WRITTEN TESTIMONY OF DR. ROBERT P. KADLEC
U.S. SENATE HEALTH, EDUCATION, LABOR & PENSIONS COMMITTEE
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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 five years since it 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%, 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, 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. **<u>Strengthen the role and authorities of the Assistant Secretary of Preparedness and Response (ASPR) in the Department of Health and Human Services (HHS).</u> 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 threaten 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. **<u>Maintaining a capable public health and medical infrastructure to respond to catastrophic events.</u> 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. **<u>Promoting a robust medical countermeasure (MCM) development, manufacturing, distribution and dispensing enterprise.</u> 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 U.S. 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 US 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 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.