S 1873

Biodefense and Pandemic Vaccine and Drug Development Act of 2005

Congress: 109 (2005–2007, Ended)
Chamber: Senate
Policy Area: Health
Introduced: Oct 17, 2005
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Sponsor

Name: Sen. Burr, Richard [R-NC]
Party: Republican • **State:** NC • **Chamber:** Senate

Cosponsors (5 total)

Cosponsor	Party / State	Role	Date Joined
Sen. Alexander, Lamar [R-TN]	R · TN		Oct 17, 2005
Sen. Enzi, Michael B. [R-WY]	R · WY		Oct 17, 2005
Sen. Frist, William H. [R-TN]	R · TN		Oct 17, 2005
Sen. Gregg, Judd [R-NH]	R · NH		Oct 17, 2005
Sen. Dole, Elizabeth [R-NC]	R · NC		Oct 19, 2005

Committee Activity

Committee	Chamber	Activity	Date
Health, Education, Labor, and Pensions Committee	Senate	Reported By	Oct 24, 2005

Subjects & Policy Tags

Policy Area:

Health

Related Bills

Bill	Relationship	Last Action
109 HR 5533	Related bill	**Nov 13, 2006:** Read twice and referred to the Committee on Health, Education, Labor, and Pensions.

Summary (as of Oct 24, 2005)

Biodefense and Pandemic Vaccine and Drug Development Act of 2005 - (Sec. 3) Amends the Public Health Service Act to establish the Biomedical Advanced Research and Development Agency (BARDA) within the Department of Health and Human Services (HHS) to coordinate and oversee activities that support and accelerate advanced research and development of qualified countermeasures to exposure to hazardous agents or infectious diseases or qualified pandemic or epidemic products.

Requires the Secretary of HHS, acting through the Director of BARDA, to: (1) increase appropriate communication between the federal government and relevant industries, academia, and other persons; (2) conduct continuous searches and support calls for potential countermeasures or products for drugs, biological products, devices, or research tools to diagnose, mitigate, prevent, or treat harm from existing, emerging or possible chemical, biological, radiological, and nuclear agents or potential pandemic infectious diseases that threaten public health and national security; (3) direct the countermeasure and advanced research and development of HHS; (4) award contracts, grants, cooperative agreements, and enter into other transactions to support the cost of such research and development and to ensure accelerated development of countermeasures and products; (5) establish an office within BARDA to facilitate regular and ongoing communication between BARDA and the Food and Drug Administration (FDA) regarding the status of BARDA advanced research and development activities; and (6) coordinate with the FDA to facilitate regulatory review and approval of promising classes of countermeasures or products through the development of research tools.

Allows the Secretary, acting through the Director, to award contracts, grants, cooperative agreements or enter into other transactions to promote innovation in technologies supporting the advanced research and development and production of qualified or security countermeasures or qualified pandemic or epidemic products.

Allows the Director to submit to the President and Congress an annual budget estimate for qualified countermeasure and pandemic or epidemic product advanced research and development and other BARDA activities.

Allows the Secretary, acting through the Director, to: (1) support advanced research and development and innovation of potential countermeasures or products by highly qualified persons outside the United States; and (2) establish one or more federally funded research and development centers or university affiliated research centers.

Allows the Director to: (1) give priority to supporting and facilitating advanced research and development of countermeasures or products, and formulations of countermeasures or products, that are likely to be safe and effective for pediatric populations, pregnant women, and other vulnerable populations; and (2) establish working groups to identify innovative technologies that have the potential to be developed as countermeasures or products and to advise the Director on functions.

Requires the Director to establish and convene a Vulnerable Populations Working Group composed of experts on pediatric populations, pregnant women, and other vulnerable populations to advise the Director regarding countermeasures effects on such populations.

Establishes the National Biodefense Advisory Board to provide expert advice and guidance to the Secretary on the threats, challenges, and opportunities presented by advances in biological and life sciences and the threat from natural infectious diseases and chemical, biological, radiological, and nuclear agents.

Establishes the Biodefense Medical Countermeasure Development Fund to be administered by the Director.

(Sec. 4) Revises the definition of qualified countermeasure to include "research tool" which means the full range of tools and systems that assist in the discovery, development, or manufacture of drugs, biological products, or devices.

(Sec. 5) Amends the Federal Food, Drug, and Cosmetic Act (FFDCA) to extend the period of market exclusivity for designated countermeasure products from seven years to ten years.

(Sec. 6) Prohibits any cause of action for liability for damages related to a security countermeasure or a qualified pandemic and epidemic product unless the Secretary, acting through an administrative law judge, finds by clear and convincing evidence that a violation of the FFDCA occurred and that such violation was a result of willful misconduct.

