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Project BioShield Act of 2004

Congress: 108 (2003–2005, Ended)

Chamber: Senate

Policy Area: Health

Introduced: Mar 11, 2003

Current Status: Became Public Law No: 108-276.

Latest Action: Became Public Law No: 108-276. (Jul 21, 2004)

Law: 108-276 (Enacted Jul 21, 2004)

Official Text: https://www.congress.gov/bill/108th-congress/senate-bill/15

Sponsor

Name: Sen. Gregg, Judd [R-NH]

Party: Republican • State: NH • Chamber: Senate

Cosponsors (11 total)

Cosponsor	Party / State	Role	Date Joined
Sen. Alexander, Lamar [R-TN]	R · TN		Mar 11, 2003
Sen. Enzi, Michael B. [R-WY]	R · WY		Mar 11, 2003
Sen. Frist, William H. [R-TN]	R · TN		Mar 11, 2003
Sen. Graham, Lindsey [R-SC]	R · SC		Mar 11, 2003
Sen. Roberts, Pat [R-KS]	R · KS		Mar 11, 2003
Sen. Sessions, Jeff [R-AL]	R · AL		Mar 11, 2003
Sen. Warner, John [R-VA]	R · VA		Mar 11, 2003
Sen. Bond, Christopher S. [R-MO]	R · MO		Mar 12, 2003
Sen. Inhofe, James M. [R-OK]	R · OK		Mar 19, 2003
Sen. Stevens, Ted [R-AK]	R · AK		Mar 25, 2003
Sen. Fitzgerald, Peter [R-IL]	R · IL		Apr 9, 2003

Committee Activity

Committee	Chamber	Activity	Date
Health, Education, Labor, and Pensions Committee	Senate	Reported By	Mar 25, 2003

Subjects & Policy Tags

Policy Area:

Health

Related Bills

Bill	Relationship	Last Action
108 HR 2122	Companion bill	Jul 17, 2003: Received in the Senate. Read twice. Placed on Senate Legislative Calendar under General Orders. Calendar No. 214.

(This measure has not been amended since it was passed by the Senate on May 19, 2004. The summary of that version is repeated here.)

Project BioShield Act of 2004 - (Sec. 2) Amends the Public Health Service Act to authorize the Secretary of Health and Human Services (the Secretary) to: (1) conduct and support research and development activities regarding qualified countermeasures (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), including by entering into interagency agreements for research and development; and (2) provide that biocontaminant laboratories and specialized research facilities under such agreements shall be available to the Secretary to respond to public health emergencies affecting national security.

Allows the Secretary to expedite procurement to respond to pressing research and development needs by: (1) using simplified procurement procedures for products and services that cost more than the simplified acquisition threshold; (2) allowing other than full and open competition in certain instances; (3) increasing the micropurchase threshold to allow the Secretary to use those procedures; and (4) limiting review of the Secretary's procurement decisions.

Allows the Secretary to employ other procedures to respond to pressing qualified countermeasure research and development needs, including expediting peer review procedures in certain instances, contracting with experts or consultants, and appointing professional and technical employees to positions at the National Institutes of Health.

Requires that appropriate internal controls be instituted for the authority given to the Secretary under this section.

Amends the Public Health Service Act to allow the Director of the National Institutes of Health to act through the Director of the National Institute of Allergy and Infectious Diseases (NIAID) to provide grants for the modernization and construction of biomedical and behavioral research facilities. Increases the Federal share of such NIAID-funded projects.

Authorizes appropriations for the National Vaccine Program for FY 2004 and 2005.

Adds the Secretary of Homeland Security to the working group on the prevention, preparedness, and response to bioterrorism and other public health emergencies.

(Sec. 3) Amends the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 to direct the Secretary to: (1) coordinate with the Secretary of Homeland Security to maintain the Strategic National Stockpile (a stockpile of drugs, vaccines, and medical devices and supplies to provide for the emergency health security of the United States in the event of a bioterrorist attack or other public health emergency); (2) deploy the Stockpile to respond to an actual or potential emergency as required by the Secretary of Homeland Security; and (3) deploy the Stockpile to respond to an actual or potential public health emergency or other situation in which deployment is necessary to protect the public health or safety.

