



No. 67

May 19, 2004

## S. 15 – The Project BioShield Act of 2004

Calendar No. 53

*Reported by the Senate Committee on Health, Education, Labor, and Pensions (HELP) with an amendment in the nature of a substitute, 21 to 0, on March 25, 2003. No written report.*

### NOTEWORTHY

- Under a unanimous consent agreement, following the conclusion of Morning Business, the Senate will consider S. 15 with two hours of debate, equally divided. The only amendment in order will be a Gregg/Kennedy substitute containing revisions to the measure as agreed to. This Notice describes the Gregg/Kennedy substitute.
- During his State of the Union Address in 2003, President Bush announced the Project BioShield initiative as a comprehensive effort to develop and make available modern, effective drugs and vaccines to protect against attack by biological and chemical weapons or other dangerous pathogens.
- Project BioShield was introduced on March 11, 2003 by HELP Committee Chairman Gregg as part of S. 15 – a larger measure that also compensated individuals injured by the smallpox vaccine and contained clarifications to the current Vaccine Injury Compensation Program. Congress addressed those provisions earlier last year. The Gregg/Kennedy substitute only focuses on Project BioShield.
- The House passed its version of Project BioShield (H.R. 2122) in July of last year. Meanwhile, the Department of Homeland Security (DHS) Appropriations Act, 2004 [P.L. 108-90] appropriated \$5.593 billion for FY2004-FY2013 for “necessary expenses for securing medical countermeasures against biological terror attacks.”
- Under the unanimous consent agreement, the managers’ substitute includes the required authorizing language to expend the \$5.593 billion as appropriated.

---

## HIGHLIGHTS

---

- The managers' substitute amends the Public Health Service Act to give the Secretary of Health and Human Services the new authority to conduct and support research and development for "countermeasures" (which include drugs, biological products, and devices) against biological, chemical, radiological, and nuclear agents, as prioritized by the Secretary of Homeland Security (DHS) and Secretary of Health and Human Services (HHS).
- The legislation authorizes the use of (already appropriated) federal funding to help spur development of such countermeasures. A special fund will be created specifically for the procurement of necessary countermeasures, but procurement is permitted only if the Secretaries of DHS and HHS jointly recommend such purchase to the President. The authorized amount is \$5.593 billion, the amount which already was appropriated for biodefense countermeasures in the Department of Homeland Security Appropriations Act for FY04 [P.L. 108-90].
- The legislation also grants the Food and Drug Administration "emergency use authorization," so that the agency may permit certain treatments in an emergency even if the agency had not yet approved the products for general use. The authorization is granted only if alternative treatments are not available. It also requires a finding by the Secretary of HHS, based on expert analysis, that the benefits of a proposed treatment outweigh any known risks.
- Finally, the managers' amendment transfers overall responsibility for the Strategic National Stockpile to HHS. The Department will maintain the Stockpile in coordination with the DHS.

---

## BACKGROUND

---

Once the medical community has been able to detect that a bioterror attack has occurred, it must be able to quickly initiate a full-scale response. One key aspect to assuring a proper response is Project BioShield, which was proposed by President Bush during his State of the Union Address in 2003. This is a comprehensive effort to develop and make available modern effective drugs and vaccines to protect against and treat attacks from biological and chemical weapons or other dangerous pathogens. The President demonstrated his commitment to the effort in saying, "The

budget I send you will propose almost \$6 billion to quickly make available effective vaccines and treatments against agents like anthrax, botulinum toxin, Ebola, and plague. We must assume that our enemies would use these diseases as weapons, and we must act before the dangers are upon us.”

Since 1999, HHS, in conjunction with the National Institutes of Health (NIH), Centers for Disease Control and Prevention (CDC), and the Food and Drug Administration (FDA), has been involved in developing and improving its bioterror detection and response capabilities. This includes: prevention of bioterrorism; surveillance of infectious disease; medical and public health readiness for mass casualty events; research and development of new drugs and devices; improved infrastructure for information technology systems; and enhanced capabilities of the Strategic National Stockpile.

Congress has lent its support for these functions by providing new funding and greater flexibility to meet such goals with the passage of the “Public Health Security and Bioterrorism Preparedness and Response Act of 2002,” signed into law on June 12, 2002 [P.L. 107-188]; and The Homeland Security Act of 2002, signed on November 25, 2002 [P.L. 107-296]. While these measures bolster the nation’s ability to respond effectively to bioterrorist threats, additional assistance is needed to spur the actual development, research, and procurement of countermeasures.

A CDC assessment issued in February of 2002 determined that smallpox, anthrax, plague, botulism, tularemia, and Ebola present the greatest “potential for adverse public health impact with mass casualties, and require broad-based public health preparedness efforts (e.g., improved surveillance, laboratory diagnosis, and stockpiling of specific medications).” Yet today, the need for reliable countermeasures exceeds current vaccination capability. As medical science advances, it is clear that, in addition to vaccines, other countermeasures, such as devices, drugs, and antitoxins, need to be made available. This task is complicated by the fact that only a limited number of vendors actually manufacture such treatments. Given that such manufacturing is a highly specialized process that requires an extensive infrastructure, it is critical to support those vendors currently involved in this market and to create incentives for new vendors to enter this field.

