U.S. Senate Judiciary Committee
Subcommittee on Terrorism and Homeland Security
Hearing September 22, 2009

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

Mr. Chairman, Senator Kyl, and distinguished Members of the Subcommittee:

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.*

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. 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.

But today, we are not talking about al Qaeda labs on the far side of the globe. We are talking about the security of our own labs here at home.

Enhanced Biosecurity Measures in U.S. Laboratories

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 recently introduced by Senators Lieberman and Collins 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 their 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.

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

We recognize that the recently introduced Lieberman-Collins bill 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 recommend that the tiered-system proposed in the Lieberman-Collins bill be expanded to three tiers, not just one. 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.

I look forward to your questions.