to CBRN agents with or without medical intervention.

In Step No. 3, PHEMCE establishes medical countermeasure requirements. PHEMCE uses the consequence modeling results to determine how much of a countermeasure is needed, how it would be administered, and how it would need to be stored. Preferred characteristics, such as oral administration instead of injection and room temperature storage instead of refrigeration, are an important part of this step.

In Step No. 4, PHEMCE prioritizes development and acquisition of medical countermeasures needed for the Strategic National Stockpile. Its acquisition priorities include diagnostic devices in drugs or vaccines to mitigate the health effects of exposure to all of the agents that DHS deemed to be material threats.

PHEMCE acquires any countermeasures that are immediately available and it also supports research and development for the many countermeasures that are not immediately available. This occurs in four additional stages led by NIH and BARDA, as shown in the light blue areas of our graphic.

First, basic research is geared to better understand the health effects of CBRN agents. Next, applied research validates and tests concepts to identify the potential countermeasures and scientific or practical limitations of any products produced.

Early development demonstrates basic safety, reproducibility, and ability to use the countermeasures in humans. Advanced development further evaluates the safety and effectiveness of countermeasures. In addition, in this stage HHS determines whether manufacturing, scale-up production, and licensing can be achieved in a timely and reliable manner.

I would like to take just another minute to highlight several development challenges that serve to temper what we can expect from this process no matter how well it is implemented. One chal-

lenge is that the failure rate in research and development of CBRN medical countermeasures can be high; HHS estimates it may exceed 80 percent for products in early development.

Another is the difficulty of attracting large pharmaceutical companies who have the experience needed to meet complex requirements but little incentive to participate. Other challenges can be addressed through process or management improvements, such as regulatory challenges with the Animal Rule, regulatory challenges in determining appropriate countermeasure doses for children, and logistical challenges that HHS faces in managing the Strategic National Stockpile.

That concludes my remarks and I would be happy to answer your questions or those of the other committee Members.

[The statement of Ms. Bascetta follows:]

PREPARED STATEMENT OF CYNTHIA A. BASCETTA

APRIL 13, 2011

GAO HIGHLIGHTS

Highlights of GAO–11–567T, a testimony before the Subcommittee on Emergency Preparedness, Response, and Communications, Committee on Homeland Security, House of Representatives.

Why GAO Did This Study

The anthrax attacks of 2001 and a radiation leak after the recent natural disaster in Japan highlighted concerns that the United States is vulnerable to threats from chemical, biological, radiological, and nuclear (CBRN) agents, which can cause widespread illness and death. Medical countermeasures—such as drugs, vaccines, and diagnostic devices—can prevent or treat the health effects of exposure, but few are currently available for many of these CBRN agents.

GAO was asked to testify on the Department of Health and Human Services' (HHS) CBRN medical countermeasure development and acquisition activities. This statement focuses on: (1) How HHS determines needed CBRN medical countermeasures and priorities for development and acquisition and (2) selected challenges to medical countermeasure development and acquisition. This statement of preliminary findings is based on on-going work. To do this work, GAO examined relevant laws and Presidential directives, analyzed Federal agency documents and reports from advisory boards and expert groups, and interviewed officials from HHS and the Department of Homeland Security (DHS) about the processes for developing and acquiring CBRN medical countermeasures and the challenges related to those efforts. GAO shared the information in this statement with HHS. HHS provided technical comments, which GAO incorporated as appropriate.

PUBLIC HEALTH PREPAREDNESS.—DEVELOPING AND ACQUIRING MEDICAL COUNTERMEASURES AGAINST CHEMICAL, BIOLOGICAL, RADIOLOGICAL, AND NUCLEAR AGENTS

What GAO Found

HHS coordinates and leads Federal efforts to determine CBRN medical countermeasure priorities and develop and acquire CBRN medical countermeasures, primarily through an interagency body that includes other Federal agencies with related responsibilities, such as DHS and the Department of Defense. HHS's medical countermeasure acquisition strategy is based on a four-step process: (1) Identify and assess the threat of CBRN agents, (2) assess medical and public health consequences of attacks with these agents, (3) establish medical countermeasure requirements, and (4) identify and prioritize near-, mid-, and long-term development and acquisition. Through these processes, HHS determines which countermeasures to buy for specific CBRN agents, including the desired characteristics of these countermeasures—such as how many doses a vaccine requires to confer immunity—the needed quantity of certain medical countermeasures, and the acquisition priorities. While a few CBRN countermeasures can be immediately acquired, most have not yet been developed. Therefore, HHS and the interagency body support and oversee several stages of research and development to try to obtain usable countermeasures. These include basic cellular and biological research to understand the effects of

these agents on humans; applied research to validate approaches, such as testing the effectiveness of treatment in animals; early development to assess the safety of potential countermeasures; and advanced development, in which the products are more fully evaluated for safety and effectiveness, including their formulation and manufacturing processes.

The Federal Government faces a variety of challenges in developing and acquiring medical countermeasures, such as the high failure rate in research and development and difficulties meeting regulatory requirements. For example, the failure rate for development and licensure of most drugs, vaccines, and diagnostic devices can be more than 80 percent, depending on the stage of scientific research and development. Given this risk, as well as a lack of a commercial market for most medical countermeasures, attracting large, experienced pharmaceutical firms to research and develop them is challenging. Smaller biotechnology companies are more likely to be developing medical countermeasures, but HHS must provide more guidance to these less experienced small companies than might be typical with larger companies. In addition, several challenges exist related to regulatory processes for evaluating promising medical countermeasures. These challenges include: (1) Proving a countermeasure's effectiveness using animals as proxies for humans, because humans cannot ethically be used in studies involving CBRN agents; (2) determining appropriate doses of countermeasures for children, who may be more vulnerable to exposure to CBRN agents; and (3) evaluating the safety and effectiveness of medical countermeasures for use in a public health emergency if they have not yet been approved or licensed. Finally, HHS faces the logistical challenge of on-going replenishment of expiring medical countermeasures in the U.S. Strategic National Stockpile, the National repository of medications, medical supplies, and equipment for public health emergencies.

Chairman Bilirakis, Ranking Member Richardson, and Members of the subcommittee: I am pleased to be here today to discuss the Department of Health and Human Services' (HHS) chemical, biological, radiological, and nuclear (CBRN) medical countermeasure development and acquisition activities and associated challenges.[1] The anthrax attacks of 2001 raised concerns that the United States is vulnerable to intentional threats from CBRN agents. In addition, the recent earthquake and resulting tsunami in Japan that caused a nuclear reactor to rupture highlighted a population's vulnerability to unintentional CBRN exposure, such as to radiation. CBRN agents have the potential to cause widespread illness and death, which can be partially mitigated through the use of medical countermeasures. Medical countermeasures for CBRN agents include drugs, vaccines, and devices to diagnose, treat, prevent, or mitigate potential effects of exposure. Members of Congress, Federal commissions, and other experts have noted the need for the United States to acquire available medical countermeasures and develop new ones to protect the public from attacks with CBRN agents. While rapid diagnosis, treatment, and prevention may minimize the public health impact of a release of these agents, there are currently few countermeasures available for many CBRN agents, and research and development to create usable countermeasures is a lengthy and complex process.

You asked us to provide information about HHS's CBRN medical countermeasure development and acquisition activities. My statement today addresses: (1) How HHS determines needed CBRN medical countermeasures and priorities for development and acquisition, and (2) selected challenges to Federal CBRN medical countermeasure development and acquisition.

To develop preliminary findings based on our on-going work on HHS's CBRN medical countermeasure development and acquisition activities and selected challenges of these activities, we reviewed relevant laws and agency documents and interviewed Federal officials. Specifically, to understand how HHS determines needed CBRN medical countermeasures and priorities for developing and acquiring them, we examined relevant laws and reviewed Presidential directives that guide HHS's CBRN medical countermeasure development and acquisition activities. We obtained and analyzed HHS planning documents for medical countermeasure development and acquisition, such as public health and medical consequence modeling reports and strategy and implementation plans for medical countermeasure development and acquisition priorities. We interviewed officials from the Department of Homeland Security (DHS) about their activities related to CBRN agents and medical countermeasures. We also interviewed officials from HHS offices and agencies, including the Biomedical Advanced Research and Development Authority (BARDA) within the Office of the Assistant Secretary for Preparedness and Response (ASPR), the Centers for Disease Control and Prevention (CDC), the Food and Drug Adminis-

[1] See appendix I for a list of abbreviations used in this statement.

tration (FDA), and the National Institutes of Health (NIH), to obtain information on their activities related to medical countermeasure development and acquisition. These officials participate in the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE), HHS's interagency decision-making body responsible for providing recommendations to the Secretary of HHS regarding CBRN medical countermeasure development and acquisition. To identify selected challenges that the Federal Government faces in developing and acquiring CBRN medical countermeasures, we reviewed reports from Federal agencies, advisory boards, and nongovernmental organizations and interviewed Federal officials from the agencies identified above and other experts. We included selected challenges that were discussed in multiple reports published by Federal agencies or other expert groups, such as the Institute of Medicine, or those mentioned to us by officials from multiple Federal agencies or organizations. We did not include any challenges that related to interagency coordination and agency investments in medical countermeasure development and acquisition because we are currently examining these issues for ongoing audit work. In addition, because it was not the focus of this hearing, we excluded HHS processes for and challenges in distributing CBRN medical countermeasures from the scope of this statement. We shared the information in this statement with HHS. HHS provided technical comments, which we incorporated as appropriate.

We are conducting this performance audit in accordance with generally accepted Government auditing standards. This statement is based on work conducted from March 2011 to April 2011. The performance audit standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

BACKGROUND

Several Federal departments and agencies have responsibilities for assessing the threat of CBRN agents and determining requirements and priorities for developing and acquiring medical countermeasures for these agents, as part of their mission and, in some cases, as specifically required by law.

DHS leads Federal interagency coordination and planning for emergency response to catastrophic CBRN incidents. Under the Project BioShield Act of 2004, DHS is required, in consultation with HHS, to assess the threat of CBRN agents.[2]

HHS leads the Federal medical and public health response to potential CBRN incidents.

- HHS established PHEMCE in 2006. PHEMCE is a Federal interagency decision-making body responsible for providing recommendations to the Secretary of HHS on: (1) Prioritized requirements for CBRN medical countermeasures, (2) coordination of medical countermeasure development and acquisition activities to address the requirements, and (3) strategies for distributing medical countermeasures held in the U.S. Strategic National Stockpile (SNS), the National repository of medications, medical supplies, and equipment for use in a public health emergency. As required by the Pandemic and All-Hazards Preparedness Act of 2006, PHEMCE also conducts annual reviews of the SNS, the results of which are used to make necessary additions or modifications to its contents.[3] PHEMCE is composed primarily of officials from HHS's ASPR, BARDA, CDC, FDA, and NIH, which also have specific agency responsibilities for countermeasure development and acquisition. In addition, PHEMCE includes officials from DHS, the Department of Defense (DOD), the Department of Veterans Affairs, the Department of Agriculture, and the Executive Office of the President.
- Within HHS, ASPR is responsible for leading Federal Government efforts to research, develop, evaluate, and acquire public health emergency medical countermeasures to prevent, treat, or mitigate the potential health effects from exposure to CBRN agents. Under the Project BioShield Act, HHS is responsible for arranging for the acquisition of certain medical countermeasures, some of which may not yet be FDA-approved or licensed.[4] These countermeasures also include those for children and other vulnerable populations, such as those for the elderly and immunocompromised individuals. The Project BioShield Act authorized the Special Reserve Fund for acquisition of these countermeasures.[5]

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[2] 42 U.S.C. § 247d–6b(c)(2)(A).
[3] 42 U.S.C. § 247d–6b(a)(1).
[4] 42 U.S.C. § 247b(c)(7)(C)(i).
[5] 42 U.S.C. § 247d–6b(c)(1)(A). The Department of Homeland Security Appropriations Act of 2004 appropriated over $5.5 billion to the Special Reserve Fund to be available for obligation

- Within ASPR, BARDA—established by the Pandemic and All-Hazards Preparedness Act of 2006—is responsible for overseeing and funding advanced development and acquisition of CBRN medical countermeasures.[6]
- CDC is responsible for maintaining the SNS. CDC also supports State and local public health departments in their efforts to detect and respond to public health emergencies such as CBRN incidents, including providing guidance and recommendations for the mass distribution and use of medical countermeasures.
- FDA is responsible for assessing the safety and effectiveness of CBRN medical countermeasures and regulates their development, approval and licensure, and postmarket surveillance.[7] FDA also provides technical support for the development of tools to support medical countermeasure development. Under the Project BioShield Act, as delegated by the HHS Secretary, FDA may temporarily authorize the emergency use of unapproved or unlicensed medical products in certain circumstances through emergency use authorizations (EUA).[8]
- The National Institutes of Health (NIH) is responsible for conducting and coordinating basic and applied research to develop new or enhanced medical countermeasures and related medical tools for CBRN agents.
- The National Biodefense Science Board (NBSB), established by the Pandemic and All-Hazards Preparedness Act, provides the HHS Secretary with expert advice and guidance on scientific and technical matters related to current and future CBRN agents, including those that occur naturally.[9]

DOD has exclusive responsibility for research, development, acquisition, and deployment of medical countermeasures to prevent or mitigate the health effects of CBRN agents and naturally occurring diseases on Armed Forces personnel. Under the PHEMCE structure, DOD also coordinates with HHS on the Integrated Portfolio to identify common medical countermeasure priorities.[10]

HHS, THROUGH PHEMCE, USES A FOUR-STEP PROCESS TO DETERMINE ACQUISITION PRIORITIES FOR MEDICAL COUNTERMEASURES AND OVERSEES THEIR DEVELOPMENT

HHS coordinates and leads Federal efforts to determine CBRN medical countermeasure priorities and develop and acquire CBRN medical countermeasures, primarily through PHEMCE. HHS's medical countermeasure acquisition strategy is based on a four-step process: (1) Identify and assess the threat of CBRN agents, (2) assess medical and public health consequences of attacks with these agents, (3) establish medical countermeasure requirements, and (4) identify and prioritize near-, mid-, and long-term development and acquisition programs.[11] Because desired

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from fiscal year 2004 through fiscal year 2013. Pub. L. No. 108–90, 117 Stat. 1137, 1148 (2003). The Project BioShield Act also authorizes the Federal Government to use specific contracting authorities to procure certain medical countermeasures for these agents and requires HHS to report on these contracting authorities and procurements using the Special Reserve Fund, among other information. 42 U.S.C. §§ 247d–6b, 247d–6c.

[6] 42 U.S.C. § 247d–7e. The act also gave BARDA the authority to make advance and milestone-based payments to vendors prior to product delivery to the SNS. 42 U.S.C. § 247d–7e(c)(5)(C), (D).

[7] In FDA regulations, drugs are "approved," vaccines and other biologics are "licensed," and devices may either be "approved" or "cleared." For this statement, we use the term "approve" to refer to both approval and clearance.

[8] 21 U.S.C. § 360bbb–3. FDA can issue EUAs only after the HHS Secretary declares a public health emergency and under certain circumstances. For example, FDA can issue EUAs in declared emergencies only if the agent specified in the emergency declaration can cause a serious or life-threatening disease or condition; the known and potential benefits outweigh the known and potential risks of the countermeasure to diagnose, prevent, or treat the condition; and there is no adequate, approved, and available alternative to the product, among other requirements. FDA has issued 19 EUAs since 2004. In 2005, FDA issued an EUA for an anthrax vaccine to allow vaccination of DOD personnel. FDA has also issued several EUAs for medical countermeasures to diagnose and treat pandemic strains of influenza. The only currently active EUA is for anthrax antibiotics in home kits for postal workers to be used in the event of an anthrax attack.

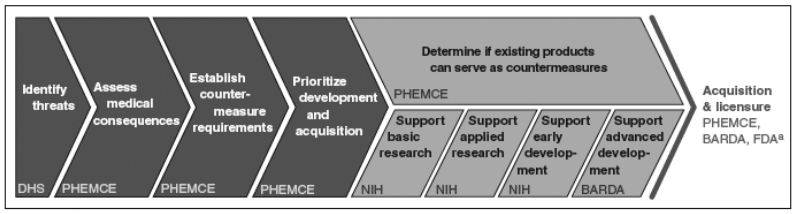
[9] 42 U.S.C. § 247d–7f.

[10] The Integrated Portfolio is intended to reduce duplication of effort and provide a mechanism for HHS and DOD to share information and resources for common CBRN medical countermeasure priorities.

[11] PHEMCE's near-term development and acquisition period is fiscal years 2007 and 2008; the mid-term period is fiscal year 2009 through fiscal year 2013, and the long-term period is beyond fiscal year 2013. PHEMCE established these development and acquisition periods to correspond with appropriations for the Special Reserve Fund. The Department of Homeland Security Appropriations Act appropriated over $5.5 billion for the Special Reserve Fund to be available for obligation through fiscal year 2013 but provided that no more than $3.4 billion may be obligated through fiscal year 2008.

CBRN medical countermeasures may not be immediately available for acquisition, HHS oversees and supports the various stages of research and development of these countermeasures, also under PHEMCE. (See figure 1.)

Figure 1: Medical Countermeasures: Process to Prioritize Development and Acquisition



With input from HHS, DHS leads the first step in the process to assess, on an on-going basis, the threat of CBRN agents and determine which of these agents pose a material threat to National security, as required by the Project BioShield Act.[12] The material threat assessments (MTA) that DHS issues examine the threat posed by given CBRN agents or classes of agents for plausible, high-consequence scenarios and provide estimates of the number of people exposed to different dose levels of an agent in the scenarios. Since 2004, DHS has determined that 13 of these CBRN agents pose a material threat, based on the MTAs.[13]

In the second step, HHS and its PHEMCE partners use the data from the MTA scenarios to assess the public health and medical consequences of an attack using these agents.[14] Public health consequence modeling estimates the number of individuals who may become ill, be hospitalized, or die from exposure to and infection with CBRN agents, with or without medical intervention. To develop these estimates from the MTA exposure data, HHS consults with experts and uses available scientific data, such as data on how much of an agent is needed to cause infection and how long it takes to develop symptoms of disease after exposure. In addition, HHS assesses the status of current countermeasure development and availability, including applicable countermeasures that DOD may be developing. Through consequence modeling, HHS determines the public health impact on the affected population in terms of the potential health effects throughout the course of disease based on different time frames for medical countermeasure delivery and treatment. According to HHS officials, consequence modeling allows PHEMCE to consider public health preparedness needs, such as whether a particular countermeasure is plausible or feasible for a certain CBRN agent and the amount that would be needed.

In the third step, PHEMCE uses the consequence modeling results to determine requirements for needed medical countermeasures, including the needed quantity and the desired characteristics, such as how they would be used and stored. HHS officials told us that these requirements would include the preferred method of administration, such as oral administration of a medicine that can be stored at room temperature. PHEMCE partners consult with experts and incorporate intelligence information and information on State and local response capabilities to determine ideal countermeasure characteristics. If countermeasures that meet these characteristics are not immediately available, HHS may acquire countermeasures that are currently available and work with manufacturers over time to develop countermeasures that better meet the ideal characteristics.[15]

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[12] Pub. L. No. 108–276, § 3(a), 118 Stat. 835, 842 (2004) (codified as amended at 42 U.S.C. § 247d–6b(c)(2)(A)(B)).

[13] The 13 agents that DHS determined pose a material threat to National security and public health are Bacillus anthracis (anthrax), Burkholderia mallei (glanders), Burkholderia pseudomallei (melioidosis), Clostridium botulinum (botulism toxin), Ebola virus (hemorrhagic fever), Francisella tularensis (tularemia), Junin virus (hemorrhagic fever), Marburg virus (hemorrhagic fever), multidrug-resistant Bacillus anthracis (MDR anthrax), Rickettsia prowazekii (typhus), Variola major (smallpox), Yersinia pestis (plague), and radiological and nuclear materials.

[14] To date, DHS has not issued determinations that any of the assessed chemical agents pose a material threat to the United States. Nevertheless, HHS has assessed the public health consequences of chemical agents for which DHS has developed MTAs.

[15] For example, HHS officials said that they would like to acquire an anthrax vaccine that confers immunity in a single dose, but because no such vaccine was available when HHS set the requirements, the Department initially acquired a vaccine that could provide immunity in six doses. Through further research, HHS was able to determine that this vaccine could be administered in fewer doses.

In the fourth step, the established medical countermeasure requirements help HHS assess and prioritize its countermeasure investments, and, according to HHS officials, form the basis for development and acquisition solicitations and contracts. Based on the requirements, in 2007, PHEMCE set its medical countermeasure acquisition priorities to focus on spending the remainder of the Project BioShield Special Reserve Fund for certain CBRN agents that DHS determined posed a material threat to National security. In addition, PHEMCE priorities focus on obtaining medical countermeasures for postexposure prevention or treatment of disease caused by those CBRN agents. HHS grouped these priorities in time frames for the near term (fiscal year 2007 through fiscal year 2008), midterm (fiscal year 2009 through fiscal year 2013), and long term (beyond fiscal year 2013). PHEMCE's stated priorities include acquiring diagnostics for each biological agent deemed a material threat, smallpox vaccine, medical countermeasures for Ebola and Marburg viruses, and medications to treat the acute and delayed effects of radiation. PHEMCE also uses the results of its annual SNS review to reassess prioritization of CBRN medical countermeasures, based on any SNS acquisitions made after the initial 2007 prioritizations.

BARDA oversees the acquisition and delivery of medical countermeasures into the SNS. If a medical countermeasure is not FDA-approved or licensed, its acquisition is funded by BARDA using the Project BioShield Special Reserve Fund. If a medical countermeasure is FDA-approved or licensed for use in treating the health effects of a CBRN agent, CDC purchases the countermeasure for the SNS. HHS officials told us that once FDA approves or licenses a countermeasure acquired with the Special Reserve Fund, BARDA is still responsible for overseeing its acquisition through the end of the Project BioShield contract. BARDA is also responsible for negotiating with the manufacturer to obtain additional quantities of the countermeasure in the event of a CBRN attack. CDC officials told us that they develop a 5-year project plan for each countermeasure in the SNS upon acquisition to evaluate specific needs over time—such as shelf life, replacement costs of expiring products, and storage and space requirements—and update the plan every year, or more frequently if conditions change.

HHS officials told us that of the few available medical countermeasures for CBRN agents, some are FDA-approved or licensed specifically for CBRN use. Other countermeasures that HHS has acquired for CBRN use have been approved or licensed for other uses only. For example, there are no currently available rapid diagnostic tools for any of the biological agents that DHS deemed material threats other than anthrax, nor are there any available medical countermeasures for postexposure prevention of disease for Ebola and Marburg viruses.

NIH and BARDA oversee and support CBRN medical countermeasure research and development, which is conducted in several stages.[16] (See figure 1.)

- *Early research*.—Early, or basic, research seeks to better understand CBRN agents and the response of the host organism to the agents through the study of the cellular and molecular biology of agents and hosts, their physiologic processes, and their genome sequences and structures. According to NIH officials, individual researchers typically initiate research in this stage. NIH assesses these research projects and their application for specific CBRN agents.
- *Applied research*.—Applied, or translational, research builds on basic research by validating and testing concepts in practical settings to identify potential products. NIH officials told us that the agency funds applied research to identify scientific or practical limitations that may affect the potential of a scientific concept to develop into a medical countermeasure product.
- *Early development*.—NIH moves successful concepts from the applied research stage into the early development stage, in which it funds research to demonstrate basic safety, reproducibility, and ability to be used in humans. In its requests for research proposals for early development, NIH officials told us that the agency specifies its needs by product modes and categories, such as therapeutics, diagnostics, and vaccines; NIH can further specify the characteristics of a medical countermeasure, and companies agree to the terms of the contract up front.
- *Advanced development*.—BARDA oversees and funds CBRN advanced research and development. In this stage, potential medical countermeasures are further evaluated in animal studies to demonstrate safety and effectiveness for preventing, diagnosing, or treating disease in humans. Successful products are then available for development and acquisition. In addition, in this stage,

[16] FDA works with researchers throughout the development stages, to review safety and effectiveness test results, ensure that research meets FDA's regulatory requirements, and approve successful products for licensure.

BARDA determines that manufacturing, scale-up production, and licensing of countermeasures can be achieved in a timely and reliable manner. BARDA also awards contracts using the Project BioShield Special Reserve Fund to acquire medical countermeasures for the SNS that are reasonably expected to qualify for FDA approval or licensure within 8 years.

CHALLENGES TO DEVELOPMENT AND ACQUISITION OF MEDICAL COUNTERMEASURES INCLUDE HIGH FAILURE RATES IN RESEARCH AND DIFFICULTIES MEETING REGULATORY REQUIREMENTS

The Federal Government faces a variety of challenges in developing and acquiring medical countermeasures, such as the high failure rate in research and development and difficulties meeting regulatory requirements. One scientific challenge is that, as with other medical products, the failure rate for development of certain CBRN medical countermeasures can be high, depending on the stage of scientific research and development. HHS estimates that the failure rate for development and licensure of most drugs, vaccines, and diagnostic devices in the early development stage can be more than 80 percent, with an increasing probability of success as the product moves further through development. Because most CBRN research does not result in viable medical countermeasures, HHS officials told us that they try to fund a larger set of candidates in earlier stages of research in order to increase the likelihood that at least one candidate countermeasure may be successful. HHS officials noted that they would ideally prefer to have at least two successfully developed medical countermeasures from different manufacturers available for a particular CBRN agent for several reasons, such as if certain segments of the population are resistant to one of the countermeasures or if one of the companies experiences manufacturing problems.

Given the high risk of failure in research, as well as a lack of a commercial market for most CBRN countermeasures, attracting companies experienced in meeting the complex requirements necessary to develop a new product is also challenging. The private sector—especially large pharmaceutical companies—has little incentive to invest millions of dollars to develop a potential new medical countermeasure because the lack of a commercial market makes a return on investment less likely or less lucrative. The Project BioShield Act facilitates the creation of a Government market by authorizing the Government to commit to make the Special Reserve Fund available to acquire certain medical countermeasures, including those that are not yet licensed or approved, provided they meet certain conditions.[17] In addition, the Pandemic and All-Hazards Preparedness Act established BARDA to support advanced research and development by, for example, awarding contracts and grants for countermeasure advanced research and development.[18] BARDA provides funding for advanced research and development for those countermeasures that are not eligible for the Special Reserve Fund. Nevertheless, despite the Special Reserve Fund and BARDA support, HHS and others have noted that engaging large pharmaceutical companies remains a challenge. In addition, smaller biotechnology companies conducting much of the research and development for medical countermeasures generally have less experience with drug development. As a result, FDA officials told us that they have to provide more regulatory and scientific guidance to these companies than they might provide to larger pharmaceutical companies, which generally have more experience with bringing products through the regulatory process.

There are also several challenges related to the regulatory processes for evaluating the development of promising medical countermeasures. For example, researchers face challenges proving the effectiveness of potential countermeasures because they cannot ethically or feasibly test the effectiveness of countermeasures on humans due to the dangers posed by CBRN agents. However, because FDA requires evidence of a countermeasure's effectiveness for approval or licensure, researchers can submit evidence of effectiveness obtained from appropriate studies in animals in accordance with FDA's Animal Rule. The Animal Rule states that in selected circumstances, when it is neither ethical nor feasible to conduct human efficacy studies, FDA may grant marketing approval based on adequate and well-controlled animal studies when the results of those studies establish that the drug or biological product is reasonably likely to produce clinical benefit in humans.[19] Under this rule, researchers can demonstrate effectiveness of medical countermeasures if the way a disease occurs in the animal being studied adequately mimics the way the disease occurs in humans. However, animals that manifest the disease in the same way as

[17] 42 U.S.C. § 247d–6b(c)(4)(A).
[18] 42 U.S.C. § 247d–7e(c)(4)(B).
[19] 21 C.F.R. §§ 314.600–.650; 601.90–.95.

humans may not always exist for a given CBRN agent. For example, according to FDA officials, smallpox occurs only in humans, and related viruses that occur in animals, such as monkey pox, may not be similar enough to mimic smallpox in humans. Because of the complexities of using animal studies as models for human reactions to agents and potential countermeasures, FDA would prefer to meet with researchers earlier and more frequently, and FDA takes longer to evaluate product applications for CBRN medical countermeasures than to evaluate other medical products. In addition, the NBSB and others have reported that researchers face difficulty in applying FDA's draft guidance on the Animal Rule, which is currently under revision. According to the guidance, the agent tested in the animal must be identical to the agent that causes human disease. However, as discussed above, some animal studies may not meet that criterion and therefore cannot be used to demonstrate a countermeasure's effectiveness. To date, FDA has not approved any newly developed CBRN medical countermeasures based on animal model testing.[20]

Determining appropriate doses of CBRN countermeasures for children, who may be more vulnerable to the adverse effects of a CBRN agent, also involves regulatory challenges.[21] Most approved or licensed CBRN medical countermeasures have been approved for use in adults only and lack pediatric dosing information. In addition, several candidate medical countermeasures currently in development lack or have limited pediatric dosing information. Regulations restrict children's participation in clinical trials when they do not benefit from them;[22] therefore, developing pediatric dosing information relies on existing adult data or data from animal studies.

There are also challenges in the processes for evaluating the emergency use of a promising medical countermeasure that has not been FDA-approved or licensed for treatment or postexposure prevention of disease for a given CBRN agent. In order for the Government to use an unapproved countermeasure to respond to a CBRN event, FDA must issue an EUA. FDA can issue EUAs only after the HHS Secretary declares a public health emergency. In order for FDA to issue an EUA, CDC, or another Government or private entity has to submit detailed information for FDA to evaluate, such as available safety and effectiveness information, a discussion of risks and benefits of using the unapproved countermeasure, draft fact sheets for health care providers and patients, and instructions for using the countermeasure. While CDC or other entities may submit all available data for FDA review in advance, such as when CDC acquires a countermeasure for the SNS, the agency must formally submit the EUA request at the time of the declared emergency. In the event of an attack with a CBRN agent that can cause disease within hours or days after exposure, CDC and FDA would have to process the final documents quickly in order for FDA to issue EUAs for appropriate medical countermeasures. Further, the Project BioShield Act precludes the use of data collected during the emergency use of an unapproved product to constitute a clinical investigation to support later product approval.[23]

Finally, CDC faces the logistical challenge of on-going replenishment of expiring medical countermeasures in the SNS. CDC can work with FDA to extend the expiration date of certain drugs in the stockpile, and thereby defer the cost of replacing the countermeasure and extend its availability for use in a potential CBRN event. In such cases, however, FDA has to conduct studies to ensure stability and quality of each drug. In addition, CDC faces the cost of relabeling the products to reflect the new expiration date. If the shelf life of an expiring countermeasure cannot be extended, CDC must replace it. For some countermeasures in the SNS, CDC may not face this challenge. For example, CDC officials told us that anthrax vaccine is moved out of the SNS before expiration because CDC rotates it out to DOD facilities for routine use.[24] In addition, other countermeasures may be held for the SNS by private vendors and can be used commercially, provided that the vendors hold a certain amount for use in the event of a public health emergency.

Chairman Bilirakis, this concludes my prepared statement. I would be happy to answer any questions that you, Ranking Member Richardson, or other Members of the subcommittee may have.

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[20] Under the Animal Rule, FDA has approved existing products for CBRN use, such as drugs to treat the effects of nerve gas and cyanide exposure.

[21] See National Commission on Children and Disasters, *2010 Report to the President and Congress* (Rockville, MD: October 2010). According to the report, in a CBRN incident children may be more vulnerable to exposure than adults because children inhale more air and consume more water in comparison to their body weight than adults.

[22] 21 C.F.R. §§ 50.50–.56.

[23] 21 U.S.C. § 360bbb–3(k).

[24] CDC and DOD have an agreement to share anthrax vaccine, which CDC holds in the SNS for DOD use.

APPENDIX I: ABBREVIATIONS

ASPR: Office of the Assistant Secretary for Preparedness and Response
BARDA: Biomedical Advanced Research and Development Authority
CBRN: Chemical, Biological, Radiological, and Nuclear
CDC: Centers for Disease Control and Prevention
DHS: Department of Homeland Security
DOD: Department of Defense
EUA: Emergency Use Authorization
FDA: Food and Drug Administration
HHS: Department of Health and Human Services
MTA: Material Threat Assessment
NBSB: National Biodefense Science Board
NIH: National Institutes of Health
PHEMCE: Public Health Emergency Medical Countermeasures Enterprise
SNS: U.S. Strategic National Stockpile

Mr. BILIRAKIS. Thank you very much.

Dr. Pillai, you are recognized for 5 minutes.

STATEMENT OF SEGARAN P. PILLAI, CHIEF MEDICAL AND SCIENCE ADVISOR, CHEMICAL AND BIOLOGICAL DIVISION, SCIENCE AND TECHNOLOGY DIRECTORATE, DEPARTMENT OF HOMELAND SECURITY

Dr. PILLAI. Good afternoon, Chairman Bilirakis, Ranking Member Richardson, and distinguished Members of the subcommittee. It is an honor to appear before you today.

In fulfilling the Department of Homeland Security's mission to protect the American people the Science and Technology Directorate strives to equip the decision-makers with tools for better assessing the significant risk that chemical, biological, radiological, and nuclear threats pose to the Nation. In my statement today I intend to discuss the utilization of DHS S&T's Risk Assessment and Material Threat Assessment products which support the issuance of the Material Threat Determinations (MTD) that inform the Federal Government's medical countermeasures position.

On July 21, 2004 President George W. Bush signed into law the Project BioShield Act of 2004. The purpose of BioShield is to celebrate and encourage the research, development, acquisition, and availability of safe and effective medical countermeasures to protect the United States from CBRN threats. It requires the Secretary of Homeland Security, in consultation with the Secretary of Health and Human Services and the heads of other agencies as appropriate, to make determinations of CBRN agents that are material threats to the U.S. population.

It also authorizes the Secretary of Health and Human Services to determine the public health consequence and recommend countermeasures to such threats. If suitable countermeasures do not already exist this process can result in a joint DHS–HHS recommendation to the President or his delegate, the director of the Office of Management and Budget, to authorize the use of BioShield special reserve funds.

The BioShield medical countermeasure acquisition strategy must be driven by many factors, including threat agents' potential cause to public health emergencies sufficient to affect National security and the potential for effective, feasible, and pragmatic medical interventions to counter their effects. Thus, the first step in the

BioShield process is to determine the relative risks and threat of specific CBRN agents.

To support this, DHS S&T conducts quantitative Terrorism Risk Assessments of CBRN agents as mandated under HSPD 10, 18, and 22, which provide the combined understanding of the likelihood and the specific consequence of a broad range of possible CBRN terrorist attacks. These assessments inform the relative risk associated with specific CBRN agents and assist the understanding as to which agents pose a relatively higher or lower threat to the American public.

These risk assessments support Federal, State, and local agencies to guide their—defense and preparations and preparedness-related investments, as well as the direct HHS planning requirements by identifying the top-tier CBRN agents that poses a high risk to the Nation. In addition, DHS leverages the risk assessments to conduct the material threat assessments on high-risk agents.

Specific to the material threat assessment process, DHS develops and models the possible high-consequence scenario taking into account acquisition, production, examination efficacy—conditions. This model is used to derive an estimate of the number of potentially exposed individuals. These estimates are then provided to HHS to conduct its public health consequence model studies, which serves as the basis for determining public health impacts.

At the conclusion of these studies, a meeting within DHS and HHS takes place to collectively determine the public health impact of an agent and its potential to affect National security. If the material threat assessments results indicate that a significant number of fatalities will result from the possible high-consequence scenario it is deemed a threat and the under secretary for science and technology, in collaboration and coordination with the office of health effects, infrastructure protection, intelligence analysis, and policy recommends to the DHS Secretary for consideration to issue an NPD. To date, DHS has issued 12 NPDs for biological agents, one for radiological materials, and one for nuclear detonation impacts.

Correct provision of CBRN agents and terrorism risk is an inherently dynamic and challenging problem. As the threat space evolves so do the technical approaches. Continually updating and gathering new data and feedback ensures that the assessments are backed by state-of-the-art science.

DHS is committed to continual improvement of the risk and threat assessments, as it is vital to appropriately capture the CBRN landscape to help prioritize resources.

In conclusion, I would like to thank you for the opportunity to discuss DHS S&T's risk assessment and material threat assessment products, which supports the material threat determinations that informs medical countermeasures decisions. I look forward to answering any questions you may ask and working with you to solve the homeland security challenges of our time.

[The statement of Mr. Pillai follows:]

PREPARED STATEMENT OF SEGARAN P. PILLAI

APRIL 13, 2011

INTRODUCTION

Good afternoon, Chairman Bilirakis, Ranking Member Richardson and distinguished Members of the subcommittee. It is an honor to appear before you today. In fulfilling the Department of Homeland Security's (DHS) mission to protect the American people, the Science and Technology Directorate (S&T) strives to equip decisionmakers with tools for better assessing the significant risks that chemical, biological, radiological, and nuclear (CBRN) threats pose to the Nation. In my statement today, I intend to discuss the utilization of the DHS S&T's Risk Assessment and Material Threat Assessment products which support the issuance of the Material Threat Determinations (MTD) that inform the Federal Government's medical countermeasure decisions.

On July 21, 2004, President George W. Bush signed into law the Project BioShield Act of 2004 (Pub. L. 108–276) (BioShield). The purpose of BioShield is to accelerate and encourage the research, development, acquisition, and availability of safe and effective medical countermeasures to protect the United States from CBRN threats. In 2004 Congress appropriated $5.6 billion for a Special Reserve Fund for use over 10 years (fiscal year 2004–fiscal year 2013) to acquire those medical countermeasures. Section 3(a)(2) of BioShield, adding section 319F–2(c)(2) to the Public Health Service Act, requires the Secretary of Homeland Security, in consultation with the Secretary of Health and Human Services (HHS) and the heads of other agencies as appropriate, to make determinations of CBRN agents that are material threats to the U.S. population. Section 319F–2(c)(2)(B) authorizes the Secretary of HHS to determine the public health consequences and recommend countermeasures to such threats. If suitable countermeasures do not already exist, this process can culminate in a joint DHS–HHS recommendation to the President or his delegate, the Director of the Office of Management and Budget, to authorize the use of BioShield special reserve funds.

To determine the most effective ways to mitigate the effects of CBRN threats or incidents, it is essential to understand that the threat classes (i.e., chemical, biological, radiological, and nuclear) are distinct in their feasibility, likelihood of use, and potential public health consequences. The BioShield medical countermeasure acquisition strategy must be driven by many factors, including threat agents' potential to cause a public health emergency affecting National security and the potential for effective, feasible, and pragmatic medical intervention to counter their effects. Thus, the first step in the BioShield process is determining the relative risks of specific CBRN agents. DHS conducts quantitative Terrorism Risk Assessments (TRAs) of biological, chemical, radiological, and nuclear attacks to better understand the likelihood and associated consequences of specific types of CBRN terrorist attacks. The TRAs accomplish this by integrating the information derived from the intelligence and law enforcement communities with input from the scientific, medical, and public health communities. The assessments establish the relative risk associated with specific chemical, biological, radiological, and nuclear agents and assist with understanding which agents pose relatively higher or lower threats to the American public. "High risk" agents are then subjected to a secondary, detailed analysis called the Material Threat Assessment (MTA) to support DHS issuance of MTDs in collaboration with HHS.

SUMMARY OF TERRORISM RISK ASSESSMENT PROCESS

Under Homeland Security Presidential Directives (HSPD) 10, 22, and 18, DHS is mandated to conduct the Biological Terrorism Risk Assessment, the Chemical Terrorism Risk Assessment, the Radiological and Nuclear Terrorism Risk Assessment, and the Integrated CBRN Terrorism Risk Assessment.

Federal agency stakeholders provide input on the scope of each TRA by participating in the Terrorism Risk Assessment Working Groups. These recommendations form the basis of each assessment's models, methodology, and improvements. DHS has conducted biennial TRAs since 2006 and each updated assessment includes refinements to the methodology and technical approach that are guided by input obtained from HHS, DoD, EPA, the intelligence agencies and other Federal agencies and stakeholders, as well as the National Academy of Sciences.

Once Federal agency stakeholder inputs are established, the next phase of the process involves refining the assessments through stakeholder coordination. This phase begins with the elicitation of intelligence from the law enforcement community on threats, including adversary group types and weaponization preferences.

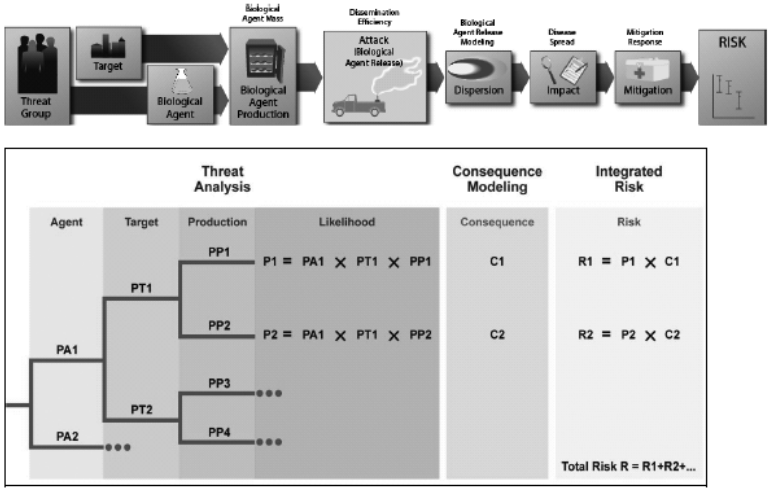
Each assessment incorporates a broad set of scenarios that consider multiple routes of exposure, multiple targets, different dissemination approaches and scales of attack, and modeling data from sources across Government, academic, and private sectors. These results are then shared with the inter- and intra-agency stakeholders in a draft report for review and comment.

After inter- and intra-agency reviews have been conducted and input incorporated, the final TRA reports are released to the National Security Staff and interagency stakeholders. The Risk Assessments address HHS planning requirements by identifying top-tier CBRN agents (i.e. relative risk ranking where risk is the likelihood of an attack combined with the associated consequences) that pose a high risk to the Nation. These Risk Assessments are then leveraged to support the conduct of MTAs on high-risk agents. Results of the MTAs are a critical element of consideration in issuing an MTD.

DHS TERRORISM RISK ASSESSMENT PRODUCTS

Biological Terrorism Risk Assessment (BTRA).—To inform decisions about biodefense investments, DHS S&T performs the BTRA every 2 years. The BTRA is a comprehensive, probabilistic risk assessment that integrates the judgments of the intelligence and law enforcement communities with input from the scientific, medical, and public health communities. The BTRA is a strategic level assessment designed to: (1) Aide in identifying and prioritizing credible, high-impact threats, (2) aid in identifying and prioritizing vulnerabilities and knowledge gaps, and (3) provide a systematic, science-based, common framework for "what if" analyses.

Figure 1. Overview of BTRA Modeling Tool



The probabilistic risk assessment methodology captures the scenarios in an event tree format allowing the model to address different classes of agents, including a full spectrum of attack scenarios, beginning with the relevant characteristics of the adversary groups under consideration, and ending with the effectiveness of the response. In the simple example above, the terrorist enters the event tree on the left-hand side with attack conception. The first branch in this simple binary example is the selection of the bioagent. The tree then splits and the second event is the selection of the target, followed by production and dissemination, etc. The accumulation of all steps in the sequence defines a scenario, with a total relative probability defined by the product of the all of the branch probabilities. For each scenario, an estimate of the overall consequence is made. The risk from each branch is then determined as the probability times the consequences, and the total risk is the sum of the risks of all of the branches. Of course, for the branches in which the terrorist fails, there are no consequences and therefore the risk is zero.

The event tree in the 2010 BTRA has 21 events and multiple branches at each event level. The 2010 study scope considers four terrorist types (international, state-sponsored, domestic, lone wolf) exploiting 43 different bioagents (38 human, five

livestock pathogens) that may be obtained from two locations (foreign and domestic) by five routes of acquisition (among them theft and environmental isolation). The adversary may use multiple methods of production and weaponization to attack any of 20 different targets (including a subway, stadium, transportation, or outdoor events) using eight modes of dissemination (food, aerosol, etc.). Human health and economic consequences are then calculated for each scenario path in the event tree and combined with probabilities to estimate the risk associated with millions of enumerated scenarios. This enables a comprehensive evaluation of not only what is possible but also probable in bioterrorism. The study model allows for risk data visualization by agent, target, adversary group and other factors to inform understanding. The probabilistic risk assessment methodology also supports an evaluation of the impact of knowledge gaps and incorporates explicit consideration of the inherent uncertainty in bioterrorism modeling.

Chemical Terrorism Risk Assessment (CTRA).—The CTRA provides a comprehensive analysis of the homeland security risks from a broad range of chemical threat agent materials, including toxic industrial chemicals, traditional chemical warfare agents, and emerging threats. The CTRA, developed by S&T's Chemical Security Analysis Center (CSAC), uses information from across the intelligence community, the law enforcement community, and technical experts from the Government and chemical industries to assess the capabilities and intentions of different types of terrorist groups, and the feasibility of acquiring a given chemical threat material. Multiple Federal agencies are involved in providing information on medical consequences of these attacks, and the capabilities that are available to mitigate the effects of an attack. Using scientific information and advanced modeling capabilities, the consequences of possible chemical attack scenarios are calculated, providing information on the numbers of people likely to be killed or injured in the attacks.

The final estimates of overall risk produced by the assessment combine the likelihood of each attack scenario, the possibility of law enforcement interdiction, and the magnitude of the consequences for each attack. The 2010 CTRA provides a relative risk assessment of 100 representative chemicals for three routes of exposure (inhalation, dermal, ingestion) over 30 different scenario types. This relative assessment of the chemical risk captures the broad range of threats posed by a number of classes of chemical compounds.

CSAC is applying the same probabilistic methodology to assess the risks of chemicals regulated under the Chemical Facility Antiterrorism Standards. This assessment, termed the Chemical Infrastructure Risk Assessment, provides DHS with tools to understand the risk of a chemical release from chemical facilities or while in transport, and to determine the impact of current threat reduction activities.

