U.S. Senate Homeland Security and Governmental Affairs Committee
Hearing on the WMD Prevention and Preparedness Act of 2009
September 22, 2009

Statement from Chairman Bob Graham and Vice Chairman Jim Talent, Commission on the Prevention of Weapons of Mass Destruction Proliferation and Terrorism

Mr. Chairman, Senator Collins, and distinguished Members of the Committee:

Thank you for the opportunity for us to speak to you today on behalf of the Commission on the Prevention of Weapons of Mass Destruction Proliferation and Terrorism. Congress created our Commission early in 2008, based on the recommendation of the 9/11 Commission, assigning us the task of assessing the risk of WMD terrorism and recommending steps that could be taken to prevent a successful attack on the United States. Our Commission interviewed hundreds of experts and reviewed thousands of pages of information. We want to thank those Commissioners -- Graham Allison, Robin Cleveland, Stephen Rademaker, Timothy Roemer, Wendy Sherman, Henry Sokolski, and Rich Verma -- who worked tirelessly to produce our Report, *World at Risk.*

The Commission's Report assessed both nuclear and biological threats, and provided 13 recommendations and 49 action items. Most of our comments today, however, will focus on the biological threat we identified, a very real and growing threat to America and the world, and also the focus of the legislation you recently introduced: *The Weapons of Mass Destruction Prevention and Preparedness Act of 2009*.

The Commissioners unanimously concluded that unless we act urgently and decisively, it was more likely than not that terrorists would attack a major city somewhere in the world with a weapon of mass destruction by 2013. And we determined that terrorists are more likely to obtain and use a biological weapon than a nuclear weapon. This conclusion was publicly affirmed by then Director of National Intelligence (DNI) Mike McConnell.

Three primary reasons stand out in support of our conclusion. First, developing and dispersing a biological weapon would not be expensive -- and it will only get cheaper and easier. Second, the lethality of an effectively dispersed biological weapon could rival or exceed that of an improvised nuclear device. Third, the constraints that a bioterrorist would confront in making an effective bioweapon are significantly fewer than those facing nuclear terrorists. Virtually all pathogens suitable for use in a biological weapon are readily available in nature. The equipment required to produce a large quantity from a small seed stock, and then "weaponize" the material – that is, to make it into a form that could be effectively dispersed -- are of a dual-use nature and are readily available on the internet. The most effective delivery methods are well known in the pharmaceutical, agricultural, and insect-control industries.

This is not speculation. Al Qaeda was well down the road to producing such weapons prior to 9/11. Due to the ease in creating a clandestine production capability, our intelligence community had no knowledge of two such facilities in Afghanistan prior to their capture by U.S. troops. Facilities with more sophisticated equipment than those found could be in operation today without our knowledge.

First, Mr. Chairman, we want to thank you and Senator Collins for the extraordinary leadership you have shown in response to our Report. The biggest internal enemy we face in dealing with this threat is the natural inertia of government. The only way to overcome this inertia is for our top political leaders to make guarding against this threat a personal priority and to persist over time in demanding action. Our Report has received support everywhere, but only this Committee under your leadership has stepped forward to turn our Commission's recommendations into action. As nothing else could have done, your determination has produced a concentration of will and energy in the Congress to produce real action, including confronting and resolving the good faith points of conflict about how best to accomplish certain tasks.

- Title I of the legislation is in direct response to recommendation 1-2: "The Department of Homeland Security (DHS) should take the lead in developing a national strategy for advancing microbial forensics capabilities." (page 28), and recommendation 1-3: "The

Department of Health and Human Services (HHS), in coordination with the Department of Homeland Security, should lead an interagency effort to tighten government oversight of high-containment laboratories." (page 29)

- Title II is in direct response to recommendation 1-5: "The Department of Health and Human Services, in coordination with the Department of Homeland Security, should take steps to enhance the nation's capacity for rapid response to prevent an anthrax attack from inflicting mass casualties." (page 32)

- Title III is in direct response to recommendation 2-3: "The Department of Health and Human Services (primarily through the Centers for Disease Control and Prevention) should work to strengthen global disease surveillance networks." (page 40)

- Title IV is in direct response to recommendation 10: "The intelligence community should address its weakening science and technology base in nuclear science and biotechnology and enhance collaboration on WMD issues with specialists outside the intelligence community, including nongovernmental and foreign experts." (page 100), and "The intelligence community should expedite efforts to recruit people with critical language capabilities and cultural backgrounds. In conjunction with this effort, the intelligence community should streamline the hiring process, especially for applicants with critical language capabilities." (page 99)

- Title V is in direct response to recommendation 13: "The next administration must work to openly and honestly engage the American citizen, encouraging a participatory approach to meeting the challenges of the new century. The federal government should practice greater openness of public information so that citizens better understand the threat and the risk this threat poses to them." (page 109)

We appear here today to offer our specific comments on these five titles.

