

## **The Pandemic and All-Hazards Preparedness Act (S. 3678) Passes United States Senate By Unanimous Consent; House Action Now Required By Week's End**

The anthrax attacks that occurred in Florida, New York and the Senate killed five people, crippled the mail delivery system, and cost more than a billion dollars to clean up. These attacks remind us that biological weapons are a real threat and we need to be prepared. Further, as we brace for a possible global pandemic that could result in deaths that could exceed a nuclear attack or a world war, preparedness measures need to be taken and instituted in order to protect the public.

Toward this end, the bipartisan Pandemic and All-Hazards Preparedness Act (S. 3678) which passed the Senate last evening by unanimous consent, builds on what Project BioShield started by providing additional research funds and accelerating the medical countermeasures development cycle which is a positive and necessary step for all interested parties - manufacturers, government and the general public. This legislation is needed to foster countermeasure product development.

Most significantly, the Bill creates the Biomedical Advanced Research and Development Authority (BARDA) within the Department of Health and Human Services. BARDA would have the funding and authority to enter into contracts to support advanced research and development and to support innovation of countermeasures. This bill is needed to ensure the country is prepared and authorities can act quickly to save lives.

Through BARDA, contracts and grants for advanced research and development will be made to companies working on products to protect the American people. The passage of the BARDA bill is a significant step forward in the effort to ensure the US is prepared to properly address public health threats, from bioterrorism to infectious disease.

Some important points of the bill include:

- BARDA is given the authority to directly invest in medical countermeasure advanced research and development to bridge the "valley of death" - which refers to the period between early-stage research and final product development - where most products fail. Currently, many promising countermeasures are not making it through the 'valley of death' and thus, never reach the point of eligibility for procurement by Project BioShield. This procurement is essential to many medical countermeasures as the government

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is the sole customer of such products. The BARDA bill authorizes over a billion dollars for advanced research and development over 2007 and 2008.

- BARDA addresses a number of critical functions involving our nations' public health infrastructure and capacity to handle a sudden surge in medical care needs. It goes a long way to ensure better coordination and accountability at all levels of government - from the state and local health departments to Secretary Leavitt at HHS.
- BARDA will receive good development and procurement advice - the act would establish a National Biodefense Science Board to bring industry and government together to provide expert advice to the Secretary on current and future trends and advances in biological and life sciences, biotechnology, and genetic engineering. It will also identify new technologies that counter bioterrorism attacks or infectious diseases. Additionally, the act permits collaboration and consultation with agency leaders, academia and industry on countermeasure development, manufacturing and distribution.
- BARDA promotes innovation to reduce the time and cost of medical countermeasure development. The Defense Advanced Research Projects Agency (DARPA), most well known for creating the Internet, has had tremendous success in a similar role.

The BARDA bill will allow industry and government the opportunity to work in a more effective and efficient manner. Government will be better able to address the needs and the concerns of the industry through BARDA and the National Biodefense Science Board as a result of the new channels of communication that will be created. A mechanism will be fashioned whereby industry and government will be able to be in constant contact on current trends, global health issues and national concerns. In turn industry will be better protected through the "valley of death."

This legislation has strong bipartisan support, led by Senator Burr and was passed overwhelmingly in the HELP Committee, with support from the Ranking Member, Senator Ted Kennedy. Fourteen of the 20 Senators that sit on the HELP Committee co-sponsored the bill, which provides good indication of the support that the bill enjoys. Action is now required by the House of Representatives, which plans to adjourn Friday. Congressman Mike Rogers (R-MI), along with Congresswoman Anna Eshoo (D-CA) have introduced a companion bill that passed the house in September.

MLA contributed significantly with assisting Congress to draft this bill. MLA is ahead of the curve and stands ready - once the bill passes - to work with manufacturers to navigate BARDA and to be awarded support for advanced countermeasure development.

Please call your House Member to urge immediate passage of S. 3678 at (202) 225-3121 to ensure this critical bill becomes a law before Congress adjourns.

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