Radiological and Nuclear Terrorism Risk Assessment (RNTRA).—A collaborative effort led by S&T and Domestic Nuclear Detection Office (DNDO), the RNTRA assessment is updated biennially with information from the intelligence community, coordinated by the DHS Office of Intelligence and Analysis, and the interagency contributions from the Department of Energy, Nuclear Regulatory Commission, HHS, the Department of Defense (DoD), the Environmental Protection Agency (EPA), and many other Federal agencies. The RNTRA includes over 2 million attack scenarios from the highest consequence to most plausible. These scenarios consider: International and domestic terrorist groups as well as lone wolf scenarios; 11 radiological agents and three sizes of improvised nuclear devices; multiple modes of radiological agent dissemination; and many plausible targets such as public entertainment venues, transportation targets, and supply chain networks. The scenarios are coupled with analyzing the public health response, management and distribution of medical countermeasures and resultant fatalities, illnesses and economic consequences using integrated dispersion modeling and National laboratory nuclear effects modeling. This assessment provides decision-makers with an understanding of radiological and nuclear terrorism risks as they relate to illnesses and injuries, fatalities, latent cancer morbidities and mortalities and economic cost from both regional and National perspectives.

Integrated CBRN Terrorism Risk Assessment (ITRA).—The ITRA is the only Federal report that provides an assessment of the relative risks associated with chemical, biological, radiological, and nuclear terrorism in the homeland. The assessment is conducted biennially and provided to the Executive Office of the President's National Security Staff as mandated by HSPD–18. While the purpose of the ITRA intended by HSPD–18 is to inform resource allocation for medical countermeasures, the assessment can be leveraged by a broader range of Federal decision-makers to support development of risk management strategies that have tangible operational impact on WMD terrorism risk such as prevention, protection, surveillance and detection, response and recovery activities. The ITRA capability is based on integration and harmonization of each of the threat agent specific assessments (BTRA,

CTRA and RNTRA) augmented with intelligence information that establishes the relative likelihood that a terrorist will select a biological, chemical, radiological, or nuclear weapon. The ITRA encompasses more than 10 million attack scenarios across broad ranges of consequence and likelihood. They include various terrorist organizations, more than 150 specific agents, multiple modes of agent dissemination, and many potential targets such as public entertainment venues, transportation targets, and certain supply chain networks. These types of scenarios are coupled with modeling of the public health response, management and distribution of medical countermeasures to arrive at an estimated risk of fatalities, illnesses, and economic consequences associated with attack scenarios.

Federal, State, and local agencies can leverage these assessments to guide their WMD defense-related investments focused on prevention, protection, surveillance, detection, response and recovery-related preparedness efforts. This includes guiding prioritization, development, acquisition, and maintenance of medical countermeasures. The assessments are accomplished through formal DHS working groups, where DHS engages with HHS, DoD, the National intelligence agencies, and several other Federal agencies such as EPA and NRC. This approach includes several steps in which working group members engage with DHS to develop requirements, provide technical input, and conduct a critical review of the TRAs.

MATERIAL THREAT ASSESSMENT PROCESS

The first step in the BioShield process is threat identification and prioritization in order to inform medical countermeasure development and acquisition. DHS has the lead in threat identification and leverages the DHS Integrated Terrorism Risk Assessment findings to determine which CBRN agents present a greater risk based on the relative risk ranking against the U.S. population sufficient to affect National security. Specifically, for the highest-ranked agents in the TRA, DHS evaluates the intelligence and threat information and develops and models a highly plausible consequence scenario taking into account acquisition, production, dissemination efficacy, source strength, and meteorological conditions. This model is used to derive an estimate of the number of potentially exposed individuals at various levels of exposure, which becomes part of the MTA. The estimates are provided to HHS, which conducts its Public Health Consequence Modeling (PHCM) as the basis for determining public health impacts. At the conclusion of these studies, a meeting between DHS and HHS takes place to collectively determine the potential impact on public health and its potential to affect National security. If the PHCM results indicate that a significant number of fatalities will result from the highly plausible scenario with a particular agent, it is deemed a "threat" and the DHS Under Secretary of Science and Technology recommends to the DHS Secretary the issuance of an MTD, as outlined in Figure 2. Although the predominant role of DHS in the initial stages of the BioShield process is in conducting the MTAs, assessing the findings of the PHCM and issuing MTDs, DHS is actively involved in the subsequent interagency process and has the joint statutory responsibility with HHS in recommending to the Office of Management and Budget (OMB) to release the BioShield Special Reserve Funds.

For agents considered to be a material threat, HHS determines whether these agents lack an existing, effective countermeasure and whether a countermeasure should be procured using BioShield reserve funds. If so, then HHS uses the interagency Public Health Emergency Medical Countermeasure Enterprise (PHEMCE), created by HHS in 2006, to define countermeasure requirements and acquisition options. The PHEMCE is overseen by an Enterprise Senior Council (ESC), previously known as the Enterprise Governance Board, to take a more integrated, systematic, end-to-end approach to the medical countermeasure mission, including research, development, acquisition, storage, maintenance, deployment, and guidance for utilization. Currently, the ESC serves as the primary conduit for communication among entities involved in the medical countermeasure mission and coordinates the implementation not only of BioShield, but also: HSPDs 18 and 22; the National Pandemic Influenza Strategy; the Strategic Plan for Countermeasure Research, Development, and Procurement required by the Pandemic and All-Hazards Preparedness Act; and other strategic planning documents. The DHS Office of Health Affairs and S&T are both members of the ESC. To date, DHS has issued 12 MTDs for biological agents, one MTD for radiological materials, and one MTD for nuclear detonation effects.

Figure 2. Process for Risk Assessments through Issuance of a MTD

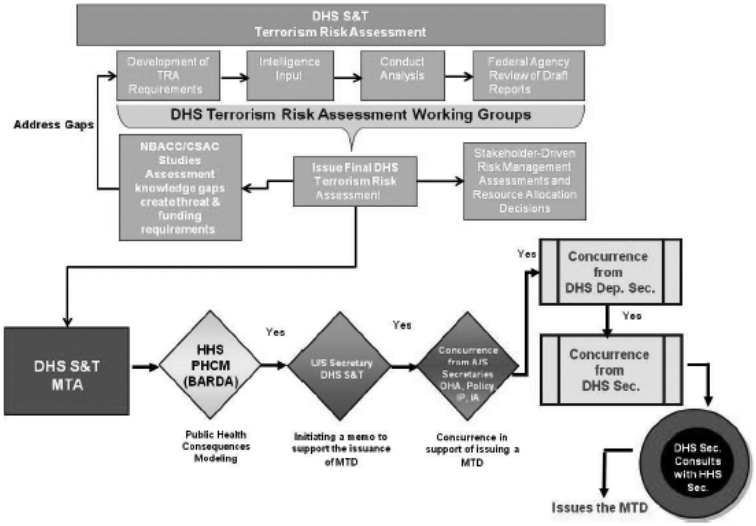
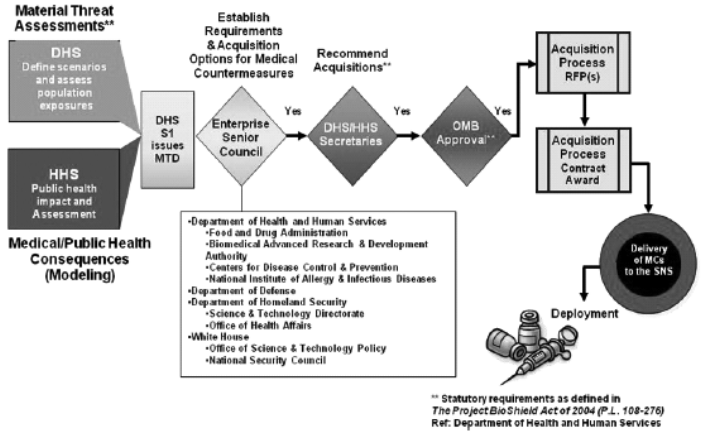


Figure 3. Project BioShield Acquisition Process



TRA IMPROVEMENT ON PROCESS AND METHODOLOGY LIMITATIONS IDENTIFIED THROUGH THE NATIONAL ACADEMIES REPORT AND STAKEHOLDER FEEDBACK

Since their origin, the DHS Risk Assessment Programs have been very proactive in soliciting internal and external expert review of methodology, data inputs, outputs, and findings. Characterization of the biothreat and bioterrorism risk is an inherently dynamic problem. DHS is committed to continual improvement of the Terrorism Risk Assessments to support stakeholder decision-making. The main challenges we face in evaluating the WMD terrorism risk are that we must rely on historical data and information about our adversaries' future plans—both of which are limited. DHS continues to work closely with HHS, DoD, EPA, and other stakeholders to provide transparency and to address, document, codify, and implement requirements aimed to improve the technical quality and utility of the TRAs.

As the first Biological Terrorism Risk Assessment represented the pioneer of the TRAs, it garnered much attention. In response to the DHS-commissioned 2008 National Academy of Sciences (NAS) Report: "Department of Homeland Security Bioterrorism Risk Assessment: A Call for Change," the National Research Council provided 13 recommendations. S&T was able to take action on several NAS recommendations in 2008, addressed others in the 2010 BTRA, and has research dollars invested to address the longer-term challenges, such as modeling the intelligent, adaptive adversary. Since 2006, BTRA has improved in its lexicon, transparency, and external peer review; the scope of consequences considered; platform flexibility; validation and verification; normalization methodology; communication strategy; and overall approach.

The BTRA program has been pushing forward on improvements as quickly as science allows, and the process remains committed to addressing any and all deficiencies noted in the report. Meanwhile, the scientific community continues to debate the evolving new science of terrorism risk assessment and S&T continues to research new approaches. It is clear that providing sound risk-informed guidance to our leadership is a job that is too important not to get right. The models are continually reviewed, updated, and exercised to support partner decision making, and by doing so, DHS adds significant value to the biodefense decision and policy development National dialog.

INFORMING CURRENT BIOLOGICAL DEFENSE RESEARCH AND THE VALUE OF KNOWLEDGE PRODUCTS

In order to enable our TRAs and MTAs to achieve greater fidelity, the National Biodefense Analysis and Countermeasures Center (NBACC) supports S&T by providing knowledge and understanding of biological agents, closing the knowledge gaps on those known agents, and supporting attribution. The direction and prioritization of NBACC's scientific research are informed by DHS in coordination with interagency partners who serve on our science advisory groups. Reducing the uncertainty in the BTRA is an important target outcome of NBACC's work.

In the current fiscal year, DHS's priority for the National Biological Threat Characterization Center (NBTCC) within NBACC is to develop plans for assessing and reducing knowledge gaps for traditional/nontraditional threat agents. These include specific and/or general properties associated with acquisition, production, dissemination, stability, virulence and pathogenesis, and medical countermeasure efficacy.

CONCLUSION

Thank you for the opportunity to discuss DHS's S&T Risk Assessment products and the Material Threat Assessment products which support the Material Threat Determinations that inform medical countermeasure decisions.

Characterizing CBRN agents and terrorism risk is an inherently dynamic and challenging problem. As the threat space evolves, so do technical approaches; by continually updating and gathering new data and feedback on the TRAs and MTAs, we ensure that the assessments are backed by the best available science, and that risk reduction strategies are continually re-evaluated to support program effectiveness. DHS is committed to the continual improvement of risk assessments to support stakeholder decision making, investments, and strategic planning initiatives. It is vital to appropriately capture the CBRN terrorism landscape to help prioritize resources and indicate areas which may need additional focus.

Thank you for inviting me to appear before you today. I look forward to answering any questions you may have.

Mr. BILIRAKIS. Thank you, Dr. Pillai.

Dr. Hatchett, you are recognized for 5 minutes.

STATEMENT OF RICHARD J. HATCHETT, CHIEF MEDICAL OFFICER AND DEPUTY DIRECTOR, STRATEGIC SCIENCES AND MANAGEMENT, DEPARTMENT OF HEALTH AND HUMAN SERVICES

Dr. HATCHETT. Thank you.

Good afternoon, Chairman Bilirakis, Ranking Member Richardson, Representative Marino. I am pleased to discuss our efforts to develop medical countermeasures against chemical, biological, radiological, and nuclear threats. The drugs, vaccines, and biological

therapeutics, and diagnostic and non-pharmaceutical devices we use to prevent, mitigate, and treat the health consequences of CBRN agents are one of our chief bulwarks against such threats.

The Department of Health and Human Services has invested more than a decade and billions of dollars in developing such products to protect civilian populations. Within the interagency PHEMCE, BARDA works closely with the NIH, CDC, and FDA, as well as the Departments of Homeland Security, Defense, Veterans Affairs, and Agriculture, to define and prioritize requirements, coordinate research, product development and procurement, and establish strategies for the deployment and use of products held in the Strategic National Stockpile, or SNS.

Requirements answer the question of: What do we need and how much should we buy? Dr. Pillai described DHS's role in establishing material threat determinations and developing material threat assessments of the number of people who might be exposed in a given event. These, in turn, inform public health consequence assessments of how many people would benefit from a given medical countermeasure.

DHS also provides the integrated terrorism risk assessment, which helps us determine program priorities. Collectively, these assessments help us to align and prioritize our investments while coordinating our efforts with those of our Federal partners.

A prime example of our commitment to such coordination is the integrated portfolio for CBRN medical countermeasures managed by HHS and the Department of Defense. Through the integrated portfolio, HHS and DOD leverage each other's efforts to address a broad range of common threats and requirements with greater efficiency and economy.

The enterprise has notable successes to its credit. We have procured eight countermeasures for the SNS using Project BioShield funds, reducing our vulnerability to anthrax, smallpox, botulism, and radiation threats in the process. The SNS has an adequate supply of smallpox vaccine for the entire country and we have met our requirement for heptavalent botulinum antitoxin.

But our efforts to support the development of medical countermeasures have faced and continue to face many challenges. Eight years ago Congress envisioned that the authorities and funding provided through Project BioShield would solve our medical countermeasures problem.

The important authorities and funding from Project BioShield have been necessary but not sufficient conditions for success. We have spent the years since Project BioShield was established coming to better understand our private sector partners and the challenges they face, and in making improvements—not least through Congress' passage of the Pandemic and All-Hazards Preparedness Act—to our model for partnering with them.

Under the form of last year's PHEMCE review we stepped back and took a systems approach to addressing these challenges. The result of the review is that we have undertaken an ambitious and important initiative involving multiple components to fundamentally alter the environment within which medical countermeasures development occurs. The goal is to shape a tightly integrated end-to-end enterprise in which promising concepts and discoveries are

readily translated into candidate countermeasures and moved through the development pipeline with the Government coming to the table at every stage as a full and active partner.

The four major initiatives proposed by the review—the creation of, first, a concept acceleration program at the National Institute of Allergy and Infectious Diseases; second, a nonprofit, independent medical countermeasures strategic investor; third, centers for innovation in advanced development and manufacturing; and fourth, a robust medical countermeasures regulatory science program at the FDA—will create a more complete arch of support across the entire chain of development.

Collectively, these initiatives will mitigate the technical, regulatory, business, and Governmental risks that companies face in undertaking medical countermeasures development while simultaneously reducing their opportunity costs for working in this area. In parallel, we are also restructuring the way we do business, with all of the HHS components working together and seamlessly from the beginning with a focus on continual quality improvement.

Let me be clear about one thing: These initiatives are not substitutes for the market guarantee provided by Project BioShield. By altering the environment within which medical countermeasures development occurs and by increasing the speed and rapidity with which products enter and move through the pipeline we believe these initiatives will help Project BioShield realize its full potential.

Thank you, again, for inviting me to testify, and I would certainly be happy to answer any questions that you may have in this——

[The statement of Dr. Hatchett follows:]

PREPARED STATEMENT OF RICHARD J. HATCHETT

APRIL 13, 2011

Good afternoon Chairman Bilirakis, Ranking Member Richardson, and distinguished Members of the subcommittee. Thank you for inviting me here today to testify on the Department of Health and Human Services' (HHS) efforts to prepare for and protect against chemical, biological, radiological, and nuclear (CBRN) threats. My name is Richard Hatchett and I serve as the Chief Medical Officer and Deputy Director for Strategic Sciences and Management at the HHS Biomedical Advanced Research and Development Authority. I am pleased to join my Department of Homeland Security and Department of Defense colleagues, as well as the Government Accountability Office, to discuss these very important issues. The threats that our Nation faces continue to evolve, and we know that we cannot identify and characterize them all in advance. It is critical that we have the capability, as a Nation, to be resilient when disaster strikes—and to be resilient, we must be able to respond quickly and effectively to all disasters with the appropriate resources necessary to limit casualties and disruptions to communities.

INTRODUCTION—ASPR/BARDA MISSION

The HHS Assistant Secretary for Preparedness and Response, Dr. Nicole Lurie, serves as the principal advisor to the Secretary on all matters related to Federal public health and medical preparedness and response for public health emergencies. The Office of the ASPR (or ASPR) promotes community preparedness and resilience; builds public health partnerships with Federal departments and agencies, State and local governments, non-governmental organizations, academic institutions and private sector partners; and coordinates Federal public health and medical response capabilities.

Within ASPR, the Biomedical Advanced Research and Development Authority (BARDA) is responsible for developing and procuring safe and effective medical

countermeasures (MCMs) against CBRN threats, pandemic influenza, and emerging infectious diseases. A principal BARDA responsibility is to help bring promising MCMs through the so-called "valley of death." The "valley of death" describes a period of time during MCM research and development when promising innovative technologies fail to advance to a marketable product due to entrepreneurial capital shortage or other similar cause. Left to their own devices and resources, most of our small biotech partners would find that the "valley of death" poses a nearly insuperable set of financial, technical, and regulatory challenges. BARDA provides the financial and technical resources our partners need to address these challenges. BARDA supports medical countermeasure activities such as industrialization, nonclinical and clinical testing, development of manufacturing technologies and scale-up, submissions for FDA regulatory review, and procurement for the Strategic National Stockpile (SNS). BARDA works closely with its HHS partners at the National Institutes of Health (NIH), the Centers for Disease Control and Prevention (CDC), the U.S. Food and Drug Administration (FDA), as well as at the Department of Defense (DoD) and the Department of Homeland Security (DHS) to ensure the Nation has appropriate MCMs to save lives during a CBRN event.

As the BARDA Chief Medical Officer and Deputy Director for Strategic Sciences and Management, one of my primary responsibilities is to ensure we have safe and effective medical countermeasures available for our response efforts. One of the key avenues BARDA uses to align its work with that of our HHS and interagency partners is the HHS Public Health Emergency Medical Countermeasures Enterprise, or PHEMCE, which encompasses the development, manufacturing, production, stockpiling, and deployment and use strategies of products deemed critical to protecting or treating our population against a variety of CBRN threats, as well as against pandemic influenza and other emerging infectious diseases. My written testimony discusses the PHEMCE MCM requirements setting process; BARDA's MCM procurement and advanced research and development efforts; our collaboration with Federal partners and outreach efforts to industry; and identified gaps and challenges related to MCM development and procurement and how we are addressing these challenges.

THE PUBLIC HEALTH EMERGENCY MEDICAL COUNTERMEASURE ENTERPRISE

In July 2006, HHS established the Public Health Emergency Medical Countermeasures Enterprise to improve the Federal coordination of Government policy, investments, and activities related to the development and procurement of medical countermeasures for CBRN threats. The overarching mission of the PHEMCE is to:

- define and prioritize requirements for public health emergency medical countermeasures;
- coordinate research, early and late stage product development, and procurement activities addressing these requirements; and
- set deployment and use strategies for medical countermeasures held in the SNS.

ASPR leads the PHEMCE, which includes the CDC, the FDA, and the NIH. The PHEMCE also includes key interagency partners from DHS, DoD, the VA, and the USDA. The PHEMCE uses a decision forum named the Enterprise Senior Council (ESC) for MCM policy and implementation development. The ESC is chaired by the ASPR and is comprised of the senior leadership of the Enterprise. Together, the PHEMCE organizations and agencies work to improve our preparedness for public health emergencies with respect to the development, stockpiling, and use of medical countermeasures.

PHEMCE MCM Requirement-Setting Process

Simply stated, medical countermeasure requirements answer the questions of "What do we need, and how much should we buy?" For CBRN threats, these MCM requirements serve two critical functions:

- to improve the outcome of public health emergencies by focusing MCM activities across a wide range of key stakeholders, and
- to align the multibillion-dollar investments of the NIH, BARDA, and CDC in the discovery, advanced development, acquisition, deployment, and use of MCMs; and
- to coordinate programs effectively with interagency partners at USDA, VA, DoD and DHS.

The current PHEMCE MCM requirements process includes the following activities:

- *Threat Assessments*.—DHS develops Material Threat Assessments (MTAs) to support use of Project BioShield Special Reserve Fund acquisitions based on "plausible, high-consequence" scenarios. To date, CBRN medical counter-

measure requirements have derived from these scenarios. The classified MTAs prepared by DHS estimate the number of people in the population exposed to specified levels of a given threat agent. Issuance by DHS of a Material Threat Determination (MTD) based on the information in the MTA and on risk assessments is a requirement for use of Project BioShield Special Reserve Funds.

- *Medical and Public Health Consequence Assessments*.—ASPR modeling staff collaborate with threat-specific Requirement Working Groups (including Subject Matter Experts) to develop medical and public health consequence assessments using epidemiological modeling tools that estimate the number of people who would benefit from a particular medical countermeasure using the population exposure numbers derived from the MTA. Subject Matter Experts review and discuss the appropriate disease-related parameters that should be included in the modeling and what those values should be. They review the modeling outputs and provide feedback on the model and the results in an iterative and highly collaborative process.
- *Consultation with Subject Matter Experts*.—ASPR staff consult with a wide range of Federal subject matter experts (with expertise in areas including, but not limited to, microbiology, health physics, chemistry, toxicology, medical care, and diagnostics) through the PHEMCE Requirements Working Groups and Integrated Program Teams. Expertise from non-Federal personnel is sought as needed and appropriate.
- *Consultation with End-Users*.—Through one-on-one, small, and large group settings, PHEMCE partners work with emergency planners as well as public health, first responder, and hospital-based end-users of medical countermeasures at the local, State, regional, and National levels to understand the concept of operations (CONOPs) under which the medical countermeasures will actually be used. Examples of past interactions include roundtable settings, one-on-one interviews supporting interactive design methodologies, and the annual PHEMCE Stakeholders Workshop. Of note, there is an Institute of Medicine Study Committee presently looking at issues related to pre-deployment of MCMs in community settings.
- *Leadership Approval*.—CBRN medical countermeasure requirements are approved through a formal governance process within the PHEMCE. Following concurrence by the appropriate PHEMCE Requirements Working Group and Integrated Program Team, the draft requirements are briefed to the interagency Enterprise Executive Committee and to interagency leadership at the Enterprise Senior Council.
- *Requirement Revision*.—ASPR leads re-examination and update of requirements at the request of the PHEMCE leadership or as needed as response capabilities and CONOPs evolve or new technological or threat information is gained, or as real events present new information through lessons learned (e.g. 2009 H1N1, or the Japan nuclear crisis).

MCM requirements fall into two major classes: (1) Scenario-based requirements, and (2) product-specific requirements.

(1) Scenario-Based Requirements establish the classes and quantities of MCMs necessary to effectively respond to plausible, high-consequence scenarios for each threat agent. Medical and public health consequence assessments are used to inform these requirements.

(2) Product-Specific Requirements determine the acceptable (threshold) and ideal (objective) characteristics for individual MCM product types. These are set through consideration of existing research and development technologies and response capabilities, and are communicated in the form of a Target Product Profile that calls out minimal qualities acceptable and goal characteristics for medical countermeasures HHS will pursue. Product-Specific Requirements also specify the quantity of a product with ideal characteristics that might be acquired to meet the specified needs, along with an indication of how variations in product characteristics might affect the quantity sought. Final acquisition quantities are determined based on product-specific characteristics and other considerations in the acquisition strategy and plans developed by program staff.

MCM PROCUREMENTS, ADVANCED RESEARCH AND DEVELOPMENT, AND OUTREACH TO INDUSTRY

Once the requirements setting process is complete, and the PHEMCE determines that advanced development or acquisition of unlicensed medical countermeasures is appropriate to meet these requirements, BARDA funds these activities to protect the American civilian population against CBRN and naturally occurring threats to public health. Further, BARDA collaborates with intra- and inter-agency partners in

MCM research that may be a precursor need for meeting these requirements and has a robust process for screening new technologies and interacting with the private sector on novel MCM technologies and products.

Project BioShield MCM Procurements

Project BioShield, authorized by the Project BioShield Act of 2004 (Pub. L. 108–276), established the Special Reserve Fund, a market signal, a guarantee, and a secure funding source for the procurement of critical medical countermeasures, such as vaccines, therapeutics, and diagnostics that are close to licensure. It provides a tangible guarantee to industry that a market will exist for these products. The Project BioShield Act also provides additional and more flexible authorities and funding to support and expedite the development and procurement of CBRN MCMs. Finally, the Project BioShield Act provides the Secretary with the authority to authorize the use of unapproved products or the unapproved use of approved products during emergencies.

In 2003, Congress appropriated $5.593 billion to support Project BioShield over a 10-year period. Since its inception, ASPR has used Project BioShield funds to procure:

- anthrax therapeutics and vaccines;
- heptavalent botulinum antitoxin;
- smallpox vaccine; and
- a number of MCM products intended for use after radiological and/or nuclear events.

Of the $5.593 billion originally appropriated, $2.348 billion remains available. The difference includes $2.130 billion directed towards the procurement of MCMs and $1.114 billion transferred, rescinded, or spent on ARD contracts.

Advanced Research and Development

Using its Advanced Research and Development (ARD) authority, BARDA bridges the "valley of death" funding gap that exists between the early stages of product development and the procurement of approved or approvable medical countermeasures under Project BioShield. Given that commercial markets do not exist for many of the products we are trying to develop, robust funding for ARD is essential if we are to build a substantial pipeline of products to diagnose and treat illness with, or prevent the effects of CBRN agents. The fiscal year 2011 budget includes a request that $476 million be made available from Project BioShield balances to support such ARD projects. Current priority investment areas include anthrax vaccines and treatments, broad spectrum antimicrobial drugs, and treatments and diagnostics for illnesses associated with exposure to radiation. In fiscal year 2012, the budget requests another $765 million from Project BioShield balances to support these priorities.

Integrated Portfolio for CBRN Medical Countermeasures

The DoD and HHS each identify medical countermeasure requirements to address their different missions and focus. Historically, DoD has prioritized the development of MCMs to protect our military prior to exposure to CBRN agents, whereas HHS's focus has been on responding to threats to the civilian population once exposure has occurred. However, there are areas of common requirements or interest where medical countermeasure candidates, resources, and information can be appropriately shared to maximize opportunities for success in the development of medical countermeasures for the highest priority threats. BARDA, in partnership with other HHS and DoD partners, is leading an Integrated Portfolio for CBRN Medical Countermeasures to leverage resources and programs across the agencies that develop and acquire CBRN medical countermeasures to more effectively address the broad range of common threats and requirements. Members of the *Integrated Portfolio* working to integrate HHS and DoD efforts include BARDA, biodefense programs at NIH, and multiple elements of the DoD Chemical and Biological Defense Program.

BARDA TechWatch Program

BARDA has developed an active *TechWatch* program, which provides an opportunity for external organizations to meet with the Federal Government to discuss their new and innovative medical countermeasure technologies. Companies may request meetings with Government subject matter experts to discuss their products and plans for submitting proposals in response to BARDA's Broad Agency Announcements (BAAs) through the PHEMCE portal website *www.medicalcountermeasures.gov.* These meetings provide the Federal Government with the latest information about emerging technology and inform strategic and programmatic planning for effective public health emergency response. The TechWatch program has been highly successful in improving communication with potential

partners. Those companies who utilize *TechWatch* prior to submitting a white paper in response to a BAA are three times more likely to be invited to submit a full proposal than companies that proceed directly to the white paper without the benefit of a *TechWatch* meeting.

MEDICAL COUNTERMEASURE ENTERPRISE REVIEW

Recently, our department undertook an effort to address gaps and challenges in MCM development and procurement by improving the efficiency of our translational efforts, enhancing the advanced development and manufacturing services we provide our partners, clarifying regulatory pathways, and building a strong base for MCM regulatory science at the FDA. These initiatives, once implemented, will provide the capability to speed MCM development and respond faster and more effectively to rapidly evolving public health threats. In December 2009, on the heels of the 2009–H1N1 pandemic, HHS Secretary Kathleen Sebelius requested a complete review of the MCM enterprise and assigned this responsibility to ASPR. The goal of the review was the end-to-end transformation of the enterprise: To improve its performance, enhance collaborations with the private sector, and prepare the Nation for the threats of the 21st Century—those we can predict as well as those we cannot. The MCM Enterprise Review, released in August 2010, identifies "processes, policies, and infrastructure required to take a product concept derived from a national requirement through research, early and advanced development, manufacturing, regulatory approval, procurement, and stockpiling." Specifically, this review looked across the entire arc of product development, from early discovery through regulatory approval, and identified the chokepoints where product development was stalling or failing. To address these chokepoints, which create technical, business, and regulatory risks for small innovator companies and form the basis of the MCM "valley of death," the Review proposes a series of initiatives:

- The establishment of a Concept Acceleration Program at the NIH National Institute of Allergy and Infectious Diseases to work with partner agencies, academic researches, biotech companies, and large pharmaceutical companies to identify promising scientific discoveries and expedite their transformation into practical, usable products.
- The establishment of a nonprofit [501(c)3 or equivalent] Strategic Investor firm to spur innovation by supporting companies that possess strategic technologies that might otherwise lack the necessary financial capital or business acumen to develop a commercially viable approved product.
- The establishment of U.S.-based Centers for Innovation in Advanced Development and Manufacturing.
- A major investment in regulatory sciences and review capabilities at the FDA focused on CBRN MCMs.

The Concept Acceleration Program will leverage existing intramural and extramural research programs as well as applied and translational resources throughout NIH, CDC, FDA, and DOD to speed the translation of promising concepts into candidate MCMs.

The Strategic Investor initiative would spur innovation and provide the kinds of business and financial services and support that venture capital firms typically provide, mitigating the risk that funded pharmaceutical manufacturing firms will fail because of poor management, an inadequate business model, or lack of financial expertise. The Strategic Investor initiative is critical to transitioning MCM development and procurement from a "one bug, one drug" approach to an enterprise capable of responding to any threat at any time.

The Centers for Innovation will be created to reduce risk, increase product yields, and reduce total life-cycle costs through flexible manufacturing. These U.S.-based Centers are expected primarily to provide, on a routine basis, core services that include advanced development and manufacturing capabilities of USG-supported developers of medical countermeasures for chemical, biological, radiological, and nuclear MCMs to address National preparedness and response priorities and needs. In the event of a pandemic, the Centers will also be available to assist in the manufacture of influenza vaccine and other biologics. The Request for Proposals for this latter initiative was published on March 30, 2011, and we have been working closely with our colleagues at DoD, who are preparing a complementary initiative for release in the near future.

Finally, expanding regulatory science and review capabilities at the FDA will strengthen and clarify the MCM regulatory process, which will expedite MCM development.

Collectively, these initiatives, once implemented, will help us establish a more nimble and diversified approach in preparing for and responding to CBRN and other threats.

MCM DISTRIBUTION—EXECUTIVE ORDER 13527

Finally, Mr. Chairman and Members of the subcommittee, I must address the importance of the entire MCM continuum—from research and development to procurement to distribution and dispensing. The MCM enterprise is one component of a broader response strategy to mitigate the effects of a CBRN event. To be resilient in the face of CBRN disasters, we need a fully integrated and coordinated strategy to address how the various sectors of our health care system will work together to respond and save lives. We need an integrated health care system that can address patients' needs when and where necessary. After we work to procure valuable CBRN medical countermeasures, we need adaptable distribution and dispensing plans in place capable of quickly delivering these countermeasures to every American who needs them.

On December 30, 2009, the President issued Executive Order 13527 establishing the Federal Government policy, in the event of a biological attack, to plan and prepare for the timely provision of medical countermeasures to the American people through a rapid Federal response in coordination with State, local, territorial, and Tribal governments. Section 2 of the Executive Order tasks HHS and DHS, in coordination with the USPS to develop a national USPS medical countermeasures dispensing model for U.S. cities to respond to a large-scale biological attack, with anthrax as the primary threat consideration. This dispensing model was delivered to the President on June 30, 2010 and was included in a recent grant announcement issued through ASPR. The President's fiscal year 2011 budget requested $10 million to fund this initiative. However, these funds were eliminated in the previous, current, and proposed continuing resolutions to fund Government operations in fiscal year 2011. The President's fiscal year 2012 budget requests $5 million for this initiative.

CONCLUSION

In closing, I want to reiterate that as the threats we face evolve, we will continue to work closely with our colleagues at DHS, DoD, and across Government to ensure that our investments are rational and sustainable. We understand the importance of thorough surveillance and early detection to limit the impact of a CBRN event and will continue to work closely with our partners to build upon existing infrastructure and align supporting investments and capabilities. We continue to face significant challenges in the realm of MCM research and development and hope that through implementation of the priorities established in the MCM Enterprise Review, we can transform the way we collaborate with our industry partners while demonstrating our sustained commitment to developing new and promising MCMs. Medical countermeasures are a bulwark against the deliberate and natural threats we face, a critical link in the chain of preparedness.

I speak for all my colleagues throughout HHS in saying that we look forward to working with you on the matters I have raised this afternoon. With the leadership and support of Congress, and in collaboration with our agency partners, we have made substantial progress in MCM development and procurements. We have accumulated a great deal of practical experience over the last decade and have a deep understanding of the challenges our private sector and academic partners face. To meet these challenges, we have made changes in our governance—continual improvements in our processes and institutions, our standard operating procedures, and our collaborations with our DHS and DoD partners. We are in the process of transforming the MCM Enterprise to ensure its sustainability while meeting the threats of the future.

Let me assure you that we take our mission of preparing the Nation against these threats with the utmost seriousness and that we know how much we still have left to do.

Thank you again for inviting me to testify. At this time I would be happy to address any questions you may have.

Mr. BILIRAKIS. Thank you, Dr. Hatchett.

Dr. Parker, you are recognized for 5 minutes and then we will recess because we have four votes. Then we will come back as soon as the last vote is completed.

So you are recognized, sir, for 5 minutes.

STATEMENT OF GERALD W. PARKER, JR., DEPUTY ASSISTANT TO THE SECRETARY OF DEFENSE, CHEMICAL AND BIOLOGICAL DEFENSE, DEPARTMENT OF DEFENSE

Dr. PARKER. Thank you.

Chairman Bilirakis, Ranking Member Richardson, and Representative Marino, I am honored to be here to discuss the Department of Defense efforts to develop medical countermeasures to protect the warfighter and the Nation. First I would like to briefly describe the DOD chemical and biological defense enterprise. We have a process in place to analyze threats and gaps in our capabilities so we provide our warfighters the protection they need to carry out their mission, protect our country, and come home safe and healthy.

The joint staff works with the services and combatant commands through the joint requirements office to establish requirements. Our joint science and technology office manages research and development to fill our S&T product development pipeline. As medical countermeasure candidates mature, products transition to the joint holding executive office for advanced development, manufacturing, and testing to address all regulatory requirements leading to FDA approval.

From research to acquisition our efforts are product-focused, with target product profiles developed early to guide countermeasure development.

The DOD works in close partnership with HHS and DHS through the integrated National portfolio to ensure we are not duplicating efforts and to leverage capabilities. It is a great partnership.

I have a unique perspective of having worked on biodefense with each of the agencies represented here today, and I would also like, though, to emphasize the exceptional DOD outcome-based, product-focused contributions. We have a rich history in infectious disease and medical biological defense R&D, with DOD playing a significant role in developing eight of the 15 adult vaccines licensed in the United States since 1962. Since 2000 our efforts have led to eight more FDA approvals for diagnostics and licensed medical countermeasures for anthrax, smallpox, and nerve agents.

However, we recognize that we must develop new ways to confront the growing and evolving risk of chemical, biological, radiological, and nuclear threats as well as emerging infectious disease. The average 12 to 15 years to develop a medical countermeasure against a single threat is too long and too costly.

This National security challenge demands new approaches. The Department's needs for specific medical countermeasures are variable in number, ranging from tens of thousands of doses to a few million doses, owing to unique operational requirements and our global presence.

The potential spectrum of threats and the many diseases we confront globally are diverse. Yet, today we have numerous unmet requirements for medical countermeasures. It is crucial that we close these gaps.

DOD is responding to this challenge by building an integrated capability to respond to the threat through enhanced diagnostics, detection, and global biosurveillance and through innovative indus-

trial capacity for advanced development and adaptive manufacturing capabilities that will capitalize on multi-use platform technologies. DOD pioneered this approach beginning in 2006 when we initiated the Transformational Medical Technologies Initiative, or TMT, to change the approach to medical countermeasures development and the science base and to invigorate the S&T pipeline.

TMT has made exceptional progress in our ability to identify, characterize, and discover new drug candidates rapidly. But we need to apply similar innovative approaches to establish new development, regulatory sciences, and manufacturing capabilities.

We are preparing to implement the Medical Countermeasures Initiative through our cooperative partnership with industry to establish industrial capacity and expertise for the rapid development agile manufacturing of medical countermeasures. To this end, we are collaborating closely with the Department of Health and Human Services to create and integrate National capability to produce medical countermeasures in a more cost-effective manner and rapidly in the face of any attack or threat.

The DOD is looking to address the operational needs of the military while HHS must address the large-scale production needed to meet the needs of the U.S. population. Both efforts are integrated and complementary.

During fiscal year 2012 the DOD plans to award a long-term contract to establish an advanced development and agile manufacturing capability. The Department of Defense must have the ability to fight and win in an environment that might be compromised by threats of a bioattack or endemic diseases. This includes the timely provision of safe and effective vaccines and treatments for our military and our coalition partners.

These threats on our troops and citizens are very real and ever-changing in the 21st Century. I appreciate the strong leadership from the White House and the Congress on this critical issue and the opportunity to testify today. I will be pleased to answer your questions.

Thank you.

[The statement of Dr. Parker follows:]

PREPARED STATEMENT OF GERALD W. PARKER, JR.

APRIL 13, 2011

INTRODUCTION

Chairman Bilirakis, Ranking Member Richardson, and Members of the subcommittee, thank you for giving me this opportunity to discuss Department of Defense efforts to develop medical countermeasures to protect the Warfighter and the Nation.

DoD has to confront the growing and evolving risk of chemical, biological, radiological, and nuclear threats, and emerging infectious disease. Our National security is challenged to both accurately identify and rapidly respond to an attack or naturally occurring outbreak with countermeasures that limit impacts and loss of life. DoD is responding to this challenge by building an end-to-end, integrated capability to respond to the threat through enhanced diagnostics, detection, and biosurveillance; and through innovative industrial capacity for advanced development and adaptive manufacture of medical countermeasures for rapid response.

The potential threats today are much more difficult to plan against. We face a broad array of both natural and man-made challenges. The world is smaller so global pandemics come to our shores faster, and DoD personnel are deployed around the world coming into contact with endemic diseases unlikely to be seen in North Amer-

ica. The emergence and rapid advance of synthetic biology will make it easier over time for an adversary, whether state or non-state, to develop modified pathogens. These challenges will only increase with the exponential growth in the field of biotechnology, global industrialization, and the wealth of scientific information becomes even more available through mass communications.

Our over-arching goal, of course, is to prevent an attack or infectious disease outbreak in the first place. The Department has expanded prevention efforts underway that include international scientific engagements to promote a culture of laboratory responsibility, enhance scientific collaboration, and to secure dangerous pathogens. Should a crisis occur, however, we will have to act swiftly and decisively with the capability to rapidly indentify and characterize the threat, activate response plans, and rapidly distribute and disseminate medical countermeasures in sufficient quantities.

Before addressing medical countermeasure development challenges and solutions, I want to take the opportunity to emphasize the strong and productive collaboration we share with the Department of Health and Human Services and the Department of Homeland Security on many levels, and particularly through the Public Health Emergency Medical Countermeasures Enterprise. Through this Medical Countermeasures Enterprise, we have developed the Integrated Portfolio for CBRN Medical Countermeasures to develop medical countermeasures required for National and Homeland Security. Our relationship with HHS and DHS through the Enterprise is synergy at its best—we team our expertise, avoid duplicating efforts, and participate in joint acquisition and stockpiling when possible.

As a former laboratory director, I want to mention that the Department of Defense has an incomparable set of laboratory assets and scientific expertise based throughout the United States and around the globe engaging in basic and applied research, advanced technology development to prove concepts for medical products and information, and response to threats against health and performance. These include medical research and technology aimed at endemic disease threats, chemical and biological warfare threats, environmental hazards, battle sequelae, systems hazards, operational stressors, and combat injuries.

Our overseas laboratories are National assets that advance U.S. diplomacy through the study of infectious diseases of critical regional public health importance. By contributing to the health infrastructure of another country, we contribute to that country's security and by extension to U.S. security as well. The laboratory missions also include the evaluation of vaccines, therapeutic agents, diagnostic assays, and vector control measures. New international collaborations include the Republic of Georgia-U.S. Biosurveillance and Research Center which engages scientists in diagnostic and epidemiological studies, and medical countermeasures research. DoD endeavors with coalition partners are exemplified by the work in the Republic of South Korea where diagnostic, detection, biosurveillance, and laboratory capabilities to protect U.S. forces are tested and deployed. This work is done in collaboration with the Republic of Korea Defense, Health, and other Ministries to improve our collective preparedness and response posture to emerging infectious disease threats of any origin in this critical geographic region.

CHALLENGES TO PROGRESS ON MEDICAL COUNTERMEASURES

The December 2010 *National Strategy for Countering Biological Threats* highlighted the significant threat posed by especially dangerous pathogens to our people, forces, and coalition partners. The Department of Defense must have the ability to fight and win in an environment that might be compromised by diseases or threat of a bioattack. This includes the timely provision of safe and effective vaccines and treatments for our Joint Service Members and our coalition partners.

The events of the 2009 H1N1 pandemic, along with the on-going challenges and costs associated with development of chemical, biological, radiological, and nuclear medical countermeasures, revealed major gaps in advanced development and access to domestic surge manufacturing capacity. These and other challenges underscored by the Public Health Emergency Medical Countermeasures Enterprise Review in August 2010, revealed the need for a whole-of-government approach.

Factors that have limited progress for developing biodefense vaccines include the inability to leverage the expertise and capabilities of larger, experienced biopharmaceutical companies due to the high opportunity costs of entering the limited chemical, biological, radiological, and nuclear medical countermeasure market. The result is a reliance on small biotechnology firms that are engines of innovation and critical for discovery and early development of medical countermeasure candidates, but they have limited advanced development and regulatory experience and limited manufac-

turing capabilities. This is a costly, inefficient, and risky approach to meet critical biodefense and public health needs.

The cost and time required to develop and obtain Food and Drug Administration approval to market a new biologic and/or drug is costly, takes years, and is a risky endeavor even for large, experienced pharmaceutical companies or for medical countermeasure candidates that have well-established regulatory and development pathways and a commercial market.

The Department's needs for medical countermeasures are variable in number, ranging from tens of thousands to a few million doses, owing to unique operational vaccine and treatment requirements due to our global presence. The potential spectrum of CBRN threats and emerging infectious diseases is diverse, and we have too many gaps and unmet requirements for medical countermeasure vaccines and treatments.

It is crucial that we close the vaccine, antimicrobial, and antiviral drug gaps. We cannot afford to take the average 12 to 15 years to develop a medical countermeasure against a single threat, nor can we afford to use the traditional and costly "one bug-one drug" development paradigm. This National security challenge requires new approaches for medical countermeasure advanced development and manufacturing to counter anticipated and unanticipated threats from an attack or naturally occurring infectious disease threats. The DoD approach to overcome some of these challenges is to bring innovation to manufacturing processes in an analogous way that the Transformational Medical Technology program brought innovation to discovery and early development. The approach will capitalize on platform technologies that can be multi-use and give us an ability to quickly characterize the pathogen and promptly develop a countermeasure.

INTEGRATED BIODEFENSE APPROACH

The Department will address these gaps holistically and as an integrated set of capabilities including establishment of critical industrial capacity to respond swiftly and effectively to these evolving threats. These capabilities focus on the need to quickly and precisely detect, diagnose, and identify the threat, develop, or refine a medical countermeasure, and manufacture quickly those countermeasures in useful quantities.

Detection and Initial Response

The first step in this integrated set of functions is detection, and includes the entire system and processes that can quickly determine the nature of the infectious disease or emerging threat. Our ability to obtain early warning about the emergence and progression of new and/or particularly dangerous threats feeds directly into our ability to prepare effective vaccines and therapeutics.

Detection capabilities are a priority for DoD and include pursuit of research, development, and acquisition of medical diagnostics, environmental detection, and data fusion, management, and decision tools.

One diagnostic capability currently fielded with our forces in over 300 locations worldwide is the Joint Biological Agent Identification and Diagnostic System. It is capable of rapidly identifying multiple biological agents, such as anthrax, plague, and avian influenza. In response to the 2009 H1N1 pandemic, genomic signatures and assays obtained from the CDC were quickly ported to the JBAID system under FDA Emergency Use Authorization enabling use of this deployed platform for both military and public health needs. The utility of this genomic based diagnostic system has been very successful, enough to warrant investments and a new development thrust in next-generation diagnostics.

We are also working closely with the Department of Homeland Security and the Department of Health and Human Services on biosurveillance, diagnostics, environmental detection, laboratory capabilities, integrating operations, and data systems, and participating in joint exercises in support of a National biomonitoring architecture. In BioWatch cities, for example, military installations are included in the local emergency management and public health incident command centers enabling shared situational awareness through local, State, and National operations centers. We are also integrated through the National Biosurveillance Integration System, which serves as the platform for information exchange between agencies and facilitates the early recognition of biological events, including natural disease outbreaks, accidental or intentional use of biological agents, and emergent biohazards. DoD also collaborates with the DHS National Biodefense Analysis and Countermeasures Center for biological risk assessments and bioforensic analysis to support attribution.

DoD global biosurveillance activities are enhanced by establishing strategic research partnerships and scientific cooperation efforts with partner nations. Global

biosurveillance initiatives and medical diplomacy through overseas labs foster ongoing communication, collaboration, and information networks among the U.S. Government agencies, non-governmental organizations, academia, and international partners. The Armed Forces Health Surveillance Center Global Emerging Infections Surveillance and Response System is a centralized communication hub to help coordinate DoD resources and link with other U.S. and international disease surveillance efforts. This center links DoD laboratories, research facilities, and the military health system to facilitate rapid recognition and response to protect the health of the forces and National security. Within DoD, a new laboratory information and communications system, the Electronic Integrated Disease Surveillance System, can link together the different levels of a National disease surveillance network within a country providing near-real-time information flow that can be disseminated to the appropriate organizations in a timely manner. DoD's overarching interest is to improve the capability for international surveillance, countering biological threats, and responding to emerging infectious diseases of intentional or natural origins. This is done in close collaboration with CDC global disease detection efforts.

