Alliance for Biosecurity

Testimony

of

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before the

Subcommittee on Health, House Energy and Commerce Committee

"Project BioShield Reauthorization Issues"

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Mr. Chairman, Members of the Subcommittee: I welcome the opportunity to testify before you today on behalf of the Alliance for Biosecurity and commend this committee for its focus on the vital issue of biodefense and Project BioShield legislation.

I am David Wright, Co-Chair of the Alliance for Biosecurity and President and Chief Executive Officer of PharmAthene, a biotechnology company specializing in the development and commercialization of biological and chemical defense countermeasures. The Alliance for Biosecurity is a consortium that includes the Center for Biosecurity of the University of Pittsburgh Medical Center and 12 biotechnology and pharmaceutical companies committed to promoting a new era in the prevention and treatment of severe infectious diseases -- particularly those that present global security challenges -- through innovative and accelerated research, development, and production of countermeasures.

The Alliance includes companies focused on infectious disease like GlaxoSmithKline, Chiron, and Pfizer. Other member companies, such as Acambis, VaxGen, and BioPort have been successful in garnering contracts under Project BioShield and its precursor programs, while members like PharmAthene and other Alliance companies are poised to compete for new procurement contracts. We believe that based on this considerable collective experience, the Alliance is well positioned to address lessons learned from current implementation of Project BioShield and assist in the development of solutions to improve the program going forward. A list of our members appears at the conclusion of this testimony.

Project BioShield was a critical first step in demonstrating the government's commitment to biodefense. The Alliance applauds the commitment demonstrated by Congress towards this initiative as well as the hard work undertaken by government officials to implement a complex new program. Now that the foundation has been laid, the Alliance believes that more targeted action, expanded public/private partnerships, and clear and accountable leadership is needed to provide the support and incentives necessary to develop the robust biodefense industry as envisioned in the original BioShield legislation. The majority of medicines and vaccines needed to protect our citizens during an attack do not now exist, and creating a robust biodefense infrastructure and pipeline of countermeasures simply cannot be accomplished overnight. The modest number of companies now working on biodefense projects are increasingly unlikely to continue to

invest in this challenging area absent strong new biodefense legislation that supports and facilitates countermeasure development and production for our nation's Strategic National Stockpile. For these reasons, in considering the reauthorization of certain provisions under the current Project BioShield Act, we urge you to support passage of focused and strategic improvements to this critical biodefense legislation this year.

On behalf of the Alliance, I would like to discuss three key areas, which, if addressed, could significantly advance the biodefense market and the availability of critical countermeasures to protect the American people.

- **Clarity in Establishing a Central Authority**

The first issue involves clarifying who is in charge and ensuring that the responsible Government agencies understand the intricacies and challenges of drug development. Such a critical knowledge base should inform the Government's research, development and procurement decisions. Currently, there is a bewildering array of agencies with overlapping and conflicting authority over biosecurity. A biodefense structure that streamlines decision-making and identifies a clear point of accountability within the government is urgently needed. The Alliance supports a restructuring of the current process that creates a clearly identified centralized biodefense authority. The centralized authority should coordinate with NIH to identify and prioritize early countermeasure development, fund advanced development of promising countermeasures (the period

sometimes referred to as the "valley of death") and oversee all SNS procurement. This central authority could also coordinate closely with DHS on the threat assessments. It is absolutely critical that the new central authority be led and staffed by people who are knowledgeable about commercial drug development, including medicine and vaccine research and development, clinical testing, and manufacturing processes. A major influx of personnel with expertise and experience in drug development would greatly improve the central authority's ability to work quickly and efficiently with industry to acquire needed countermeasures for our nation's stockpile. Ideally, such people would also have experience with biodefense drug development and some experience with non-clinical testing under the FDA's "Animal Rule".

These changes could be accomplished through, for instance, the establishment of the proposed Biomedical Advanced Research and Development Agency (BARDA) in Senate bill 1873 if it were explicitly given clear authority, or through other administrative mechanisms.

In March, Secretary Leavitt indicated in testimony before the Senate his intention to restructure the Office of Public Health Emergency Preparedness to improve the efficiency of development and procurement of countermeasures. He expressed a willingness to work with Congress on these changes and we strongly desire and hope he

will reach out to industry as well. I emphasize that we will only be successful in this endeavor if government and industry work together in partnership. This brings me to my second recommendation:

- **Building a Partnership Between Government and Industry**

This is another critical component to revitalizing Project BioShield. The development of bioterror countermeasures is a very risky endeavor, more risky in fact than traditional pharmaceutical development for several reasons: there is only one customer – the US government, procurement funds are limited and only one, or a limited number of products per category will actually be purchased. It is, therefore, crucial that DHHS work with industry to communicate in a transparent fashion its priorities across all countermeasure targets, estimated timelines for procurement, and expected procurement quantities. We urge DHHS to actively communicate with companies and to include industry early and often in the process. We wish to closely partner with government to accomplish our nation's biodefense goals. The Alliance believes that improved information sharing and partnering between the US government and industry would result in more companies entering this market and better products that meet the government's specifications. For example, the new centralized authority could improve communication with industry by:

