

Alliance for Biosecurity

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August 30, 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 Additional 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 appreciative of this opportunity to submit additional comments to the Subcommittee on issues pertaining to BioShield for your consideration. The Alliance submitted initial comments to you on July 27, 2005. As described in that letter, 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. These threats include destabilizing epidemics resulting from naturally occurring disease outbreaks and deliberate terror attacks using naturally occurring pathogens or agents deliberately engineered for increased virulence.

We look forward to discussing these comments with you and to providing additional information and suggestions to Congress and the Administration on policy issues critical to biosecurity.

Executive Summary

- Ø A new Biosecurity Partnership is needed. Industry, both biotechnology and pharmaceutical companies, academia and government must all participate to ensure our biosecurity.

- Ø There is an urgent need to centralize authority and accountability for biosecurity within the US government.
- Ø A final resolution of the liability issue must be achieved.
- Ø Appropriate incentives must be provided to spur development of medical countermeasures, including both countermeasures that are likely to be purchased only by the government and those for which alternative commercial markets exist.
- Ø Better communication between government and its partners is required.

Call for a New Biosecurity Partnership

Our nation is not prepared to respond to national security threats resulting from either bioterror attacks or destabilizing infectious disease outbreaks. Noteworthy investments have been made by the government and by industry to bolster US defenses against a bioterror attack. (Indeed, good work is being done by the NIH to support basic research into pathogens that could present bioterrorism threats.) However, the piecemeal initiatives and investments made to date lack a coordinated and focused national security imperative necessary to accomplish the goal of preparing our nation in a timely way with effective defenses and a plan to deploy them. New medicines and vaccines are urgently needed, yet a market for medical countermeasures does not exist, and very few biopharma companies can take the significant risks required to invest in biodefense products in the current environment.

A public-private partnership is desperately needed to usher in a new, functional era for medical countermeasure research, development and procurement. Government, academia, large pharmaceutical companies, and innovative biotechnology companies each have crucial roles to play in this partnership. A collective call to action, increased communication and coordination, and a commitment to reform are indispensable components of a biosecurity partnership. Alliance members believe that such a concerted effort can be very successful – not only in providing targeted vaccines and medicines to our Strategic National Stockpile in the near term, but also in creating an enduring scientific framework and infrastructure that will support countermeasure development for unknown threats in our future. The respective assets of biotechnology and pharmaceutical companies (briefly described below) must be leveraged and supported to achieve this vision. In addition, as with all highly ambitious national goals that are difficult to achieve, government must exert significant leadership.

We urge Congress to construct a “BioShield II” package that provides the grounds for this new partnership by establishing a holistic framework for biosecurity. This framework should be characterized by a central point of authority and accountability in the government that is empowered to define the government market for medical countermeasures and work with industry to accelerate and support development of needed vaccines and medicines. Passing a BioShield II bill that merely adds uncoordinated elements/incentives in a “laundry list” fashion without adequate funding will not purposefully advance a sophisticated biosecurity defense for our nation. Alliance members stand ready to work with Congress and the Administration on this ambitious goal of forging a new public-private biosecurity partnership.

Role of Industry

The countermeasure development area is still seen by most companies as risky, cumbersome and uncertain from a regulatory perspective, and highly speculative financially. There is principally only one customer (the US federal government), procurement funds are limited, and only one or a limited number of products per category are expected to actually be purchased. Private equity sources therefore cannot be easily enticed by the prospect of higher financial returns when asked to invest in this high-risk area. The development pathway for biodefense products is not straightforward, especially for those medicines and vaccines that must be tested using the FDA's Animal Rule. There is a shortage of animal models acceptable to the FDA, and the process for development of new models is unclear. Short and long-term opportunity costs related to diversion of human and capital resources also deter corporate investment, as well as uncertainty about the size and sustainability of the market for countermeasures.

It is commonly understood that only a small selection of biotech companies and very few large pharma companies have active R&D programs for medical countermeasures. The Alliance believes that the unique strengths of *both* biotech and pharma companies must be harnessed and deployed to accomplish biosecurity preparedness for the nation. The efforts of the biopharma industry should complement and advance the basic research sponsored by NIH and DOD and undertaken by many academic researchers.