DoD supports civil authorities in chemical, biological, radiological, and nuclear consequence management operations to save lives and reduce the effects of a weapon of mass destruction attack. We recognize the importance of maintaining a force that is ready and able to respond to these special threats and is prepared to rapidly support civil authorities in response to an event. The Department has established elements to provide forces as soon as possible to support any consequence management scenario that may occur. This includes command and control, decontamination of personnel and equipment, hazardous material handling and disposal, air and land transportation, aerial evacuation, emergency medical treatment, and sustainment. Other units provide casualty/patient decontamination, emergency medical support, and casualty search and extraction. We are continually looking for ways to improve support to civil authorities, increasing life-saving capabilities and reducing response times. By the end of 2012 there will be 10 Homeland Response Force units capable of responding within hours in each of the FEMA regions to provide more life-saving capabilities faster using the same approximately 18,000 personnel assigned to this mission.

Medical Countermeasures Discovery and Development

The second step of our integrated biodefense enterprise includes the entire scope of efforts to discover and develop a medical countermeasure candidate to a chemical, biological, radiological, and nuclear threat or new pathogen. These countermeasures must be rapidly demonstrated to be safe and effective through streamlined, but still rigorous, techniques. The Transformational Medical Technologies program, established as a DoD Initiative in 2006, focuses on the discovery and refinement of medical countermeasures in response to emerging threats and has been so successful it is now becoming the base approach for the entire medical discovery program.

The Transformational Medical Technologies program addresses novel threats, biologically engineered pathogens, or emerging infectious diseases by developing new detection and therapeutic capabilities. The goal is to provide a rapid response capability to identify and characterize an unknown, and then apply a broad spectrum medical countermeasure. If none exist, a therapeutic platform will discover and develop medical countermeasure candidates quickly.

For example, in 2009 we redirected a therapeutic platform focused on developing therapeutics for hemorrhagic fever viruses to discover and refine medical countermeasures against an outbreak of an unknown pathogen. Our systems quickly identified the unknown sample as the H1N1 virus, and a new antiviral was synthesized within 14 days. This is a revolutionary change from traditional discovery methods which can take years. However, traditional advanced development and manufacturing is not rapid, and will require further innovation. Even so, the H1N1 antiviral showed great promise in animal studies and is now entering clinical trials. Still, we must bring innovation to advanced development and manufacturing as well.

Advanced Development and Manufacturing

The essential third step is access to critical industrial capacity and expertise for the agile development and manufacturing of medical countermeasures in quantities to treat affected populations rapidly. We are preparing to implement the Medical Countermeasures Initiative through a cooperative partnership with industry. One of the innovation drivers will be the ability to manufacture medical countermeasures in a flexible fashion to include "on-demand" surge capacity for specific products in the event of a National security emergency or change manufacturing runs on different products as the need arises. The Medical Countermeasures Initiative encompasses two components: Science and technology, and advanced development and

manufacturing. A related component is the planned National test and evaluation facility for animal studies necessary for FDA approval. The science and technology component will concentrate on three areas: Novel platform/expression systems, advancement of regulatory science, and advancements in flexible manufacturing technologies. The advanced development component will concentrate on integrating novel platform/expression systems into a production process and establishing a Technical Center of Excellence to provide advanced development core services and a flexible manufacturing capability for DoD and National security needs. Ultimately, the Medical Countermeasures Initiative will coalesce to provide a "one-stop" shop for all future DoD medical countermeasure development.

Although platform and new manufacturing technologies coupled with new facility design make this approach technically feasible, it is not without risks and challenges. The technologies are new and the underpinning regulatory science will have to be developed in parallel as the products develop.

DoD intends to engage the most capable performer(s) to integrate innovative manufacturing technologies and to perform advanced development using scalable commercial manufacturing processes for meeting the Department's medical countermeasure requirements. Developing the right industry partnerships, small biotechnology endeavors generating new innovations needed for the revolutionary breakthroughs and larger companies with advanced development and licensure experience, will require the right incentives. We anticipate the need to motivate entry into the MCM niche, possibly cost-sharing, intellectual property rights, indemnification, or other attributes deemed necessary to generate interest.

INTERAGENCY COLLABORATION

The FDA has already started promoting regulatory innovation and investment in regulatory science in order to provide private sector partners with more access to regulators and greater clarity about the pathways to product approval. We are collaborating with the FDA and our other interagency, private sector, and academic partners to explore solutions to complex scientific regulatory problems and to identify situations in which the application of new science could simplify or speed product development and streamline the FDA regulatory approval process for medical countermeasures. Regulatory science is a critical enabling factor, particularly for unique challenges of developing biological defense medical countermeasures where pivotal efficacy studies must be done in animal model systems. Together, we will develop strategies and assemble new tools for mutual success. Whether it is a member of our Armed Forces in the field or a fellow citizen in our neighborhood, safe and effective FDA approved medical countermeasures are needed when an event occurs.

Collaboration with the Department of Health and Human Services is essential to the successful implementation of the DoD Medical Countermeasures Initiative. Not only does this include the FDA, but the DoD advanced development and manufacturing capability must complement the parallel, but distinct, Biomedical Advanced Research and Development Authority work to establish Centers of Excellence for Advanced Development and Manufacturing. Leveraging the regulatory sciences component of the DoD's Medical Countermeasures Initiative will aid in surmounting these challenges by supporting the FDA in developing new methods for regulatory assessments so those assessments will not hamper moving advanced development programs forward. By working closely with HHS, we expect to provide one part of a National advanced development and manufacturing capability to support National security and meet unique DoD operational requirements.

Our Nation must have the nimble, flexible capability to produce medical countermeasures in a more cost-effective manner and rapidly in the face of any attack or threat, whether known or unknown, novel or reemerging, natural or intentional. President Obama called for this in last year's State of the Union Address. Our effort, along with the complementary manufacturing efforts within the Department of Health and Human Services, will provide surge production when necessary and will address the science and technology efforts to develop the next generation medical countermeasure platform technologies, critical industrial manufacturing systems and regulatory science technologies. DoD has to commit to flexible manufacturing technologies because of the breadth of medical countermeasures we need to protect our troops and support global operations, and because of the varying numbers of doses required for each of these. We do not need to give every service member every vaccine, but we do need to be prepared to provide the levels of protection required.

There is no way to draw a line between National security and public health so we coordinate closely with our public health colleagues. We have a great partnership

with other U.S. agencies and are careful to maintain our focus on National security to avoid overlap with established U.S. public health efforts.

The Department of Defense has a long and proud history in infectious disease medical research and development. The DoD played a significant role in developing eight of the 15 adult vaccines licensed in the United States since 1962. Currently used worldwide, these include vaccines for influenza, meningococcal disease, hepatitis, rubella, adenovirus, typhoid, and Japanese encephalitis. In the high-risk business of vaccine production, experience breeds proficiency and efficiency, curbing the scientific, regulatory, and financial risk that can stifle product development. Since 2000, biodefense efforts have resulted in eight FDA approvals for diagnostics and medical countermeasures (including licensed medical countermeasures for anthrax, smallpox, and nerve agents) generated in our pipeline. Still in the advanced development pipeline are 14 candidates for next-generation countermeasures against anthrax, smallpox, botulism, alphaviruses, plague, influenza, and other emerging infectious diseases; chemical agents; and radiological threats. We anticipate more FDA approvals in the next 5 years.

DoD brings a unique capability to the National biodefense portfolio: Detection and diagnostics sound the alarm, the Transformational Medical Technologies program or similar rapid response efforts generate new medical countermeasure candidates, and the Medical Countermeasures Initiative will establish the critical industrial capacity and expertise for advanced development and manufacture of medical countermeasure.

CONCLUSION

We are putting more emphasis on biodefense, particularly medical biodefense, leveraging the rapid growth in new technologies for our purposes. These threats on our troops or citizens are very real and ever-changing in the 21st Century. The Department of Defense must develop a nimble and agile program to respond. My organization is working to strengthen our capabilities to effectively prevent, deter, and defeat these threats. We are working with interagency partners, to include the Departments of Homeland Security and Health and Human Services, to better detect threats and protect the Nation from harm before an event occurs: We are changing the way we address research and development so we can be better stewards of the pipeline that we share with HHS, and we are becoming more responsive and proactive. I appreciate the opportunity to testify today and would be pleased to answer your questions.

Mr. BILIRAKIS. Thank you very much. Appreciate it, Dr. Parker.

Again, the subcommittee will stand in recess until the conclusion of the votes. We will reconvene immediately following the last vote as soon as I get a quorum.

So thank you very much and thanks for your understanding. We will see you in a few minutes. We have four votes.

[Recess.]

Mr. BILIRAKIS. Okay. We will go ahead and continue. Appreciate you waiting for us. Appreciate your patience.

The Ranking Member is ready, so I will ask—I will recognize myself for 5 minutes to ask questions.

The first question will be for Dr. Pillai and Dr. Hatchett. In what ways does DHS work with HHS on the threat assessments so as to ensure that, as a customer, HHS is getting what it needs out of the assessments?

Dr. PILLAI. We from DHS are responsible for conducting the threat assessments and risk assessments. Based on the products that we develop is the support of customers at HHS as well as interagencies. With that said, we have actually held multiple working group meetings as well as multiple durations of the product in the draft stage.

In the working group meetings we have participation from HHS, ask for members from BARDA, members from CDC, FDA, NIH, and AID, a factor, as well as members from DOD, the intel community, as well as EPA and others. So collectively we try to leverage

all of the information and knowledge from all of the subject matter experts to develop the material threat assessments and the risk assessment products to support HHS in the process.

Basically, it is very collectively, collaborative architecture to support this effort. With that said, that we have been very proactive in soliciting comments and recommendations and suggestions from HHS to better improve the product over the period of time.

We continue to receive comments from them, and we continue to address them as appropriate, and we continue to refine these models and these tools to support HHS to the best of our ability.

Mr. BILIRAKIS. Dr. Hatchett.

Dr. HATCHETT. Yes, sir. Just to reiterate what Dr. Pillai said, we felt we have contributed subject matter experts in the early stages of the development of the various assessments. We, through the PHEMCE—I should underscore the public health emergency medical countermeasures enterprise incorporates DHS subject matter experts in our on-going assessments once we receive the material threat assessments in performing our public health consequence modeling and in making subsequent determinations about requirements as they relate to medical countermeasures, per se.

The integrated terrorism risk assessment has been an integrated process since that process was initiated several years ago. There have been multiple iterations—of course, the National Academy of Science's report, and it is a process of continual improvement towards our goal of an integrated threat assessment and we work closely with our colleagues at DHS.

Mr. BILIRAKIS. Thank you.

Next question for Dr. Pillai: Are you confident that your single high-consequence scenario is the best approach for setting medical countermeasure requirements? If not, what are the plans for revisiting the material threat assessments to increase their reliability and utility?

Dr. PILLAI. There are many approaches that one can take to support medical countermeasures requirements. One of these approaches is basically taking a look at the high possible consequence scenario and then utilizing that particular scenario to drive the medical countermeasures requirement.

The benefit of doing that is basically you are capturing all of the threat space and potentially, if you develop countermeasure requirements, supposedly addressing the high-consequence scenario, basically captured all of the potential low-consequence scenarios that might take place. With that said, originally when we started developing our material threat assessments at DHS the intent of the material threat assessments were basically to support material threat determination in support of the Secretary at DHS. With that said, there is on-going discussions and collaborations at the current time between HHS and DHS to better refine the product so that we can support HHS in their medical countermeasures requirement generation process.

With that said, one of the ideas and suggestions we ask is potentially redefining the MTAs, or refining the MTAs in such a fashion that it will take a look at multiple scenarios so that it has got much broader application in terms of supporting HHS in their MCM requirements. The other alternate approach is basically

leveraging the integrated CBNR risk assessment with some minor refinement along with some risk mitigation strategies to support HHS in their needs in terms of medical countermeasures requirement.

Mr. BILIRAKIS. One last question for Ms. Bascetta.

Your office is undertaking a look at DHS's threat and risk assessments to try to understand how this work informs HHS investments. I understand that your analysis is still underway, but have you formed any initial impressions about how this process between the two departments is working? Similarly, can you speak to relationships within HHS, such as between BARDA and CDC for the setting the requirements and priorities?

Ms. BASCETTA. You are correct that our work is underway, and we are actually not at the point where we have findings or conclusions that I could share. But I am happy to say that, in fact, I believe that since 2004 and especially since PHEMCE was established in 2006 there has been a significant amount of progress and we have a lot of documentation about constructive meetings that have gone on between HHS and DHS.

Within HHS we haven't looked at how well the components are working together, but I can say that in other work that we have done we have noted that HHS is a large department and many of their components are set up with different specific missions. You know, in the spirit of maximizing their resources we would encourage them to continue to look for ways to reduce fragmentation and to ensure that there isn't overlap that, you know, isn't—to ensure that there is, you know, better traction from the resources that they have. But we don't have evidence, at this point, that there is a problem that we would point to.

Mr. BILIRAKIS. Okay. Thank you very much.

I now recognize our Ranking Member, Ms. Richardson, for 5 minutes or so.

You are recognized.

Ms. RICHARDSON. Thank you, Mr. Chairman. My questions are for Mr. Hatchett.

Mr. Hatchett, with regard to the potassium iodide, the scientific need for this particular countermeasure is obviously well-established over many years. Congress, in fact, has done its part by providing the financial mechanisms to stockpile KI with the Project BioShield Act of 2004, which funds countermeasures against biological and chemical, radiological, and nuclear agents, roughly some $5.6 billion through fiscal year 2013.

Could you please explain to this subcommittee why KI has not been stockpiled as directed by Congress? What specific countermeasures have been done? Where has the money been spent thus far?

Dr. HATCHETT. Representative Richardson, with respect to potassium iodide, it actually was procured for the Strategic National Stockpile. ThyroShield, the liquid formulation of potassium iodide, was procured and offered to States in compliance with the 2002 Bioterrorism Act.

The current domestic requirements for potassium iodide have been met through the existing program that is administered by the Nuclear Regulatory Commission in conjunction with FEMA and

State and local authorities in States that have nuclear power plants or are adjacent to nuclear power plants. So——

Ms. RICHARDSON. So, have you—the various State agencies to see if, in fact, they have sufficient stockpile that is required?

Dr. HATCHETT. Well, as I said, this is a long-standing program between Nuclear Regulatory Commission and FEMA specifically for the procurement, distribution, and dispensing of potassium iodide, so I would defer the question to my colleagues at NRC. I will say that when we had ThyroShield in the Strategic National Stockpile and we offered it to States there were some States that accepted the offer of the liquid potassium iodide solutions.

Ms. RICHARDSON. So, could you give this committee an update of where the States are regarding this issue?

Dr. HATCHETT. Yes, ma'am. I will need to get back to you for the record, if that is acceptable.

Ms. RICHARDSON. So——

Dr. HATCHETT. HHS administers the Project BioShield funds. We have used Project BioShield, actually, for the procurement of the ThyroShield product as well as for the procurement of another radiation countermeasure, calcium-DTPA, and its—zinc-DTPA.

Ms. RICHARDSON. So can you provide for this committee where the $5.6 billion has gone?

Dr. HATCHETT. Yes. A detailed explanation would be easier to submit in writing, but I would be happy to do that.

Ms. RICHARDSON. Okay. If you say that States are ready, I don't know if you know much about—but I come by way of California, and of the more recent situation with Japan where there is quite an outcry for potassium iodide, and in fact, it was not available. So how is it that you can say that it is supposed to be available when in my State it wasn't and we were, you know, one of the States along the pathway of the potential radiation?

Dr. HATCHETT. Couple of answers. The Nuclear Regulatory Commission program focuses on the emergency protection zones around nuclear power plants, and so its focus, in terms of purchasing and distributing the potassium iodide focuses on the EPZs around the nuclear power plants. Potassium iodide is an over-the-counter medication. It is available.

I will say, with respect to the demand for potassium iodide in California, public health officials had a great deal of concern about that demand because there was not an indication for people to take potassium iodide, and potassium iodide, if taken inappropriately, can be associated with toxic events.

Ms. RICHARDSON. Okay. So whether folks were supposed to have taken it or not, it is my understanding that KI is currently only required to be stockpiled within the 10-mile radius. In light of what happened at Chernobyl or Fukushima and the Pacifica tolls in Nevada and Utah they are testing, and radioactive iodine has traveled 100 miles, which is far beyond the 10-mile area.

Dr. HATCHETT. Yes, ma'am. We are actively initiating a process to review our requirement for potassium iodide in the Strategic National Stockpile. This was initiated as a response to the Fukushima Daiichi catastrophe.

We will certainly take the lessons learned from that in reassessing our requirement.

Ms. RICHARDSON. So, to your knowledge, are you saying that you are not aware that the administration is still concurring that 10 miles is sufficient? Is that not correct?

Dr. HATCHETT. The current policy is that 10 miles is sufficient. That would——

Ms. RICHARDSON. You are currently reviewing that—is that what you said?

Dr. HATCHETT. What we will be reviewing at HHS is the role of potassium iodide in a centralized Strategic National Stockpile. I am certain that there will be an interagency broader review that will look at the zero-to-10-mile issue, but that would involve other interagency partners such as DHS, FEMA, and the Nuclear Regulatory Commission.

Ms. RICHARDSON. So, will you supply this committee that information and then also supply us the information regarding the stockpile, verifying whether, in fact, that is happening within the States?

Dr. HATCHETT. Yes, ma'am.

Ms. RICHARDSON. Okay. Then I do have a second round of questions——

Mr. BILIRAKIS. Yes. We are going to do a second round, yes. I am interested in that issue too, as you are.

So please supply that information to us. I would really appreciate it.

Dr. Hatchett, by the way of reorganization the assistant secretary for preparedness and response directed that the activities of BARDA's contracts office be separated from those of BARDA's technical group, yet the contracts office has contracting officers, not the scientific expertise needed to determine whether or not companies have met their scientific milestones. We have heard from many avenues that this model is ineffective.

Can you explain to the committee why this action was taken? How do you explain the substantial complaints about contracting, that contracts take too long, that streamlining authorities are not being taken advantage of, and that contracting officers are making decisions that should be made by policy or technical staff? This is no small question and it appears to be the source of serious development and procurement problems at BARDA. So that is my first question and I have a second question.

Dr. HATCHETT. Okay. I think you have actually asked multiple questions and——let me take them in sequence.

The change in reporting for the head of the contracting office—the head of the contracting office used to report to Dr. Robinson, the director of BARDA. He now reports to Dr. Lurie, the assistant secretary for preparedness and response. Physically, the contracting office is physically still in its same location, which is in an office that is shared with BARDA staff, so there has been no disruption of the relationships between BARDA program staff and BARDA contracting staff.

The idea that technical decisions are being made by contracting officers actually is not correct. BARDA and the contracting staff and their office of finance within ASPR has created a decision gate process that is modeled on other substantial acquisition programs at the Department of Defense, Department of Energy, NASA, et

cetera, and as well as—it included a review of similar cost estimates in private sector pharmaceutical companies.

That decision gate process provides for milestone-based decisions about moving forward with specific projects, and those milestone-based decisions are—they use an in-process review, which brings in subject matter experts from across HHS and the interagency to review the progress of specific projects and to make appropriate decisions about whether they should move forward or whether sufficient concerns have arisen that adjustments need to be made.

Is that a sufficient answer to your question, sir?

Mr. BILIRAKIS. I think that is it, but I would like to speak with you, again, follow up on this.

Then the next question is, why hasn't HHS ever exercised its other transaction authority?

Dr. HATCHETT. I think certainly we have not identified, to date, a specific requirement for using the other transaction authority. We actually do anticipate that we will be using it in the relatively near term, particularly in support of our broad spectrum antimicrobial program. The other transaction authority will help facilitate public-private partnerships for the development of multiuse countermeasures, particularly where some of those uses for which the products are being developed fall outside the CBRN sphere. So I would ask you to standby and we hope to be——

Mr. BILIRAKIS. All right. Thank you.

Dr. Parker, I am pleased to hear from your testimony that DOD works in tandem with DHS and HHS to leverage your efforts and expertise. Unfortunately, for the civilian medical countermeasures enterprise some will argue that much of industry has already been lost, that the barriers to effective partnership with the Federal Government for developing CBRN medical countermeasures are too high.

But yet, DOD made the public-private development partnership work for stealth bombers. Why can't we do the same for medical countermeasures?

Dr. PARKER. Well, actually in medical countermeasures DOD shares some of the very similar challenges that HHS shares in this arena, and we are both—we are working together to—actually have worked together to much better understand what those challenges are. The collective approaches we are taking now are trying to address those barriers so we can create much more effective partnerships and real-time communication between the Government at all levels, our industry partners, and also to encourage and promote the gleaning together with our industry partners the right looks of what we need from innovation, particularly from small biotechnology companies.

But also we need to leverage and take advantage of some of the experience base of some of the larger pharmaceutical companies that have more demonstrated experience navigating the regulatory pathway, the scale-up manufacturing, and so forth, and trying to calibrate, you know, the exact-like index of Government partners, the experience of folks in industry, and our innovators from biotechnology, including coming in from academia.

The experiences, you know, in Chernobyl and just in the last 5 to 6 years in this area, we have learned a lot, I think, both in Gov-

ernment and both industry about the challenges. Biodefense is a hard area. It really is—does demand a very multidisciplinary approach and an interagency approach. Collectively, I think, with our Government partners and our industry partners I think today we have a much better understanding and we are trying to work on those and reduce those barriers so we can deliver those needed medical countermeasures for our citizens and our troops.

Mr. BILIRAKIS. Thank you, Dr. Parker.

Now I will recognize Ms. Richardson for 5 minutes.

Ms. RICHARDSON. Thank you, Mr. Chairman.

First of all, for Dr. Pillai—I apologize if I pronounced that wrong—several weeks ago this committee had a hearing featuring the head of DHS office of health affairs. Questions remain regarding how OHA fits inside the DHS enterprise. This committee wants to ensure that the roles are clearly defined in order to prevent an overlap and a duplication of efforts.

What role will the science and technology S&T directorate play in the biodefense in DHS and how does that role differ from or overlap with the statutory responsibilities of the chief medical officer who is statutorily required to coordinate the biodefense at DHS?

Dr. PILLAI. Thank you, ma'am for the question. From DHS science and technology perspective we are focused, really, on the R&D aspects. We conduct research and development-related activities as well as threat assessments, risk assessments to support the director as well as the Department as a whole.

The office of health affairs has the responsibility to oversee the—such as Biowatch and—in addition to that, they also serve as the chief medical advisor to the Secretary of DHS in terms of medical countermeasures procurement-related activities as well as our requirements-related activities.

Ms. RICHARDSON. Okay.

Mr. Hatchett, could you describe for me what is the process regarding anthrax vaccine, what is available?

Dr. HATCHETT. Yes, ma'am. Thank you for the question.

We, as you are probably aware, do currently stockpile anthrax vaccine, the AVA, Anthrax Vaccine Adsorbed, in the Strategic National Stockpile. We are supporting, through advanced development contracts, the development of recombinant protective energy vaccines, which are considered to be next-generation vaccines.

We are also supporting——

Ms. RICHARDSON. When you say supporting what do you mean by supporting? Because it is my understanding we have had some problems in that area.

Dr. HATCHETT. We are funding the advanced development of the RPA vaccines. We have funded the procurement of the AVA vaccine for the Strategic National Stockpile.

I would say that the technical challenges have certainly been profound in terms of developing the next-generation vaccine. We have been supporting these vaccines for many years and we continue to support them.

Ms. RICHARDSON. Okay. It is my understanding that—opportunity to—companies, and it is my understanding that we are using a 40-year-old vaccine, other products are potentially avail-

able, that there has been much delay in terms of—well, first of all, confusion in terms of whether a product should be developed in the United Kingdom, whether it should be done here in the United States, and once companies make a commitment and they come here then it is on and on with multiple changes.

So have you had an opportunity or who within your organization has been working on this project?

Dr. HATCHETT. We have an anthrax vaccine group within the CBRN division of BARDA that superintends our contracts in this area. The AVA vaccine has been licensed for some time. I don't know the length of time.

But we are actually working—our colleagues at the National Institutes of Health are currently funding studies to improve and optimize the existing vaccine. We are funding a number of contracts, as I said, to develop the next-generation vaccines. I can't, in this forum, speak to the commercial and proprietary details of the individual contracts but would be happy to get back to you for the record.

Ms. RICHARDSON. So would you be willing to discuss some of the problems that we are having? I might have pronounced it improperly, but I can supply you with the details if you need it.

Dr. HATCHETT. Yes, ma'am. I think you mean——

Ms. RICHARDSON. Yes. Thank you.

Dr. HATCHETT. We are currently working with them. I mean, they are receiving funding from us currently.

Ms. RICHARDSON. But I don't know if you are aware of some of the difficulties that have been brought to this committee's attention.

Dr. HATCHETT. I am aware of them, but this isn't the appropriate forum to discuss them for proprietary reasons.

Ms. RICHARDSON. Okay. But it is the appropriate forum if it is not being done correctly and the American public is at risk because—have been delayed. This is actually the forum. So I am going to suffice to say, do we have a commitment from you that you will meet with them and get an understanding of what the problems are and then give an update to the committee?

Dr. HATCHETT. Yes, ma'am.

Ms. RICHARDSON. Okay. Thank you.

I would also like to acknowledge we have the CEO, Mr. Alan Morris, who is with Anbex Corporation, and they work with potassium iodide. Similarly, as I said, coming from California, it is my understanding some of these companies who actually work with the Government, who supply to the Government, don't seem to have some of the same communication open levels to be able to get us where we need to be.

Because if in the event something happens then it is not probably—we need to make sure it is going to be our responsibility, as a part of being on this committee, that we didn't sit idly by knowing that you are not ready. I am not convinced at this point that we are properly ready.

Dr. HATCHETT. Yes, ma'am. Thank you for the comment.

With respect to potassium iodide and the manufacturers, we have been in frequent contact both with Anbex, with their U.S. distributor—I believe their U.S. distributor, Heyltex, and with Flem-

ing, which is the manufacturer of ThyroShield—to understand the current demand for the products, to understand their production capacity and how long it would take to manufacture additional potassium iodide should there be a requirement for immediate procurement. So we have battled very aggressively to stay on top of those issues.

Ms. RICHARDSON. Will you follow up with them as well?

Dr. HATCHETT. We are in at least weekly touch with them already, but yes, we will continue to do that.

Ms. RICHARDSON. Give a report to the committee?

Dr. HATCHETT. Yes, ma'am.

Ms. RICHARDSON. Thank you.

Mr. BILIRAKIS. Thank you very much.

I believe that we will finish with this panel. I thank you very much for your patience. Thanks for your testimony, and you are dismissed.

We will call up the second panel.

Good afternoon. Thanks for your patience.

I welcome our second panel. Our first witness is Ms. Phyllis Arthur. Ms. Arthur is senior director for vaccines, immunotherapeutics—I am sorry, that is a mouthful—and diagnostics policy at the Biotechnology Industry Organization. In this role Ms. Arthur is responsible for working with member companies on vaccines, molecular diagnostics, and biodefense policy on policy, legislative, and regulatory issues.

Ms. Arthur joined BIO in July 2009. Prior to joining BIO she held numerous positions with Merck. Ms. Arthur received her Bachelor's in economic and international politics from Goucher College and her MBA from the University of Pennsylvania Wharton School of Business.

Our next witness is Mr. John Clerici. Mr. Clerici is a founding principal of Tiber Creek Partners and a partner in the Government contracts practice at McKenna Long & Aldridge, where he assists companies developing biotechnology for emerging disease and engineer threats.

Mr. Clerici was instrumental in the passage of the Public Readiness and Emergency Preparedness Act as well as the creation of BARDA. Mr. Clerici has also served as a judge advocate in the United States Air Force. He received his undergraduate degree from Catholic University and his Juris Doctor from the University of North Carolina at Chapel Hill.

Welcome.

Finally, we will receive testimony from Dr. Daniel Fagbuyi. Dr. Fagbuyi is the medical director of disaster preparedness and emergency management at Children's National Medical Center in Washington, DC. He is an assistant professor of pediatrics and emergency medicine at George Washington University School of Medicine with board certification in pediatrics and pediatric emergency medicine.

Dr. Fagbuyi was recently appointed to the National Biodefense Science Board by Secretary Sebelius. Dr. Fagbuyi served in the United States Army where he served as a battalion surgeon during Operation Iraqi Freedom. Dr. Fagbuyi received his medical degree from George Washington University School of Medicine.

Welcome to all the panelists, and we look forward to your testimony.

Ms. Arthur, you are recognized to testify for 5 minutes. Thank you, and welcome.

STATEMENT OF PHYLLIS ARTHUR, SENIOR DIRECTOR, VACCINES, IMMUNOTHERAPEUTICS, AND DIAGNOSTICS POLICY, BIOTECHNOLOGY INDUSTRY ORGANIZATION

Ms. ARTHUR. Thank you.

Good afternoon, Chairman Bilirakis, Ranking Member Richardson, other Members, and ladies and gentlemen. As you may know, BIO represents more than 1,100 companies, academic institutions, State biotechnology centers and related organizations in all 50 States.

BIO members include a broad mix of small, medium, and large companies involved in medical countermeasures, or MCMs. These companies develop and manufacture products for the detection, diagnosis, treatment, prevention, and delivery of countermeasures in the response to CBRN threats.

Ensuring the availability of MCMs that will save lives during a public health crisis or man-made attack is the responsibility of the U.S. Government. The lack of a viable commercial market for countermeasures necessitates the active engagement of the Government in their development.

Bipartisan Congressional efforts have created and funded an enterprise that has begun to show success, leading to the stockpiling of several new countermeasures in the areas of smallpox and anthrax as well as the awarding of new procurement contracts for other countermeasures. Future investments are pivotal to continue that success and further strengthen and improve our responsiveness.

BIO has identified three core areas that have limited industry's participation in the countermeasures enterprise: First, defining a viable market value for MCMs versus the opportunity cost of investing in a different area; second, management of cost and risk, especially in the regulatory process; and third, sustainability of this market over time.

The Project BioShield Act of 2004 accomplished several important goals, including the creation of a special reserve fund, or SRF. BioShield was designed to guarantee companies that the Government will purchase new successfully developed countermeasures for placing in the Strategic National Stockpile.

Annual appropriations to BARDA and the existence of the SRF define the marketplace for MCMs. Companies can save these funds when comparing the opportunity costs of developing—of pursuing the development of specific countermeasures. Company time and funds spend on developing these products devotes scarce resources away from commercial products and must be subjected to the same rate of return analysis.

In addition, private investors place little value on this type of research as the market is difficult to calculate and a guarantee of product success is not certain. Therefore, there are limited private sector funds.

Part of the opportunity costs assessed by industry is the time required to achieve success. While the industry finds BARDA an effective partner in advanced development, the acquisition and contracting functions to acquire new countermeasures are viewed as lengthy, opaque, and unpredictable.

The development of countermeasures is a unique, resource-intensive, complex process that can impact the opportunity costs. Countermeasures are approved via a convoluted regulatory pathway requiring use of animal models to prove efficacy, which adds an extra dimension of risk and uncertainty.

BIO strongly supports the recommendations to invest significantly in FDA review and regulatory science processes. FDA needs to be given an affirmative role in solving the scientific and regulatory hurdles—of solving the regulatory hurdles of MCMs. BIO recommends that the FDA be strongly encouraged to work collaboratively with company sponsors to design development plans and associated studies, especially those requiring the use of animal models.

Due to the long development timelines for biological products, industry partners need to be able to plan and communicate with their investors. BIO recommends that Congress formally establish a process by which HHS and all its relevant agencies develop an integrated 5-year plan that can be shared with all stakeholders, and specifically industry.

Lastly, it is critical the United States build capability to detect and identify new threats, such as emerging diseases or genetically modified pathogens. To increase speed and accuracy in detecting emerging diseases and threats BIO recommends that efforts be made to extend the surveillance network and invest in new platforms and design tools that can increase efficiency and reduce costs.

The reauthorization of PAHPA and the replenishment of the BioShield SRF are critical to these efforts. Therefore, BIO strongly urges Congress to replenish the SRF simultaneously with the reauthorization of PAHPA. The SRF should be funded at a level that incentivizes private industry to actively participate in the MCM process.

BIO commends the committee for holding this important hearing and stands ready to work with Congress on these important issues. Congress has the opportunity to implement changes to the PHEMCE that will improve preparedness, accelerate approvals, and reduce the cost of developing essential medical countermeasures, and we look forward to working together with you on these efforts.

Thank you.

[The statement of Ms. Arthur follows:]

PREPARED STATEMENT OF PHYLLIS ARTHUR

APRIL 13, 2011

Good morning Chairman Bilirakis, Ranking Member Richardson, Members of the committee, ladies and gentleman. I am Phyllis Arthur, Senior Director for Vaccines, Immunotherapeutics, and Diagnostics Policy at the Biotechnology Industry Organization (BIO). BIO represents more than 1,100 companies, academic institutions, State biotechnology centers and related organizations in all 50 States.

In the area of biodefense, BIO represents a broad mix of small, medium, and large companies involved in the research, development, and manufacturing of medical countermeasures or MCM's. These companies develop and manufacture biological products for the detection, diagnosis, treatment, prevention, and delivery of countermeasures in response to chemical, biological, radiological, and nuclear events.

Ensuring the availability of MCM's that will save lives during a public health crisis (such as pandemic influenza) or weapons of mass destruction attack (such as anthrax) is the responsibility of the U.S. Government. BIO and its members were therefore encouraged when Secretary Sebelius engaged the Department of Health and Human Services (HHS) in an intense review of the Public Health and Emergency Preparedness Enterprise (PHEMCE). BIO actively engaged in this process, participating in stakeholder meetings related to most facets of the Enterprise. Some of the recommendations from industry were incorporated into the final review and still others can be included in the upcoming reauthorization of the Pandemic and All-Hazards Preparedness Act (PAHPA) or other biodefense-related vehicles moving through Congress.

The lack of a viable commercial market for most of these products necessitates the active engagement of the Government in the development of these essential products. Over the last 10 years, bipartisan Congressional efforts have created and funded an Enterprise that has begun to show success. In the past 2 years, several key countermeasures in the area of smallpox and anthrax have been delivered to the Strategic National Stockpile. Furthermore several key procurement contracts have been issued that will lead to the final development of other countermeasures. Future plans and investments are pivotal to continue that success and further strengthen and improve the responsiveness of the United States.

One of the goals of the U.S. Government in conducting the MCM review was to identify and solve those issues limiting companies of all sizes from successfully engaging in the countermeasures process. BIO identified three core issues that have limited industry's participation in PHEMCE. These issues fall into three categories: (1) Defining a viable market value for MCMs versus the opportunity cost of investing in a different area; (2) management of cost and risk, especially in the regulatory process; and (3) sustainability of the market over time.

(1) DEFINING A VIABLE MARKET VALUE FOR MCMS

The Project BioShield Act of 2004 accomplished several important goals, but the most significant part was the creation of the Special Reserve Fund (SRF). BioShield is designed to guarantee companies that the Government will purchase new, successfully developed countermeasures for placement in the Strategic National Stockpile (SNS). Annual appropriations to the Biomedical Advanced Research and Development Authority (BARDA), which was created in 2006 and manages Project Bioshield and PHEMCE, and the existence of the SRF, define the marketplace for MCM's. Companies consider the amount of resources available through BARDA and the SRF when comparing the opportunity cost of pursuing the development of a specific countermeasure. The time, and company funds, spent on these products diverts R&D and manufacturing resources away from commercial products and must be subjected to the same rates of return analysis. In addition, private investors place little to no value on this type of research as the market is difficult to calculate and the guarantee of Government purchase is uncertain. Therefore, there are very limited private sector funds to support companies in the MCM space.

Part of the opportunity cost assessed by industry is the time required to achieve success. While industry, particularly small biotechnology companies, finds BARDA an increasingly desirable and effective partner in advanced development, the acquisition and contracting functions to acquire new countermeasures are viewed as lengthy, opaque, and unpredictable. The trigger to transition a program from advanced development to procurement is unclear. Target dates to complete contract awards are typically not met, some acquisitions are delayed by years or canceled. The negotiation process is needlessly lengthy with technical and security issues resolved prior to pricing discussions. The rationale and potential triggers for contract options are unclear. Lastly, while Federal Acquisition Regulations (FAR § 12.102(f)(1)) states that contracting officers "may treat any acquisition of supplies or services that, as determined by the head of the agency, are to be used to facilitate defense against or recovery from nuclear, biological, chemical, or radiological attack, as an acquisition of commercial items," not a single novel countermeasure has been designated as a commercial item. The signal to industry is that despite the enormous risks of development of novel countermeasures, pricing of new drugs and vaccines developed as countermeasures, is far below that in commercial markets.

(2) MANAGEMENT OF COST AND RISK AND THE REGULATORY PROCESS FOR MCMS

The development of countermeasures is a unique, resource-intensive, and complex process that can be costly and fraught with risk. One of the most significant risks is that countermeasures are approved via a convoluted regulatory pathway. In many respects the regulatory process for MCM's is no different from commercial biologicals. Products can take 8–12 years to develop at a cost of $800 million to $1 billion and failure is common at all stages of development. Yet in other ways MCM development and approval is much more complicated. The required use of animal models to prove efficacy adds an extra dimension of risk and uncertainty to this process.

The coordination and collaboration between the various Government agencies involved in the Enterprise can add to the overall uncertainty surrounding MCM's. The prioritization of threats is not transparent so it is not clear which pathogens, platforms, indications and target populations are the most important. Indeed one Government agency may view these threats in different ways from the others, thus leading to conflicting or overlapping programs with differing priorities. While BARDA and its Department of Defense counterparts have been working more collaboratively to coordinate their requirements, the FDA has not been as involved in the discussion of threats or in the early development of these requirements. The lack of full integration across the Enterprise, especially as it pertains to the approval process for countermeasures, has, in several instances, led to significant delays and new regulatory actions by companies in order to achieve licensure for a product.

One of the most significant recommendations from the PHEMCE review was the recommendation to invest significantly in the FDA review and regulatory science processes. This is a recommendation that is strongly supported by BIO and its members. The FDA has tremendous expertise in the science of drug development and the manufacturing of complex drugs, diagnostics, and biologics. Effectively integrating FDA into the MCM development efforts will ensure that the Government can have more rapid access to fully licensed medicines, devices, and diagnostics for National security threats in a cost-effective manner.

To meet this goal FDA needs to be given an affirmative role in solving the scientific and regulatory hurdles, not just the review and approval, of MCM's. This can best be accomplished by encouraging the FDA to work collaboratively with company sponsors to design development plans and associated studies, especially those requiring use of animal models. The current structure and resources provide a disincentive for FDA to spend time on these complex issues in partnership with industry. Additionally, FDA funding targeted to improving MCM efforts should be linked to measurable metrics.

BIO recommends that the FDA become more involved in the development of MCM's through a combination of planning and coordination activities and implementation of specific measurements for MCM initiatives.

(3) SUSTAINABILITY OF THE MCM MARKET

The Project BioShield Act and PAHPA helped to build processes to advance clinical and manufacturing infrastructure to protect against a multitude of biological threats. While there have been successes in several strategic portfolios within HHS, currently the United States is decades away from having an adequate arsenal of countermeasures to safeguard our citizens. In addition to developing and stockpiling countermeasures against currently anticipated threats, it is critical that the United States builds capability to respond to new threats such as newly emerging diseases and genetically-modified pathogens.

The reauthorization of PAHPA and the replenishment of the BioShield SRF are critical to these efforts. Therefore BIO strongly urges Congress to replenish the Special Reserve Fund simultaneously with the reauthorization of PAHPA. The SRF should be funded at a level that incentivizes private industry to actively participate in the MCM process.

The PHEMCE review highlighted the importance of a 5-year plan for the Enterprise with goals tied to measurable outputs and outcomes. Due to the long development timelines for biological products, industry partners need to be able to plan and communicate with their investors on the anticipated value and impact of its MCM projects with some increased level of certainty. BIO recommends that Congress formally establish a process by which HHS and its relevant agencies (NIH, CDC, FDA, and ASPR) develop an integrated 5-year plan that can be shared with all stakeholders. A systematic, transparent vision from the U.S. Government will help companies assess the viability of both their existing and future countermeasures' pro-

grams. This multi-year strategic plan, coupled with modifications to the contracting processes, could encourage increased industry participation.

Lastly, one of the most critical parts of responsiveness involves the Nation's ability to detect and identify these threats to best mount the proper and timely response. BIO members are also concerned that the U.S. Government make the right investments in global and U.S. surveillance testing and reporting networks. Efforts should be made to extend the network and invest and explore common platforms and design tools that can increase efficiency and reduce costs. Improving interagency coordination within the U.S. National network, while striving to modernize its technical and technological capabilities, would increase speed and accuracy in detecting emerging diseases and threats.

BIO commends the committee for holding this important hearing and stands ready to work with Congress on these important issues. Ensuring the availability of MCMs is a critical responsibility of the U.S. Government. The lack of viable commercial markets for these products necessitates the active engagement of Government in supporting the development of these essential products. Over the last 10 years, bipartisan Congressional efforts have created and funded a public health emergency medical countermeasure enterprise (PHEMCE) that has begun to show success. Future plans and investments are essential to this effort.

Congress has the opportunity to implement changes to the PHEMCE that will improve preparedness, accelerate approvals and reduce the cost of developing essential medical countermeasures, including medical devices, and we look forward to working together with you in these efforts.

Mr. BILIRAKIS. Thank you, Ms. Arthur. Appreciate it.

Mr. Clerici, you are recognized for 5 minutes.

STATEMENT OF JOHN M. CLERICI, PRINCIPAL, TIBER CREEK PARTNERS, LLC

Mr. CLERICI. Thank you.

Good afternoon Mr. Chairman and Congresswoman Richardson. For the last decade my colleagues and I have had the opportunity to work with dozens of companies pursuing medical countermeasures targeting CBRN and emerging infectious disease. From this vantage point I have personally seen both the good and the bad of the process and am delighted to share those observations with you today.

As the subcommittee is aware, in the last decade Congress has passed several pieces of legislation to address public health preparedness, including the PAHPA legislation. In addition, Congress has provided billions in appropriation.

The PAHPA legislation created BARDA, and it has achieved its goals of providing BARDA with the toolbox it needs to do its job. PAHPA should be reauthorized this year by Congress without need for significant modification.

However, the toolbox provided to BARDA through PAHPA has been locked away while the organization is subjected to persistent internal and external reviews as well as constant shifts in strategic direction. Following what was generally viewed by the informed public health community as a very successful response to the 2009 influenza pandemic, BARDA underwent no less than three internal and external reviews during the course of 2010 to analyze its effectiveness. These reviews resulted in near standstill activity for almost a year and culminated in yet another shift of priorities for the organization.

The solution here is simple. There must be a clear statement of priorities, including the allocation of resources and funding, with a realistic and achievable schedule for implementation that will actu-

ally be followed without delay. This does not require legislative change or even a future appropriation.

Turning to my second observation, there have been several recent examples where a public health emergency has presented a situation that allows public health officials to retrospectively and proactively examine what could be done better or learned from the event. I am concerned that several of these situations have passed without proactive action. Let me offer an example to make this point.

In March 2009 there was a widely reported incident in San Diego where a young Marine developed progressive vaccinia, a disease that closely resembles smallpox, after he received a smallpox vaccination. There was a tremendous response by military doctors, the CDC, and the FDA to respond to this incident. However, curiously, neither ASPR nor its parent organization ASPR—pardon me, neither BARDA nor its parent organization, ASPR, was part of this response.

There were multiple products used to treat this patient, including products currently in the Strategic National Stockpile, as well as experimental products in late-stage development for a smallpox incident. The lessons learned from this case are extremely valuable for understanding what a mass casualty event involving smallpox would look like and determining effective therapeutics.

Based on my understanding, there has been no affirmative outreach by either BARDA or ASPR to debrief the industry responders to understand what they learned about this incident. To the opposite, when BARDA was asked during the course of an active procurement by a prospective offerer to affirmatively consider the experience of human use of these products in evaluating which products were most appropriate for stockpile that request was declined.

My strong belief is this failure to be proactive is not a result of inaction or lack of forethought by the BARDA leadership. Rather, the likely cause is unnecessary interference with the BARDA leadership and program managers by the contracting officers based upon perceived restrictions of Federal acquisition regulations.

I emphasize the word perceived given that there is absolutely nothing that prevents these interactions from taking place. Yet, it has been my experience that communications from the BARDA leadership have been unnecessarily constrained by contracting officers to the significant detriment of BARDA's mission.

My final observation is the need to be a greater focus on the sustainability of the overall public health enterprise. Reauthorization of Project BioShield and replenishment of the SRF is a key component in this sustainability. I strongly encourage Congress to do both in conjunction with the reauthorization of PAHPA.

To ensure sustainability the first order of business must be to make sure that the products currently in the SNS are maintained at their current level. For products such as the licensed anthrax vaccine or smallpox vaccines that means ensuring CDC has both the funding and the processes it needs to ensure the levels of nonexpired vaccine in the stockpile at a very minimum are maintained.

The CDC must also stockpile adequate levels of countermeasures to match the material threat assessments conducted by the Department of Homeland Security. For products that have yet to achieve

FDA approval, including the anthrax therapeutics and next-generation smallpox vaccines, that also means that BARDA must expeditiously exercise the options in those contracts to retain the supply of unexpired products at the level currently in the stockpile. This will also ensure the substantial investment BARDA has made in the manufacturing capacity to support these products is not lost.

Next, the medical countermeasures review correctly placed significant importance upon the need to procure broad spectrum, dual-use products—that is, products that both have a CBRN and commercial use. Once approved by the FDA for commercial indication, the cost to the Government to sustain these products for CBRN use is far lower than the need to re-procure and stockpile products that are usable only for a public health emergency.

Although the benefits of dual-use technologies are clear, it appears that products that lack this dual-use potential are still being favored for procurement under Project BioShield, although BARDA has funded these programs in advanced development. This lack of consistency with the clear mandate of medical countermeasure review is puzzling.

Given the clear investment in creating and staffing the organization, BARDA should also have a clear role in the response to non-biodefense public threats, such as the rise of multi-drug resistant pathogens, the super bugs that are killing far more people at every—far more people every year than 9/11 and even HIV. Emerging tropical diseases like dengue and global health diseases such as tuberculosis are impacting the United States, with a growing number of cases of dengue and TB in Florida, Hawaii, and elsewhere. BARDA should play a significant role in addressing these emerging diseases.

