

# Center for Biosecurity

---



January 21, 2009

The Honorable Ike Skelton  
2206 Rayburn House Office Building  
Washington, DC 20515

The Honorable John M. McHugh  
2366 Rayburn House Office Building  
Washington, DC 20515

Dear Representatives Skelton and McHugh:

The leadership and staff of the Center for Biosecurity of the University of Pittsburgh Medical Center (UPMC) thank you and your colleagues for holding a hearing on preventing weapons of mass destruction proliferation and terrorism. We respectfully submit this letter as testimony for the hearing.

**Bioterrorism is an urgent threat requiring decisive action.**

The Center for Biosecurity strongly agrees with the Weapons of Mass Destruction (WMD) Commission report "World at Risk" that the threat of bioterrorism is urgent, growing, and requires decisive action. Recommendations such as enhancing the nation's capabilities for a rapid response to prevent biological attacks from inflicting mass casualties, and engaging the international community to counter biosecurity risks are valuable measures that could make an appreciable difference to national security.

The Commission's recommendation to enhance the nation's capabilities to rapidly respond to a biological attack, in particular, requires urgent attention. In a large-scale attack, delivering life-saving medical countermeasures to those who were exposed could avert mass casualties. Unfortunately, therapeutics and vaccines are only available for a few likely biological threats. The architecture has been put into place to accelerate medical countermeasure development with the creation of the Biomedical Advanced Research and Development Authority (BARDA) in the Department of Health and Human Services, but BARDA has not yet been adequately funded. In addition, the nation is not yet prepared to deliver those drugs and vaccines to those who were exposed to a biological weapon, nor to provide adequate medical care for the many who could be victims in such an attack. Important strides have been made in public health infrastructure and health care in recent years to begin to cope with these challenges, but there is much further to go to be able to address them. In these hard economic times when state budgets are being cut, this situation is likely to become worse.

The Commission also highlights the importance of laboratory oversight and securing dangerous pathogens. Laboratory security is indeed critical and has increased greatly since the anthrax letters were mailed in 2001. However, there are inherent limitations to our ability to secure dangerous pathogens given their ready availability outside of laboratories in the U.S. and

around the world. There is also a real danger that draconian or costly security measures will prevent scientists from working on treatments or vaccines that the country needs to treat emerging infectious diseases or to respond to a bioterrorism attack.

This testimony highlights what the Center for Biosecurity of UPMC judges to be valuable preventive measures for addressing the biological terrorism threat stemming from laboratories—including personnel accountability, public-private partnerships with synthetic genomics companies, the availability of medical countermeasures as a deterrent to bioweapons development and use, and the Select Agent Program and Biosafety Improvement Act of 2008 (introduced in the 110<sup>th</sup> Congress, S.3127 and H.R. 6671). Taken together, we believe they are key elements of a web of prevention that should deter biological weapons development and use, guide the operations of U.S. laboratories, and serve as a model for other countries.

### **Pathogen Security: Strengths and Potential Improvements**

**The Select Agent program has increased accountability for pathogens since the anthrax attacks of 2001.** After the 2001 anthrax attacks, the United States government (USG) could not easily determine who worked with anthrax and where research was performed. The Select Agent Program now provides that accountability and limits access to pathogens by restricted persons, as defined by the USA PATRIOT Act. The program was implemented on March 18, 2005, using authorities granted by the USA PATRIOT Act and the Public Health Security and Bioterrorism Preparedness and Response Act of 2002. The program is run by the CDC, by the USDA's Animal and Plant Health Inspection Service (APHIS), and by the Department of Justice, which performs background checks on the scientists in the program.

The 3 agencies regulate the possession and transfer of “select” agents—more than 70 viruses, bacteria, toxins, and rickettsia that have been deemed possible biological threats. The USDA regulates pathogens relevant to agriculture, such as Foot and Mouth Disease virus, and CDC regulates human pathogens such as Ebola virus. “Overlap” pathogens that affect humans and agriculture are regulated by both CDC and APHIS, which inspect laboratories jointly. Dividing regulatory responsibilities between USDA and HHS is intended to produce inspectors who are familiar with and have expertise in the research that is being conducted.

