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A NATION PREPARED: STRENGTHENING MEDICAL AND PUBLIC PREPAREDNESS AND RESPONSE

HEARING

OF THE

COMMITTEE ON HEALTH, EDUCATION, LABOR, AND PENSIONS

UNITED STATES SENATE

ONE HUNDRED TWELFTH CONGRESS

FIRST SESSION

ON

EXAMINING STRENGTHENING MEDICAL AND PUBLIC HEALTH PREPAREDNESS AND RESPONSE

MAY 17, 2011

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C O N T E N T S

STATEMENTS

TUESDAY, MAY 17, 2011

A NATION PREPARED: STRENGTHENING MEDICAL AND PUBLIC PREPAREDNESS AND RESPONSE

TUESDAY, MAY 17, 2011

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

The committee met, pursuant to notice, at 2:37 p.m. in Room 430, Dirksen Office Building, Hon. Tom Harkin, Chairman of the committee, presiding.

Present: Senators Harkin, Enzi, Casey, Whitehouse, Blumenthal, Burr, Hatch, and Roberts.

OPENING STATEMENT OF SENATOR HARKIN

The CHAIRMAN. The committee on Health, Education, Labor, and Pensions will come to order.

I am pleased to convene this hearing today on a very important issue, defending our Nation against public health threats. Such threats are diverse in origin and include exposure to chemical, biological, radiological or nuclear agents. Sometimes these threats occur naturally, the 2009 H1N1 pandemic influenza, for example, or they can be the result of malicious intent, such as the intentional release of the anthrax in 2001. A recent and very challenging example is the radiation leak that occurred at the nuclear plant damaged in Japan's massive earthquake.

It is not just known threats that place the health and well-being of Americans at risk, there are just as many emerging or unknown threats against which protection is critical. Because the impact of these threats could be catastrophic, it is imperative we continue to strengthen the Nation's ability to adequately prepare for and appropriately respond to a public health emergency. Building our Nation's response capacity requires close collaboration among Federal, State and local governments, hospitals and healthcare providers, businesses, schools, and indeed all Americans.

I have long taken very seriously the Federal Government's role in being prepared for a public health emergency, public health preparedness, as it is called. We have made tremendous progress in preparedness during the last decade. One important aspect of public health preparedness is the advanced development and procurement of medical countermeasures. These are the vaccines, therapies and diagnostics needed to prevent or respond to a bioterrorism event or other public health emergency.

In an effort to ensure that we have the appropriate medical countermeasures, we need to continue to support innovative research into promising new products and ensure that products are readily available during a time of emergency. We also need to address the scientific challenges of identifying safe and effective medical countermeasures when human trials are not available or ethical. Such scientific challenges pose regulatory issues that we will hear more about from our distinguished panel of witnesses today.

Underlying all of our preparedness activities is the issue of how to ensure that our most vulnerable citizens will be protected should disaster strike. We know that many populations, including individuals with disabilities, seniors and children may have unique needs that we have the responsibility to address during a public health emergency. This came to the forefront during Hurricane Katrina and people with disabilities. In the past, when faced with catastrophic events, we have too often seen such needs go unmet.

The purpose of this hearing is to learn more about the significant progress our Nation has made in preparing for and responding to public health threats and challenges and the barriers that may exist. It is even more important to discuss ways in which we can use lessons learned to create a stronger and more prepared Nation.

So I look forward to hearing suggestions from our witnesses on ways to strengthen our public health preparedness as this committee begins its work on reauthorizing the Pandemic and All-Hazards Preparedness Act, known as PAHPA, hopefully during this congressional session.

I yield to Senator Enzi for an opening statement.

Senator ENZI. Mr. Chairman, I am going to yield to Senator Burr for a statement. If you have two on your side, then I will have one as well. If you don't, I will put mine in the record. But I need to have Senator Burr do an opening statement because in 2006 he was the lead——

The CHAIRMAN. That is right.

Senator ENZI [continuing]. On doing this particular bill and I sat with him in a number of negotiation sessions with Senator Kennedy and Senator Dodd, as they worked out all of the issues that we were aware of at that time. And he did just a masterful job and really understands this bill and was really in charge of it and it is largely thanks to him that we were able to get it done.

And of course we were worried about bird flu at that time and we had the measures in place. So I would yield to Senator Burr.

STATEMENT OF SENATOR BURR

Senator BURR. Mr. Chairman, thank you. And Senator Enzi, thank you for yielding to me for an opening statement. I welcome our entire panels, especially Dr. Lurie for being here.

Mr. Chairman, one of the committee's greatest responsibilities is ensuring that our Nation has the medical and public health preparedness and response capabilities necessary to respond to all hazards and all threats, whether natural or manmade. The Pandemic and All Hazard Preparedness Act answered the critical question of who is in charge through the creation of the Assistant Secretary for Preparedness and Response. This law strengthened our medical surge capabilities and improved State and local public

health security. PAHPA also enhanced medical countermeasure research, development and procurement through the creation of the Biomedical Advanced Research and Development Authority.

As we work to reauthorize the Pandemic and All Hazards Preparedness Act and BioShield, it is critical that this committee take a hard look at what is working well and what is not working well. The good news is that we have come a long way, and as H1N1 demonstrated, we are better prepared to respond to the public health emergencies today than we were 5 years ago. But while we have come a long way, we know that much work remains to be done, and we cannot lose sight of the urgency surrounding our work in this area.

Just today, news broke that the department plans to make cuts to preparedness programs. This raises significant questions as to how the administration is prioritizing and coordinating their preparedness and response mission. Medical and public health preparedness and response is a matter of national security. PAHPA's reauthorization is the opportunity to make the targeted and strategic changes to the medical and public health preparedness and response authorities and programs necessary to strengthen and improve our capabilities to successfully respond to all threats.

We have the opportunity to draw upon the lessons learned after 5 years, the 2009 H1N1 influenza pandemic, the Haiti disaster, the Gulf oil spill and the recent disaster in Japan. Many of these incidents underscore the ability of Mother Nature to throw us a biological curve ball with the potential to wreak havoc on the scale of the 1918 pandemic. The death of Osama bin Laden is a sobering reminder that the 21st century threats are real and we must be prepared to address chemical, biological, radiological and nuclear threats.

The Commission on the Prevention of WMD Proliferation and Terrorism has repeatedly warned that it is,

> "more likely than not, that a weapon of mass destruction will be used in a terrorist act by the end of 2013 and that we must make bioterrorism a higher priority."

Just last year the WMD Commission again warned that we are, "woefully behind in our capability to rapidly produce vaccines and therapeutics," which we all know is critical for responding to CBRN threats, whether natural or manmade.

Last year the administration's Public Health Emergency Medical Countermeasures Enterprise review concluded,

> 'Our Nation must have the nimble, flexible capability to produce medical countermeasures rapidly in the face of an attack or threat, known or unknown, including a novel, previously unrecognized, naturally occurring emerging infectious disease."

If we are to achieve the shared goal of having a prepared Nation capable of responding to all hazards and all threats, we must ensure the continuity of critical medical preparedness and public health preparedness authorities and programs. We must ensure that these programs are targeted, sound in achieving the measured results and returns American taxpayers expect and deserve.

Where we have not gotten the policy exactly right, we must take this opportunity to refocus, to strengthen and to improve these programs and authorities. This includes ensuring that our medical countermeasures public/private partnerships reflect modern day threats and the Food and Drug Administration provides the regulatory certainty and support to ensure a robust medical countermeasure enterprise. We must foster and accelerate the development and innovation of medical countermeasures, which includes fully funding BARDA's advanced research and development. Let me restate that, which requires fully funding BARDA's advanced research and development funding.

We have always been able to come together in a bipartisan manner on this issue when it comes to prioritizing medical and public health preparedness and response. Our work in this area is a matter of national security.

And to the Chairman and the Ranking Member I look forward to again partnering with my colleagues to reauthorize PAHPA and BioShield and to do it in this Congress. I thank the Chair.

The CHAIRMAN. Thank you, Senator Burr and thank you also for your great leadership on this whole issue, as Senator Enzi said, going back several years when you led the effort in this committee. Thank you for that leadership very much.

And Senator Casey, also, I guess the two of you are co-sponsoring the reauthorization bill this year. I would recognize Senator Casey for an opening statement—if you want.

STATEMENT OF SENATOR CASEY

Senator CASEY. I will submit a statement for the record. Thank you, Mr. Chairman.

[The prepared statement of Senator Casey follows:]

PREPARED STATEMENT OF SENATOR CASEY

I'd like to thank my distinguished colleagues, Senator Harkin, Senator Enzi and Senator Burr, for their efforts to ensure that our Nation is prepared for a medical emergency. I am honored to be working with you on a bipartisan reauthorization of the Pandemic All Hazards Preparedness Act.

I'd also like to recognize our distinguished panelists here today—Dr. Lurie it is good to see you again—and thank you for your tireless work on protecting Americans from public health threats.

Few issues are as central to the role of the Federal Government as protecting its citizens from a public health emergency—be it natural or manmade.

Recent disasters from the past few years—the earthquake in Haiti and in Japan, and the H1N1 outbreak closer to home—have illuminated both the strengths and weaknesses of our preparedness and response capabilities.

In light of the recent capture of Osama Bin Laden, many have suggested that the United States needs to be even more vigilant about a possible terrorist attack.

I, like many Americans, am concerned about what progress we have made in the past few years since the Pandemic All Hazards Preparedness Act was passed in developing and licensing medicines

that will help inoculate and cure the greatest health threats we face.

Since 2004, the Department of Homeland Security has determined that 13 chemical, biological, radiological, and nuclear agents pose a high consequence in terms of people exposed to the pathogens. These are anthrax, glanders, melioidiosis, botulism toxin, Ebola virus, tularemia, a variety of hemorrhagic fevers, typhus, smallpox, plague, and radiological and nuclear materials.

Through my work with Senator Burr on the Weapons of Mass Destruction Caucus, I know all too well how real these threats are and what a catastrophic disaster such an attack would impose.

I know, too, that we have made progress in some of these areas when it comes to developing medical countermeasures. But I am concerned about reports that progress is coming along very slowly—and that we do not have the right level of scientific knowledge and resources devoted to this priority.

I look forward to hearing your testimony today and discussing what else we, in Congress, can do to support the public health preparedness and response enterprise.

The CHAIRMAN. I appreciate that very much, Senator Casey.

Senator Enzi.

STATEMENT OF SENATOR ENZI

Senator ENZI. Mr. Chairman, I'll submit mine to the record. And I will turn over the Ranking Member duties to Senator Burr. I have to be at another meeting.

I do want to thank Senators Hatch and Roberts for their work on this issue as well, before, and the leadership they provided and the fact that they're here to participate today, too.

[The prepared statement of Senator Enzi follows:]

PREPARED STATEMENT OF SENATOR ENZI

Good afternoon. From the start, I would like to thank the Chairman for holding this hearing and for his attention to public health and medical preparedness and response. I would also like to thank Assistant Secretary Lurie and the distinguished panel of witnesses who made time in their busy schedules to appear here today to discuss these matters critical to our national security. Thank you for your time in appearing before the committee and I look forward to your testimony.

In 2006, our Nation took a critical step in shoring up the national security and safety of all citizens when Congress passed the Pandemic and All-Hazards Preparedness Act. I want to thank Senator Burr for his continued leadership on this critically important issue. I would also like to thank my colleagues on both sides of the aisle; this issue enjoys broad bipartisan support and leadership from many members.

We have made tremendous progress in the past 5 years to ensure that we are prepared to meet all known and unknown hazards that threaten our citizens. At the same time, there are still gaps in the system that need to be filled and threats yet to be addressed. We have seen first-hand the critical need for a robust and active public health system that is able to anticipate and respond to threats

quickly and effectively. We experienced the H1N1 pandemic that tested our Nation's ability to meet the public health needs of our citizens, learned from the public health emergency response in Haiti, and more recently, took action in helping to mitigate the nuclear crisis in Japan. We need to take these experiences and incorporate the lessons learned as we continue to strengthen our preparedness and improve our response capabilities.

One of the areas we can always improve on is coordination and accountability. Along each step of the process it is essential to ensure that Federal, State and local entities are working in concert with each other. It is critical that roles and responsibilities are well-defined so that there is no uncertainty in a time of crisis and so attention can be focused on the threat at hand. One thing that we can be certain of is that our enemies will be coordinated in any attack against us; therefore we need a clear strategy for preventing and responding to such potential threats.

PAHPA invested in the development, production, and procurement of medical countermeasures to ensure we are prepared to address any potential chemical, biological, radiological, or nuclear threats, particularly against those who would do us harm. It is important that we continue the momentum achieved by the creation of BARDA and BioShield. This is one area in which I particularly look forward to hearing from the witnesses about the successes and challenges for future countermeasure development.

As always with government programs, I strongly emphasize and encourage responsible use of Federal funding. When it comes to national public health preparedness programs, we have the important responsibility to be careful stewards of Federal funds and at the same time strengthen our safety systems. Building in more metrics to improve accountability across the full public health emergency enterprise helps encourage enhanced fiscal management and better outcomes.

While the Federal Government plays a critical role, it is truly the dedicated professionals at the State and local level who respond to public health emergencies. State and local governments have risen to the challenges of the past 5 years, and the people who serve in all levels of government know first-hand the challenges of preparing and responding to public health threats. I am proud of their work and applaud their often unseen efforts to make sure every citizen is safe in the event of a public health crisis.

The very real threats facing our Nation are serious and sobering. I am, however, confident in the enterprising spirit of Americans and our ability to protect our country. Faced with the realities of the world we live in, we need to harness our abilities to think beyond the expected threats and prepare for those we don't know.

Thank you, Chairman Harkin. I look forward to hearing from this excellent panel of witnesses.

The CHAIRMAN. Thank you very much, Senator Enzi. Now I have the privilege of introducing Dr. Nicole Lurie and then I am going to turn the chair over to Senator Casey.

So, I would like to welcome Dr. Nicole Lurie, the Assistant Secretary for Preparedness and Response at the Department of Health and Human Services.

Dr. Lurie comes to us today with significant experience in the field of public health and preparedness. For the last several years she has worked with HHS, the Department of Veterans Affairs and State and local health departments on H1N1 preparedness. Prior to joining HHS, Dr. Lurie directed the RAND Corporation's Center for Population Health and Health Disparities and served as co-director of RAND's Center for Domestic and International Health.

We thank you, Dr. Lurie, for joining us today and sharing your expertise with the committee.

That will be our first panel. And then we will go to our second panel after that. And Dr. Lurie, your statement will be made a part of the record in its entirety.

I am going to turn the chair over to Senator Casey at this time. But please proceed, as you so desire.

STATEMENT OF NICOLE LURIE, M.D., M.S.P.H., ASSISTANT SECRETARY FOR PREPAREDNESS AND RESPONSE, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, WASHINGTON, DC.

Dr. LURIE. Thank you, Chairman Harkin, Ranking Member Enzi and distinguished members of the committee and especially the papa of PAHPA here, Mr. Burr.

Recent events serve to remind us——

[Laughter.]

Dr. LURIE [continuing]. Of the significant challenges that we face from an ever present terrorist threat to unprecedented weather events and how quickly and unpredictably the call to support the American people can arise. Since joining ASPR almost 2 years ago I've had the privilege to share with you some of our accomplishments, many of which were made possible by the authorities provided in PAHPA and were a direct result of coordinated and collaborative efforts across HHS. In fact, every aspect of HHS has been involved with our office during responses over the past 2 years.

H1N1 tested our ability to adapt and respond to a novel influenza stream. The experience highlighted the interdependence of public health, the healthcare system and community and business organizations. It confirmed that emergencies, particularly large ones that tax an entire health and public healthcare system, requires us to innovate. One result is that we are looking at how we can be more flexible in getting the right resources, whether countermeasures or healthcare professionals, to where they are needed in an emergency, and at the right time.

Both H1N1 and the Japanese nuclear situation demonstrated the importance of deploying medical countermeasures as quickly as possible after an incident. We are advancing efforts to strengthen the development of new and promising countermeasures and to ensure that safe, effective countermeasures can be quickly delivered to populations in need. Our efforts in this area are aligned through the Public Health Emergency Countermeasures Enterprise, or PHEMCE, an interagency body that defines and prioritizes medical countermeasures requirements, research, investments and procurements. The Secretary's Countermeasures Enterprise Review included recommendations to strengthen and improve this enterprise

so that we get the products we need to manage an unprecedented health emergency.

One critical demonstration of the U.S. Government's commitment to ensuring we have the tools to treat the affects of these agents is the BioShield Program. Since its inception we have successfully procured products for the Strategic National Stockpile to treat the affects of anthrax, botulism, smallpox and products for radiologic and nuclear events.

As you may have heard, just last week we announced a major BioShield contract for a smallpox antiviral. This award is a prime example of how the system is supposed to work. Taking a product without a viable commercial market from early research through advanced development under BARDA, to procurement, significantly strengthening our ability to protect the United States from a bio threat.

The Haiti earthquake demonstrated the readiness of our country to extend extraordinary humanitarian assistance and taught us valuable lessons that we are now acting on. For example, we are strengthening how we do domestic operations within the National Disaster Medical System to best serve stakeholders and are approving methods for collecting health data through the NDMS electronic medical record to better identify specific populations needs to ensure that we have a nimble and flexible NDMS response that is right-sized and focused on the right need.

As we work to address the needs of at-risk population, we join FEMA in adopting a whole community approach to our planning. We have taken steps to ensure that at-risk individuals, children, pregnant women, seniors and other individuals who have specific needs, are included at every step of our planning for medical countermeasures. The whole community approach leads us to focus on the local level, including State and local government and private sector partners in strengthening preparedness efforts and in being innovative in how we do so.

PAHPA authorized two cooperative agreement programs that have been critical to ensuring that State and local jurisdictions have the resources to prepare for public health incidents, the Hospital Preparedness Program and the Public Health Preparedness Cooperative Agreements. And while these programs aim to strengthen different parts of the system, they share common objectives. A key priority for me is the alignment of these programs to ensure efficient use of limited resources and eliminate duplicative or conflicting programmatic guidance and reducing the programmatic burden for grantees.

State and local jurisdictions rely on these programs to enhance preparedness and response and there are now numerous examples of States being able to handle events without Federal augmentation. A few weeks ago I visited areas of the south impacted on by the recent tornados and I heard firsthand how important these programs were to effective response. These and other experiences have confirmed the critical importance of a single point of contact for coordinating preparedness and response envisioned by PAHPA.

The experience, since its passage, has shown clearly that every part of the public health and medical community is critical to making our Nation and our communities more resilient. And the na-

tional health security strategy, that you envisioned, charts our way forward.

We applaud Congress' wisdom in enacting PAHPA as the foundation for this approach and I look forward to working with all of you as PAHPA is reauthorized in this Congress. I would be happy to take any questions that you might have.

[The prepared statement of Dr. Lurie follows:]

PREPARED STATEMENT OF NICOLE LURIE, M.D., M.S.P.H.

Good afternoon Chairman Harkin, Ranking Member Enzi, and distinguished members of the committee. I am pleased to be here today on behalf of the U.S. Department of Health and Human Services (HHS) to testify on national public health preparedness and response. My name is Nicole Lurie and I serve as the HHS Assistant Secretary for Preparedness and Response. Today, I will discuss how critically important the Pandemic and All Hazards Preparedness Act (PAHPA; the Act) is to our public health preparedness and the progress we have made since its enactment in 2006.

First, I would like to recognize the Congress, and especially this committee, for its strong leadership in advancing the public health and preparedness of our Nation by enacting this important legislation in 2006. PAHPA has supported our efforts to foster stronger, more resilient communities able to respond to and recover from public health emergencies. PAHPA established the foundation for a consolidated and thorough response to emergencies and HHS has since built on these authorities to ensure the Nation has the tools necessary to save lives.

THE PANDEMIC AND ALL-HAZARDS PREPAREDNESS ACT ESTABLISHED A FORMALIZED APPROACH TO PUBLIC HEALTH PREPAREDNESS

PAHPA strengthened our country's foundation for public health preparedness by helping us fix some of the problems our Nation encountered when preparing for and responding to disasters in the past. As we have seen from a variety of recent emergencies and disasters as of late—including tornados, floods, influenza pandemic, earthquakes, damage to a nuclear facility and a large oil spill—there is always a significant impact to the public's medical care and public health.

The Pandemic and All-Hazards Preparedness Act has been instrumental to support State and local preparedness and response efforts. Since the passage of the Act, HHS has implemented a number of initiatives to strengthen preparedness and response efforts. We look forward to working with you on improvements to strengthen our public health and medical preparedness and response.

The Pandemic and All-Hazards Preparedness Act designated the HHS Secretary as the lead Federal official for public health and medical response to emergencies and incidents covered by the National Response Plan and its successor plans, and created my office, the Office of the Assistant Secretary for Preparedness and Response (ASPR). Under the Act, ASPR serves as the principal advisor to the Secretary on all matters related to Federal public health and medical preparedness and response and plays a pivotal role in coordinating emergency response efforts across the various HHS agencies and among our Federal interagency partners.