This is one area where I believe Congress should affirmatively act to modify PAHPA legislation to explicitly give BARDA the mandate to address drug resistance as well as emerging infectious disease. This may require additional appropriations to support this expanded mission, but it is an area that needs to be addressed and BARDA is likely suited for—is ideally suited for this mission.

In closing, I would like to go back to the discussion about Japan. If we look towards Japan, the lack of proactive decisions to inventory what drugs are currently available to respond to a nuclear emergency, of not ensuring that well-conceived protocols are written in advance of these emergencies, and the failing to hear the wake-up call the events of the last month to prepare America for a nuclear incident could be devastating, as Congressman Richardson already pointed out.

The decision made here—made today, or better yet, the decisions that are not being made today, will almost certainly result in leaving our homeland vulnerable.

I thank you, Mr. Chairman and Congresswoman Richardson, for doing everything you can to protect our homeland. Thank you.

[The statement of Mr. Clerici follows:]

PREPARED STATEMENT OF JOHN M. CLERICI

APRIL 13, 2011

Good afternoon Mr. Chairman, Congresswoman Richardson, and Members of the subcommittee. My name is John Clerici and I am a principal of Tiber Creek Part-

ners, a firm dedicated to assisting biotechnology companies throughout the world to ensure the development of the very best products that will have a positive impact upon public health and emerging infectious disease. For the last decade, my colleagues and I have had the opportunity to work with dozens of companies pursuing medical countermeasures targeting chemical, biological, radiological, and nuclear (CBRN) threats, many of which now sit in the U.S. Strategic National Stockpile and a number of which were deployed for use during the 2009 influenza pandemic. We have been involved in nearly every effort by the U.S. Government to support and purchase these products over the last 12 years, including working with many of your colleagues in Congress to support legislation to protect the American people from a variety of public health threats. From this vantage point, I personally have seen both the good and the bad of this process and I am delighted to share those observations with you in the hope that we can build upon the successes and learn from the challenges over the last decade with the mutual goal of ensuring our Nation is as prepared as possible.

I have three main observations that I would like to share with the subcommittee this afternoon regarding the current efforts by what collectively is known as the "Public Health Emergency Medical Countermeasures Enterprise" in identifying and procuring medical countermeasures to address bioterrorism, nuclear preparedness, and emerging infectious disease.

First, the current laws passed during the last decade have proved generally satisfactory to provide the relevant public health officials with the legal authorities, funding and structure necessary to carry out their mission. However, the implementation of these laws has been unnecessarily burdened by constant internal and external reviews, delayed action, bureaucracy, and a lack of transparency. This has had a devastating effect upon the willingness of the private sector to participate in these programs. Second, there have been several recent instances, to include the ongoing crisis in Japan, where there has appeared to be a lack of proactive efforts to look toward an incident as a reminder that we need to bolster the knowledge base and understanding of what a mass casualty event in the United States would look like, and additionally demonstrates our need to more fully understand how medical countermeasures would be used, what resources are needed that are not currently available, and how best to reach those in need. I am concerned we are not being proactive to learn the proper lessons from these events. Last, there is a similar lack of proactive planning to address the sustainability of the medical countermeasures that have already been developed and purchased to maximize the value of the investments already made, as well to take full advantage of the benefits of sustainable, dual-use, broad-spectrum technologies.

With your permission, I would like discuss each of these observations in greater detail and offer some thoughts on proposed solutions that I believe are easily achievable in the short term.

As the subcommittee is aware, in the last decade, Congress has passed several key pieces of legislation to address public health preparedness, including the Bioterrorism Act of 2002, the Project BioShield Act of 2004, the PREP Act of 2005, and the Pandemic and All Hazards Preparedness Act of 2006 (known as PAHPA). In addition, Congress has provided billions in appropriations to support these programs. The PAHPA legislation, which created the Biomedical Advanced Research and Development Authority (BARDA), was meant to fill in the gaps in Project BioShield to help companies through the "valley of death" between advanced development and FDA approval, as well as streamline the procurement process. This bipartisan legislation, which earned the unanimous support of the House and Senate, was carefully crafted to provide the Executive branch all the authorities needed to carry out this important public health mission. I do not think it can be disputed that PAHPA achieved its goal of providing BARDA with the toolbox it needs to do its job. Thus PAHPA should be reauthorized by Congress this year without the need for significant modification.

However, what was not anticipated by Congress in passing PAHPA, and what requires immediate attention, is the reality that the toolbox Congress provided to BARDA has been locked away while the organization is subjected to persistent internal and external reviews, as well as constant shifts in strategic direction, that have left industry confused and disheartened. Following what was generally viewed by the informed public health community as a very successful response to the 2009 influenza pandemic, BARDA underwent no less than three internal and external reviews during the course of 2010 to analyze its effectiveness. These reviews resulted in a near stand-still of activity for almost a year and culminated in yet another shift in priorities for the organization. This included a transfer in critical human and financial resources away from implementing the Draft Strategic Plan announced in 2007, and toward implementation of the August 2010 "Public Health Emergency

Medical Countermeasures Enterprise Review." Although the Medical Countermeasures Review provides broad suggestions, it does not provide the necessary transparency to industry regarding what products are required, in what quantities, and paid for with what budgets, all of which had been outlined in the 2007 Draft Strategic Plan. This information is absolutely critical in order for industry to devote its scarce resources to the public health preparedness sector.

This is not to say that all of the recommendations of the MCM review are flawed or that reviews are unwarranted. However, this constant shift in priorities and funding, along with delays, has presented considerable uncertainty that has directly impacted the ability of companies to participate in medical countermeasure initiatives. This lack of transparency is an enormous barrier to long-term private sector interest in working the U.S. Government on medical countermeasures.

Moreover, the continued delays in both issuing requests for proposal and awarding contracts have placed tremendous pressure upon industry to justify its continued participation in the U.S.-funded public health efforts. As you can imagine, in these financial times, when the management of a biotech, no matter the size, cannot tell its investors when an opportunity is coming and how much the opportunity will be potentially worth to the company, the resources dedicated in pursuit of that effort will be cut, plain and simple. The solution to this problem is not to make the function into a Government-run entity, as some have suggested, but rather to adjust the Government's performance to maximize private sector participation as envisioned by Project BioShield.

To exemplify this point, consider that there are currently four FDA-approved products that have the immediate potential to benefit victims of a nuclear incident—regardless of whether it was caused by nature, as in what has happened in Japan, or detonation of a improvised nuclear device, an event the co-chairs of the 9/11 Commission described as "certain" to occur in their lifetime. Three of these products are made by the two of the largest of biotechnology companies in the world and have not only been on the market for over 10 years, but have been used in nuclear accidents in the past. The BARDA leadership is well aware of these products and is eager to see procurement of these products move forward. Yet after over 2 years of discussions, no Requests for Proposal have been issued to allow the Government to acquire these products, even though the funding is currently available in the Special Reserve Fund under Project BioShield to do so.

I am aware that at least two of these companies are under extreme pressure from their management to justify any continued efforts in pursuing these projects due to these delays. One of those companies feeling this pressure is a small, yet well-funded, biotech, whose investors view efforts to try to assist BARDA as an unwarranted distraction, even though this company has an FDA-approved product that would have an immediate benefit to victims of a terrorist attack, as well as a natural disaster. Small biotechs are exactly the innovative engines the Government needs to address these public health problems. If these companies ultimately have to walk away due to these unwarranted delays, there is no question it will cost lives in the future.

The solution here is simple. There must be a clear statement of priorities, including allocation of resources and funding, with a realistic and achievable schedule for implementation that will actually be followed without delay. This does not require legislative change or even future appropriations. But it is absolutely critical in order for industry's participation in public health preparedness efforts to continue.

Turning to my second observation, there are several recent examples where a public health emergency has presented a situation that allows public officials to not only assess the ability of the United States to respond in a "live fire" exercise, but also to retrospectively, and proactively, examine what could be done better or could be learned from the event. I'm concerned that several of these situations have passed without proactive action to learn from the event. Let me offer three, specific examples to make this point.

The subcommittee is well aware of the growing challenges facing Japan as well as the flurry of discussions these incidents have sparked regarding the state of U.S. preparedness for all three aspects—the earthquake, the tsunami, and the nuclear emergency—of the disaster. There are medical countermeasures currently available as well as products under development in the United States, many of which are funded by BARDA and DOD, which could play an important role in one or more the elements of the response in Japan.

It is completely understandable that the United States cannot and should not act without being requested to do so by the Japanese government. It is equally understandable that BARDA cannot and should not be placed in the position of supporting the use of a non-FDA approved product outside of the authority provided by Project BioShield. However, it seems that it would be appropriate for BARDA

to proactively reach out to its industry partners to: (1) Determine what products, if any, are currently available should they be requested by Japan and in what quantities and location; and (2) should these products be requested for use in Japan, what type of protocols, including Phase 4 and Emergency Use protocols, need to be in place to ensure the products are used as safely and effectively as possible. Having this information in hand today is key to being able to respond immediately if a request for assistance is received from Japan (or any other country facing a nuclear incident), rather than having to delay the response while this information is collected in a reactionary fashion. None of these actions require a request by Japan from assistance, nor do they require legislative action or additional funding. Yet, based upon discussions with several of the relevant companies, this proactive outreach has not occurred.

In a similar vein, the subcommittee may be aware that there have been several recent incidents of anthrax infection in heroin users in Scotland. The U.K. public health officials have faced unique challenges with these patients and have gained considerable insights into how different therapeutics have contributed to and failed to contribute to the survival of these patients. I personally met with the lead U.K. officials handling this response in September of last year and, as you would imagine, they had a wealth of unique and valuable information regarding the course of the disease in these patients. I understand this information has been shared by the United Kingdom with their U.S. counterparts. But yet again, based upon, my discussions with industry and the U.K officials, there has yet to be a proactive effort by U.S. officials to share the information and data gleaned from these incidents with the companies developing anthrax treatments, nor has it been shared with researchers who are working to understand disease pathogenesis.

Finally, in March 2009, there was a widely reported incident in San Diego where a young Marine developed Progressive Vaccinia, a virus that closely resembles smallpox, after having received a smallpox vaccination. There was a tremendous response by military doctors, the Centers for Disease Control and Prevention, and the FDA to respond to this incident. There were multiple products used to treat this patient, including products currently in the Strategic National Stockpile as well as experimental products in late stage development for use in a smallpox incident. The lessons learned from this case are extremely valuable for understanding what a mass casualty event involving smallpox would look like, and for determining effective deployment of therapeutics. But yet again, based upon my understanding, there has been no affirmative outreach by BARDA or DOD to debrief the industry responders to understand what they learned from this incident. To the opposite, when BARDA was asked during the course of an active procurement by a prospective offeror to affirmatively consider the experience of the human use of these products in evaluating which products were most appropriate for stockpile, the request was declined.

These examples demonstrate a frustrating pattern where opportunities to learn are being lost and relevant information is not being even accumulated, much less considered. At the same time, companies that are being asked to propose to various procurement opportunities must develop a "Target Product Profile," not only as part of their proposal, but more importantly, to guide the interactions with FDA. However, it is impossible to develop a TPP in the absence of an accurate understanding for how the product will be used in a public health emergency. This understanding can only be gained through a meaningful dialogue between industry and Government—incidents such as those I've outlined present a very unique situation for such a dialogue that is being utterly missed.

My strong belief is this failure to be proactive is not a result of inaction or lack of forethought by the leadership at BARDA. Rather, the likely cause is an unnecessary and non-productive interference with the ability of the BARDA leadership and program managers to communicate with industry by the perceived restrictions of the Federal Acquisition Regulations (FAR). I emphasize the word "perceived" given that based on the clear language of the FAR and my over 16 years of experience in Government contracts law (both inside and outside the Government) there is absolutely nothing the prevents such interactions from taking place. To the contrary, as was recently made clear in a memorandum issued by Dan Gordon, President Obama's head of the Office of Federal Procurement Policy, transparent interactions with industry are an essential part of the procurement system and should not be inappropriately constrained by agency contracting officers. Despite this clear guidance from the top procurement officials in the administration, it has been my experience that communications from the BARDA leadership and program managers has been unnecessarily constrained by the contracting officials to the significant detriment of BARDA's mission.

In the past, the procurement function and the contracting officers themselves were part of BARDA, and thus, the BARDA Director had greater influence to ensure both transparent communication as well as proper allocation of priorities by the contracting officers supporting the procurement process for medical countermeasures. Just over a year ago, this function was moved outside of the direct supervision of the BARDA Director, as was the requirement setting process. Since this has occurred, there has been a marked decline in the speed and efficiency of the contracting process. Reverting back to the prior organization, where the BARDA Director has responsibility and accountability for the contracting officers and requirements process supporting BARDA, would be a welcome change that would not require any change in legislation or additional costs to implement. Further, increased Congressional oversight to encourage greater proactive response from the Public Health Enterprise, as a whole, would most certainly be a benefit.

The final observation I'd like to discuss today is the need for there to be greater focus on the sustainability of the overall Public Health Enterprise to ensure the investments made by BARDA are maximized. Reauthorization of Project BioShield and the replenishment of the soon-to-be exhausted Special Reserve Fund is a key component of sustainability. I strongly encourage Congress to do both in conjunction with the reauthorization of PAHPA. That said, even without any legislative action or additional funding, it is incumbent upon the Public Health Enterprise to make the best use possible of the remaining balance of BioShield funding and other resources to ensure sustainability.

The first order of business must to be to ensure that the products currently in the SNS are maintained at their current level. For products such as the licensed anthrax and smallpox vaccines, that means ensuring the CDC has both the funding and processes it needs to ensure the levels of non-expired vaccine in the stockpile, at a very minimum, are maintained. However, it should be a top priority that we stockpile levels of countermeasures to match the Material Threat Assessments conducted by the Department of Homeland Security in order to protect the civilian population, our first responders, and our military men and women should an event occur. For example, we currently fall far short of having adequate stockpiles of licensed anthrax vaccine to meet the stated 75 million dose requirement set by the Material Threat Assessment. Addressing this should be a priority.

For products that have yet to achieve FDA approval, including anthrax therapeutics and next-generation smallpox vaccines being procured under Project BioShield, that also means BARDA must exercise the options in those contracts to retain the supply of unexpired products at the levels currently in the stockpile, as well as to ensure that the substantial investment BARDA has made in the manufacturing capacity to support those products is not lost. Given that BARDA has recently undertaken an effort to create multiple "Centers of Innovation for Advanced Development and Manufacturing" to supplement the Nation's manufacturing capacity, an effort that is expected to take decades and cost billions to achieve, it seems the first, near-term step in maintaining a viable manufacturing capacity for medical countermeasures must begin with ensuring the investments made in the current capacity are not lost.

Next, the Medical Countermeasures Review correctly placed significant importance upon the need to procure broad spectrum, dual-use products—that is, products that have both a CBRN and commercial use. These products will be, by definition, more likely to achieve FDA approval given that the human data derived to support the commercial indication will supplement the animal data needed for approval under the Animal Efficacy Rule for the CBRN indication. Once approved by FDA for a commercial indication, the cost to the Government to sustain these products for CBRN use is also far lower than the need to re-procure and stockpile products that are only usable in the event of a public health emergency. Although the benefits of dual-use technologies are clear, and are articulated in the 2010 Medical Countermeasures Review, it appears that products that lack this dual-use potential are still being favored for procurement under Project BioShield. This lack of consistency with the clear mandate of Medical Countermeasures Review is puzzling to say the least.

Given the investment in creating and staffing the organization, BARDA should also have a clear role in the response to non-biodefense threats to public health such as the rise of multi-drug resistant pathogens—the "super bugs" that are killing far more people every year than the losses we suffered on 9/11. Emerging tropical diseases like dengue and global health diseases such as tuberculosis are also impacting the United States, with a growing number of cases of dengue and TB in Florida, Hawaii, and elsewhere. BARDA should play a significant role addressing these diseases. The investment in the infrastructure to create and support BARDA, as well as the obvious benefits and synergies of expanding the mission to include emerging

infectious disease, make clear this is a worthy focus for BARDA. This is the one area where I believe Congress should affirmatively act to modify the PAHPA legislation to explicitly give BARDA the mandate to address drug resistance—both bacterial and viral—as well as emerging infectious disease as a whole. This may require additional appropriations to support this expanded mission, but it is an area that needs to be addressed and BARDA is ideally suited to take on this mission.

In closing, I would like to return to both the 2009 influenza pandemic as well as the events in Japan.

On the morning of September 11, 2001, a trusted advisor to the Secretary of HHS had a meeting scheduled with the Secretary to raise the issue of the emergence of the H5N1 virus in Asia and how the United States should prepare for an influenza pandemic like the one that devastated the world in 1918 as described in John Barry's book "The Great Influenza." That meeting never occurred that day for obvious reasons, however, it was eventually rescheduled. HHS went on to make critical investments to secure the egg supply for flu vaccines, to bolster the U.S. vaccine base, stockpile millions of doses of flu antivirals, as well as diagnostics, and to support the passage of legislation to address liability issues that up-to-then had restrained our ability to prepare. That trusted advisor became the first Assistant Secretary for Preparedness, where, as the precursor to what is now BARDA, he made critical decisions regarding influenza vaccines and therapeutics, anthrax vaccine and therapeutics, smallpox vaccines, and radiation countermeasures. These decisions were implemented by a skeleton staff made up mostly of detailees from other parts of HHS and retired public health leaders who offered their time in order to help protect the Nation. The procurements were managed by a single contracting officer at the CDC, for which this was an extra duty. About half of those decisions, in retrospect, ultimately did not result in outcomes that immediately protected the homeland. However, about half of them did. The Assistant Secretary withstood enormous criticism for the decisions that did not appear to be immediately beneficial, and got little credit for the decisions that proved right, including those critical decisions that helped prepare the Nation for the 2009 pandemic. Mr. Chairman, as the baseball teams that have Spring Training in your district are aware, a .500 batting average is something to be proud off. The bottom line is decisions were made then that clearly protected the United States. Yet, today, decision-making is ground to a halt by concerns about the perception that could result from a failure and overly bureaucratic procedures while the security of our homeland suffers.

If we look toward to Japan, the lack of proactive decisions to inventory what drugs are currently available to respond to a nuclear emergency, of not ensuring that well-conceived protocols are written in advance to ensure their appropriate deployment if these products are ever used, and of failing to hear the wakeup call the events of the last month signal for the need to prepare in America could prove devastating. The decisions made to today—or better put, the decisions that are not being made today—will almost certainly result in leaving our Homeland vulnerable. I thank you Mr. Chairman and this committee for doing everything you can to ensure that our homeland remains secure.

Mr. BILIRAKIS. Thank you, sir.

I now recognize Dr. Fagbuyi for 5 minutes.

Welcome, sir. Thank you.

STATEMENT OF DANIEL B. FAGBUYI, MEDICAL DIRECTOR, DISASTER PREPAREDNESS AND EMERGENCY MANAGEMENT, CHILDREN'S NATIONAL MEDICAL CENTER

Dr. FAGBUYI. Good afternoon, Chairman Bilirakis and Ranking Member Richardson. Thank you for holding today's hearing on such an important topic, medical countermeasures.

My name is Dan Fagbuyi. I am representing the Academy of Pediatrics, a nonprofit professional organization of more than 60,000 primary care pediatricians, pediatric medical subspecialists, and pediatric subspecialists dedicated to the health, safety, and well-being of children of all races.

I serve as the Academy Disaster Preparedness Advisory Council member, and you have heard the saying that children are not little adults. Why does this matter when it comes to medical countermeasures and disaster preparedness? Well, children are particu-

larly vulnerable to aerosolized biological or chemical agents because they breathe more times per minute than do adults, meaning that they would be exposed to a larger dose of an aerosolized substance.

Children are also more vulnerable to agents that act on or are absorbed through the skin because their skin is thinner and they have much larger skin-to-body surface ratio than adults. They have immature immune systems which put them at risk for CBRN-type agents and are more vulnerable to radiological agents due to their more rapid metabolic and cellular growth rates.

So consider this: When children are critically ill or injured their bodies respond differently than adults to similar insults. Consequently, pediatric treatment needs are unique in a number of ways, and I will start with children actually need different doses and different formulizations of medicines than adults because certain drugs and biologic agents have certain safety and efficacy profiles that are different in developing children.

Children also need different-sized equipment and other medical devices than adults. In fact, our day-to-day emergency readiness requires the presence of many different sizes of key resuscitation equipment in infants—for infants, for preschool children, school-aged children, and adolescents. From needles and tubing to oxygen and ventilator masks, all these are different in children. Children also display unique developmental and psychological responses to acute injury and illness, and also, as well, to mass casualty events, and are at greater risk for post-traumatic stress disorder and acute-traumatic stress disorder.

While we have a lot of work ahead of us to adequately plan and prepare for children in disastrous situations there are several programs that have really moved the needle, one of which is emergency medical services for children, EMSC, which has played a crucial role in driving a significant amount of improvement in pediatric emergency care, including disaster preparedness.

Despite a modest appropriation of slightly more than $20 million for EMSC, EMSC has managed to affect changes by providing pediatric emergency care initiatives in every State, territory, and the District of Columbia, as well as National improvement programs and protocols that will be critical in an event of National emergency.

In the area of medical therapeutics there are two laws—the BPCA, Best Pharmaceuticals for Children Act, and PREA—have incentivized and required drugs to be studied in children. These studies have identified safety issues, altered dosing, have led to new indications and have shown some drugs even lack efficacy in children. Nearly 400 drugs have been labeled for children as a result.

When it comes to medical countermeasures, progress has been made to improve the availability of pediatric countermeasures but much more work needs to be done. Most recently, pediatric labeling was added to pralidoxime for the treatment of nerve agent poisoning. However, labeling took 7 years, during which time no new data was presented.

It is hard to understand why that took so long. Pediatric labeling was the first step. HHS and BARDA need to support the manufac-

ture and purchase of child-specific auto-injector so that pralidoxime can be forward deployed and administered in the field.

In the event of a radioactive release such as what we experienced in—was experienced in Japan, children should be administered potassium iodide, as our Ranking Member had mentioned, as quickly as possible, and to be appropriate in dosage and treatment to prevent the long-term consequences. The big question, if a liquid formulation of potassium iodide exists and is safe and effective but if the Federal Government and State governments do not purchase this to be stockpiled in the Strategic National Stockpile in the event of a radiation exposure and in sufficient quantities to treat our Nation's children, how secure are we really?

In other policy recommendations, the Academy of Pediatrics has specific recommendations for policymakers, and there are many that I listed in my written testimony but I will just highlight one. The medical countermeasure enterprise led by the Federal Government should set a goal to achieve parity between adult and child medical countermeasures developed and included in the Strategic National Stockpile and other Federally funded caches.

This includes amending the PAHPA Act to require that the HHS Secretary, acting through BARDA, prioritize children. Children should be distinguished as a separate population from the broader at-risk category currently at the Health and Human Services.

These also preposition medical countermeasures as a crucial piece and it needs to be in locations where children gather, such as schools and in child care facilities. They must not be an afterthought.

In conclusion, the Academy of Pediatrics thanks this committee for the opportunity to testify on this important issue of medical countermeasures. Children are our future.

Finally, I want to give you a recent poll which was conducted at the Academy of Pediatrics and the Children's Health Fund: 76 percent of Americans agree that if resources are limited children should be given a higher priority for lifesaving treatments; 75 percent believe that if tough decisions must be made lifesaving treatments should be provided to children rather than adults with the same medical condition; and 92 percent agree that if there were a terrorist attack our country should have the same medical treatments readily available for children as are now available for adults.

When disaster strikes, we as a Nation must be prepared with the medical countermeasures to keep our children healthy and ensure that we have and they have an opportunity to achieve optimal health outcomes. As a pediatrician and a father of three, I look forward to your questions. Thank you.

[The statement of Dr. Fagbuyi follows:]

PREPARED STATEMENT OF DANIEL B. FAGBUYI

APRIL 13, 2011

Chairman Bilirakis and Ranking Member Richardson, thank you for holding today's hearing on such an important topic, medical countermeasures. My name is Dan Fagbuyi, MD FAAP, and I am representing the American Academy of Pediatrics, a non-profit professional organization of more than 60,000 primary care pediatricians, pediatric medical sub-specialists, and pediatric surgical specialists dedicated to the health, safety, and well-being of infants, children, adolescents, and young adults. For more than a decade, the Academy has engaged in a broad range

of activities related to disaster preparedness, including policy statements on clinical care and tools for pediatricians in crisis situations.

I am currently the Medical Director of Disaster Preparedness and Emergency Management at Children's National Medical Center in Washington, DC. I am an Assistant Professor of Pediatrics and Emergency Medicine at The George Washington University School of Medicine with board certification in both Pediatrics and Pediatric Emergency Medicine. I have the distinct honor of recently being appointed by the U.S. Secretary of Health and Human Services, Kathleen Sebelius, to serve on the National Biodefense Science Board. As a Major in U.S. Army, I was involved in combat and civil military operations, serving as a battalion surgeon on the front lines and caring for more than 800 soldiers while deployed for Operation Iraqi Freedom with the U.S. Army's 101st Airborne Division.

Recent events in Japan make today's hearing especially timely and critical. The Academy strongly supports the Federal Government's response to the Japanese government and its people. We have been in touch with our pediatrician colleagues through the Japan Pediatric Society to offer the Academy's assistance and, as of today, we have raised $51,519 in gifts and pledges for Disaster Relief for Japan through the AAP Friends of Children Disaster Relief Fund.

The recovery and relief efforts in Japan will take time and for countless families, especially those who lost loved ones, life will never be the same. Recovery for the most vulnerable citizens, children, may present several unique challenges and it is important that we as Americans look within our own borders to assess whether our planning and exercises our Government and communities engage in, our medical capabilities, the training of our first responders, and the preparedness of our Nation's hospitals, Federal, State, and local governments, and families, adequately account for the needs of children should a disaster strike.

Unfortunately, today, the reality is that none of those systems are fully prepared to address the needs of nearly 25 percent of the population, children. We need to work to change this realty.

CHILDREN ARE MORE VULNERABLE THAN ADULTS

You've heard the saying that children are not little adults. Why is that and, more importantly, why does that matter when it comes to medical countermeasures and disaster preparedness?

- Children are particularly vulnerable to aerosolized biological or chemical agents because they normally breathe more times per minute than do adults, meaning they would be exposed to larger doses of an aerosolized substance in the same period of time. Also, because such agents (e.g. sarin and chlorine) are heavier than air, they accumulate close to the ground—right in the breathing zone of children.
- Children are also much more vulnerable to agents that act on or are absorbed through the skin because their skin is thinner and they have a much larger skin surface-to-body mass ratio than adults.
- Children are more vulnerable to the effects of agents that produce vomiting or diarrhea because they have smaller body fluid reserves than adults, increasing the risk of rapid progression to dehydration or shock.[1]
- Children have much smaller circulating blood volumes than adults, so without timely intervention, relatively small amounts of blood loss can quickly tip the physiological scale from reversible shock to profound, irreversible shock or death. An infant or small child can literally bleed to death from a large scalp laceration.
- Children have significant developmental vulnerabilities not shared by adults. Infants, toddlers, and young children may not have the motor skills to escape from the site of a hazard or disaster. Even if they are able to walk, young children may not have the cognitive ability to know when to flee from danger, or when to follow directions from strangers such as in an evacuation, or to cooperate with decontamination.[2] As we all learned from Katrina, children are also notably vulnerable when they are separated from their parents or guardians.
- Children have immature immune systems that make them more susceptible to biological, chemical, radiological agents.

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[1] Committee on Environmental Health and Committee on Infectious Disease. Chemical-Biological Terrorism and Its Impact on Children: A Subject Review. *Pediatrics,* Vol. 105 No. 3 March 2000. (update scheduled for publication in Pediatrics September 2006.)

[2] American Academy of Pediatrics. Children, Terrorism & Disasters Toolkit. The Youngest Victims: Disaster Preparedness to Meet Children's Needs. *http://www.aap.org/terrorism/topics/PhysiciansSheet.pdf*

- Children are also more vulnerable to radiological agents due to their more rapid metabolic and cellular growth rates.

CHILDREN HAVE UNIQUE TREATMENT NEEDS

When children are critically ill or injured, their bodies respond differently than adults exposed to similar insults. Consequently, pediatric treatment needs are unique in a number of ways:

- Children need different dosages and formulations of medicine than adults—not only because they are smaller, but also because certain drugs and biological agents may have adverse effects in developing children that are not of concern for adults.
- Children need different-sized equipment and other medical devices than adults. In fact, our day-to-day emergency readiness requires the presence of many different sizes of key resuscitation equipment for infants, pre-school and school-aged children, and adolescents. From needles and tubing, to oxygen masks and ventilators, to imaging equipment and laboratory technology, children need equipment that has been specifically designed for their size.
- Children demand special consideration during decontamination efforts. Because children lose body heat more quickly than adults, mass decontamination systems that may be safe for adults can cause hypothermia in young children unless special heating precautions or other warming equipment is provided.[3] Hypothermia can have a profoundly detrimental impact on a child's survival from illness or injury.
- Children display unique developmental and psychological responses to acute illness and injury, as well as to mass casualty events. Compared to adults, children appear to be at greater risk for acute- and post-traumatic stress disorders. The identification and optimal management of these disorders in children requires professionals with expertise in pediatric mental health.[4] When disaster strikes and these professionals are not readily available, it may fall to the responsibility of first responders who need to be adequately prepared, trained, and equipped for children.
- Children may be developmentally unable to communicate their needs with health care providers. The medical treatment of children is optimized with the presence of parents and/or family members. Timely reunification of children with parents and family-centered care should be a priority for all levels of emergency care. In a 2008 survey of hospital preparedness by the Centers for Disease Control and Prevention (CDC), only 42.6 percent of hospitals had a tracking system for accompanied and unaccompanied children, about 34 percent of hospitals had plans for reunification of children with families, and 31.1 percent for protocols to identify and protect displaced children.[5]

CHILDREN NEED CARE FROM PROVIDERS TRAINED TO MEET THEIR UNIQUE NEEDS

Because children respond differently than adults in a medical crisis, it is critical that all health care workers be able to recognize the unique signs and symptoms in children that may indicate a life-threatening situation, and then possess the experience and skill to intervene accordingly.[6] As already noted, a child's condition can rapidly deteriorate from stable to life-threatening as they have less blood and fluid reserves, are more sensitive to changes in body temperature, and have faster metabolisms. Once cardio-pulmonary arrest has occurred, the prognosis is particularly dismal in children, with less than 20% surviving the event, and with 75% of the survivors sustaining permanent disability.

Therefore, the goal in pediatric emergency care is to recognize pre-cardiopulmonary arrest conditions and intervene before they occur. While children represent 25 to 30% of all emergency department visits in the United States, and 5 to 10% of all EMS ambulance patients, the number of these children who require this advanced level of emergency and critical care, and use of the associated cog-

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[3] American Academy of Pediatrics. Children, Terrorism & Disasters Toolkit. The Youngest Victims: Disaster Preparedness to Meet Children's Needs. *http://www.aap.org/terrorism/topics/PhysiciansSheet.pdf*

[4] Hagan, J and the Committee on Psychosocial Aspects of Child and Family Health and the Task Force on Terrorism. Psychosocial Implications of Disaster or Terrorism on Children: A Guide for the Pediatrician. *Pediatrics,* Vol. 116, No. 3, September 2005.

[5] Niska R and Shimizu I. Hospital Preparedness for Emergency Response: United States, 2008. National Health Statistics Reports, No. 37, March 24, 2011.

[6] Markenson D, Reynolds S, Committee on Pediatric Emergency and Medicine and Task Force on Terrorism. The Pediatrician and Disaster Preparedness. *Pediatrics,* Vol. 117 No. 2 February 2006.

nitive and technical abilities, is quite small. This creates a special problem for pre-hospital and hospital-based emergency care providers, as they have limited exposure and opportunities to maintain their pediatric assessment and resuscitation skills. Fifty percent of U.S. Emergency Departments (EDs) provide care for fewer than 10 children per day.[7]

This committee is no doubt familiar with ED overcrowding as a day-to-day reality. Imagine layering on top of the current situation, a widespread mass care or mass casualty event involving children, including children with special health care needs. The experience is much like what my institution saw with H1N1.[8] Large volumes of patients and their families seeking medical care; having to educate pharmacies on how to constitute Oseltamivir for the pediatric population with cherry syrup; creating innovative strategies to address the surge of patients on top of the baseline patients; engaging the community and demystifying vaccine concerns; ensuring that media message was consistent and accurate and medically sound, ensuring infection control and so on. Fortunately for all of us, the overall morbidity of H1N1 was less than expected, though children were disproportionately impacted by the pandemic.

The science of ED surge remains relatively undeveloped.[9] What we do know is that when it comes to pediatrics, less than one-third (32.4 percent) of hospitals have guidelines for increasing pediatric surge capacity. In the face of a disaster, all hospitals will need to increase their capacity.

The vital clinical ability to recognize and respond to the needs of an ill or injured child must be present at all levels of care—from the pre-hospital setting, to emergency department care, to definitive inpatient medical and surgical care. The outcome for the most severely ill or injured children, and for the rapidly growing number of special needs children with chronic medical conditions, is optimized in centers that offer pediatric critical care and trauma services and pediatric medical and surgical subspecialty care. As it is not feasible to provide this level of expertise in all hospital settings, existing emergency and trauma care systems and State and Federal disaster plans need to address regionalization of pediatric emergency and critical care within and across State lines, leveraging inter-facility transport as a means to maximize the outcome of the most severely ill and injured children.

Children with special health care needs[10] are the fastest growing subset of children, representing 15 to 20% of the pediatric population.[11] These children pose unique emergency and disaster care challenges well beyond those of otherwise healthy children. Our emergency medical services systems, and our disaster response plans, must consider and meet the needs of this group of children.

EMERGENCY MEDICAL SERVICES FOR CHILDREN

The Emergency Medical Services for Children (EMSC) program has played a crucial role in driving significant improvements in pediatric emergency care, including disaster preparedness. Despite a modest appropriation of slightly more than $20 million, EMSC has managed to effect these changes despite the lack of pediatric emphasis in other related Government programs. EMSC has funded pediatric emergency care improvement initiatives in every State, territory, and the District of Columbia, as well as National improvement programs. These include the development of equipment lists for ambulances, guidelines for hospital emergency preparedness, pediatric treatment protocols, and handbooks for school nurses and other providers that would be critical in the event of an emergency. EMSC supports training for emergency medical technicians and paramedics who often have little background in caring for children, and has underwritten the development of vital educational materials and treatment guidelines. In the 21 years since the program was established, child injury death rates have dropped by 40 percent.

NATIONAL COMMISSION ON CHILDREN AND DISASTERS

Recognizing how far children lagged behind in disaster preparedness, response, and recovery, Congress saw fit to create the National Commission on Children and

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[7] Gausche-Hill M, Schmitz C, Lewis RJ. Pediatric preparedness of United States emergency departments: a 2003 survey. *Pediatrics.* 2007;120(6):1229–1237.

[8] Fagbuyi DB, et al. A Rapid Medical Screening Process Improves Emergency Department Patient Flow During Surge Associated With Novel H1N1 Influenza Virus. *Annals of Emergency Medicine,* Vol. 57, No. 1, January 2011.

[9] Nager AL, Khanna K. Emergency department surge: models and practical implications. J Trauma. 2009;67(2 Suppl):S96–99.

[10] MacPherson M et.al. A New Definition of Children with Special Health Care Needs. *Pediatrics,* Vol. 102, No. 1, July 1998.

[11] Van Dyck P et.al. Prevalence and Characteristics of Children With Special Health Care Needs. *Arch Pediatr Adolesc Med,* Vol. 158, No. 9, September 2004.

Disasters in 2008. The Commission produced two reports, the most recent in October 2010, in which it makes comprehensive recommendations aimed at the Federal Government and policymakers, some of whom are testifying at today's hearing. The Commission also called on the President to develop and present to Congress a National Strategy on Children and Disasters. Such a National strategy from the President would serve as a clarion call to Government, the private sector, communities, and families to engage one another in setting and achieving goals and priorities for children.

Of note to this committee given the subject of today's hearing, the Commission recommended that Congress, HHS, and DHS/FEMA should ensure availability of and access to pediatric medical countermeasures at the Federal, State, and local levels for chemical, biological, radiological, nuclear, and explosive threats.[12] The Commission offers several proposals to carry out this recommendation which include amendments to the Emergency Use Authorization authority to allow the FDA to authorize pediatric indications of medical countermeasures for emergency use before an emergency is known or imminent as well as funding and grant guidance for the development, acquisition, and stockpiling of medical countermeasures for children. The Academy strongly supports this recommendation.

I am saddened to report that the Commission officially terminated on April 4, pursuant to the statute that established it. The Academy opposes the termination of the Commission and will continue to urge Congress to move quickly to reconstitute the Commission. I had the pleasure of partaking in the discussions of the medical care subcommittee of the Commission and the achievements this Commission made with its Federal partners, professional organizations, and the public have been tremendous.

The Academy supported the creation of the Commission and we are committed to helping carry on the work of implementing the Commission's outstanding recommendations. It is unacceptable to us, and it should be to Congress as well, to allow the Commission's recommendations to simply sit on a shelf and gather dust.

MEDICAL PRODUCTS FOR CHILDREN

In 1977, AAP experts first published a policy statement saying that not only was it ethical to study drugs in children, it was unethical not to. Since that time, the Academy has advocated strongly that children deserve the same standards of therapeutic evidence as adults. The first step forward in public policy solutions to the lack of pediatric drug research came in 1997 when Congress passed the Food and Drug Administration Modernization Act. This law contained the first authorization of pediatric exclusivity, an incentive to study drugs in children. This program was reauthorized as the Best Pharmaceuticals for Children Act (BPCA) in 2002. In 2003, the Pediatric Research Equity Act (PREA), a requirement for pediatric studies, was passed after the Pediatric Rule was struck down. Finally in 2007, BPCA and PREA were reauthorized together, creating an integrated system for pediatric research incentives and requirements.

The uniqueness of pediatric therapeutics has been proven over and over again by surprising and unexpected results. BPCA and PREA studies have revealed safety issues, altered dosing, led to new indications, and have shown some drugs to lack efficacy in children. In total, nearly 400 drugs have been labeled for children as a result of BPCA and PREA. These laws have also served as a model for international advances in pediatric therapeutics, including the development of a parallel pediatric program used by the European Medicines Agency (EMEA). We can say unequivocally that BPCA and PREA have dramatically improved pediatric practice.

There are real opportunities to harness the experience of these programs and the strong leadership of the Food and Drug Administration with BARDA and their industry partners to improve pediatric labeling for medical countermeasure. There are opportunities for collaborations with the National Institutes of Health (NIH) as well. Within the last week, NIH released the 2011 BPCA Priority List of Needs in Pediatric Therapeutics and among the drugs identified by the NIH are several in the biodefense arena. The Academy looks forward to working with Congress to reauthorize and strengthen BPCA and PREA, two laws that have done so much to improve children's health.

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[12] National Commission on Children and Disasters. *2010 Report to the President and Congress.* AHRQ Publication No. 10–M037. Rockville, MD: Agency for Healthcare Research and Quality. October 2010.

MEDICAL COUNTERMEASURES FOR CHILDREN

Progress has been made to improve the availability of pediatric countermeasures but much more work needs to be done. Most recently, pediatric labeling was added to pralidoxime for the treatment of nerve agent poisoning. However, that labeling took 7 years during which time no new data was presented. It is hard to understand why it took that long. Pediatric labeling was the first step. HHS/BARDA needs to support the manufacture and purchase of a child-specific auto-injector so that pralidoxime can be forward deployed and administered in the field.

In the event of a radioactive release much like we saw in Japan, children must be administered potassium iodide as quickly as possible, ideally within 2 hours, and in an appropriate form and dosage to prevent long-term health effects.[13] The liquid formulation of potassium iodide exists and is safe and effective but if Federal and State governments do not purchase it to be stockpiled in the event of radiation exposure and in sufficient quantities to treat all of our Nation's children, how secure are we really?

The Academy looks forward to the approval of pediatric labeling for midazolam to treat nerve gas exposure. Those studies are well underway at NIH and the Academy hopes that NIH and FDA are closely coordinating their efforts in order to expedite the approval of pediatric labeling.

OTHER POLICY RECOMMENDATIONS

The American Academy of Pediatrics has specific recommendations for all policymakers regarding children and medical countermeasures:

- The medical countermeasure enterprise, led by the Federal Government, should set a goal to achieve parity between adult and child medical countermeasures developed and included in the Strategic National Stockpile (SNS) and all other Federally-funded caches.
- The Pandemic and All-Hazards Preparedness Act should be amended to require that the Secretary, acting through BARDA, prioritize children.
- Children must be distinguished as a separate population from the broader "at-risk" individuals' category and the HHS Secretary should create an Office of Preparedness and Response for Children to be headed by a Director who reports to the Secretary.
- The Federal Government should conduct a comprehensive review of the contents of the SNS and all other Federally-funded caches to assess how many products have pediatric labeling and, for those that don't, the Government should create a plan by which pediatric labeling can be added.
- The Emergency Use Authorization process should be amended to allow the FDA to authorize pediatric indications of medical countermeasures for emergency use before an emergency is known or imminent.
- The Federal Government must give guidance to States that ensures they purchase adequate supplies of countermeasures for children, especially liquid potassium iodide in States with or near nuclear facilities. And, there must be accountability for States' plans for maintenance and distribution of medical countermeasures for children.
- Prepositioning of medical countermeasures is critical. All prepositioning strategies must include locations where children gather, e.g. schools and child care facilities and they must include plans for children with special health care needs.
- Because "children" encompass individuals from birth through adolescence, it is often insufficient to have a single size device to serve all children. In the case of respiratory masks, for example, different sizes are needed for infants, young children, and teenagers. Both individual facilities and the SNS must take this into account and provide for these needs. Similarly, drugs must be available in appropriate formulations and dosages for children. Infants cannot be expected to take pills. Needles must be provided in smaller sizes. In many cases, dosages for children should be determined not by age but by weight.
- Utilize pediatric subject matter expertise in identifying gaps, setting priorities, planning, and exercising all-hazard disaster response capabilities.
- Federal agencies such as FDA, BARDA, and NIH must coordinate their efforts with the goal of prioritizing pediatric medical countermeasures.

[13] Committee on Environmental Health. Radiation Disasters and Children. *Pediatrics,* Vol. 111, No. 6, June 2003.

CONCLUSION

The American Academy of Pediatrics thanks the committee for this opportunity to testify on the important issue of medical countermeasures. America's children represent the future of our Nation, our most precious National resource. They must not be an afterthought in medical countermeasures and disaster planning. The Academy looks forward to working with you to protect and promote the health and well-being of all children, especially in emergency and disaster preparedness. We would like to offer the children and disasters website of the Academy as a resource to you as you work on disaster preparedness issues. It can be found at *www.aap.org/disasters.*

Finally, we would like to leave you with the findings of recent public opinion polling conducted by the AAP in partnership with Children's Health Fund on the use of resources related to disaster planning and response specific to children's issues. The poll found:

- 76% of Americans agree that if resources are limited, children should be given a higher priority for life-saving treatments;
- 75% believe that if tough decisions must be made, life-saving treatments should be provided to children rather than adults with the same medical condition; and
- 92% agree that if there were a terrorist attack, our country should have the same medical treatments readily available for children as are now available for adults

You represent fathers, mothers, grandparents, uncles, and aunts; our children deserve better. When disaster strikes, we as a Nation must be better prepared with the medical countermeasures to keep our children healthy and ensure they have the opportunity to achieve optimal health outcomes. As a pediatrician and a father of three, I look forward to your questions and to working with you to address the preparedness needs of all children.

Mr. BILIRAKIS. Thank you, Doctor. Appreciate it very much.

I recognize myself for 5 minutes.

To the doctor, we appreciate your testimony describing how children are a particularly vulnerable population when it comes to CBRN threats. Many would argue that our preparedness and ability to deal with children and other vulnerable populations in a disaster lags behind our preparedness for adults. I know you mentioned this, so I am going to give you an opportunity to elaborate.

Can you please elaborate on your comments about potassium iodide for children if you have more to say? That is my first question.

Dr. FAGBUYI. Thank you.

The issue with regards to potassium iodide, it is a countermeasure. It is safe and effective; the FDA has recommended it. It should be stockpiled. It should not be allowed to expire if it does exist in the stockpile.

The stockpile actually should be evaluated to ensure that there are pediatric countermeasures in the stockpile sufficient enough to address the same needs that would be appropriate for a threat that would affect adults. That is something that is important and should be evaluated.

With regards to KI, you can talk about amount, and what is the zone, and how far it should be deployed out, and who should have it, but if States and Federal Governments don't stockpile it and if we don't actually have enough in quantity then it doesn't matter if it is 10 miles, 20 miles, 30 miles. If you don't have enough you don't have enough.

Mr. BILIRAKIS. Okay. I would like to follow up with you after the hearing as well on this issue.

Mr. Clerici, your testimony indicates that the main challenge we face in this enterprise is not one of authority but one of culture. As a contracts lawyer it is your perception that many of the flaws in the system—in other words, is it your perception that many of

the flaws in the system could be fixed if it would simply make better use of existing authorities, of the other transaction authority, of allowable transactions with industry under the FARR, of getting out RFPs and contracts quickly instead of waiting for years? So my question is: What needs to change to fix this and how can Congress help?

Mr. CLERICI. Thank you, Mr. Chairman. You clearly point out, it goes beyond just interactions with the procurement. It is the BioShield legislation itself.

The vision of BioShield was actually to anticipate that Government has to act differently with respect to these non-Governmental contractors, and there are special authorities in the BioShield legislation other than—beyond the other transactions authority that you mentioned on the last panel that have not been used at all, let alone to their fullest. It is a frustrating problem because here you have, in my view—the funding is available, which as we sit here today, as you vote on the continuing resolution of the budget, that is a rare benefit that you don't really see in these times.

The leadership is actually very strong as well. I think Dr. Robinson and his team are very, very accessible to industry. It is what happens after that, after you have talked to that team down below where the problems seem to arise.

The program has morphed into much more, at the Department of Defense, acquisition program based upon a very long timeline rather than the sense of urgency imparted upon the legislation with Project BioShield. The frustrating part, Mr. Chairman, is I am not sure what Congress can do. It has given them all the authority; it has given them all the tools and they actually do have strong leadership.

You know, your oversight authority is certainly an important way to follow this, as well as kind of just reminding them that the legislation was meant to convey that sense of urgency of the events of 9/11 and after that has been somewhat lost as we move further and further away from the event.