Allows security countermeasures to be procured using the special reserve fund (a biodefense countermeasures appropriations account set up pursuant to this Act). Defines "security countermeasure" as a countermeasure that is either authorized for emergency use or that the Secretary determines is a priority, is necessary, and is an approved drug or a drug reasonably likely to be approved within eight years.

Provides that in order for a countermeasure to be procured using the special reserve fund: (1) the Secretary of Homeland

Security must identify a chemical, biological, radiological or nuclear agent as a material threat to the U.S. population sufficient to affect national security; (2) the Secretary must determine that a countermeasure is necessary to protect the public health; (3) the Secretary must assess the availability and appropriateness of the countermeasure to address the identified material threat; (4) the Secretary of Homeland Security and the Secretary must jointly submit to the President a proposal to issue a call for the development of needed countermeasures that are either not available or cleared only for alternative purposes; (5) the Secretaries must make a commitment that they will recommend that the special reserve fund be made available for the procurement of such a countermeasure; (6) the President must approve the proposal; (7) the Secretaries must make specified information known to persons who may respond to a call for the countermeasure involved, including the specifications of the needed countermeasure; (8) the Secretary must determine which countermeasures can appropriately be procured using the special reserve fund by considering the quantities needed, the feasibility of producing and delivering such a quantity within eight years, and the lack of a commercial market; (9) the Secretaries and the Director of the Office of Management Budget must submit to the President a recommendation that the special reserve fund be used to procure the countermeasure; and (10) the President must approve the recommendation. Requires the Secretary and the Secretary of Homeland Security to notify designated congressional committees promptly that a material threat has been identified for which countermeasures are necessary to protect the public health and that the President has approved a recommendation for countermeasure procurement using the special reserve fund.

Amends the Homeland Security Act to change the responsibilities of the Secretary of Homeland Security as they relate to the Stockpile.

Authorizes appropriations: (1) for FY 2004 through 2013 for the special reserve fund to procure security countermeasures approved by the President; (2) for FY 2004 through 2006 for the hiring of personnel to carry out terror threat assessments; and (3) for the acquisition and deployment of secure intelligence-sharing facilities. Transfers the functions, personnel, assets, unexpended balances, and liabilities of the Stockpile from the Secretary of Homeland Security to the Secretary.

(Sec. 4) Amends the Federal Food, Drug, and Cosmetic Act to allow the Secretary to authorize the introduction into interstate commerce of a drug, device, or biological product intended for emergency use, specifically allowing the use of unapproved products, or the unapproved use of approved products, upon: (1) a determination by the Secretary of Homeland Security that there is a domestic emergency, or a significant potential for a domestic emergency, involving a heightened risk of attack with a specified biological, chemical, radiological, or nuclear agent; or (2) a determination by the Secretary of a public health emergency that affects, or has a significant potential to affect, national security and that involves a specified biological, chemical, radiological, or nuclear agent or a specified disease or condition that may be attributable to such agent. (Current law allows the Secretary to authorize the use of such emergency products only upon a determination by the Secretary of Defense of a military emergency involving a heightened risk to U.S. forces of an attack.)

Amends the National Defense Authorization Act for Fiscal Year 2004 to continue provisions governing the emergency use of products with respect to members of the Armed Forces.

(Sec. 5) Requires the Secretary of Health and Human Services to report to Congress on the exercise of authority under this Act and on additional barriers to the procurement of security countermeasures.

Requires the Comptroller General to: (1) review the Secretary's use of the authorities granted under this Act and make recommendations to improve the utilization or effectiveness of such authorities; (2) assess the adequacy of the internal

controls instituted by the Secretary and make recommendations to improve their effectiveness; (3) identify any purchases or procurements that would not have been made or that would have been significantly delayed without the authorities provided to the Secretary; (4) determine to what extent authorized activities under this Act have enhanced the development of biomedical countermeasures affecting national security and recommend improvements; (5) assess the availability of countermeasures to address threats identified by the Secretary of Homeland Security; (6) assess the extent to which programs and activities under this Act will reduce any gap between the threat and the availability of countermeasures to an acceptable level of risk; and (7) assess the threats to national security posed by technology that will enable the development of antibiotic resistant, mutated, or bioengineered strains of biological agents and recommend strategies for addressing such threats.