Guided by the authorities in PAHPA, HHS established organizational priorities and enhanced its operations and response capabilities. Moreover, to carry out PAHPA authorities, ASPR's mission was defined as leading the country in preparing for, responding to, and recovering from health effects of emergencies and disasters by supporting our communities' abilities to withstand adversity, strengthening our health and response systems, and enhancing national health security. The future of Federal public health and medical preparedness and response is a "whole community" approach. This approach requires that we institutionalize community resilience by building practices nationally that strengthen preparedness efforts implemented by local institutions including State and local government and private sector partners; creating a fundamental body of knowledge for preparedness, response, and recovery; and encouraging innovative efforts to build the Nation's capacity to stabilize and recover from an event. We are also working to ensure that our public and private sector partners are promoting a culture of budget preparedness to quickly and efficiently get resources where they are needed before and after a disaster.

THE NATIONAL HEALTH SECURITY STRATEGY ESTABLISHED A COMMON STRATEGIC FRAMEWORK TO ALIGN NATIONAL PREPAREDNESS EFFORTS

Since the enactment of PAHPA in 2006, HHS has had many significant accomplishments preparing for and responding to public health incidents. To help better align efforts internally, support and promote coordination efforts with Federal, State, local, and private sector partners, and be efficient stewards of Federal dollars, in December 2009 we released the *National Health Security Strategy* (NHSS)—a blueprint for preparedness and response. PAHPA required the completion of a NHSS as a first step in ensuring we have a fully integrated and coordinated strategy to address how various sectors of our medical and public health systems will work together to respond to emergencies and save lives.

The principle at the heart of the strategy is that our public health security is about ensuring resilient communities; health systems that coordinate and work together during disasters; and public and private sectors working together. National health security is a shared responsibility—from individuals and families, to private industry, to every level of government. It recognizes that to build community resilience we need effective public health systems working seamlessly in collaboration with a strong healthcare system. The NHSS also promotes building more resilient communities by including at-risk populations in planning and day-to-day operations. Supporting this strategy, HHS has taken steps to ensure that at-risk individuals—children, pregnant women, senior citizens, individuals with disabilities, and others who have special needs—are included in all planning scenarios, guidance documents, plans, and will be effectively treated in the event of a public health emergency.

Recognizing that we have learned a great deal about these strategic planning processes in the past 4 years, we are interested in efforts that enhance operational and long-term planning efforts while also streamlining requirements. In support of the principles of the NHSS, State and local jurisdictions have operational plans that describe operations during pandemic influenza incidents. These plans—required by PAHPA—include a framework that guides communications and logistics, and coordinates general response efforts during pandemic influenza incidents. At the time PAHPA was enacted, these plans were a relatively new concept—the original provision was to ensure that any plan in place was strong and relevant. To ensure the Nation is prepared for threats beyond pandemic influenza, we believe these plans should include planning for all-hazards.

THE MEDICAL COUNTERMEASURE REVIEW ESTABLISHED THE STRATEGIC AND OPERATIONAL PLAN FOR HHS COUNTERMEASURE PREPAREDNESS

To ensure the Nation has adequate countermeasures available to respond quickly and efficiently following a chemical, biological, radiological, nuclear (CBRN), or other public health emergency, HHS released the *Public Health Emergency Medical Countermeasures Enterprise Review* (MCM Review) in August 2010. The MCM Review identifies "processes, policies, and activities required to take a product concept derived from a national requirement through research, early and advanced development, manufacturing, regulatory approval, procurement, and stockpiling." This ground-breaking review looked across the entire spectrum of product development, from early discovery through regulatory approval, and identified the choke points where product development was stalling or failing. To address these choke points, which create technical, business, and regulatory risks for small innovator companies and form the basis of the medical countermeasure "valley of death," the MCM Review proposes:

- The establishment of a Concept Acceleration Program at the National Institutes of Health (NIH) National Institute of Allergy and Infectious Diseases to work with partner agencies, academic researches, biotechnology companies, and large pharmaceutical companies to identify promising scientific discoveries and expedite their transformation into practical, usable products;
- The establishment of a nonprofit Strategic Investor firm to spur innovation and create a viable biodefense business sector by supporting companies that possess strategic technologies applicable to both commercial and government needs, but which 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; and,
- An increased investment in regulatory sciences and review capabilities at the Food and Drug Administration (FDA) focused on pandemic influenza, chemical, biological, radiological, and nuclear (CBRN) medical countermeasures (MCMs).

The Concept Acceleration Program (CAP) will leverage existing intramural and extramural research programs as well as applied and translational resources throughout the NIH, Centers for Disease Control and Prevention (CDC), FDA, and Department of Defense (DOD) to expedite the translation of promising concepts into candidate MCMs. We are committed to applying $50M towards CAP activities in fiscal year 2011. Evaluations are in progress to identify CAP biological product candidates.

With congressional authorization, the Strategic Investor initiative will spur innovation and provide the kinds of business and financial services and support that venture capital firms typically provide, while mitigating the risk that biotechnology firms face. The Strategic Investor initiative will promote the transition of MCM development and procurement from a "one bug, one drug" approach to an enterprise capable of responding to any threat at any time. It is important to note that the Strategic Investor is intended to work in concert with the BioShield program, not replace it.

In March, we published a request for proposals for the Centers for Innovation in Advanced Development, that we will create to reduce risk, increase domestic manufacturing and surge capacity for MCM, 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 to commercial partners who collaborate with HHS's Biomedical Advanced Research and Development Authority (BARDA). These services include advanced development and manufacturing capabilities and other technical services needed by the developers of medical countermeasures for MCMs to address national preparedness and response priorities and needs. In the event of a pandemic, the Centers will also be available to manufacture influenza vaccine and other biologics, as well as provide training opportunities for the pharmaceutical workforce.

Finally, expanding regulatory science and review capabilities at the FDA will strengthen and clarify the MCM regulatory process, which will expedite MCM development and availability. Regulatory uncertainty is a major barrier to engaging MCM developers in the MCM Enterprise. This initiative will provide private sector partners with greater access to regulators and greater clarity about the pathways to product approval, which will reduce uncertainty and foster greater engagement and program success.

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

PAHPA HELPED SPUR DEVELOPMENT AND PROCUREMENT OF MEDICAL COUNTERMEASURES

Prior to PAHPA, the Project BioShield Act of 2004 authorized the Project BioShield program and established the Special Reserve Fund (SRF). The Project BioShield Act provides additional and more flexible authorities and funding to support and expedite the development and procurement of CBRN medical countermeasures. The SRF is a secure funding source for the procurement of critical medical countermeasures, such as vaccines, therapeutics, and diagnostics that are close to or have achieved licensure. The SRF, as industry partners and other non-governmental stakeholders have continually asserted, is a market guarantee for medical countermeasure development and clearly demonstrates U.S. Government's commitment to the procurement of security countermeasures. Finally, the Project BioShield Act provides the Secretary with the authority to authorize the emergency use of unapproved products or the unapproved use of approved products, if certain standards are met.

Since its inception, we have drawn steadily on the use of Special Reserve Funds and have developed and procured:

- Anthrax therapeutics and vaccines;
- Heptavalent botulinum antitoxin;
- Smallpox vaccine for immunocompromised persons; and
- A number of MCM products intended for use after radiological or nuclear events.

PAHPA included authorities that strengthened Project BioShield and HHS was able to leverage these authorities to promote successful collaboration and procurement to keep the Nation safe against CBRN threats. In order to improve the Federal coordination of government policy, investments, and activities related to the development and procurement of medical countermeasures for CBRN threats, in July 2006, HHS established the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE). ASPR leads the PHEMCE, which includes principal representa-

tives of CDC, FDA, and NIH. PHEMCE also includes key interagency partners from DOD, the Department of Homeland Security (DHS), the Department of Veterans Affairs (VA), and the Department of Agriculture (USDA).

The overarching mission of 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 Strategic National Stockpile (SNS).

Using its Advanced Research and Development (ARD) authority, HHS bridges the "valley of death" funding a gap that exists between the early stages of product development and the procurement of medical countermeasures under Project BioShield. Congress recognized that since 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 and sustain a substantial pipeline of products to diagnose and treat illness, or prevent the effects of CBRN agents. 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 President's Budget requests $765M from Project BioShield balances to support these priorities.

While the imminent threat of H1N1 influenza has subsided, avian influenza viruses continue to circulate, and critical work continues to prepare for the next influenza pandemic. One of the functions of the Centers for Innovation in Advanced Development and Manufacturing mentioned earlier, in addition to providing development and manufacturing of medical countermeasures to CBRN threats, will be to expand domestic pandemic influenza vaccine manufacturing surge capacity. HHS continues to develop flu antiviral drugs and vaccines and a more robust domestic vaccine manufacturing capability. We are focused on ensuring the Nation has access to safe and effective vaccine as soon as possible following the start of an influenza pandemic. We continue to implement strategies that work toward producing influenza vaccine more rapidly during an influenza pandemic, including the development and implementation of more rapid testing methods for vaccine release and the establishment of domestic recombinant and cell-based vaccine manufacturing capabilities. Supporting this effort, shortening the timeframe for vaccine availability with new and faster product testing and next generation influenza vaccines made in the United States will achieve better products faster. I am pleased to inform you that we are already making great progress in these efforts.

HHS HAS SIGNIFICANT ACCOMPLISHMENTS SINCE THE ENACTMENT OF PAHPA

We have accomplished much since the passage of PAHPA and were able to respond to a number of public health emergencies including:

- The first pandemic in 40 years;
- An earthquake in the western hemisphere's poorest country;
- The largest oil spill in history;
- The 2011 Japan earthquake, tsunami, and associated radiological contamination event; and,
- Other domestic events including hurricanes, floods, and tornadoes.

In addition, as I mentioned previously in my testimony, we were also successful in procuring and stockpiling medical countermeasures to protect against CBRN threats, as well as against pandemic influenza and other emerging infectious diseases.

Since I was sworn in as the Assistant Secretary for Preparedness and Response, one thing has been clear—the investments we've made in the last decade have had a positive effect on our ability to respond to emergencies. In each response, HHS provided support to State, local, or international partners and in return learned valuable lessons to guide future response operations. We are working internally to strengthen and incorporate the lessons learned from these and other recent responses to ensure future response efforts are enhanced.

The Japanese earthquake and subsequent nuclear reactor crisis is an example of a catastrophic scenario that would present formidable public health and healthcare challenges to the United States should such an event occur here. We already knew the importance of deploying medical countermeasures as quickly as possible following an incident. However, as a result of this crisis, we have expedited efforts internally to ensure adequate countermeasures are stockpiled and can be deployed as soon as possible following incidents. It is critical that we have the flexibility to use

and deploy countermeasures as soon as possible following the start of a public health incident to help reduce morbidity and mortality.

Beyond medical countermeasures, many lessons learned during our 2009 H1N1 pandemic response will strengthen HHS's ability to respond to other emergency events. The 2009 H1N1 experience stressed the interdependence of the public health, pre- and post-hospital care, primary care, hospital care systems and community and business organizations. It also confirmed the need for a "whole of community" approach in planning and responding to a disaster, and confirmed that, going forward, we must address the entire healthcare community in our preparedness activities. The Department is considering proposals to strengthen the ability for medical and public health professionals to be of assistance in an emergency situation.

Lastly, after our response to the Haiti earthquake we have taken actions to: streamline internal operations to ensure providers are adequately supported; provide needed services quickly and efficiently following disasters; and, ensure we have access to information that supports surveillance of the spread of illness. I am pleased to inform you that we have been working to strengthen the National Disaster Medical System (NDMS). NDMS is a federally coordinated system closely linked to the Hospital Preparedness program that augments the Nation's medical response capability. The primary purpose of the NDMS is to supplement an integrated National medical response capability for assisting State and local authorities in dealing with the medical impacts of major peacetime disasters. NDMS now uses an Electronic Medical Record (EMR) system that standardizes recordkeeping and promotes enhanced health surveillance during disasters. This, and other enhancements we have made, enable us to better identify population needs as we respond, including in the area of pediatrics. These developments in identifying the needs of populations, specifically pediatric and at-risk populations, will support a better and more focused response in the future.

All of the accomplishments I have just described were supported through the close collaboration of many HHS partners including CDC, NIH, FDA, ASPR as well as the Centers for Medicare and Medicaid Services (CMS), the Substance Abuse and Mental Health Services Administration (SAMHSA), and the Indian Health Service (IHS), just to name a few.

HHS has a number of programs and tools that aid State and local response and coordinate efforts during disasters. The ASPR Hospital Preparedness Program (HPP) has advanced the preparedness of hospitals and communities in numerous ways, including through planning for all-hazards, increasing surge capacity, tracking the availability of beds and other resources using electronic systems, and developing communication systems that are interoperable with other response partners. We recently issued a report on the Hospital Preparedness Program that describes the achievements of our State partners in building healthcare preparedness across the Nation, and illustrates how States have used the capabilities developed and funded through the program in both large and small incidents. One specific accomplishment detailed in this report is that more than 76 percent of hospitals participating in the HPP met 90 percent or more of all program measures for all-hazards preparedness in 2009. This is a significant accomplishment and clearly demonstrates participants' commitment to investing in preparedness. Copies of this report were provided to each member of the committee in advance of this afternoon's hearing.

In addition to HPP, CDC's Public Health Emergency Preparedness (PHEP) cooperative agreements provide funding to enable State and local public health departments to have the capacities and capabilities to effectively respond to the public health consequences of not only terrorist threats, but also infectious disease outbreaks, natural disasters, and biological, chemical, nuclear, and radiological emergencies.

To promote coordination and efficient use of resources, we are working together to determine the best path forward for alignment of the HPP and PHEP grant programs to ensure we are efficient with resources and that we eliminate duplicative or conflicting programmatic and administrative efforts for grantees. Once we complete our internal alignment process, we will engage interagency partners to examine additional opportunities for synergy with other Federal preparedness grants. Consistent with Presidential Policy Directive 8, we are working toward a framework for priority-setting, review, and reporting measures; development of a common pathway to focus dollars, measure outcomes, reduce duplication, and enhance return on investment and reporting; and enhanced data sharing for improved situational awareness during a response.

PAHPA authorized the HPP and PHEP grant programs. These programs, as I have just mentioned, are critical to ensuring State and local jurisdictions have the tools and resources to prepare for public health incidents.

CONCLUSION

The experiences since the passage of PAHPA have shown clearly that every part of the public health and medical community is critical to building resilience. We applaud Congress' wisdom in enacting PAHPA as the foundation for this approach, which is so critical to our preparedness.

At this time I would be happy to address any questions you may have.

Senator CASEY [presiding]. Doctor thanks very much. I appreciate your testimony. We will have questions and we will do it in the order that the Senators arrived. I will start with Senator Blumenthal and then I will take myself out of the line up temporarily, for questions, and we will go to Senator Burr and then Senator Hatch.

Senator Blumenthal.

STATEMENT OF SENATOR BLUMENTHAL

Senator BLUMENTHAL. Thank you very much, Mr. Chairman and thank you for your work on this issue which has been instrumental and Senator Burr as well. And thank you for being here, Dr. Lurie.

I have a number of questions raised by your written testimony. First, you speak briefly about some of the thermal burn countermeasures, and I know that you have focused on this issue. I wonder if you are satisfied that we have procured sufficient quantities and quality? Whether HHS and BARDA has done enough to ensure there are sufficient quantities and quality, because I think they are vital to have in our national stockpile.

Dr. LURIE. Thank you for that question.

One of the very important things that PAHPA did was provide us the flexibility and funding to be able to do advanced development of products. I think at first we thought maybe we could just go out and buy them or that, you know, having a fund for procurement would be enough of an incentive for industry to come and make all the products that we need.

It turned out that there really wasn't very much in the pipeline. And I think thermal burns is a great example of where there really wasn't very much in the pipeline to start. And so we have really had to, as I think you know, reach back in the system and have developed, through Dr. Robinson and BARDA, a very sophisticated advanced research and development program so that we can develop these products to the point that they could at least be used under emergency use authorization, not through licensure and then procure it through the stockpile.

Senator BLUMENTHAL. Do you think there is a bottleneck in either the development or the procurement process? And if so, where would it be?

Dr. LURIE. The Secretary's Medical Countermeasures Review took a really hard look at this last year and we identified a number of bottlenecks in the process and have now set to work on each of these and maybe sort of taking them in some order. The first really comes from taking early concepts at NIH and pulling them through to a point where the developers can get the help they need to be ready for an advanced development process.

A second has to do with the way we support companies. And you know that the President's budget is seeking authority for what we are calling a strategic investor, to help companies leverage venture

capital and on the business end to be able to move some of these forward.

A third major area, for example, is in the area of regulatory science. And I think we have all recommended a fairly big push here in the area of regulatory science.

I could go on and on about bottlenecks, but I will also just comment that we have made pretty radical changes in how we do the governance of the medical countermeasures inside. And so already in doing that I think we have eliminated a number of the bottlenecks and already been able to speed up our contracting processes.

Senator BLUMENTHAL. I thank you for that answer and I will follow up perhaps to seek additional information. I want to sort of switch topics.

As a member of the Armed Services Committee I am aware of the 2006 Quadrennial Defense Review and its focus on the need for a more integrated military/civilian response in this area. And I know it is not directly within your purview, but I wonder, as the point person, so to speak, on the overall emergency issue, would you agree that there is a need to formalize the pathway for improving a civilian/military integrative response?

Dr. LURIE. I think actually we have been making tremendous progress in that area. In the countermeasures development end of this we have an integrated portfolio where we and DOD sit together and talk about what to do. We now formally have liaisons between our two offices so that we can coordinate better. And we actively work with our DOD partners on a number of issues including patient movement in a disaster and worked closely with them in Haiti.

You know, right now the large national level exercises going on around, ironically, an earthquake on the New Madrid fault and speaking at this moment we are exercising patient movement with our DOD colleagues.

Senator BLUMENTHAL. My time has just about expired but I have one last, quick question and I would like to followup on this one as well. I have become very concerned about the shortages of certain kinds of pharmaceutical drugs for hospitals, which seems to be quite alarming and increasingly prevalent, in Connecticut and around the country. And I wonder if that issue is one that has been factored into your planning for emergency preparedness.

Dr. LURIE. It is something that we look at quite a bit and we have a whole critical infrastructure protection program that looks at this, including partnerships with private sector companies, big box stores so that we can look at the availability of products. We started a whole initiative to be able to do a better job tracking products through the pipeline. But I agree with you, that there is a lot more work to do here and I would love to be able to follow up with you about that.

Senator BLUMENTHAL. Thank you. Thank you very much, Dr. Lurie and thanks for your great work in the department.

Dr. LURIE. Thank you.

Senator BLUMENTHAL. Thank you, Mr. Chairman.

Senator CASEY. Thank you, Senator Blumenthal.

Senator Burr.

Senator BURR. Thank you, Mr. Chairman. My hope is, and I pledge to Senator Blumenthal, if the committee will look into the drug shortage I will be right there with him.

Senator BLUMENTHAL. Thank you.

Senator BURR. I think it falls well outside the space that we are here to talk about today, but indeed it is a problem and it is a problem that leads us then to the FDA and to other areas that need examination by this committee and other committees.

Nicki, welcome. Let me just ask you, one of the most important questions of the PAHPA legislation was this determination of who is in charge and we chose, when we wrote it, that we would create this new entity and it would in fact be the Assistant Secretary for Preparedness and Response. I would like you to sort of share with us, in your own words, describe what it is you do.

Dr. LURIE. That is a great question and I thank you for it. And I also want to thank you, again, for the wisdom in determining that there really needed to be a focal point for this issue and leadership in the department, really somebody in an office that focuses on preparedness day-to-day and coordinates all of the HHS aspects of response.

Let me talk first about the response end of things and then go back to the other end of things. In response, the Assistant Secretary for Preparedness and Response is in charge of coordinating the HHS aspects of emergency response and working with the rest of the interagency. So we stand up, through our Secretary's operations center, for all of our components. Thanks to PAHPA, the National Disaster Medical System is moved back to us and we are prepared to mobilize a very robust health and public health response.

At the same time we mobilize the policy components of the response so that there is rapid decisionmaking and coordination across all of the department. I kid you not when I say that every aspect of the department, ranging from the Agency for Child and Families to the Office of Refugee Resettlement or the Agency on Aging has been involved with us in response.

Between disasters, and often during them, we look at how we can better prepare, whether it is through our healthcare system preparedness or public health preparedness, strengthening our NDMS and strengthening our medical countermeasures enterprise and working on a set of policies related to that. Again, all of these involve a tremendous amount of coordination across the department with our partners at CDC, NIH, FDA, SAMSA, etc. and with the interagency partners such as DHS, DOD, the VA and others.

I think having this focal point for leadership has proved to be really important. And I would like to think that the way that we have handled all the responses in the past 2 years has been a real testament to that.

Senator BURR. You alluded to the relationship with these other agencies and I think it is important for members to understand that there are certain things that we moved under your jurisdiction and we moved them from these other agencies. But, you are a customer to them from a standpoint of what threats might exist, because that is determined at——

Dr. LURIE. Yes.

