

Alliance for Biosecurity

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August 31, 2006

Via Facsimile (fax number) and Courier

The Honorable _____
The United State Senate
[address]
Washington, DC 20510

Re: Alliance for Biosecurity Support for Substitute Amendment to S. 3678

Dear Senator _____ :

On behalf of the Alliance for Biosecurity, we urge the US Senate to pass, this year, the substitute amendment to S. 3678, sponsored by Senators Burr and Kennedy, which combines the Pandemic and All-Hazards Preparedness Act (S. 3678) and the Biodefense and Pandemic Vaccine and Drug Development Act (S. 2564). Passage of the bi-partisan substitute amendment will demonstrate the Senate's 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 and membership list are attached.

Our nation is vulnerable to severe and potentially devastating biothreats, both because it lacks the improved public health infrastructure that would be needed to distribute medical countermeasures efficiently under emergency conditions, and because our country does not have the vast majority of medical countermeasures needed to protect our citizens. Such countermeasures will realistically take years (even up to a decade or more) to develop, the work is costly and success uncertain, and the modest number of companies now so engaged are increasingly unlikely to continue to invest in this challenging area absent strong biodefense legislation that facilitates the development and production of countermeasures for our nation.

The S. 3678 bi-partisan substitute amendment would accomplish a number of important objectives. It would reinforce the nation's public health infrastructure. It would also enable advanced research and development for medical countermeasures by creating, within HHS, a new entity, the Biomedical Advanced Research and Development Authority (BARDA), responsible for guiding and funding countermeasures as their development passes through the so-called "Valley of Death" between basic research and final procurement under the BioShield program. Presently, there is no entity within HHS to serve this vital purpose, which leaves the nation ill-prepared to respond to a biological attack. Currently, the private capital markets, and not government priorities, largely determine which products cross the Valley of Death. BARDA would fill this void, by partnering with developers of countermeasures to better address the economic realities of their work, and by providing the federal government with tools to manage and guide the development of the medicines and vaccines that will best meet the nation's needs.

Acambis, Inc. ▪ Center for Biosecurity of UPMC ▪ DOR BioPharma, Inc. ▪
Elusys Therapeutics, Inc. ▪ Emergent BioSolutions ▪ GlaxoSmithKline ▪ Human Genome Sciences, Inc. ▪
Novartis Vaccines and Diagnostics, Inc. ▪ Pfizer Inc. ▪ PharmAthene ▪ VaxGen, Inc.

The bi-partisan substitute amendment to S. 3678 also would advance our nation's state of preparedness by (1) permitting milestone payments for countermeasures under development, (2) creating a National Biodefense Science Board, which would provide a means for stakeholder input on technical and scientific issues, and (3) improving the partnership and communication between the FDA and countermeasure developers.

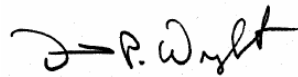
Ultimately, our biosecurity depends on how well we meet the larger, long-term challenge of building our national base of research and development in a number of medical fields, particularly anti-infectives, anti-virals and vaccines. The long historical decline in investment by industry must be reversed, and that is a journey that will take years. But it begins with steps like the one we ask Congress to take today. The S. 3678 bi-partisan substitute amendment is significant on its own merits, and also because it will confirm to all, not least the biodefense industry and its investors, that the nation will meet the challenge, and will approach it in a spirit of partnership with industry to support countermeasure development and procurement. If Congress does not act, many companies may quickly turn their attention to drug development programs that provide a more predictable and promising return. If companies now in the biosecurity sector were to exit the field, the nation would run the risk that, even in the face of a bioterrorist attack or pandemic, there could be a significant, multi-year time lag before companies can realign capital investments, rebuild critical infrastructure and scientific expertise, and raise funding to enable them to reinitiate countermeasure development projects.

The Burr-Kennedy substitute amendment to S. 3678 will provide the government with critically needed new tools to improve the public health infrastructure and manage the development of new medical countermeasures. We urge the Senate to act this year and pass the substitute amendment. Members of the Alliance would be pleased to meet with Senators and their staff as this bi-partisan substitute amendment is reviewed.

Respectfully submitted on behalf of the Alliance,



Susan Berger,
Director, Science, Knowledge & Policy
Pfizer, Inc.
Co-Chair, Alliance for Biosecurity



David P. Wright
President and CEO
PharmAthene
Co-Chair, Alliance for Biosecurity



Tara O'Toole, MD
CEO and Director, Center for Biosecurity
University of Pittsburgh Medical Center
Strategic Director, Alliance for Biosecurity

Copies to:

Richard Cheney, Vice President of the United States

Anthony Fauci, Director, National Institute of Allergy and Infectious Diseases, NIH

Steven Galson, Director, Center for Drug Evaluation and Research, FDA

Jesse Goodman, Director, Center for Biologics Evaluation and Research, FDA

Noreen Hynes, Director, Office of Public Health Emergency Medical Countermeasures, DHHS

Boris Lushniak, Assistant Commissioner for Counterterrorism Policy, FDA

Maureen McCarthy, Director of the Office of Research and Development, Science and Technology
Directorate, DHS

Gerald Parker, Principal Deputy Assistant Secretary for Public Health Emergency Preparedness, DHHS

William Raub, Science Advisor to the Secretary, DHHS

Jeffrey Runge, Acting Undersecretary for Science and Technology, DHS

Stan Sokul, Acting Chief of Staff, Office of Science and Technology Policy, Executive Office of the
President

Craig Vanderwagen, Assistant Secretary for Public Health Emergency Preparedness, DHHS

Rajeev Venkayya, Special Assistant to the President for Biodefense, White House Homeland Security
Council, Executive Office of the President

John Vitko, Director, Chemical and Biological Countermeasures Portfolio, Science and Technology
Directorate, DHS