

**U.S. House of Representatives  
Committee on Homeland Security  
Hearing on the WMD Prevention and Preparedness Act of 2010  
April 21, 2010**

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

Mr. Chairman and distinguished members, thank you for the opportunity 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*, in December, 2008.

In 2009, the Commission was authorized for an additional year of work, to assist Congress and the Administration to improve understanding of its findings and turn its concrete recommendations into actions. In accordance with that authorization, and based upon close consultation with Commissioners, we submitted a report card assessing the U.S. Government's progress in protecting the United States from weapons of mass destruction proliferation and terrorism. This report card provided an assessment of the progress that the U.S. government has made in implementing the recommendations of the Commission.

While progress had been made in many areas, the overall assessment for biological threats was not good. We submit a copy of that report card for the record. While certainly not every assessment was poor, we found that the government simply had not paid consistent and urgent attention to the means of responding quickly and effectively so that bioweapons no longer constitute a threat of mass destruction. The failures did not begin with the current group of leaders. Each of the last three Administrations has been slow to recognize and respond to the biothreat. The difference is that the danger has grown to the point that we no longer have the luxury of a slow learning curve. The clock is ticking, and time is running out.

The Commission has concluded its work as a congressionally mandated organization, as of February 26, 2010. We are committed to continuing this bipartisan work, however, and will continue to monitor progress on the Commission's recommendations in our newly formed WMD Center, a bipartisan, not-for-profit research and education organization. It is our hope that by identifying areas of progress, as well as those in need of further attention, appropriate action will be taken to mitigate the threat posed by weapons of mass destruction to the United States.

## THE COMMISSION'S FINDINGS

The Commission's Report assessed both nuclear and biological threats, and provided 13 recommendations and 49 action items. 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. Furthermore, we determined that terrorists are more likely to obtain and use a biological weapon than a nuclear weapon. Shortly thereafter, this conclusion was publicly affirmed by then Director of National Intelligence (DNI) Mike McConnell.

There are several reasons for our conclusion that a bioattack is actually more likely than a nuclear attack. Many pathogens suitable for use in a biological attack are found in the natural environment, all over the globe. The lethality of an effectively dispersed biological weapon could rival or exceed that of an improvised nuclear device. 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 – is of a dual-use nature and readily available on the internet. The most effective delivery methods are well known in the pharmaceutical, agricultural, and insect-control industries. It is much more straightforward to stockpile weaponized pathogens than nuclear material, raising the terrible specter that terrorists could attack an American city using a bioweapon, then quickly "reload" and attack again within a matter of days or weeks.

So, while it is certainly possible for terrorist groups to get a nuclear weapon, it is less difficult for them to develop and disperse a bio-weapon. There may be even fewer barriers for terrorist groups with close ties to those nation states which are accumulating both the materials and scientific capability for weaponization. All of the ingredients are in place for a biological weapon to be in the hands of a terrorist organization, which is subject to none of the international law constraints and retaliatory consequences which might impede a nation state from its use.

None of this is 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 and a separate, but parallel bioweapons development program al Qaeda ran in Malaysia. Facilities with more sophisticated equipment than those found could be in operation today without our knowledge.

When would we find out about such a facility? It is possible, even likely, that we would not know until after an attack took place. Consider this scenario: a team of engineers sympathetic to al Qaeda bring a seed culture of anthrax spores to the U.S. from an overseas laboratory. They purchase and modify a truck so that it sprays anthrax spores into the air. The load up the truck with its deadly cargo, and slowly drive it through the downtown traffic of a mid-sized city during rush hour, at the end of the day. No one notices the truck, or finds it at all unusual that the truck is emitting fumes. No BioWatch sensors go off. Days later, however, desperately ill people start flooding emergency rooms. In the following weeks, 13,000 people die. The city may need to be cleaned up so that people can safely enter the downtown area, at a cost of billions of dollars. And as tragic as this event could be, the terrorists remain at large, free to commit the same murder twice. Antibiotics would likely arrive quickly, but there would be national demands for a

vaccine—but there is not nearly enough anthrax vaccine to satisfy the demands from even one small city. Unfortunately, this scenario is not considered ‘worst-case’ or unrealistic, but it is in fact the National Planning Scenario for a biological attack. It was released 5 years ago this month. Five years—the clock is ticking, and we are not prepared.

The Obama administration appears to agree with our concern regarding the threat of 21<sup>st</sup> century bioterrorism. The following is a quote from National Strategy for Countering Biological Threats signed by President Obama on November 23, 2009.

The effective dissemination of a lethal biological agent within an unprotected population could place at risk the lives of hundreds of thousands of people. The unmitigated consequences of such an event could overwhelm our public health capabilities, potentially causing an untold number of deaths. The economic cost could exceed one trillion dollars for each such incident. In addition, there could be significant societal and political consequences that would derive from the incident’s direct impact on our way of life and the public’s trust in government.

#### **WEAPONS OF MASS DESTRUCTION PREVENTION AND PREPAREDNESS ACT OF 2010**

First, Mr. Chairman, we want to thank you and your committee for the extraordinary leadership you have shown by holding this hearing about the WMD Prevention and Preparedness Act of 2010. We realize that the WMD issue spreads across many committee jurisdictions and will require unprecedented leadership, coordination and cooperation. 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 take bold actions.