Senator BURR [continuing]. The Department of Homeland Security. And there are other aspects that are controlled at the Centers for Disease Control. Are there areas that you feel would be beneficial in addressing the comprehensive nature of your role that we should look at as we reauthorize this to move out of other agencies and consolidate within your direct supervision?

Dr. LURIE. I think it is a really good question. I think as we have worked through particularly the countermeasures aspects of this over the past couple of years, I think we have developed a much closer and more collaborative relationship with DHS on the issues that relate to the determination of threats. And I think we have been able to make much more robust our requirement setting process so that we actually can work much more collaborative with the other agencies around setting those requirements and then actually doing the research and development and getting the countermeasures made and licensed.

Likewise, we've worked much more closely with DOD in the integrated portfolio aspects of this.

Senator BURR. I agree we have made tremendous strides with DOD. But let me just point this out publicly, creating your slot was to have a single individual we could look at when there might have been a breakdown and say, "Okay, it is your responsibility, what happened." So as we go through this reauthorization, if in fact there are areas that we need to look at, legislatively, that need to move to or from where they currently are, I sort of put you in charge of letting us know before we get this legislation done. If not, you have areas that you have no control over that we are going to point to you as the—or to whoever is in your slot—as the person to directly hold responsible. And they are going to say, "You know, I didn't have jurisdiction over it. Tell us now."

Dr. LURIE. Fair enough. I appreciate that very much and will continue to give it some thought and be happy to talk more about it.

Senator BURR. During the H1N1 pandemic the government made a substantial commitment to adjuvants to the Strategic National Stockpile, however today an adjuvanted vaccine could only be made available under an emergency use authorization since it has not been approved by the FDA. Adjuvanted seasonal influenza vaccines have been used in Europe for over 12 years. Last year the President's Council on Advisors on Science and Technology issued a report recommending, "a goal of approving a minimum of two adjuvant vaccines in the next 2 years." We are almost a year into this recommendation, without approval of an adjuvant.

Given the potential public health benefit of this technology for patients for both seasonal and pandemic influenza vaccines, how will you ensure the approval of adjuvants is appropriately prioritized?

Dr. LURIE. Great question. We have invested and are continuing to invest in the development of safe and effective adjuvants and understand that adjuvants may be—well be one of the answers to more effective influenza vaccines going forward.

My understanding right now is that FDA is poised to act on applications for adjuvanted vaccines when they receive them. And I think for a seasonal flu vaccine that is the current situation. We

are continuing to work very closely with FDA to move along products in the regulatory pathway and pipeline. We, as I commented before, have been really redoing the way we do some of the governance, so there should be fewer delays and fewer surprises when things get to that point. And the investment in regulatory science ought to help FDA be able to do a lot of the things it needs to do in the regulatory area, faster and better.

Senator BURR. Thank you. Mr. Chairman, you have been kind with the time.

Let me just point to members something that the Secretary has alluded to and I mentioned briefly and that is the emergency use authority that is required for nonFDA-approved product to be used. We have products in the stockpile today that are yet to be FDA approved. They can only be used if there is an emergency use authorization. So, given that it is very difficult to determine how you expedite things at the FDA, and I am being generous in the way I said that, and hopefully diplomatic, it is very important that members understand we are going to have quite a discussion before PAHPA reauthorization comes up, about whether we need to redefine emergency use authority and whether we set a new threshold for that.

If we don't, we could find ourselves in a situation that we have a real threat, we have an inability to respond in a timely fashion and much like we were faced with H1N1 where there were some delays in emergency use authorization, we actually had kids in this country die because we couldn't initiate that fast enough. And there is no one person that is to blame, it is a process that had never thought through the speed with which we might need to do that. And I just warn the members to flag that as we move forward.

I thank the Chair.

Senator CASEY. Thank you, Senator Burr.

Senator Roberts.

STATEMENT OF SENATOR ROBERTS

Senator ROBERTS. Thank you, Mr. Acting Chairman, the Senator from New Jersey—or pardon me, Pennsylvania. You can be New Jersey too if you would like. Start a trend.

[Laughter.]

Senator CASEY. Senator, I would note for the record, our witness was educated at the University of Pennsylvania.

I just want to throw that in.

Senator ROBERTS. All right.

[Laughter.]

That is why she is so learned and uses those 25, 35 cent words in the right place. I am going to ask a follow up on the Richard Burr dynamite question, and I want to thank Senator Burr for really highlighting this. He was very generous in his comments and diplomatic. Obviously I won't be.

In your testimony you suggest a need for an increased investment in the regulatory sciences and review capabilities at FDA focused on pandemic influenza, chemical, biological, radiological, nuclear and medical countermeasures, I might toss in agra-terrorism, but I am told by staff not to do that.

At any rate, can you be more specific on the Senator's question and my question on what you mean by investment in the regulatory sciences and the review capabilities. Do you mean more funding for FTE folks, or do you mean—what? What do you mean?

The reason I am asking is that I don't think we are—we lack specificity in the guidelines for FDA and what we don't need is additional regulations. I don't know whether you want the full-time employees and I am not sure what that means in terms of investment in regulatory sciences and review capabilities.

We have to speed this up. The Senator is exactly correct, I come from the Ag Committee and we go over all sorts of threats all the time to the Nation's food supply. If that happens, it happens. We can't just wait until that happens and then try to figure out what to do. As a first responder, it is the sheriff out there usually in one of my small towns in Kansas.

I am talking more rather than listening. Would you like to respond?

Dr. LURIE. I would defer to the FDA about the FTE issue. But I would observe that as we did the countermeasures review one of the things that we heard, both from FDA and from our partners in industry, was an issue that if you would get to the end of the line you would want to move a product forward for licensure and the science to be able to do that just wasn't there. That is not the time to think about doing the science.

And because you are from Kansas and talked about animals, I will talk about the animal rule in that regard. You know, we have a notion that for things that can't be tried in people, it would be a good idea to test them in animals under the animal rule. But it turns out, for example, that we don't have really good animal models, because we haven't invested in the science, as an example, to figure out how to use that most effectively so that we can do the science to know if a product is going to be safe and effective and move it on toward licensure. The same thing with different kinds of assays, the same thing with different kinds of staff and expertise, for example. So that investment in science is really intended to speed up the—and clarify a number of the regulatory issues involved.

I know we had a discussion internally just last week about new diagnostics. For example, for flu vaccine. In order for FDA to be able to look at those and regulate them, there is probably some science that needs to get done first. And we ought to be doing it now, so 2 or 3 years from now, when those products are ready to come to FDA we are ready to meet the companies where they are.

Senator ROBERTS. If you can put a little Zocor or Lipitor in the pipeline so we don't have so much cholesterol, that would be very helpful.

[Laughter.]

Many of the recommendations and suggested changes for consideration during the reauthorization also suggest a need for additional resources, of which we don't have any. Considering the current and economic and fiscal crisis, if you had to prioritize these suggestions, which would you say is the No. 1 need?

Dr. LURIE. Prioritize which suggestions?

Senator ROBERTS. Which one would you say is the No. 1 need? Of the recommendations of the suggestions, of the changes for consideration during the reauthorization, in the entire reauthorization bill, what is your No. 1 priority goal, given the limited resources that we have?

Dr. LURIE. I actually think you are asking me to choose among my children here. And as the mother of three boys that is probably a dangerous thing to do.

Senator ROBERTS. Yes, it is.

Dr. LURIE. But I would offer a couple of things. I would offer that continuing to focus on our Medical Countermeasure Enterprise is critically important. I would offer that strengthening day-to-day systems in public health and healthcare preparedness are also really, really critical as we go forward here.

Senator ROBERTS. I thank you very much. Thank you for the job you are doing.

Dr. LURIE. Thank you.

Senator ROBERTS. Thank you, Mr. Chairman.

Senator CASEY. Thank you, Senator Roberts.

I might jump in here. I was second on the list, so I gave up my spot. But let me just——

Senator ROBERTS. Thank you.

Senator CASEY. Let me just present a couple of questions to Dr. Lurie. First of all, thanks for your service in a tough time to be in government but also having the significant and burdensome responsibilities you have. We are grateful for that.

I wanted to highlight, and I know you have addressed this today and at other times, but I wanted to highlight some of the process here to see where you are. Instead of using the acronym, I will read it all, the Pandemic and All Hazards Preparedness Act was passed, part of that, as you know better than I, was the implementation or the anticipated implementation of the National Health Securities Strategy. Can you give us kind of a brief sense of where that is in the process?

And we know that over these years, I guess 5 years now roughly, there have been reports and reviews and studies concluded that inform what we are doing on these. And there are lots of ideas out there. But how do you report to us (a) on the progress of—or the timeline for the implementation plan, but also, (b) how do you incorporate all these other reviews or studies into that kind of a plan?

Dr. LURIE. Great question. And we very much appreciated the opportunity to develop the National Health Security Strategy. It is the first really of its kind and that was released December 2009, on time. We have been working through, punctuated by a few disasters, completing the biennial implementation plan which has been out for public comment and is just about done.

At the same time, we haven't waited for the implementation plan to begin to implement in a number of areas. As you know, the strategy is wide ranging and lays out really a set of capabilities for our Nation to be prepared and health secure. So whether it is through the Public Health Emergency Preparedness or the Hospital Preparedness grants, we have already begun, for example, to

incorporate many of the concepts from the National Health Securities Strategy into grant guidance.

The National Securities Strategy places a big focus on building community resilience, so there is a lot of work going on there, same with strengthening emergency preparedness and response systems. And our work with NDMS and others has continued to move us in those directions.

So, a lot of the implementation is going on as the plan is being written. It is on track and I think we are moving forward.

Senator CASEY. I was noting in your testimony, I want to read it verbatim, on the bottom of page 2 when you describe your mission. You say, and I am quoting that your mission is defined as,

> "leading the country in preparing for, responding to and recovering from health effects of emergencies and disasters by three things really, supporting our communities' ability"—communities' abilities, I should say—"to withstand adversity, strengthening our health and response systems and third, enhancing national health security."

That is a tall order for any person or any group of folks working on these difficult preparation, response and recovery issues. I would ask you kind of a basic question that is probably on the minds of a lot of citizens, but also those who are enacting public policy or legislating in this area. What do you feel most secure about in terms of the work you have done to date, in terms of your work as it relates to our own security?

What keeps you up at night? What worries you the most in terms of not just the threats, there are plenty of them that we can all imagine and articulate. But I am not talking about what worries you about the threat, I want to know more about what are you most worried about in terms of our preparation and our response to what we know are a long list of significant threats.

Dr. LURIE. Right. No, it is a great question and I do feel like we have made a lot of progress over the last decade and I think we still have a lot of progress to make.

I would glibly tell you that if I didn't sleep at night I couldn't do my job during the day. But the things that I worry most about, No. 1, are a threat that we have never thought about and anticipated before coming our way, our ability to recognize it when we see it and to act quickly on it. That is why there is so much focus on the rapid, nimble, flexible capacity to make a countermeasure against something we have never seen before.

It is also why we have placed so much focus on capabilities rather than planning for scenarios, what capabilities do we need to have in place so that we can mix and match and pull off a shelf and respond to whatever comes our way. It is building those capabilities that I think is terribly important. Those, I think, are really the issues that keep me up at night.

The other thing that keeps me up at night is knowing that the Federal Government can't do this all alone, you know, that our State and local partners and our private sector partners are in this with us and indeed the National Health Securities Strategy lays that out. In these really tough financial times when everybody is kind of stretched to the limit, I actually worry that we could back-

slide on some of our progress and that would be a dangerous situation for us to be in.

Senator CASEY. I'm over my time, and I want to turn to Senator Whitehouse. But, let me just ask you this. If you had, as you do in hearings like this, the opportunity to say, "I need x, or we need x", to complete the mission that I just read from and outlined from your testimony, what would you hope you would have that you don't have now in terms of authority and then more particularly, tools or the removal of impediments that we all know are part and parcel of often what we try to do in the Federal Government.

Dr. LURIE. I think we are here because the authorities in PAHPA are so important and I think we need to continue and reauthorize those authorities that we have, maybe with a little bit of tweaking around the edges to be able to act on some of the lessons learned and do some of the things that we need to do a little bit better. I think the authorities that we have to make and procure countermeasures continue to be really important and things that we need to reauthorize.

And then we need to work very closely with our partners around the country, some of whom are represented on the next panel. You know, whether it is State and local public health, the healthcare community, industry, faith-based organizations or others, because as I said, we are all in this together at the end of the day. It is really my responsibility to keep all the spinning plates up in the air, to keep us all together and coordinated and moving forward, working together there.

Senator CASEY. Senator Whitehouse.

STATEMENT OF SENATOR WHITEHOUSE

Senator WHITEHOUSE. Thanks, Chairman Casey and welcome, Dr. Lurie.

Just to take off on your last answer about the unforeseen threat and our capacity to, as you said—have a rapid, flexible and nimble capability to build a medical countermeasure. How do you evaluate our current capabilities for rapid response in the event of an attack using an unknown biological agent? How can we facilitate this rapid, flexible and nimble development of medical countermeasures? And is the new advanced development and manufacturing initiative at BARDA adequate to meet those standards?

Dr. LURIE. Great question. So I think the first thing I would say is the first challenge that we face is the ability to recognize, as quickly as we can, that this threat is upon us, to be able to detect it, figure out what it is so that we know what to do about it. And that is an issue of strengthening our public health and surveillance systems, not just at the CDC but both internationally and—

Senator WHITEHOUSE. We are going to go into that in a moment. But go on ahead to the development of the countermeasures.

Dr. LURIE. So in the development of the countermeasures, the move toward advanced development and manufacturing the flexible, nimble capacity, the way to get there, we believe, is through the initiatives outlined in the Medical Countermeasures Review including the advanced development and manufacturing facilities which we think will be central to being able to do that.

Senator WHITEHOUSE. How do you keep the biggest players who are the custodians of yesterday's technology from using their political brawn and their economic might to crowd out new entrants who may actually have a better technology but would cause economic harm to the bigger players if they are—if that competition were added into the mix? What is the way in which you particularly look out for the new technologies and keep the process from being captured by those who have a vested interest in the status quo?

Dr. LURIE. What we look out for and we look for those new technologies through the Concept Acceleration Program at NIH. Through, if authorized, the strategic investor, so that we can—and we can put different kinds of investments into those new players and those new technologies. Also new are the technology but not necessarily the business skills to be able to pull it off and get to where they need to get to, then through providing those core services through the advanced development and manufacturing facilities so that they can actually take their projects to scale and move forward to a point where we are able to move to a full product development and licensure.

So those are all different ways in which we want to look out for the innovators and welcome any and all innovation to the table and be sure that the playing field is level for them.

Senator WHITEHOUSE. And is the BARDA process—how would you evaluate that in this light?

Dr. LURIE. I think the BARDA—remember, BARDA got stood up from scratch a couple of years ago. I think the BARDA process is working incredibly well. I would note that compared to where we were a couple years ago, we now have 70 projects under advanced development, which is really stunning considering that we started at zero. So I think it is working quite well and we have identified ways to make it even more nimble and more welcoming for innovators.

Senator WHITEHOUSE. And back to your point about the ability to detect the threat in the first instance. The draft—Biennial Implementation Plan from July 2010 specifically mentions linking your National Health Security infrastructure into the developing National Health Information infrastructure which got such a boost from the American Recovery and Reinvestment Act. And it specifically mentions incorporating the role of health information exchanges to advance real-time information dispersal.

Rhode Island is one of the States that is at the forefront of developing health information exchange. It is a very difficult thing to develop. And compared to the value to be returned on a successful health information exchange, I think we are very under-invested in supporting the HIE, the Health Information Exchange development, particularly out at the head of the trail where the real work is being done.

I am wondering what you see as your role, from a public health perspective, in trying to support and facilitate the development of these health information exchanges. At the local level, are you working with ONCHIT on this? Are you engaged in that part of it? How important do you see this as a priority?

Dr. LURIE. We work with ONC all the time, including around the sort of constructs that relate—and the regs that relate to meaningful use and how to move forward. It was really interesting, during the pandemic, what you saw were some real breakthroughs, consistent with the CDC's bio-surveillance strategy in how we use real-time healthcare data to do surveillance, to do, tracking of antiviral prescriptions, to do a number of things.

I agree with you that there is a long way to go, but I think over the past year we have started to see a lot of progress in that area. We will continue to work very closely with ONC going forward.

The other place we work with them, by the way, is in the electronic health record for the National Disaster Medical System, another place that enables us to have real-time situational awareness of what is happening in a disaster and to be able to pivot quickly if we need to.

Senator WHITEHOUSE. Thank you. Thank you, Mr. Chairman.

I know that Pennsylvania has been a real leader in this area as well. But as we transform from a health information infrastructure that basically has computers on doctors' desks, but you still have to go out and get the information from the hospital, from the lab, from the pharmacy, from the imaging place, from the specialist into a really integrated health information infrastructure, the Health Information Exchange is the key infrastructure that links all that together. And that is really, I think, going to be the accelerator in terms of our ability, from a safety and cost savings perspective, or a public health perspective, to have rapid access to that information so that we can do that early detection. And so I hope that we will continue to focus on that and see that as an area for investment on this public health and safety side, not just through the ONC. Thanks very much.

Senator CASEY. Thanks, Senator Whitehouse.

Doctor, we are going to let you go in a moment. I just have one quick question. I think you spoke to this before, if not directly but in part. One of the things that often will confront the Federal Government is how you work in coordination, the old problem with silos and the inability of agencies or offices to coordinate and work together. It is especially maddening to taxpayers when they have to work together in their lives and sometimes government can't.

But when you, in terms of what BARDA does day-to-day and then with regard to coordination, which I hope is a lot of coordination with both FDA and NIH, just if you could, for a moment, speak to that coordination that is so important in getting this right.

Dr. LURIE. One of the things that we instituted since I have been there has been both a series of what we call portfolio reviews. So everybody sits down at the table together, including the DOD, and shares what it is they are doing. This was really the first time that kind of thing had happened and it spun a whole lot of collaboration.

Going forward, working in BARDA, they are using a system which I, as a primary care doctor, sort of call case management. You know, we have the scientists from NIH and FDA and CDC at BARDA sitting down, often with the developers of new products, at regular intervals, starting at the beginning, to identify what the

issues are and work them out and work them out often on a quarterly basis, again, so that we are coordinated, there aren't surprises, we identify where there are gaps that need to be filled through this portfolio review process. And again, it is my job to bring everybody together to coordinate and get those gaps filled.

I have been actually quite pleased with how it is working. I am sure it is a work in progress, that we can continue to do better. Quality improvement has been one of the centerpieces of sort of how I do business in our office and will continue to adapt that philosophy to continue to make things better and better.

Senator CASEY. Doctor, thank you very much.

Dr. LURIE. Thank you.

Senator CASEY. We appreciate your testimony and your service.

Dr. LURIE. Thank you. It has absolutely been an honor to serve the American people in this time.

Senator CASEY. Thank you.

Now we will move to our second panel and maybe as we are getting organized, I can, with the assistance of Senator Burr, read through some of the biographical and background material for our next panel.

Senator Burr, would you like to start or—I have the introductions of three, but Dr. Kadlec, would you like to do that first?

Senator BURR. I would love to do that.

Senator CASEY. Great, thank you.

Senator BURR. It is an honor and a privilege to introduce Dr. Bob Kadlec who many on this committee affectionately call Dr. Bob. I have had the pleasure of knowing Bob for many years. He served our Nation in many distinguished capacities. He served 26 years as a military officer and physician in the United States Air Force, serving in senior positions in the White House, the Department of Defense and as a senior staffer here in the U.S. Senate.

Dr. Bob is a veteran of Operation Desert Storm and Iraqi Freedom. His military decorations include the Bronze Star and the Joint Distinguished Meritorious Service Medal with Hope Leaf Cluster. Until January 2009 Bob served as a special assistant to the President and senior director for bio-defense policy on the Homeland Security Council. Dr. Bob is currently a member—or a director in public health practice at PRTM.

I am also told—and I can see her now—I am pleased to say that Dr. Bob's wife, Dr. Ann Vertis, and his daughters, Margaret and Samantha, are in attendance today. I am glad to see that you could join us. Let me say to your daughter's, Bob, you should be very proud of your dad and the work he has done to protect the American people and serve this Nation.

I look forward to your testimony, Bob, as I do to the rest of our witnesses today.

STATEMENT OF ROBERT P. KADLEC, M.D., MTH&H, MA, VICE PRESIDENT, GLOBAL PUBLIC SECTOR, PRTM MANAGEMENT CONSULTANTS, WASHINGTON, DC

Dr. KADLEC. Thank you, Senator Burr, for that very generous introduction. I have to admit my family is here as part of my human shield program.

[Laughter.]

It is great to be back in the familiar setting such as this, Mr. Acting Chairman, members that are here today. And also know that it is a very different viewpoint from this side of the dais than up there. And so I am very sensitive to that, but really what I hope to focus in on, and my comments will be very brief and to the point. One thing that I would like to just mention, that in my military career I spent a long part of that in the special operations community for which I had the privilege to serve with many joint special operation activities and units, but the thing I took away from that critical thing was the necessity for unity of command, and I will get to that point a little bit later on.