- *Instituting a consistent update mechanism (for example with a list serve or website) to alert industry to key activities – issuance of a new Material Threat Assessment or Determination, or an upcoming RFI, RFP or other notice.*

- *Holding an annual or biannual Advance Planning Briefing* to share information on current programs, identify new areas of interest, and seek industry partners. DOD does this routinely.

- *Allowing industry to present data on their technologies to inter-agency working groups.* The decision-making process for bioterror products is fragmented and involves many different agencies and departments. DHHS should provide an opportunity for companies with promising technologies to regularly present products to the group and engage in a discussion with working group members. These types of interactions would help industry to develop products that better meet the government's needs.

- *Allowing industry access to data on relevant animal models.* Initiating research with the appropriate animal model(s) is a key factor in the success of drug development. It is also critical in the acceptance of company data by the FDA. Unfortunately, there is no direct mechanism to establish communication/relationships with US government scientists. Allowing

communication between US government resources and companies developing products in this area will provide an opportunity for industry to more consistently design the animal studies, which are critical in determining efficacy.

- *Clearly identifying a lead/group/point of contact with specific responsibility for interfacing with industry on a daily basis.* Maintaining good relations and facilitating clear communications with an active and engaged industrial base is critical for the success of the BioShield program, now and in the future.

- **Commitment to Fund Biosecurity**

The final point I would like to address today focuses on the U.S. government's commitment to fund biosecurity. The current reserve fund of $5.6 billion established under Project BioShield, to be used over a 10-year period, is insufficient to address all but a few of the most pressing biological threats. Potential public health disasters caused by exposure to known and emerging pathogens must be viewed as a pressing national security issue. We know that the raw materials and scientific knowledge necessary to develop bioweapons are widely available. 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 do not match the threat. Further, discussions among Alliance companies and DHHS officials indicate that after only two years into the BioShield program, the paucity

of funding and limitations on how much can be spent annually is already adversely affecting the willingness or perceived ability of government staff to make procurement commitments and issue RFPs.

Industry is looking to Congress and the Administration to signal that biosecurity preparedness is a national security priority justifying a considerable commitment by the government. In order to do this, a major paradigm shift is needed in how our nation thinks about defense against bioterrorism and, at the same time, defense against emerging infectious diseases that have the potential to be significantly destabilizing.

We urge this committee 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 Project BioShield. Currently, the average chance for a drug that enters Phase I clinical trials to eventually be approved is about 8 percent; for cancer drugs, it is about 5 percent. For companies to face similar odds in developing biodefense countermeasures, it is critical for them and their investors to feel confident that the government has defined and will support a reliable market for the procurement of the countermeasures.

If additional direct funding cannot at this point be provided, we urge Congress to consider in biodefense legislation indirect incentives that could greatly increase the

number of companies prepared to invest in countermeasure development. Bioterrorism countermeasures are much like drugs intended for diseases that afflict very few people (so-called "orphan" drugs), in that neither class of medicine has a sufficient market to adequately encourage development. Congress recognized that market-based incentives such as additional marketing exclusivity could provide an efficient means of encouraging drug development when it enacted the Orphan Drugs Act, and that Act has been successful in encouraging the development of new drugs for orphan diseases. In a similar way, other forms of incentives could be explored as a means of encouraging the development of bioterrorism countermeasures. The Alliance is available to dialogue with the Subcommittee to explore such options.

In summary, if we wish to create and maintain a biodefense industry that fosters innovation and investment by the private sector, then we must heed the lessons learned from current implementation and apply new solutions to the challenges posed by such a marketplace. Developing a central authority for biosecurity, improving co-operation and communication between government and industry by forming a real partnership, and committing the necessary funding to make meaningful progress, are each practical recommendations for improvement. On behalf of the Alliance for Biosecurity and its members, I respectfully submit these recommendations for your consideration.

MEMBERS OF THE ALLIANCE FOR BIOSECURITY:

Acambis, Inc.

Caprion Pharmaceuticals, Inc.

Center for Biosecurity of the University of Pittsburgh Medical Center

Chiron Corporation

DOR BioPharma, Inc.

Dynport Vaccines Co., LLC, a CSC company

Emergent BioSolutions

GlaxoSmithKline

Human Genome Sciences, Inc.

Idenix Pharmaceuticals, Inc.

Pfizer Inc.

PharmAthene

VaxGen, Inc.