Enhanced Biosecurity Measures in U.S. Laboratories, in Title I:

Certain principles animated the section of our Report dealing with laboratory security. We were concerned about (1) the proliferation of high-containment labs, which were not only unregulated but often unknown to the government, (2) the fragmentation of government oversight among several agencies, (3) the need for a thorough review and update of the Select Agent Program, and (4) the importance of regulating labs in a way that did not discourage robust scientific research in the United States.

Enhanced biosecurity measures should improve security, streamline oversight, and focus our resources on the real risks. By correctly applying risk management principles, the United States can increase security without impeding science or critical U.S. industries. Scientists are, after all, our key line of defense against biological weapons. Without their work, we would not have the drugs, vaccines, and diagnostic tests needed to protect the American people in the event of a biological attack. The work of developing medicines is difficult, takes a long time, and is fraught with challenges. We still do not, for example, have drugs or vaccines for many of the biological agents weaponized by the Soviet Union. Therefore, it is in our national security interest to make sure that our laboratories continue to develop medical countermeasures, while still operating safely and securely.

We believe that the legislation implements many of the provisions of our Report, and in certain respects improves on our recommendations. For example, the bill introduces into the Select Agent Program the idea of stratifying risks, which we think is a real advance in achieving the right regulatory balance. *Stratification of risks into tiers allows for more realistic assessments of risk, and will benefit public health investigations.* The bill calls for the Secretary of Health and Human Services to designate as "Tier I" agents the most dangerous subset of the pathogens included in the Select Agent Program that have clear potential for use as biological weapons. Stratifying the Select Agent list will allow us to focus increased security on genuine risks, and will allow public health-related research involving non-Tier I agents to proceed without excessive regulation.

Multiple studies were conducted as a result of our Report. Virtually all of them, from both the public and private sectors, have called or will call for the stratification of agents. The

overwhelming recommendation from the scientific community is that any legislation employ a tiered approach.

Accordingly, although our Report does not deal with the stratification issue, we recommend that the legislation go further, requiring the HHS Secretary to stratify the current Select Agent list into Tiers I, II and III. This would be the best means for securing the most dangerous pathogens while causing the fewest impediments to scientific research. Tier I should include deadly pathogens that can be weaponized. Tier II should include pathogens that are dangerous but cannot feasibly be used as bioweapons. Tier III should include the majority of biological agents that are of lesser security and public health concerns. These agents would require only facility registration, as described in Section 103 of the Bill. Our primary objective, again, is to distinguish those pathogens that pose great danger from those that do not.

Today, 82 Select Agents receive the highest level of security focus and regulation. We believe the correct number of top-tier agents is closer to 8 than 80. A three-tiered system would allow us to place the greatest security emphasis on those agents that can most feasibly be weaponized, and thus have the highest probability of being used for bioterrorism. Under the current system, smallpox and anthrax, the two most feared pathogens that could be used for a large-scale bioattack, are in the same category as the herpes B virus, which virtually no expert considers to be suitable for use as a bioweapon -- unless you want to kill monkeys.

We should note that our recommendation to stratify biological agents for *security* purposes is distinct from the measures that scientists need to take for *safety*. Many pathogens, including those that cause tuberculosis, HIV, and herpes B, require special safety precautions, though most experts do not consider them to be feasible for use as bioweapons. We encourage the further refinement of safety systems and procedures for all types of biological research, so that research can be conducted with the highest level of safety.

Fragmentation of oversight should be eliminated in pathogen security. In our Report, we concluded that the fragmentation of government oversight of laboratories was a national security problem. We determined that there should be *one* set of requirements concerning pathogens for

the scientific community to follow, instead of having separate regulatory programs from multiple departments. The authority to oversee and enforce these requirements must be vested in one lead agency so that the regulated community has a single coherent, consolidated and streamlined set of regulations to follow.