I just want to start out by saying there is nothing more sacred than protecting and defending the constitution of this country. But I would say a very close second is protecting and saving American lives in the event of a deliberate attack on our Nation. And that is obviously what the conversation here is today and I believe it is something that all members of government, all parties, all branches of government certainly have as a sacred duty.

And with that, in preparing for this testimony, I really spent a little time looking at the history of this issue, the issue for preparing our country for national security emergencies, and found that there was an Executive Order, 11490, and I am sure nobody remembers it, signed by Richard Nixon in 1969, that was the predetermining step before he actually renounced the Offensive BW Program in the country. And that Executive order, which placed health and education and welfare department in charge of responding to public health emergencies, that was the result from radiological, chemical or biological events, was reaffirmed by Reagan in 1988, Clinton by 1998 and obviously during the Bush administration several presidential directives and Executive orders were yielded.

But I want to point out the essential role of Congress in this, because if you look at the history of this, very little measurable progress was done. And I don't want to say we lived the Einstein definition of insanity, but clearly these Executive orders didn't have the power or weight behind them to do what was needed. And yet, in 2000, before the events of 9/11, this committee, this Congress and Members of the House basically started a very deliberate, incremental movement with the passage of the Public Health Preparedness Act in 2000 (just to note, the chairman, Chairman Harkin, Senator Enzi were part of that, Representative Burr, I think he is related, sir, did it from the house side), but the point is beginning before this they recognized this as a serious issue.

And then since 2000 until the PAHPA Act was passed six major pieces of legislation were passed by this Congress. And so the whole notion that the power of authorization, oversight and appropriations are key to basically addressing this issue. I certainly applaud the efforts by this Chairman and the Ranking Committee Members and certainly Senator Burr and Senator Casey, yourself and the other Members, to basically take this task forward.

The one thing I want to point out and the three areas that I think deserve special attention is, when this was created—the ASPR—it was really about leadership, leading the effort around Emergency Support Function Number Eight subject to training, or-

ganizing, equipping the health assets of the country, primarily Federal, to basically respond to catastrophic events.

I would say that we have made some half steps in that direction, but quite frankly, we are not there yet.

It does take some scrutiny to look at the entities within HHS that don't necessarily formulate that critical operational control or span of control for Dr. Lurie as she sits here today. If you ask, who deploys the Strategic National Stockpile or who makes decisions on those kinds of issues, I think you would be surprised by the answer. It is essential that someone be in charge, as Senator Burr has said. And it is essential that that person have the authority and powers within that position to do the necessary things.

Senator Blumenthal asked a very insightful question, subject to the issue of DOD and I would add also VA in that respect. We have huge health assets that should be mobilized, on call to support the response to a major catastrophic event in our country and yet we don't have that necessarily in place.

The second issue is about the State and local public health infrastructure and you will hear from others about the parties around that, other than much of the progress that has been made in the last decade could be lost based on the attrition, based on the tremendous physical pressures, as well as the aging population of the workforce as we go forward.

And the third element here, as quite a bit of the discussion has already really been around the Medical Countermeasures Enterprise, but the notion that is, and this is extraordinary and a credit to the people at BARDA, that they have been able to basically produce a number of products, get them in the stockpile and basically operate at a budget that has been somewhere between 20 percent to 40 percent of their actual authorization. I wouldn't expect that our SEALS would do as well against Osama bin Laden or any of our forces would do as well if we only funded them at 40 percent of their funding level.

I think with that, I am just left with the great awe and appreciation for what this Congress has done, this committee has done in the past. If there is any group in Congress that gets this problem and knows how to get it done, it is the HELP Committee. And I think under the leadership of the Chairman and the Ranking Member, as well as you, Senator Casey and Senator Burr, I am convinced that we will have further success and make further progress. Thank you.

[The prepared statement of Dr. Kadlec follows:]

PREPARED STATEMENT OF ROBERT P. KADLEC

SUMMARY

Reauthorizing the Pandemic and All Hazards Preparedness (P.L. 109–417) and Project BioShield (P.L. 108–276) Acts is a timely and urgent national security issue. Much progress has been achieved through the implementation of both laws. It is a priority to further refine and improve the overall state of all hazard public health and medical preparedness and response.

Despite the death of Bin Laden, the threat of domestic terrorist attacks using Chemical, Biological and Radio-Nuclear (CBRN) agents remains a serious concern. In February 2011, the Directors of CIA and NCTC both testified that Al Qaeda and Al Qaeda of the Arabian Peninsula are intent on conducting attacks using CBRN agents. The head of the FBI's WMD Directorate stated that there is a 100 percent probability of a terrorist WMD attack on the United States. Both Senators Harkin

and Lugar publicly expressed their concern about the risk of bioterrorism following the death of Bin Laden.

The challenge associated with deliberate CBRN attacks particularly involving biological agents should not be confused with natural disease outbreaks. Insights learned from the former U.S.-offensive biological weapons program indicate that biological attacks can have the lethal equivalence of a thermo-nuclear weapon. Unlike Mother Nature, a deliberate thinking enemy could employ multiple biological agents in overwhelming doses that are resistant to common treatments. Responding to bioterrorism requires a speed and complexity of effort that is greater than what would be likely needed in natural disease outbreak.

There are 3 areas that should receive consideration as part of this reauthorization process:

1. **Strengthen the role and responsibilities of the HHS Assistant Secretary of Preparedness and Response (ASPR).** The original intent creating the ASPR was to put "someone in charge" of public health and medical preparedness and response. As in military or special operations, unity of command is essential to ensure an effective response to protect and save American lives during an attack or influenza pandemic. Despite efforts to date, the lines of operational command and policy oversight within HHS and across the relevant Interagency remain unclear.

2. **Maintain a capable public health and medical infrastructure to respond to catastrophic events.** Recent fiscal crises at the State and local levels have severely impacted that state of preparedness and response with the loss of highly trained and qualified personnel. Continuation of Public Health Emergency Preparedness and Hospital Preparedness Grant programs is essential to maintain needed capabilities.

3. **Promoting a robust medical countermeasure (MCM) development, manufacturing and distribution and dispensing enterprise.** HHS should be required to submit multi-year budget plans for MCM development and procurement and authorized to accelerate MCM development. Further measures should be enacted to support companies developing CBRN MCM that have no or limited commercial market overcome the funding and regulatory challenges. Efforts underway to improve the speed of dispensing MCM to augment existing modalities should be accelerated to improve preparedness and response. These should include utilizing approaches such as the U.S. Postal Service home delivery; development of FDA approved medkits and first responder pre-event anthrax vaccination.

Chairman Harkin and Senator Enzi, it is a distinct privilege and pleasure to appear before you today. The reauthorization of the Pandemic All-Hazard Preparedness Act (PAHPA) is a timely and urgent issue. In the course of the intervening 5 years since its passage; many of this law's provisions have been implemented and in many cases resulted in improvements in our overall preparedness and response for all-hazard incidents. No doubt, there are some provisions that have not resulted in what Congress envisioned and deserve reconsideration.

Further, the recent review conducted by the Obama administration following the H1N1 Influenza Pandemic evaluating the status of the medical countermeasure enterprise, has identified opportunities for further improvements to the advanced development, regulatory support and manufacture of certain medical countermeasures. The results of this review are also worthy of consideration during this process. This hearing and reauthorization process is also timely in light of the anticipated expenditure of the $5.6 billion advanced appropriations contained in the Project BioShield Special Reserve Fund. Hopefully your deliberations will seriously consider reauthorizing this important act as well.

There is urgency to these efforts as well. The death of Bin Laden is an important inflection point in the war against Al Qaeda and Islamic extremism. As President Obama has explicitly stated, the threat from terrorism has not abated. Mr. Chairman, you and Senator Lugar recently highlighted the potential increased risk of bioterrorism following Bin Laden's death.

I note other recent authoritative statements by key Intelligence and FBI officials as reason for continued concern that should lead to urgency to improve our preparedness and response for a range of possible conventional and unconventional attacks. In February of this year, both the Central Intelligence Agency (CIA) Director Leon Panetta and National Counter-Terrorism Center (NCTC) Director Michael Leiter highlighted their concern about continued high interest by both Al Qaeda and Al Qaeda of the Arabian Peninsula to obtain and use radiological materials in dirty bombs, or chemical or biological agents, particularly anthrax, in attacks. Dr. Vahid Majidi of the FBI WMD Directorate rated the probability of a WMD attack in the United States at 100 percent, either from a known terrorist group or an unknown

"lone wolf" actor. In light of Bin Laden's demise, there should be a greater urgency about correcting deficiencies. In some cases, as in the development or manufacture of certain medical countermeasures (MCM) or addressing manpower shortages in critical public health or medical professions; there is a significant lead time to rectify shortfalls.

While we have recently experienced significant natural disasters or accidents, they do not reflect the risk of a catastrophe from a deliberate WMD attack by a thinking enemy. Insights learned from the former U.S.-offensive biological weapons program highlight several important considerations. The impact of an aerosolized biological agent attack can have the lethal equivalence of a nuclear weapon. Adversaries, States, groups or even individuals, who are intent to use such weapons will do so with the specific intent to defeat one's defenses through the potential delivery of multiple virulent agents, overwhelming infectious doses, antibiotic resistant strains or all the above. The belief that deliberate attacks are similar to or less challenging than natural emerging disease pandemics is not only false but dangerous.

Though the title of this Committee on Health, Education, Labor, and Pensions, doesn't reflect it; the issue of preparedness and response is vital to national and homeland security. Unfortunately, your efforts don't receive the press or notoriety of your colleagues on the Armed Services, Homeland Security and Intelligence Committees. I suggest that your efforts here today and the weeks and months ahead can build on PAHPA's achievements and advance preparedness and response. I suggest that there are three areas that should receive your particular attention, consideration and effort.

1. *Strengthen the role and authorities of the Assistant Secretary of Preparedness and Response (ASPR) in the Department of Health and Human Services (HHS).* The original intent of legislation was to put "someone" in charge of medical and public health preparedness and response. Second only to protecting and defending the Constitution, protecting and saving Americans whose lives are threatened from potentially catastrophic attacks or natural disasters is a sacred obligation. The model used to create the ASPR was the one used to create the military Regional Combatant Commanders. In advance of a contingency, they set the requirements for the forces that would be committed in the event of hostilities. Should a contingency occur, that regional combatant commander would assume operational control of those assets and prosecute the mission under a unified command structure. This doesn't mean that units are physically moved, it means the operational scheme is pre-determined and that those capabilities are trained and equipped to ensure success.

Prior to the creation of the ASPR, no one was in charge and no one was accountable for public health or medical preparedness and response. That is what the ASPR was created to do. It is a tall order in a non-national security Department like HHS to immediately embrace or transform itself in such a fashion. However, the ASPR was the result of careful and thoughtful consideration to consolidate these functions under one person who is presidentially appointed and confirmed by the Senate to ensure that American lives can be protected and saved should a catastrophe happen. As with any transformational change, progress comes haltingly. The objective should never be forgotten: Protecting and saving American lives from the threat of weapons of mass destruction or pandemics is the ASPR's sacred duty.

The ASPR should have the necessary policy oversight and operational control in the event of or anticipation of a public health emergency of all the HHS elements, including CDC response and designated Inter-agency assets under Emergency Support Function Eight of the National Response Framework during an anticipated or actual public health emergency. This goal has not been fully achieved but is essential to ensure the success of this mission.

2. *Maintaining a capable public health and medical infrastructure to respond to catastrophic events.* Much progress has been achieved through the funds authorized and appropriated to the Public Health Emergency Preparedness and Hospital Preparedness Grant programs. Mr. Chairman, I particularly recall your vision of creating a national public health system that was similar to our national highway system: standardized, interconnected, and promoting not only public health but national security. You will hear from others concerning the incredible strain that the recent fiscal crisis has wreaked on State and local public health programs, particularly concerning the retention of qualified personnel. People are the cornerstone of public health preparedness and response.

3. *Promoting a robust medical countermeasure (MCM) development, manufacturing, distribution and dispensing enterprise.* Much effort and attention was recently given to the issue of MCM development and manufacturing. During the H1N1 pandemic, deficiencies in our ability to rapidly produce vaccines were noted. The recently announced Medical Countermeasure Initiative by HHS highlights some

important opportunities to improve the process by which the Government subsidizes the development and production of these necessary products. While there has been much focus on the threat of pandemic influenza, I am concerned that the challenges and risk around the development of national security MCM for chemical, biological and radio-nuclear threats remains high. Despite limited advanced development funding, BARDA has had several notable successes including developing and stockpiling Bavarian Nordic's smallpox vaccine, Human Genome Sciences anthrax monoclonal antibody and SIGA's and Chimerix's smallpox antiviral drugs. More should be done to assist companies who are attempting to navigate the difficult funding and regulatory pathways while developing vital national security MCM that have no or limited commercial market. Simply requiring HHS to develop and submit multi-year budget plans outlining their priorities and intended procurements would go a long way to assist both Congress and companies involved in this endeavor. Further, BARDA should have the resources necessary to conduct a robust advanced development portfolio and have the flexibility to accelerate advanced development of select products as required. BARDA's efforts and budget should reflect the priority of creating MCM for national security.

There also needs to be clear requirements concerning what should be our policy in the event of either a credible threat of or actual biological attack. In response to the threat of smallpox, the United States has stockpiled enough vaccine for every American and now is stockpiling antiviral drugs. We will soon be able to take smallpox "off the table" and go on to create a credible deterrent against this threat. We have not made similar policy determinations for other potential threats. The recent Fukushima disaster starkly highlights a policy decision as to whether we should pre-position potassium iodide in metropolitan areas at risk for nuclear or radiological attacks. These policy requirements are essential to guide decisions concerning not only procurement but building adequate capacity to produce the range of CBRN vaccines and biological products that may be needed in a crisis.

The proposal to improve the FDA's ability to assist such companies and provide the necessary dedicated regulatory support is an important initiative that deserves congressional backing. Ensuring BARDA has the necessary means to conduct its support of and the ability to accelerate advanced development remains a serious shortfall in the overall U.S. Government approach in producing national security MCM.

Significantly, there remain serious shortfalls in our capabilities to rapidly distribute and dispense MCM in the event a deliberate attack. I note that President Obama signed an Executive order in December 2009 instructing Federal Departments and Agencies to examine how they can assist State and local authorities to more rapidly dispense MCM to populations that may be affected by CBRN attacks. An essential measure that was identified is the forward deployment of MCM so they can be rapidly accessed by essential first responders, health care workers and the public. There are a range of options that should be aggressively pursued including development of medkits for use by first responders, their families and available to the public; utilizing existing distribution systems with the U.S. Postal Service and retail pharmacies; and options for vaccinating first responders against the most likely threat of anthrax. There is an urgent need to act now to prepare to prevent the potential significant loss of life, social chaos and loss of confidence in the U.S. Government in the event of an attack.

I very much appreciate the opportunity to appear before you all today and look forward to your questions.

Senator CASEY. Doctor, thank you very much for your testimony and for your work on these important issues.

I want to note for the record, I should have said this before, that of course all of the witnesses testimony, if you wanted to submit something in writing you can do that as well, that will be made a part of the record if you submit it, in addition to anything that you obviously say by way of summary.

What I will do next is I will introduce our next three witnesses by way of biography and background and then we will start picking up the testimony again with Phyllis Arthur.

Let me add as well, any panelist who wants to introduce members of your family, all of us realize that when someone serves in public office, appointed or elected, that the family serves as well, so they deserve recognition and commendation.

Next, and I am moving from left to right here, next is Phyllis Arthur. Phyllis, we welcome you. Ms. Arthur is the senior director for vaccines of immunotherapeutics and diagnostic policy at the Biotechnology Industry Organization, known as BIO. And Ms. Arthur is a recognized expert in the field of vaccines. Before joining BIO she worked in marketing and sales in the vaccine division at Merck and Company. And through her career she has launched several new vaccines in the United States and abroad, most notably Gardasil, the first vaccine for HPV. We appreciate your presence here and your testimony, Phyllis Arthur.

Next, Dr. Michael Anderson. Dr. Anderson is the vice president, associate chief medical officer at University Hospitals in Cleveland. In addition to his leadership position Dr. Anderson serves as the associate professor of pediatric critical care at Rainbow Babies & Children's Hospital. In 2008 Dr. Anderson was appointed to the National Commission on Children and Disasters. And as a member of this commission, he was charged with analyzing our readiness to care for children in disasters and issuing recommendations to the President and to the Congress. Welcome, Doctor.

And finally, Ms. Susan Cooper. Susan Cooper is the commissioner of Tennessee's Department of Health. She is the first nurse to serve in this capacity. Commissioner Cooper has a wealth of public health and emergency preparedness experience. She has helped develop Tennessee's healthcare safety net and programs addressing the threat of Type 2 Diabetes. Commissioner Cooper also serves on the executive committee of the Board of Directors of the Association of State and Territorial Health Officials. Ms. Cooper, thank you very much—or Commissioner, I should say.

I think we will go back to Ms. Arthur, if you wanted to provide your testimony. And again, if any of you want to introduce family, you have that option. Thank you.

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

Ms. ARTHUR. Thank you. Good afternoon. Thank you for that nice introduction, Chairman Casey, Ranking Member Burr. I will say I am a graduate of the University of Pennsylvania, so I will give that shout out.

Members of the committee, ladies and gentlemen, as stated, I am Phyllis Arthur, with BIO. BIO represents a broad mix of companies involved in the research, development and manufacture of biologicals, including products for the detection, diagnosis, treatment, prevention, and delivery of medical countermeasures, or MCMs, in response to chemical, biological, radiological and nuclear threats.

These companies consider themselves integral partners with the U.S. Government in the development of these vital countermeasures that are needed to protect the American people. And therefore, BIO has focused its recommendations on changes that are essential to both attract and of course retain companies in the Enterprise. Over the last 10 years, as Assistant Secretary Lurie

pointed out, bipartisan congressional efforts have created and funded an MCM Enterprise that has begun to show success.

In partnership with industry the U.S. Government has responded to the 2009 H1N1 pandemic, prepared for a possible pandemic of bird flu, made numerous improvements to existing flu production and issued contracts on a host of different platforms for strategic treats, including delivering two key countermeasures for smallpox and anthrax to the Strategic National Stockpile. Presently there are more than 50 companies conducting research and development in influenza vaccines in over seven different platforms. In addition, there are 25 companies, actually maybe more, that are currently working on new treatments, vaccines and diagnostic countermeasures related to CBRN threats.

Developing CBRN countermeasures can be even more complex than influenza. First the targeted diseases are less well understood. Second, determining the best development pathway to demonstrate safety and efficacy requires a great deal of scientific collaboration between industry and the key Federal agencies, especially in special populations such as children and pregnant women. Third, many bio-threats are complex and unique and they may require specific diagnostic tools, vaccines and treatments requiring separate, detailed clinical plans.

BIO has identified three key priorities to improve preparedness and reduce the time to develop and approve essential countermeasures. First, provide greater transparency and clarity in the MCM market, the contracting process and in advanced research and development activities. Second, improve the clarity, consistency and integration of the FDA in the development and approval of MCMs. And third, ensure the future of the Enterprise while simultaneously reauthorizing Project BioShield and Special Reserve Fund with PAHPA.

The Project BioShield Act accomplished several important goals, including the creation of the Special Reserve Fund which is designed to guarantee companies that the government will purchase new, successfully developed countermeasures for the SNS. The existence of the SRF and the annual appropriations to BARDA define the marketplace for MCMs, because there is not a viable commercial market for these products. Company resources allocated to countermeasures divert R&D and manufacturing away from commercial products and they must be subjected to the same rates of return. In addition, private investors are wary of investing in this type of research.

So BIO recommends that HHS be required to provide biannual reports outlining BARDA advanced development activities and the length of time to BioShield requirements and procurement awards. BIO also recommends greater transparency in BARDA and BioShield contact requirements, including the early establishment of required product characteristics.

One of the most significant risks unique to countermeasures development is certainly the testing and the clinical trial design requirements. These are less well-established. Clinical trials often require the use of multiple animal models to prove human efficacy and this adds to the uncertainty. The most significant recommendation from the PHEMCE review was to invest in the FDA

and its review and regulatory science processes. This would enable FDA to have an affirmative role in solving the scientific and regulatory hurdles of MCMs.

BIO and its members strongly support this recommendation and encourage the FDA to work collaboratively with company sponsors throughout the entire MCM process to help design development plans and associated studies, especially those requiring the use of animal models. Implementation of new MCM initiatives should be coupled with specific measurements for success.

The Project BioShield Act and PAHPA help to build processes to advance clinical and manufacturing infrastructure to protect against a multitude of biological threats. In addition to developing and stockpiling countermeasures, devices and diagnostics against currently anticipated threats, it is crucial that the United States build the capacity to respond to novel threats, such as newly emerging diseases and genetically modified pathogens. The reauthorization of PAHPA and BioShield SRF are critical to these efforts.