The participation of both the biotech and pharmaceutical industries in medical countermeasure development is more likely to lead to the successful and timely procurement of medicines and vaccines for the Strategic National Stockpile than if only one of these industry groups are involved. Small and mid-sized biotech companies are often adept at discovering platform technologies and novel drugs. Many choose to specialize in niche areas, some even choosing to focus on the development of specific technologies and techniques rather than specific drugs. However, generally biotechs have limited access to capital and less experience in developing and producing products. Large pharma companies typically have more research and development resources, are more familiar with the federal regulatory process, have a proven track record in moving products through development to licensure, and have the capacity and infrastructure to produce large quantities of medicines and vaccines. However, the opportunity costs of developing medical countermeasures are higher for big pharma, and the liability risks are also greater.

Both government and industry must think creatively to steer industry's capabilities and energy to this critical national security area and to usher in a new, exceptional level of collaboration between industry, government, and research academia. In our initial July 27th letter to you, Alliance members broadly outlined key barriers to achieving this goal and offered suggestions for improving and streamlining research, development and procurement of medical countermeasures. We provide below additional suggestions for (1) initiatives to bolster industry/government collaboration in this area and (2) potential BioShield II provisions that could serve to incentivize industry and advance work in this area.

It is also important for industry and government to partner and explore alternative, innovative ways to streamline and transform traditional research and development models,

thereby decreasing costs and timelines currently required for R&D. It should be a national goal to radically accelerate medical countermeasure discovery, development, and production. Significantly accelerated drug development could lead to decreased health care costs overall (through preventing or decreasing morbidity and mortality), an improved ability to defend against unanticipated, bioengineered threats, and an increase in R&D for medicines that treat a broad spectrum of infectious disease threats – both natural and the result of bioterrorism. While there are some existing efforts underway to address the overarching problem that product discovery and development is increasingly challenging and costly, Alliance members will focus specifically on medical countermeasure R&D and consider ways of harnessing the assets and talents of multiple companies and government in this important national venture.

Need for Increased Communication & Collaboration

There are significant initiatives that industry and government should consider implementing now, many of which may not require additional legislation. The Alliance would be happy to discuss these further with Congress and government officials. Each of these initiatives is aimed at supporting a new public-private partnership by increasing the communication and collaboration between government and industry. Examples of potential initiatives include:

- § Institute a consistent mechanism at DHHS (e.g., a list-serve or website) to alert industry to key activities and developments, such as the issuance of an upcoming Request for Information (RFI), Request for Proposal (RFP), or other notice. Other agencies do this effectively. For example, NIH often contacts interested parties by e-mail or phone if a relevant notice is released or upcoming. DOD staff also will alert interested parties prior to the issuance of a relevant notice.
- § Hold annual or biannual “advance planning briefings” at DHHS. Each year DOD holds planning briefings for industry and other interested partners where the department provides information on the current systems and programs, identifies new areas of interest, and seeks industry partners. Program managers give presentations about department needs and then meet with interested companies one-on-one.
- § Allow industry to present data on their technologies to inter-agency working groups. The decision-making process for biodefense products is fragmented and involves many different agencies and departments. It is difficult for companies to identify all of the parties involved and present information or seek guidance. DHHS could provide an opportunity for companies with promising technologies to regularly engage in discussions with working group members. These types of interactions would help industry to develop medicines and vaccines that better meet the government’s needs.
- § Increase appropriate communication between industry and government. Industry communication should not be limited to written responses to RFIs or RFPs. Appropriate prohibitions on the discussion of products under review should be maintained, but discussion related to products that are not under review could be allowed. Company input during the pre-requirements and requirements phase should be encouraged to inform the requirements development process.
- § Encourage involvement of industry scientists and others with explicit expertise in the development and production of vaccines and medicines in the review of NIH contracts

and grants related to development projects. This would result in the funding of better designed projects, leading to higher degrees of success.

- § Allow industry access to data on relevant animal models. Developing acceptable animal models is a key factor in the success of medical countermeasure development and is critical to the acceptance of company data by the FDA. Currently, each company is proceeding with its own interpretation of the published literature; this could lead to inconsistencies in study design and, ultimately, more difficulty in evaluating the potential of one medicine versus another. Promoting open communications on animal models would provide opportunities for industry to more consistently and effectively design successful animal studies to determine the efficacy of medicines/vaccines. A number of agencies and departments are involved in animal model development (including, to varying degrees, FDA, NIH, CDC, and DOD). DHHS could take the lead in establishing a mechanism to work more closely with industry, particularly for countermeasures identified in RFPs for which there are no current animal models.