As of April 2008, approximately 14,000 people from a total of 324 government, academic, and private sector entities in the U.S. have been cleared by DOJ to work with these pathogens. If researchers have not been cleared by the DOJ, then they cannot legally acquire these pathogens or have access to them in a laboratory.

Despite the increased accountability created by the Select Agent Program, there are fixed, inherent limitations to pathogen security strategies. With the exception of smallpox and 1918 influenza, all select agents occur naturally (13 in the U.S.) and most are found worldwide in laboratories, hospitals, and/or in the natural environment. New synthetic genomic technologies already circumvent the need to acquire select agents from a laboratory, and the process for creating viruses from scratch is growing increasingly straightforward. Even as we work to

improve the Select Agent Program, we have to recognize that, in general, there are immovable limits to the effectiveness of such programs and other forms of biological weapons deterrence are needed.

**As is, the Select Agent Program needs fine tuning, as it has resulted in negative consequences to public health, science, and international collaborations.**

- **Surveillance in the United States:** Clinical laboratories have several days to either destroy a select agent sample or transfer it to a laboratory for further analysis. Due to concerns of running afoul of the regulations, more clinical laboratories are destroying samples immediately. This limits needed research on diseases of public health concern and closes opportunities for forensic analysis, a potential security problem.
- **International collaborations:** As reported in *Science* magazine, the select agent regulations “force some foreign partners to serve as mere sample exporters . . . American collaborations will be unwelcome in many developing countries of the world.” (ref: *Science* Vol 306, p. 2177, 24 December 2004). For example, a researcher in the U.S. who had collaborative relationships with labs in Bogota and Caracas for work with Venezuelan Equine Encephalitis (VEE) had to sever those ties because lab security in Colombia and Venezuela did not meet U.S. standards. While VEE is endemic in both of those areas, the researcher must now import samples instead of working with his international colleagues on the samples they continue to collect. The same has occurred with anthrax research collaborations as well. As a result, “Anthrax Euronet” (<http://tinyurl.com/6aplxxy>), a Europe-wide collaborative research network for anthrax was in part created to counter the difficulty of working and sharing samples with American scientists. Isolating U.S. researchers harms research, public health surveillance, and opportunities to understand what other researchers around the world are pursuing.
- **Surveillance and international research:** Avian influenza samples are closely analyzed for clues about the evolution of the virus and its potential effects on humans. Should an avian influenza virus evolve to become contagious among humans, it will be urgent to start vaccine development with that infectious strain. Unfortunately, due to the expense and regulatory burden, particularly on host country laboratories, it is easier to analyze the samples in other countries, *because no other country has a Select Agent Program comparable to the U.S. program*. This was also a consideration for SARS: the fear that American scientists would be isolated and vaccine development hindered led a group of 13 prominent scientists to write a letter to the CDC in 2004 asking that SARS be kept off the select agent list. The select agent rules would make it difficult to maintain research collaborations with China, and without China’s cooperation, the research would not advance.

**An opportunity to address the weaknesses in the Select Agent Program exists in the Select Agent Program and Biosafety Improvement Act of 2008, which was introduced in the 110<sup>th</sup> Congress (S. 3127 and H.R. 6671).** This important piece of legislation would ensure that needed biodefense research can proceed without compromises to the quality of research, the safety of laboratory workers, or the safety of surrounding communities.