Mr. BILIRAKIS. Thank you.

My next question is for Ms. Arthur. In your opinion is the Government working with industry to develop sufficient broad spectrum technologies thereby getting away from the one bug, one drug problem? This seems like just the type of challenge that biotechnology companies would be poised to tackle.

Ms. ARTHUR. So actually, thank you for your question. I think that BARDA and the DOD both are working in concert with industry to try to maximize these multiplatform, multiuse opportunities. I think that one of the things that we face is actually what is the regulatory process for those products going forward?

So in the end it is still true that the FDA approves a product for a specific indication. They don't approve the idea of how you might use this for multiple products, so it is very important, as we stress, that the agencies work together with the FDA to think through how we move these new platforms that have dual use through the regulatory process with clarity. Hopefully I answered your question.

Mr. BILIRAKIS. Thank you.

Mr. Clerici, can you please elaborate on your statement that HHS was unresponsive to industry offers to help provide products that would mitigate the radiological crisis in Japan? Why do you think that BARDA has not been proactive in this regard, second? Then the last question is, further, what needs to happen to ensure that the United States has stockpiled the countermeasures it would need to respond to a rad-nuc incident of its own?

Mr. CLERICI. Yes, Mr. Chairman. So in my experience there are three or four products out there that are licensed, FDA-approved for other indications that are related to what would occur or what has occurred in Japan. Those companies are very well aware of BARDA and vice-versa. BARDA's leadership, again, has done, I think, an outstanding job of making an outreach to those teams.

Based upon my understanding, since the events in Japan there has been very little interaction to understand how many of those products are on hand, what are the protocols that would be used during an event such as Japan if Japan asked for them, or what sort of file could be done to make sure the data that comes from where these products are actually used can go to license these products here in the United States for the nuclear indication.

Why I think that has happened is a couple reasons, Mr. Chairman. First, I think that there is sensitivity to the Japanese. They have not asked for our help; we certainly can't offer it in the abstract. However, there is nothing wrong with being prepared for them to ask us those questions, and even that exercise alone I think would be very important.

The second problem, I think, goes back to the procurement problem. I think that there is sensitivity among the program folks who very much want to have these exchanges with industry but they might be viewed as favoring industry or somehow endorsing them along the way. This is the time, essentially, to kind of act very proactively and I think we are missing it.

The last one is a high level of sensitivity around endorsing a product for an unapproved use. We are very sensitive about offering a promotion and everything that goes along with that. But by definition these products that are FDA-approved are a little bit different than a product that is earlier in development, and particularly those products that have already been used in nuclear events outside the country in South America and others.

Seems there should be a little less sensitivity on that issue that I am not actually seeing.

Mr. BILIRAKIS. One last question for Ms. Arthur.

Ms. Arthur, you mentioned in the testimony that the Federal Government must provide an MCM market that is sustainable and therefore of interest to industry. Was the 10-year advance appropriation for BioShield a reasonable model? If not, what do you suggest now that the funds are nearing their expiration date?

Ms. ARTHUR. Thank you. That is a good question.

So, there have actually been several suggestions of what number would be the best number to put in BioShield to really serve as the right size for the marketplace that required all of these products—as the doctor pointed out, you don't just want products that treat adults; you want products to treat pediatrics, geriatrics,

immunocompromised persons, and each of those indications is its own development process.

So I think that the Weapons of Mass Destruction Commission actually suggested a number that was order of magnitude higher than $5.6 billion, and I would have to get back to the committee with the correct number, but there are some published data that show that the number would need to be bigger in order to actually prove a marketplace size big enough to give you all of the countermeasures that would be required for the—to fulfill all the needs. I hope I answered your question.

Mr. BILIRAKIS. Get back to us on that.

Ms. ARTHUR. We absolutely will.

Mr. BILIRAKIS. I am sure the Ranking Member would be interested as well. Thank you.

Okay, Ms. Richardson, you are recognized for 5 minutes or so.

Ms. RICHARDSON. Thank you, Mr. Chairman.

Let me start off my first question with Mr. Clerici. From your perspective, which research and development works better, DOD's or HHS?

Mr. CLERICI. There are certain aspects of the DOD model, particularly in the program that Dr. Parker mentioned, the Transformation Medical Technologies program, that I think have been very strong. In fact, BARDA has actually adopted some of those practices—two-stage procurement, where you submit a very short white paper and then you are screened out and don't have to spend the time to go through a full proposal. That has been very positive.

I have also seen examples that have been fairly public that DOD has been more aggressive. There is one example of a influenza therapeutic that was discussed in a recent publication after the H1N1 pandemic arose where DOD acted very aggressively. So in that respect I think that is a positive light.

BARDA faces a lot greater challenges than DOD, quite frankly. You talked about the population differences. Generally speaking, the military is buying products for the warfighter, 18- to, you know, 35-year-old healthy people. BARDA has to address the entire population.

The other struggle that BARDA faces, which is kind of counterintuitive, is BARDA actually has the authority to use products that aren't FDA-approved; DOD does not. DOD must develop a product all the way through licensure before it can be used in a military setting. That creates challenges because of the Animal Rule and kind of the expectations around what BARDA's mission is.

So I think I would have to say that in many respects DOD has been faster and better; in other respects I understand that BARDA has a much bigger challenge on its hands. But there are lessons that can be learned.

Ms. RICHARDSON. Okay.

Ms. Arthur, will changes described in the August 2010 PHEMCE review fix all of the problems with HHS's process in developing medical countermeasures? What is missing from those recommendations? Which of the recommendations should not be implemented?

Ms. ARTHUR. Well, now, thank you.

I think that a great—the review actually did touch on several of the most important issues that would go a long way to increasing industry involvement. Certainly the FDA investment is the most important and the most—the biggest hurdle that industry faces today.

I think that in addition what might be missing is the opportunity to have more transparency of a longer-range plan. To discuss these products takes anywhere from 8 to 12 years to develop and that actually means that this annual procurement process and appropriations process does not necessarily allow companies to have their security that their investors are planning where they will be in the process and how they will be leveraging their funds and hitting their milestones over the long term.

So the ability to do a more long-range plan that can be shared transparently with stakeholders would be added benefit to industry.

I think there are several provisions inside the review that industry is still looking at—the strategic investor and the flexible manufacturing. I want to make sure that we work with BARDA and the DOD to understand exactly how those would be implemented and to make sure that there are no—or as few negative implications for commercialization of some of these dual-use products as possible.

So while everything in the review was certainly meant to increase the incentive for industry to be involved, a few of the proposals might need to be finessed and worked on with industry and partnership.

Ms. RICHARDSON. Okay. Thank you.

Doctor, since you are the director of disaster preparedness and emergency management at the Children's National Medical Center, to your knowledge—I don't know if you were in the room when I asked the question about stockpiling—to your knowledge is there an adequate stockpiling of children-related vaccines and so on?

Dr. FAGBUYI. Thank you, ma'am. I do not know that. I am not privy to that.

However, from the lessons that we learned from H1N1, for example, I will give—Oseltamivir is a drug we used that was the medical countermeasure at least that the population was—was distributed to the population. That was a logistical nightmare trying to get that to different hospitals and other end-users, the patients themselves.

In addition, pharmacies didn't even know how to constitute it right for a pediatric patient. There was an issue of cherry syrup shortage. What is going to happen with cherry syrup? What is that about? Well, that is how you mix it for it to be more palatable, and to constitute it right for the dosing for the pediatric patient.

So that is a preview. That gives me an opportunity to say, well, I question the rest of the things then with that. That is where the Academy stands at. We need to actually look back into the stockpile, see what is actually there. What is in there? Does it have pediatric indications and can it be used in a patient? Does it have pediatric instructions that are clear so that people make sure they are using the right dose?

People should engage with the pediatric experts who do this often to be able to make sure that that is changed. I hope that answers your question, ma'am.

Ms. RICHARDSON. Absolutely.

Thank you. I yield back.

Mr. BILIRAKIS. Thank you very much.

I want to thank the witnesses for their valuable testimony, thank my Ranking Member for her great questions, and I am sure you will agree this is a very timely hearing and hopefully this will bring the issues to the forefront because these are so very important.

The Members of the committee may have some additional questions for you and we ask you to respond in writing please. The hearing record will be held open for 10 days.

Without objection, the subcommittee stands adjourned. Thank you.

[Whereupon, at 4:31 p.m., the subcommittee was adjourned.]

APPENDIX

QUESTIONS FROM CHAIRMAN GUS M. BILIRAKIS FOR CYNTHIA A. BASCETTA

Question 1. Medical countermeasures aren't just about vaccines and antibiotics, but also include appropriate diagnostic measures to determine who is actually exposed. We have no rapid diagnostic tools stockpiled for any of the material threats. In your opinion, is the civilian medical countermeasures program developing appropriate diagnostics to meet the material threat determinations?

Answer. Our current work is examining HHS's chemical, biological, rediological, and nuclear (CBRN) medical countermeasure development and acquisition activities, and the Department has a stated interest in developing and acquiring vaccines, antibiotics, diagnostic devices, and other countermeasures. As we reported in our testimony, the Federal Government faces a variety of challenges in developing and acquiring these countermeasures, such as the high failure rate in research and development and difficulties meeting regulatory requirements. These challenges apply to diagnostic devices as well as vaccines and antibiotics. However, we have not reviewed issues specific to the development of diagnostics, but we agree that diagnostics are an important component of response to certain types of threats.

Question 2. Do you believe that the distribution of funds for medical countermeasures is appropriate? That is, is the way the funds are spent actually resulting in enough and useful countermeasures?

Answer. Our current work is examining how much HHS has invested in CBRN medical countermeasure research, development, and acquisition and its progress in these activities. However, we are unable to make a determination as to whether HHS is spending its funds appropriately. As we reported in our testimony, countermeasure research and development is a lengthy and complex process. In addition, given the high failure rates and other challenges, it is also an expensive process, especially in the advanced research and development stages. HHS is making some changes to its countermeasure enterprise and processes intended to improve countermeasure development and acquisition, which we are also examining in our current work. While it is too early to determine how some of these changes will affect countermeasure development and acquisition, our work will include a review of how investments in countermeasure development have been guided by threat and risk assessments.

QUESTIONS FROM RANKING MEMBER LAURA RICHARDSON FOR RICHARD J. HATCHETT

Question 1. Does HHS support the goal of achieving parity within the SNS between countermeasures for children and those available for adults?

Answer. The Department of Health and Human Services (HHS) supports the goal of achieving parity within the Strategic National Stockpile (SNS) between medical countermeasures (MCMs) available for children and those for adults. HHS inventories the SNS on a yearly basis to assess and rectify MCM gaps, and there has been a specific focus on pediatric MCM requirements and gaps in the 2010 SNS Annual Review [relates to QFR No. 2 below] that will be reviewed and prioritized by the Enterprise Senior Council.

In many cases, a gap exists because either a pediatric formulation of a countermeasure has not been developed or an existing countermeasure has not been approved by the Food and Drug Administration (FDA) for use in pediatric populations. HHS is working diligently to overcome the challenges to obtaining FDA approval for pediatric MCM. Because pediatric MCM research must be conducted in accordance with 21 CFR Part 50, Subpart D (50.50–50.56): "Additional Safeguards for Children in Clinical Investigations," and with 45 CFR Part 46, Subpart D, "Additional Protections for Children Involved as Subjects in Research," as relevant, the ability to conduct studies is limited and consequently the opportunity to collect sufficient data on the safety and efficacy of MCMs in pediatric populations is limited.

Furthermore, the ethics and feasibility of collecting data on the use of MCMs against CBRN threats in children are particularly challenging.

HHS is working to stimulate pediatric MCM development by integrating considerations for pediatric populations in every stage of development, including requirements setting, research, and program management. The National Institutes of Health (NIH) is spearheading clinical trials to obtain the data necessary for FDA approval of pediatric MCMs, such as midazolam to treat seizures resulting from nerve agent exposure. Since 2004, HHS's Biomedical Advanced Research and Development Authority (BARDA) has invested over $2 billion to support MCM development in healthy and special populations including pediatric populations. This includes MCMs for anthrax vaccines and therapeutics; heptavalent botulinum antitoxin; Smallpox vaccine for immunocompromised persons; and a number of products intended for use after radiological or nuclear events. Additionally, HHS is putting in place new mechanisms, such as a working group focused specifically on the issues of developing and dispensing MCMs to pediatric and obstetric populations, to improve the development and acquisition of safe and effective countermeasures for children.

Question 2. Will the ASPR conduct a comprehensive review of the contents of the SNS and provide this committee and the public a report on how many have pediatric labeling?

Answer. An annual review of the SNS formulary is mandated by Homeland Security Presidential Directive 21: Public Health and Medical Preparedness (HSPD–21) and Section 319F–2(a)(1) of the Public Health Service (PHS) Act, as added by Section 102(c) of the Pandemic and All Hazards Preparedness Act (PAHPA), Public Law 109–417.[1]

PAHPA directs the SNS Annual Review to address medical countermeasure assets for at-risk individuals, including pediatric populations. To enhance preparedness planning for pediatric populations, the 2010 SNS Annual Review process specifically examined the medical countermeasure requirements needed to cover the U.S. pediatric population (defined as individuals aged 0–21 years).[2] The HHS-led working groups that contribute input into formulary decisions have accounted for pediatric medications, formulations (some of which are also appropriate for persons unable to swallow pills), and dosages where available. This ensures that SNS requirements will include medical countermeasures appropriate for pediatrics wherever possible. The overall quantitative gaps were examined, while also pinpointing areas where existing medical countermeasures are insufficient to meet the specific needs of pediatric populations. The results of this Review will be available in 2012, as required under HSPD–21.

The issue of pediatric labeling of MCMs is very important to HHS. This is a complex subject that presents challenges beyond its impact on medical countermeasures stockpiled in the SNS, as the majority of medications on the market today have not undergone clinical studies in children. The FDA maintains an informative web page that addresses the challenge of identifying safe pediatric uses for existing MCM that have not been tested and labeled for children (*http://www.fda.gov/Drugs/ResourcesForYou/Consumers/ucm143565.htm).*

The ability to use the medical countermeasures provided by SNS during an incident depends on necessary mechanisms that allow for deployment, dispensing, and utilization of those assets. In order to treat individuals at the State and local level with medical countermeasures that have not been approved, licensed, or cleared by FDA for their intended uses (e.g., off-label pediatric applications), Emergency Use Authorization (EUA) or Investigational New Drug protocols must be in place for each product for the intended purpose. CDC also continues to prepare for potential deployment and use of medical countermeasures by preparing pre-EUA documents and working with FDA to streamline the process for obtaining an EUA at the time of an incident.

Question 3. In light of recent events in Japan, is the administration currently considering changing the policy to limit the availability of potassium iodide (KI) to just 10 miles around nuclear power plant facilities?

Answer. The Nuclear Regulatory Commission (NRC) has principal Federal responsibility for policy recommendations regarding the use of potassium iodide (KI) in

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[1] *http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=50-&showFR=1&subpartNode=21:1.0.1.1.19.4.*

[2] The 0–21 year age range is consistent with the definition generally used by the practicing community of pediatricians and pediatric stakeholder groups. An estimated 30% of the U.S. population is included in this age range. There are diverse medical countermeasure formulation requirements within this range however (e.g. suspension formulations are designated for children 0–9 years of age (14% of the U.S. population)).

proximity to nuclear power plant facilities. Consequently, this question is more appropriately suited for the NRC to address. It should also be noted that the final authority to make any determinations regarding implementation of KI distribution beyond 10 miles of nuclear power stations resides with States, which have to develop preparedness plans and submit them to the Federal Emergency Management Agency (FEMA), Department of Homeland Security, for review.

Question 4a. At present, is there enough liquid KI in the SNS for all children, especially children living in States with or near nuclear facilities?

Question 4b. If not, what is being done to ensure liquid formulation KI will be available for all children?

Answer. The Nuclear Regulatory Commission currently implements the program for providing KI to the States that have populations living in the Emergency Planning Zones (EPZ) surrounding nuclear power plants in the United States. Following the decision not to distribute KI in the 10–20 mile radius of nuclear power stations, the KI tablets originally purchased for the SNS to carry out this requirement were turned over to the NRC for the purpose of supporting these populations, and the KI liquid solution was offered to the States by HHS and SNS to address their childhood populations; however, it was declined by nearly all States due to the logistical issues and cost associated with accepting, stockpiling, and distributing this product to communities within 20 miles of a nuclear power station.

While KI liquid solution does reside in the SNS and could cover the childhood populations in many scenarios of potential radioiodine release from a nuclear power station, it is expiring and there is no operational requirement to maintain it in the SNS formulary. KI should be administered for risk of exposure, or within of 4–6 hours or less of exposure, to be effective, and thus National stockpiling of KI would not appear to be an effective strategy that allows for utilization in a timely manner.

The quantities of bottles of liquid KI held in SNS inventory are treated as Controlled Unclassified Information, but HHS would be happy to provide this information in another manner that permits appropriate safeguards. Due to the packaging of KI liquid solution, it would be expected that one bottle would be provided per family with one or more children even though there are multiple doses in each bottle. Thus, the number of children that could be treated for prophylaxis with KI liquid solution following a release of radioactive iodine is, at a minimum, equal to the number of available bottles.

The amount of excess KI liquid solution currently held in the SNS would be insufficient to treat the total pediatric population of the United States, if the entire Nation was at risk. HHS does not currently have information on the size and demographic breakdown of populations surrounding U.S. nuclear power plants to calculate the requirement for KI liquid solution to treat the entire pediatric population in those areas.

The Office of the Assistant Secretary for Preparedness and Response is leading an interagency effort to evaluate the need for a National stockpile of KI that could include the liquid formulation of KI. We would welcome the opportunity to provide an update to the subcommittee when this review is complete.

Question 5. Please describe how BARDA coordinates with pharmaceutical companies developing MCMs—specifically MCMs for anthrax.

Answer. BARDA coordinates with large and small pharmaceutical and biotechnology companies through many different venues and mechanisms. Companies that have been awarded contracts by BARDA for the development of anthrax countermeasures are in constant communication with relevant program managers, project officers, and contracting officers and specialists. As warranted, companies with active contracts participate in interagency "In-process Reviews" to discuss progress toward project milestones or deviations of cost, schedule, or performance.

BARDA senior leaders participate in and present BARDA plans and priorities at National and international biodefense, pharmaceutical, and biotechnology meetings. Subject matter experts from BARDA participate in a myriad of scientific and product development conferences throughout the world, broadening the understanding of BARDA's mission in the private sector.

BARDA also supports public meetings that bring together scientists and pharmaceutical companies. BARDA, as mandated in PAHPA, convenes meetings with representatives from relevant industries, academia, other Federal agencies, international agencies as appropriate, and other interested persons at least once per year, providing an opportunity for the private sector to interact with USG staff and ask questions related to BARDA's mission, planning, priorities, and requirements. The next BARDA Industry Day will be conducted June 7–9 in San Diego, CA, with a similar meeting planned for Boston in October. Representatives of the Office of Acquisition Management, Contracts, and Grants within ASPR will also participate in and jointly sponsor both of these conferences.

BARDA also has an open electronic portal (medicalcountermeasures.gov) for industry to request a meeting with the USG, and find information related to: (1) Procurement and grant opportunities, (2) public meetings and conferences, (3) specific product guidance, (4) available resources, and (5) PHEMCE and BARDA strategic and implementation plans and reports.

Lastly, BARDA has a solicitation (Broad Agency Announcement; BAA) open year-round for product developers to engage BARDA through product development proposals. This solicitation allows private industry the ability to present ideas and projects to BARDA under an expedited review process. Although the solicitation calls for proposals based on all chemical, biological, radiological, and nuclear MCMs, BARDA has also issued Specific Instructions under the solicitation for anthrax countermeasures. Collectively, these activities are broadening BARDA's portfolio of anthrax medical countermeasure candidates and making it more feasible that these products will be available for future procurements.

QUESTIONS FROM CHAIRMAN GUS M. BILIRAKIS FOR GERALD W. PARKER

Question 1. In your testimony, you indicated that DOD is integrated with other agencies through the National Biosurveillance Integration System (NBIS). Can you please expand on this comment, by describing the ways in which DOD participates (through information exchange, liaison officers, etc.)? Please also describe any memoranda of agreement, memoranda of understanding, etc. that have been signed, and how these have facilitated information sharing.

Answer. Biosurveillance includes the process of data gathering and monitoring of potentially valuable information sources for tracking both naturally-occurring and man-made emerging epidemics. The ability to detect an outbreak early, investigate and verify the biological threat, and determine the extent of the outbreak all aid in responding to and mitigating the consequences of the outbreak. The Global Emerging Infections Surveillance and Response System (GEIS), operated by the Armed Forces Health Surveillance Center (AFHSC) through a network of U.S. and overseas laboratories, creates a centralized coordination and communication hub to help organize DoD resources and link U.S. and international efforts.

DoD has entered into a Memorandum of Understanding (MOU) with the Department of Homeland Security, the Department of Agriculture, the Department of Health and Human Services, the Department of the Interior, the Department of State, and other agencies to participate in the establishment of the National Biological Integration System (NBIS). NBIS focuses on biosurveillance and early recognition and notification of hazards.

This MOU has removed bureaucratic hurdles and clarified roles and requirements for DoD to share GEIS information with the Centers for Disease Control and Prevention and NBIS for integration into an overall National pattern. In particular, it allows DoD to participate in quarterly sessions of the NBIS Interagency Working Group and the NBIS Interagency Oversight Council. Moreover, DoD is involved in NBIS Protocol Activations, as needed (e.g., E. Coli outbreak in Germany). The NBIS representatives also participate in the DoD Joint Biosurveillance Working Group, contributing to discussions across the community that fields the necessary tools for operational users to gather data from environmental sensors, diagnostic results, or open source communications. The possibility exists for an MOU with DHS to allow DoD to place a military liaison with NBIS. In connection with the above, DoD's efforts are designed to capture all relevant biosurveillance information in a central location for better coordination with NBIS and other interagency and international partners.

Question 2. The Department of Defense's Transformational Medical Technologies Initiative targets development of countermeasures that are broad spectrum, that is, effective against an array of threat agents. The civilian enterprise is also attempting a similar effort. Can you please provide the subcommittee with insights and best practices into how to advance this challenging, but necessary, endeavor in the civilian sector?

Answer. Transformational Medical Technologies (TMT) investments are focused on broad-spectrum medical countermeasure (MCM) solutions, either individual MCMs that target conserved pathogen- or host-based targets or MCMs that are based on an adaptable platform technology that may be tailored to a new or emerging pathogen. These efforts attempt to mitigate the risk associated with both engineered and naturally evolved resistance in the pathogen.

All medical countermeasure development toward licensure must adhere to Food and Drug Administration (FDA) regulations to demonstrate efficacy and to protect their respective populations, the general population and the warfighter, from unsafe drugs. The traditional FDA approval process presumes one indication per drug and

one drug per target. The key breakthrough TMT seeks is a safe FDA approval process for a platform and not merely a product. In this regard, TMT has advanced further than the civilian sector. TMT New Drug Application submissions to FDA for approval consideration are the first examples under a new "fast-track" FDA process, still being developed.

All products must comply with, and progress through, appropriate FDA regulatory processes governing their development and ultimate approval and use. Any civilian effort addressing MCMs should include working directly, and often, with the FDA and other organizations to promote and support new approaches to regulatory science.

Civilian investments in broad-spectrum countermeasures should carefully consider the risks and benefits of a relabeling approach and assess whether relabeling or new discoveries will address their needs and gaps. Existing FDA-approved MCMs, and candidates under development by the civilian sector, are primarily pathogen-directed and well-characterized. FDA-approved products could be (and are being) relabeled for additional indications. Consideration must include additional costs to license any subsequent indication necessary to reach broad-spectrum status with the FDA. The cost estimates should reflect the approximate cost to achieve FDA approval for the first indication, and the additional costs for new indications. Alternatives include designing MCMs against broadly conserved targets not easily subverted because they have a critical and necessary role in the pathogenesis of the infectious agent.

To enable MCM discovery, TMT has invested in both in silico and in vitro platforms that enable rapid screening of candidates for off-target effects, such as toxicity and drug-to-drug interactions. TMT supports development of computational tools that provide rapid analysis of potential targets, based on genomic sequence data. To enable MCM development under the FDA Animal Rule, TMT is investing in a range of tools to make drug testing in animals more predictive of the human experience. Collectively, these tools will improve the confidence for using data extrapolated from animal models for MCM evaluation. Broad-spectrum investments should include enabling technologies to support this critical but original effort.

TAKING MEASURE OF COUNTERMEASURES (PART II): A REVIEW OF EFFORTS TO PROTECT THE HOMELAND THROUGH DISTRIBUTION AND DISPENSING OF CHEMICAL, BIOLOGICAL, RADIOLOGICAL, AND NUCLEAR MEDICAL COUNTERMEASURES

Thursday, May 12, 2011

U.S. HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON EMERGENCY PREPAREDNESS,
RESPONSE, AND COMMUNICATIONS,
COMMITTEE ON HOMELAND SECURITY,
Washington, DC.

The subcommittee met, pursuant to call, at 1:00 p.m., in Room 311, Cannon House Office Building, Hon. Gus M. Bilirakis [Chairman of the subcommittee] presiding.

Present: Representatives Bilirakis, Marino, and Richardson.

Mr. BILIRAKIS. The Subcommittee on Emergency Preparedness, Response, and Communications will come to order.

The subcommittee is meeting today to receive testimony on Federal, State, and local efforts to distribute and dispense medical countermeasures in the event of a CBRN attack, pandemic, or other emergency.

I now recognize myself for an opening statement.

At the outset, I would like to thank our witnesses for their flexibility on the timing of today's hearing. Thank you very much. Appreciate it.

This hearing is the second in a series considering medical countermeasures. Last month, the subcommittee received testimony on Federal efforts to work with industry to research, develop, and acquire medical countermeasures. Today, the subcommittee will focus on efforts to get those medications, diagnostics, and other medical supplies to individuals who need them in the event of a CBRN attack, pandemic, or other emergency.

Our enemies have made no secret of their desire to use weapons of mass destruction to attack the United States. Last year, the Committee on Homeland Security received testimony from former Senators Graham and Talent, the commissioners of the Commission on the Prevention of Weapons of Mass Destruction Proliferation and Terrorism.

At the hearing, the commissioners noted that it is more likely than not that there will be a weapon of mass destruction used someplace on Earth by a terrorist group before the end of the year

2013 and that it is more likely that the weapons will be biological rather than nuclear.

This assessment, along with the anthrax attacks in 2001, the H1N1 pandemic in 2009, and the disaster in Japan, highlights the need for robust plans for countermeasure distribution and dispensing.

The WMD commission issued a report card on U.S. Government efforts to protect the Nation from WMD terrorism last year. Sadly, the Government received a grade of "F" on its efforts to enhance the Nation's capabilities for rapid response to prevent biological attacks from inflicting mass casualties. Of course we can and must do better.

I look forward to hearing from our Federal witnesses about whether we have made strides in this area since January 2010, since the report card was issued. What lessons have we learned from the response to the H1N1 pandemic that can help us enhance our preparedness and response?

I would also like their opinion on whether the Federal Government is investing adequate resources in the Strategic National Stockpile to ensure that we have appropriate quantities of the right drugs, diagnostics, and supplies. In light of the radiological emergency in Japan, we must not squander this opportunity to assess our own preparedness for a radiological or nuclear disaster, which I fear is, as I said, substantially inadequate.

I am interested in hearing from all of our witnesses, especially our State and local witnesses on the second panel, on their view of the various distribution models and where we need to be today to respond to any event that may happen tomorrow. Which models are the most promising to reach the largest population as expeditiously as possible? What innovative efforts are being implemented at the local level to ensure prompt dispensing?

Last, we must consider how effectively the Federal Government is interfacing with States and localities to ensure that resources and guidance are provided and that planning is coordinated. We must ensure that the public is appropriately informed of the threats they face and that the first responders who treat them have the guidance and opportunities for pre-event vaccination that they deserve.

With that, I welcome our witnesses, and I look forward to their testimony.

Right on time, I will recognize the Ranking Member for her statement. Thank you. You are recognized.

Ms. RICHARDSON. Thank you, Mr. Chairman. Thank you for convening this very important hearing about our Nation's readiness for distributing and dispensing medical countermeasures.

I would also like to express my gratitude to those of you who have served on our behalf. We are very grateful for that, and thank you.

As a representative of the 37th Congressional District, I understand the critical importance of developing effective nuclear biological and radiological and chemical countermeasures. The Port of Long Beach and other critical infrastructure is throughout my entire district, not to mention the large population that Los Angeles

County faces, us being the largest county in the entire United States.

We must ensure that the Federal, State, and local efforts are coordinated to ensure a seamless and expeditious distribution and dispensing process to respond to bioterror, pandemic events, or emergencies caused by a natural disaster.

There have been major improvements to the Nation's public health infrastructure over the last decade, especially since the anthrax attacks that we had and even faced here in Washington, DC. Most importantly, however, our State and local health departments, who serve as the backbone of our distribution and dispensing efforts, have made great progress in planning and navigating through complex logistical challenges.

However, we must ensure that the Federal efforts support State and local health departments, who, under law, have the primary responsibility for the health of our citizens. Therefore, when we consider the Federal efforts that should be taken, unfortunately a decade of gains to our State and local public health departments are endangered based upon the budget cuts, or the proposed budget cuts.

According to a December 2010 study by the Trust for America's Health, entitled, "Ready or Not? Protecting the Public's Health from Diseases, Disasters, and Bioterrorism," 33 States and Washington, DC, have cut funding for public health since 2008. Also, since fiscal year 2005, Federal support for public health preparedness has also been cut by 27 percent. Funds for public health allocated during the 2009 pandemic flu response and through the Recovery Act helped to provide some support but did not address the need to build a sustainable capacity for a large-scale response.

The erosion of the State and local public health infrastructure and workforce leaves us at risk of not being adequately prepared to have the basic capabilities to meet time-sensitive goals of dispensing medical countermeasures.

I look forward to hearing specific effects that you might feel would be impacting your area based upon the cuts that have been proposed. We, in Congress, must assure you and provide the support you deserve to address these health challenges. Inadequate emergency health preparedness puts our Nation at risk, and we must be resolved now, prior to being tested by another large-scale emergency.

In addition to funding issues, I would like to hear about the lessons learned from the 2009 H1N1 response and what is being done to protect our at-most-risk populations, especially children in schools and daycare centers.

Again, I thank you for being here today, and I look forward to your testimony.

Mr. BILIRAKIS. Thank you very much.

Others Members of the subcommittee are reminded that opening statements may be submitted for the record.

Before I introduce our first panel, I ask unanimous consent to insert in the record a statement from the National Association of Chain Drug Stores.

Without objection, so ordered.

[The information follows:]

STATEMENT OF THE NATIONAL ASSOCIATION OF CHAIN DRUG STORES

MAY 12, 2011

NACDS thanks the committee for the opportunity to submit a statement for the hearing on "Taking Measure of Countermeasures: A Review of Efforts to Protect the Homeland Through Distribution and Dispensing of CBRN Medical Countermeasures." Rapid access to medical countermeasures is critical for preventing and treating illness caused by public health emergencies. As the Institute of Medicine reported, public health cannot do this job alone—collaboration from the private sector will be necessary to reach large numbers of people in the community. NACDS, its member companies, and the 120,000 dedicated pharmacists who work in community pharmacies are uniquely equipped and stand ready to assist policymakers and public health officials at all levels of government in ensuring convenient access to countermeasures in a medically-relevant time frame following an emergency.

The National Association of Chain Drug Stores (NACDS) represents traditional drug stores, supermarkets, and mass merchants with pharmacies—from regional chains with four stores to National companies. Chains operate 39,000 pharmacies, and employ more than 2.7 million employees, including 118,000 full-time pharmacists. They fill nearly 2.6 billion prescriptions annually, which is more than 72 percent of annual prescriptions in the United States. The total economic impact of all retail stores with pharmacies transcends their $830 billion in annual sales. Every $1 spent in these stores creates a ripple effect of $1.96 in other industries, for a total economic impact of $1.57 trillion, equal to 11 percent of GDP. NACDS represents 137 chains that operate these pharmacies in neighborhoods across America, and NACDS members also include more than 900 pharmacy and consumer packaged goods suppliers and service providers, and over 60 international members from 23 countries. For more information about NACDS, visit *www.NACDS.org*.

ENGAGE THE PRIVATE SECTOR IN COUNTERMEASURE DISPENSING

Experts in emergency preparedness have reported that most communities lack adequate mechanisms and capacity in public health to expeditiously dispense countermeasures to all of the target populations following a public health emergency. Various dispensing modalities have been discussed, including home delivery by the U.S. Postal Service, the development of Points of Dispensing (PODs) and pre-positioning of medications in households, among others.

Policymakers should be encouraged to engage the Nation's community pharmacies as primary PODs to help extend the reach of public health. Put simply, dispensing is a normal pharmacy function; nearly 2.6 billion prescriptions are filled in community pharmacies annually. Pharmacists are among the most accessible health providers, and most Americans live within 5 miles of a community pharmacy. In a July 2009 PriceWaterhouseCoopers survey, respondents reported the least amount of difficulty in accessing care from pharmacists. In addition, pharmacists are highly trusted health care professionals, and have rated in the top three in each of the past 8 years in Gallup's survey of integrity across professions. Pharmacists also have the advantage of being able to administer vaccinations in all 50 States. More than 100,000 pharmacists Nation-wide are qualified to administer vaccinations.

PHARMACIES: EXTENDING THE REACH OF PUBLIC HEALTH

The value of community pharmacies in extending the reach of public health has clearly been recognized by Federal officials and State public health officials following their active participation in the response following Hurricane Katrina and during the 2009 H1N1 influenza pandemic. Pharmacists have performed a range of services to targeted patient populations following emergencies, including dispensing countermeasures, administering vaccines, patient screening and triage, education of the public, and monitoring for adverse events. Pharmacies have existing technological infrastructures that can be leveraged to triage patients, have lot space to accommodate surges in patient demand, and sell personal protective equipment and medical supplies that may also be important in preventing or treating CBRN threats. An increasing percentage of pharmacies have drive-through windows that can augment patient throughput and assist with social distancing to prevent infectious exposure.

Pharmacy Engagement During H1N1 Influenza Pandemic

The 2009 H1N1 vaccination campaign was the largest such undertaking in history, requiring broad coordination across the entire health care continuum to increase the number of vaccine providers. NACDS and its members were actively engaged in the planning and execution of public health H1N1 influenza response.

NACDS convened a stakeholder workgroup meeting that produced the *Operational Framework for Partnering with Pharmacies for the Administration of 2009 H1N1 Vaccine,* published by the Association of State and Territorial Health Officials, which served as guidance for the relationship between community pharmacies and State public health planners. The Framework included a template "provider agreement" between public health and community pharmacies, and a template "executive order" proposing emergency amendments to expand State-level use of community pharmacies in H1N1 vaccination programs. As a result of the framework, community pharmacies enrolled broadly in State vaccine provider networks. Several States also issued emergency orders to expand the ability of pharmacists to administer H1N1 vaccine, by lowering age limits and streamlining vaccination protocols. While the vaccine was first available in October 2009, many pharmacies did not start receiving them from State and local health departments until November or December.

In December 2009, the Centers for Disease Control and Prevention (CDC) launched the H1N1 Vaccine Retail Initiative to supplement State and local public health vaccination efforts. Through this program, CDC partnered with retail pharmacies and retail clinics to directly provide H1N1 vaccine. Ten retail pharmacy chains participated, totaling 10,700 retail locations served. These pharmacies received over 5.4 million doses of 2009 H1N1 vaccine directly from CDC. All told, 10% of 2009 H1N1 influenza vaccinations were provided in a community pharmacy location.

Pharmacies were also the primary provider of countermeasures to H1N1 influenza, including Tamiflu and Relenza. The shortage of commercially manufactured Tamiflu oral suspension—an important treatment for high-priority pediatric patients—necessitated that trained pharmacy personnel compound the product with guidance from the Food and Drug Administration (FDA) and CDC. The unique skill set of pharmacists make them well-prepared to compound countermeasures into a formulation that can be used by the most vulnerable populations.

Preserving Adherence to Chronic Medications

In addition to rapid access of countermeasures, it is critical that patients continue to access life-sustaining medicines for chronic conditions such as diabetes, high blood pressure, or respiratory disorders during public health emergencies. This problem, known as poor "medication adherence" is a well-documented, enduring challenge to achieving positive outcomes in patients with chronic disease. The New England Healthcare Institute (NEHI) estimated that poor medication adherence in all its manifestations costs the Nation $290 billion annually—13% of total health care expenditures—resulting from a worsening of disease, avoidable hospitalizations, and emergency room visits. Preserving patient medication adherence can mitigate patient surges at hospitals and emergency rooms, which may free up these venues to focus on the most at-risk patients. Utilizing pharmacies as PODs may reinforce the message that patients must continue the safe and appropriate use of their chronic medications during public health emergencies.

MAXIMIZING PHARMACY PARTICIPATION IN PUBLIC HEALTH EFFORTS

Community pharmacy support of public health programs has led to partnerships that have significantly improved patient care, but also has involved on-going challenges. During the H1N1 influenza pandemic, the wide variety of State and local processes and restrictions added complexity to community pharmacy support and we would recommend a more uniform process in the future. Aligning processes in and across States for ordering products, claims process, reimbursement, inventory monitoring, vaccine regulations, and reverse distribution would serve to enhance the ability of pharmacies to participate in public health campaigns. Policymakers must also address liability issues related to employing rapid countermeasure dispensing models. To enhance preparedness and response to any CBRN attack, it is critical that any National medical countermeasure dispensing strategy actively engage private sector partners—including community pharmacies—to address these issues prior to an attack.

CONCLUSION

NACDS thanks the committee for consideration of our comments on efforts to engage pharmacies in countermeasure dispensing. As the face of neighborhood health care, community pharmacies remain committed to assist public health efforts to protect our citizens through convenient access to countermeasures. We look forward to working with Congress and the public health community to ensure the Nation's community pharmacies are used to the greatest extent possible.

Mr. BILIRAKIS. I am pleased to welcome our witnesses.

Our first witness is Dr. Alexander Garza. Dr. Garza is the Assistant Secretary for Health Affairs and Chief Medical Officer of the Department of Homeland Security. He manages the Department's medical and health security matters, oversees the health aspects of contingency planning for all chemical, biological, radiological, and nuclear hazards, and leads a coordinated effort to ensure that the Department is prepared to respond to biological and chemical weapons of mass destruction.

Prior to joining the Department in August 2009, Dr. Garza spent 13 years as a practicing physician and medical educator. He most recently served as the Director of Military Programs at the ER One Institute at the Washington Hospital Center and has served as the Associate Medical Director of Emergency Medical Services for the State of New Mexico and Director of EMS for the Kansas City, Missouri, Health Department.

Dr. Garza holds a medical degree from the University of Missouri Columbia School of Medicine, a master's of public health from the St. Louis University School of Public Health, and a bachelor's degree of science and biology from the University of Missouri-Kansas City.

Prior to earning his medical degree, he served as a paramedic and an emergency medical technician. He is a fellow of the American College of Emergency Physicians and a member of the American Public Health Association.

Welcome, Dr. Garza.

Our next witness is Rear Admiral Ali Khan. Dr. Khan is the Assistant Surgeon General and Director of the Centers for Disease Control and Prevention's Office of Public Health Preparedness and Response, a position he assumed in August 2010. In his capacity, Dr. Khan leads the CDC's efforts to prepare for and respond to public health threats and manages the Strategic National Stockpile.

Dr. Khan joined CDC and the U.S. Public Health Service Commission Corps in 1991. Over the course of his career, Dr. Khan has focused on bioterrorism, global health, and emerging infectious diseases and serves as one of the main architects of the CDC's Public Health Bioterrorism Preparedness Program.

Dr. Khan received his medical degree from Downstate Medical Center in Brooklyn, New York, and completed a joint residency in internal medicine and pediatrics at the University of Michigan—Ann Arbor. He has a master's of public health from Emory University, where he also serves as an adjunct professor.

Welcome.

Your entire written statements will appear in the record. I ask that you each summarize your testimony for 5 minutes.

We will start with Dr. Garza. Thank you.

STATEMENTS OF ALEXANDER G. GARZA, MD, MPH, ASSISTANT SECRETARY FOR HEALTH AFFAIRS, CHIEF MEDICAL OFFICER, DEPARTMENT OF HOMELAND SECURITY

Dr. GARZA. Thank you, sir.

Good afternoon, Chairman Bilirakis, Ranking Member Richardson, and distinguished Members of the subcommittee. Thank you for inviting me to testify before you today. It is an honor to be here

to discuss the Office of Health Affairs programs that support the Department of Homeland Security's efforts in medical countermeasures.

Today I will discuss a number of OHA initiatives that help to mitigate biological threats and help prepare the Nation to detect and respond to a biological incident. I will also speak about how DHS coordinates with State and local governments, how our activities were related to the Executive Order No. 13527, and how we worked to ensure to a resilient DHS workforce.

OHA supports and coordinates with our Federal partners, especially the Centers for Disease Control and Prevention and the Food and Drug Administration, on medical countermeasure issues. OHA works closely with the DHS Science and Technology Directorate to assess current and emerging chemical, biological, radiological, and nuclear risks to the United States population.

The threat of an attack using a biological agent is real and requires vigilance. A wide-area attack using Bacillus anthracis is one of the most serious biological threats facing the United States. However, even a small, well-coordinated biological attack will have significant consequences.

The Federal Government has recognized that, in order to minimize the effects of such an attack, two critical capabilities must be in place: First, the Nation must be able to rapidly determine that an attack has occurred before people become ill. Second, we must have the capability to rapidly distribute medical countermeasures to the affected population.

Through early detection via our BioWatch system, OHA works to mitigate the consequences of a biological incident. BioWatch is a Nation-wide environmental surveillance system that detects the release of selected aerosolized biological agents of concern. Early detection give decision-makers the capability to act to protect their communities by providing medical countermeasures in a timely fashion, with the goal of saving lives.

Through the BioWatch program, we have essentially built local biodefense capability by expanding public health participation in, and coordination with, the National network of BioWatch jurisdictional advisory committees as well as local fusion centers.

In addition, OHA provides health and medical expertise in planning and exercise efforts that advance National preparedness and response capabilities. In 2009, Secretary Napolitano directed OHA to develop the Anthrax Response Exercise Series. These were comprehensive anthrax response exercises that have been conducted in each of the 10 FEMA regions in coordination with State and local governments. OHA has also led efforts to provide our State and local partners with guidance for the protection of personnel responding to a wide-area anthrax attack.

On December 30, 2009, President Obama signed Executive Order 13527 establishing Federal capability for the timely provision of medical countermeasures following a biological attack. OHA participated in all aspects of the response for DHS to this Executive Order and is the lead office for the Department's efforts on section 4, which directs Federal agencies to establish mechanisms for the provision of medical countermeasures to personnel to ensure the continuity of mission-essential functions.

In addition, the Department and HHS have the responsibility to develop a plan to provide medical countermeasures to mission-essential personnel to ensure the continuity of operations. We lead this efforts for DHS, and we set the stage for the Federal interagency.

The Department builds National resilience by ensuring the protection of our workforce. Due to the nature of our workforce's security mission, DHS personnel could be exposed during response activities or in their interactions with the millions of people they meet every day at airports, ports of entry, to name a few.

As previously discussed, individuals exposed to anthrax spores must be protected in a timely manner. Added to this is the understanding that a biological attack is an act of terrorism. These issues underlie the importance of the Department's plans to preposition medical countermeasures in caches across the country for our workforce.

We have spearheaded the MCM strategy and oversee the purchase and storage of our countermeasures for our workforce. This strategy includes all of our employees and personnel, as well as those in care and custody of DHS. We collaborate with offices across the Department to assure the Department-wide strategy is met.

We are following the Secretary's directive to lead by example and continue to work on developing strategies to make sure countermeasures are available to support our mission-critical functions.

I thank you again for the opportunity to testify today, and I look forward to any questions that you may have. Thank you.

[The statement of Dr. Garza follows:]

PREPARED STATEMENT OF ALEXANDER G. GARZA

MAY 12, 2011

Good afternoon, Chairman Bilirakis, Ranking Member Richardson, and distinguished Members of the subcommittee. Thank you for inviting me to testify before you today. It is an honor to be here to discuss the Office of Health Affairs' (OHA) programs that support the Department of Homeland Security's efforts in medical countermeasures (MCM) distribution and dispensing.

Today I will discuss a number of OHA initiatives that help to mitigate biological threats and help prepare the Nation to quickly detect and respond to a biological attack. I will also speak about how DHS assists and coordinates with State and local governments, our activities relating to Executive Order (E.O.) 13527, and how we work every day to ensure a resilient Nation and DHS workforce.

OHA Initiatives That Help Mitigate Biological Threats and Help Prepare the Nation to Quickly Detect and Respond to Biological Events

OHA supports and coordinates routinely with our Federal partners, especially the Department of Health and Human Services (HHS), including the Assistant Secretary for Preparedness and Response (ASPR), the Centers for Disease Control and Prevention (CDC), and the Food and Drug Administration (FDA), on medical countermeasures issues. OHA and the DHS Science and Technology Directorate (S&T) represent DHS as ex officio members of the HHS-led interagency Public Health Emergency Medical Countermeasures Enterprise Senior Council, which is the primary conduit for communication among entities involved in the MCM mission.

OHA also works closely with S&T, which has the DHS lead to assess current and emerging threats that occur naturally or are chemical, biological, radiological, or nuclear agents, and to determine which agents present a significant threat to the U.S. population. S&T produces the Bioterrorism Risk Assessment (BTRA), a strategic assessment of bioterrorism risk, updated biennially, that integrates the findings of the intelligence and law enforcement communities with input from the scientific, medical, and public health communities. OHA provides subject matter expertise to S&T

in developing the BTRA, and has worked closely with the BTRA program managers to develop tailored assessments designed to address specific knowledge gaps or areas of uncertainty identified within OHA programs. OHA applies these assessments when operating, managing, and supporting the Department's biodefense programs.

The threat of an attack using a biological agent is real and requires that we remain vigilant. A wide-area attack using aerosolized *Bacillus anthracis,* the bacteria that causes anthrax, is one of the most serious mass casualty biological threats facing the United States. An anthrax attack could potentially encompass hundreds of square miles, expose hundreds of thousands of people, and cause illness, death, fear, societal disruption, and economic damage. If untreated, the disease is nearly 100 percent fatal, which means that those exposed must receive life-saving MCM as soon as possible.

