AAU Memo on Principles to Guide Development of HHS Bioterrorism Regulations

July 16, 2002

The Honorable Tommy Thompson  
Secretary of Health and Human Services  
Department of Health and Human Services  
200 Independence Avenue, SW  
Hubert H. Humphrey Building  
Washington, DC 20201

Dear Secretary Thompson,

The Association of American Universities represents 61 leading public and private research universities in the US, many of which perform research utilizing hazardous agents and toxins, which are designated as "select agents" under existing CDC regulations. Accordingly, we have an interest in the new Public Health Security and Bioterrorism Preparedness Response Act of 2002 (Public Law 107-188), which requires these regulations to be modified.

We want to work with the federal government to ensure that hazardous agents and toxins are kept away from criminals and terrorists. At the same time, we want to ensure that necessary research, including research that could protect the public from the threat of bioterrorism, is not unduly impeded. In this spirit, we hope the enclosed comments, which have been provided by the AAU staff to the CDC staff, will be of assistance as HHS prepares the regulations which PL 107-188 requires you to promulgate by December of this year.

Cordially,

Nils Hasselmo  
President

Enclosure (1)  
cc: Dr. Eve Slater, Assistant Secretary for Health  
Dr. Julie L. Gerberding, Director, Centers for Disease Control  
NH/GLL/law
Principles to Guide Development of HHS Bioterrorism Regulations

Universities believe that the public must be protected from the threat of bioterrorism and that dangerous biological agents and toxins must be kept away from terrorists and criminals. The university community supports Public Law 107-188 and agrees with the Administration and Congress that the laws and regulations to control the handling, storage, transfer, receipt, use of, and access to, select agents needed to be strengthened and expanded. At the same time, research and education are a necessary part of protecting the public and developing vaccines, medicines, antitoxins and cures. The conduct of research requires access to hazardous materials by appropriately trained and screened persons.

Keeping in mind all of these imperatives, the AAU offers the following candidate principles that could help the Department of Health and Human Services as it prepares to write new regulations by December 9, 2002 governing the handling, storage, transfer, receipt, use of, and access to, select agents, as required under Public Law 107-188. The first principle also addresses the Center for Disease Control (CDC)'s notice in the July 2, 2002 Federal Register (Vol. 67, No. 127, pps. 44464-5).

1. **Clarity must be provided as to which "facilities" are required to provide notification.** The CDC's July 2 Federal Register notice ("Proposed Data Collections Submitted for Public Comment and Recommendations") states that, "Facilities that do not possess a listed biological agent or toxin are required to complete the declaration of non-possession and submit the form." The term "facility" is defined only as "a single geographic site, such as a building or complex of buildings at a single mailing address." This is extremely confusing. Only those facilities that possess listed agents should be required to provide notification. Otherwise, the notice could be interpreted to require every collection of buildings of any kind to notify CDC that select agents are not present.

2. **Inventory requirements should take into account that organisms can multiply rapidly.** Universities do not object to developing an inventory of every select agent present at an institution, as part of the registration process. However, an inventory of the approximate measures of volumes and concentrations of stock samples should be an acceptable method of measuring hazardous organisms. A precise inventory could be meaningless because the amount of organic substances on hand at any time may change from day to day. (Section 201, new 42 U.S.C. 351A(d)).
3. **Registration may take longer than notification.** Clarification is needed regarding institutions' obligation to notify the Department of possession of select agents, and register with the Department under new regulations. The law says that institutions (described as "persons" in the bill) must notify HHS of possession of select agents within 90 days, but the law does not state how much time an institution may take to register. This time period should be clarified in regulations, and the regulations should recognize that registering a facility may take longer than simply notifying the Department that select agents are present at a facility, as more paperwork is involved. (Section 202(a)).

4. **The level of physical security and access controls should be tiered,** according to those that are the most virulent, dangerous, or prone to be used by terrorists. Centers for Disease Control Biosafety Levels (described in CDC's publication Biosafety in Microbiological and Biomedical Laboratories) and Categories for select agents, and Drug Enforcement Administration (21 CFR) regulations governing handling of controlled substances for research purposes are structured this way. This would appear consistent with the language in the new law stating that safeguard and security requirements should be "commensurate with the risk such agent or toxin poses to public health and safety (including the risk of use in domestic or international terrorism)." Not all listed viruses, bacteria, rickettsiae, fungi and/or toxins pose the same level of threat. For example, smallpox and some of the hemorrhagic fever viruses should have the highest level of security, while other listed agents may not require the same degree of security. Also, new regulations should impose the tightest security requirements on large facilities capable of producing quantities suitable for weaponization, not on small academic laboratories. (Section 201, new 42 U.S.C. 351A(e)(1)).

