

Alliance for Biosecurity

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July 27, 2005

Senator Richard Burr, Chair
Subcommittee on Bioterrorism and Public Health Preparedness
217 Russell Senate Office Building
Washington, DC 20510

Senator Edward Kennedy, Ranking Member
Subcommittee on Bioterrorism and Public Health Preparedness
317 Russell Senate Office Building
Washington, DC 20510

Re: Alliance for Biosecurity Comments on BioShield to the Subcommittee
on Bioterrorism and Public Health Preparedness, U.S. Senate Committee
on Health, Education, Labor, and Pensions

Dear Senators Kennedy and Burr:

The Alliance for Biosecurity is a newly formed collaboration between leading biotechnology and pharmaceutical companies and the Center for Biosecurity of the University of Pittsburgh Medical Center. Our membership list is attached. 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 national and global security challenges in the 21st century. These threats include destabilizing epidemics resulting from naturally occurring disease outbreaks and deliberate terror attacks using conventional or bioengineered bioweapons.

The Alliance for Biosecurity believes that the scientific basis exists for inaugurating a new era in the prevention and treatment of infectious disease threats. Biosecurity is an achievable goal that can be reached through rational application of biological knowledge, innovative approaches to drug and vaccine research and development, and proactive public policy.

We applaud Congress's current interest in addressing biosecurity gaps through the legislative process. The Alliance seeks to be a responsible contributor to an informed dialogue on biosecurity issues. We offer these initial comments on issues pertaining to BioShield for your consideration, and we will submit further, more detailed observations on selected topics within the coming months. We will also look for future opportunities to productively engage with

Congress and the Administration on policy issues critical to biosecurity and the Alliance's mission.

Initial Observations

Bioweapons have proven to be effective, have the potential to be massively lethal, and are increasingly easy to design, manipulate, produce, and distribute. A covert bioattack against civilians, or a campaign of such attacks, could present a strategic threat to U.S. and international security.

New medicines and vaccines – and the infrastructure to sustain them -- are urgently needed to counter possible bioterrorist attacks using traditional as well as engineered agents, and to treat emerging infectious diseases that present security challenges. Ideally, medical countermeasures and the research knowledge base that supports them could be leveraged against a range of known and unknown bioagents.

The discovery and development of safe and effective medicines and vaccines is a complex, challenging, and risky endeavor that can take up to 10-15 years and can cost hundreds of millions of dollars. Currently, most pharmaceutical and biotech companies are reducing or withdrawing investments in new anti-infectives. [See Infectious Diseases Society of America Report, *Bad Bugs, No Drugs* (July 2004), pp. 14-15.] This trend is due, in part, to market forces and investor expectations, coupled with the risk and expense of research and development. The liability issues associated with medicines and vaccines that may be used on a large scale under emergency conditions are also a significant impediment to investment.

The impact of this reality on biosecurity is significant. The US capacity to respond quickly to sudden and unpredictable surges in demand for life-saving vaccines or antibiotics is limited and woefully inadequate. It is important to understand that currently there is *no* functional commercial market *demand* for medical countermeasures. Therefore, viable and predictable markets must be created in order to: (1) develop, acquire, and maintain medical countermeasures on a sustainable basis; and (2) develop medicines and vaccines for the most serious naturally-occurring infectious diseases that present security risks. In this regard, it may be useful for the government to consider lessons learned from the Department of Defense's experience developing and procuring weapon systems and medical products with no commercial market.

Both the biopharma industry and government have essential roles to play in fashioning a favorable environment for the production of these desperately needed medical countermeasures. An open and on-going dialogue between industry and government is therefore essential to ensure that the capacities and needs of all parties are understood. The Alliance provides below some initial observations and suggested solutions. Alliance members will continue to collaborate on proposed solutions, and we anticipate providing Congress with more detailed proposals in the coming months.

Proposed Solutions

Government Leadership

Government would send a meaningful signal by emphasizing that medical countermeasures are a necessary component of our national security and are urgently needed. This sense of urgency would also be communicated by establishing a central point of authority and accountability for biosecurity in the U.S. government. It is absolutely essential to have one political appointee/department have the clear authority, power, and resources to take ultimate responsibility for the nation's biosecurity and related programs. Currently, there are many individuals across government with some degree of accountability for biodefense, but there is no leader with a mandate from Congress or the President to oversee and coordinate the country's biodefense efforts. A successful biodefense process must be built on leadership and improved coordination among agencies and departments overseeing these programs, especially NIH, HHS, and DHS. We urge Congress to address this pivotal issue.