As of the time we prepared this statement, we had not seen actual bill language, but we appreciate the summary of the bill provided by your staff, and are happy to provide comments based on that summary.

#### **INTELLIGENCE**

As we understand it, the bill, if enacted, would require the DNI, in coordination with the Secretary of Homeland Security and other appropriate Federal Agencies to develop and maintain a National Intelligence Strategy for Countering WMDs. It also calls for improving national capabilities to collect, analyze, and disseminate intelligence related to WMDs. We understand the DNI is already working on the 2010 National Intelligence Strategy for Countering Biological Threats.

Based on a recently completed tour of nations in two of the most vulnerable regions, there are significant gaps in our intelligence relating the nation state- terrorist links. Recognizing the inherent difficulty of collecting intelligence in these venues, doing so should be the highest priority of American intelligence.

We commend these provisions. Increased attention in this area is of vital importance and, we understand, would underscore the DNI’s own initiatives. We hope that the drive to produce this report would spur the intelligence community to acquire and retain additional 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. Indeed, recommendation 11 in our report, *World at Risk*, was that the United States must build a national security workforce for the 21<sup>st</sup> century.

One important issue not addressed in the intelligence section is the problem of not including public health personnel in many of the fusion centers. Only a handful of these centers currently include public health officials. We all need to understand, in the 21<sup>st</sup> century, public health is a critical element of national and homeland security. Public health resources need to be fully integrated with law enforcement and traditional first responders.

We also 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.

#### PREPAREDNESS: GETTING FIRST RESPONDERS READY, AND ENGAGING THE PUBLIC

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. There are vast arrays 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 by itself 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. We submit for the record the WMD Commission's final product, a brochure for community preparedness. *We All Have Role: Working with your Community to Prepare for Natural and Man-Made Disasters*.

We have found that the federal government can do more to make sure that state, local, and tribal governments can respond in a crisis, and so we support this legislation's call for sharing security information with state, local, and tribal governments (title 1, section 111). State and local governments, as well as health departments, need more comprehensive threat information in order to prepare for emergencies, as well as gain support from leadership and staff in preparedness activities.

We support the bill's provisions for the Department of Homeland Security to put forward threat bulletins and guidance to local governments (Title 2, section 202), and crafting important messages ahead of a crisis (title 204). We recommend that the public be involved in the creation

and approval of threat information and alerts. This will help to ensure that these alerts effectively reach and motivate their target audience.

#### SECURE, PRODUCTIVE U.S. LABORATORIES AT THE FOREFRONT OF SCIENCE

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 enhanced security but did not discourage robust scientific research in the United States.

Enhanced biosecurity measures should improve security, streamline oversight, and focus our resources on the greatest risks. By correctly applying risk management principles, the United States can increase security without impeding science or critical U.S. industries. Without robust scientific research, we will 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 this legislation highlights 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 designation of “Tier I” agents to be the most dangerous subset of the pathogens that have clear potential for use as biological weapons. 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 employs a tiered approach.

We therefore commend the Committee for introducing the stratification approach into this bill and recommend that the Tier 1 list be developed by the Secretary of DHS in consultation with the Secretary of HHS. 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.

Stratifying the Select Agent list should allow us to focus increased security on the highest risks and allow public health-related research involving non-Tier I agents to proceed without excessive regulation. We suggest that care be taken to avoid duplicating the unintended negative consequences of the current Select Agent program. Security restrictions must not preclude international cooperation, which is necessary for public health and infectious disease surveillance, as well as our national security. For example, we should not repeat what happened at the beginning of the H1N1 pandemic, when flu samples from sick patients in Mexico were not shipped to U.S. laboratory scientists to analyze, but to Canada-- because U.S. import and shipping regulations were so restrictive. We also do not want to “close our windows,” so to

speak, into the activities of other nations' laboratories. Scientists from the U.S. should be able to collaborate on Rift Valley Fever or Venezuelan equine encephalitis research with scientists where those diseases are endemic. If we don't, other countries' scientists will. For these reasons, the Select Agent program status quo needs to be changed, and we recommend calling for adjustments to ease restrictions on non-tier 1 agents.

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 last December, we "have too many agencies, too many turf fights, and unclear oversight entities." That must end.

We recognize that the bill would require the Secretary of the Department of Homeland Security to develop enhanced biosecurity measures, and would require them to inspect all Tier 1 laboratories. 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 and security communities with a view towards constantly improving the regulatory model given all the concerns of the communities involved. To sum up,

we recommend 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. We also do not have the luxury of time to bring another agency up to speed. HHS has been doing a positive service in this area, and we do not want to change ships in midstream.

