

Alliance for Biosecurity

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November 23, 2005

By Hand

Senate Committee on Health, Environment, Labor, and Pensions
428 Dirksen Senate Office Building
Washington, DC 20510-6300

Re: Alliance for Biosecurity Comments on the Biodefense and Pandemic Vaccine and Drug Development Act of 2005 (S. 1873)

Dear Senators Burr and Kennedy,

On behalf of the Alliance for Biosecurity, we commend the HELP Committee for its hard work and leadership on the many significant and complex biodefense issues facing our nation. Your Committee has demonstrated considerable commitment to building on the foundation of the initial BioShield legislation and addressing limitations to the current U.S. biosecurity infrastructure. The Alliance appreciates your efforts to propose biodefense legislation, and we welcome this opportunity to comment. The Alliance is a collaboration between biotechnology and pharmaceutical companies and the Center for Biosecurity of the University of Pittsburgh Medical Center. The mission of the Alliance 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.

S. 1873 can become an important catalyst for the establishment of a robust biodefense industry. The experience and the technical expertise of the private sector engaged in therapeutic and vaccine research and development is indispensable to the biodefense effort. In order to attract new participants to the field and to build the critical mass necessary for sustainability, the bill must be ambitious, clear, and far-reaching. We limit our comments today to four areas in particular need of clarity in the bill— funding levels, the authority of BARDA, liability protection, and intellectual property rights. The Alliance understands that the bill is evolving in response to conversations about these and other issues; we are commenting on the latest public version of the bill.

Members of the Alliance will further consider the nature and extent of the indirect incentives provided in the bill. We share your interest in increasing engagement of talented companies in the biodefense area, and we are concerned that the incentives provided in the bill are insufficient for this purpose. We are also conscious that indirect incentives must be evaluated and implemented in a responsible manner, with an understanding of their potential impact and implications. Adequate incentives would provide the needed stimulus for pharmaceutical and additional biotechnology companies to invest large sums of capital into

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ID Biomedical Corporation ▪ Idenix Pharmaceuticals, Inc. ▪ Pfizer Inc. ▪ PharmAthene ▪ VaxGen, Inc.

countermeasure development for the first time. This issue deserves careful attention, because an appropriate incentives package could dramatically amplify biodefense resources committed by industry.

Commitment to Fund Biosecurity

Potential public health disasters caused by exposure to known and emerging pathogens must be viewed as a pressing national security issue. The raw materials and scientific knowledge necessary to develop bioweapons are widely available, and advances in biological sciences have accelerated the potential pace of their development. The scale of social and economic disruption that would be caused by a bioterror attack could be unlike anything in recent US history – even the aftermath of Hurricane Katrina. Yet, the current levels of funding for biosecurity would suggest that our country does not anticipate the need to prepare in any serious or concerted way for such a possibility for the wide array of potential biothreats.

Industry is looking to Congress and the Administration to signal that biosecurity preparedness is a national security priority justifying a joint and considerable commitment by government and industry to turn around the distinct and well-documented trend away from infectious disease research. In order to do this, a major paradigmatic shift is needed in how our nation thinks about defense against biological agents that could intentionally be used as weapons and, at the same time, defense against emerging infectious diseases that have the potential to be significantly destabilizing.

The current size of the special reserve fund established under the Project BioShield Act of 2004 for the procurement of countermeasures is insufficient to address all but a few of the most pressing biological threats. (For example, the first BioShield contract for rPA anthrax vaccine cost approximately \$877 million, which is 16% of the entire ten-year \$5.6 billion BioShield purchase fund. This contract purchases enough vaccine to vaccinate only 25 million people, and anthrax is only one of many biosecurity threats facing the nation.) The proposed bill expands the scope of countermeasures eligible for BioShield funding, and a major influx of money into the fund is needed to support this expansion. We urge you to champion a level of funding for countermeasure development that is commensurate with the magnitude of the national security threat and corresponding requirements. Sufficient, sustained funding is absolutely critical to the success of the proposed Act.

Clarity in Establishing a Central Authority

A barrier to companies with an interest in countermeasure development is the bewildering array of agencies with overlapping and conflicting authority over biosecurity. The Alliance fully supports the creation of a new central government authority with accountability, power, and resources to take ultimate responsibility for the nation's biosecurity and related programs. The establishment of the Biomedical Advanced Research and Development Agency (BARDA) within HHS could accomplish this goal. BARDA can fill a critical gap in the development of new countermeasures between the basic science discoveries supported by NIH and the procurement of finished products by BioShield.

The Alliance recommends that the decisional authority of BARDA's Director be made explicitly clear in the bill. This will ensure streamlined decision-making and a clear point of accountability within the government. It is important that BARDA's role and authority be unambiguously defined, so that it does not become just an added layer of bureaucracy in the government's countermeasure development scheme. Already, the agencies and departments involved in biosecurity to some degree include FDA, NIH, CDC, ORDC, DHS, DOD, and OMB. The current disjointed and diffuse authority over biodefense acts as a major deterrent to companies of all sizes engaging in this area.

The current bill is unclear as to BARDA's role in the countermeasure procurement process. The Alliance believes that BARDA should be given authority both to support advanced product development and to manage the procurement process, including prioritizing products to be procured. BARDA should also have the ability to coordinate with DHS and encourage timely risk assessments, which would appreciably advance biosecurity preparedness by helping to define markets and encourage a biodefense industry.

We also recommend that the qualifications of the Director of BARDA be specified in the bill or in report language. Amongst other attributes, we believe such a person must have a good understanding of medicine and vaccine research and development, clinical testing, and manufacturing processes. BARDA would be an excellent opportunity to infuse the government with expertise in the biosciences and biopharma industry. The Director and BARDA staff should have experience working with the biopharma industry, and also understand the important roles of government and academia. We recommend that the Director possess the scientific and managerial ability to identify promising projects, play a key role in prioritizing them, and help to guide them to completion. It would also be important for the Director to play a leadership role in exploring and promoting ways to greatly accelerate development timelines.

Liability Protections and Intellectual Property Rights


Respecting intellectual property and providing adequate liability protections are key in developing a framework in which industry will participate in countermeasure development. Striking the right balance on liability protection is especially important in preparedness planning for a destabilizing bioterrorist attack. For ethical reasons, most of the bioterror countermeasures will not be widely tested in humans prior to use in a national public health crisis. In the event of such a crisis, a decision could be made that thousands or even millions of people should be offered a medical countermeasure for the first time. The potential for adverse events in such a scenario is very real.

Potential liability issues must be managed and explicitly decided in advance. Many companies simply could not participate in countermeasure development without a clear and acceptable resolution of the liability issues up front. The Alliance encourages Congress to continue its important deliberations on this issue and to seek a viable resolution that will make it possible for potential contributors in the development of medical countermeasures to engage and remain in this area. In addition, government should provide fair compensation for those harmed.

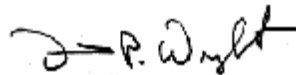
Alliance members also urge Congress to set predictable rules for the treatment of intellectual property rights. It is critical to establish fair and unambiguous guidelines for the treatment of companies' intellectual property rights in the event of a public health emergency requiring the use of medical countermeasures. Intellectual property protection is essential for industry innovation.

The Alliance for Biosecurity appreciates this opportunity to submit these comments, and we thank you again for your leadership on these issues.

Respectfully submitted on behalf of the Alliance,



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Co-Chair, Alliance for Biosecurity



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