Therefore, BIO strongly urges Congress to simultaneously reauthorize the SRF with PAHPA. The SRF should be funded at a level that incentivizes private industry to actively participate. Furthermore, Congress should clearly articulate that development of MCMs is a national security priority and that funding for these efforts be treated as national security spending.

Since 2001 the Enterprise has had some successes. However, much remains to be done. Future planning and sustained investment in global surveillance networks, our public health infrastructure, MCM development and distribution systems is critical to adequately alert, prevent and recover from any future CBRN or natural biological event.

BIO commends the committee for holding this hearing and we stand ready to work with Congress to implement these important issues. Thank you.

[The prepared statement of Ms. Arthur follows:]

PREPARED STATEMENT OF PHYLLIS ARTHUR

BIO represents a broad mix of small, medium and large companies that develop and manufacture biological products for the detection, diagnosis, treatment, prevention and delivery of countermeasures in response to chemical, biological, radiological and nuclear (CBRN) events.

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. In partnership with industry the U.S. Government:

- Responded to the 2009 H1N1 pandemic;
- Invested in products to prepare for a possible bird flu pandemic;
- Completed a comprehensive review of influenza vaccine production issues;
- Issued contracts for novel platforms for seasonal and pandemic influenza vaccines, diagnostics and antivirals as well as the final development of novel treatments for smallpox, new antibiotics and innovative treatments for the side effects associated with acute radiation syndrome (ARS); and
- Acquired and delivered key countermeasures to vaccinate against smallpox and treat anthrax to the Strategic National Stockpile (SNS).

Among the goals of the U.S. Government in conducting the medical countermeasure (MCM) review issued in August 2010 were identifying issues limiting companies of all sizes from successfully engaging in the countermeasures process and proposing solutions to increase engagement. BIO has identified three key priorities that will help achieve a greater degree of industry participation and urges the committee to consider incorporating them into the legislation to reauthorize the Pan-

demic All-Hazards and Preparedness Act (PAHPA) of 2006. Priorities include: (1) providing greater transparency and clarity in the MCM market establishment, the contracting process, and in advanced research and development activities; (2) improving the clarity, consistency and integration of FDA in the development of MCMs; and (3) sustaining the MCM market by ensuring that Project Bioshield and the Special Reserve Fund (SRF) are simultaneously reauthorized with PAHPA.

(1) DEFINING A VIABLE MARKET VALUE FOR MCMS

Project BioShield was designed to serve as a symbol of the U.S. Government's commitment to purchase new, successfully developed countermeasures for placement in the SNS. The acquisition and contracting processes at HHS to acquire new countermeasures are viewed by industry partners of all sizes as lengthy, opaque, and unpredictable. BIO recommends greater transparency in BARDA/BioShield contract requirements including the early establishment of product characteristics required. BIO also recommends that HHS be required to provide bi-annual reports outlining BARDA advanced development timelines/activities and the length of time to BioShield procurement award and that appropriate action be taken if timelines are not met.

(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. Testing and clinical trial design requirements are not well-established, requiring the use of multiple animal models to prove efficacy, which adds an extra dimension of risk and uncertainty to this process.

BIO and its members strongly support making significant investments in FDA review and regulatory science initiatives related to medical countermeasures. FDA should play an affirmative role in solving the scientific and regulatory hurdles that exist, not just the review and approval, of MCMs. This can best be accomplished by encouraging the FDA to work collaboratively with company sponsors throughout the *entire* MCM development process to design development plans and associated studies, especially those requiring use of animal models.

BIO recommends that the FDA become more involved in the development of MCMs 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, currently the United States is decades away from having an adequate arsenal of countermeasures to safeguard our citizens. The reauthorization of PAHPA and the replenishment of the BioShield SRF are critical to these efforts.

Therefore BIO strongly urges Congress to reauthorize 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 and should be designated as a national security or homeland security priority.

Good morning Chairman Harkin, Ranking Member Enzi, 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 manufacture of medical countermeasures or MCMs. 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 (CBRN) events.

One of the goals of the Department of Health and Human Services' (HHS) review of the Public Health and Emergency Medical Countermeasures Enterprise (PHEMCE) was to identify and solve those issues limiting companies of all sizes from successfully engaging in the countermeasure process. In its input on both the HHS PHEMCE review and reauthorization of the Pandemic and All-Hazards Preparedness Act (PAHPA) of 2006, BIO has stressed one overarching principle: the

biopharmaceutical industry wants to be an integral partner with the U.S. Government in the development and stockpile delivery of these vitally important countermeasures to protect the American people. Therefore BIO has focused its recommendations on changes that are essential to both attract *and retain* companies of all sizes to the Enterprise. Maintaining the skills and know-how of companies that have already weathered the complicated MCM development and contracting process must be as important to the U.S. Government as attracting new companies to the MCM development space.

BIO has identified three key priorities to improve preparedness, accelerate approvals and reduce the time needed to develop essential MCMs. We urge the committee to address these areas in the reauthorization of PAHPA. These include: (1) providing greater transparency and clarity in the MCM market establishment, the contracting process, and in advanced research and development activities; (2) improving the clarity, consistency and integration of FDA in the development and approval of MCMs; and (3) ensuring that the future of the PHEMCE is adequately funded by simultaneously reauthorizing Project Bioshield and the Special Reserve Fund (SRF) with PAHPA.

INVESTMENTS HAVE YIELDED SUCCESS

Over the last 10 years, bipartisan congressional efforts have created and funded an Enterprise that has begun to show success. Some of the most important accomplishments involve pandemic influenza preparedness. Not only did government agencies and industry partners mount a well-thought out response to the 2009 H1N1 pandemic, they also invested in products to prepare for a possible avian/bird (H5N1) pandemic and conducted a comprehensive review of influenza vaccine production issues. This review resulted in the President's Council of Advisors on Science and Technology (PCAST) report in August of 2010.[1] This report made important and attainable recommendations for both existing and future technology to meet the challenges of responding to future pandemics. Some of these are currently being implemented, but all should be fully considered and supported with adequate resources.

Currently, there are more than 50 biotechnology companies conducting research and development in new seasonal and pandemic influenza vaccines in over seven different novel technologies and platforms. Other companies are developing new antivirals and diagnostic tools as well. While the Biomedical Advanced Research and Development Authority (BARDA) has invested in new manufacturing facilities and issued new contracts for several of these innovative platforms, more investment at every phase of development is vital from both the public and private sectors if America wants to realize our full potential.

Developing countermeasures to respond to bioterrorism threats is even more complex than influenza. First, the targeted diseases are less well-characterized and studied, especially in special populations such as children and pregnant women, and the study of these diseases often relies on complicated animal models. Second, how the MCM will be used in response to an attack determines how it should be designed and clinically studied. Thus, determining the best development pathway to demonstrate safety and efficacy requires a great deal of scientific collaboration between industry and the key Federal agencies. Third, for each unique biothreat, the goal is to have a diagnostic tool to identify the threat as well as countermeasures to prevent illness and others to treat those who become infected. Lastly, many of the technologies being applied for medical countermeasures are relatively new themselves. They hold great promise as methods to solve the pivotal clinical issues that these threats pose, but they also require more significant investment at every research stage to help increase the probability of success.

Despite these challenges there have been some successes in the development and procurement of MCMs for the treatment and prevention of lethal biothreats, such as anthrax, botulinum toxin and smallpox. In the past 2 years, key countermeasures to vaccinate against smallpox and treat exposure to anthrax have been delivered to the Strategic National Stockpile (SNS). Furthermore, several key procurement and advanced development contracts have been issued that will lead to the final development of novel technologies for smallpox, new broad spectrum antibiotics and innovative treatments for the side effects associated with acute radiation syndrome (ARS).

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[1] Executive Office of the President, President's Council of Advisors on Science and Technology, *Report to the President on Re-engineering the Influenza Vaccine Production Enterprise to Meet the Challenges of Pandemic Influenza*, August 2010.

RECOMMENDED ACTIONS

BIO has identified three challenges that limit industry's participation in PHEMCE and we urge Congress to address them in the PAHPA reauthorization: (1) defining a viable market value for MCMs versus the opportunity cost of investing in alternative therapeutic areas; (2) management of cost and risk, especially in the regulatory process; and (3) the 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 was the creation of the Special Reserve Fund. BioShield is designed to guarantee companies that the government will purchase new, successfully developed countermeasures for placement in the Strategic National Stockpile. The existence of the SRF and the annual appropriations to BARDA, which support MCM advanced development and CDC procurement funding, define the marketplace for MCMs. 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 resources allocated for 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, development and contract award projections are seldom met, and the guarantee of government purchase is not always clear. Therefore, there are very limited external private funds to support companies in the MCM space.

Another part of the opportunity cost assessed by industry is the time required to achieve success. While industry, particularly small biotechnology companies, finds BARDA a good and effective partner, 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 and some acquisitions are delayed by months, years, or even canceled. The negotiation process is lengthy and the rationale and potential triggers for contract options are unclear. The signal to industry is that despite the enormous risks of development, new drugs and vaccines developed as countermeasures have far less value than commercial products.

BIO recommends that HHS be required to provide bi-annual reports to Congress outlining BARDA advanced development activities and the status of achieving key milestones, the length of time to BioShield procurement award, and other BioShield procurement activities. BIO also recommends greater transparency in BARDA/BioShield contract requirements including the early establishment of required product characteristics.

(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 is costly and fraught with risk. One of the most significant risks is that countermeasures are approved via a convoluted regulatory pathway. Similar to commercial biologicals, new countermeasures 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 most other ways MCM development and approval is much more complicated. Testing and clinical trial design requirements are less well-established, requiring the use of multiple animal models to prove efficacy, which adds an extra dimension of risk and uncertainty to this process.

One of the most significant recommendations from the PHEMCE review was to invest significantly in the FDA review and regulatory science processes. BIO and its members strongly support this recommendation, and have worked to ensure FDA was allowed a transfer of money for such purposes as part of the fiscal year 2011 FDA appropriation. The FDA has tremendous expertise in the science of drug development and the manufacturing of complex drugs, diagnostics and biologics. 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 the need for unexpected regulatory actions by companies in order to achieve licensure for a product. 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 MCMs. This can

best be accomplished by encouraging the FDA to work collaboratively with company sponsors throughout the *entire* MCM development process 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, BIO recommends that 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 build the capability to respond to novel threats such as newly emerging diseases and genetically modified pathogens. The U.S. Government can help increase the Nation's preparedness by undertaking several other key actions.

First, the reauthorization of PAHPA and the BioShield SRF are critical to these efforts. Therefore, BIO strongly urges Congress to reauthorize 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.

Furthermore, Congress should clearly articulate that development of MCMs is a national security priority and that funding for these efforts be treated as national security and/or homeland security spending.

Second, 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. Ineffective coordination and collaboration between the various government agencies involved in the Enterprise adds 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.

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 MCM projects with some increased level of certainty. A systematic, transparent vision from the U.S. Government will help companies assess the viability of both their existing and future countermeasures' programs. This multi-year strategic plan, coupled with modifications to the contracting processes, would encourage increased industry participation.

Third, BIO recommends the continued investment in distribution and public health infrastructure. Both the PHEMCE review and the PCAST report on Pandemic Influenza considered the breadth of the preparedness continuum—surveillance, rapid manufacturing of MCMs, diagnosis, and ultimate delivery to the public. In order to benefit the public, the U.S. Government must know when and how to deploy and administer countermeasures. Some of the PHEMCE and PCAST recommendations will require longer-term investments, such as training public health and medical first-responders, while others can be implemented in the near-term through more effective planning and with modest resources. For example, stockpiling strategies for products that are applicable to many different emergencies—such as needles, syringes, and critical assay compounds, can ensure rapid availability and avoid supply chain disruptions.

Lastly, one of the most critical elements of responsiveness involves the Nation's ability to detect and identify these threats to best mount a proper and timely response. BIO members are also concerned that the U.S. Government makes the right investments in global and U.S. surveillance testing and reporting networks. Efforts should be made to extend the network and to invest in 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 mod-

ernize its technical and technological capabilities, would increase speed and accuracy in detecting emerging diseases and threats.

IMPROVING THE MCM PROCESS REQUIRES SUSTAINED PARTNERSHIP

Because there is no viable commercial market for most MCMs, it is essential for Federal, State and local governments to be involved in the detection of threats and the development and dissemination of the products in the event of an emergency. As is true with typical biologics development, it takes many products in development to arrive at one successfully licensed vaccine, antimicrobial or diagnostic test. If our collective goal is to use innovative technology to help solve vital national security issues, then everyone must be willing to acknowledge the higher degree of risk and uncertainty inherent in MCM development. Future plans and investments are pivotal to sustain current successes and further strengthen and improve the Nation's preparedness.

BIO commends the committee for holding this important hearing and stands ready to work with Congress on these important issues. BIO strongly encourages the committee to improve preparedness and accelerate development and approval of essential MCMs by: (1) providing greater transparency and clarity in the MCM market establishment, the contracting administration process, and in advanced research and development activities; (2) improving the clarity, consistency and integration of FDA in the development of MCMs; and (3) ensuring that Project Bioshield and the Special Reserve Fund are simultaneously reauthorized with PAHPA.

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. It is critical that future plans and investments be made that will build upon this success.

Senator CASEY. Thanks, Ms. Arthur.

Dr. Anderson.

STATEMENT OF MICHAEL R. ANDERSON, M.D., FAAP, VICE PRESIDENT AND ASSOCIATE CHIEF MEDICAL OFFICER AT UNIVERSITY HOSPITALS AND ASSOCIATE PROFESSOR OF PEDIATRIC CRITICAL CARE AT RAINBOW BABIES & CHILDREN'S HOSPITAL, CLEVELAND, OH

Dr. ANDERSON. Good afternoon, Mr. Chairman and members of the HELP Committee. I am Dr. Michael Anderson, a practicing pediatric intensive care physician at Rainbow Babies & Children's Hospital in Cleveland.

None of my family members are here, although last week I was here with about a million eighth graders on a bus. So I feel that my family has been in town recently.

Up until April I was also proud of serving as vice chairman of the National Commission on Children and Disasters, a commission created out of the strong leadership of this committee.

On behalf of the American Academy of Pediatrics, I would like to thank you for holding today's hearing on such an important topic, strengthening our medical and public health preparedness and response.

Recent events in Alabama, Mississippi, Louisiana and the Chairman's own State of Iowa, make today's hearing especially timely. These events and the tragedy in Japan are a stark reminder that disasters can and do strike, oftentimes obviously without warning. Therefore, as a Nation, as individuals and families and importantly as healthcare professionals we must plan ahead and we must be prepared.

As a clinician and someone active at the State and local and national level on pediatric disaster readiness and response, I can tell you that our Nation's preparedness has improved dramatically with the legislation like PAHPA and the Emergency Medical Services

Act for Children. Through the leadership of this committee we have made tremendous progress, but from what I see as a pediatrician and a former commissioner, we are not fully prepared to address the needs of 25 percent of our population, our Nation's children.

You have heard the saying that children are not little adults. My written testimony goes into detail about why this is the case, from a clinical standpoint. The reason it matters the most when it comes to medical and public health preparedness is that children live in every part of this country. When a disaster strikes, children will show up at hospitals, not just children's hospitals. They will need care by EMS professionals in the pre-hospital setting. They will be in shelters, live in temporary housing and may be separated from their parents and caregivers. If each and every one of these settings and others are not able to handle the unique physical and mental health needs of children, including children with disabilities, our work is far from finished.

The Academy supports the efforts of this committee to reauthorize PAHPA and urges the committee to use this bill as an opportunity to redouble our efforts at the Federal level to prioritize the needs of children and including children with disabilities and other vulnerable populations.

While I recognize this is a tough fiscal climate, I believe a significant step would be to remove children from the broader at-risk population category in the law and designate an office with the authority and funding necessary to adequately meet the needs of children during a disaster. This is especially critical now that our commission has been terminated. I appreciate the sensitivities around this recommendation, but I continue to believe it is vitally important.

But there are many other ways that we can strengthen our preparedness. No. 1, when it comes to medical countermeasures for children, it would be very helpful for the Federal Government to set a goal to achieve parity between adult and pediatric medical countermeasures developed and included in the SNS and other federally funded caches. Among the recent advancement for children is the approval of pediatric labeling for Pollodoxin for the treatment of nerve agent poisoning meaning it can now be stockpiled in the SNS for that indication. However, that labeling took 7 years to get approval, with no new data. We must figure out how to streamline that process.

Two programs this committee is very familiar with, BPCA and the Pediatric Research Equity Act have resulted in the labeling or re-labeling of 400 new drugs for children with new safety, efficacy and dosing information and this is a huge advance in the field of pediatrics. The Academy looks forward to working with this committee to reauthorize these two vital programs and maximize their potential to improve pediatric labeling of MCM so that they can be stockpiled.

No. 2, volunteerism. I am proud to be a member of the National Disaster Medical System. But the NDMS and the Medical Reserve Corps need more clinicians. Thought should be given to how we might make it easier for clinicians to participate and how we might tailor pre-certification or training programs to reach clinicians on a broader scale all while ensuring recruitment of clinicians for spe-

cific populations such as geriatrics, pediatrics and individuals with disabilities or medical conditions.

Third, among the lessons learned from H1N1 is that hospital preparedness is critical. HHS has recently announced that 76 percent of hospitals participating in the HPP program meet 90 percent of their core measures. However, a 2008 CDC study showed that only a third of hospitals had guidelines for pediatric surge capacity, only 34 percent had plans for reunification of children with their families and 40 percent had a tracking system for unaccompanied children. The disparities in these findings is striking and I have included several recommendations in my written testimony of how we could deal with this.

I want to thank the committee for this opportunity. I look forward to your questions. America's children represent the future of our Nation and our more precious resource, they must not be an afterthought in medical and public healthcare preparedness and response. Thank you.

[The prepared statement of Dr. Anderson follows:]

PREPARED STATEMENT OF MICHAEL R. ANDERSON, M.D., FAAP

Chairman Harkin and Ranking Member Enzi, thank you for holding today's hearing on such an important topic, strengthening our medical and public health preparedness and response. My name is Mike Anderson, M.D., 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 before, during, and after disaster situations.

I am vice president and associate chief medical officer at University Hospitals Case Medical Center and associate professor of pediatrics at the Case Western Reserve School of Medicine in Cleveland, OH. I am also a practicing pediatric critical care specialist at Rainbow Babies & Children's Hospital. In my capacity as a practicing clinician, I have been active at the local, State, and national level in pediatric disaster readiness and response. In 2008, I was appointed by President George W. Bush to the National Commission on Children and Disasters (the Commission) which was created by Congress under the strong leadership of Chairman Harkin, former Senator Chris Dodd, and many others. I had the distinct honor of serving as the Commission's vice chair until its termination in early April 2011.

Recent events in Alabama, Mississippi, and in the Chairman's home State of Iowa make today's hearing especially timely and critical. These events and the tragedy in Japan are a stark reminder that disasters can and do strike, and oftentimes without warning. Therefore, as a nation and as individuals and families, we must plan ahead and we must be prepared.

The recovery and relief efforts here in the United States from tornadoes and flooding and from the earthquake and tsunami 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 of our population, children, may present several unique challenges and it is important that we, as Americans, assess whether the planning and exercises our government and communities engage in; whether our medical capabilities and the training of our first responders; and whether the preparedness of our Nation's hospitals, Federal, State and local governments, and families, adequately account for the needs of children and other populations in the event of a disaster.

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 reality. The Academy supports the efforts of this committee to reauthorize the *Pandemic and All-Hazards Preparedness Act (PAHPA)* and urges the committee to use the reauthorization bill as an opportunity to redouble our efforts at the Federal level to prioritize the needs of children, including children with special heath care needs.

The most significant step Congress could take to achieve this goal would be to remove children from the broader at-risk population category and designate an office with the authority and funding necessary to adequately meet the needs of children during a disaster. This is especially critical now that the National Commission on Children and Disasters has terminated. The Commission provided the needed, and previously lacking, focus and attention to children's needs in disaster planning and preparedness within Federal agencies. Additionally, removing children from the broader at-risk population category would allow Federal agencies to better direct resources and attention to populations such as individuals with disabilities, senior citizens, and pregnant women.

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 and public health preparedness and response?

• 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 Hurricane 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.

• 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

[1] Committee on Environmental Health and Committee on Infectious Diseases. Chemical-Biological Terrorism and Its Impact on Children. *Pediatrics*, Vol. 118, No. 3 September 2006. *http://aappolicy.aappublications.org/cgi/reprint/pediatrics;118/3/1267.pdf*.

[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*.

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. Additionally, a first responder wearing a Hazmat suit can be scary for a child so decontamination systems should ideally be designed so that parents can remain with their children and help them through the decontamination process.

• 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.

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.[5] 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 percent surviving the event, and with 75 percent 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 percent of all emergency department visits in the United States, and 5 to 10 percent 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 cognitive and technical abilities, is quite small. This creates a special problem for prehospital 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.[6] The Academy, jointly with the American College of Emergency Physicians, and the Emergency Nurses Association, issued guidelines to help hospitals with identifying and training a pediatric advocate within their institutions to implement certain protocols and help improve hospital preparedness.[7]

Children with special health care needs represent 13.9 percent of U.S. children, and 21.8 percent of households with children include at least one child with a special health care need.[8] Children with chronic medical conditions, including children with special health care needs, rely on multiple medications, medical devices, and complex management plans, which can cause them to be at increased risk of acute deterioration, medical errors, and suboptimal outcomes, especially in emergency situations.[9] These children pose unique emergency and disaster care challenges well

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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] 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.

