

Center for Biosecurity

UPMC | University of Pittsburgh
Medical Center

March 3, 2009

The Honorable Jane Harman
2400 Rayburn House Office Building
Washington, DC 20515-0536

The Honorable Mike Rogers
133 Cannon House Office Building
Washington, DC 20515-2208

Dear Representatives Harman and Rogers:

The leadership and staff of the Center for Biosecurity of the University of Pittsburgh Medical Center (UPMC) thank you and your colleagues for your leadership in introducing **H.R. 1225, The Select Agent Program and Biosafety Improvement Act of 2009**. The Center for Biosecurity strongly supports and endorses this bill. It is an important piece of legislation that would ensure that needed biodefense research can proceed securely and without compromises to the quality of the research, laboratory worker safety, or the safety of the communities surrounding the laboratories.

Among the many important parts of this Act are the following:

- **Select Agent Program evaluation:** Scrutiny of the Select Agent Program is of key importance following the FBI's assertion that the 2001 anthrax attacks came from a biodefense research laboratory. The Act calls for an evaluation of the program to ensure that it is indeed enhancing biosecurity and biosafety while promoting scientific advances. A thorough evaluation of the program could also suggest improvements in oversight and accountability.
- **Evaluation of ways to improve oversight of biocontainment laboratories:** High-containment laboratories are necessary if we are to produce the scientific advances needed to develop medical countermeasures against bioweapons and emerging diseases. However, recent, highly publicized laboratory errors and siting controversies have raised questions about whether the governing framework, oversight, and standards for biosafety and biosecurity measures are adequate. The Select Agent Program and Biosafety Improvement Act of 2008 calls for an evaluation of the siting and oversight of biocontainment laboratories, and will address topics such as lessons learned, commissioning, operation, maintenance, and worker training. Gathering this information and improving upon the program has the potential to speed up the process for newly constructed laboratories to become productive, maximize the use of specialized facilities of some laboratories, and result in increased safety of the research.

- **Improving training for laboratory workers, developing minimum standards for biosafety training:** As new high-containment laboratories become operational in the coming years, additional qualified staff will also be needed. Conventional methods of biosafety training for high-containment research—that is, intensive one-on-one training within a mentor-apprentice relationship—will likely not be sufficient to handle the influx of researchers and technicians into the field. Core competencies and standards for biosafety and biosecurity, the requirement of which is written into the Act, would be useful and important for training new staff on safety practices. It could also conserve experienced mentors' valuable time and abilities and shorten the time it takes for labs to become productive.
- **Biological Laboratory Incident Reporting System:** Generally, there is a disincentive to report laboratory acquired infections and other mishaps at research institutions. Infections lead to negative publicity and scrutiny from the granting agency, adversely affecting future research funding. In addition, after a scientist acquires an infection in the laboratory, neither the scientist nor the laboratory wishes to advertise the mistake. Many experts believe that nonlethal infections are underreported, and operational problems or 'near misses' were generally not reported. Without reporting, and without analysis of these incidents, lessons cannot be learned from the experience. Laboratory procedures cannot be analyzed in light of the accidents, so that future accidents can be avoided. Thus, it is an important step forward that the Act requires HHS and USDA to establish a voluntary reporting system that can clear these barriers so biosafety can be enhanced through shared learning from operational experiences, and so that the public can be reassured that accidents are being thoroughly examined and contained.

Protecting the nation against destabilizing large-scale epidemics, whether natural or man-made, is an urgent priority. The anthrax attacks in 2001, the SARS epidemic in 2003, and the current threat of avian influenza all are important examples of why we must conduct research to determine how microbes work and how to defeat them with medicines and vaccines. The Select Agent Program and Biosafety Improvement Act of 2009 sets the stage for achieving biosafety and biosecurity goals while continuing to advance our knowledge and control of these deadly diseases.

Again, thank you for your leadership on this important national security and public health issue. The Center for Biosecurity appreciates your leadership in introducing this important piece of legislation and stands ready to work with you to see it enacted. Please feel free to contact us if you have any questions or concerns.

Representatives Harman and Rogers
Page 3
March 3, 2009

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 HELP Committee:

Senator Edward Kennedy
Senator Michael B. Enzi

Senate Homeland Security and Governmental Affairs

Senator Joseph I. Lieberman
Senator Susan M. Collins

**House Subcommittee on Intelligence, Information Sharing and Terrorism Risk
Assessment**

Representative Michael T. McCaul

House Subcommittee on Agriculture

Representative Collin C. Peterson
Representative Frank D. Lucas

House Committee on the Judiciary

Representative John Conyers, Jr.
Representative Lamar Smith

Representatives Harman and Rogers
Page 4
March 3, 2009

House Committee on Energy and Commerce

Representative Henry A. Waxman
Representative Joe Barton

House Subcommittee on Oversight and Investigations

Representative Bart Stupak
Representative John Shimkus

House Subcommittee on Health

Representative Frank Pallone, Jr.
Representative Nathan Deal

United States Department of Agriculture

Tom Vilsack, Secretary of USDA
Freeda Isaac, Director, Select Agent Program

Department of Health and Human Services

Kathleen Sebelius, Secretary of HHS Nominee

National Institutes of Health

Raynard S. Kington, Director (Acting)
Anthony S. Fauci, Director, NIAID
Michael Kurilla, Director, Office of BioDefense Research Affairs and Associate Director for BioDefense Production Development, NIAID
Amy Patterson, Director, Office of Biotechnology Activities
Deborah A. Wilson, Director, Division of Occupational Health & Safety, Office of Research Services

Centers for Disease Control and Prevention

Richard E. Besser, Director (Acting)
Daniel Marc Sosin, Director (Acting), Coordinating Office for Terrorism Preparedness and Emergency Response
Robbin S. Weyant, Director, Division of Select Agents and Toxins
Casey Chosewood, Director, Office of Health and Safety