While improvement on the above issues absent new BioShield legislation would not be sufficient, we believe these changes are critical to ensuring a vibrant biodefense market. The Committee on Health, Education, Labor and Pensions, as part of its responsibility for oversight of Project BioShield implementation, can play an important role in advocating these changes.

Government Leadership

In our letter to you on July 27, the Alliance emphasized the urgent need to centralize authority and accountability for biosecurity within the US government. The current institutional fragmentation poses significant problems of coordination and eroding responsibilities, resulting in duplication of work and overall delays in medical countermeasure research and development. A number of agencies and departments are involved in the medical countermeasure requirements process, including DHHS, DHS, DOD, OMB, and many others. The current process is too complicated and cumbersome, and it is unclear who or which department has ultimate decision-making authority. It is absolutely critical for this process to be streamlined.

A central point of authority within the government with responsibility for managing advance product development and acquisition of medical countermeasures will promote a long-term, comprehensive, and successful strategy for our nation's biosecurity needs. It is critical to have careful coordination of the efforts of the various government entities so that activities are efficient and complementary, rather than duplicative or incompatible. Centralizing authority could be accomplished through a variety of means. One approach would be to empower an existing government agency or department, giving it cross-organizational authority. Another option would be to create and empower a new institutional entity, although this may be more difficult to accomplish.

The attributes of an effective central authority for countermeasure development would include, among other things:

- § A mission-directed focus. That is, the authority must determine future biodefense capabilities and then drive the research, development, and acquisition decisions;
- § A commitment to regularly and directly interact with and communicate with industry;

- § The ability to conduct vulnerabilities-based risk assessments that identify broad national needs for new countermeasures and for improving the overall drug development process (as opposed to threat-based risk assessments that only define narrow needs to counter specific pathogens);
- § Access to threat assessments and a close relationship with DHS;
- § The ability to define and guarantee a government market for medical countermeasures;
- § An understanding of medical countermeasure R&D;
- § An understanding of the public health infrastructure;
- § A sophisticated understanding of the functions of all participants in the process (e.g., NIH, FDA, DHS, DHHS, industry, etc.);
- § The scientific and managerial ability to identify promising development projects, prioritize them, and assist in their successful completion; and
- § The ability to coordinate with other parts of the government in order to explore and promote ways to accelerate the development timelines for medicines and vaccines targeting all infectious diseases.

Success of a new central authority would be dependent upon providing adequate resources – both financial and technical. For instance, it will require a significant number of technically skilled full-time employees with license to pursue high-risk/high-yield projects. Accomplishing this single (if ambitious) task would go a long way toward resolving a number of major, recurring, and preventable problems with the current biosecurity infrastructure.

Final Resolution of the Liability Issue

Liability exposure associated with the development and production of medical countermeasures acts as a strong disincentive for industry and delays procurement contracting. Indeed for many large pharmaceutical companies, resolving the liability issue is a prerequisite to investment in the biodefense area. For many countermeasures, efficacy studies in humans cannot be ethically conducted because they would involve administering a potentially lethal or disabling toxic substance to healthy volunteers. Moreover, absent large scale clinical trials, direct adverse events and adverse drug interactions may go unnoticed. Further complicating matters, distinguishing the drug side-effect profile from the pathology of the biological agent can be difficult. Finally, because medical countermeasures may be widely distributed at one time, widespread, contemporaneous side-effects may occur before a manufacturer has the opportunity to modify the drug's labeling to warn against certain drug interactions or caution use in select subpopulations. Even with these risks, government may need to supply large numbers of citizens with these countermeasures in the event of an attack or destabilizing epidemic in the US. Existing liability protections are inadequate to address these concerns.¹

¹ Under P.L. 85-804 and Executive Order 10789, as amended, agency heads may agree to indemnify contractors engaged in "unusually hazardous" activities when it would facilitate national defense. However, such indemnification will only be granted upon the award of a procurement contract – companies do not know when responding to RFPs (and in conducting R&D prior to the awarding of a contract) whether indemnification will be provided. Moreover, the agencies have interpreted "national

The Alliance supports liability protections like those suggested by Senator Gregg in S.1437 and Senators Lieberman, Hatch, and Brownback in S.975. These bills would substitute the government as a defendant in liability suits involving medical countermeasures. As we stated in our previous submission, the Alliance strongly supports fair compensation for those harmed. We encourage Congress to consider this issue further and revise existing proposals, as necessary.