Currently, under the Select Agent Rule, as defined by 42 CFR 73, 7 CFR 331 and 9 CFR 121, HHS and the Department of Agriculture (USDA) regulate select agents. Human pathogens are regulated by HHS; plant and animal pathogens are regulated by USDA, and facilities that house pathogens that are a concern for humans and livestock are inspected jointly. Accounts of this process suggest that HHS and USDA cooperate well in meeting their regulatory responsibilities. Given the distinct expertise on these pathogens in USDA and HHS, it is appropriate that USDA's expertise be brought to bear on livestock and crops, and that of HHS for human pathogens. However, it is our belief that in constructing a regulatory system for pathogens that can infect humans, *one* cabinet secretary should be in charge. As Commissioner Robin Cleveland stated before this committee last December, we "have too many agencies, too many turf fights, and unclear oversight entities." That must end.

We recognize that the bill you recently introduced would assign overall oversight authority to the Secretary of the Department of Homeland Security. In our Report, we recommended that HHS "lead an interagency review." This recommendation was implemented by Executive Order in January. The review called for will soon be completed. The Report also called for HHS "to lead an interagency effort to tighten government oversight on high-containment laboratories." Based on what we have learned from several recent studies, numerous meetings with representatives from the executive and legislative branches, and the scientific community, we continue to recommend that overall oversight authority and responsibility for lab security be assigned to the Secretary of Health and Human Services, with recommendations on scientific matters from USDA and security matters from DHS. The Secretary should solicit, possibly through the creation of an advisory council, the recommendations from the scientific community with a view towards constantly improving the regulatory model given all the concerns of the communities involved.

To sum up, we applaud your efforts on Title I of the bill. We suggest taking the tiered approach even further than the current draft. On the question of the lead agency, our Commissioners recommended that HHS take the lead. We continue to take that position, and believe that it will lead to the improved regulatory process that we all seek.

Response to a Weapon of Mass Destruction Attack, Title II:

A national strategy is sorely needed to establish effective and timely distribution of emergency medical countermeasures (MCMs). Countermeasures could serve to blunt the impact of an attack, save lives, and thwart the terrorists' objectives—but only if they are delivered when and where they are needed.

We recommend that the legislation not imply a federal-centric approach, but emphasize the need for cooperation among, and the strides that need to be taken by, state and local government, and non-governmental organizations. Based on the work already accomplished by the U.S. Postal Service (USPS) during the past four years, it is important to understand that this capability requires a national strategy that includes federal, state and local involvement. But a national strategy should not imply federal control. In the cities where USPS has run pilot programs (Seattle, Philadelphia, and Boston), we have seen the importance of a fully integrated partnership in the planning and execution of distribution efforts. For instance, even if USPS is perfectly prepared to deliver MCMs to households in a metropolitan area, it has no hope of succeeding without the complete preparedness and cooperation of state and local law enforcement.

We praise USPS for their extraordinary efforts during the past four years. This is the way government programs should work: first, a series of low-cost pilot programs should be created to test procedures that identify strengths and weaknesses; second, a national strategy should be designed based on the lessons learned from pilot programs; and, third, appropriate funding should be provided for full-scale development. This third step is lacking. If we expect USPS to complete this large-scale, life-saving effort, they must be provided with adequate funding.

It is also important to note that the postal service be considered as one option for local communities under the ongoing Cities Readiness Initiative. It is not the sole option. Some jurisdictions have looked closely at whether USPS could successfully deliver medical countermeasures in their communities and have decided against it. Local leaders know their jurisdictions; they know what will and what won't work. Their knowledge of their community and their residents must be heeded if we are to respond in a timely and effective way.

We also feel obligated to comment on a key issue regarding medical countermeasures not addressed in this bill. Yes, we must have a system capable of rapidly dispensing MCMs during a crisis, but we must first have the required items to dispense. A world-class delivery system that does not have the appropriate products is of no value. Several months ago the Obama Administration attempted to raid the BioShield Reserve Fund to pay for H1N1 flu preparedness—certainly an important program, but one that needed funding on its own merits. Thankfully, this raid was not successful because leaders in Congress, who understand the importance of BioShield to our biodefense program, prevented it. Unfortunately, the story on funding for the Biomedical Advanced Research and Development Act (BARDA) does not have a similar good ending -- at least not yet. There is, however, still time to correct this funding shortfall. The current funding request for FY 2010 is $305 million. The needed funding level is $1.7 billion per fiscal year.

America must develop the capability to produce vaccines and therapeutics rapidly and inexpensively. Both the BioShield Reserve Fund and BARDA will be key elements in reaching this goal, but only if they receive proper support and funding. Developing this capability over the long-term will lead us to a security environment where biological weapons can be removed from the category of WMD. That must be the long-term biodefense strategy for America, but it will be unattainable if we do not properly fund these key programs.