It is also critical for government programs intended to support the development and procurement of medicine and vaccine countermeasures to be expertly and adequately funded, staffed, and managed. The complex technical, scientific, and drug development issues presented by countermeasure development programs would benefit from emphasizing the value of technical expertise in government oversight

Viable Markets for Medical Countermeasures

In order to create a stable and viable market for medical countermeasures, the government should, to the maximum extent possible:

- § Identify the threats. Government threat assessments are a critical-path component of countermeasure market identification. Alliance members appreciate that the threat assessment process, by its very nature, is a challenging, complex, and imprecise endeavor. Government may wish to evaluate the current process and consider whether (1) there are acceptable ways to accelerate the process in order to provide companies more lead-time to respond to identified threats through investment in R&D; and (2) whether the current process can adequately identify "21st century" threats in addition to currently known pathogens/bioweapons. It is important to recognize that potent, novel pathogens –both naturally occurring and deliberately engineered – also pose great risk to national and global security.
- § Define and guarantee the minimum market. Government should clearly articulate the types and specific amounts of medicine and vaccine countermeasures that it intends to acquire as early as possible in the process. Understandably, government predictions of needs will not always be accurate. But, at the same time, it is important to acknowledge the fact that industry responds best to certainty and predictability.
- § Maintain a transparent and predictable process. Clear timelines, deadlines, and deliverables must be established for both industry and government throughout the research, development, and procurement process.

- § Provide explicit liability protection and fair compensation. For ethical reasons, many medical countermeasures will never be tested in humans, and may first be used by children, adults, and the elderly only in the wake of a bioterror attack or other public health crisis. The potential for adverse events in such a scenario is very real. Potential liability issues must be managed and decided in advance to cover researchers, healthcare workers, and manufacturers in the event of the mass use of medical countermeasures in public health emergencies. In addition, government should provide for fair compensation for those harmed.
- § 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.
- § Consider other fair measures that will make the market for medical countermeasures an attractive one, such that companies will be induced to compete. Significant measures are necessary to stimulate aggressive industry innovation and engagement in medical countermeasure research and development. Identifying and guaranteeing markets may not be sufficient to encourage a sustained commitment to countermeasure development by biopharma companies. Therefore, it is important to consider novel measures to inspire a new focus by companies in this critical area.

Distribution and Usage of Medical Countermeasures

In creating a market for medical countermeasures, it is vital to understand and acknowledge the emergency conditions under which these types of medicines and vaccines could be needed and used by healthcare workers and the public in the future. In the event of a bioterrorist attack, medical need by those affected or at risk will be immediate. It may be necessary under such conditions to provide mass administration of vaccines and/or medicines that have not yet been approved by regulatory health authorities or proven safe and effective in humans. Government should plan now for this type of public health emergency by developing ethical, responsible, and fair guidelines that will govern how medicine and vaccine countermeasures will be distributed. For instance, government should undertake efforts to communicate emergency use plans to local health departments and frontline providers, and consider ways to facilitate development of realistic implementation activities.

Effective Research and Development

Increased scientific collaboration between companies and between industry and government is essential to accelerating development of much needed medicine and vaccine countermeasures. For its part, industry should explore opportunities to appropriately collaborate and share information in a pre-competitive fashion in order to improve the science and technology foundation applicable to countermeasure development.

Sustainable and long-term biosecurity policy also must include an effective government strategy for encouraging the development of technologies, tools, and countermeasures for infectious diseases and future agents (e.g., emerging pathogens and bioengineered agents)

that present security threats. At every critical juncture during the process that begins with early discovery through the actual stockpiling of a medical countermeasure, industry and government should partner responsibly and actively look for opportunities to accelerate and facilitate the process.

Sufficient funding and support for mid and late-stage development programs are particularly important. Most government funding now goes to supporting basic research and early-stage development. Attention to the critical mid and late-stages of research will significantly improve the current gap in financial and programmatic support that now hampers medical countermeasure development (commonly referred to as the "Valley of Death").

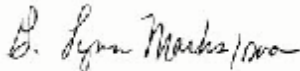
Realistic Levels of Commitment

The 2004 BioShield legislation set aside approximately \$5.6 billion through the year 2013 for the procurement of medical countermeasures. Approximately \$1 billion of the fund has been committed for the procurement of three countermeasures to date. According to a 2000 Defense Science Board study, countermeasures could be needed for at least 19 agents considered to be major threats. Clearly, the remaining BioShield funds will be insufficient for this purpose. (See Attachment A)

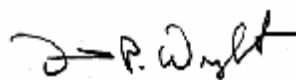
Achieving acceptable biosecurity at acceptable costs will require a new strategy and a major national commitment. The level and sustainability of funding for the nation's medical countermeasures and underlying infrastructure must be commensurate with the government's threat assessment of the challenges presented. The government's calculation of the realistic scope of this biosecurity endeavor should be made soon, in order to most effectively deploy the resources made available.