Liability protections like those proposed would simplify and expedite the BioShield contracting process for both the acquisition agency and manufacturers. As Dr. Phillip Russell, former acting Director of the Office of Research and Development Coordination within the DHHS Office of the Assistant Secretary for Public Health Emergency Preparedness, has noted in prior testimony², the inability of the acquisition agency to provide assurance of liability protection at the initiation of a contract is a strong disincentive to many companies and a burden on others. Current processes for securing protection are slow and expensive. A clear, certain, and upfront resolution of the liability issue would remove a major barrier to companies that might otherwise be interested in medical countermeasure development.

Incentives

In our previous submission, we commented that the current level of funding for countermeasure research and development is insufficient. The level of funding for achieving biosecurity should be commensurate with the government's assessment of the threat the country faces. There have been a number of proposals offered to incentivize the development of countermeasures. Some of these proposals focus on spurring private investment while others rely on increased support and oversight by government. There may not be a "one-size-fits-all" solution to encourage companies to invest in biodefense R&D. A mix of direct and indirect incentives may ultimately be required to encourage broad industry participation.

Government Support

An effective biodefense strategy requires ensuring that companies have adequate resources to bring promising drug candidates from mid and late-stage development through FDA approval. Below we outline problems with the current funding process and discuss several options that have been proposed as solutions.

defense" narrowly, resulting in disqualification of products for use against pandemics. Where indemnification is provided, contractors are generally required to first exhaust private insurance before being reimbursed by the government. The Safety Act (Homeland Security Act of 2002, P.L. No. 107-296, Title VIII, Subtitle G, §§ 861-865) provides liability protection for any product designated by the Secretary of DHS as a "qualified anti-terrorism technology." However, the Safety Act does not address potential liability of manufacturers for products that may be used prior to a terrorist attack, such as vaccines; it requires manufacturers to assert Safety Act protection as an *affirmative defense*; and coverage is determined on a product-by-product basis and involves a lengthy qualification process that requires demonstration of prior use and effectiveness, which may be inapplicable to medical countermeasures used for the first time in a public health emergency.

² Testimony before the Subcommittee on Bioterrorism and Public Health Preparedness, Hearing on "Crossing the Valley of Death: Bringing Promising Medical Countermeasures to Bioshield," June 9, 2005.

Need for Earlier Market Definition

Project BioShield was landmark legislation, signaling the government's interest in creating a biodefense industry. However, there remains much uncertainty as to the size and scope of the market, leading to difficulties for companies in obtaining investment capital. It can be particularly difficult for companies to obtain sufficient capital to fund research and development during the period from identification of drug candidates to the time that a drug becomes eligible for procurement under a BioShield contract. For products that have no commercial market potential, during this period private investors not only face the risk that product development will fail, but the additional risk that even if product development is successful, there will ultimately be no market, public or private, for the product.

To address this problem, the Alliance has previously commented on the need for the government to (i) accelerate the process of conducting threat assessments, and (ii) clearly articulate the types and specific amounts of medicine and vaccine countermeasures that it intends to acquire as early as possible. We understand that DHS is currently conducting a formal risk assessment of a broad set of biological agents to help prioritize the nation's biodefense activities. We encourage the government to translate these risks as early as possible into defined medical countermeasure requirements.

Advanced Development Funding

For many companies, the current BioShield payment scheme is not practical. It relies on companies being able to obtain adequate funding from private investors, who are often reluctant to fund biodefense research. While a BioShield contract gives investors added confidence that there will ultimately be a buyer for the product if it is successfully developed, biodefense research is uniquely challenging and investors still face many uncertainties. As a result, access to capital can be a significant problem for smaller companies. This can result in promising new vaccine and therapeutic drug candidates prematurely losing funding.