[6] Gausche-Hill M, Schmitz C, Lewis RJ. Pediatric preparedness of United States emergency departments: a 2003 survey. *Pediatrics*. 2007;120(6):1229–37.

[7] American Academy of Pediatrics, American College of Emergency Physicians, and Emergency Nurses Association. Joint Policy Statement: Guidelines for Care in the Emergency Department. *Pediatrics*, Vol. 124, No. 4 (2009): 1233–43. *http://aappolicy.aappublications.org/cgi/reprint/pediatrics;124/4/1233.pdf*.

[8] U.S. Department of Health and Human Services, Health Resources and Services Administration, Maternal and Child Health Bureau. The National Survey of Children with Special Health Care Needs Chartbook 2005–6. Rockville, MD: U.S. Department of Health and Human Services, 2007.

[9] American Academy of Pediatrics. Policy Statement—Emergency Information Forms and Emergency Preparedness for Children with Special Health Care Needs. *Pediatrics*, Vol. 125, No. 4 April 2010. *http://aappolicy.aappublications.org/cgi/reprint/pediatrics;125/4/829.pdf*.

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.

CLINICIANS' ROLE BEFORE, DURING, AND AFTER A DISASTER

Clinicians, including pediatricians, play an integral role in disaster preparedness. From my personal experience, families view pediatricians as their expert and trusted source of information. As part of the network of health responders, pediatricians need to be able to answer concerns of patients and families, recognize signs of possible exposure to a weapon of terror, understand first-line response to such attacks, and sufficiently participate in disaster planning to ensure that the unique needs of children are addressed satisfactorily in the overall process.[10] However, the challenges that face pediatricians and other clinicians in their daily practices are heightened during a disaster situation.

It is important to point out that more than 95 percent of office-based pediatricians practice in settings defined as "small businesses" by the U.S. Small Business Administration. Fifty percent of private office-based pediatricians work in practices of 3 or fewer physicians with 8 or fewer non-physician staff; 70 percent work in practices of no more than 5 physicians and no more than 15 non-physician staff. Children live in every part of the country and, as such, pediatricians are part of the recovery effort in all communities after a disaster. When disaster strikes, pediatricians may become displaced, losing their workplaces and/or their homes. During the immediate aftermath of a disaster, they may be unable to practice, leaving children without access to care within their medical home. Every effort should be made at the Federal, State, and local level to help pediatricians with assistance relocating or rebuilding within their communities.

Many clinicians, myself included, are volunteers with the National Disaster Medical System (NDMS). The NDMS plays a vital role in our Nation's preparedness but the NDMS and the Volunteer Medical Reserve Corps (MRC) need more clinicians. Thought should be given to how we might make it easier on clinicians to volunteer and how we might tailor pre-certification or training programs to reach clinicians on a broader scale. Special attention should be paid to the recruitment of clinicians for specific populations such as geriatrics, pediatrics, and individuals with disabilities or chronic medical conditions.

Disaster preparedness starts at home with one's own preparedness. The Academy has provided guidance to pediatricians about preparedness in their own offices and communities.[11] For clinicians, there may be great value in reviewing what type of education, if any, they are receiving during medical school and subsequent training around disaster preparedness. A core curriculum around disaster preparedness, including at-risk population such as children, may be helpful.

HOSPITAL PREPAREDNESS FOR CHILDREN

This committee is no doubt familiar with ED overcrowding as a day-to-day reality for many, if not most, hospitals. Imagine layering on top of the current situation, a widespread mass care or mass casualty event involving children. This scenario played out in hospitals across the country in 2009 during the H1N1 pandemic. Large volumes of patients and their families sought medical care; pharmacies had to be educated on how to constitute Oseltamivir for the pediatric populations; hospitals had to create innovative strategies to address the surge of patients on top of the baseline patients; physicians and other health care providers worked to engage their communities and demystify vaccine safety concerns; physician groups like the AAP partnered with the government to ensure that media messages were consistent and accurate with medically sound and timely information. While children were disproportionately affected by this strain of influenza virus, fortunately the overall morbidity of this strain was less than expected.

The experience of H1N1 taught us many lessons. Among them is the fact that the science of ED surge remains relatively undeveloped.[12] In a 2008 survey of hospital preparedness by the Centers for Disease Control and Prevention (CDC), less than one-third (32.4 percent) of hospitals had guidelines for increasing pediatric surge ca-

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[10] American Academy of Pediatrics. Policy Statement—The Pediatrician and Disaster Preparedness. *Pediatrics*, Vol. 117, No. 2 February 2006. *http://aappolicy.aappublications.org/cgi/reprint/pediatrics;117/2/560.pdf*.

[11] 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. *http://aappolicy.aappublications.org/cgi/reprint/pediatrics;117/2/e340.pdf*.

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

pacity. About one-third (34 percent) of hospitals had plans for reunification of children with families, and only 42.6 percent of hospitals had a tracking system for accompanied and unaccompanied children.[13]

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 as well as 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.

This committee has helped hospitals make notable progress with their disaster preparedness upon the creation of the Hospital Preparedness Program, formerly the National Bioterrorism Hospital Preparedness Program, under PAHPA. The Assistant Secretary for Preparedness and Response (ASPR) at the Department of Health and Human Services recently announced that more than 76 percent of hospitals participating in the National Hospital Preparedness Program (HPP) met 90 percent or more of all program measures for all-hazards preparedness in 2009.[14] Without question, the leadership of the ASPR and the congressional support through appropriations for the Hospital Preparedness Program has made our Nation better prepared.

The disparity between the CDC's 2008 data on hospital preparedness and ASPR's recent announcement is striking. As Congress looks ahead to the reauthorization of PAHPA and the ASPR develops grant guidance for the HPP program for fiscal year 2012, attention should be paid to what criteria hospitals are being asked to meet for children, including children with special health care needs, through the Hospital Preparedness Program. A "Whole Community" approach to the HPP program and other grant programs may be very beneficial for children and other at-risk populations. The AAP commends the HPP program for prioritizing the "Needs of At-Risk Populations," including children, as one of four overarching requirements that must be incorporated into the development and maintenance of all program sub-capabilities but we feel that specific requirements and performance measures pertaining to pediatric preparedness in the HPP program are currently lacking and should be included in the future.

To ensure the needs of children, including children with special health care needs, are integrated into hospital planning, the AAP recommends the following:

- All hospital emergency departments should stand ready to care for ill or injured children through the adoption of the AAP's Joint Guidelines for Care of Children in the Emergency Department.[15]
- All health care professionals who may treat children during an emergency should have adequate pediatric disaster clinical and psychosocial support training and equipment.
- The creation of guidelines for addressing pediatric surge capacity and a formal regionalized pediatric system of care including written transfer protocols and memoranda of understandings (MOUs) with other hospitals.
- The needs of children should be specifically addressed in exercises and drills including the National Level Exercise.
- The inclusion of a focus on mental and behavioral health for children in disaster planning activities and the enhancement of pre-disaster preparedness and just-in-time training in pediatric disaster mental and behavioral health, including psychological first aid, and bereavement support.
- The creation of tracking systems for accompanied and unaccompanied children and establishment of plans for reunification of children with families and protocols to identify and protect displaced children.

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

[14] *http://www.hhs.gov/news/press/2011pres/05/20110505a.html*.

[15] American Academy of Pediatrics, American College of Emergency Physicians, and Emergency Nurses Association. Joint Policy Statement: Guidelines for Care in the Emergency Department. *Pediatrics*, Vol. 124, No. 4 (2009): 1233–43, *http://aappolicy.aappublications.org/cgi/reprint/pediatrics;124/4/1233.pdf*.

EMERGENCY MEDICAL SERVICES FOR CHILDREN

The Academy commends the work of the HELP Committee to reauthorize the Emergency Medical Services for Children (EMSC) program in the *Patient Protection and Affordable Care Act* and urges Congress to fully fund the EMSC program at its authorized level of $27,562,500 in fiscal year 2012. It is fitting that this hearing is being held 1 day before national EMSC Day. The 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 27 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, led by this committee, saw fit to create the National Commission on Children and 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. 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, the Commission recommended that Congress, HHS, and the Department of Homeland Security/Federal Emergency Management Agency 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.[16] The Commission offered 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 these recommendations.

The Commission, through the leadership of its Chair Mark Shriver and my fellow Commissioners, made great progress within the Federal agencies to improve our Nation's preparedness for children. The Commission also raised public awareness of the many gaps that exist for children. Despite the efforts of many on this committee, the Commission terminated last month as was required by the authorizing language that created it. The Academy opposes the termination of the Commission and urges Congress to move quickly to reconstitute it. 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, under this committee's leadership, 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 pedi-

[16] 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.

atric 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. These vital programs for children will expire on September 30, 2012 and the AAP looks forward to working with the committee to reauthorize them.

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 (FDA) with Biomedical Advanced Research and Development Authority (BARDA) and their industry partners to improve pediatric labeling for medical countermeasures. There are opportunities for collaborations with the National Institutes of Health (NIH) as well. Within the last month, 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 maximize the potential of BPCA and PREA in the medical countermeasures enterprise.

MEDICAL COUNTERMEASURES FOR AT-RISK POPULATIONS

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 meaning it can now be stockpiled for that indication in children. 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 and BARDA need 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.[17] 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.

ADDITIONAL 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.
- PAHPA should be amended to require that the Secretary, acting through BARDA, prioritize children.
- 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

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

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, child care facilities, and camps, and they must include plans for children with special healthcare 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 adolescents. 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.

CONCLUSION

The American Academy of Pediatrics thanks the committee for this opportunity to testify on the important issue of medical and public health preparedness and response. America's children represent the future of our Nation, our most precious national resource. Children must not be an afterthought in disaster planning and medical countermeasures. 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 Web site 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 released 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 percent of Americans agree that if resources are limited, children should be given a higher priority for life-saving treatments;

• 75 percent 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 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.

You represent fathers, mothers, grandparents, uncles and aunts, our children deserve better. When disaster strikes, we as a nation must be adequately prepared so that our children will be protected and can achieve their full potential. As a pediatrician and a father, I look forward to your questions and to working with you to address the preparedness needs of all children.

Senator CASEY. Thank you, Doctor.

Commissioner Cooper.

STATEMENT OF SUSAN R. COOPER, MSN, RN, COMMISSIONER, TENNESSEE DEPARTMENT OF HEALTH, NASHVILLE, TN

Ms. COOPER. Thank you. I don't have any family here either and so I will just say thanks to all the public health folks in Tennessee who work every day to protect, promote and improve the health of those that live in, work in and travel through our great State.

Mr. Chairman and distinguished committee members, it is truly a special privilege today to be before you to discuss an issue of such great importance to our Nation, public health and medical preparedness and response. The thoughts I will share with you today are my own, but they are shared with so many public health professionals at the State and local levels across this country who devote considerable time, attention and resources preparing to most effectively manage the consequences of an array of emerging and

evolving threats such as disease outbreaks and disasters in order to prevent or reduce illness, injury and death.

You know, as we sit here today we are just 4 months away from the 10th anniversary of the attacks of September 11th, which were followed 1 month later by the anthrax attacks. These two acts of terrorism were seminal events that made it evident to all Americans and all Tennesseans of the dangers that we can expect to face. By everyone's account here there is no question that tremendous progress has been made over the past 10 years. We are much better prepared now than we were on that memorable Tuesday morning.

You have heard of several reports that are out. The Centers for Disease Control and Prevention in September 2010 reported that they reviewed preparedness activities of the States and territories and in our four largest cities. And they concluded that much progress has been made to build and strengthen national public health preparedness and response capabilities. This report provided that a national snapshot that shows that all States have reporting capacity systems that can receive urgent disease reports at any time of the day or night, 7 days a week. They have capabilities to receive, distribute and dispense strategic national stockpile assets and nearly all States can rapidly respond within 30 minutes to a health alert network message, which provides information to State and local public health practitioners, clinicians and public health labs about urgent health events.

We know that every State has developed and continues to refine the pandemic planning as required by PAHPA. The Trust for America's Health Annual Ready or Not Report acknowledges again that the country has made great strides. It showed that last year all but one State has increased or maintained its lab response network.

One more illustration. Just last month, released from ASPR, was the report that talked about hospital preparedness. And we can show now what the numerous ways, including planning for all hazards, increasing search capacity and tracking the availability of beds and other resources and developing communication systems that are interoperable with partners.

We still have work to do, though. It is really great to see how well we are doing in writing, from all these respected authorities, but I am where the rubber hits the road and I am here to tell you that the progress is palpable but this system is fragile and it is the point that I will come back to in just a few moments.

Our decade-long commitment in investing and strengthening the Nation's public health enterprise has and continues to pay off. But we see, every single day, examples where these systems are being put into practice. If you just look back over the past year, there is no doubt in my mind that my colleagues in Alabama and Louisiana who have faced disasters with the Gulf oil spill, you think about the flooding in North Dakota, you think about the effects of the tsunami in Hawaii and Washington State and Oregon and then you think about my State of Tennessee who has just suffered through the super cell tornados, terrible devastation in many of our rural counties and significant flooding in Memphis. We have signs of the emergency preparedness system working well every single day.

When we look at preparedness though, we need to consider that public health preparedness is not an endpoint it is a process and it cannot remain static. We have to continuously rigorously review what we are doing and revise our State plans.

One additional point is the critical importance role that our partners play. When you look at our experience with H1N1 and our ability to work with retail pharmacies across our State, this added to our public health response capacity and I think we need to take a stronger look in that direction as well.

I want to conclude with just a few points. First of all, I think there is a need to reauthorize PAHPA with a few minor adjustments. Second, is that we face very difficult times and hard budget decisions must be made. But when it comes to our preparedness programs I will tell you in Tennessee alone our base preparedness funding has decreased by 37 percent from 2004 to 2011 with an additional cut in just an announcement that came out. Our Nation's State and local public health system is seriously frayed. We have seen budget cuts at all levels of government that have resulted in more than 44,000 State and local public health jobs, staffs, FTEs, going away. These job losses represent 14 percent of State health workforce and 20 percent of local health workforce. In the midst of a crisis is not the time to find your staff. You have to be prepared to respond.

The last point is about community resilience. One of the best ways to help a community become more resilient is to improve their overall health. No State or community is ever completely prepared to address the health and medical consequences of a major disaster, terrorist event or pandemic. We have improved since 2001 but we still have a way to go.

If you think about the reports I cited earlier that demonstrated progress, they also identified that more needs to be done. Protecting the public from threats is a matter of national security and protecting the public's health is no exception.

Thank you. We will be happy to answer any questions.

[The prepared statement of Ms. Cooper follows:]

PREPARED STATEMENT OF SUSAN R. COOPER, MSN, RN

Preparedness Approach—Our approach to preparedness follows two main principles:

(1) build capacity and capabilities that can effectively address all hazards, both for everyday emergencies, as well as for catastrophic events; and

(2) preparedness is not an end point, it's a process that must continually be developed, maintained, refined, and improved.

Capabilities—While the birth of our modern day preparedness and response efforts was appropriately centered on bioterrorism, we quickly learned that the most effective and efficient way to protect the public was to know all of your vulnerabilities, anticipate those threats, and build systems, programs, and services that are flexible and agile enough to handle anything that may come our way. Building and maintaining capabilities in such areas as: (1) incident management; (2) information sharing and public warning; (3) biosurveillance (epidemiology and laboratory services); (4) countermeasures distribution and dispensing; (5) surge management for mass health care delivery, mass fatalities, and the coordination of volunteers; and (6) community resilience are in so many ways universal in their application to any and all hazards.

Disaster Threats—Emergencies and disasters impact the health of Americans every day. Public health responds to all hazards, be it a disease outbreak, a pandemic, the health consequences of natural disasters, or a man-made incident, like a terrorist attack. And these events happen in big cities, rural and suburban com-

munities, and in every State. Not only last year at this time, but even as we speak today, in Tennessee, we have and are experiencing episodes of severe weather and flooding (2010/2011). Even as this is occurring, we must concurrently plan for the continuing threat of a New Madrid Seismic Zone earthquake and the catastrophic impact it would have on the State. Other threats that have manifested in emergency response include: white powder incidents (ongoing since 2002), sheltering of hurricane evacuees from partner States (2005/2008), TVA coal fly ash spill (2008), ice storms (2009), and the H1N1 influenza pandemic (2009). As each unique disaster is evaluated for areas of improvement, the lessons learned are carried forward to improve future response efforts.

Priorities—Engagement with partners, effective communications, and building community resilience are at the heart of every public health agency's goals in emergency preparedness and response. In Tennessee, we've focused on these priorities as follows:

(1) *Partner collaboration*—Community partners from healthcare (H1N1 retail pharmacy), business, media, State and local governmental agencies and bordering States have all been at the table to contribute to planning and response efforts. This is especially valuable as we continually strive to improve our medical countermeasures distribution and administration operations.

(2) *Information Sharing and Situational Awareness*—With the assistance of preparedness funding, the Tennessee Emergency Medical, Awareness, Response, and Resources suite of information systems has been developed and includes the Hospital Resource Tracking System, Tennessee Health Alert Network, Tennessee Volunteer Mobilizer, and the Tennessee Countermeasure Response Network. We also established Regional Medical Communication Centers to improve interoperable communications among EMS agencies, emergency management, hospitals, and public health to support a medical response. Interoperability initiatives are paramount to the success of data exchange between response partners.

(3) *Community resilience*—To ensure comprehensive community resilience and preparedness, Tennessee has adopted an all-hazard planning approach. This approach must include prevention strategies that are innovative and aggressively outreach to multiple population groups. Some of these initiatives include the annually high rates of childhood immunizations, collaborations with mental health providers for disaster response, child care center preparedness planning, vulnerable population outreach and information sharing, ongoing dialogue with professional associations, and a proactive training and exercises.

Chairman Harkin, Ranking Member Enzi, and distinguished committee members, it is my special privilege to appear before you today to discuss an issue of great importance to our Nation, public health and medical preparedness and response. The thoughts I will be sharing with you today, while my own, are also embraced by my many State and local public health colleagues across the country that devote considerable time, attention, and resources preparing to most effectively manage the consequences of an array of emerging and evolving threats, such as disease outbreaks and disasters, in order to prevent or reduce illness, injury, and death. In the few minutes I have for opening remarks, I would like to talk about how far we have come and what more we must do to maintain our state of readiness.

We sit here today just 4 months away from the 10th anniversary of the attacks of September 11, which were followed just 1 month later by the anthrax attacks. These two acts of terrorism were seminal events that made it very evident to all Americans of the dangers we can expect to face in the future and the need to rapidly escalate our bioterrorism preparedness efforts that began in earnest just 2 years earlier in 1999.

By everyone's account, there is no question that tremendous progress has been made over the last 10 years. We are so much better prepared now than we were on that memorable sunny Tuesday morning in mid-September 2001.

In the Centers for Disease Control and Prevention (CDC) September 2010 report where they reviewed the preparedness activities of the States, territories, and the four largest U.S. cities, CDC concluded that, "much progress has been made to build and strengthen national public health preparedness and response capabilities." This report provides a national snapshot that shows that all States have a reporting capacity system that can receive urgent disease reports at any time of the day, seven days a week; have capabilities to receive, distribute, and dispense Strategic National Stockpile assets; and nearly all States can rapidly respond within 30 minutes to Health Alert Network messages, which provide information to State and local public health practitioners, clinicians, and public health laboratories about urgent health events. We also know that every State has developed and continues to refine its

pandemic planning, as required by the Pandemic and All Hazards Preparedness Act (PAHPA).

The Trust for America's Health annual Ready or Not Report in December 2010 acknowledges that, "over the past decade, the country has made great strides in preparing for public health emergencies." This report shows that last year all but one State increased or maintained its Laboratory Response Network capability for chemical threats and 43 States and DC can currently send and receive important electronic health information with health care providers in their jurisdiction.

One more illustration, just last month, in April 2011, the HHS Office of the Assistant Secretary for Preparedness and Response (ASPR) reported that we have advanced the preparedness of hospitals and communities in numerous ways, including through planning for all-hazards, increasing surge capacity, tracking the availability of beds and other resources using electronic systems, and developing communication systems that are interoperable with other response partners. We can now also work with greater speed and improved response time since so often time is of the essence when it comes to information sharing, laboratory detection of biological threats, and getting vaccines and antibiotics to the public who may be in harm's way.

While it is great to see this in writing from respected authorities, for those of us on the job and in the communities doing this work, this progress is very palpable, but yet fragile, a point I will come back to in a few moments.

Our decade-long commitment of investing in and strengthening the Nation's public health enterprise has and continues to pay off in so many ways. Congress, and especially this committee, should be applauded for its work on laws like PAHPA that give States, territories, localities, and tribes the resources and tools needed to get the job done.