International Measures to Prevent Biological Terrorism, Title III:

The bill rightly supports international measures that contribute to effective cooperation on the shared, global biological threat. We know that a terrorist attack will not happen in a vacuum and an attack in another part of the world can—and will—affect the United States.

We suggest that care be taken in this legislation to avoid duplicating the unintended negative consequences, which resulted from the Select Agent regulations. Security restrictions must not preclude international cooperation, which is necessary for public health, infectious disease surveillance, as well as our national security. We do not want to "close our windows," so to speak, into the activities of other nations' laboratories.

Of course, the cornerstone of international efforts to prevent biological weapons and terrorism is the 1972 Biological Weapons Convention (BWC). This agreement was the first to declare an entire class of weapons to be off limits. While the treaty has some inevitable limitations—particularly the difficulty in detecting violators—it remains a powerful norm: no nation brags about their biological weapons capability.

It is our obligation to strengthen this norm, internationally. Right now, the clock is ticking on the BWC—the next BWC review conference, in which every article of the entire treaty is reviewed, takes place in 2011. We must propose a new action plan for achieving universal adherence to the BWC, so that all nations of the world are signatories to this pact. We also need to promote new ideas for how the BWC may be implemented on a national level. This conference presents the United States with an opportunity to showcase the progress we have made here at home in both lab safety and lab security. We will have the opportunity to set the global standards of success.

Government organization, Title IV

We commend the provision calling for the DNI to develop a strategy to strengthen our WMD-related intelligence capabilities. Increased attention in this area is of vital importance and, we understand, would underscore the DNI's own initiatives. We also strongly support the provisions of this bill that would strengthen the intelligence community's expertise in the nuclear

and biological fields; prioritize pre-service and in-service training and retention of people with critical scientific, language, and foreign area skills; and ensure that the threat posed by biological weapons remains among the highest national intelligence priorities for collection and analysis.

Additionally, we recommend that the bill include a provision directing the Secretary of Defense to provide a classified report to the committees with primary oversight of the Department of Defense, Intelligence Community and Department of Homeland Security on the efficacy of the biological weapons tests conducted by the United States during the 1950s and 1960s. Some commentators assert that bioweapons are not of concern, primarily because they have not been used on a widespread basis. We are entirely confident that the report we call for, if properly done, would dispel any doubts about the threat that bioweapons pose to the safety and security of our society and our allies.

Emergency Management and Citizen Engagement, Title V

We strongly believe that a well-informed, organized and mobilized citizenry has long been one of the United States' greatest resources. An engaged citizenry is, in fact, the foundation for national resilience in the event of a natural disaster or a WMD attack.

Consistent with the Commission's Report, we must create a culture of preparedness and resilience across our nation. The most important statement we could offer to our colleagues concerning preparedness and emergency management is that there are a vast array of capabilities found across our society that can and must be organized and, when needed, mobilized in the event of a natural disaster or WMD attack. These capabilities are primarily the combined assets of state and local governments, our diverse business communities, nongovernmental organizations, professional and service organizations and all citizens. The federal government cannot hope to possess the capabilities needed in the event of a major disaster – but it can lend vital support if local and regional actors have organized beforehand.

For example, a few years ago, officials in Iowa asked BENS, or Business Executives for National Security, to assist them in building a public-private partnership to strengthen disaster

preparedness. After extended discussions with a growing number of local and regional stakeholders, both in government and the private sector, the Safeguard Iowa Partnership was launched – a formal working partnership involving state and local governments and private organizations that understood the benefits of collaborating. When historic floods struck the state 18 months later, the trusted relationships, communication and coordination from this partnership demonstrated an improved emergency management capability that the federal government could not have prescribed or created. Moreover, such an entity can and should be established in every state and region to meet the particular needs of that area. We commend the work of BENS in helping to create an innovative approach to emergency response, preparedness, and resilience. We believe that the model they have established can and should be emulated elsewhere across the country and is applicable to both natural disasters and WMD attacks.

Finally, we would like to extend our appreciation to Senator Akaka for recently introducing the *Energy Development Program Implementation Act of 2009*. This bill will create an alternative energy peace corps, as called for 31 years ago by the *Nuclear Nonproliferation Act of 1978*. As our Report recommended, this bill would help reduce the further spread of nuclear technologies ostensibly for civilian purposes. It deserves bipartisan support.

Conclusion

We commend Senator Lieberman and Senator Collins for introducing a very important piece of legislation. We look forward to participating in a robust discussion on Capitol Hill and with the Administration and stakeholders as the *WMD Prevention and Preparedness Act of 2009* makes its way through the legislative process, and stand ready to help where we can, to promote important strides for our national security.