The Project BioShield Act authorizes up to 10% of contract amounts to be paid out prior to product delivery. These funds could be used to support milestone or progress payments to companies that have received a contract to supply product to the Strategic National Stockpile. This would aid smaller companies in completing costly advanced development work and scale up requirements. Unfortunately, to date DHHS has not chosen to utilize this authority. The Alliance requests that forthcoming legislation or guidance identify more specific criteria for application of Project BioShield's 10% provision.

Another more systematic approach to the funding problem would be to authorize a new program to support advanced development and production activities occurring after a product moves out of the basic research and very early development phases and loses eligibility for NIH funding. These activities could be managed by the new central point of authority for biodefense countermeasure development discussed earlier. Such a program could take the form of competitive contracts offered to several companies to achieve the first milestone, with subsequent milestone contracts awarded to the company(ies) that successfully completes the first milestone and that presents the best proposal for next steps. The timing and amount of milestone or progress payments would be determined based on mutually agreed upon deliverables as set forth in the contract. Funds would need to be separately appropriated for

these activities. By providing direct funding to companies during these challenging development steps, there would be greater assurance of final product delivery.

While this type of program would help alleviate some risk and uncertainty in the development process, it would result in the government bearing greater risk of R&D failure.

Private Market Incentives

Some Alliance members prefer the flexibility that a privately funded investment approach offers. Several proposals have been offered to incentivize countermeasure development through private investment that minimize the transfer of R&D risks to the government.

Wild Card Patent Extension

Under S.975, a company that successfully develops a countermeasure under a BioShield contract could receive an extension of up to two years on any patent owned or licensed by that company at the time it entered into the contract (“wild card patent extension”). A company would be eligible for this incentive only if its countermeasure is considered superior to existing products and contains a new active ingredient (known as a “new molecular entity”). Under S.975, the countermeasure would need to be approved by the FDA, and the requirements of the procurement contract fulfilled. The Secretary of DHHS would be given discretion to determine whether to award wild card patent extension and its precise duration after considering such factors as the importance of the countermeasure in question, the difficulty, risk, and expense associated with its development, and the impact of the extension on the public.³

The wild card option has been proposed as one option to encourage the development of countermeasures that have little commercial market potential. The process required to research and develop medicines is costly, lengthy, and risky. A typical medicine candidate takes 10 to 15 years from discovery in the laboratory to approval by the FDA. The industry estimates that only one of 5,000 to 10,000 compounds initially screened will become an approved drug. The costs of bringing a new drug from laboratory concept through approval has been estimated by some to be as high as \$800 million when both direct and capital costs are included. (*Joseph A. DiMasi et al., The Price of Innovation: New Estimates of Drug Development Costs, 22 J. Health Econ.*

³ There has been much confusion as to whether wild card patent extension could be awarded to a company that defines as a “countermeasure” existing medicines products that treat only minor side-effects of other countermeasures. This confusion stems from the definition of “security countermeasure” under the Project BioShield Act. Under the Act, BioShield funds can be used to purchase a “security countermeasure,” which includes any drug, biological product, or device to treat, identify, or prevent harm from any biological, chemical, radiological, or nuclear agent that has been identified as a material threat, or to treat, identify, or prevent harm from a condition that may result in adverse health consequences or death and may be caused by administering such a drug, biological product or device. While entering into a BioShield contract is one criterion under S.975 for becoming eligible for wild card patent extension, as noted above, the countermeasure must be considered superior to existing products and contain a new molecular entity. Thus, a company could not receive a wild card extension for an existing drug or a new drug that offers no benefit over existing treatments.

151 (2003)). These costs are of the same magnitude whether the drug is intended to serve, for example, 2 million people or 200 million people.

The Alliance believes that the wild card option would indeed be effective in encouraging pharmaceutical and biotech companies to actively engage in countermeasure research and development. It would signal to companies that countermeasure R&D is truly a national priority requiring the commitment of resources. However, we also recognize that this approach would shift biodefense costs onto private healthcare payors. The Alliance believes that achieving biosecurity should not come at the expense of any one group, and it would be preferable for the government to pay directly for medical countermeasures. However, there are currently no indications that this direct, significant investment will be made.

Government must be realistic about what it expects to achieve through the existing limited BioShield procurement fund. Should Congress decide that some form of the wild card option is preferable to the government itself making the significant investment in this area that is necessary, additional refinements to the current proposal may be needed to address concerns that have been raised. Alliance members would be happy to offer suggestions as to how this could be achieved.