Requires the Secretary and the Secretary of Homeland Security to report jointly on where there is a lack of adequate large scale biocontaminant facilities necessary for the testing of security countermeasures in accordance with Food and Drug Administration requirements.

(Sec. 6) Directs the Secretary to ensure that diverse institutions, including Historically Black Colleges and Universities and those serving large proportions of underrepresented populations, are meaningfully aware of available research and development grants, contracts, cooperative agreements, and procurements conducted under this Act.

(Sec. 7) Requires the Secretary to determine whether the countermeasures being developed are subject to existing export-related controls and, if not, recommend to appropriate Federal agencies that such countermeasures should be on the list of controlled items subject to such controls.

(Sec. 8) Directs the Secretary, the Secretary of Homeland Security, and the Secretary of Defense to ensure that the activities of their respective Departments coordinate, complement, and do not unnecessarily duplicate programs designed to protect the homeland from biological, chemical, radiological, and nuclear agents. Directs such Secretaries to each appoint an official to coordinate such programs for their respective Departments.

(Sec. 9) Amends title 11 of the Social Security Act to allow the Secretary to waive certain requirements during emergencies, including: (1) requirements pertaining to direction or reallocation of an individual to receive medical screening in an alternate location pursuant to an appropriate State emergency preparedness plan; and (2) sanctions for noncompliance with specified requirements of the Health Insurance Portability and Accountability Act of 1996.

Actions Timeline

- **Jul 21, 2004:** Signed by President.
- **Jul 21, 2004:** Signed by President.
- **Jul 21, 2004:** Became Public Law No: 108-276.
- **Jul 21, 2004:** Became Public Law No: 108-276.
- **Jul 16, 2004:** Presented to President.
- **Jul 16, 2004:** Presented to President.
- **Jul 14, 2004:** Consideration initiated by previous order of the House.
- **Jul 14, 2004:** Considered by a previous order of the House. (consideration: CR H5721-5741)
- **Jul 14, 2004:** DEBATE - Pursuant to a previous order, the House proceeded with ninety minutes of debate on S. 15.
- **Jul 14, 2004:** The previous question was ordered pursuant to a previous order of the House. (consideration: CR H5740)
- **Jul 14, 2004:** Passed/agreed to in House: On passage Passed by the Yeas and Nays: 414 - 2 (Roll no. 376).(text: CR H5721-5729)
- **Jul 14, 2004:** On passage Passed by the Yeas and Nays: 414 - 2 (Roll no. 376). (text: CR H5721-5729)
- **Jul 14, 2004:** Motion to reconsider laid on the table Agreed to without objection.
- **May 20, 2004:** Received in the House.
- **May 20, 2004:** Message on Senate action sent to the House.
- **May 20, 2004:** Held at the desk.
- **May 19, 2004:** Measure laid before Senate by unanimous consent. (consideration: CR S5744-5767; text of measure as reported in Senate: CR S5744-5760)
- **May 19, 2004:** The committee substitute as amended agreed to by Unanimous Consent.
- **May 19, 2004:** Passed/agreed to in Senate: Passed Senate with an amendment and an amendment to the Title by Yea-Nay Vote. 99 - 0. Record Vote Number: 99.
- **May 19, 2004:** Passed Senate with an amendment and an amendment to the Title by Yea-Nay Vote. 99 - 0. Record Vote Number: 99.
- **Mar 27, 2003:** Star Print ordered on the reported bill.
- **Mar 25, 2003:** Committee on Health, Education, Labor, and Pensions. Reported by Senator Gregg with an amendment in the nature of a substitute. Without written report.
- **Mar 25, 2003:** Committee on Health, Education, Labor, and Pensions. Reported by Senator Gregg with an amendment in the nature of a substitute. Without written report.
- **Mar 25, 2003:** Placed on Senate Legislative Calendar under General Orders. Calendar No. 53.
- **Mar 19, 2003:** Committee on Health, Education, Labor, and Pensions. Ordered to be reported with an amendment in the nature of a substitute favorably.
- **Mar 11, 2003:** Introduced in Senate
- **Mar 11, 2003:** Read twice and referred to the Committee on Health, Education, Labor, and Pensions.