- **Program evaluation for the Select Agent Program:** This is an essential step toward ensuring that the Select Agent Program enhances biosecurity and biosafety while promoting scientific advances. A thorough evaluation of the program could identify improvements that increase security and productivity.
- **Evaluation of ways to improve oversight of biocontainment laboratories:** High-containment laboratories are required to produce the scientific advances needed to develop medical countermeasures against bioweapons and emerging diseases. The Act calls for an evaluation of the siting and oversight of biocontainment laboratories and will address such topics as lessons learned, commissioning, operation, maintenance, and worker training.
- **Improving training for laboratory workers, developing minimum standards for biosafety training:** Core competencies and standards for biosafety and biosecurity, the requirement of which is written into the Act, would be useful and important for safety training for new staff.
- **Biological laboratory incident reporting system:** Many experts believe that non-lethal infections are under-reported, while operational problems or “near misses” are generally not reported. Without reporting and analysis of incidents, it is impossible to learn from experience and to prevent accidents in the future. Thus, the Act requires HHS and USDA to establish a voluntary reporting system. This has the potential to enhance biosafety through shared learning from operational experiences and to reassure the public that accidents are being thoroughly examined and contained.

**The select agent list should be reexamined and modified to better reflect potential dangers.**

Not all of the select agents are of equal importance or danger. While some accountability and security may be desirable for all of the pathogens on the list, a tiered approach may better reflect the actual security risks and would reduce costs.

#### **Additional Personnel Accountability Programs**

**Effective personnel accountability measures for scientists working on these pathogens:** To be feasible and effective, the types of measures described above must substantively diminish the risk of misuse of secure pathogens. They must also refrain from impairing laboratory operations to such an extent that research and development of countermeasures is impeded or halted. The

following programs related to improving personnel accountability are likely to meet those criteria.

- **Management training and accountability:** Without doubt, those who run labs should be aware of all activity within their domain. That said, there is no security measure that can prevent a determined insider from stealing select agents and manufacturing a biological weapon off-site. However, it is much less likely that an insider could manipulate large quantities of a biological agent without arousing suspicion among attentive coworkers and managers. The Select Agent Program and Biosafety Improvement Act of 2008 (S. 3127 and H.R. 6671) calls for a voluntary reporting system that could be used if a scientist witnessed suspicious actions in a lab.
- **Promoting biosafety:** Increased biosafety training and monitoring can achieve many of the goals of a security program without irreparably alienating the workforce or impeding research. Such a program would lead to increased interactions between scientists and their managers for training, which could bring potential security problems to light. It would also lead to safer research and fewer laboratory-acquired infections. High containment laboratories are already required to have a biosafety officer who trains staff and monitors the laboratories, but greater numbers of biosafety officers are needed who understand the research and can thus offer productive expertise. NIH could work with the American Biological Safety Association to determine necessary credentialing standards. Biosafety training is already required for all high-containment work, but core competencies and standards developed by CDC and NIH could increase adherence and awareness.

#### **Some Personnel Reliability Programs Should be Excluded**

**Personnel Reliability Programs for biological research:** New DoD procedures isolate scientists from their colleagues by requiring numerous tests, including psychological tests, and by penalizing them for all infractions. These practices are antithetical to a culture of safety and threaten the viability of continued research on medical countermeasures. Unfortunately, these methods are being implemented by NIH for intramural research.

**The “two-man rule” should be avoided because it is costly, it increases safety risks for workers, and will not be effective.** The two-man rule, followed in nuclear research, mandates that one person works while another watches. This rule should not be applied to research on select pathogens. The practice would expose greater numbers of lab workers (the watchers) to the risk of infection. Furthermore, the cost of implementing this rule would be substantial, as scientists must monitor experiments around the clock. Finally, the rule would confer little to no security benefit because it still would be possible for one lab worker to remove pathogens without being noticed.

### **Guiding the Future of Pathogen Acquisition**

#### **The U.S. government should fund industry group standards for genomics screening.**

Commercial gene foundries have formed 2 international industry associations that are developing standards for screening customer orders. The USG should encourage these efforts and work to expand screening internationally. It is not appropriate for the government to further regulate this field for a number of reasons: it is an international business, not easily subject to U.S. regulation; the technology is rapidly becoming more accessible to individual laboratories, so scientists could decide to make their own genes if it becomes too onerous to go through a commercial supplier; our scientific understanding about what is a dangerous genetic sequence will change with increased knowledge of pathogenicity; and, there are many different ways a sequence could be changed and still maintain its functionality. Suggestions such as a government-curated list of approved sequences or even government-sanctioned screening software have the potential to rapidly become irrelevant in this evolving field.