Patent Restoration

Patent restoration has been proposed as another mechanism for incentivizing the development of countermeasures. Under existing law, one patent per drug product is eligible for an extension that is equal to one-half of the time spent in preapproval clinical trials, plus the whole of the time spent awaiting FDA approval, minus any time that the applicant did not seek product approval with due diligence. The extension is capped at five years. Under the proposals S.3 and S.975, a company that successfully develops a countermeasure under a BioShield contract could receive full restoration of the time spent in preapproval clinical trials as opposed to the half allowed under current law. The proposal implicitly relies on capitalization and opportunity costs, as well as the advantages of being first to market, to ensure that companies expeditiously seek product approval.

The Alliance believes that the patent restoration option would be effective in incentivizing the development of drugs that otherwise have commercial market potential. For instance, providing full patent restoration would encourage research and development into broad spectrum antibiotics and antivirals. It would have less of an effect with respect to development of countermeasures that are purchased once for stockpiling but otherwise are not purchased by the general public or repurchased by the government unless the stockpile becomes depleted.

The government should make clear that BioShield funds can be used to purchase products that otherwise have commercial market potential. Currently, in determining whether BioShield funds should be used to purchase a countermeasure, the Secretary of DHHS is required to consider whether there is a significant commercial market for the product. This is interpreted by some as suggesting that such products have less chance of being purchased by the government. Yet, as we noted in our previous comments, most pharmaceutical and biotech companies are reducing or withdrawing investments in new anti-infectives. Broad-spectrum anti-infectives hold the greatest potential for use against a newly engineered biological agent or

naturally occurring disease outbreak, and BioShield funds should be available for their procurement.

Other Incentives

Providing incentives for further research on existing products is another option that has been proposed to make countermeasures available as quickly as possible. Such incentives could be modeled on existing mechanisms for encouraging drug research and development, such as data exclusivity, pediatric exclusivity, and orphan drug exclusivity. For instance, pediatric exclusivity has been used successfully to encourage pediatric research on existing drugs for adults. Pediatric exclusivity provides innovators an additional six months of exclusive marketing in exchange for conducting clinical investigations in pediatric populations. The Alliance believes that a comparable mechanism would be effective in encouraging biodefense research on existing drugs.

Conclusion

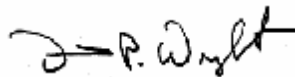
We hope that the comments contained in this letter are useful in your important deliberations on a BioShield II bill. We have focused these comments only on certain issues, and we urge you to read these comments in conjunction with our prior submission on 27 July. It is worth reiterating the central importance of forming a functional partnership between industry and government to achieve our nation's biosecurity goals. A centralized authority within the government that can define and communicate its medical countermeasure needs and support and communicate with industry throughout the process would greatly advance our joint work in this area.

The Alliance for Biosecurity 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

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Senator Lamar Alexander
Senator Jeff Bingaman
Senator Mike DeWine
Senator Chris Dodd
Senator John Ensign
Senator Michael Enzi
Senator Bill Frist
Senator Judd Gregg
Senator Tom Harkin
Senator Orrin Hatch
Senator Patty Murray
Senator Barbara Mikulski
Senator Jack Reed
Senator Pat Roberts

Senator Sam Brownback

Senator Joe Lieberman

Representative Joe Barton, Chair, House Committee on Energy and Commerce

Representative John Dingell, Ranking Member, House Committee on Energy and Commerce

Representative Bennie Thompson, Ranking Member, House Homeland Security Committee

Majority Staff Director, House Homeland Security Committee

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Boris D. Lushniak, Assistant Commissioner for Counterterrorism Policy, FDA

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Benjamin Petro, Director of the Knowledge Integration Program Office, Science and Technology Directorate, DHS

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Rajeev Venkayya, Director for Health and Biodefense, Homeland Security Council, Executive Office of the President

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

Alliance for Biosecurity

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 Vaccine Co. LLC, a CSC Company

Emergent Biosolutions

GlaxoSmithKline

Human Genome Sciences, Inc.

ID Biomedical Corporation

Idenix Pharmaceuticals, Inc.

Pfizer Inc.

PharmAthene

VaxGen, Inc.

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