Our approach to preparedness follows two main principles: (1) build capacity and capabilities that can effectively address all hazards, both for everyday emergencies, as well as for catastrophic events, and (2) preparedness is not an end point, it's a process that must continually be developed, maintained, refined, and improved. Allow me to elaborate.

While the birth of our modern day preparedness and response efforts was appropriately centered on bioterrorism, we quickly learned that the most effective and efficient way to protect the public was to know all of your vulnerabilities, anticipate those threats, and build systems, programs, and services that are flexible and agile enough to handle anything that may come our way. Building and maintaining capabilities in such areas as: (1) incident management; (2) information sharing and public warning; (3) biosurveillance (epidemiology and laboratory services); (4) countermeasures distribution and dispensing; (5) surge management for mass health care delivery, mass fatalities, and the coordination of volunteers; and (6) community resilience are in so many ways universal in their application to any and all hazards.

Just thinking back over the last year, there is no doubt in my mind that my colleagues—like Don Williamson, the State health officer in Alabama, and Jimmy Guidry, the medical director and State health officer in Louisiana, in their handling of the Gulf Coast Deepwater Horizon Oil Rig Disaster; or Terry Dwelle, the State health officer in North Dakota, dealing with the flooding of the Red River; or Loretta Fuddy, the director of health in Hawaii, and Mary Selecky, the secretary of health in Washington State, as they work hand in glove with their emergency management and environmental protection counterparts on the Japanese Earthquake/Tsunami and nuclear reactor radiation release crisis—they all will tell you that the strength and success of their response can be directly attributed to years of planning and preparedness following an all hazards model. Even as we sit here today, there are multiple States still recovering from the severe weather of late April/early May that included severe super-cell tornado outbreaks and repeated rounds of severe rain that have now resulted in raging flood waters in the Mississippi River valley.

And in my State of Tennessee, we live in the New Madrid Seismic Zone, which includes the States of Tennessee, Kentucky, Missouri, Arkansas, and Illinois. The planning assumptions for a catastrophic earthquake of a magnitude seven or greater in this area could impact 50 percent of Tennessee's population. Such an earthquake would overload response capabilities and cripple local and State government. Tennessee projections include: 33,000 injuries, 3,000 fatalities and 7,000 seriously injured; 342,000 in need of shelter; 2.1 million without food, water, or ice; 107,000 structures totally destroyed; 265,000 structures with major damage; 1,000 damaged bridges, 330 collapsed; 608 schools collapsed and unusable; 54 hospitals damaged; and 50 percent of all emergency vehicles destroyed. Up to seven other States may experience similar levels of loss of life, damage and destruction.

We have been engaged in a wide array of public health emergency responses including multiple white powder incidents (ongoing since 2002), sheltering of hurri-

cane evacuees from partner States (2005/2008), TVA coal fly ash spill (2008), ice storm (2009), and the H1N1 influenza pandemic (2009). More recently, the response activities associated with the severe flooding in both May of 2010 and 2011 included shelter staffing and support, vaccinations, water sampling, community assessments, vector control, prescription assistance, the use of emergency response information systems, and the creation of public information messages and fact sheets that were posted to the State's Web site and disseminated to the public and response partners. Of note, our previous work in 2010 was leveraged during our 2011 flood response allowing us to be ready, agile, and fully engaged. As a result of planning, exercising, frequent communications, and improvements in community health, Tennesseans responded to assist their neighbors and their communities. The results of these efforts represented a visual picture of the successes of the preparedness interventions. The successful public health response and recovery was made possible by preparedness funding.

Regarding my second point about preparedness being a process, not an end point, the main thought here is that plans cannot remain static, they must be periodically and rigorously reviewed and revised based on experience, lessons learned, and evolving information; sophisticated laboratory and field equipment must be properly maintained and serviced; the public health workforce must remain sharp and skilled requiring ongoing training; and our plans and people must go through regular drills and exercises to reinforce our strengths and identify gaps and weaknesses where we need to improve on a continuous basis. This takes not only ongoing commitment, but resources.

Before I share with you my final thoughts, one additional point I want to make is the critical importance and value of partner collaboration, information sharing and situational awareness, and community resilience. In Tennessee, community partners from healthcare, business, media, State and local governmental agencies and bordering States have all been at the table to contribute to planning and response efforts. One example includes the partnership with retail pharmacies and their ability to participate in both the H1N1 vaccination campaign and antiviral medication distribution to the under-insured. These partners equate to public health force multipliers and can have a significant impact on prevention of disease. These relationships will continue to be fostered to ensure all-hazards response capabilities exist. This is especially valuable as we continually strive to improve our medical countermeasures distribution and administration operations.

With the assistance of preparedness funding, the Tennessee Emergency Medical, Awareness, Response, and Resources (TEMARR) suite of information systems has been developed. TEMARR integrates numerous systems, technologies, programs, and leadership from across the State to respond to emergencies. Collectively, the TEMARR systems provide a broad picture of situational awareness and are used to more effectively manage and monitor Tennessee Department of Health (TDH) responses to disasters using national and international data exchange standards. We now have the capacity to better understand the disaster itself, alert key response agencies, identify and contact pre-credentialed first responders, allocate resource needs in terms of people and equipment, apply all required resources to the disaster, quickly triage and track all persons impacted, and transport them to the correct healthcare facility. Using ASPR funds, the State established eight Regional Medical Communication Centers as a joint venture between hospitals and TDH. Prior to the centers, limited interoperable communications existed among EMS agencies, emergency management, hospitals, and public health across the State to support a medical response.

The above information systems could not have been developed without preparedness funding and will quickly disappear without sustained funding. By developing and delivering the TEMARR systems to the State we eliminated the need for multiple agencies to construct or procure like capabilities. The use of statewide solutions, that meet the needs of system users, provides for the sustainability of information technology infrastructure. The innovative use of interoperability standards supported by the U.S. Department of Homeland Security Office of Interoperability and Compatibility has promoted data exchange and collaboration at the Federal, State, and local level. Other critically needed efforts beyond pure requirements and standards development are to continue collaboration with the HHS Office of the National Coordinator (ONC) for Health Information Technology and ASPR, and to merge, integrate or support the transparent movement of message traffic across health information exchanges.

To ensure comprehensive community resilience and preparedness, Tennessee has adopted an all-hazard planning approach. This approach must include prevention strategies that are innovative and aggressively outreach to multiple population groups. Some of these initiatives include the annually high rates of childhood immu-

nizations, collaborations with mental health providers for disaster response, child care center preparedness planning, vulnerable population outreach and information sharing, ongoing dialogue with professional associations, and proactive training and exercises.

As we look toward the future, with your permission, I would like to respectfully share with you three recommendations for your consideration:

• First is the need to reauthorize PAHPA. The Pandemic and All Hazards Preparedness Act is a well-designed and effective law that served us well. That being said, over the 5 years of it being in existence and in working with and using PAHPA, a short list of potential revisions and additions have been identified that would make a reauthorized PAHPA even stronger and more effective. I know your staff have been in contact with ASTHO leadership and discussed our suggestions for consideration.

• Next, even during these very difficult fiscal times when hard budget decisions have to be made, adequate funding through the CDC Public Health Emergency Preparedness (PHEP) and ASPR Hospital Preparedness Program (HPP) cooperative agreements to States must be maintained. We cannot let our progress erode. Tennessee-base preparedness funding has decreased by 37 percent from 2004 to 2011.

The Nation's State and local public health system is already seriously frayed due to the adverse impact of the recession on State and local governments. Budget cuts at all levels of government are jeopardizing the significant gains that State, territorial, and local health departments made in prevention and preparedness programs during the past decade. From 2008–10, more than 44,000 jobs were lost in State and local health departments, reducing staff such as public health physicians and nurses, laboratory specialists, and epidemiologists. These job losses represent 14 percent of the State health workforce and 20 percent of the local health workforce. Recent reports from both the Association of State and Territorial Health Officials (ASTHO) and the National Association of County and City Health Officials (NACCHO), on the impact of budget cuts on the health of Americans indicate that, since 2008, State and local health agencies have been forced to reduce critical public health programs, such as immunizations, HIV/AIDS prevention and treatment activities, and all-hazards preparedness and response efforts.

• My last point is that of community resilience. One of the best ways to help a community become more resilient is to improve their overall health through prevention. A healthier community and a healthier individual will fare far better in an emergency than a community or individual that is coping with underlying preventable health conditions, such as obesity, heart disease, or diabetes. Ensuring that adequate resources and attention is paid to addressing America's major health problems and common risk factors will have a major impact on the overall preparedness and response capacity of public health, and all other, emergency responders. These can be addressed through other Public Health Service Act programs authorized by this committee, such as the Prevention and Public Health Fund, Community Transformation Grants, and the Preventive Health and Health Services Block Grant, just to name a few.

No State or community is ever completely prepared to address the health and medical consequences of a major disaster, terrorist event, or pandemic. However, since 2001, States have significantly improved and demonstrated their ability to prevent, respond to, recover from, and reduce the effects of a full range of threats and hazards. Through planning, training, education, drills, exercises, and building partnerships, State public health agencies have improved disease surveillance and laboratory testing, patient care surge capacity, decontamination capacity, and availability and deployment of pharmaceutical and other medical supplies. If you recall the reports I cited earlier that demonstrated progress, they also identify more that needs to be done, which requires our collective attention. ***Protecting the public from threats is a matter of national security, and protecting the public's health is no exception.***

Thank you for this opportunity and I would gladly address any of your questions.

Senator CASEY. Commissioner, thank you. And thanks for reminding us of some of the challenges people are experiencing right now, horrific tragedies.

Dr. Anderson, I wanted to start with you with regard to children. And I know you spoke to this in your statement. I wanted to turn to your prepared statement and ask you to amplify or maybe reiterate some of what you said. You say, and I'm looking at page 5 and page 6, you say in that third paragraph under the general

heading, "Hospital Preparedness for Children": "In the face of a disaster all hospitals will need to increase their capacity." And then you go on to talk about pre-hospital setting, emergency, surgical.

Then on page 7 you say, in the second full paragraph,

> "As Congress looks ahead to the reauthorization of PAHPA and the ASPR develops grant guidance for the HPP program for this fiscal year coming up, attention should be paid to what criteria hospitals are being asked to meet for children, including children with special healthcare needs."

And it goes on from there. And you referred to some recommendations that the Academy has. Can you go through those and highlight—I am not saying you have to go through all of them, it is in your testimony, but just highlight why you are making those recommendations.

Dr. ANDERSON. Excellent question, Senator. What we look to at the American Academy of Pediatrics and the world of children's hospitals is really helping non-children's hospitals prepare for the needs of kids. And it really starts with day-in and day-out preparedness. We are talking about big disasters, mass casualty events—hospitals that aren't used to seeing a lot of kids have to be prepared every day, because parents are going to see emergency room and think, OK, I now have my child at a place that is going to give wonderful care. We need to assure that as best we can.

The AAP has put out several statements. Here is the stuff you need, and it starts with equipment because the equipment for children is very, very different. Here is the training you need, there are wonderful courses if you don't take care of kids a lot, to sort of dust off the memory. And by the way, one of the most important recommendations are to have a coordinator at each and every hospital in this country, each and every ER that is that pediatric person, that is always that sort of annoying, clanging person. Have we thought about the kids? Do we have the right stuff? Hey, beautiful new decontamination chamber. How are you going to do kids? How are you going to decontaminate kids in wheelchairs? So we have to start from a day-in and day-out preparedness and then figure out when the big one hits how are we going to surge up.

Several of my co-panelists and Dr. Lurie mentioned we learned a lot of lessons from H1N1. We were reaching out to community hospitals in northeast Ohio saying,

> "If this gets really big and our children's hospitals are closed or only taking the sickest of the sick, are you prepared, community hospital, to keep kids overnight, to admit children, when you haven't done that in 20 years?"

We also have some recommendations, if we hit that sort of surge capacity, how do you reach out and find physicians to come help you staff it. How do you find the right equipment? How do you work with your local children's hospital in a regionalized approach to sort of figure out what children need the children's hospital and what kids could stay locally.

So, to make a long story as short as I can, it starts with day-in and day-out preparedness. Are you ready for what we call "the disaster of one," that really sick kid you are not used to taking care

of and then how do you ramp up if you've got more and more of those kids.

Senator CASEY. How prepared do you think we are just as it relates to this particular issue? Hospitals preparing for treating children and caring for children in the aftermath of a disaster?

Dr. ANDERSON. As a practicing ICU or PICU doctor, I think we are better prepared than we have been. There were some very disconcerting studies in the early 2000's that showed only 6 percent, repeat 6 percent, of ERs had the right equipment. I think that number is a lot better now. I think we are seeing people really take these recommendations seriously.

I think unfortunately we are learning lessons from Katrina, from tornados, etc. But I still think there is a lot of work to be done. It is important to celebrate our successes but it is much more important to advocate for getting better prepared.

Senator CASEY. And based upon your experience and based upon your interfacing with folks who are the real world of running hospitals and delivering healthcare, often when someone in that real world hears government say the following words, "thou shalt" and then gives the directive that folks running a hospital or running a business say, "that is easy for you to say, let me tell you the impediments to compliance." What do you hear in terms of hospitals saying, "we would love to do all this but we can't?" Is it mostly access to capital?

Or is it something more significant?

Dr. ANDERSON. It is a great question, because we have heard some push back. It is another unfunded mandate. I have to come up with this list of stuff and this list of—we are not asking for a $2 million suite off of your ER that has all the latest technology. The basics are the basics, and that is training, very readily available courses, the basics of equipment. The basics, if you are going to have a drill, which disaster drills are part of Joint Commission accreditation, why not include kids? The chances are 22 percent of our population are children, why not just include them in the drill.

We do occasionally hear, as advocates for kids, a little push back, this is another unfunded mandate, but we are not asking for big stuff here. This is a coordinator, equipment, training and drills and I think that is pretty straightforward, quite frankly.

Senator CASEY. I will come back to some of our others, but Senator Burr.

Senator BURR. Thank you, Mr. Chairman. I had high hopes that when the average age on the dais today got below 60 the air conditioning would come back on and it would get cooler in here.

[Laughter.]

I think we are making progress, but it is a slow process.

Let me also just make a comment and I will be as diplomatic as I can. I always find it amazing that we could be at a point in time talking about the reauthorization of PAHPA, the importance of it and that the key individuals that work within the framework of it, who came here to testify didn't find it interesting enough to stay and listen to the second panel where we talked about how it is working within BIO, within hospitals, within the community health network and from somebody who was one of the most instrumental architects of the original bill.

I say that to the whole cadre of HHS folks and I hope whoever was assigned the responsibility to stay in the room and take notes, that you take pretty darn good ones, because I find it appalling that those officials who ask to serve in this capacity and carry this out don't find any significance in staying and hearing what this panel has to say, but more importantly, what the questions are of the members for the second panel.

With that, Commissioner Cooper, let me just ask you. What do you see as the key challenges for the public health departments regarding bio-surveillance and the capacity to detect novel and unknown viruses?

Ms. COOPER. It is a great question. There are several challenges. One is just the technology to do so. It would be nice to be able to pull up a screen on a computer, any given day, and be able to track any outbreak in any hospital or any physician's office in our State. We can't do that right now.

The second thing is workforce capacity is a struggle for us. If you look at the challenges we face, I talked a little bit about the number of folks that have gotten out of the public health field, if you just look at my health department, our State health department, by December 2012, 42 percent of the State public health workforce is eligible for retirement. And when you look at those jobs that have been eliminated you are talking about public health physicians, nurses, epidemiologists, laboratorians, that is a workforce that needs to be replenished. And we have significant challenges in drawing people into the field of public health.

Also, we have had great support from our Federal partners along the way, but as Admiral Lurie said, there is much more to be done. We need some real-time detection devices that can give an isolate right where you find it, whether it is in a community, in a hospital instead of having to vet it through multiple laboratories.

Senator BURR. I am sure I am not telling you anything that you don't know, but if today the CDC were to provide access—if they contracted with one of a couple of companies that monitor prescriptions that were written yesterday, and they allowed local health departments access to that, you could look by zip code all the way down to the four digit additional, meaning you could detect, almost in a city block, individuals who had seen different doctors or gone to different hospitals and were treated for similar things, cluing you in to a problem. We don't, today, make that available.

It is not a technological breakthrough, this is something that is at our fingertips today where right and left hands don't understand the capabilities that we can provide in real-time, in a 24-hour period we could know, regardless of where in Tennessee, there had been exposure to anthrax because of what was determined from a diagnostic standpoint, what was prescribed from a pharmaceutical standpoint and you could start looking at, did this happen at the workplace or did it happen at the home based upon what those area codes or zip codes in fact told us.

I am going to run out of time. I want to go to Dr. Bob real quick and just say, are we prepared? And if not, what do we need to do?

Dr. KADLEC. Sir, I will go back to an occasion on June 30, 2008 when I told the last president, after 8 years and $50 billion, that we weren't prepared for a modest-size anthrax attack. And basi-

cally said, the difficulty we have, is that when you look end to end we have some of the pieces in place, but not all the pieces in place. So if you look at that one particular problem alone, you raise the issue of detection, we have some capabilities in that space, but still we don't have point-of-care diagnostics for clinicians to be able to rapidly make that diagnosis in any major metropolitan emergency room. Along the chain of that we have 60 million 60-day courses of antibiotics and we have no guarantee that we can get them to the people who need them when they need them. That the distribution mechanisms we have in place may be too slow to deal with the kind of event that we would anticipate in that way. In some ways we lack a little bit of imagination of how to address that problem. In many ways, some of the challenges there are logistics.

The third one is, we just have to basically make a commitment to do this. We have a stockpile of anthrax vaccine that quite frankly sits in a nice cool place and at some point in time will expire and will be thrown away. And yet we could basically use that material today and have volunteers, first responders, members of the National Guard, members of different first responder communities basically use that product.

And the last one is, then why don't we have antibiotics if people want to store them in their home and there is a way to do this responsibly so to prevent abuse, potentially avoid antibiotic resistance in populations to basically develop these med kits? Again, an FDA issue that could be readily done.

So there are a variety of things that could be done along this whole chain, but quite frankly we haven't just made a commitment to get it done. And so in some ways we study the problem to death, but we just don't act on the things that we know that we could do to effectively change that equation today.

Senator BURR. I thank you for that and hope that all of you will make yourselves available for additional questions from me and from all the members. But more importantly, if there are details that you have, as we go through the reauthorization, that you will share those ideas with us no matter how around the edges they might be. It is important that we try to incorporate it.

I had a conversation several weeks ago with somebody that had inquired about the BARDA process and a particular countermeasure for a known threat. And as I understand it, the response they got was, "well that is not an imminent threat, therefore that is sort of on the back burner." When this was created we didn't ask DHS to list whether threats were imminent, we just asked them to list if they were real.

I think it was our belief, that if that could happen, then we need to be prepared. None of us have the foresight to know who or when somebody might use it or whether Mother Nature herself will present us a curve ball. That is one of the reasons that we set it up the way we did where another agency establishes that threat and, from within HHS, their mission is to bring a countermeasure or a vaccine to the stockpile or capabilities of having it to offset it. We never envisioned that there were threats that were not imminent. They are all imminent if in fact they fall into the category that we have resolved.

So I thank all of you and I look forward to working with my colleagues on this panel. I believe that reauthorization is absolutely essential. I think we can do it better than we did it before. It will not be easy and we will have some push back from people within the government simply because we are going to have to challenge the culture that is out there right now.

I thank the Chair.

Senator CASEY. Thank you, Senator Burr and thanks for your work on these issues.

I want to move to Senator Whitehouse.

Senator WHITEHOUSE. Thank you, Mr. Chairman. It has been a very good hearing so I haven't been patient at all, I have been very interested and I appreciate that the witnesses have come here and shared their expertise with us.

Dr. Kadlec, could you evaluate for me the—I don't—they are not exactly different strategies, but they are sort of more like opposite ends of the spectrum on strategy. One is prepare in advance, build your medical countermeasures in advance, stockpile them in vast numbers and develop a rapid development and deployment strategy so that when something, to use Senator Burr's description, a curve ball comes down the road that you haven't stockpiled for, you are in a place where you can move rapidly to protect the public health in that circumstance.

And if it is appropriate, if you could distinguish between the two strategies or the two ends of the spectrum strategy in the light of known threats, like flu and anthrax versus the unknowns that might be coming at us or the modified biologics that might be coming at us.

Dr. KADLEC. The best way to look at it, is as book ends. So if you had to look at a book end of the policy and capabilities that were developed for smallpox, for example, it was a clear policy decision to basically take smallpox off the table, for which we basically procured or had in our possession 300 million doses of the smallpox vaccine. And we are looking now to basically expand that stockpile by ensuring that particularly for people with compromised immune systems that you could have a product that wouldn't be harmful to them if you had to prospectively immunize them in advance of a threat, credible threat, or if there were an outbreak that you could reasonably protect them to ensure that the vaccine itself wouldn't harm them. So that is one end of it.