The Federal Government recognizes two critical capabilities must be in place in order to minimize the effects of a biological attack. First, the Nation must be able to rapidly determine that an attack has occurred. Second, we must have the capability to quickly distribute MCM to the entire affected population before clinical symptoms appear.

Through early detection, OHA works to mitigate the consequences of a biological incident. OHA's Biowatch program is a Federally managed, locally operated, Nationwide environmental surveillance system that detects the release of certain aerosolized biological agents before exposed individuals develop symptoms of illness. This "detect to treat" approach provides the public health community with an opportunity to respond to a release of a biological agent as quickly as possible in order to mitigate the potentially catastrophic impact on the population. Early detection allows communities to provide medical countermeasures to affected persons in a timely manner in order to save more lives.

For this reason, OHA is investing in the development of advanced detection technology that aims to significantly reduce the time between a release of a biothreat agent and confirmation of the release by Biowatch technology. The transition to an automated detection system, called "Generation 3", is intended to confirm a release within 4 to 6 hours in the locations that Biowatch covers. Reducing the time it takes to properly detect and confirm a release is critical because earlier detection allows for earlier distribution of lifesaving MCM to effectively protect the exposed population.

DHS Assists and Coordinates with State and Local Governments

OHA works directly with State and local leaders to develop capabilities to respond to health threats. We have done this by expanding local public health participation in, and coordination with, the National network of BioWatch jurisdictional advisory committees as well as State and urban area fusion centers.

Furthermore, OHA provides health and medical expertise to planning and exercise efforts that advance National preparedness and response capabilities. To increase preparedness for and resilience to biological threats, Secretary Napolitano initiated the Anthrax Response Exercise Series (ARES) exercises, which are comprehensive anthrax response exercises conducted in each of the 10 Federal Emergency Management Agency (FEMA) regions in coordination with State and local governments. Completed in fall 2010, the ARES series was valuable to State, local, and regional stakeholders for a number of reasons. It increased awareness in the areas of biodetection, notification, and early response protocols. It also provided the opportunity to combine exercise program requirements (biodetection strategies, including BioWatch and State exercise plans) while engaging both large and small metropolitan areas throughout the United States.

ARES successfully provided an opportunity for Federal, State, local, and regional partners to come together and better understand their roles and responsibilities supporting biodetection, notification, and response. ARES created an opportunity for all levels of government to define and refine their MCM programs and plans. We plan to continue to build on the success of ARES by conducting workshops in additional cities for 2011 and 2012.

In addition to ARES and other exercise activities that allow State and local governments to strengthen their National response capabilities, OHA also provides our State and local partners with guidance for protection of personnel responding to a wide-area anthrax attack. Through the Federal interagency process, OHA led the effort to develop consensus guidance regarding appropriate protective measures for responders in the immediate post-attack environment of an aerosolized anthrax attack. The guidance reflects the most current understanding of the unique environment that would exist after a wide-area anthrax release. The guidance is a prudent step to provide to first responders the best information on protective measures cur-

rently available. The responder community had requested guidance in this area, and DHS and Federal partners are committed to continually updating the guidance to ensure that it reflects the best science.

Executive Order 13527: Establishing Federal Capability for the Timely Provision of Medical Countermeasures Following a Biological Attack

In addition to assisting and coordinating with State and local governments, OHA also actively engages in Federal interagency efforts to strengthen the Nation's ability to prepare for, respond to, and recover from natural disasters and terrorist attacks. On December 30, 2009, President Obama signed Executive Order (E.O.) 13527, "Establishing Federal Capability for the Timely Provision of Medical Countermeasures Following a Biological Attack." The E.O. seeks to mitigate illness and prevent death, sustain critical infrastructure, and complement State, local, territorial, and Tribal government MCM distribution capacity.

Section 2 of the E.O. directs the development of a National United States Postal Service (USPS) MCM dispensing model for U.S. cities to respond to a large-scale biological attack. This model has the capacity for rapid residential delivery of MCM for self administration across all U.S. communities. In collaboration with the Departments of Justice, Defense, HHS, and USPS, DHS supported the development of the USPS model. Upon request, DHS will assist State and local governments through Emergency Support Function (ESF)–13 to provide required law enforcement support for the U.S. Postal model in those jurisdictions considering this modality of distributing MCM.

Section 3 of the E.O. directs the development of a Federal rapid response capacity to supplement State and local governments and the private sector's capabilities to deploy MCM. This effort is being co-led by FEMA and ASPR, and OHA has provided subject matter expertise.

Section 4 of the E.O. directs Federal agencies to establish mechanisms for the provision of MCM to personnel to ensure that the mission essential functions of the Executive branch departments and agencies continue to be performed following a biological attack. In addition, the Department and HHS have the responsibility to develop a plan to provide MCM directly to mission-essential personnel to ensure continuity of operations. OHA leads this effort for DHS. We are pleased to say that DHS is among the first Federal agencies to have met this requirement of the E.O.

In April 2010, DHS established the Anthrax Preparedness and Response Steering Committee to develop specific products to improve preparedness and response efforts that include the activities mandated in the E.O. The Steering Committee leads the Department's efforts in enhancing readiness and immediate response in the event of wide-area aerosolized anthrax attack and includes senior leaders from across the Department.

DHS Workforce and Health Protection OHA works each day to build resilience across the country and within the Department. We do so by leading and strengthening our Nation's collective efforts to secure our country from the threats we face. We also build resilience by ensuring the protection of our workforce, as mandated in Section 4 of the E.O.

In Section 4, the President ordered the Federal Government to establish mechanisms for the provision of MCM to personnel performing mission-essential functions. Secretary Napolitano further directed the Department to develop a plan and seek funding for a capacity to provide emergency antibiotics to all DHS employees in an attacked area, not just those who are mission-essential.

The DHS workforce includes a wide variety of mission-essential personnel who work in varying geographical locations throughout the United States and internationally. Due to the nature of DHS workforce's security mission, some DHS personnel could be exposed during response activities or in their interactions with millions of people each day at airports and ports of entry.

As previously discussed, individuals exposed to anthrax spores can survive if they take antibiotics quickly, underlining the importance of the Department's plans to pre-position MCM in caches across the country for employees. In the event of an anthrax attack, all affected DHS personnel and their families will also have access to MCM through existing community MCM dispensing plans.

OHA spearheaded an MCM strategy for DHS employees and oversees the purchase and storage of MCM for the DHS workforce. This includes all employees and personnel and individuals in the custody and care of DHS. The MCM strategy and implementation plan is a multi-year, multi-layered approach which consists of four phases, each building upon the previous and is subjected to the availability of funding to achieve its goal of covering the entire DHS workforce. This scalable approach will ensure the sustainability of the program.

The goal of the first phase is to protect and mitigate the effect of an anthrax exposure by delivering MCMs post-event to employees. This phase is currently underway. We purchased courses of MCM that are stored at a central location and at regional locations to cover Federal employees and those in DHS's care and custody. OHA, in coordination with DHS components, identified accessible and secure facilities for storage of MCM. Additional cache locations will be identified over time to improve coverage and proximity to employees. OHA also builds points of dispensing capability to dispense MCM as needed by providing training to appropriate personnel.

Leading by example and pushing forward the Federal interagency effort for MCM dispensing and distribution, OHA collaborates routinely with various offices within DHS to ensure synergistic efforts in implementing this Department-wide strategy. OHA provided guidance and comprehensive planning information to DHS components through the Anthrax Operations Plans Department Guidance Statement (DGS). We also provide medical guidance and logistical and operational support to DHS component offices as they finalize their MCM plans. To supplement the DGS, OHA has also provided medical guidance in the form of Standard Operating Procedures, including for storage of MCM, administration of MCM for anthrax spore exposure, non-medical points of dispensing for MCM, and working and service animal anthrax spore exposure. OHA is now in the process of credentialing DHS personnel who will provide the medical oversight of MCM storage and dispensing.

Among the first departments to fulfill the mandates required by the E.O., OHA is also sharing lessons learned and coordinating with the interagency process to ensure the consistency of plans across the Federal Government, including our partners at HHS, CDC, and FDA. Along with ASPR, we co-chair a working group to protect mission-essential employees of Executive branch departments and agencies in the event of a wide-area aerosol anthrax attack.

Conclusion

OHA manages and oversees the DHS MCM program and works to mitigate biological threats by preparing the Nation to quickly detect and respond to a biological attack through early detection and rapid distribution of MCM. DHS leads and strengthens our Nation's collective efforts to secure our country from threats, assisting and coordinating with State and local governments, and helping to ensure a resilient DHS workforce. Thank you again for the opportunity to testify today. I look forward to any questions that you may have.

Mr. BILIRAKIS. Thank you.

Dr. Khan, welcome, sir.

STATEMENT OF REAR ADMIRAL ALI S. KHAN, MD, MPH, DIRECTOR, OFFICER OF PUBLIC HEALTH PREPAREDNESS AND RESPONSE, CENTERS FOR DISEASE CONTROL AND PREVENTION

Dr. KHAN. Good afternoon. Thank you for the invitation to address the subcommittee today. My remarks will focus on the role of the medical countermeasures, including the CDC's Strategic National Stockpile, to protect the public's health and, ultimately, our Nation's security.

I would like you all to imagine a 5-pound bag of sugar. Instead of sugar, let's imagine that it is full of anthrax spores. Now, while the anthrax bacterium is a naturally occurring organism, there is nothing natural about well-produced anthrax spores. In 2001, these anthrax spores were mailed to news reporters and U.S. Senators, and you know better than most of the world about anthrax and the risk of anthrax and how real it is. I had the opportunity and privilege to serve here for 3 months during those attacks in Washington, DC.

Now, these attacks involved letters which held just one gram of powdered spores, about the amount in a sugar packet. Yet, 22 people were infected and 5 died. In comparison, an equivalent of this

5-pound bag that I mentioned earlier could infect 100,000 people or more.

If that were to occur, every hour of delay in pretreating these people with antibiotics will lead to not just increased illness and death but also social, political, and economic disruption, as we saw with the limited attack in 2001. Given this, it is quite clear that this is a National health security issue.

That is why the Strategic National Stockpile is such a vital resource for us here in the United States for the American people. Fortunately for us, CDC, DHS, and Federal, State, and local partners are working diligently to make sure that, if such an attack would ever occur, our Nation would be ready to minimize disease and loss of life—ready to rapidly detect and identify disease in our communities, ready to quickly deploy these lifesaving countermeasures from CDC's Strategic National Stockpile, ready to mitigate the attack, and ready to assess the effectiveness and safety of our public health interventions.

Now, to be ready, we require an entire public health system to use these medical countermeasures for the people who need them most. This public health system includes public health nurses, disease detectives, lab workers, who are essentially helping protect health every day from threats.

During an emergency, CDC also must be able to provide clinical guidance, track these medical countermeasures and how they are used, and monitor adverse events. Thus, to protect our National health security, CDC goes beyond stockpiling and delivering medical countermeasures. We support our State and local partners to help them build their capabilities and abilities to distribute, dispense, and utilize those assets, recognizing that all response is essentially local. We provide approximately $600 million in funding and technical assistance to our State and local partners to help them develop tests to improve their public health preparedness capability, including this distribution and dispensing of medical countermeasures.

In my visit to States, including the States represented by the two of you, I have seen really visible, measurable improvements in preparedness in multiple areas, specifically incident management, laboratory capabilities, and risk communications. Throughout the Nation, we have seen the value of this investment in public health in how much better we were able to respond to H1N1 than if we had not made that investment.

Now, public health preparedness is a dynamic process, and we must remain responsive to both the changing threats out there and the environment. To do this, we work very closely with our Federal partners. DHS is one of our strongest partners. We work together on deciding the best medical countermeasures to have ready, developing new lab tests, including for BioWatch that you just heard, and improving our ability to utilize medical countermeasures better than we currently do.

Now, it is important for us to be very innovative in this time, to make sure that we have rapid, efficient, and cost-effective ways to protect our National health security. Since—you referenced—the meeting in January 2010, we are reconsidering the number of SNS storage sites to have drugs more available to people rapidly; we are

phasing out legacy perhaps for more efficient programs; we are continuing to examine the formulary of the SNS, specifically for drug-resistant anthrax; and we are thinking about stretching the amount of countermeasures we have by using various studies to look at using different amounts of those existing countermeasures.

So, in the end, let me say, we cannot control when or where an outbreak pandemic or natural disaster, terrorist attack may occur to threaten the public's health, but we can control how we respond to it. This is an issue of National health security for us.

I thank you again for the invitation to testify before you today, and I will be happy to answer any questions you may have.

[The statement of Dr. Khan follows:]

PREPARED STATEMENT OF ALI S. KHAN

MAY 12, 2011

INTRODUCTION

Good afternoon, Chairman Bilirakis, Ranking Member Richardson, and Members of the subcommittee. I am Dr. Ali Khan, an Assistant Surgeon General and Director of the Office of Public Health Preparedness and Response, at the Centers for Disease Control and Prevention (CDC). Thank you for the invitation to address the subcommittee today. My remarks will discuss the role of medical countermeasures (MCM), including the CDC Strategic National Stockpile (SNS), in strengthening our Nation's public health preparedness and response, and ultimately our Nation's health security.

BACKGROUND

Threats to the public's health are always present. These threats can range from a local food-borne disease outbreak to the tornadoes that devastated the southeastern United States 2 weeks ago to the anthrax attacks in the fall of 2001. We cannot control when or where an outbreak, pandemic, natural disaster, nuclear incident, or terrorist attack may occur and threaten the public's health, but we can control how we respond to it. Threats to public health are threats to the Nation's health security.

Because of its unique abilities to respond to infectious, occupational, or environmental incidents, CDC plays a pivotal role in ensuring that State and local public health systems are prepared for public health emergencies. CDC provides funding and technical assistance for State, local, Tribal, and territorial public health departments through the Public Health Emergency Preparedness (PHEP) cooperative agreement. PHEP cooperative agreement funding provides approximately $700 million annually to 50 States, four localities, and eight U.S. territories and freely associated States for building and strengthening their abilities to respond to public health threats.

The same systems that we use to meet everyday public health needs are at the core of public health preparedness and response for unforeseen and unpredictable public health threats. State and local surveillance and epidemiologic investigations allow us to detect an emerging health threat and assess its scope, and laboratories identify and characterize the biological, chemical, or radiological agent causing it. The public health workforce at the State, local, and Federal levels uses information from these resources to make decisions about how to respond to a public health emergency. In some cases, responding involves the use of MCM to protect or treat people who have been exposed, infected, or injured, or to protect the health care workers and others responding to the incident such as first responders and critical infrastructure personnel.

The SNS is a National repository of MCM. It contains antibiotics, antiviral drugs, chemical antidotes, antitoxins, vaccines, life-supporting medications, and medical supplies that are available to State and local health departments during a public health emergency and when local supplies are depleted or unavailable. The specific MCM in the SNS formulary for response to CBRN events are based largely on assessments by HHS of the need for MCM to address material threats to National security identified by Department of Homeland Security (DHS).

The SNS is a vital and valuable resource for protecting the American people. Many threats against the public health component of National security are from

chemical, biological, radiological, or nuclear (CBRN) agents for which there are few, if any, commercially available life-saving MCM. The SNS is, in many cases, the only viable purchaser and holder of necessary quantities of these scarce materials which are vital for a successful response to many incidents.

As important as the National capability to obtain and hold these MCM is, the success of health security interventions of the SNS depends on several factors. These include the detection and characterization of an event to the timely delivery of these assets to the site of an incident to the local plans for receiving, distributing, and dispensing them in the communities. The SNS has developed, tested, and used pathways to accomplish these goals. CDC's job is not finished, and the SNS continues to work towards more rapid, efficient, and cost-effective ways to accomplish this mission.

IMPORTANCE OF STATE AND LOCAL PARTNERSHIPS

CDC is working to continually improve our capability to deliver SNS assets to affected areas during a public health emergency. This work has led to the recent reformulation of the 12-hour push packages—assets designed to provide a broad spectrum of potentially beneficial interventions in the early hours of an emergency when we do not have complete information—that expanded the capability of each 12-hour push package for use in response to a biological incident, such as an anthrax release. CDC has also increased the number of storage locations to allow for better and faster distribution across the country. The result is that the SNS can deliver large amounts of MCM anywhere in the United States and the U.S. territories in a very short window of time, and CDC continues to work to decrease that time window even further.

Getting these products to the people who need them during an emergency depends on sufficient infrastructure and planning at the State and local levels. CDC goes beyond stockpiling and delivering SNS MCM assets to supporting our partners at the State and local levels to develop and refine their abilities to effectively receive and utilize MCM delivered from the SNS. CDC is also exploring innovative ways to dispense them to communities by cultivating strong collaborative partnerships among planners, emergency responders, and businesses at the State and local levels. CDC supports these partners by providing funding through the PHEP cooperative agreement, technical assistance, distribution plans, and performance measurement consultation.

CDC provides technical assistance to State and local health departments on receiving and dispensing SNS and other medical assets. This assistance includes written guidance, on-site and video teleconference consultations, training and exercise support (e.g., workshops, National training summit, tools to design and test response plans), and direct assistance of CDC personnel at State health departments. Just as the nature and contents of the SNS have evolved over time, the guidance, assistance, and support CDC offers to States have also adapted to changing needs. SNS Program Services Consultants (Consultants) are CDC employees available to support States and localities that receive PHEP cooperative agreement funding to engage the SNS. SNS Consultants regularly provide direct, on-site technical assistance to State and local personnel on interpreting guidance, developing and refining plans, conducting training and exercises, and evaluating capabilities and performance. SNS Consultants are backed up by dedicated training, exercise, and response teams from CDC that conduct regular training in Atlanta and provide on-site training and exercise support to States.

State and local public health responders depend on the implementation of emergency contracts and, in some cases, mobilization of volunteer workforces to distribute MCM during an event. CDC recognizes that volunteers are critical to the final dispensing of MCM and sponsors grant-funded pilot studies of innovative means to recruit volunteers. All of these functions feed into the on-going development of the capabilities critical to the effective dispensing of MCM to the communities of each State.

Every State maintains plans to receive, distribute, and dispense MCM received from the SNS. These plans are all unique and account for the local infrastructure and supporting Government and commercial partnerships at the State and local levels. These plans are evaluated and exercised by the SNS coordinators at the State and local levels and reviewed by the SNS Consultants as part of annual reviews. To facilitate the improvement of plans and aid in the development of new capabilities, CDC maintains several forums to actively share promising practices and innovative concepts and foster discussions among SNS Consultants and State and local staff. CDC has also developed several modeling tools that facilitate planning at the

Federal, State, and local levels, providing officials with ways to evaluate plans without resource-intensive drills or exercises.

To evaluate the effectiveness of each State's plans to use MCM, SNS Consultants conduct regular Technical Assistance Reviews (TARs) at least annually to ensure continued readiness. These reviews use an objective, quantitative scoring framework to assess plans for receiving, distributing, and dispensing SNS assets. CDC conducts these reviews at the State, local, and territorial levels and provides each level with a tool to help them identify gaps in their plans.

The purpose of this technical assistance and performance measurement consultation is to ensure that each State and local health department has the ability to utilize SNS MCM assets during the window where it would make a difference from a public health standpoint. Because different incidents require different modes of dispensing and different timelines for effective treatment, CDC has established a flexible framework for the delivery of MCM from the SNS, through partnerships with air and ground transportation providers, from a network of storage locations. Within this framework, CDC staff can ensure the best combination of location and method of transportation to support the delivery of MCM within the required time frame.

During the 2009 H1N1 influenza pandemic response (April 2009 to spring 2010), there was a clear need to provide antiviral drugs and personal protective equipment to minimize illness and death. The SNS distribution planning and MCM holdings helped CDC to rapidly deploy large quantities of key medical assets, including 11 million regimens of antiviral drugs as part of the deployment of 25% of pro rata allocations of pandemic influenza MCM, including personal protective equipment to all U.S. States and territories. CDC also released 300,000 bottles of Tamiflu® oral suspension for pediatric use to fill production gaps and meet increasing demand. Later, SNS distributed 234,000 additional bottles of the suspension to all U.S. States and territories. HHS also authorized the release of 59.5 million N95 respirators from the SNS to all U.S. States and territories that requested them. The SNS achieved all planned timelines for this distribution.

Lessons learned from real-world events such as the 2009 H1N1 influenza pandemic response and on-going work with the SNS have been applied to a broad range of public health problems. For example, California relied on its extensive public health preparedness, planning, and training to distribute and dispense MCM to respond to an outbreak of pertussis, or whooping cough, in 2010.[1] Surveillance systems first brought the increase in the number of cases among pediatric hospital patients to the attention of the California Department of Public Health (CDPH) in early 2010. To prevent transmission of pertussis to vulnerable infants, CDPH offered free vaccine and encouraged hospitals and local health departments to support vaccination of new mothers and newborn caregivers. County public health departments across California applied elements of SNS planning and public health preparedness to develop and disseminate educational materials and clinical guidance, raise community awareness, and set up accessible and innovative vaccine dispensing points, from mobile clinics to grocery stores, to reach their communities. The success of this response can be attributed to not only prior SNS planning among CDC, State, local, and private partners, but also the capability of the public health workforce in counties across California to receive and administer the vaccine in a timely manner.

FEDERAL PARTNER COLLABORATION

CDC collaborates with Federal partners on several MCM efforts. The Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) is a coordinated interagency effort to define and prioritize public health emergency MCM requirements, focus research, development, and procurement activities for identified requirements, and establish deployment and use strategies for MCM in the SNS. PHEMCE is led by the HHS Office of the Assistant Secretary for Preparedness and Response (ASPR) and includes key Federal interagency partners, including DHS. Together, the PHEMCE partners work to optimize our preparedness for public health emergencies with respect to the creation, stockpiling, and use of MCM.

CDC also collaborates with ASPR and other Federal partners on the interagency implementation of Executive Order 13527, "Establishing Federal Capability for the Timely Provision of Medical Countermeasures Following a Biological Attack." CDC is currently looking at ways to further reduce the time required to deploy assets at the Federal level and to better understand the costs associated with these changes,

[1] CDC. Notes from the Field: Pertussis—California, January—June 2010. MMWR June 9, 2010; 59(26):817.

particularly at the State and local levels, where resources are limited. CDC subject matter experts have participated in DHS- and ASPR-led interagency working groups to generate the planning documents required by the Executive Order. Through these working group interactions, CDC is addressing the public health issues associated with the implementation of the Executive Order. These collaborative efforts with DHS have resulted in plans to respond that will better protect the public's health.

CDC is also working with Federal partners to optimize the use of MCM. For example, CDC is collaborating with DHS and the Food and Drug Administration (FDA) to establish a process to validate laboratory methods that will enable the public health community to respond effectively and appropriately. This process will be used in the Laboratory Response Network, which is managed by CDC. CDC is also working with the Biomedical Advanced Research and Development Authority (BARDA) to enhance our abilities to rapidly test clinical specimens and determine who has been exposed to a biological agent in order to provide effective post-exposure prophylaxis. DHS and CDC are also working to develop rapid antimicrobial resistance testing to quickly identify agents that may be resistant to first-line MCM in the SNS, conduct anthrax-related exercises, and develop risk assessments for CBRN threats.

PHEMCE RECOMMENDATIONS GUIDE SNS PROCUREMENTS

The contents of the SNS are determined by the PHEMCE, which assesses the SNS' formulary and makes recommendations based on current scientific evidence about future procurements. PHEMCE provides priorities to guide the allocation of funds to the most critical MCM requirements and the recommended MCM are added to the SNS as resources allow.

The current PHEMCE process for identifying MCM requirements includes activities to identify and assess CBRN threats through DHS threat prioritization; assess medical and public health consequences for a given threat scenario and use of MCM for each threat agent through HHS public health modeling; and consult with subject matter experts. ASPR then assesses MCM requirements by incorporating the DHS threat prioritization and medical and public health consequence assessments with evaluations of current levels of preparedness, concepts of utilization, and product specifications.

Maintaining the inventory of the SNS poses a significant challenge. All MCM stockpiled in the SNS are subject to FDA regulations. These regulations include a requirement to label products with expiration dates that are intended to protect the public from ineffective products. While some of these FDA-approved MCM are included in the FDA Shelf Life Extension Program, extension is not an option for the majority of MCM, and so all of the MCM will eventually expire. SNS appropriations must be used not only to procure new MCM, but also to replace items that have expired. Therefore, there are many resource demands for expanding capabilities to meet PHEMCE requirements.

Innovation is critical to ensuring that public health preparedness remains dynamic and responsive to changing needs. For example, we continue to examine the formulary to address new threats like multi-drug resistant anthrax. CDC is also seeking innovative ways to use the existing, limited supply of MCM in the SNS. For example, CDC is providing technical support to the National Institutes of Health (NIH) and BARDA to conduct anthrax vaccine dose sparing studies to explore the effectiveness of using smaller doses of anthrax vaccine for each person to potentially use the current product in the SNS to treat more individuals.

OPTIMIZING THE USE OF MCM IN THE SNS

In addition to the previously mentioned Federal partnership activities to optimize the use of MCM, CDC's ability to use the MCM provided by SNS during an event depends on the necessary regulatory mechanisms that allow for deployment, dispensing, and utilization of SNS MCM assets. In order to treat individuals at the State and local level with MCM that have not been approved, licensed, or cleared by FDA for their intended uses, Emergency Use Authorization (EUA) or Investigational New Drug protocols must be in place for each product for the intended purpose. CDC also continues to prepare for potential deployment and use of MCM by preparing pre-EUA documents and working with FDA to streamline the process for obtaining an EUA at the time of an incident. For example, at the request of DHS and with FDA, CDC is assisting in the development of an EUA for certain MCM that could be pre-authorized, rather than waiting until an emergency occurs. This supports continuity of operations planning through implementation of Executive Order 13527 and would allow Federal agencies to store and forward place caches

of MCM to treat mission-essential personnel, thereby shortening the time frame in which MCM would be made available for use and ensuring continuity of operations.

In addition, during an emergency, CDC must be able to provide clinical guidance for public health and medical professionals. Difficult allocation decisions should also be made in advance of an emergency to the extent possible. For example, prioritization policies are needed to identify populations at highest risk of exposure following an incident because the need for certain limited MCM would likely exceed supply. CDC is currently beginning the process of developing an anthrax vaccine policy that would provide guidance on priority populations for vaccination as well as those who should not be vaccinated, much like we do annually for influenza.

CDC is also working with State and local partners to identify ways and develop systems to better track MCM supply during a public health emergency response. During the 2009 H1N1 influenza pandemic, the Federal Government was able to distribute antiviral drugs and other MCM to the States, in accordance with pandemic influenza response plans. This activity ensured the availability of MCM at the State level. However, there was no standard mechanism to track distribution at the local level. While State and local partners cooperated in CDC's efforts to establish this level of visibility as the response progressed, the lack of detailed, accurate inventory tracking information was challenging for the decision-making process for further SNS deployments. CDC is applying lessons learned from the response to understand the most effective and efficient means to distribute and track antiviral drugs during a pandemic.

The optimal use of MCM also requires rapid feedback on how well drugs and other interventions are working and how effectively individuals are able to use public health information to protect themselves and their families. As with other drugs, monitoring for adverse events related to the use of MCM is important to guide future recommendations. Providing decisionmakers and public health authorities with adverse event data is useful not only for identifying new concerns, but also for demonstrating that safety monitoring is a vital part of any emergency response.

CHALLENGES TO MAINTAINING A STRONG, FLEXIBLE SYSTEM

We have been successful in expanding CDC and public health resources for preparedness through Federal interagency support and strong State and local collaboration, but there is still much work to do.

CDC staff and the interagency participants in PHEMCE diligently evaluate the SNS to ensure that the public receives the best value for the funding invested, and that the holdings of the SNS are scientifically reviewed and prioritized.

The result of this decoupled system for determining requirements and budgets is that CDC prioritizes the use of funds to meet the requirements.

Other challenges include professional shortages in State and local workforce and limited subject matter expert capacity for MCM data review. In addition, limited safety and efficacy data is available for many MCM for special populations such as children and pregnant women. CDC is working with HHS, FDA, and NIH to seek innovative ways to obtain critical data to improve the evidence base for use in these populations.

CONCLUSIONS

The SNS is a unique Federal asset. Effectively using the SNS requires a collaborative effort by State, local, Tribal, territorial, and Federal partners on everything from MCM development to development of diagnostics to detection of an event to distribution and dispensing of MCM. CDC is seeking ways to ensure appropriate use of resources in the current fiscal environment. We see examples every day across the Nation of how public health preparedness and planning to use MCM from the SNS are being incorporated into everyday public health systems.

CDC continues to work with Federal partners, including DHS, to integrate Federal capabilities in the overall effort to identify, develop, acquire, distribute, and dispense MCM—with the ultimate goal of getting MCM to the people who need them. Being prepared to protect the public's health is ultimately an issue of health security.

I thank you again for the invitation to testify before you today. I will be happy to answer any questions you may have.

Mr. BILIRAKIS. Thank you. Thank you, Dr. Khan. I appreciate it. Thank you, Dr. Garza.

We are in the middle of votes now, and we expect it to be a pretty long series of votes. So we are going to submit our questions for the record, if that is okay.

I appreciate that. We will reconvene with the second panel following the last vote, as soon as we get a quorum.

So thank you very much. We should be back in roughly 1 hour, but we want to dismiss the first panel. Thank you.

Ms. RICHARDSON. Thank you very much. I will not return. We are meeting with the President this afternoon. Thank you very much.

Dr. KHAN. Thank you very much.

[Recess.]

Mr. BILIRAKIS. I want to welcome our second panel. Thanks for being so patient with us.

I have Mr. McHargue—I believe that is how you pronounce it—and he is the Director of Emergency Operations for the Florida Department of Health.

Welcome, sir.

Next we have Mr. David Starr, and he is the Director of the Countermeasures Response Unit within the Office of Emergency Preparedness and Response at the New York City Department of Health and Mental Hygiene.

Then we have Chief Lawrence Tan. If you could tell where you are from, as well.

I believe we have one more witness. I believe there is one more. Dr. Levi—excuse me—and he is the Executive Director of the Trust for America's Health.

So why don't we go ahead and start, begin testimony with Mr. McHargue.

I have a markup. I know that the Member over here, Mr. Marino, also has, I think, an intelligence classified briefing. But let's get in as much as we possibly can. We look forward to asking you questions and your responses. Thank you.

We will go ahead and start with Mr. McHargue. Thank you.

STATEMENT OF MIKE MC HARGUE, DIRECTOR OF EMERGENCY OPERATIONS, DIVISION OF EMERGENCY MEDICAL OPERATIONS, FLORIDA DEPARTMENT OF HEALTH

Mr. MCHARGUE. Thank you, Chairman Bilirakis and distinguished Members of the committee. On behalf of Dr. Frank Farmer, State surgeon general, we thank you for allowing us to be here today to speak on this most important matter.

Consistent with the National Response Framework, we plan under the assumption that CBRN incidents will produce catastrophic impact and will overwhelm local resources, requiring immediate and sustained State and Federal support. The ability to quickly assess and meet local needs for medical supplies and search capability, including pharmaceuticals, is vital to stabilize the impacted community. This simply cannot be accomplished in a vacuum and without effective partnerships, defined through plans and honed by training and exercises.

At the State level, we rely heavily on partnerships with the Federal agencies charged with developing strategies, plans, and stockpiles through the Public Health Emergency Medical Counter-

measures Enterprise and the array of programs and initiatives it sponsors. It is through these efforts that States have mechanisms to rapidly surge medical countermeasures in the face of CBRN threats.

The contribution by our Federal partners through the regional medical coordinators and other medical countermeasure program staff are invaluable. To be effective, we must work together at all levels to be prepared to address the potentially devastating consequences of such incidents. The stakes are high, the challenges are real, and our commitment to meet them, like yours, is unwavering.

In Florida, preparedness is operationalized in three overlapping structures: Public health, emergency management, and domestic security. Our preparedness and response strategy is built upon the 37 National target capabilities. The Department of Health coordinates an integrated public health system with a network of county health departments. The structure enhances the integration and coordination between other local and State entities, such as emergency management and domestic security.

Chapter 252, Florida statute, establishes the comprehensive emergency management plan and provides the framework for responses to all hazards. Also, as a member State with FEMA Region 4, our partnerships fully engage Federal agencies and assets.

Florida's domestic security structure is an interdisciplinary one that is implemented through a framework of seven regional domestic security task forces involving disciplines at all levels. Florida's strategy is dependent upon first-responder input to recommend what needs to be done, how do we do it, and what resources are required.

Through a variety of Federally-sponsored or -recognized programs, Florida has an on-going and robust capability to identify the characteristics of a variety of chemical, biological, and radiological agents and their effects on populations. These programs integrate with Federal partners at every touchpoint.

We also learn from every incident. In the 2010 H1N1 pandemic, a series of advisory groups was used to provide clinical guidance on our State strategies and response. This has developed into the establishment of a standing medical advisory group to assist the department and the State emergency response team with several things, such as: Recommendations on protective actions for the public; providing protection for first responders; evaluation of contraindications in a mass prophylaxis incident; and, of course, with SNS or managed inventory, the allocation and apportionment to impacted populations.

Further, the State has broadened that capability through demonstrated partnership with the Poison Control System to rapidly identify both the conditions within the State as well as serve as the key contact point for adverse reactions reported by citizens.

As we talk about points of dispensing and their effectiveness, the Florida strategy provides that points of dispensing would be utilized for countermeasure dispensing in every county of our State. These PODs can be used to dispense medications into the community for virtually any disease outbreak or CBRN threat. This in-

cludes dispensing material from the Strategic National Stockpile or its managed inventory.

The State has deployed medical countermeasures during real-world events, things like antivirals and antibiotics; the anthrax event in Palm Beach in 2001; vaccines for H1N1; and PPE, personal protective equipment, to hospitals, county school systems, and other partners.

Florida caches pharmaceuticals locally to be dispensed to the responders at the onset of an incident, with the Strategic National Stockpile and managed inventory stockpiles then being apportioned to meet the civilian need. We are pleased to say that just today, sir, our plan just received a score of 100 percent from the CDC technical assistance review that was conducted in January of this year. We believe our plan is effective.

Since the development of the first three Federal programs—SNS, CHEMPACK, and the Cities Readiness Initiative—Florida has continued to develop its program to best manage the logistics efforts to maximize the time windows to move this important product. The SNS capability provided, we feel, is the most significant partner asset we have utilized to date to meet the needs of citizens impacted by CBRN incidents.

The State uses an on-line training program that has trained over 3,000 Florida Department of Health staff, volunteers, and partner agencies on the operations and management of the SNS program. This is available on-line and should be of interest to the committee and partners.

In closing, the determination of the scope of the distribution of medical countermeasures is one best determined by the collective guidance of State and Federal subject-matter experts, our partners. Once we receive the guidance, it is our mission to provide the appropriate countermeasure to the affected population and to do so quickly and effectively. Given the recent events that affect the Nation, with influenza to the broad range of services required for Nationally-occurring events, I feel that we have developed an appropriate structure to meet the demand.

I thank you for your time, and I am open to your questions.

[The statement of Mr. McHargue follows:]

PREPARED STATEMENT OF MIKE MCHARGUE

MAY 12, 2011

Good afternoon, Chairman Bilirakis, and distinguished Members of the subcommittee. On behalf of Dr. Frank Farmer, State Surgeon General, I want to thank you for allowing me to represent the Florida Department of Health on this most important matter here today. My name is Michael McHargue, Director of Public Health and Medical Planning and Response for the Bureau of Preparedness and Response of the Florida Department of Health. My role is the Emergency Coordinating Officer and lead for Emergency Support Function 8, Public Health and Medical, of the State of Florida. I work in concert with the State Emergency Response Team (SERT), which functions at the behest of Governor Rick Scott. As the lead for ESF8, I coordinate Health and Medical resources and capabilities as one of 18 Emergency Support Functions of the Florida State Emergency Response Team. Integrated planning and response is critical to achieving successful outcomes. Though important, the health and medical countermeasures that are of interest to this committee are but one part of the total response required to address a threat of this type. The medical logistics structure, partnership, and process are the lifeblood of public protection.

Over the next few minutes, I hope to provide you with an overview of Florida's on-going efforts in meeting the broad array of challenges that either impact the State on a regular basis, or that we sincerely hope to not have to confront.

STATE LEVEL OVERVIEW

Preparedness is founded on the principle of incremental, integrated and, simultaneous planning across all disciplines and layers of government—local, State, and Federal—for all types of hazards, and is accomplished in a continuous cycle of planning, equipping, training, and exercising, underpinned by evaluation at each phase. In Florida, preparedness is operationalized in three overlapping structures: Public health, emergency management, and domestic security. As stated above, our preparedness is heavily reliant on the local, State, and Federal partnerships necessary to span jurisdictions and to provide resources for incidents that might be deemed as catastrophic. Public health and medical preparedness is essential to ensuring that the Florida Department of Health's mission of protecting the health and safety of all residents and visitors to our State is achieved. Facilitating collaboration among the State's health care partners, including pre-hospital, hospital, and medical practitioners, is critical in order to respond as a system of care. Florida's *Public Health and Health Care Preparedness Strategic Plan 2011–2013* goals, objectives, and strategies unifies the principles of the three structures and provides the direction for preparing the State's public health and medical system. This strategy is built upon the 37 National Target Capabilities.

PUBLIC HEALTH SYSTEM

Public Health Preparedness is essential to achieving the Florida Department of Health's mission of protecting the health and safety of all residents and visitors to our State. Facilitating collaboration among the State's health care partners, including pre-hospital, hospital, and medical practitioners, is critical to responding as a health care system. The Department of Health is structured as an integrated public health system with the county health departments being statutory entities under the direction of the State Department of Health. This structure enhances the integration and coordination between other local and State entities such as emergency management and domestic security. Emergency Management Structure Chapter 252, Florida Statutes, establishes the Comprehensive Emergency Management Plan, and provides the framework through which the State of Florida prepares for, responds to, recovers from, and mitigates the impact of a wide variety of disasters that could adversely affect the health, safety, and/or general welfare of residents and visitors to the State. It also provides guidance to State and local officials on procedures, organizational structure and responsibilities, and serves as a blueprint for an integrated and coordinated local, State, and Federal response. As a member State within FEMA Region IV, our plans and partnerships fully engage Federal partners and assets. Domestic Security Structure Florida has a dynamic interdisciplinary domestic security strategy which is founded on five goals:

1. Prepare for all hazards, natural or man-made, to include terrorism.
2. Prevent, preempt, and deter acts of terrorism.
3. Protect Florida's citizens, visitors, and critical infrastructure.
4. Respond in an immediate, effective, and coordinated manner, focused on the victims of the attack.
5. Recover quickly and restore our way of life following a terrorist act.

The framework for Florida's strategy is seven Regional Domestic Security Task Forces. From its inception, Florida's strategy has depended on the first responders to recommend what is needed and to prioritize implementation of planning, training, and equipment projects through the domestic security structure.

MONITORING AND DETECTION OF THE THREAT

The State has an on-going and robust capability to identify the characteristics of a variety of chemical, biological, and radiological agents and their effects on the population. The ESSENCE syndromic surveillance system is operational in three-fourths of all hospitals throughout the State, covering approximately 85% of all emergency department visits. This system is coupled real-time with regional epidemiologists working in disease control, as well as food and waterborne investigations.

Constant updating of the health care system occurs through the use of the Florida Department of Health Emergency Notification System (FDENS), as well as the EpiCom system, a State reporting and messaging board built along the structure of Epi-X, the CDC notification and update system for a variety of threats to our subject matter experts. This system, coupled with local surveillance within the county

health department structure, provides an on-going framework for the response. To aid in the rapid identification of the threat agent, the State Laboratory Response Network (LRN) laboratory capability is available, coupled with a laboratory surge structure that utilizes both hospital and academic laboratory capability.

POPULATIONS AFFECTED

Due to the on-going activities the State faces with natural disasters, the on-going analysis of all populations, including vulnerable populations, has been a yearly activity since the storms of 2004. Every county has a profile developed that analyzes the age, race, indigence, medical status, and birth rates for the community. These data are coupled with environmental factors that may impact the community in any event. Florida possesses the capability to rapidly access, compile, and depict these data using sophisticated GIS mapping, and can share the results of same using web-based communication, as well as, redundant mobile communications systems.

EVALUATIONS AND RECOMMENDATIONS FOR COUNTERMEASURES

In the 2010 H1N1 pandemic, a series of advisory groups was used to provide clinical guidance on various aspects our State strategies and response. This has developed into the establishment of a Medical Advisory Group to assist both the Department and the SERT in:

- Evaluating CDC guidance for appropriateness to the State situation.
- Evaluation of contraindications in a mass prophylaxis event.
- Other issues as needed. In an event such as BioWatch, for example, the group would be evaluating the allocation and apportionment strategy.
- Provide both protective actions and the medical protocols.
- Make recommendations to protect first responders.

The State has broadened that capability by developing a key rapport with the Poison Control system to rapidly identify both the conditions within the State, as well as, serve as the key contact point for adverse reactions reported by the citizens.

INFORMATION MANAGEMENT BRANCH

During the response deployments for H1N1, Haiti, then Deepwater Horizon, there was an increasing and diverse need for information. The proliferation of rumors and the expanding role of social media necessitated the development of this Branch in the Operations section of the Incident Management Structure. The Branch is assigned all of the messaging for the Department of Health and functions within the Joint Information Center (JIC) established by the State Emergency Response Team (SERT). As stated previously, the SERT is the vehicle that ensures the coordinated input and output of public information for Florida's citizens.

POINTS OF DISPENSING (POD) STRATEGY

The Florida strategy provides that Points of Dispensing (POD) would be utilized for countermeasure dispensing in every county in the State. Local PODs have been established in both open and closed environments. Adaptation of the POD for issues related to radiation, for example, are incorporated into the current planning for the incident. Most recently, the H1N1 pandemic provided an opportunity to demonstrate Florida's POD Strategy State-wide.

The H1N1 campaign highlighted two successes for the Florida plan. Forty-three of the 67 counties provided school-based immunization clinics for students (an example of a closed POD). One of Florida's counties received a National award for the vaccine strategy within its school system. The second success was incorporating major pharmaceutical chains to dispense antiviral medication during the early days of the pandemic. This partnership, combined with distribution within the county health department system, led to increased access and availability.

LOGISTICS ANNEX

The Florida Department of Health's Emergency Operations Plan Logistics Support Annex integrates with the State Unified Logistics Plan to ensure that the flow of medical supplies, equipment, pharmaceuticals, and auxiliary personnel is performed in a unified manner in cooperation with other State of Florida emergency response elements. Effective public health and medical logistics management ensures that all functions are executed in a unified manner in order to reduce costs and ensure the appropriate support actions are accomplished in a timely manner.

The scope of the Logistics Support Annex is to develop and coordinate a FDOH State-wide strategy including operational objectives and tactical standard operating procedures for the procurement, receipt, storage, distribution, dispensing, and recov-

ery of pharmaceuticals, medical supplies, and equipment in support of State-wide response activities.

Florida strategy for delivery systems incorporates a hub and spoke concept for delivery. The Department uses two main warehousing facilities, coupled with Receive, Stage, and Store (RSS) sites strategically located throughout the State. The present format is being developed to establish a single drop point within the county and then redistribution to the POD sites. Given the unique nature of Florida's structure and communities, the apportionment of countermeasures will be a highly dynamic event.

Florida has provided personal protective equipment (PPE) to Advanced Life Support Pre-Hospital Emergency Medical Services (EMS) providers and acute care hospitals. A pre-defined standard PPE package was allocated based on the number of licensed vehicles for EMS providers and number of licensed beds for hospitals. Allocation to the agency level was determined through an assessment of current capacity and prioritized by the Regional Domestic Security Task Force, Health and Medical Committees. A minimum standard level of PPE has been established by the State Working Group for Preparedness, Health, Medical, Hospital, EMS Committee's Hospital Equipment Task Team. The current focus of PPE provision is on the sustainment and maintenance of PPE and the training required for using the PPE.

The State has deployed medical countermeasures during events such as antivirals, antibiotics (anthrax event in Palm Beach), vaccines, and PPE to the hospital and county school systems. Caches of ventilators and a concurrent strategy for them is part of the overall response continuum. Other key items presently part of the core distribution strategy include PPE and other protective measures from responders.

In terms of the pharmaceutical strategy, the caches held by the State are designed to be dispensed to the responders at the outset of the event, with the Strategic National Stockpile and Managed Inventory stockpiles then being apportioned to meet the civilian need.

STRATEGIC NATIONAL STOCKPILE (SNS)

CDC's Strategic National Stockpile (SNS) is a National repository of antibiotics, chemical antidotes, antitoxins, vaccines, and other life-saving medications. During a public health emergency, State and local public health systems may be overwhelmed. SNS is designed to supplement and re-supply State and local public health agencies in the event of such an emergency.

Florida has a robust State-wide SNS program with an emphasis on maintaining a ready Receipt, Staging & Storage (RSS) infrastructure which includes enhancement of current State plans and supporting documentation for receipt of SNS assets, development and conduct of training and exercise activities for State and Federal partners.

The State has an on-line training program which allows Florida Department of Health staff, volunteers, and partner agencies an opportunity to learn the operations and management of the SNS program. The program, *Florida's Introduction to Strategic National Stockpile and Mass Dispensing, http://www.doh.state.fl.us/demo/php/FL__Mass__Dispensing.html* has trained over 3,000 people. The objectives of this course are: The scope and purpose of Florida's Strategic National Stockpile Program, the community's mass dispensing roles and responsibilities, the two primary methods of distributing and dispensing supplies, and how mass dispensing incidents are managed.

CITIES READINESS INITIATIVE (CRI)

The Cities Readiness Initiative is a Federal funding mechanism targeted at major U.S. cities to assist with preparedness activities related to the achievement of State and county SNS program goals.

- Florida's CRI program includes providing consistent guidance, feedback, and evaluation to 14 CRI counties and 53 non-CRI counties via multiple venues.
- Provide technical assistance to 67 counties for planning development/refinement, training, and exercise related to the SNS/CRI programs.
- Perform program monitoring, tracking, and presenting project funding, program deliverables, and performance measures.

CHEMPACK

CHEMPACK is a joint Federal-State program designed to implement the forward placement of chemical nerve agent antidotes to State/local areas in order to reduce treatment response times. Placement of 108 CHEMPACK containers in the State of

Florida was completed in November, 2007. The program is currently in sustainment phase.

