

## President Bush Signs Project BioShield Act into Law – BioShield II Now on the Drawing Board

On July 21, 2004, President Bush signed the Project BioShield Act of 2004 (“BioShield”) into law. According to the President, “By authorizing unprecedented funding providing new capabilities, Project BioShield will help America purchase, develop and deploy cutting-edge defenses against catastrophic [bioterror] attack.”

This *Homeland Security Bulletin* briefly summarizes the BioShield Act of 2004 and prospects for “BioShield II” – proposed legislation that is meant to build on the strengths of BioShield I. It also describes the formation of the Biodefense Industry Group to monitor and shape BioShield’s implementing regulations.

### In This Issue:

- [Project BioShield Act of 2004](#)
- [Looking to the Future: BioShield II](#)
- [Next Steps: Developing Implementing Regulations](#)

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## Project BioShield Act of 2004

BioShield originated in the President’s State of the Union Address in January 2003. It derives from the events of September 11 -- as well as the October 2001 anthrax attacks -- and from the concern that the pharmaceutical industry and the U.S. government historically have not worked together to address the threat of bioterrorism and public health emergencies caused by biological, chemical, radiological, or nuclear (BCRN) agents.

The purpose of BioShield is to accelerate the research, development, purchase, and availability of countermeasures to combat bioterrorist or BCRN threats that could cause public health emergencies affecting national security. While recent decades have yielded rapid progress in the treatment of many serious naturally occurring diseases, many countermeasures for potential agents of terrorism have no market other than the government and, therefore, have not generated significant commercial interest.

BioShield makes three significant strides in alleviating the lack of commercial involvement in biological countermeasure development:

- It 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.
- It authorizes the procurement of biomedical countermeasures for the nation's stockpile using a special reserve fund and fully funds the effort with \$5.6 billion over the next 10 years.
- It 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”). Although this final provision permits some relaxation of the FDA approval process, Congressional testimony notes that its use should be limited to dire circumstances.

### ▶ **BioShield Funding**

BioShield amends the Public Health Service Act (“PHSA”) to authorize appropriations of up to \$5.6 billion for fiscal year 2004 through 2013 for procurement of certain security countermeasures (drugs, devices, and biological products to treat, identify, and prevent the public health consequences of terrorism). Of this amount, \$890 million is available in fiscal year 2004 and \$2.5 billion will be available in fiscal year 2005, with the remainder to be available during fiscal year 2006 through 2013. Funding to buy these security countermeasures is provided to the Department of Homeland Security (“DHS”), but the HHS is tasked with procuring and stockpiling the countermeasures.

### ▶ **Government Guarantees of Production Contracts**

BioShield erects a bridge to connect the ability of the government to spend research and development funds under the existing National Institutes of Health budget and HHS's willingness to pay for production contracts under Project BioShield. Prior to the passage of BioShield, large pharmaceuticals indicated unwillingness to take on a governmental research and development contract in the absence of some guarantee of a production contract in the event their R&D efforts turned out to be successful. Considering these companies have a variety of profitable opportunities they could pursue, attracting them to develop and manufacture our nation's needed biodefense measures will require some assurance of a return on the investment they will make during the R&D stage of a given project. BioShield begins the process that is meant to give them that protection by allowing HHS to link R&D funding with guaranteed production contracts.

### ▶ **Acquisition Process for Security Countermeasures**

Under BioShield, the Bush Administration plans to acquire and maintain stockpiles of seven security countermeasures to combat five biological agents. Based on existing science and a current assessment of potential threats to public health, the five agents are:

- Smallpox
- Anthrax
- Botulinum toxin
- Plague
- Ebola

## Looking to the Future: BioShield II

Legislation to improve upon and expand BioShield is already in the works. The so-called “BioShield II” aims to resolve liability issues in the original BioShield legislation, clarify intellectual property protection, and enable more funding.

### ▶ Improving Liability Protection

Efforts are under way to improve liability protection for developers of bioterror products. Two tools used to protect contractors from liability are Public Law 85-804 and the SAFETY Act. P.L. 85-804 provides executive authority to the Secretaries of DHS and HHS to grant federal indemnification to products or services that are necessary for national security. However, P.L. 85-804 is difficult to obtain since it requires the Federal government to serve as a back-stop to an entity’s private insurance.

The SAFETY Act (“the Act”) is a provision in the Homeland Security Act of 2002 that provides liability protection to DHS-approved products or services. The Act specifically provides protection for technologies that allegedly fail in the event of a terrorist attack. However, the Act’s liability protections may not be triggered in the absence of a terrorist attack. Thus, vaccines deployed prior to an attack and other potential medical countermeasures administered to first responders prior to entering a potentially contaminated environment fall into a “gap” in the SAFETY Act. Three solutions have been proposed to solve this dilemma:

- Congress could amend the SAFETY Act to permit coverage in the situation of a possible terrorist attack.
- Congress could extend to HHS the authority to indemnify and/or immunize suppliers of biodefense vaccines along the lines of similar authorities available to protect suppliers of smallpox vaccines.
- DHS Secretary Tom Ridge could declare that, due to the anthrax attacks in 2001, an act of terrorism has already occurred as understood under the SAFETY Act.

BioShield II proposes to resolve the dilemmas inherent in P.L. 85-804 and the SAFETY Act by protecting developers of biodefense products by providing adequate tort protections to companies that provide these critical items. A number of legislators in both the House and Senate, including Senators Lieberman, Hatch, and Gregg and Congressmen Davis, Weldon, Dix, and Andrews, are expected to support BioShield II legislation that would protect private organizations engaged in research and development and production of biomedical countermeasures.

## Next Steps: Developing BioShield’s Implementing Regulations

Regulations are now needed to ensure full and effective implementation of BioShield. A number of areas are ripe for clarification and strengthening, including:

- 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 BioShield.

### ▶ **The Biodefense Industry Group (BIG)**

HHS will begin the process of drafting implementing regulations for BioShield immediately. To ensure enhanced biodefense industry involvement in the process, McKenna Long & Aldridge LLP (MLA) has formed the Biodefense Industry Group (BIG). MLA successfully established a similar coalition to help shape the regulations for the SAFETY Act, a provision of the Homeland Security Act of 2004. For more information, please visit <http://www.mckennalong.com/attachment.html/articles/991/BIG+-+Letter+and+Abstract.pdf>. Should you have any questions about these issues or are interested in participating in the BIG’s work, please contact either [Frank Rapoport](#) at (202) 496-7406 or [John Clerici](#) at (202) 496-7574.

[↗ Back to top](#)

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