Authorizes the Secretary to issue a declaration that an actual or potential public health emergency makes advisable the distribution, administration, or use of a security countermeasure or qualified pandemic or epidemic product.

(Sec. 7) Requires the Secretary, if the Secretary issues a proclamation stating that there is a critical public health need for a covered individual to received a covered countermeasure, to establish a process to provide compensation to individuals involved in an emergency response plan who are injured as a result of a countermeasure.

(Sec. 8) Authorizes the Secretary to: (1) award rebates for the expansion of surge capacity for manufacturing vaccines, qualified countermeasures, or qualified pandemic or epidemic products and for research; and (2) award grants to a manufacturer to purchase or improve real property and tangible personal property used in the research and development, manufacture, or distribution of such a vaccine, countermeasure, or product.

(Sec. 9) Requires the Secretary to establish within FDA a team of experts on manufacturing and regulatory activities to provide technical assistance to the manufacturers of qualified countermeasures, security countermeasures, or vaccines if the Secretary determines that a shortage or potential shortage may occur.

(Sec. 10) Requires the Secretary, acting through the Director of the National Institutes of Health (NIH), to award grants to study the physiological responses of certain animal species and juvenile models to chemical, biological, radiological, or nuclear agents or toxins or potential pandemic infectious disease and to develop and validate such animal models.

(Sec. 11) Requires the Secretary to establish the Animal Model/Research Tool Scientific Advisory Committee to provide advice, information, and recommendations on: (1) accepted animal models for diseases and conditions associated with any biological, chemical, radiological, or nuclear agent or toxin or potential pandemic infectious disease; and (2) strategies to accelerate animal model and research tool development and validation.

(Sec. 12) Amends the Clayton Act to allow the Secretary or Director of BARDA to conduct meetings and consultations with parties involved in the development of security countermeasures, qualified countermeasures, or qualified pandemic or epidemic products for the purpose of the development, manufacture, distribution, purchase, sale, or storage of countermeasures or products consistent with this Act. Requires such meetings or consultations to be conducted in such manner as to ensure that national security, confidential, and proprietary information is not disclosed outside the meeting or consultation. Prohibits the Secretary or Director from requiring the disclosure of confidential commercial or proprietary information. Exempts such meetings and consultations from antitrust laws. Requires the Secretary or Director to file a written agreement regarding covered activities. Requires the Attorney General to determine whether such an agreement would likely violate the antitrust laws, in which case the filing shall be deemed to be a request for an exemption from the antitrust laws, limited to the performance of the agreement. Requires the Attorney General to grant an exemption if: (1) the agreement involved is necessary to ensure the availability of countermeasures or products; (2) the exemption from the antitrust laws would promote the public interest; and (3) there is no substantial competitive impact to areas not

directly related to the purposes of the agreement.

Sets forth reporting requirements.

(Sec. 13) Allows partial payment on a procurement contract for a security countermeasure for significant milestones or a payment to increase manufacturing capacity. Allows procurement contracts to provide: (1) for advance payments for milestones; (2) that the vendor is the sole and exclusive supplier of the product to the government for a specified period on the condition that the vendor is able to satisfy the government's needs; (3) that the vendor establish domestic manufacturing capacity of the product to ensure that additional production is available as necessary; (4) dosing and administration requirements for countermeasures; and (5) the amount of funding that will be dedicated by the Secretary for countermeasure research and development; and (6) specifications the countermeasure must meet to qualify for procurement under a contract.

(Sec. 14) Establishes the National Pathology Center to: (1) conduct and support research, education, training, and other programs with respect to the science and clinical practice of pathology; (2) maintain and improve a pathology tissue repository; and (3) provide pathology consultation services for civil and military health professionals. Establishes a Board of Regents. Transfers the functions of the Armed Forces Institute of Pathology, with exceptions, to the Center.

Actions Timeline

- **Oct 24, 2005:** Committee on Health, Education, Labor, and Pensions. Reported by Senator Enzi with an amendment in the nature of a substitute. Without written report.
- **Oct 24, 2005:** Committee on Health, Education, Labor, and Pensions. Reported by Senator Enzi with an amendment in the nature of a substitute. Without written report.
- **Oct 24, 2005:** Placed on Senate Legislative Calendar under General Orders. Calendar No. 257.
- **Oct 18, 2005:** Committee on Health, Education, Labor, and Pensions. Ordered to be reported with an amendment in the nature of a substitute favorably.
- **Oct 17, 2005:** Introduced in Senate
- **Oct 17, 2005:** Read twice and referred to the Committee on Health, Education, Labor, and Pensions. (text of measure as introduced: CR S11424-11433)