In closing, the determination of the scope of the distribution of medical countermeasures is one best determined by the collective guidance of State and Federal subject matter experts. Once we receive this guidance, it is our mission to frame the structure to provide the appropriate countermeasure to the affected population. Given the recent events that affected the Nation with influenza, to the broad range of services required for naturally occurring events, I feel that we have developed an appropriate structure to meet the demand. I thank you for your time and will now hopefully be able to answer any questions you might have.

Mr. BILIRAKIS. Thank you very much.

Mr. Starr, you are recognized.

I failed to say, the entire statement will be entered into the record.

You are recognized for 5 minutes, sir.

STATEMENT OF DAVID STARR, DIRECTOR, COUNTERMEASURES RESPONSE UNIT, EMERGENCY PREPAREDNESS AND RESPONSE, NEW YORK CITY DEPARTMENT OF HEALTH AND MENTAL HYGIENE

Mr. STARR. Good afternoon, Chairman Bilirakis and Members—Member—of the committee. Thank you for inviting me here today to testify on New York City's efforts to prepare for the rapid distribution of dispensing of medical countermeasures in the event of a public health emergency. My name is David Starr, and I am the director of countermeasures response at the New York City Department of Health and Mental Hygiene.

In New York City, our goals are simple: To maximize the speed and efficacy of distribution operations and to increase access to countermeasures by the general public. New York City has worked hard to develop robust plans for the receipt of the Strategic National Stockpile assets and their distribution dispensing to the public. Currently, two warehouses stand ready to receive and distribute SNS assets, and we have identified close to 200 facilities city-wide that could be used as points of dispensing, or PODs.

PODs, of course, are temporary dispensing sites set up at the time of an emergency, and each is designed to dispense oral medications to approximately 40,000 people in less than 48 hours. We have trained more than 1,500 city employees as POD managers.

We have developed our capacity to provide critical supplies and medication to hospitals and primary-care centers after the initial 72 hours and have reviewed plans for these facilities to dispense medication to their staff and patients. We maintain a local cache of medications for our first responders.

In response to the emergence of H1N1 influenza in 2009, we had an opportunity to implement existing emergency plans. Our ability to mobilize quickly was proven when the SNS notified us of inbound assets at approximately 1:00 a.m. on Monday, April 27, and our receiving warehouse was ready as the first trucks arrived around 5:00 a.m.

That fall, New York City implemented an ambitious school-based vaccination program and the largest POD operation in recent history. We directed the receipt, repackaging, and delivery of more than 1,800 orders of vaccine and supplies to schools, providing more than 200,000 flu vaccinations to children across the city.

We mobilized several thousand city employees and volunteers for POD operations in 29 sites over 5 weekends, vaccinating close to 50,000 more New Yorkers. At one site, almost 6,000 people were vaccinated over 2 days. The response from the public at this site, even from those who waited an hour in a cold rain, was overwhelmingly positive.

Even these experiences did not reach the threshold we set for ourselves for a city-wide dispensing effort. Though we are pleased with our accomplishments, complacency is the greatest enemy to progress. Preparedness is a continuum that must be nurtured with constant attention, creativity, and predictable financial support.

When terrorism or a potentially deadly influenza outbreak is in the news, Federal resources increase. However, once the threat dims, interest and resources dwindle.

In 2004, Cities Readiness Initiative funding was provided to prepare 21 high-risk U.S. cities and metropolitan areas to effectively respond to a large-scale bioterrorist attack. In the following years, the number of CRI cities increased to 72, but, without additional resources, many of the highest-risk cities experienced a decrease in support. In 2008, New York City's CRI grant was cut by 25 percent and has remained at that level since.

Since 2002, New York City has also experienced a decrease of about 26 percent in overall public health emergency preparedness, or PHEP, P–H–E–P, financial support. The administration's fiscal year 2012 budget request includes another cut to this funding. On a per capita basis, New York City, despite its obvious high risk, ranks 13 out of the 18 jurisdictions awarded a new risk-based funding allocation in this year's proposed CDC grant. Even that is partially offset by a cut in our basic program grant.

Stable Federal funding is absolutely necessary for State and local responders to increase and maintain current levels of preparedness. If preparedness funds continue to decline, New York City's ability to sustain its preparedness infrastructure, so carefully constructed over the last decade, will be in jeopardy.

There are also operational issues that need attention. We continue to work for the prepositioning of countermeasures in local warehouses and the relaxation of the terms of the FDA's emergency use authorization for the legal dispensing of countermeasures in the first hours of an emergency.

There is also a need to better align the requirements, timelines, and deliverables of the different funding streams. The PHEP grant from the CDC, the Hospital Preparedness Grant from the Office of the Assistant Secretary for Preparedness and Response, and the Urban Areas Security Initiative Grant from the Department of Homeland Security all have unique reporting and administrative requirements. Any effort to align these requirements would reduce administrative costs and improve efficiency. Fortunately, our Federal partners are willing to listen, and we are making progress on these and other issues.

We very much appreciate the work of Chairman King, Chairman Bilirakis, and the other Members of this committee. Thank you for your support of our efforts to protect our citizens and for the opportunity to speak to you today.

[The statement of Mr. Starr follows:]

PREPARED STATEMENT OF DAVID STARR

MAY 12, 2011

Good afternoon Chairman Bilirakis, Ranking Member Richardson, and Members of the subcommittee. Thank you for inviting me here today to testify on New York City's efforts to prepare for the rapid distribution and dispensing of medical countermeasures in the event of a public health emergency. My name is David Starr and I serve as the Director of Countermeasures Response in the Office of Emergency Preparedness and Response at the NYC Department of Health and Mental Hygiene. I have been privileged to be involved in NYC's emergency medical countermeasure planning for more than 5 years. I currently supervise operational planning for the receipt and distribution of Strategic National Stockpile (SNS) assets and the opening of emergency dispensing sites city-wide, development of emergency staffing plans to support such an operation—including the expansion of New York City's Medical Reserve Corps (MRC)—and special projects to supplement current dispensing plans. Our goals remain consistent: To maximize the speed and efficacy of distribution and dispensing operations and to increase access to countermeasures by the general public.

Over the last decade, New York City has worked hard to develop robust plans for the receipt of SNS assets and their further distribution and dispensing to the public. Currently, two receiving warehouses stand ready to receive and distribute SNS assets within hours of notification. We are linked to the two sites with a state-of-the-art warehouse management system, enabling us to both monitor and direct warehouse operations remotely. We have identified close to 200 facilities city-wide that could be used as "Points of Dispensing" or PODs—temporary dispensing sites set up at the time of an emergency. Each POD is designed to dispense oral medications to approximately 40,000 people in less than 48 hours. Setting up and running these PODs would present enormous logistical challenges.

We are working hard to overcome the challenges. In New York City, each POD is operated with pre-trained leadership teams of 6 and about 90 additional staff who receive "Just-in-Time" training. If NYC were to open all PODs for a city-wide emergency dispensing operation, we would need approximately 1,200 leadership staff and 20,000 general staff for the first shift. To support the leadership staffing needs of such an operation, we have trained over 1,500 city employees as potential POD leadership team members. We continue to build that number by identifying and training additional staff. For general staff, NYC plans include accessing the city's substantial workforce of nearly 300,000 individuals, and engaging volunteers from various organizations to respond. The New York City Medical Reserve Corps is another source of staff for PODs, and consists of more than 9,000 pre-credentialed and pre-registered health care professionals who have volunteered their services during emergencies.

We have also developed our capacity to provide critical supplies and medication to hospitals and primary care centers after the initial 72 hours, and we have reviewed plans for these health care facilities to dispense medication to their staff and patients. We maintain a local cache of medications for our first responders, whose agencies maintain internal plans for dispensing these medications to their own employees.

Admittedly, these plans and protocols are merely words and ideas until implemented in exercises and real-life responses. The response to the H1N1 influenza outbreak in 2009 allowed us to put into practice many of our plans and protocols. Within days of its emergence in a Queens high school, New York City received antiviral medications and respirators from the SNS. Our ability to mobilize quickly was proven when the SNS notified our staff of inbound assets at approximately 1:00 a.m. on Monday, April 27 and our receiving warehouse was ready as the first trucks arrived around 5:00 a.m. As the response in the fall unfolded, our operational capacity was further tested. New York City planned an ambitious school-based vaccination program, as well as the largest POD operation in recent history. Our warehouse quickly set up a parallel vaccine distribution operation, expanding their refrigerated vaccine processing area, purchasing additional vaccine supplies and training select staff on vaccine handling. New York City then directed the receipt, repackaging, and delivery of more than 1,800 orders of vaccine and supplies to schools—at the peak, making 90 deliveries per day, including 15 priority deliveries before 9:00 a.m. Through this emergency school-based vaccination program, we provided an estimated 202,000 flu vaccinations to children across the city.

In addition, New York City mobilized several thousand city employees and Medical Reserve Core volunteers for POD operations in 29 sites over five weekends. The vast majority of these employees were trained "Just in Time" per our current proto-

cols. We vaccinated close to 50,000 New Yorkers in these PODs, and in one site on the Upper East Side, almost 6,000 people were vaccinated within 2 days. The response from the public at this site—even from those who waited an hour in a cold rain—was overwhelmingly positive. However, even the valuable H1N1 experience did not reach the threshold we set for ourselves for a city-wide dispensing effort.

These operations allowed us to test our distribution and dispensing site selection, staffing, command and control, and training protocols and a substantial number of changes to existing plans resulted from this experience. We have altered our process for selecting POD sites to assure selected sites are most suitable to support the operation and we made selection criteria more stringent. In addition, we have conducted population-density analysis to achieve optimal coverage among our selected sites. We have revamped our training program and are conducting drills to test these new protocols. We know that we must not stop with these accomplishments. Opening 200 temporary sites across an urban area the size, density, and diversity of New York City is fraught with obstacles, and while we attempt to identify and mitigate these obstacles, we are constantly seeking innovative solutions to maximize dispensing speed and increase access to needed countermeasures.

The greatest danger to our efforts is complacency; the hard work doesn't end. The Federal Government has worked to define target capabilities and benchmarks relative to countermeasure distribution and dispensing, and we meet and exceed those that have been defined. However, in the absence of a real-life catastrophic incident, the operational success of our plans is extremely difficult to predict. We don't have a textbook we can open, or a workbook or checklist to complete that tells us if we are truly prepared or not. Preparedness is not a binary concept, you are not either prepared or not prepared, it's a continuum that must be nurtured with constant attention, creativity, and predictable financial support. However, I can say with assuredness that in the arena of countermeasure distribution and dispensing, we are far more prepared than we were a decade ago, or even 3 years ago. Maintaining these achievements and continuing our progress requires constant vigilance.

When terrorism, or H5N1, or H1N1 is in the news, Federal resources increase. However, once the threat dims, interest and resources dwindle as well. After 9/11, everyone was a New Yorker, and there was no debate about the increased threat faced by New Yorkers and other urban areas. In 2004, Cities Readiness Initiative (CRI) funding in the Public Health Emergency Preparedness grant was provided to prepare major U.S. cities and metropolitan areas to effectively respond to a large-scale bioterrorist event by building capacity to dispense antibiotics to their entire identified population within 48 hours.

New York City initially received $5.1 million in 2004 as one of 21 cities in the country considered at highest risk. In the following years, the number of CRI cities increased to 72. The Cities Readiness Initiative became everybody's readiness initiative, but without additional resources, many of the highest-risk cities saw a decrease in support. In 2008, New York City's CRI grant was cut by 25%, and has remained at that level since.

New York City has also experienced decreases in overall Public Health Emergency Preparedness (PHEP) grant funding as well—approximately 26% since 2002; the administration's budget for fiscal year 2012 proposes another cut in funding for PHEP State and Local Capacity. While the Center for Disease Control has developed a pilot risk-based funding pool for fiscal year 2011, this additional funding for New York City is—in current proposals—partly offset by a 4% cut in our basic grant. Furthermore, we have been informed that current proposals are not final, and levels are expected to decrease even more. In regard to the new risk-based funding, on a per capita basis, New York City, despite its obvious high risk, ranks 13th out the 18 jurisdictions to be awarded risk funding. Although we have long supported risk-based funding, we are also concerned that the uncertainty of continuation of this funding stream and the large cut in program funding would leave us with a much larger overall funding gap in fiscal year 2012 and beyond.

Stable Federal funding is absolutely necessary for State and local responders to increase and maintain levels of preparedness. As we undertake new initiatives and maintain our state of readiness, there is a cost. We pay contingency fees to various private partners to build operational capacity and integrate response planning. We pay to identify, survey, and map POD sites. We pay for modeling and other scientific analyses to improve our plan elements. We pay for transportation redundancy to deliver countermeasures to our citizens. We pay to maintain a robust warehouse management system, and for climate monitoring systems that operate in all sites where we store pharmaceuticals. We pay for the annual training of POD leadership staff. We continually strive to identify gaps, holes, and weaknesses in our plans and often pay to fill, patch, and reinforce them. Most of all, we pay for essential staff, including the highly dedicated individuals in public health that help to build and maintain

our preparedness. Simply put, if preparedness funds continue to decline, our city's ability to sustain its preparedness infrastructure will be jeopardized.

There are also many operational issues that need additional attention—as we have communicated to the various Federal agencies we depend on for guidance and support. We continue to push for the pre-positioning of a limited quantity of Federal countermeasures in local warehouses to speed the opening of the first PODs to the public. We have advocated for the relaxation of the terms of the Emergency Use Authorization that the FDA will require for the legal dispensing of countermeasures in an emergency. And while our plans center primarily on the rapid dispensing of oral medications, we are moving forward with planning for the dispensing of the additional days of antibiotics needed by an exposed population following a widespread anthrax attack, as well as the administration of the three-dose course of anthrax vaccine as recommended by the CDC. There is great need for more guidance in regard to these matters, and we continue to push for clarity.

The structure of our funding is also confusing and sometimes encourages duplication of effort. We continue to use, to the best of our ability, funds from many different sources including the PHEP grant from CDC, the hospital preparedness grant from the office of Assistant Secretary for Preparedness and Response/HHS and the UASI grant from Department of Homeland Security. However, each of these funding streams has unique characteristics and requirements. We understand that a perfect synergy may not be possible, but some effort to align requirements, timelines, and deliverables could significantly reduce the administrative burden that draws resources from efforts to improve public health preparedness.

Fortunately, we benefit from having Federal partners that are willing to listen, and there has been marked improvement over the years. We've seen our Federal partners consider options to speed the initial delivery of countermeasures to our warehouses, and a willingness to entertain different models of Emergency Use Authorizations that would help States and local jurisdictions dispense countermeasures legally in the first hours of an emergency.

We are also grateful for the continued interest of Congress and the work of Chairman King and this committee. Thank you for your support of our efforts to protect our citizens, and for the opportunity to comment today.

Mr. BILIRAKIS. Thank you very much.

Now, Mr. Lawrence Tan, Chief Tan, you are recognized for 5 minutes.

STATEMENT OF LAWRENCE E. TAN, EMERGENCY MEDICAL SERVICES DIVISION, DEPARTMENT OF PUBLIC SAFETY, NEW CASTLE COUNTY, DELAWARE

Mr. TAN. Thank you, Chairman Bilirakis and Members of the subcommittee. Thank you for giving me this opportunity to discuss the issue of medical countermeasures' development and distribution from the perspective of the emergency services sector.

I am Lawrence Tan, Chief of Emergency Medical Services for New Castle County, Delaware, and here representing the Emergency Services Sector Coalition on Medical Countermeasures. I am also the current president of the International Association of Emergency Medical Service Chiefs, a professional organization that represents the leadership of EMS agencies that performed over 3.3 million emergency responses and transported over 2.78 million patients in America.

Recent events underscore the importance of these hearings and the responsibilities of subcommittee in developing policies that prepare the Nation and ensure our resilience. Given the recent events and the impending anniversary of September 11, it is clear that we may yet face another terrorist attack in the coming months.

The events of 9/11 demonstrated the potential for long-term health effects and unforeseen costs resulting from terrorism on unprotected populations. The anthrax attacks of 2001 demonstrated the vulnerability of the United States to intentional threats from

chemical, biological, radiological, and nuclear incidents. More recently, the earthquake and resulting tsunami in Japan and implosion of the Fukushima nuclear plant have dramatically heightened awareness about the fragility of response capability and capacity and have focused international awareness on the potential impact of unintentional radiological exposure.

A biological attack on an unprepared nation has significant potential to disrupt our Nation's security, hospitals, public health services, and critical infrastructure, to include the emergency services sector.

As the Chair cited in his opening statement, the Graham-Talent Commission has stated, "It is more likely than not that a weapon of mass destruction, and most likely a biological weapon, will be used in a terrorist attack sometime in the world by the end of 2013."

The issue the terrorism aside, our society operates with the potential for a hazardous-material disaster each day. Accidental chemical and biological incidents can occur anytime and could have significant detrimental effect on our local communities.

The current methods of distributing medical countermeasures have not proven capable of meeting our National goals—in particular, the protection of the emergency services sector. New approaches are needed to ensure that those on the front lines of the response community and their families are protected.

Several exercises and reports have described that the stockpiling and distribution practices are currently inadequate in many parts of the Nation to protect the population against an intentional anthrax attack. The prospect of critical infrastructure failure is real and will be compounded by lack of a National strategy to protect first responders. Ensuring our first responders' capability and capacity must be a priority in any National medical countermeasure strategy.

We have examples of when the Nation has shown it is not prepared to protect emergency services personnel, such as during the H1N1 pandemic, when determinations about the protective value of masks were inconsistent with the operational needs. Additionally, changes in prioritization of vaccine distribution were made without consulting local incident commanders.

The emergency services sector is, by definition, the tip of the spear during a domestic response within the United States and its territories. Emergency services personnel are likely to be among the first exposed in an event and need the earliest possible access to medical countermeasures.

History has demonstrated there is no front line in the global war on terrorism and that all parts of the world, including our local communities, are potential targets. Protecting those who we depend on to respond during these crises is essential for our community response, resilience, and recovery and, thus, our Nation's security. This includes planning with, by, and for the emergency services sector a medical countermeasure program that protects these personnel and their families.

As an emergency medical services chief, I have a responsibility not only for the community for which I am charged to provide critical lifesaving services but for the safety and welfare of the per-

sonnel that deliver that care each and every day. We ask these personnel to rise to the needs of the community during a chemical, biological, radiological, or nuclear incident. Imagine the potential stressors on that individual responder being asked to handle the community's needs during a catastrophic event, all the while wondering if the needs of their own family members are being fulfilled.

It is imperative that we include the families of the emergency services sector personnel in the planning for any medical countermeasures. The effective continuity of operations of the emergency services sector as a fundamental component of the Nation's critical infrastructure may well depend on these personnel having timely access to medical countermeasures both for themselves and their families.

The time is right to provide emergency service sector personnel with emergency caches of prepositioned, personal, and institutional medical countermeasures.

A more fundamental review of the medical countermeasure enterprise is warranted if we, as a Nation, want a medical countermeasure system that will protect us through the threats of the 21st Century. The alphabet soup of programs—the Cities Readiness Initiative, the Metropolitan Medical Response System, the Biological Advance Research Development Authority—were conceived separately and remained uncoordinated.

The Medical Countermeasure Enterprise Review provides the emergency services sector and the Federal agencies an opportunity to improve our Nation's protective posture. But the medical countermeasure enterprise must maintain a larger perspective than just the Federal Government and must evolve to include an end-user's point of view.

Many of the emergency services sector professional associations have joined together to form a new coalition on medical countermeasures to assist with this effort and provide a single voice in these important issues for the Nation and ensure that the evolving National policy protects our response personnel and their families. We offer the following recommendations for your consideration:

First, develop an advisory board comprising emergency services representative to engage in defining end-user requirements, similar to battlefield medicine practices, and to advise on the effective distribution practices.

Second, develop a medical countermeasures strategy that enhances National resilience by protecting the protectors of our Nation's critical infrastructure.

Third, develop pilot projects to position medical countermeasures for emergency services personnel and their families.

Fourth, ensure the continuity of the CHEMPACK program, including pilot programs to expand the formulary and examine local pharmaceutical control.

We thank you for your time and attention. We realize that you certainly have my complete remarks already entered in the record. I sincerely appreciate the opportunity to come before you this afternoon to present a perspective from the emergency response community on this vital subject.

I would certainly welcome any feedback or questions from the Chairman.

[The statement of Mr. Tan follows:]

PREPARED STATEMENT OF LAWRENCE E. TAN

MAY 12, 2011

INTRODUCTION

Chairman Bilirakis, Ranking Member Richardson, and Members of the subcommittee, thank you for giving me this opportunity to discuss the issue of medical countermeasures development and distribution from the perspective of the emergency services sector. I am Lawrence E. Tan, Chief of Emergency Medical Services for New Castle County, Delaware, and here representing the Emergency Services Sector Coalition on Medical Countermeasures. I am also the current President of the International Association of Emergency Medical Service Chiefs, a professional organization that represents the leadership of emergency medical services agencies that performed over 3.3 million emergency responses and transported over 2.78 million patients in America.

Recent events underscore the importance of these hearings and the responsibilities of the subcommittee in developing policies that prepare the Nation and ensure our resilience. Given the recent events and the impending anniversary of September 11 it is clear that we may yet face another terrorist attack in the coming months.

The events of 9/11 demonstrated the potential for long-term health effects and unforeseen costs resulting from terrorism on unprotected populations. The anthrax attacks of 2001 demonstrated the vulnerability of the United States to intentional threats from chemical, biological, radiological, and nuclear incidents. More recently, the earthquake and resulting tsunami in Japan and implosion of the Fukushima nuclear plant have dramatically heightened awareness about the fragility of response capability and capacity, and have focused international awareness on the potential impact of unintentional radiation exposure.

A biological attack on an unprepared nation has significant potential to disrupt our Nation's security, hospitals, public health services, critical infrastructure to include the emergency services sector (ESS). The Graham-Talent Commission on the Prevention of Weapons of Mass Destruction Proliferation and Terrorism stated "it is more likely than not that a weapon of mass destruction [most likely a biological weapon] will be used in a terrorist attack somewhere in the world by the end of 2013." The issue of terrorism aside, our society operates with the potential for a hazardous materials disaster each day. Accidental chemical and biological incidents can occur anytime and could have significant detrimental effect on our local communities.

The current methods of distributing medical countermeasures have not proven capable of meeting our National goals, in particular the protection of the emergency services sector. New approaches are needed to ensure that those on the front lines of the response community and their families are protected. Several exercises and reports have described that the stockpiling and distribution practices are currently inadequate in many parts of the Nation to protect the population against an intentional anthrax attack.

The prospect of critical infrastructure failure is real, and would be compounded by a lack of a National strategy to protect first responders. Ensuring first responder's capability and capacity must be a priority in any National medical countermeasure strategy. There are examples when the Nation has shown it is not prepared to protect emergency services personnel: During the H1N1 pandemic, determinations about the protective value of masks were inconsistent with operational needs. Additionally, changes in prioritization of vaccine distribution were made without consulting local incident commanders.

The emergency services sector is, by definition the tip of the spear during a domestic response within the United States and its territories. Emergency services personnel are likely to be among the first exposed in an event, and need the earliest possible access to medical countermeasures. History has demonstrated there is no "front line" in the Global War on Terrorism, and that all parts of the world, including our local communities, are potential targets. Protecting those who we depend on to respond during these crises, is essential for our community response, resilience, and recovery, and thus our Nation's security. This includes planning with, by and for the emergency services sector a medical countermeasure program that protects these personnel and their families. As an emergency medical services chief, I have a responsibility not only for the community for which I am charged to provide critical lifesaving services, but for the safety and welfare of the personnel that deliver that care each and every day. We ask these personnel to rise to the needs of

their communities during a chemical, biological, radiological, or nuclear incident. Imagine the potential stressors on an individual responder being asked to handle the community's needs during a catastrophic event, while wondering if the needs of their own family members are being fulfilled. It is imperative that we include the families of the emergency services sector personnel in the planning for any medical countermeasures. The effective continuity of operations of the emergency services sector as a fundamental component of the Nation's critical infrastructure, may well depend on these very personnel having timely access to medical countermeasures for both themselves and their families.

The time is right to provide emergency service sector personnel with emergency caches of pre-positioned personal and institutional medical countermeasures. The existing processes developed since 2004 to distribute "medkits" to postal workers could be extended to include the protection of our fire service, law enforcement, emergency medical services, public works, emergency health care, public health providers, and other components of our critical infrastructure or in short—the Emergency Services Sector.

In an age of asymmetrical threats, where the "battlefield" extends far from foreign fields into our local communities, we must take advantage of our strengths, in this case our innovations in medical protection and stockpiling. The Graham-Talent commission clearly identified our lack of preparedness to ensure the continuity of government and civil society in the event of a biological attack. Given the already identified gaps in preparedness; innovation and new methods will be needed to address these shortfalls.

The recent Public Health Emergency Medical Counter-measure Enterprise (PHEMCE) review, which was reported to this subcommittee last month, took important steps towards improving the process of developing medical countermeasures in our private and military labs. The recommendations from the review, as were previously reported are:

- the establishment of a Concept Acceleration Program at the National Institutes of Health to identify promising scientific discoveries;
- the establishment of a strategic investment corporation to spur innovation;
- the establishment of a Center for Innovation in Advanced Development and Manufacturing; and
- a major investment in regulatory sciences and review capabilities at the Food & Drug Administration.

Each recommendation is important; however the review did not address the crucial issues of distribution and dissemination of currently stockpiled countermeasures. The review also failed to substantially engage the emergency services sector either as end-users of the countermeasures or in their role within the incident command component of a response. The medical countermeasure enterprise is not exclusively a public health mission separate and singular from the response to a large-scale incident. Medical counter-measure dispensing is one part of an overall response that includes resource allocation, security, and public information. It is important to note that even with the existing Federally stockpiled assets, the overall response will likely be coordinated through local emergency management resources.

A more fundamental review of the medical countermeasure enterprise is warranted if we as a Nation want a medical counter-measure system that will protect us through the potential threats of the 21st Century. The alphabet soup of programs (Citizen Ready Initiative, Metropolitan Medical Response System, Biological Advance Research Development Authority) were conceived separately and remain uncoordinated. The PHEMCE review provides the emergency services sector and the Federal agencies an opportunity to improve our Nation's protective posture. But the PHEMCE must maintain a perspective larger than the Federal Government and must evolve to include an end user's point-of-view.

Many of the emergency services sector professional associations have joined together to form a new Coalition on Medical Countermeasures to assist with this effort and provide a single voice on these important issues for the Nation, and to insure that the evolving National policy protects both our response personnel and their families.

We offer the following recommendations for your consideration:

- develop an advisory board comprising emergency services representatives to engage in defining end-user requirements similar to battlefield medicine practices, and to advise on effective distribution practices;
- develop a medical countermeasure strategy that enhances National resilience by protecting the protectors of our Nation's critical infrastructure;
- develop pilot projects (in at least the Tier 1 Urban Area Security Initiative "UASI" cities) to position medical countermeasures for emergency services personnel and their families;

- ensure the continuity of the Chempack program, including pilot programs to expand the formulary and examine local pharmaceutical control.

The Strategic National Stockpile, the Biological Advanced Development and Research Authority, and the Metropolitan Medical Response System are all mature systems which in cooperation with each other, are capable of devising a new level of protection for the Nation, and ensuring the protection of the emergency services sector.

A medical countermeasure program that does not effectively protect the emergency services sector as the first group likely to be exposed during the performance of their duties, is insufficient. It would seem logical to include those we depend on to respond to the needs of our communities during these catastrophic incidents, and have the most to lose during a chemical, biological, radiological, or nuclear event, in the development of an effective medical countermeasure program. Protecting America's emergency responders will not only contribute to our National resilience, but it's the right thing to do. The axiom of "form follows function" leads us to urge the policymakers to verify the inclusion of the first response community at the beginning, and throughout the development of any medical countermeasure system.

Thank you for your time and attention. I sincerely appreciate the opportunity to come before you this afternoon to present a perspective from the emergency response community on this vital subject. I would welcome any feedback or questions.

Mr. BILIRAKIS. Thank you, sir.

Dr. Levi, you are recognized for 5 minutes.

STATEMENT OF JEFFREY LEVI, PH.D., EXECUTIVE DIRECTOR, TRUST FOR AMERICA'S HEALTH

Mr. LEVI. Thank you, Mr. Chairman. Thank you, Mr. Marino. I am delighted to be testifying here on behalf of Trust for America's Health, a non-profit, non-partisan organization dedicated to saving lives by protecting the health of every community and working to make disease prevention a National priority.

I have two major points to make in my testimony today. First, our Nation faces continuing natural and manmade threats that require an on-going commitment to public health preparedness. This is a National security threat as direct as any we face abroad. Second, if we are to achieve the goal of rapid distribution and dispensing of CBRN medical countermeasures, we must fund public health preparedness with the same level of commitment as we have made to other National security priorities.

As you know, research and development of medical countermeasures are only half of the battle in our capacity to quickly respond to a public health disaster. These medicines, diagnostics, vaccines, and devices must also reach the potential victims. That is why we need a well-staffed, well-trained, and well-funded public health system to ensure these drugs reach the mouths or arms of every impacted individual.

This means we must assure reliable, predictable funding for public health preparedness, in contrast to the 27 percent decline faced over the last several years. We must also assure that State and local health departments are given flexibility to use all employees, supported with Federal funds, during an emergency and not be hamstrung by categorical restrictions. We must fully embrace the spirit of all-hazards in the Pandemic and All-Hazards Preparedness Act by recognizing that almost every public health program contributes to preparedness.

Since 2003, Trust for America's Health has been tracking our Nation's progress and improving our preparedness through our annual report, entitled, "Ready or Not? Protecting the Public's Health from Diseases, Disasters, and Bioterrorism."

In our 2010 report, we found that States had made enormous progress since the events of 2001 in planning for and responding to disasters. The public health emergency preparedness and hospital preparedness programs, Federal, State, and local attention to the role of public health in emergency preparedness, and local attention to the role of public health in emergency preparedness, and real-world experiences, such as the H1N1 outbreak, have helped us bring preparedness to the next level.

However, the report also found that the economic crisis is putting almost a decade of gain at serious risk. While emergency H1N1 and stimulus funds may have helped States weather the storm of the pandemic, we cannot continue to fund preparedness on a disaster-by-disaster basis.

Our report laid out several remaining public health gaps that need to be addressed, each of which affects our ability to distribute and dispense medical countermeasures. We have a workforce and infrastructure gap, a surge capacity gap, a surveillance gap, and also a gap in community resiliency support, and, finally, gaps in medical countermeasure development.

My written testimony details these issues, but let me focus on just a few key points now.

The economy recession has led to cuts in public health staffing and eroded the basic capabilities of State and local health departments. Our report found that 33 States and the District of Columbia cut public health funding between fiscal years 2009 and 2010, with 18 of these States cutting funding for the second year in a row. If we took another snapshot today, I fear to say that almost every State would have cut public health funding.

In addition, Federal support for public health preparedness has dropped by 27 percent between fiscal 2005 and 2010, when you adjust for inflation. We are fully expecting further cuts to the public health preparedness programs in fiscal 2011 and 2012.

The National Association of County and City Health Officials reports that we have lost 19 percent of the local health department workforce since 2008. This poses a growing threat to our response capacity.

Surge capacity—the ability of the medical system to care for a massive influx of patients—requires on-going planning, funding, and coordination across health care, public health, first responders, and the private sector. The medical system will be an integral partner in distributing countermeasures, as we saw during H1N1, so we must prepare them to triage and identify targeted recipients. We believe efforts currently under way to build regional collaboration into the Hospital Preparedness Program are essential to leveraging the capacity of the inpatient and ambulatory care health-care systems for medical asset dispensing.

Finally, the Nation still lacks an integrated National approach to biosurveillance, the gathering and analysis of data related to threats to human health, to achieve early-warning detection and situational awareness. An interoperable, coordinated National biosurveillance system would significantly improve the country's capability to quickly detect an outbreak or attack and, thus, target our medical countermeasures appropriately.

The lack of an overarching Federal biosurveillance strategy has led to fragmentation, multiple separate surveillance systems, and barriers to relevant agencies' prioritizing and synthesizing data. We urge HHS to lead the development of a National strategy, which should examine means to achieve interoperability and transparency among the various surveillance systems.

Thank you for this opportunity to weigh in with this subcommittee as you consider the end-to-end realities of a medical response to a disaster. I look forward to your questions.

[The statement of Mr. Levi follows:]

PREPARED STATEMENT OF JEFFREY LEVI

Chairman Bilirakis, Ranking Member Richardson, and Members of the subcommittee: My name is Jeffrey Levi, and I am Executive Director of Trust for America's Health (TFAH), a nonprofit, nonpartisan organization dedicated to saving lives by protecting the health of every community and working to make disease prevention a National priority. I am grateful for the opportunity to testify before the subcommittee today on the distribution and dispensing of medical countermeasures (MCM) for chemical, biological, radiological, and nuclear (CBRN) threats.

I have two major points to make in my testimony today:

First, our Nation faces continuing natural and man-made threats that require an on-going commitment to public health preparedness. This is a National security threat—as direct as any we face abroad. The death of Osama bin Laden does not erase that threat; there are still very creative terrorists out there and our guard cannot be let down.

Second, we must fund public health preparedness with the same level of commitment as we have made to other National security priorities. This means: (a) We must assure reliable, predictable funding for public health preparedness, in contrast to the 27 percent decline faced over the last several years; (b) we must assure that State and local health departments are given flexibility to use all employees supported with Federal funds during an emergency and not be hamstrung by categorical restrictions; (c) and we must fully embrace the spirit of "all hazards" in the Pandemic and All-Hazards Preparedness Act (PAHPA) by recognizing that almost every public health program contributes to preparedness. As our health care system modernizes—especially with regard to health information technology—we must be sure public health programs, such as biosurveillance, adapt as well, including by leveraging existing resources in more creative ways.

As you know, research and development of medical countermeasures are only half of the battle in our capacity to quickly respond to a public health disaster. These medicines, diagnostics, vaccines, and devices must also reach the potential victims. That is why we need a well-staffed, well-trained, and well-funded public health system to ensure these drugs reach the mouths or arms of every impacted individual.

The public health system has always been integral in our response to natural disasters and terrorist attacks. Public health was on the frontlines of the response to 9/11 and to the anthrax attacks. It is as fundamental to the Nation's security as our military and as fundamental to local protection as fire and rescue. Passage of PAHPA codified and expanded the Federal Government's support for this role. As a result of this legislation, and the investments that followed, our Nation is more prepared than ever. We saw this in the response to the H1N1 outbreak in 2009, when nearly every State and jurisdiction implemented its pandemic influenza plan in response to the H1N1 outbreak, with activities including disease surveillance, ongoing communication updates, carrying out vaccination campaigns and the coordination of response efforts with partners.[1]

Since 2003 TFAH has been tracking our Nation's progress in improving our preparedness through our annual report entitled *Ready or Not: Protecting the Public's Health from Diseases, Disasters, and Bioterrorism.* In our 2010 report, we found that States had made enormous progress since the events of 2001 in planning for and responding to disasters. The Public Health Emergency Preparedness and Hospital Preparedness Programs, Federal, State, and local attention to the role of public health in emergency preparedness, and real-world experiences such as the H1N1 outbreak have helped us bring preparedness to the next level. However, the report

[1] Centers for Disease Control and Prevention, *Public Health Preparedness: Strengthening the Nation's Emergency Response State by State,* September 2010. Available from: *http://emergency.cdc.gov/publications/2010phprep/pdf/complete__PHPREP__report.pdf.*

also found that the economic crisis is putting almost a decade of gains at serious risk. While emergency H1N1 and stimulus funds may have helped States weather the storm of the pandemic, we cannot continue to fund preparedness on a disaster-by-disaster basis.

Our report laid out several remaining public health gaps that need to be addressed, each of which impacts our ability to distribute and dispense medical countermeasures: A workforce and infrastructure gap, a surge capacity gap, a surveillance gap, a gap in community resiliency support, and gaps in medical countermeasure development. I'll address these in turn.

Workforce and Infrastructure Gap.—The economic recession has led to cuts in public health staffing and eroded the basic capabilities of State and local health departments. Our report found that 33 States and the District of Columbia cut public health funding from fiscal years 2008–09 to 2009–10, with 18 of these States cutting funding for the second year in a row. In addition, Federal support for public health preparedness was cut by 27 percent between fiscal year 2005 and fiscal year 2010 (adjusted for inflation). We also expect to see major cuts to Federal public health preparedness programs in both fiscal year 2011 and 2012. The National Association of County and City Health Officials reports that we have lost roughly 19 percent of the local health department workforce since 2008. This loss of experience has a staggering impact on preparedness, as workers cannot simply be hired and trained once a disaster strikes. Strengthening the public health preparedness infrastructure is critical to ensuring the health protection of our Nation through distribution and dispensing of medical material. It also requires adequate funding and human resources to recruit and train personnel, stockpile life-saving countermeasures, develop and exercise plans to distribute assets, and identify and engage partners to support the public health mission. The resources required to truly modernize public health systems must be made available to bring public health into the 21st Century and improve preparedness.

During the 2009–2010 H1N1 influenza outbreak, State and local health departments were on the front lines responding to the pandemic, though many were limited in their efforts as a result of Federal and State budget cuts, particularly those that have occurred over the past 5 years. These budget crises demonstrated, among other things, the need to build in mechanisms to allow more flexibility in how staff, funded by Federal grant programs, are used during emergencies. In the H1N1 influenza response, the ability to re-assign staff from other funded projects in health departments could have improved the financial and human resource efficiencies of that agency's response to the influenza pandemic, especially during the earlier response phases when additional funding was not yet available and jurisdictions needed to mobilize "all hands on deck."

The Department of Health and Human Services (HHS) and Department of Homeland Security (DHS) have been working to align grant programs that aim to build our Nation's emergency preparedness capacity, including the Public Health Emergency Preparedness (PHEP) grants, Hospital Preparedness Program (HPP), and FEMA grants. Currently the PHEP and HPP grants, both of which are often distributed through public health departments, have separate application and reporting requirements, overarching goals, and in some cases conflicting performance metrics. We believe the alignment process should include coordinating grant priorities and goals, grant cycles, and streamlining application and reporting mechanisms to achieve maximum efficiency. We hope this committee works with your counterparts in Energy & Commerce to ensure the alignment process continues.

Surge Capacity Gap.—Surge capacity, the ability of the medical system to care for a massive influx of patients, requires on-going planning, funding, and coordination across health care, public health, first responder, and private sectors. The medical system will be an integral partner in distributing medical countermeasures, as we saw during H1N1, so we must prepare them to triage and identify targeted recipients. We believe efforts currently underway to build regional collaboration into the Hospital Preparedness Program are essential to leverage the capacity of the inpatient and ambulatory health care system for medical asset dispensing.

Surge planning must also take into account the important role of volunteers in mass dispensing. The Medical Reserve Corps (MRC) is a National network of community-based groups which include volunteers from public health, medicine, nursing, and non-medical support fields. During the H1N1 outbreak, MRC units across the country participated in 2,500 response activities, including vaccination clinics, significantly augmenting the capacity of local public health to implement the immu-

nization strategy.[2] However, in a survey conducted during the outbreak, MRC units reported that fear of liability was a significant barrier to full participation.[3] HHS has also acknowledged that a patchwork of Federal liability laws is confusing and frustrating to other health care providers.[4] HHS should clarify Federal volunteer liability laws to implement one, blanket liability that applies to all volunteer health professionals and entities volunteering under a Nationally-declared public health emergency or disaster. There should also be Federal Tort Claims Act protection for MRC volunteers year-round, as these personnel participate in public health drills and training during times of non-disaster.

Surveillance Gap.—The Nation still lacks an integrated, National approach to biosurveillance, the gathering and analysis of data related to threats to human health to achieve early warning, detection, and situational awareness.[5] An interoperable, coordinated National biosurveillance system would significantly improve the country's capability to quickly detect an outbreak or attack and thus target our medical countermeasures appropriately. The lack of an overarching Federal biosurveillance strategy has led to fragmentation, multiple separate surveillance systems, and barriers to relevant agencies prioritizing and synthesizing data.[6, 7] We urge HHS to lead the development of a National strategy, which should examine means to achieve interoperability and transparency among various surveillance systems.[8]

The National strategy should also call for leveraging of new epidemiological data that may become available as a result of the development of health information technology (IT) and electronic health records (EHRs). There is no overarching coordination between public health surveillance efforts at HHS and the work of the Office of the National Coordinator (ONC). For example, as ONC develops new standards for meaningful use of health IT, it should incorporate the preparedness and biosurveillance implications of such technologies. Interoperability between public health and EHRs could not only help with early detection of an emerging disease outbreak or bioterror attack, but could also help with identification of targeted populations or geographic regions to receive medical countermeasures and tracking the post-dispensing impact of medical interventions.

Community Resiliency Support Gap.—We continue to face challenges in preparing communities to recover from a disaster, especially at-risk people. Without an ability to reach these populations, such as home-bound individuals or those with limited-English proficiency, we face significant barriers in distributing medical countermeasures to them. Public health must work with the private sector, community-based and faith-based organizations, health care organizations, and community leaders to develop trust and communication with at-risk communities before a disaster occurs. We also must address on-going vaccine access issues during times of non-disaster, especially in high-risk communities. For example, according to 2008 data, 70 percent of older non-Hispanic whites received the seasonal influenza vaccination, compared to only 51 percent and 56 percent of older African-Americans and Hispanics, respectively.[9] This indicates a systemic problem with access, acceptance, and education that must be addressed before the next mass-dispensing campaign occurs.

Gaps in Medical Countermeasure Enterprise.—As you explored in your April hearing, although we are miles ahead of where we were during the 2001 anthrax out-

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[2] Office of the Civilian Medical Reserve Corps, "Report on the Medical Reserve Corps Response to the H1N1 Influenza Pandemic April—December 2009." *http://www.medicalreservecorps.gov/file/PandemicFlu/MRC-H1N1-2009-final.pdf*.

[3] Office of the Civilian Medical Reserve Corps, "Medical Reserve Corps Units and H1N1 Influenza Related Activities: September 2009." *http://www.medicalreservecorps.gov/file/SwineFlu/MRC_Units_H1N1_Flu_Activities.pdf*.

[4] DHHS, Office of the General Counsel, "Public Health Emergencies and Federal Health Law." Presentation at 2010 Public Health Preparedness Summit, February 2010. *http://www.phprep.org/2010/Agenda/upload/Interactive-145.pdf*.

[5] Centers for Disease Control and Prevention, "Biosurveillance: A Definition, Scope, and Description of Current Capability for a National Strategy," Presentation before International Society for Disease Surveillance, 2008. *http://www.syndromic.org/conference/2008/presentations/Track%203/ISDS%20Presentation_Fleischauer_Biosurveillance_2008.ppt*.

[6] Nuzzo, Jennifer, Center for Biosecurity of UPMC. "Developing a National Biosurveillance Program," *Biosecurity and Bioterrorism.* Volume 7, Number 1, 2009. *http://www.upmc-biosecurity.org/website/resources/publications/2009/biomemo/2009-03-27-develop_natl_biosurveillance.html*.

[7] Vinter, S. et al, Trust for America's Health, *Ready or Not? 2009: Protecting the Public's Health from Diseases, Disasters, and Bioterrorism.* December, 2009. *http://healthyamericans.org/reports/bioterror09/pdf/TFAHReadyorNot200906.pdf*.

[8] Nuzzo, 2009.

[9] HHS Office of Minority Health, Immunizations Data/Statistics, April 20, 2010. *http://minorityhealth.hhs.gov/templates/browse.aspx?lvl=3&lvlid=60.*

break, our ability to spur innovation in limited-use technologies has been hampered by a lack of stable funding and some breakdowns in program administration. As the Nation revamps its approach to research and development of vaccines, medicines, diagnostics and equipment to respond to emerging public health threats, policymakers must ensure public health is involved throughout the process, from initial investment through distribution and dispensing.

We believe a Federal MCM strategy should lead to: (1) Increased coordination between all of the involved agencies within HHS, DHS, and State and local public health, from initial investment through dispensing; (2) improved transparency of the development and distribution process; and (3) an end-to-end approach—not just focused on initial investments, but on advance development, procurement, distribution, and surveillance.

There should also be a plan for stocking the Strategic National Stockpile (SNS) and for on-going replacement of expiring product, especially vaccines,[10] pediatric doses of antimicrobials, antivirals, and other products, and restocking materiel used as a result of the H1N1 outbreak. This plan should also include a professional judgment budget for replacing product expiring over the next several years.

Success at Risk: The Urban-Rural Experience.—Urban and rural areas face very different challenges in capacity to distribute and dispense medical countermeasures. For all jurisdictions, adequate workforce and resources are a continuing obstacle to effective dispensing.

The Cities Readiness Initiative (CRI) is a Federal program that directly funds the largest metropolitan statistical areas (MSA) and provides technical assistance to develop capacity to receive and distribute medical countermeasures. Fifty percent of the U.S. population is covered by the 72 jurisdictions in the CRI program.[11] The program requires each area to demonstrate plans to be able to distribute antibiotics to the entire population within 48 hours. An analysis by RAND in 2009 found that CRI had helped cities develop the workforce, partnerships, planning, and purchasing capacity to dispense medical assets, but evaluation of the real capacity of cities to carry out these plans was limited due to the nature of the data collected.[12] We hope CDC continues to refine these measures to enable evaluation of the actual capacity and capabilities of each jurisdiction, rather than just the adequacy of plans, and we urge CDC to release this data at the local level.

The impact of CRI in urban areas was demonstrated during the H1N1 outbreak. In Los Angeles County, for example, 200,000 people received free H1N1 vaccines at 109 points-of-dispensing (PODs) in a 6-week period.[13] And the county has in place plans to distribute medical assets to 10 million people within 48 hours, as required by CRI. Los Angeles is also in the process of developing partnerships with schools and child care facilities to serve as alternative dispensing sites. These kinds of partnerships are key to achieving coverage of an at-risk population (during H1N1, children), and ensuring that income, language, and transportation are not barriers to receipt of the product.

The rural perspective varies based on whether the area is part of a CRI. Those rural areas within a CRI's MSA have the benefit of additional resources and technical assistance from the Federal program, with fewer people to serve. However, in truly rural areas, additional creativity is required. For example, one rural Virginia health department pursued agreements with fast-food establishments and banks to serve as drive-thru PODs.[14] Rural areas also face different challenges due to the limitations of communications. In many areas, land-lines are the only consistent form of telecommunication, while cities can depend more reliably on internet and cell phone use.[15]

In both rural and urban areas, local health departments have had to rely on public-private partnerships to achieve maximum coverage of dispensing planning. During H1N1, health departments depended on big box stores, retail pharmacies, schools, and private physician offices to serve as distribution points. These partner-

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[10] Testimony of Robert Kadlec Before House Homeland Security Subcommittee on Emerging Threats, Cybersecurity, and Science and Technology. June 15, 2010. *http://hsc.house.gov/SiteDocuments/20100615131640-79968.pdf*.