The other end of it is, this idea of stockpiling 300 million. In between, is their 12 other potential agents of concern that we have. If you look at the list, for me anthrax on down through rickettsia or typhus. The point is we haven't made the same determination what we would need there. So in some cases we have looked at anthrax and basically said, "well, we need 80 million doses," 75 million doses in the stockpile, but we haven't made the affirmative decision, well what would happen if it would be used against us, do we want to immunize everyone in the United States? What is our ability to do that? So there's the flexibility within the known.

Then there is the issue of the unknown, as you say. And what I am concerned about is basically the idea that if you basically take this as a one off of pandemic influenza, which in some ways I think is the strategic choice to date, that you would somehow use a vari-

ety of different platforms to make a pandemic influenza vaccine, well that may be appropriate. You need 600 million, theoretically, for the whole country. The question is, what happens if you are attacked by multiple biological agents.

And maybe only one platform is capable of doing that.

So one of the things that I think is necessary in evaluating this is a little bit of, if you will red team it, also evaluating the platforms that you have to maximize that your depth, your capacities that are available go beyond what just exists maybe in one or two facilities, but really would be able to mobilize what is in the private sector.

Also looking for the technology innovations, and I think there has been some work in that space, to see what may be out there. Again, not FDA approved yet, but something that may be a decade away to do so, but yet could be leveraged in this case as well.

So the answer is, there is no clear strategy. There are some strategic options that are out there. We have made some partial decisions but we haven't, what I would say, made a holistic, comprehensive one, which I think is kind of the worse place of all to be.

Senator WHITEHOUSE. With respect to my questions earlier about the state of our capability for developing rapid response in the event of an attack using unknown biological agent and the BARDA process that is our sort of first venture into developing that capability, how are we doing?

Dr. KADLEC. I think one of the things, and the name was supposed to give it away, a kind of BARDA sounded like DARPA. Again, it was Senator Burr's concept. But, really it was to provoke the notion that somehow we would give all the authorities, as DARPA has, other transactional authorities, to really give it the maximum flexibility to basically engage to look for innovative technologies and rapidly bring and accelerate development of these products as we need to, whether it be platform technologies or specific countermeasures.

Senator WHITEHOUSE. Is it working?

Dr. KADLEC. It hasn't quite—it hasn't worked that way. I think part of it has been a resource issue. I alluded to earlier, if you only give them 40 percent of the budget that they theoretically need or they have identified they needed, you have to wonder whether they can effectively do their mission.

But I think part of it is, again pushing the envelope as to what you are willing to do. And it is a very difficult thing to suggest, particularly given all the regulatory issues around it. And now I think one of the vital pieces that have been laid on the table by a number of people is this idea of improving regulatory support, bringing the FDA into the tent and having them more as an active participant in this thing can alleviate some of the challenges.

But quite frankly, I think it does take a bigger push, and again, a bit of imagination to say, "how can we do this better, faster." Originally we even said a bit cheaper if you could, to basically work in a program that was competitive in nature, that you would highlight a number of potential candidates, bring them down the pipeline, making critical decisions, as a pharmaceutical company would do, to basically identify which, at the end, is the investment that

you have to put your money on to basically ensure you have an FDA licensed product.

But I don't think it is where we need to be. Part of it is I think some of it is authority, part of it is the regulatory involvement and part of it is a resource issue.

Senator WHITEHOUSE. Thank you, Chairman. I appreciate the hearing and I look forward to working with you and Senator Burr on the reauthorization.

Senator CASEY. Thanks, Senator Whitehouse.

I know we are running low, we are pretty much at the end of our time. But I wanted to maybe ask two more questions and then we will say something about leaving the record open.

Ms. Arthur, I wanted to ask you about this issue that I know you have had a concern about. The particular challenge you face with regard to developing countermeasures for at-risk populations. We have heard a good bit today about children. Can you highlight those, from the perspective of whether they are just bureaucratic or other challenges or whether they are scientific hurdles. But you are looking at it from the private sector, from the nongovernmental sector, we will call it. Can you outline some of those challenges?

Ms. ARTHUR. Absolutely. Thank you for the question.

Actually I think that the—looking at special populations adds an extra dimension of complexity. So, as we were talking about before, a lot of the products, the countermeasures need to be researched, generally using the animal model guidance and the animal model rule, because you really can't do the key testing on efficacy in humans, you have to do it in these animals. The problem is, it is not always clear which animal is the right model to use. And add to that, not necessarily surety about which animal is the right animal to use to exemplify children.

So you add a layer of scientific complexity that needs to be solved in concert with the FDA. So a lot of the companies that are trying to not just license a countermeasure for use in healthy adults, but in all of the population, need to really be able to work in concert with the FDA on how to answer the key question. If the goal is to have a product that you can use after exposure and you want to be able to use across all populations, you need to really think through which models to use and what questions you are going to answer and what scientific rigor you are going to have to apply to that. That is really one of the key problems that we would like to have solved through the FDA review.

So, the reason why we are supporting the FDA process so strongly is precisely because they really want to put resources toward those key scientific questions that all countermeasure sponsors have.

Senator CASEY. Thank you very much.

I just have one more question. Commissioner Cooper, are there, and I am assuming there are, particular challenges in rural communities? Can you outline some of those, because often when we turn on the news and we see some of these horrific images, they invariably seem to be in smaller communities and often communities that are, at least by demographics, rural. Any insights or—it may be better to say any concerns that you have or any sugges-

tions you have as to how we can better prepare for those communities?

Ms. COOPER. Certainly Tennessee is a very rural State. We are about 42,000 square miles, touching about eight other States. And we have worked in a very strategic fashion to put counties into regions across the State, because similar rural counties had similar issues, whether it is lack of resources. You think about community hospitals, or you may have a single healthcare provider, if you have one in that community. You think about the emergency medical system, it is more sophisticated in urban areas than it is in a rural community. All of these are key players and key partners in the public health response.

Even when I talked about earlier, the pharmacies, when you think back to H1N1 we had a very aggressive program with Tamiflu, making it available to all persons across the State. But we had two counties in our State that don't have a pharmacy in it, so you had to come up with a redundant system to address those needs.

I think our regional strategy has worked very well. I think there are some lessons to be learned from that. But again, it is really about the capacity of not just the public health but the medical system in place to respond to these emerging disasters.

Senator CASEY. I know we are wrapping up. I just wanted to make sure that I put on the record that we will keep the record open for 10 days for members of the committee to submit statements for the record and for testimony.

And unless there is something any of you would want to add, we will conclude. But certainly the record will be open, not only for more questions that will be presented, due to answer in writing, but of course if you feel the need to supplement your testimony or provide other information that is certainly an option available to you.

Thanks for your help and thanks for enlightening us as we begin this process of reauthorization.

We are adjourned. Thank you.

[Additional material follows.]

ADDITIONAL MATERIAL

PREPARED STATEMENT OF SENATOR MIKULSKI

Chairman Harkin, thank you for organizing today's hearing on public health, medical, and bioterrorism preparedness. Also, I appreciate Senator Enzi and Senator Burr's long-standing efforts to improve our Nation's ability to respond to public health emergencies.

Terrorism is a danger to us on many fronts. We must prepare ourselves to respond to all hazards that impact our Nation's security. Every day, Americans are faced with natural disasters in our communities—floods, hurricanes, earthquakes, and food safety outbreaks. These incidences challenge our Federal ability to assist those in harm's way and the States' capabilities to respond to local needs.

Today as we scrutinize every dollar spent, this hearing will be important in showing how our past investments have made us more prepared for the unexpected, and how future investments and resources can be utilized more efficiently.

I also hope this hearing will demonstrate how Congress can come together in a bipartisan fashion, and bridge the all-too-common partisan divisions, when it comes to protecting our citizens.

As I have said before, the key question we must address today is readiness. Are we ready to respond to all hazards? We are better prepared than we ever have been before, yet the distressing answer to the question is No.

If a major catastrophic health event occurs in the United States—such as the earthquake and tsunami in Japan, or another Hurricane Katrina, or a severe pandemic, or bioterrorism attack—our infrastructure for the response will be stretched to the breaking point. And our Nation's most vulnerable populations—children, the elderly, and Americans with disabilities—will be the ones most at risk.

Fortunately we do have efforts underway that must continue. We have newly developed countermeasures that we did not have a decade ago. The Strategic National Stockpile contains medicines to protect Americans against smallpox, anthrax, and nerve agents.

Maryland has been a leader in our national and public health security. Fort Detrick in Maryland is on the frontlines of bioweapons research to develop our best defense against these weapons. I am proud of these Federal employees. Also, Maryland's biopharmaceutical manufacturers are working closely with Dr. Lurie and the Biomedical Advanced Research and Development Authority to develop novel countermeasures for our Nation's Strategic National Stockpile.

Marylanders at Emergent Biosolutions, PharmAthene, Human Genome Sciences, Cangene, and Medimmune are developing the next generation anthrax vaccine; improving our manufacturing platforms for influenza vaccines; creating better medications to treat people exposed to nerve agents; and working to conquer infectious diseases like tuberculosis and typhoid.

I am also proud of the work we have done in Congress to assist our biotech companies, our pharmaceutical companies, and our

local, State, and Federal agencies in preparing for some of the most common threats we face.

I remember last time I worked with Senator Burr on this legislation, and I look forward to improving upon the law in a bipartisan fashion in order to deliver the most protection for our country. I look forward to hearing from all of our witnesses today about the accomplishments and challenges we face with developing medical countermeasures and sustaining our public health infrastructure so that health agencies are able to respond to all hazards. We must ensure our Nation is secure when national disasters strike and terrorists try to attack us.

These are national problems that require national solutions and national leadership from the Federal Government. We must not wait for the disaster to occur. We must have a plan of defense and have a plan of offense.

I look forward to working with my colleagues to make sure we are ready to combat tomorrow's threats!

PREPARED STATEMENT OF SENATOR HAGAN

I would like to thank Chairman Harkin for holding this hearing today. I would also like to thank the Assistant Secretary for Preparedness and Response at HHS, Dr. Lurie, and all the witnesses for coming before the committee to discuss strengthening our Nation's medical and public health preparedness and response.

Our experiences during the September 11 terrorist attacks, the 2001 anthrax attacks, Hurricane Katrina, the 2009 H1N1 influenza pandemic, and the 2010 Deepwater Horizon oil disaster, clearly show how important it is for our Nation to continually improve our public health emergency preparedness and response activities.

Earlier this month, the long hunt ended for the terrorist leader, Osama bin Laden. I am extremely proud of the U.S. Special Forces and our intelligence community that finally brought down this mass murderer. I am pleased that justice was served and I hope this event can bring some peace to our 9/11 families and the country.

However, the terrorist threat to our Nation remains. The Commission on the Prevention of Weapons of Mass Destruction Proliferation and Terrorism has repeatedly warned of the near-term threat of a biological attack and the need to enhance our capabilities to rapidly respond to such threats and potential attacks. Just a few months ago, the Directors of the Central Intelligence Agency and the National Counterterrorism Center testified to Congress that Al Qaeda is still intent on developing chemical, biological, radiological, and nuclear attack capabilities. Our Nation must be prepared for any such attacks and we must consider our public health preparedness as a national security objective.

The Pandemic and All-Hazards Preparedness Act of 2006 (PAHPA) reauthorization is timely and urgent. In addition to making preparedness a national security priority, we need to focus on: interagency coordination; addressing real-time detection and biosurveillance capabilities; ensuring that hospitals and clinicians are equipped in the event of a pandemic; ensuring that special populations, like children and the elderly, have access to appropriate

countermeasures; and finally, establishing a prospective multi-year plan for preparedness including research, development, and stockpiling. I look forward to hearing from our witnesses today as we discuss the reauthorization of this important legislation.

PREPARED STATEMENT OF GOVERNOR LOWELL P. WEICKER, PRESIDENT OF THE BOARD OF DIRECTORS, TRUST FOR AMERICA'S HEALTH

My name is Lowell P. Weicker, and I am president of the board of directors 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 submit testimony to the committee on reauthorization of a groundbreaking piece of legislation, the Pandemic and All-Hazards Preparedness Act (PAHPA).

PAHPA represented a major step in acknowledging and developing the role of America's public health system in preparing for and responding to major emergencies, whether natural or man-made. The reauthorization of PAHPA is an opportunity to build more prepared and resilient communities, able to weather a storm, contain its impact, and return to normal as quickly as possible. I applaud the committee for demonstrating its commitment to better preparing our Nation for disasters.

I have two major points to make in my testimony today:

First, our Nation faces continuing natural and man-made threats that require an ongoing 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 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.

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]

In TFAH's 2010 report, *Ready or Not?*, 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 (PHEP) cooperative agreement and Hospital Preparedness Program (HPP), 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 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 found that 33 States and DC cut public health funding from fiscal years 2008–9 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

[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*.

inflation). We expect to see major cuts to Federal public health preparedness programs in both fiscal year 2011 and 2012. These inconsistencies represent the greatest threats to our ability to respond to a public health catastrophe on the level of the Japan earthquake and tsunami.

We believe a modernized, prepared public health system must address several remaining gaps:

- A Workforce Gap: 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.
- A Surge Capacity Gap: Surge capacity, the ability of the medical system to care for a massive influx of patients, requires ongoing planning, funding, and coordination across healthcare, public health, first responder, and private sectors.
- A Surveillance Gap: The Nation still lacks an integrated, national approach to biosurveillance, which could significantly improve response capabilities for emergencies.
- Gaps in Medical Countermeasure Development: The research and development of vaccines, antivirals, diagnostics, and other countermeasures is years ahead of where we were during the 2001 anthrax outbreak; yet our ability to spur innovation in these limited-use technologies has been hampered by a lack of stable funding and some breakdowns in program administration.

PAHPA reauthorization represents an opportunity to fill some of these critical gaps. As you begin consideration of amending the law, TFAH would like to offer the following recommendations:

1. **Strengthen Public Health Preparedness Infrastructure:** The economic recession has led to cuts in public health staffing and eroded the basic capabilities of State and local health departments. Strengthening the public health preparedness workforce and infrastructure is critical to ensuring the health protection of our Nation. It also requires adequate funding and human resources to recruit and train personnel, stockpile life saving countermeasures, develop and exercise plans, 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.

The PHEP cooperative agreements and HPP are two key grant programs that support the development and sustainability of State and local public health preparedness infrastructure. Since their inception, these programs have increased the capacity of State and local health departments and health systems to prepare for and respond to a disaster.[2] [3] Our 2010 report found that these funding streams have contributed to major progress in workforce training, epidemiology and laboratory capacity, surveillance, and planning and exercising at the State and local level.

During the 2009–10 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 federally 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." To address these concerns, we recommend language that would:

- Establish multi-year grant cycles with greater flexibility in States' retention and use of carry forward and unexpended funds;
- Create a mechanism to fast track the awarding and programming of emergency supplemental funds into existing grant mechanisms without additional match or maintenance of funding requirements; and
- Grant authority to the Secretary to allow States to also use personnel that are part of other Federal programs in response to a public health emergency (e.g. an "all hands on deck" scenario).

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[2] Centers for Disease Control and Prevention, *Public Health Preparedness: Strengthening the Nation's Emergency Response State by State, Sept 2010. http://emergency.cdc.gov/publications/2010phprep/index.asp*.

[3] Center for Biosecurity, *Hospitals Rising to the Challenge: HPP Evaluation Report*, March 2009. *http://www.upmc-biosecurity.org/website/resources/publications/2009/2009-04-16-hpp report.html*.

• We understand that HHS and the Department of Homeland Security (DHS) have begun working to align grant programs that aim to build our Nation's emergency preparedness capacity, including PHEP, 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. I urge you to use PAHPA to ensure oversight and proper implementation of this alignment process.

2. **Modernize Biosurveillance:** Situational awareness—knowing what the threats are, and knowing what our capacity to respond is, at any given moment—is critical to responding to any emergency and we need to make sure we are building capacity using 21st century technology and approaches. We have built our disease surveillance system one disease at a time and one crisis at a time, rather than as a unified, interoperable unit. Rather than continuing these silos, we have the opportunity to think across diseases (infectious and chronic) and emergency situations, because health information technology is advancing at a rapid pace and the health care system is becoming electronic.

It is time for public health to do the same. Imagine a system where a provider inputs data into an electronic health record, the health department is rapidly informed of a cluster of unusual symptoms (indicating an outbreak), and the health department then communicates with the provider and responds quickly with the appropriate intervention. Right now, the ability of health departments to receive and analyze electronic data varies widely from jurisdiction to jurisdiction. Because the Federal Government is in the process of catalyzing adoption of electronic health records, now is the time to think about how to incorporate public health into the system. PAHPA can help fill this gap:

• PAHPA should call for a new national strategy, led by HHS and CDC, that would examine means to achieve interoperability and transparency among various surveillance systems.[4] The United States lacks an integrated, national approach to biosurveillance, and there are major variations in how quickly States collect and report data which hamper bioterrorism and disease outbreak response capabilities. 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.[5] [6] And according to a December 2010 GAO report, HHS had not provided a strategic plan for electronic situational awareness, as required by PAHPA.[7]

• 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 for Health Information Technology (ONC). The ONC should work closely with a designated person at CDC and with State/local/tribal/territorial partners, with PAHPA mandating this synchronization and collaboration. 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.

3. **Improve Vaccine and Pharmaceutical Research, Development, and Manufacturing:** The United States is falling behind in its research and development of medical countermeasures to fight public health threats. As the Nation revamps its approach to research and development of vaccines, medicines, diagnostics

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[4] 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*.

[5] Nuzzo, 2009.

[6] 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*.

[7] U.S. Government Accountability Office, *Public Health Information Technology: Additional Strategic Planning Needed to Guide HHS's Efforts to Establish Electronic Situational Awareness Capabilities. http://www.gao.gov/products/GAO–11–99*.

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. PAHPA can advance the Nation's MCM enterprise through the following activities:

• Congress should consider authorizing President's requests for MCM advancement: building an MCM Strategic Investor to leverage private capital for promising technologies; using unspent H1N1 money to establish Centers for Innovation in Advanced Development and Manufacturing; and developing end-to-end leadership to see products through from initial research through dispensing. However, bill language should request additional detail from HHS on how these programs would be implemented, including multiyear professional judgment budgets for implementation of the PHEMCE strategy.

• Report language in PAHPA should urge: (1) increased coordination between FDA, BARDA, NIH, and CDC from initial investment through dispensing; (2) improved transparency of the development process, including regulatory pathways by FDA and contracting process with BARDA and Bioshield; and (3) MCM strategy should be end-to-end—not just focused on initial investments, but on advance development, procurement, distribution, and surveillance.

• Improving SNS Management: There should be a plan for stocking the Strategic National Stockpile (SNS) and for ongoing replacement of expiring product, especially vaccines,[8] 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. The legislation should also call for increased coordination between CDC and BARDA on SNS procurement and management.

• Authorize extension of the Shelf-Life Extension Program (SLEP) to State stockpiles of medical materiel. Currently, only federally held stockpiles are eligible for the SLEP, which can be a cost-effective way to maintain State and local supplies.

4. **Enhance Surge Capacity:** In the event of a major disease outbreak or attack, the public health and health care systems would be severely overstretched. Policymakers must address the ability of the health care system to quickly expand beyond normal services during a major emergency. Investments in research and development, stockpiling, and practice in drills and tabletop exercises will aid in the timely distribution of antivirals and other equipment during an outbreak. PAHPA should facilitate health care preparedness by:

• Encouraging enhancements in the Hospital Preparedness Program (HPP). The HPP, administered by the Assistant Secretary for Preparedness and Response (ASPR), aims to prepare the Nation's health system for the medical and logistical impacts of a disaster. Rather than continuing to fund individual hospitals for preparing for a crisis, HPP has played a role in spurring creation of regional healthcare coalitions, alliances between hospitals, public health, and emergency management.[9] These coalitions allow for a shared burden and reduce surge to any single facility. However, in many regions, this is still a nascent process.[10] Building and developing these coalitions should be an explicit goal of HPP, including expanding coalitions to every city and linking them into a national system.

• Clarifying crisis standards of care. The Federal Government should provide a national framework to guide States and local entities in developing crisis standards for use during a mass casualty event. Leaving this process up to the States has not led to enough progress in developing a better understanding of the kind of care that would be available in a disaster.

• Clarifying 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. HHS has acknowledged that a patchwork of Federal liability laws is confusing and frustrating to pro-

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[8] 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.*

[9] Toner, Eric, et al., Center for Biosecurity of UPMC. *Hospitals Rising to the Challenge: The First Five Years of the U.S. Hospital Preparedness Program and Priorities Going Forward,* March, 2009. *http://www.upmc-biosecurity.org/website/resources/publications/2009/pdf/2009-04-16-hppreport.pdf.*

[10] Toner, Eric. Expert perspective in *Ready or Not? 2009. http://healthyamericans.org/assets/files/TFAH2010ReadyorNot%20FINAL.pdf.*

viders.[11] There should also be Federal Tort Claims Act protection for Medical Reserve Corps volunteers year-round, as these personnel participate in public health drills and training during times of non-disaster.

Thank you for this opportunity to weigh in as the committee considers reauthorization of PAHPA. I look forward to your questions.

[Whereupon, at 4:26 a.m., the hearing was adjourned.]

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[11] 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*.