

AAMC Association of American Medical Colleges
AAU Association of American Universities
COGR Council on Governmental Relations
NASULGC National Association of State Universities and Land-Grant Colleges

October 15, 2003

The Honorable Ann M. Veneman
Secretary
Department of Agriculture
1400 Independence Avenue, SW
Washington, DC 20250

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

Dear Secretaries Veneman and Thompson:

We represent the presidents, chancellors, and deans, as well as senior administrators, of America's leading public and private universities and academic medical centers. We are writing to express our grave concern about the possible suspension of research involving select agents due to the inability of the federal agencies involved to "promptly" conduct statutorily required background checks.

Many of our member institutions perform research utilizing biological agents and toxins designated as "select agents" under regulations established and overseen by the Centers for Disease Control and Prevention (CDC) and the Animal and Plant Health Inspection Service (APHIS), in accordance with the Public Health Security and Bioterrorism Preparedness and Response Act, Public Law 107-188. Few if any of our institutions have received their approved entity registration, and almost no information has been obtained on the results of the background screening by the Justice Department of individuals designated as Responsible Officials, Alternate Responsible Officials, and those faculty and staff needing to have access to select agents, as required by law.

With one month to go before the deadline for full implementation of the select agent regulations, there is great uncertainty and conflicting advice from federal officials as to whether research on select agents will be allowed to continue, if the Attorney General has not completed the background screening process and the agencies have not completed the registration process by November 12. The regulations themselves required institutions to submit the names of Responsible Officials, Alternate Responsible Officials, and entity information to be screened by March 12, 2003, and to submit the names of individuals needing access to be screened by April 12, 2003. The screenings were to have been completed by April 12, 2003 for the first group and by June 12, 2003 for the second. Our institutions committed a great deal of effort and expense to meet the deadlines of the phased-in regulatory regime established by the CDC and APHIS, including the September 12, 2003 deadline for implementing security plans. Meeting these deadlines required significant facility renovations to isolate select agent and toxin areas without knowing the results of the background screening for most individuals.

The Act states that the Secretaries of Agriculture and Health and Human Services and the Attorney General are to take "prompt" action with respect to screening and notification to affected individuals. The Act also instructs agencies to "minimize disruption of research", and to complete registration and screening in a timely fashion so as "not to delay this important research". However, the current situation at three major research institutions is indicative of the situation at most institutions and threatens the continuation of this critical research:

1. An academic medical center in the southwest that was just selected to receive a National Bio-Containment Laboratory grant from NIH, and earlier was selected by NIH as a Regional Center of Excellence (RCE) for Biodefense and Emerging Infectious Diseases Research, submitted 137 names for background screening. This center was just notified by letter dated October 3 regarding the results of the background screening for 23 of these individuals, but has yet to receive word back on the others whose names were submitted.
2. A land grant university in the mid-west, also a member of that region's Regional Center of Excellence, submitted 125 names for background screening. This university has not yet received either approval or disapproval for any individuals. In fact, information for 25 individuals had to be re-submitted due to the apparent loss at one of the agencies of the original information.
3. A major private research institute in the northeast, designated as a Center of Excellence by DARPA and the Defense Department, submitted 42 names for background screening. Results of the screenings have been received for only 7 individuals.

The research and education conducted by our member institutions is a critical part of protecting the public from the threat of bioterrorism. These are the activities that will lead to the development of therapies for treating illness caused by select agents and to vaccines to protect the public from harm. Any interruption of such research will place the public further at risk and is unacceptable. Our member institutions cite the following specific ramifications of having to suspend research on or prohibit access to select agents:

- a) Valuable collections of specific select agent strains will be at risk without work to sustain cultures, or worse would need to be destroyed for lack of clearance for possession;
- b) Effective response to public health crises could be greatly diminished. Diagnoses would be hampered by lack of access to reference strains;
- c) Agricultural crises would go undiagnosed and could become endemic and/or create economically significant losses; and
- d) If delays are significant, talented scientists might abandon or lose funding for important research, and some research careers might take a different direction. This would potentially damage our nation's talent base for responding to bioterrorism threats.

We urge you to take action to clear the backlog with respect to the background screenings and registration process. In addition, a reasonable interpretation of Public Law 107-188 would suggest that research involving select agents should be allowed to continue beyond the November 12 deadline, until the regulatory bodies can complete their responsibilities. In fact, the statute includes a directive to minimize disruption of research and does *not* require a November 12 deadline. The November 12 deadline was established in regulations only. The regulatory implementation schedule clearly underestimated the complex interagency coordination necessary to

meet the requirements of the Act. We strongly recommend that the Secretaries of Agriculture and Health and Human Services move immediately to issue an extension to the November 12 deadline.

Thank you for your attention to this urgent matter and we look forward to your response.

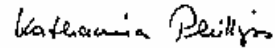
Cordially,



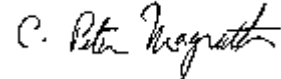
Jordan Cohen
President
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Katharina Phillips
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C. Peter Magrath
President
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cc: The Honorable John Ashcroft, Attorney General, Department of Justice
The Honorable John H. Marburger, Director, Office of Science and Technology Policy