[11] Centers for Disease Control and Prevention, "Cities Readiness Initiative," May 20, 2010. *http://www.bt.cdc.gov/cri/*.

[12] Willis, H.H., et al. RAND Corp, Initial Evaluation of the Cities Readiness Initiative, 2009. *http://www.rand.org/content/dam/rand/pubs/technical_reports/2009/RAND_TR640.pdf*.

[13] Plough, A. et al, "Pandemics and Health Equity: Lessons Learned From the H1N1 Response in Los Angeles County," *Journal of Public Health Management & Practice:* January/February 2011—Volume 17—Issue 1—p. 20–27.

[14] McMorrow, Julie, National Association of County and City Health Officials, personal communication, May 10, 2011.

[15] Ibid.

ships are an acknowledgement that public health does not have the personnel to reach everyone in a community, but also demonstrates that the private sector and other community-level organizations often have better access to the population. Federal assistance, both before and during an emergency, should embrace and grow these partnerships. This is one of the reasons we support expansion of the mission of the Hospital Preparedness Program to include the entire medical system of a region.

Thank you for this opportunity to weigh in as the subcommittee considers the end-to-end realities of a medical response to a disaster. I look forward to your questions.

Mr. BILIRAKIS. Thank you, Dr. Levi.

I want to thank all of you for being so flexible with the schedule today. You know, initially, the meeting was scheduled in the morning, but to accommodate the minority party, we—in the afternoon, we did not anticipate votes. So I apologize for that.

I would like to recognize Mr. Marino, because I know he has an important meeting to go to, for 5 minutes or so.

Sir, you are recognized.

Mr. MARINO. Thank you, Mr. Chairman.

This meeting here is just as important to me; it is just that we have to be in three different places at one time anymore.

Gentlemen, I was a district attorney for 12 years and very active in my community and in my region with emergency services. I am going to pose a scenario to you and ask you to respond to it. I may interrupt politely to expand on it, bearing in mind that we only have about 5 minutes.

We will start with the doctor, if you don't mind, sir.

Let's assume that the money that you have been budgeted last year will be cut by 50 percent. What do we do collectively—and I know people come in and say, money is the issue, money is the issue. But let's just assume the bottom line is cut 50 percent. What do we do, and how do we use it most efficiently?

I know that is a tough one, so you have a moment to think about it, but not too much. And I say "we" collectively.

Mr. LEVI. Right, right. So, you know, that is obviously a very difficult question. I mean, I think the first thing is that one would have to be honest with the American people and say, if we make cuts of this magnitude, you cannot expect the level of protection that you have assumed exists for you today.

Mr. MARINO. Okay, then where would you start? What are the priorities with that 50 percent cut?

Mr. LEVI. I think my priorities probably would be, to a large degree, the focus of this panel, making sure that State and local health departments had a true emergency response capacity. What I would be looking at are some of the things you heard from some of the other witnesses as well: Making sure we are eliminating duplication, making sure that the existing programs are as efficiently managed as possible.

I will be honest with you, I don't think that we can sustain a 50 percent cut. So it is very hard for me to even imagine what we would focus on. I think we would have to make—and I wouldn't feel comfortable doing this on the spot—would have to make some decisions. There are some threats that we just couldn't prepare for.

Mr. MARINO. Okay.

Mr. LEVI. You know, I don't think that is an acceptable approach to, you know, the most vital Government function, which is protecting us from threats over which we have no control.

Mr. MARINO. Okay.

Chief, do you want to add something to that?

Mr. TAN. I think one of the first things you would have to look at is, do we have sufficient information to determine what our greatest threats are?

From an EMS standpoint, one of the biggest gaps that we find is there is no lead Federal agency with responsibility for EMS to help coordinate what is the emerging threat for the emergency services sector so that we can focus what remaining funding we have left, in your scenario, on what is the greatest threat that is going to do the greatest amount of good for the greatest number of people.

The other is early detection and preparedness, that if we can take the intelligence and the information that is available on where our greatest gaps and threats are, push that information out to the response community so that there is preparedness activities rather than consequence management, that may leverage some greater savings, from the perspective of minimizing potential exposure rather than having to deal with the aftereffect.

Mr. MARINO. Mr. Starr, do you want to add anything different to that?

Mr. STARR. Not really. I would just like to concur with Dr. Levi. I think that you would—we couldn't fathom that kind of cut to our programs. I think that it would be a tangible and real decrease in the ability for us to function and for us to protect our population.

I don't think—our ability to cooperate with the Federal Government, to fulfill the mandates that we receive from the Federal Government under our current grant programs would be severely impacted. I mean, I doubt we could fulfill the mandates that we are getting from our Federal partners.

Mr. MARINO. Okay.

Mr. McHargue, I am going to change the question a little bit. How much of a stockpile do we need and how much notice would the pharmaceutical industry need if we avoided inventories for great periods of time for medications that you would have to dispense? Do you understand my question? You look a little perplexed.

Mr. MCHARGUE. I am. Are you speaking, sir, about the National stockpile in concert with local?

Mr. MARINO. Yes.

Mr. MCHARGUE. Well, those numbers are a moving target, I will admit that. I don't know how much testimony you want in terms of actual figures, because the strategic placement of a lot of those materials and the ability for them to be exploited or used against us, or eliminated in the case of a threat, but——

Mr. MARINO. Let me rephrase that a little bit. Say you need—I am just going to take penicillin just as an example. How long would it take, in your opinion, for you to have enough to start distribution if—how much time if you need to contact the pharmaceutical that, "Hey, we need this, and we need it now. How much can you give us?"

Mr. MCHARGUE. Well, according to the Strategic National Stockpile Plan, those assets would be rolled immediately and on the ground within 12 hours. Then it becomes our responsibility to receive, break those packages down, and distribute them into the community.

Mr. MARINO. Now, you are saying they are already produced, though, correct?

Mr. MCHARGUE. Well, that assumes availability, yes, sir.

Mr. LEVI. Right. The whole assumption of the Strategic National Stockpile is that these are things that we would need so quickly that you couldn't go to a manufacturer and say, you know, "Start producing a large quantity now." The whole principle of the Strategic National Stockpile is that we have to be able to respond immediately.

Mr. MARINO. Thank you.

Mr. TAN. Mr.——

Mr. MARINO. I have gone over my time. Please, Chief—is that all right, Chairman?

Chief, do you want to respond?

Mr. TAN. Just, I mean, in looking at medical countermeasures, one of the things that I would just offer is the fact that sometimes the cost of these medical countermeasures is prohibitive of local government being able to sufficiently have supplies that would protect the population.

A good example is the Cyanokits that are used as a medical countermeasure against cyanide. It is $700 a kit. When you start looking at trying to protect the local population, local government, local emergency response agencies would have a tremendously difficult time, in your scenario, trying to adequately prepare not only their own personnel but respond to the population, as well.

Mr. MARINO. Gentlemen, thank you very much. Thank you for waiting. I apologize for that.

Mr. BILIRAKIS. Thank you, Mr. Marino. Appreciate it. That first question was hypothetical, correct?

Mr. MARINO. Yes.

Mr. BILIRAKIS. Yes, I figured that. Just getting that on the record.

All right. My first question is to Mr. McHargue.

The Council on State and Territorial Epidemiologists conducted a survey last year to assess State-level preparedness for a radiological or nuclear event, exclusive of a nuclear plant emergency.

Can you please describe Florida's planning efforts with regard to stockpiling, distribution, and dispensing of medical countermeasures that can be used to respond to a radiological dirty bomb or nuclear attack?

Mr. MCHARGUE. Okay, I can to a limited degree, sir.

We have three nuclear power facilities in Florida that you are very familiar with, being from that State. We work very closely with the National Regulatory Commission, the State Emergency Response Team, through regular drills and exercises to test the safety of the response plans.

The caching of pharmaceuticals are limited, at best, locally. We are aware—I don't know the numbers, but in the communities surrounding the nuclear power plants, it is our understanding that

there are limited quantities of KI, for example, or like drugs. I cannot, at this moment, tell you the quantities, but I will be glad to report off-line following the hearing.

Mr. BILIRAKIS. Yeah, we would appreciate that very much.

Mr. MCHARGUE. I would be glad to do it.

Mr. BILIRAKIS. Thank you.

Mr. Starr, I am concerned about your comments regarding the considerable need for more Federal guidance and more action on matters such as prepositioning of Federal emergency medical countermeasures and some relaxation of the emergency use authorizations. I know that some locales would also like to see local implementation of the Federal Shelf-Life Extension Program for expiring countermeasures.

Two questions: Who in the Federal Government have you worked with to address these issues? Is it FDA or DHS?

Mr. STARR. It is actually, particularly in the first case, it is the CDC we have been working with about the prepositioning of medical countermeasures and the relaxation of the FDA's emergency use authorization. It is not really our place, being a recipient of CDC funds, to go past the CDC to contact the FDA.

If you remember some of Dr. Khan's comments from the first panel, they have made—and this is one of the things that is very heartening to us—they have made advances on that. I don't have details on how far they have gotten. I think that is a question for them.

The guidance, really, that we were looking for is in regard to the follow-on 50 days of antibiotics needed for anthrax exposure after the 10 days of initial distribution, as well as the three-dose regimen of vaccine that is necessary to an exposed population. Again, they have convened work groups to identify some of the issues surrounding these and provide further guidance.

So, again, we push for this type of guidance, and we are lucky enough to have partners, I think, at the Federal level that are responding as best they can.

Mr. BILIRAKIS. Thank you.

This is for Chief Tan. Anyone else who wants to chime in, you are perfectly welcome.

Your coalition was established to provide a forum for the first responder medical countermeasures policy issues. Why do you think the emergency services sector, which is one of the 18 critical infrastructure sectors, has been left out of important policy discussions surrounding review of our MCM enterprise and promulgation of guidance for response to WMDs?

Mr. TAN. I think part of the dilemma is that there is a disconnect between the public health portion and the actual response community. It is likely that when the public health community was looking at the medical countermeasures, they weren't necessarily looking at it from an emergency response perspective. They were probably looking at it more from a global population perspective.

As you prioritize these types of responses, one of the things that the coalition is looking at is, who are the people on the front lines that are going to be potentially the first to be exposed in these types of events? As I indicated during my remarks, the emergency services personnel, the emergency services sector, which is, as you

indicated, part of the critical infrastructure, is going to be at the front lines and potentially exposed to any one of these CBRNE types of events and also is most likely living within the impact area of these types of events, so their families are going to be involved, as well.

What we are hoping to do through the coalition is to raise awareness regarding the needs of the emergency services sector to have, as a part of the planning for medical countermeasures, prepositioned caches for those personnel.

Mr. BILIRAKIS. Thank you.

Anyone else want to add anything on that? Okay.

Mr. McHargue, in your testimony, you spoke of your successes in dispensing the flu vaccine during the H1N1 pandemic in 2009. In particular, you mentioned that Florida's planning incorporated major pharmaceutical chains to dispense antivirals in the early days of the pandemic.

To what extent do your State plans leverage the capacity of the private sector to dispense the CBRN medical countermeasures?

Mr. MCHARGUE. We learned through that experience with H1N1, and with the encouragement of our Governor, Rick Scott, that private enterprise is an expansion of local or public capability. Through contracts with some nationally-known pharmacies, we were able to secure and administer a lot of the H1N1 vaccines through pharmacy locations in neighborhoods where people typically go to buy their other medications, their trusted deliverers of that service.

We have not fully exploited other partnerships for the provision of the wider range of CBRN medications, but we are in the process of continuing those expanded partnerships, sir.

Mr. BILIRAKIS. Thank you.

Anyone else want to add to that?

Mr. LEVI. I guess what I would add is that, particularly in rural communities, having those public-private partnerships is going to be incredibly important. You know, in large cities, you have a relatively large infrastructure of the public health system that is able to respond. In rural communities, your health department may be one or two people serving a very large geographic community. Without those public-private partnerships, we just will not reach lots and lots of people.

Mr. BILIRAKIS. Okay, Mr. Levi, certain Federally-funded initiatives, such as the Cities Readiness Initiative, the Metropolitan Medical Response System program, and other grant programs, have a key impact at the local level with regard to preparedness and response.

In your experience examining State readiness, have you found that the States are taking full advantage of these programs? Do you think that these separate but related efforts are well-coordinated?

Mr. LEVI. Coordination could always be better, but I think we found over time that the partnerships have improved and that State preparedness programs and their counterparts in the Cities Readiness Initiative have been working more closely together. I think that is—you know, certainly, making sure that those are well-coordinated is a responsibility for the CDC.

I think the larger coordination issue is less a State-local issue and more of what Mr. Starr was referring to, which is these multiple grant mechanisms from multiple Federal agencies coming into either a State or into a city with different requirements, different timelines, multiple application processes, all ultimately serving the same goal. If those could be rationalized, coordinated, integrated in a more effective way, I think we would find people spending less time on administration and applying for grants and more time on actually doing the preparedness work.

Mr. BILIRAKIS. How many States would you say take advantage of these programs?

Mr. LEVI. Well, every State is a recipient of the Public Health Emergency Preparedness Program, as well as the Hospital Preparedness Program, which are sort of the core programs.

Mr. BILIRAKIS. Anyone else?

Okay. Well, thank you.

I have a little time. We don't have Members on the panel. Does anybody else want to maybe expand on their testimony on any particular issues since you are here?

Mr. STARR. I just wanted to say——

Mr. BILIRAKIS. Sure, please. You are recognized. Please.

Mr. STARR. Thank you.

I just wanted to add one point about Mr. Marino's earlier comment about the use of the private sector. New York City, and particularly the pharmaceutical supply chain, if the stockpile was eliminated—if I am not mistaken, his question was, if the stockpile was eliminated, how fast could the private pharmaceutical supply chain swing into action to supply the needed countermeasures in a public health emergency, and specific to anthrax and other extremely short-timelined incidents. It is too long. It would be far too long, and there is absolutely no way.

I have some experience with the pharmaceutical supply chain, at least around my region. Without any kind of Federal intervention or any kind of interaction with us, it would be too long for the private supply chain to swing into action at the level that we would need to in the timeline that we would need. I think I speak for the rest of the panel on that.

Mr. BILIRAKIS. Anyone else want to add to that?

Okay, well, thank you. I do have a markup, but I want to thank the witnesses for their valuable testimony and the Members for their questions.

The Members of the subcommittee may have some additional questions—I am sure they will, because, as I said, the Minority party is at the White House at this particular time—but we ask you to respond in writing, please. The hearing record will be open for 10 days.

Without objection, the subcommittee stands adjourned.

Thank you, folks. Appreciate it very much.

[Whereupon, at 3:35 p.m., the subcommittee was adjourned.]

APPENDIX

QUESTIONS FROM CHAIRMAN GUS M. BILIRAKIS FOR ALEXANDER G. GARZA

Question 1. What is the Department of Homeland Security's strategy for relaying imminent threat information to the public? I am not just speaking of the new National Terrorism Advisory System, but also about the need for detailed information for the public on whether to shelter in place or evacuate, and on health information like what countermeasures are appropriate and where to get them.

How will DHS get this information out in real time to local authorities and/or the public?

Answer. Thank you for the opportunity to provide information pertaining to how we disseminate information to the public and the coordination that is required with State and local governments, and with the Department of Health and Human Services (HHS), which has the Federal lead on public health communications.

The public information response to a wide-area aerosolized anthrax attack would require significant participation of many Government agencies, non-profit organizations, and the private sector. The information provided to the public about the nature of the threat, the attack, and the response would require parallel communication efforts through various channels. Different audiences will need difference pieces of the overall flow of information. It is first important to recognize that the responsibility and authority to provide detailed information to the public on immediate public health and safety matters such as shelter-in-place, evacuation, or appropriate medical countermeasures is held at the local level under a State's police powers. DHS will work with local authorities to ensure they have the most up-to-date and comprehensive information available.

The audience of those not immediately affected by the attack will require different information, particularly since identification of an anthrax attack will likely occur well after thousands have traveled across a State, the Nation, and even other parts of the world. As characterization of the event becomes better understood, DHS will be coordinating with these communities and States affected but not necessarily targeted in the attack itself; therefore, the information and strategy to provide information to those audiences will involve less details about immediate response efforts and more information about what we know about the nature of the threat (i.e. potential for multiple attacks) and the need to work closely with HHS's CDC on education (i.e. why the SNS isn't being deployed to other cities, personal protective measures to take and not to take, etc.). Communication and coordination with this group will be essential to a National response and recovery in the early stages so that limited resources are not misallocated and local officials and their constituents are educated about the decisions that are being made and why.

STRATEGY

White House Communications will provide strategic communications direction following a terrorist attack. In addition, the U.S. Domestic Communications Strategy (DCS), developed by the DHS Office of Public Affairs and Federal interagency, was designed to counter the intended consequences of terrorism against the United States. The DCS details a comprehensive set of pre-identified counterterrorism communications options that each agency could and likely would take following a terrorist attack.

Because the DCS is a broad-based strategy to meet counterterrorism objectives for all terrorist attacks, the DHS Office of Public Affairs has also developed an anthrax specific communications coordination plan. HHS and CDC will retain the Federal lead on public health communications, including providing technical assistance to State and local governments to improve their planning for emergency public information and warning. DHS's responsibilities in both operations and public communications under Homeland Security Presidential Directive—5 are to coordinate those response efforts. For this reason, DHS has developed a draft communications coordi-

nation plan that lays out roles and responsibilities within the Federal Government and the mechanism the Department will use to coordinate public communications activities across State, local, Federal, international, and private sector partners following an anthrax attack. The mechanisms include the National Incident Communications Conference Line (NICCL) and the State Incident Communications Coordination Line (SICCL). The NICCL and SICCL are managed once DHS stands up the National Joint Information Center (NJIC) and are used to coordinate Federal and State communications, respectively. A similar private sector coordination capability also exists through the NJIC. Coordination is essential to a successful response to an incident of the magnitude of a wide-area aerosolized anthrax attack, and DHS will use all of the communications channels (print and broadcast media, internet, social media, etc.) and its proven ability to coordinate large-scale incidents to provide information the public will seek during such a high-profile National incident. These communication channels include new media, such as blogs, Twitter, and other on-line publications, as well as traditional media sources.

Finally, under the National Response Framework, DHS Public Affairs is responsible for Emergency Support Function (ESF) 15—External Affairs. ESF–15 is the standard operating procedure for how the U.S. Government will conduct the external affairs response to a National-level incident requiring a large coordinated Federal response. There is intentional overlap between the anthrax planning process and the ESF–15 standard operating procedure. ESF–15 largely addresses the efforts for a large on-scene Federal communications presence.

Question 2a. OHA released draft guidance in 2009 for protecting first responders immediately after an anthrax attack.

Can you please provide a status update on when that guidance will be finalized for use by first responders? The guidance has been with OMB for sign-off for a long time.

Answer. OMB and NSS staff has been working with DHS/OHA to ensure the document is responsive to the concerns raised by Federal departments and agencies that will be our partners in implementing this guidance. OHA is now finalizing the guidance for approval and publication. It is important to note that in the interim, the draft guidance that was initially published for public comment in 2009 should guide first responders; no major changes to that guidance are being contemplated.

Question 2b. Can you please address whether the final guidance will recommend pre-event vaccination for first responders, and how would OHA help to implement such a program?

Answer. The draft guidance provides information for consideration by the responder community. It provides specific planning and program considerations if such a pre-event vaccination program is desired. In that regard, OHA and others are evaluating strategies for making some portion of the vaccine in the Strategic National Stockpile (SNS) that would otherwise go unused available to this community.

Question 3. We've heard from different avenues that it can be confusing to State and local governments to work with so many different grant programs, many of which have related guidance, and that this can encourage duplication of efforts. I know that some work has been undertaken to address this problem.

Can you please provide a description and update of DHS' work with HHS to align related grants?

Answer. The Department of Health and Human Services (HHS), Office of the Assistant Secretary for Preparedness and Response (ASPR) is leading an interagency effort to align public health and medical preparedness grants having separate authorizations, appropriations, applications, reporting, and measurement requirements. One of the main goals is to standardize the grant process—a large portion of that process includes streamlining the application submission process for the States as they respond to multiple Federal Government funding opportunities. The core interagency partners critical to the success of this endeavor are HHS/ASPR; HHS/Centers for Disease Control and Prevention (CDC); HHS/Health Resources and Services Administration; Department of Homeland Security (DHS), Federal Emergency Management Agency (FEMA); and Department of Transportation (DoT), National Highway Traffic Safety Agency (NHTSA).

The Department of Homeland Security's Office of Health Affairs has been actively engaged in the DHS/HHS Coordinating Committee. In this role, DHS along with our partners are working to align emergency preparedness grant programs throughout the Federal Government to support National preparedness strategies for end users at the State, local, Tribal, and territorial level. These funding opportunities, and related alignment activities, need to be coordinated in the most cost-effective manner possible, consistent with the applicable laws and missions of the respective agencies. This collaboration and integration is essential for establishing an effective and co-

ordinated response between all levels of government during a public health emergency.

Question 4. In response to President Obama's Executive Order on countermeasure distribution, I understand that your office has taken the lead for DHS on the conops plan for mission-essential personnel of the Executive branch. OHA has also spearheaded an MCM strategy for DHS employees, and oversees the purchase and storage of MCMs for the DHS workforce.

Can you please provide us with an update on the status of the conops plan?

What is your approach to stockpiling, distributing, and dispensing countermeasures within DHS?

Answer. Per Section 4 of President Obama's Executive Order 13527, the Department of Homeland Security (DHS) Office of Health Affairs (OHA) and the Department of Health and Human Services (HHS) have formed a joint task force in order to plan a common path forward for continuity of operations among Federal agency mission-essential functions (MEF), inclusive of Executive branch departments and agencies.

OHA and DHS Operations Coordination and Planning (OPS) have coordinated in ensuring that plans are in place across all of the DHS Components. Per the Department Guidance Statement (DGS) developed by OPS and approved by the Secretary of DHS, each of the DHS Components has developed its own Anthrax Operation Plan, which is a requirement of each Component outlined as part of this DGS. These plans identify how each Component will protect its personnel by ensuring each DHS employee will be able to receive medical countermeasures (MCM). OHA is engaged in meetings with Federal partners outside of DHS to discuss planning and coordination to improve our MCM capabilities, and is able to offer assistance, make recommendations, and share existing training and educational resources and reference materials.

Focusing specifically on stockpiling, distributing, and dispensing MCM within DHS, OHA has developed a DHS MCM Program at the direction of Secretary Napolitano to provide MCM to DHS employees in an attacked area. Currently, OHA has over 6 million tablets of antibiotic and antiviral MCM purchased and stored in a pharmaceutical logistics center ready for rapid deployment, to protect DHS employees and individuals under DHS care and custody. OHA has identified two dozen medical storage locations for local MCM stockpiles, or "caches," and has pre-positioned MCM in these storage caches around the Nation. OHA has entered into an inter-agency agreement partnership with the HHS Supply Service Center (SSC) to provide MCM supply chain management support, including sourcing, bottling/repackaging, labeling, storage, and distribution services.

In preparation for activation of Points of Dispensing (POD) for DHS employees utilizing these stockpiled MCM, OHA has established POD training material to assist all DHS Components in selecting their appropriate POD locations and POD staff members. POD training includes the roles and responsibilities for DHS POD staff members to successfully stand-up, implement, and close-down a POD for DHS employees and those under DHS care and custody. OHA has worked with each of the DHS Components to exercise their POD implementation and OHA created POD demonstration videos to assist Components in educating their personnel. OHA is also working with the DHS Office of the Chief Learning Officer to develop and disseminate training on-line for the DHS workforce with regards to Anthrax and MCM POD education.

QUESTION FROM CHAIRMAN GUS M. BILIRAKIS FOR MIKE MCHARGUE

Question. The Council on State and Territorial Epidemiologists conducted a survey last year to assess State-level preparedness for a radiological or nuclear exclusive of a nuclear power plant emergency.

Can you please describe Florida's planning efforts with regard to stockpiling, distribution, and dispensing of medical countermeasures that can be used to respond to a radiological dirty bomb or nuclear attack?

Answer. The Florida Department of Health maintains primary caches of Potassium Iodide (KI) at three County Health Departments in the State. The Health Departments have primary response capability for the nuclear reactors located in their jurisdictions. To meet this need, there are 1.615 million total doses of KI at these sites. An additional 300,000 doses are maintained in Tallahassee by the bureau of Pharmacy for a cache of approximately 2 million doses.

In addition, the State has four radiological countermeasure kits that are controlled by the State pharmacy. These kits total 2,000 doses and are designed for treat emergency responders and victims in an emergency. Each kit contains KI, Prussian blue, Zn-DTPA and Ca-DTPA. The kit also contains the appropriate med-

ical supplies for administration. The distribution capability of this product is covered under the Logistics Support Annex and utilizes the response deadlines established for SNS level events.

In an event, the State has developed a Medical Advisory Group to evaluate an allocation and apportionment methodology of both these caches as well as the use of the SNS or Vendor Inventory. Once the apportionment is made, the Health Departments, using their all-hazards approach, activate their Points of Dispensing protocols that are developed to utilize a 48-hour window to a longer more extensive delivery needs.

QUESTIONS FROM CHAIRMAN GUS M. BILIRAKIS FOR ALI S. KHAN

Question 1a. The Nuclear Regulatory Commission is responsible for stockpiling and distributing potassium iodide in the 10-mile zone around nuclear reactors. But I am concerned about our preparedness for a radiation/nuclear terrorist event.

Can you please describe the role of your office and of the SNS in the event of a radiological or nuclear attack?

Answer. I share your concern about the Nation's preparedness for a radiation event, whether it is an accidental release or a radiological or nuclear attack. During such an event, the Centers for Disease Control and Prevention (CDC) and the Agency for Toxic Substances and Disease Registry (ATSDR), stand ready to assist State, local, and territorial authorities in protecting people's health by providing technical assistance and science-based advice on steps people can take to reduce their exposure to radiation. During a radiation incident, CDC/ATSDR focuses on its public health strengths, which include:

- Laboratory and epidemiological detection and characterization of event;
- Technical assistance to States upon request;
- Clinical and self-help guidance;
- Medical countermeasures (where appropriate) to mitigate morbidity and mortality;
- Risk communication with stakeholders and the public;
- Linkage across the health system from local to State, National, and even international levels to ensure an integrated health system response; and
- Participation in interagency radiation response systems including the Federal Radiological Monitoring and Assessment Center and the Advisory Team for Environment, Food, and Health.

Many systems that we use to meet everyday public health needs are at the core of public health preparedness and response for unforeseen and unpredictable public health threats.

Within CDC, the Office of Public Health Preparedness and Response (PHPR) leads CDC's preparedness and response activities by providing strategic direction, support, and coordination for activities across CDC as well as with public health emergency response partners. When a disaster occurs, CDC must respond effectively and support international, National, State, local, Tribal, territorial, and private sector public health emergency response partners. A critical component of CDC's work during an incident is to coordinate public health response activities and provide resources to State and local public health departments. PHPR manages CDC's Emergency Operations Center (EOC), which serves as the command center for monitoring and coordinating CDC's emergency response to public health threats in the United States and abroad. Staffed around the clock, the EOC serves as CDC's central point of contact for reporting public health threats and supports the Department of Health and Human Services (HHS) Secretary's Operations Center. The EOC organizes CDC scientific experts in one location during an emergency response to analyze, validate, and efficiently exchange information as well as connect with public health emergency response partners.

PHPR also manages the Strategic National Stockpile (SNS), a National repository of large quantities of medicine, vaccines, and other medical supplies stored in strategic locations around the Nation. SNS assets, when combined with Federal, State, and local technical expertise to manage and distribute them efficiently, help ensure that key medical supplies are available during emergencies.

Question 1b. Are we stockpiling radiation/nuclear countermeasures, and if so, which countermeasures, and do we have a workable plan to distribute them?

Answer. The SNS includes radiation countermeasures which may be used to mitigate health effects from radiation exposure. In addition, the SNS maintains inventories of medical supplies that can be used for burn and blast injuries and other trauma such as those resulting from large-scale events such as an improvised nuclear detonation. Complete listings of the contents and quantities of materials held in the SNS are considered sensitive but unclassified information, and distribution

of this information is limited to guard against exploitation of gaps that could be identified through a review of SNS holdings. We will happily provide an opportunity for you to review additional information in hard copy at your convenience.

The SNS has proven plans for distribution of these products to the States. State and local authorities are then responsible for distribution to local areas and dispensing to the affected population.

CDC guidance and technical assistance have assisted the States and major cities in developing their plans to receive, distribute, and dispense SNS assets. These plans have been exercised and were used to guide implementation of their core capabilities for providing SNS assets to their populations during the 2009 H1N1 influenza pandemic.

Question 1c. What countermeasures (including preventives, treatments, and diagnostics) are missing from our arsenal?

Answer. Requirements for medical countermeasures against chemical, biological, radiological, and nuclear threats are established by the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE). In July 2006, HHS established the PHEMCE, creating a coordinated framework as we advanced an "end-to-end" approach in the development, procurement, and use of medical countermeasures. The HHS Office of the Assistant Secretary for Preparedness and Response (ASPR) leads the PHEMCE, which includes principal representatives from CDC, the U.S. Food and Drug Administration (FDA), and the National Institutes of Health (NIH) as well as key interagency partners from the Department of Defense (DoD), the Department of Homeland Security (DHS), the Department of Veterans Affairs (VA), and the Department of Agriculture. The overarching mission of the PHEMCE is to define and prioritize requirements for public health emergency medical countermeasures; coordinate research, early and late stage product development, and procurement activities addressing these requirements; and set deployment and use strategies for medical countermeasures held in the SNS. The PHEMCE also conducts an annual review of the SNS, which allows for a thorough accounting of the SNS contents each year, and an evaluation of those contents against the current medical countermeasures requirements.

As the statutorily designated entity for this activity, DHS has identified 13 specific material threats to prepare and respond to biological, radiological, and nuclear hazards. In response, HHS has taken the lead through a coordinated strategic approach—led by the PHEMCE—to maximize our preparedness to the range of threats we face while also ensuring the most efficient use of limited taxpayer dollars. Under the leadership of the ASPR, we have improved the Nation's preparedness through the development of new medical countermeasure products and procurements.

The available, existing countermeasures to hasten the body's excretion of radionuclides (chelation) cover only a limited number of radioactive isotopes, but the SNS continues to work towards stockpiling the existing radiation countermeasures to meet the current PHEMCE-established goals.

There currently are very few licensed pharmaceuticals that reduce the risk of radiation-related illness following severe radiation exposure. The PHEMCE has established goals for the development of such medical countermeasures, and BARDA and NIH, in collaboration with partners at the DoD, are supporting research towards those goals.

To date there have been no PHEMCE requirements or resources available for procurement of diagnostics for the SNS. However, radionuclide diagnostics are essential for diagnosing which radionuclides people have been exposed to, and at what levels, as well as the overall level of radiation exposure. Results of these diagnostics indicate which medical countermeasures should be delivered and for how long based on the exposure dose. Current U.S. radionuclide exposure diagnostic capability is provided by CDC's National Center for Environmental Health, in the Environmental Health Laboratory. At this time, CDC's Environmental Health Laboratory can test for only half of the priority threat radionuclides for a large-scale emergency incident, a gap that can only be filled by additional research and development. In addition, this laboratory is the only U.S. facility that can rapidly diagnose radionuclide internal contamination in people. This limits National surge capacity.

Finally, the Nation does not have the capability to rapidly conduct external monitoring of people who may have been contaminated by fallout or other sources of airborne release of radionuclides. CDC has developed guidance for State and local health departments on how to conduct a population monitoring program, but most health departments lack equipment and trained human resources to implement such a program

Question 2a. I understand that funding for the Cities Readiness Initiative comes out of HHS' Public Health Emergency Preparedness fund. The budget for that program has been steadily decreasing.

In a time of continued risk, can you please explain your rationale for that decrease?

Answer. CDC is continually evaluating what we do and constantly looking at ways to efficiently utilize existing resources to maximize health impact. Without the dedicated Cities Readiness Initiative (CRI) funding, awardees are still able to use PHEP funding for CRI-related activities within their jurisdictions. The PHEP program is structured so that awardees assess their current capabilities against the targeted public health preparedness capabilities and plan their activities to meet those targeted capabilities. Awardees that prioritize medical countermeasure dispensing may apply their PHEP funding to improving those related capabilities within their jurisdictions.

Funds for the CRI are provided through a carve-out from the total dollars appropriated annually for the Public Health Emergency Preparedness (PHEP) cooperative agreement. The distribution of PHEP funds is calculated using a formula established by statute that includes a base amount for each awardee, as determined by the Secretary, plus population-based funding. Funding also is awarded for specific preparedness activities, including CRI. Fiscal year 2011 funds for the CRI ($54 million), Chemical Laboratories ($10 million), and Risk-Based Projects ($10 million) are provided through a carve-out from the total dollars appropriated for the PHEP cooperative agreement.

Dedicated funding for CRI has decreased as overall PHEP funding has declined. The fiscal year 2011 PHEP funding level is $613,610,342, which represents a 12% ($84.6 million) reduction from fiscal year 2010 when about $698 million was awarded. CRI funding for fiscal year 2011 accounts for 8.85% of the total PHEP funding and is consistent with CRI funding levels in prior years. For instance, CRI funding was 8.87% of the total PHEP funding in fiscal year 2010, 8.50% in fiscal year 2009, and 9.1% in fiscal year 2008.

The fiscal year 2011 PHEP reductions were proportionally allocated in an effort to preserve core PHEP funding used in support of other critical preparedness activities and systems which ultimately also impact response capability for medical countermeasure use. The base portion of the PHEP funding is used by States for activities that support both CRI and non-CRI jurisdictions.

Question 2b. Can you also please explain how that drop in funding will impact the Cities Readiness Initiative? I understand you are considering a risk-based funding scheme for this program, and I would appreciate further clarity in what that means for funding distribution.

Answer. At this point, it is too early to have a full appreciation of the impact of the fiscal year 2011 reductions in PHEP funding on CRI as the funding will not be awarded until August 2011. However, anecdotal evidence received by our staff as the States prepare their cooperative agreement applications and budgets suggests that both State and local jobs may be in jeopardy of being lost. Furthermore, our State and local partners have identified their inability to sustain minimal program requirements, including the maintenance of plans, the need to preserve critical response resources, and their ability to recruit, train, and drill/exercise staff and volunteers. The success of CRI is largely contingent on plans and people. With a fiscal impact to both, the ability to sustain an effective medical countermeasure distribution and dispensing infrastructure is diminished and may result in fewer individuals adequately protected from disease and death following a public health threat.

In addition to CRI, CDC intends to direct a portion of the fiscal year 2011 PHEP funds to 10 major urban areas (including 14 States and the four directly-funded localities) for an all-hazards public health risk reduction funding initiative. This risk-based funding scheme is a pilot intended to promote and accelerate the development of strategies that mitigate the public health risks associated with higher population areas.

The jurisdictions selected for this initiative include the 10 Tier 1 urban areas in the U.S. Department of Homeland Security's Urban Area Security Initiative (UASI) grant program for fiscal year 2010. However, the purpose of the CDC funding is for all-hazards public health risk reduction and is not restricted to terrorism preparedness.

A total of $10 million will be awarded for this project, with funding to be directed to the following 10 urban areas: Boston; Chicago; Dallas/Fort Worth/Arlington; Houston; Jersey City/Newark; Los Angeles/Long Beach; New York City; Philadelphia; San Francisco; and the National Capitol Region (Washington DC).

CDC may elect to extend and/or expand the project in future years based on available funding and a review of how well initial strategies developed during the pilot may demonstrate evidence of mitigating public health, medical, and mental/behavioral health system risks associated with hazards that may be more likely to affect higher population areas.

Question 3a. HHS' budget request for the Strategic National Stockpile is $655 million, a $59 million increase over fiscal year 2010 levels. These funds will be used to replace expiring countermeasures in high-priority categories.

Can you discuss what these high-priority categories are, or at least explain how you prioritize funds for replacement countermeasures?

Answer. Requirements for medical countermeasures are set by the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE). The PHEMCE establishes goals based on analyses of scenarios that lead to the numbers of persons likely to require medical countermeasures. Priorities for purchase of replacement and new medical countermeasures are established by this group through a documented, robust governance process. The current high priorities include medical countermeasures for anthrax, smallpox, and other bacterial threats, as well as maintaining current levels of inventory.

To inform this decision process, CDC has built a capacity for on-going life-cycle analysis, which it uses to make recommendations on replacement and shelf-life extension decisions, as well as to accurately cost long-range projections of the fiscal needs relating to various products in the SNS inventory.

CDC has used these more accurate and robust cost figures in its annual budget requests to give decisionmakers at the agency, Departmental, and Congressional levels the most convincing possible notion of the true financial requirement for maintaining this National security asset.

Question 3b. Will your requirements for replacement funding increase as the Biomedical Advance Research and Development Authority (BARDA) add new countermeasures to the stockpile?

Answer. BARDA-purchased medical countermeasures are funded from the Project BioShield Special Reserve Fund for which there is no authority to provide funding for storage, management, or replacement of the medical countermeasures by the SNS. As a result, any replacement of BARDA-procured countermeasures would likely be funded by the SNS.

Question 4a. In its fiscal year 2012 budget request, HHS stated that the SNS will continue to explore non-traditional methods of distribution and dispensing of countermeasures within 48 hours, including public-private collaborations and the implementation of the closed point of dispensing (POD) concept.

Can you please describe the "closed POD" concept in greater detail?

Answer. Closed points of dispensing (PODs) will be important during a large-scale public health emergency that requires the provision of medical countermeasures, as health care providers and open or public PODs will likely be overwhelmed. A closed or private POD refers to an organization-specific POD operated by a large employer, university, or other organization with a significant employee/student/resident population that, in collaboration with its local health department, develops plans to provide medical countermeasures to its employees, contractors, students, residents, and their families. The goal of a closed POD is to use the resources of the partnering organization to take care of itself by rapidly dispensing medical countermeasures. Doing so protects its constituency and associated families and reduces the number of people that would need to go to the open PODs. Benefits of closed PODs include ease of access to life-saving medications; quick dispensing to employees and their families; enhanced business continuity plans; and the potential for increased numbers of volunteers to support open PODs, since in some cases, organizations participating as closed PODs have agreed to provide their staff as volunteers. In all cases, operation of closed PODs by other than State and local public health organizations has the effect of increasing the numbers of people who could rapidly receive medical countermeasures. Some examples include, but are not limited to employer-specific closed PODs, homeowners-association closed PODs, community-organization closed PODs, and hotel-based closed PODS.

Question 4b. Operationally, how does a closed POD like a school differ from an open POD?

Answer. Open and closed PODs differ in the size and scope of their dispensing operation because they serve different populations. Open, or public, PODs are available to the general public and are the cornerstone of all jurisdictional plans. Open PODs are often located in large community facilities known to the population, accessible by common modes of transportation, and capable of accommodating many persons at one time. They also allow for efficient dispensing to the public. Open PODs are generally staffed by State and local public health personnel, other State and local personnel, or volunteers.

Closed PODs are characterized by their focus on dispensing to a pre-defined population rather than the general public, e.g., the employees of a private company. Closed PODs are generally staffed by qualified personnel who are members of the organization operating the closed POD rather than by those persons who operate

open PODs. This arrangement effectively increases available resources to dispense medical countermeasures without adversely impacting staff at open PODS.

Question 4c. Which POD modalities have you found to be the most successful?

Answer. The experience of developing and testing these varying POD modalities in public health communities allows for the selection and implementation of the most complementary array of planned modalities to reach a given population.

Ultimately, the most successful dispensing modalities employed depend on the community. Each community is unique and has its own challenges, resources, and capabilities. No one modality or prescribed combination will work for all communities. A large-scale public health event in any community will require a layered system of dispensing using modalities that match and maximize the available resources and infrastructure.

However, if success is measured in terms of the percentage of population covered, then the most successful modality is the traditional large-scale public health-run open POD, which is typically situated at a school, auditorium, or sports arena. This modality is the cornerstone for mass dispensing for most jurisdictions. An open POD is scalable and can easily be expanded or retracted to meet the complexity of an event. Open POD operations have also been modified to include drive-through PODs, mobile PODs (using trailers to take PODs to remote locations), and household delivery of medical countermeasures by home health care nurses, Meals on Wheels, or other community-based organizations. Targeted home delivery strategies, complemented by additional strategies such as closed PODs, combine to help reduce the volume pressure on traditional open PODs.

Question 5a. What other dispensing models is CDC considering, and are guidance and funding provided to State and local governments so they can establish the modality that best fits the needs of their jurisdiction? Some of modalities would need to be Federally-driven, such as pre-deployment of medkits to peoples' homes. I am also wondering to what extent your dispensing activities are driven by a formal National dispensing strategy.

Answer. CDC has worked with State and local jurisdictions since 2002 to help them develop their plans to receive, store, distribute, and dispense medical countermeasures. CDC has provided numerous guidance documents, tools, and technical assistance opportunities to assist and assess State and local medical countermeasure distribution and dispensing plans. As noted previously, the ultimate decision of what works best is up to the individual States and localities. Listed below are some examples of dispensing modalities developed by State and local health departments.

General examples of innovative dispensing:

- Closed PODs (such as private business, faith-based organizations, military installations, homeowners associations),
- Drive-through PODs (see variations listed below),
- Mega PODs to facilitate mass dispensing in highly congested areas that are conducive to traffic gridlock,
- Mobile POD trailers,
- Tiered POD system (where the most-needed and highest population PODs open first),
- Civic groups for delivery of medication during an event,
- Community Emergency Response Team (CERT) for door-to-door delivery,
- Unusual dispensing locations such as grocery stores, long-term care facility pharmacies, mass transit stations, private physicians' offices, retail pharmacies,
- School bus delivery,
- Tele-pharmacy dispensing operations,
- U.S. Postal Service (USPS) dispensing.

Examples of variations of drive-through countermeasure dispensing:

- Omaha, Nebraska (in conjunction with the Nebraska Department of Roads and the Nebraska State Patrol): A highway closed to through traffic and with "pit stops" spaced along the highway. The car pulls into the "pit stop" and dispensing staff come to the car to conduct full-service prophylaxis dispensing. The car re-enters the highway upon completion.
- Seattle, Washington: Trailers cached throughout the county to allow almost immediate setup of multiple countermeasure dispensing locations with the ability to be mobile as needed.
- Cabell-Wayne Counties, West Virginia: Mobile countermeasure dispensing units reach rural populations. This is achieved with a 9-County "bundle team" to form a Threat Preparedness Planning Region along with the Homeland Security Committee and the local emergency planning committee.

The USPS mode of delivery is currently operational in only one city, Minneapolis, Minnesota. Other communities have shown an interest, but are unable to rally the

necessary numbers of law enforcement personnel to support the 1:1 escort of volunteer postal carriers as required by the USPS unions.

The MedKit at this point is a concept product only. It is not a licensed or commercially available product. The feasibility and commercial interest in developing the product is under further investigation by the PHEMCE.

Question 5b. BARDA published a requirement for smallpox that includes sufficient second generation smallpox vaccine to treat the 66 million people for whom the traditional smallpox vaccine is contraindicated. Enough vaccine for dispensing to 10 million people (20 million doses) is due to be delivered to the Strategic National Stockpile in 2013.

Will BioShield exercise its contract option to purchase an additional 60 million doses?

Answer. HHS is committed to ensuring that the Nation is able to respond to known threats, such as that posed by smallpox. A decision on whether to exercise the option will be made upon completion of product delivery in the base contract and after appropriate consultation with the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE).

Question 5c. Why does the pre-Emergency Use Authorization (EUA) for this pharmaceutical apply only to individuals with HIV? This population is much smaller than the 66 million stated in the BARDA requirement. Will CDC work with FDA to expand the EUA, therefore aligning it with the BARDA requirement? Does CDC have a response plan for how it would actually use this drug?

Answer. The determination of product use under an EUA is made by the FDA based on the totality of available scientific information. Based on the FDA's review of IMVAMUNE (or MVA, a third-generation investigational smallpox vaccine) data from clinical studies conducted by Bavarian Nordic (BN), FDA has communicated to CDC that the only eligible individuals for MVA vaccination under a potential EUA during a smallpox post-event emergency are HIV-positive individuals (18 years of age or older) with CD4 counts greater than 200 cells/ul who have not received a diagnosis that their condition has progressed to AIDS. FDA has stated that the eligible population for MVA under an EUA must correspond to those in which the vaccine has been studied. Therefore, at this time, only HIV-positive individuals could be vaccinated with IMVAMUNE (MVA) if an EUA were issued at this time.). Any updates to proposed product use, including additional eligible populations, will be made to the pre-EUA in accordance with FDA review determination as additional scientific information becomes available.

The PHEMCE has estimated that approximately 66.5 million individuals have relative contraindications to receiving a live-virus vaccine. This population includes those with a variety of conditions that impair the immune system such as cancer, HIV, and transplant patients. As described previously, the determination of eligible populations for IMVAMUNE (MVA) will be made by the FDA based on its review determination of the available data in the target populations and/or extrapolated from existing data. CDC is aware of BN's submission of clinical data from its study of MVA in adult subjects (18–40 years) with diagnosed atopic dermatitis to FDA. Currently, the FDA's review determination is pending; however, CDC will include any expanded use(s) of MVA under pre-EUA in accordance with FDA's review determination and in concert with the overarching post-event smallpox vaccine utilization policy/strategy.

ASPR is currently forming an interagency Smallpox Vaccine Strategy Working Group to begin initial discussion in July 2011 to determine a National smallpox vaccine strategy that considers all stockpiled smallpox vaccines, including MVA.

Question 5d. Can you please explain what an "Integrated Project Team" is, who sits on it, and to whom they report?

Answer. The PHEMCE is an interagency effort coordinated by the HHS Office of the Assistant Secretary for Preparedness and Response (ASPR). The PHEMCE includes three HHS internal agencies: CDC, FDA, and NIH. DHS, DoD, USDA, and VA have been supporting members of the PHEMCE. An Integrated Program Team (IPT) is formed for a specific threat. IPT memberships represent different Federal agencies, and composition may vary. At a minimum, membership includes CDC, FDA, NIH, BARDA, and DoD. IPTs are chaired by personnel from the ASPR. IPT chairs report to the Enterprise Executive Committee of the PHEMCE.