#### BUILDING A RESPONSE AND RECOVERY PLAN THAT ACTS AS A DETERRENT

The bill requires the Secretary of Health and Human Services, in coordination with the Secretary of Homeland Security and other appropriate Federal agencies, to develop and implement a National Medical Countermeasure Dispensing Strategy. 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 commend the Obama Administration for issuing an executive order in December, 2009, to establish federal capabilities for the timely provision of medical countermeasures following a biological attack, and we commend this committee for taking up this important, as well as complicated, effort. But, dispersal of medical countermeasures is but one link in the chain of actions that are needed to respond to a bio attack. Rapid detection and diagnosis capabilities are the first links, followed by providing actionable information to federal, state, and local leaders and the general public; having adequate supplies of appropriate medical countermeasures; quickly distributing those countermeasures; treating and isolating the sick in medical facilities; protecting the well through vaccines and prophylactic medications; and in certain cases, such as anthrax, environmental cleanup. All parts of the chain need considerable attention.

Public health agencies at the federal, state, and local levels have made great strides since 2001 to prepare the nation for biological attacks and other disasters. This is in spite of the challenges of preparing for such events, especially in light of limited and decreasing budgets. However, much more can be done to support public health, and also traditional first responders, so that the nation can effectively respond to a biological attack.

One way that the burden on public health may be eased is if the public is more prepared. We commend this committee for including provisions for the public and especially first responders, to access the vaccines and antibiotics they might need in an attack, before such an event occurs. (Title I, Section 105) For example, anthrax vaccine could and should be available to first responders, and we agree with the Committee that the government should seriously review the issue of whether and under what conditions home MedKits should be available for concerned citizens who wish to prepare themselves and their families. In considering the policies for vaccination and antimicrobial distribution in light of known biological threats to the U.S., however, we recommend that public health responders also be given priority, and that vaccination be done on a voluntary, not a mandatory, basis.

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 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 2011 is \$476 million. The Center for Biosecurity at the University of Pittsburgh Medical Center recently estimated that \$3.39 billion per year in medical countermeasure development support would be required to achieve a 90 percent probability of developing one FDA-licensed countermeasure for each of those requirements. The cost estimates of developing these pharmaceuticals were based on in-depth surveys of historical vaccine and drug development data, and reflect the high failure rate of biopharmaceutical development. It now falls to the U.S. government to fund the development of medical countermeasures based upon the level of risk that is deemed tolerable. An amount of \$1.7 billion per year would meet roughly half the estimated need to provide a significant and necessary down-payment on the nation's preparedness. Given the threat, \$1.7 billion per year for prevention and consequence management is a reasonable and comparatively sound investment.

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. We submit for the record an article we co-authored on this subject in the summer of 2009 for the Journal of Biodefense and Biosecurity.

#### DECONTAMINATION—RESOLVING LONGSTANDING QUESTIONS SO WE ARE PREPARED

We commend the committee for including the provision that DHS issue guidelines in coordination with the Environmental Protection Agency for cleaning and restoring indoor and outdoor areas affected by the release of a biological agent. These guidelines should also address methods of decontamination following a large-scale event, and should address some of the remaining questions of a technical and scientific nature that make decontamination of a large area difficult. Currently, U.S. environmental laboratory capacity is insufficient for the challenge of sampling and testing following a large biological release. Federal leadership roles should also be clarified—many federal agencies currently have roles in decontamination, but it is still unclear which agency would lead. Likewise, it is unclear who will cover the costs of decontamination, as well as the temporary relocation of building occupants. Private building owners would rightly question what their role is, at this time—if private industry is to be responsible for decontamination of their own property, there should be guidance for decontamination practices and qualified decontamination contractors available to industry in the event that they are needed.

The WMD Commission sponsored a small study to review current bio-decontamination capabilities and responsibilities. The conclusions were not encouraging. We submit the recently-published article for the record.

## THE BIOLOGICAL WEAPONS CONVENTION—AN OPPORTUNITY TO LEAD

Section 112 of the legislation intends to require the Secretary of State to promote confidence in the Biological Weapons Convention (BWC) implementation and compliance by its States Parties. It also calls for promoting universal membership in the Convention. One of the WMD Commission recommendations in *World At Risk* was that the U.S. should propose a new action plan for achieving universal adherence to the BWC (recommendation 2-4). We are supportive of the goal, as well as moving forward to address the other important gaps in our preparedness. In order to provide leadership at the 2011 BWC Conference and take advantage of this once every five years opportunity, we should be doing more to lead by example.

## THE CLOCK IS TICKING

We cannot overstate the urgency of this crisis, and the need for action, now. The international situation is fragile, with Israel and its neighbors, on the India-Pakistan border, and this fragility substantially increases the risk of terrorism with a WMD. While there are issues at stake that have gone unresolved for over 60 years, we may have only 3 more years of procrastination before the consequences reveal not a *World at Risk*, but a world immobilized by crisis.

One of our recommendations was for Congress to reform congressional oversight to better address intelligence, homeland security, and cross-cutting 21<sup>st</sup> century national security missions. The fact that we are having this hearing on April 21<sup>st</sup> 2010—more than 16 months after *World at Risk* was issued-- is evidence of the difficulty that Congress has in organizing itself to protect the people of America, and the world, from this ultimate catastrophe.

## CONCLUSION

We commend the committee for taking up this important issue. 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 2010* is introduced, and makes its way through the legislative process, and stand ready to help where we can, to promote important strides for our national security.