The Alliance for Biosecurity greatly appreciates this opportunity to submit these comments to the Subcommittee on Bioterrorism and Public Health Preparedness and looks forward to engaging in continued dialogue on this national security issue in the future.

Sincerely,



G. Lynn Marks, MD
Senior Vice President, Infectious Diseases
GlaxoSmithKline
Co-Chair, Alliance for Biosecurity



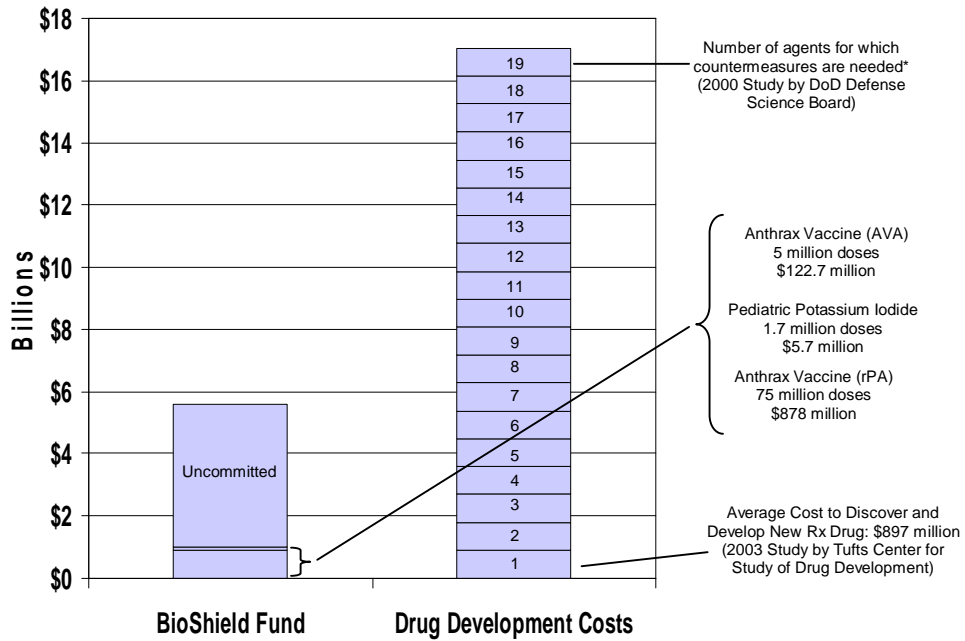
David P. Wright
President and CEO, PharmAthene
Co-Chair, Alliance for Biosecurity

cc: Senator Michael Enzi
Senator Bill Frist
Senator Joe Lieberman

Senator Judd Gregg
Senator Orrin Hatch

Attachment A

Biosecurity Costs



*Note: If each agent requires the development of 1 diagnostic + 1 vaccine + 1 therapeutic, then a total of 57 countermeasures would be necessary

Alliance for Biosecurity

Current Membership

4 Center for Biosecurity of the University of Pittsburgh Medical Center

The Center for Biosecurity is a not-for-profit group that works to catalyze advances in science and governance in order to diminish the threat of destabilizing epidemics – be they intentional or natural – and to lessen the illness, death, and civil disruption that would result if prevention efforts fail. The Center provides independent, critical research and analyses for decision-makers in government, national security, bioscience, medicine, and public health.

4 BioPharma Industry Members:

Acambis, Inc.

Caprion Pharmaceuticals, Inc.

DOR BioPharma, Inc.

Dynport Vaccines Co., LLC.

Emergent Biosolutions

GlaxoSmithKline

Human Genome Sciences, Inc.

ID Biomedical Corporation

Idenix Pharmaceuticals, Inc.

Pfizer Inc.

PharmAthene

VaxGen, Inc.

Leadership:

Lynn G. Marks, MD, *Co-Chair of the Alliance Board of Directors*
Senior Vice President, Infectious Diseases, GlaxoSmithKline

David P. Wright, *Co-Chair of the Alliance Board of Directors*
President and CEO, PharmAthene

Tara O'Toole, M.D., M.P.H., *Strategic Director*
Center for Biosecurity of the University of Pittsburgh Medical Center