

Alliance for Biosecurity

Office of the Secretary and Legal Counsel
1301 K Street, NW, Suite 900 East Tower
Washington, DC 20005
Telephone: 1.202.230.5619 • Facsimile: 1.202.230.5300

September 15, 2006

The Honorable Joe Barton
Chairman
House Energy & Commerce Committee
2125 Rayburn House Office Building
Washington, D.C. 20515

The Honorable John D. Dingell
Ranking Member
House Energy & Commerce Committee
2322 Rayburn House Office Building
Washington, D.C. 20515

The Honorable Michael J. Rogers
U.S. House of Representatives
133 Cannon House Office Building
Washington, D.C. 20515

The Honorable Anna Eshoo
U.S. House of Representatives
205 Cannon House Office Building
Washington, D.C. 20515

Re: Alliance for Biosecurity Comments on H.R. 5533
and the National Biodefense Science Board

Dear Chairman Barton, Ranking Member Dingell, Rep. Rogers, and Rep. Eshoo:

On behalf of the Alliance for Biosecurity, we applaud your commitment to H.R. 5533, the Biodefense and Pandemic Vaccine and Drug Development Act of 2006, and commend you for scheduling a mark-up of the bill in the House Energy & Commerce Committee on September 20, 2006. The Alliance urges passage of H.R. 5533 this year and recognizes that Committee approval of the bi-partisan bill represents another step in demonstrating Congress' active leadership in preparing our nation to meet the grave threats of bioterrorism and destabilizing infectious disease outbreaks.

The Alliance for Biosecurity is a collaboration between the Center for Biosecurity of the University of Pittsburgh Medical Center, pharmaceutical companies, and biotechnology companies working to develop vaccines and medicines ("medical countermeasures") for our nation's Strategic National Stockpile. The Alliance mission is to work in the public interest to promote a robust and sustainable research and development infrastructure necessary to prevent and treat the infectious disease threats that present security challenges in the 21st Century.

While the Alliance is supportive of H.R. 5533, **we are concerned over reports that the Committee is planning on removing the provision of the bill creating a National Biodefense Science Board** ("Science Board") and other Working Groups (the new Section 319M of the Public Health Service Act as created by Section 3 of H.R. 5533). The Alliance believes that the Science Board is a crucial component of the legislation and strongly urges the Committee to retain these provisions.

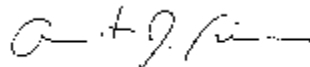
Development of medical countermeasures requires the navigation of many scientific, technical, and regulatory challenges that, in many cases, are unique to countermeasure development (e.g., use of animal models – and not humans – for efficacy testing). Success requires that government, industry, and academia maintain robust communications on these issues that are sustained over the long-term due to the long timelines inherent in medical countermeasure development and the continually changing state of the science. One of the major issues to date with the current BioShield Program has been a lack of a true partnership and effective communication between the Department of Health and Human Services (“HHS”) and external stakeholders, such as academia and industry. The Science Board and associated working groups that are created by H.R. 5533 would provide this robust and sustained communication between the government and critical stakeholders.

Further, the Science Board and working groups offer a formalized mechanism for HHS to seek input and guidance from academia and industry. Currently, no such formal mechanism exists to permit a dialogue between HHS and interested parties in a coordinated and consistent fashion. Ad Hoc workshops and meetings may not be sufficient to create a sustained partnership between government and industry.

HHS can and should benefit from utilizing the expertise offered by academia and industry to identify and address emerging chemical, biological, radiological, and nuclear (“CBRN”) threats. The Science Board will allow for an inclusive and transparent process for determining future threats and identifying strategies for developing effective medical countermeasures to diagnose, mitigate, prevent, or treat harm from such agents.

The Alliance is supportive of H.R. 5533 because it will provide government with critically needed new tools to manage the development of new medical countermeasures (e.g., the Biomedical Advanced Research and Development Authority (“BARDA”) and reform of the BioShield procurement system). We believe that the Science Board is one of the new tools that are critical to establishing an effective research and development infrastructure necessary to combat and prevent the threat posed by CBRN agents. The Alliance urges the Committee to approve H.R. 5533 with the Science Board provisions in tact.

Respectfully submitted on behalf of the Alliance,



Anita J. Cicero
Secretary and Legal Counsel