



Biodefense Industry Group (BIG): The Portal for Enhanced Commercial Involvement in the Emerging Biodefense Industry

A Call for Participation and Advocacy

What: President Bush, during his 2003 State of the Union Address, proposed that Congress enact legislation to establish **Project BioShield** ("the Act") to accelerate the research, development, purchase, and availability of countermeasures to protect the nation against chemical and biological terrorism.

Our Involvement: McKenna Long & Aldridge LLP **significantly impacted** key provisions of the BioShield statute and **testified before Congress** about BioShield on behalf of the pharmaceutical and biotech industries.

We Need Your Help: We are seeking your help in the next phase of this important project. **BIG has already kick-started efforts** to develop the all-important regulations to ensure full and effective implementation of BioShield, allowing us to further define and strengthen the statutory language of the Act. **We believe industry should have an active voice** in suggesting and defining the framework for these regulations. Areas ripe for regulatory clarification and strengthening include:


- The need for a detailed description of the process for procurement of countermeasures, including the scope of "pressing need" and "mission of Project BioShield."
- The nature of the government's commitment to recommend funding "upon first development" of a countermeasure and determining whether the countermeasure will be priced prior to development.
- The scope of the use of research and development "linkage" to guaranteed procurement contracts as stated in the committee report language.
- The scope of the use of "other transaction" authority for procurement under the Act.

We expect the regulatory process to begin immediately. **PLEASE CONTACT US BY EMAIL OR TELEPHONE**, indicating your interest and willingness to participate in this dynamic coalition of companies, contractors, and research institutions, whose purpose is to develop and implement a strategy for influencing the regulatory implementation of the Act.

BIG members will split fees and expenses equally. While you may be a member of various trade associations, these entities may or may not decide to address this topic and if they do, may not do so in a coordinated manner and with the deep knowledge we have on the subject matter. We believe that the BIG coalition will provide the singularity of purpose and focus necessary to ensure that the implementing regulations accomplish the statutory intent and language of the Act.

**McKenna Long
& Aldridge**^{LLP}
Attorneys at Law
1900 K Street, NW
Washington, DC 20006


Frank M. Rapoport
McKenna Long & Aldridge
(202) 496-7406
frapoort@mckennalong.com


John M. Clerici
McKenna Long & Aldridge
(202) 496-7574
jclerici@mckennalong.com

"Project BioShield authorizes \$5.6 billion over 10 years for the government to purchase and stockpile vaccines and drugs to fight anthrax, smallpox and other potential agents of bioterror ... [P]rivate industry plays a vital role in our biodefense efforts by taking risks to bring new treatments to the market, and we appreciate those efforts."

George W. Bush, July 21, 2004



Project BioShield Act of 2002

Historical and Legal Abstract

During his 2003 State of the Union Address, President Bush proposed that Congress enact legislation to establish Project BioShield to stimulate the development of countermeasures to protect against chemical and biological terrorism. In response to this call, the Senate passed the Project BioShield Act of 2004 (“Project BioShield” or “the Act”) on May 19, 2004, and the House likewise adopted the Senate’s bill on July 15, 2004. The President signed the bill into law on July 21, 2004.

The BioShield statute is applicable to entities engaging in biodefense research and development activities, as well as manufacturing and supplying the countermeasures themselves. McKenna Long & Aldridge LLP significantly impacted key provisions of the statute and testified before Congress about BioShield on behalf of the pharmaceutical and biotech industries. In addition to reporting to you on this Act, we seek your help in the next phase – developing the all-important regulations to ensure full and effective implementation of the Project BioShield Act.

The Act has a clear purpose: to accelerate the research, development, purchase, and availability of countermeasures to combat bioterrorism threats that could cause public health emergencies affecting national security. BioShield has three tools in promoting commercial involvement in biodefense. Specifically, the Act:

- Provides the Secretary of the Department of Health and Human Services (“HHS”) with streamlined authorities to promote the research and development of drugs and other products needed to protect Americans in the event of a bioterrorist attack;
- Authorizes the procurement of biomedical countermeasures for the nation's stockpile using a special reserve fund; and
- Provides that in the event of a national emergency, the government is authorized to make available new and promising treatments prior to approval by the Food and Drug Administration (“FDA”).

The legislation specifically calls for the Secretary to adopt regulations in several critical areas as set forth below. Specifically, the subsection of the Act entitled “Procurement” states that “[t]he Secretary shall be responsible for...promulgating such regulations as the Secretary determines necessary to implement the provisions of this subsection.” *S. 15, 319F-2(c)(7)(C)(II)*. We believe industry should have an active voice in suggesting and defining the framework for these regulations.

ATMOSPHERIC CONDITIONS LEADING TO THE ACT

The anthrax attacks in the fall of 2001 underscored the nation's vulnerability to biological terrorism. Five people were killed by those attacks and thousands required antibiotic treatment. If there had not been effective medical countermeasures for this strain of anthrax, the death toll probably would have been higher. However, effective countermeasures do not exist for many of the biological threats deemed most dangerous by the Centers for Disease Control and Prevention. For example, botulinum toxin, plague, tularemia, and many viral hemorrhagic fevers ("VHFs") lack licensed vaccines, while smallpox and VHFs lack any specific treatments. Accordingly, HHS and the Bush Administration recognized the need for better vaccines for anthrax and smallpox and better treatments for anthrax, plague, and botulism.

The purpose of Project BioShield is to incentivize more companies from the commercial marketplace to enter the government market. While recent decades have yielded rapid progress in the treatment of many serious naturally occurring diseases, many countermeasures for potential agents of terrorism, including smallpox, anthrax, botulinum toxin, ebola and the plague, have no market other than the government and, therefore, have not generated significant commercial interest.

The most significant obstacle facing commercial involvement in the development and production of biological countermeasures has been the lack of a guaranteed market for such products. In light of these concerns and conditions, our firm worked with pharmaceutical companies (large and small) to draft and redraft legislative language that would guarantee the acquisition of developed countermeasures, as well as remove many of the obstacles to streamlined acquisition. This legislation became known as the Project BioShield Act.

KEY PROVISIONS OF THE ACT

There are two key sections of the Act: Section 2 (Countermeasure Research and Development Activities) and Section 3 (Biomedical Countermeasure Procurement). Under the Act, the Secretaries of HHS and Department of Homeland Security ("DHS") are charged with acquisition of research and development property and services, as well as biomedical countermeasures.

Section 2 defines qualified countermeasure as

[A] drug, biological product or device...to treat, identify, or prevent harm from any biological, chemical, radiological, or nuclear agent that may cause a public health emergency affecting national security.

S. 15, § 319F-1(a)(2)

Under this Section, the Act provides the HHS Secretary with enhanced procurement authorities to perform, administer, or support biomedical countermeasure research and development:

- Simplified acquisition threshold is increased to \$25 million for purchase of property or services for countermeasure research and development upon a determination by the Secretary of HHS that there is a pressing need and that the mission of Project BioShield would be impaired without such a limitation; and
- Expanded use of other than full and open competition procedures for acquisition of property or services for countermeasure research and development.