---

## **BILL PROVISIONS**

---

Under the unanimous consent agreement, the managers’ substitute amends the Public Health Service Act to create a new section concerning biomedical countermeasure research and development.

## **Section One**

Cites the Act as the Project BioShield Act of 2004.

## **Section Two**

Amends Part B of title III of the Public Health Service Act, giving the Secretary of HHS new countermeasure research and development authorities. This includes expedited procurement, peer review, and contracting processes while following appropriate internal controls. In conducting a procurement, special attention is given to those countermeasures developed from only one responsible source. In addition, the Secretary is given authority to hire up to 30 professional and technical employees at NIH not subject to otherwise applicable personnel procedures and pay limitations, but subject to certain merit systems and nondiscrimination provisions of law.

## **Section Three**

Overall responsibility for the Strategic National Stockpile is transferred to HHS, which will maintain the Stockpile in coordination with DHS.

A special fund is authorized for the procurement of countermeasures (drugs, biological products, and devices) against biological, chemical, radiological, and nuclear agents. The total authorization is \$5.593 billion, the amount appropriated for biodefense countermeasures in the DHS Appropriations Act for FY04 (P.L. 108-90). Money from this fund can be used to procure a countermeasure if (a) DHS determines that a particular agent is a material threat against the U.S. population sufficient to affect national security; (b) HHS determines that the countermeasure is necessary; and (c) either the countermeasure is FDA-approved or the Secretary determines, based on existing data, that it is reasonably likely to be approved within eight years. (Alternatively, the fund can be used to procure a countermeasure that is subject to an emergency use authorization under section 4 of the bill.) The fund may be used to procure such a countermeasure only if DHS and HHS jointly recommend such use to the President, and the President approves the recommendation. (If DHS and HHS determine that a countermeasure is appropriate but is unavailable, they may, subject to Presidential approval, issue a call for development of such a countermeasure and commit themselves to recommending procurement of it if it is developed.)

Section three stipulates that of the \$5.593 billion appropriated over 10 years, \$3.4 billion may not be exceeded during FY 2004-2008. And, of that amount, funding may not exceed \$890 million during FY 2004.

## **Section Four**

Amends Chapter V of the Federal Food, Drug and Cosmetic Act to authorize the Secretary of HHS to introduce into interstate commerce a drug, biological product, or device intended for use in an actual or potential emergency if the product is not FDA-approved, or if it is approved but

for a different use. The emergency declaration is only permitted if the agent can cause a serious or life-threatening condition, there is no alternative product available, and that the benefits of use outweigh the risks. The declaration is set to expire after the threat has ceased or one year after the date on which the declaration is made (renewal exceptions are authorized pending application and notification procedures).

### **Section Five**

Requires annual reports to Congress from HHS regarding particular exercises of authority. Section five also requests a General Accounting Office report within four years after date of enactment, describing the authorized activities, identifying any procurement that would have been prohibited, and assessing the adequacy of internal controls for procurement needs.

### **Section Six**

Requires the Secretary of HHS to develop outreach activities to ensure that ethnically diverse institutions are aware of available research and development grants, contracts, cooperative agreements, and procurements.

### **Section Seven**

Requires federal inter-agency consultation to determine whether the countermeasure involved in grants or cooperative agreements is subject to existing export-related controls.

### **Section Eight**

Designates an Agency Coordination Officer to ensure that the activities of all specified Departments complement and do not unnecessarily duplicate other programs.

### **Section Nine**

Waives certain Medicaid and Medicare requirements, specifically the Emergency Medical Treatment and Labor Act (EMTALA), under emergency circumstances necessary for the direction or relocation of individuals in need of medical screening pursuant to a State emergency preparedness plan.

---

## **ADMINISTRATION POSITION**

---

At press time, the Administration had not released its Statement of Administration Policy, but the Administration is expected to support the passage of the managers' substitute. On March 25, the White House issued a fact sheet supporting legislation for Project BioShield to "ensure

resources are available to pay for ‘next-generation’ medical countermeasures.”

---

## **COST**

---

No cost estimate for the managers’ substitute is available from the Congressional Budget Office. However, the Department of Homeland Security (DHS) Appropriations Act of 2004 [P.L. 108-90] appropriated \$5.593 billion for FY2004-2013 for “necessary expenses for securing medical countermeasures against biological terror attacks.” Section three of the managers’ substitute provides the corresponding authorization for this appropriation.

---

## **POSSIBLE AMENDMENTS**

---

The only amendment made in order is a managers’ amendment, as described in the section-by-section analysis.