### **The Biological Weapons Convention: Strengthening the Norm**

#### **The cornerstone of biological nonproliferation strategies is the Biological Weapons**

**Convention (BWC).** The BWC is the first agreement among nations that declared an entire category of weapon to be off limits. The moral force of the treaty has not extended to every nation, as there are countries that almost certainly have biological weapons programs, but it is worth noting that no country openly displays its biological weapons capability. This prohibition should continue to be strengthened with vigorous U.S. support. Other international agreements that attempt to prevent terrorism, such as UN Resolution 1540, or measures such as the International Health Regulations (IHR) that limit the medical consequences of an epidemic also should be vigorously supported.

### **An Effective and Rapid Response to a Bioattack is a Deterrent**

**A nation's ability to limit deaths may deter development and use of a biological weapon.** In contrast to the consequences of use of nuclear weapons, the consequences of a biological attack can be reduced significantly by rapid medical response to detect, treat, and, if appropriate, vaccinate. Therefore, the ability to limit the effects of an attack through rapid response may be an effective deterrent.

**Strong forensics capabilities may also deter use of biological weapons.** The nation should have the strongest possible forensics capability because the ability to identify an attacker and retaliate may be an effective deterrent.

**Preparation is a no-regret investment.** Protecting the nation against destabilizing large-scale epidemics, whether natural or man-made, is an urgent priority. The 2001 anthrax attacks, the 2003 SARS epidemic, and the current threat of pandemic influenza are examples of the types of events for which a strong response is necessary. Research to determine how dangerous microbes work and how to defeat them with medicines and vaccines is crucial and must not be impeded unnecessarily through draconian and misguided measures intended to protect the nation.

January 21, 2009

**Conclusion**

The Center for Biosecurity strongly commends the WMD Commission's assessment that decisive action is needed to counter the threat of bioterrorism. To prevent an attack, we should develop a web of prevention that includes measures to ensure accountability of lab personnel, public-private partnerships with synthetic genomics companies, available medical countermeasures as a deterrent to bioweapons development and use, and the Select Agent Program and Biosafety Improvement Act of 2008 (S.3127 and H.R. 6671). It is imperative that the U.S. government do whatever may be possible to prevent an attack, but it must also prepare to lessen the illness, death, and civil disruption that would follow large-scale epidemics should prevention fail.

Again, thank you for your leadership on this important national security and public health issue. The Center for Biosecurity appreciates your leadership. Please feel free to contact us if you have any questions or concerns.

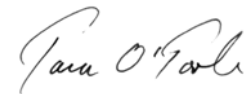
Sincerely,



Gigi Kwik Gronvall, PhD  
Senior Associate  
Center for Biosecurity of UPMC



Thomas V. Inglesby, MD  
Chief Operating Officer and Deputy Director  
Center for Biosecurity of UPMC



Tara O'Toole, MD, MPH  
Chief Executive Officer and Director  
Center for Biosecurity of UPMC

**Cc: Senate Armed Services Committee**

Senator Carl Levin, Chairman  
Senator John McCain, Ranking Minority Member

**House Committee on Energy and Commerce**

Congressman Henry A. Waxman, Chair  
Congressman Joe Barton, Ranking Minority Member

**Senate Committee on Homeland Security and Governmental Affairs**

Senator Joseph I. Lieberman, Chairman  
Senator Susan M. Collins, Ranking Minority Member

Representatives Skelton and McHugh

Page 8

January 21, 2009

Senate Committee on Health, Education, Labor and Pensions

Senator Edward M. Kennedy, Chairman

Senator Michael B. Enzi, Ranking Minority Member

Senator Richard Burr