5. **The need to limit access for security reasons should be balanced against the need for availability for research purposes.** The law states that the Secretary of HHS shall by regulation provide for "appropriate availability of biological agents and toxins for research, education, and other legitimate purposes." The regulations should adhere to this directive, which seeks an appropriate balance between keeping hazardous materials out of the hands of terrorists and criminals on the one hand; and on the other hand, facilitating the research and education that are necessary to protect the public from the threat of bioterrorism and to develop vaccines, medicines, antitoxins and cures. (Section 201, new 42 U.S.C. 351A(b)(4)).

6. **New HHS regulations should be harmonized with other Federal and State requirements, to the maximum extent possible.** In developing regulations, HHS is encouraged to consult other relevant regulations promulgated by other agencies, such as the Departments of Agriculture and Transportation, Environmental Protection Agency, Occupational Safety and Health Administration and other agency regulations governing storage, security, transfer and shipping of hazardous materials. HHS should seek to achieve as much harmonization as possible. In addition, HHS should not seek to
regulate activities (e.g., shipping) that are already regulated by other agencies. It would also be valuable to survey regulations in place in the states.

7. **The list of select agents should preserve the existing exemptions**, such as the exclusion for toxins with an LD50 for vertebrates of more than 100 nanograms per kilogram. (Section 201, new 42 U.S.C. 351A(a)(1)).

8. **CDC guidance should form the basis for the new requirements.** In general, the CDC publication Biosafety in Microbiological and Biomedical Laboratories (BMBL) provides an excellent framework for the development of new regulations in this area. HHS should not "start from scratch" in establishing a regulatory regime for the handling, storage, transfer, receipt, use of, and access to, select agents. BMBL Appendix F specifically addresses laboratory security issues and should generally form the basis of the new regime.

Regarding access, the statutory language specifies that access to select agents should be restricted only to those individuals who legitimately need to possess, use or transfer them. Current regulations provide that in registering a facility, an institution must specify what security system is in place. BMBL contains guidelines for these security systems, including methods to prevent unauthorized individuals from gaining access. Compliance with these provisions of current regulations and with BMBL guidelines should satisfy the access requirement. (Section 201, new 42 U.S.C. 351A(d)(1)).

9. **Regulations should specify requirements for notifying HHS of any changes at a registered facility.** Currently, facilities register with the CDC for a three-year period. Universities do not object to requiring that the department be notified if significant changes are made during the three-year period, such as the location of the select agents at an institution, or the design of a laboratory. However, it would be helpful if HHS would clarify exactly what changes trigger a notification requirement during the three-year period.

10. **Biosafety and biosecurity audits should only be undertaken by professionals who have been educated and trained in, and have significant experience in, these multidisciplinary fields.** It may be necessary for the Department to audit compliance with the new regulations. However, a background in financial auditing alone is insufficient to review and audit the scientific practices and procedures involved.

11. **Background checks should be completed as promptly and efficiently as possible.** The statute specifies that the background check for individuals who must handle or use select agents should be "prompt." Universities support the background check requirement and hope that it will be implemented in a manner that keeps criminals and terrorists from having access to select agents, but that could speedily approve legitimate
12. **The database check performed by the Justice Department should be deemed the only necessary background check.** Regulations should specify that if an individual is cleared by the Attorney General following the database check, the research institution has fully satisfied the requirements of P.L. 107-188 and P.L. 107-56 (the USA PATRIOT Act), Section 817 (U.S.C. 175b) to ensure that restricted persons are precluded from gaining access to select agents. In other words, if an individual has cleared the Attorney General's database check, an institution should have no further obligation to run additional background checks on that individual. The regulations should further clarify that entities such as transporters of select agents are responsible for obtaining clearances for their employees. (Section 201, new 42 U.S.C. 351A(e)(3)).

13. **Law enforcement responsibilities should fall only to law enforcement officials.** Regulations should clarify that federal law enforcement officials (and not the research institution) are responsible for taking appropriate action where someone is identified as a potential terrorist as a result of the Attorney General's background check. (Section 201, new 42 U.S.C. 351A(e)(3)).

14. **HHS should consult with universities.** An earlier version of the bill would have directed that "Regulations… shall be developed in consultation with research-performing organizations, including universities, and implemented with timeframes that take into account the need to continue research and education using biological agents and toxins.…" Unfortunately, this language was not included in the final bill. We hope that nonetheless, the Department will include consultation with research-performing organizations in developing regulations.

15. **Affected parties should be given the opportunity to comment.** The bill provides the Department 180 days after enactment to promulgate an interim final rule. This language should not preclude publishing a Notice of Proposed Rulemaking (NPRM). An NPRM should be published to give the academic and scientific communities a chance to provide input, as required in the bill language calling for consultation with research-performing organizations. (Section 202(b)).