Biodefense and Pandemic Vaccine and Drug Development Act of 2005
Section by Section Summary

SUMMARY

We must develop effective medical countermeasures to protect the United States from deliberate, accidental, and natural incidents involving biological pathogens (including potential pandemic infectious diseases such as avian influenza) and toxins, chemical agents, and nuclear and radiation materials.

Last year, Congress passed and President George W. Bush signed into law the Project BioShield Act of 2004 (Public Law 108-276). Building on the BioShield Act, the Biodefense and Pandemic Vaccine and Drug Development Act of 2005 takes further steps to better:

- Search for and identify potential medical countermeasures to protect public health and national security from biological, chemical, radiological, and nuclear threats – whether naturally occurring, accidental, or deliberate;
- Eliminate barriers to ensure rapid development of medical countermeasures against such threats, including potential pandemic infectious diseases; and
- Strengthen domestic capacity and coordination so that we respond effectively in the event of a public health emergency.

SECTION BY SECTION SUMMARY

Sec. 3 Biomedical Advanced Research and Development Agency

- Establishes the Biomedical Advanced Research and Development Agency (BARDA) in the Department of Health and Human Services.
  - BARDA is needed to:
    - Establish a single point of authority in the Federal Government for medical countermeasure development;
    - Accelerate vaccine and drug development, which currently takes 8-12 years, and spur break-through innovation in development; and
    - Bridge the "valley of death" that results in premature failures and a shrinking pool of possible countermeasures.
  - The Director of BARDA reports to the Secretary of HHS and is the principal advisor on accelerated countermeasure advanced research and development.
  - BARDA coordinates and oversees advanced research and development of promising new medical biodefense countermeasures (drugs, vaccines, etc) by:
    - Leading collaboration among the federal government, relevant industries, academia, and other entities;
    - Funding medical countermeasure advanced research and development by public and private entities;
    - Working with relevant agencies to streamline the approval and procurement processes and reduce regulatory burdens; and
    - Supporting innovation to reduce the time and cost of medical countermeasure development.

Sec. 4 Clarification of Countermeasures Covered by Project BioShield

- Clarifies that the definition of "qualified countermeasures" includes research tools and infectious diseases.

Sec. 5 Patent Provisions

- Provides "orphan drug-like" extended market exclusivity for new security countermeasures and anti-infective products that treat infectious diseases.

Sec. 6 Liability Protections for Pandemics, Epidemics, and Countermeasures

- Encourages the development of needed medical countermeasures and pandemic or epidemic products by providing liability protections.
  - These protections are necessary to:
    - Ensure that first responders delivering biodefense and pandemic or epidemic products during an emergency receive due protection; and
    - Spur potential researchers, manufacturers, and health care delivery partners to commit substantial resources and take the risks necessary to bring innovative new products to market and deliver then in a crisis.
  - The Secretary would have the authority to designate products to be used in a bioterrorist event or natural outbreak. Once the designation is established, companies and first responders would not be subject to lawsuits unless the injury resulted from a bad actor, in which case the action for damages would proceed against the bad actor.
  - This Act would NOT provide immunity for bad actors who willfully engage in misconduct that causes the injury.

Sec. 7 Compensation

- Establishes a requirement that prior to a public health emergency, if the Secretary determines that there is a critical need for first responders to receive a countermeasure, the Secretary shall establish a process to provide compensation to those individuals (based on the Smallpox Emergency Personnel Protection program).

Sec. 8 Rebates and Grants for Research, Development, and Manufacturing of Vaccines, Qualified Countermeasures and Qualified Pandemic or Epidemic Products.

- Awards rebates or grants to encourage companies to manufacture vaccines, medical countermeasures, and pandemic or epidemic products within the United States, and to conduct increased research and development.
- This proposal consistently received bipartisan support in the 108th and 109th Congress with provisions appearing in S.3, S, 975, and S. 375.

Sec. 9 Technical Assistance

- Creates an FDA rapid-action team to work with manufacturers who request assistance to identify and resolve problems by providing continuous, on-site assistance to avert a significant shortage of a vaccine or countermeasure.

Sec. 10 Animal Models for Certain Diseases

- Provides incentives for the development of animal models to accelerate the development of needed countermeasures and products. Animal models are necessary for testing the efficacy of medical countermeasures and licensing products that will protect the nation.

Sec. 11 Animal Model/Research Tool Scientific Advisory Committee

- Establishes the Animal Model/Research Tool Scientific Advisory Committee
  - Provides the Secretary of HHS recommendations, advice and information relating to scientifically accepted animal models for diseases and conditions associated with any biological, chemical, radiological, or nuclear agent; and
  - Provides strategies to accelerate animal model and research tool development.

Sec. 12 Collaboration and Coordination

- Provides a limited Anti trust exemption for the Secretary of HHS and BARDA Director allowing them to collaborate and consult with agency leaders, academia, and industry on developing needed medical countermeasures and pandemic or epidemic products.
- This provision will improve the country's efficiency during a public health emergency by allowing companies, which are involved in the development of such countermeasures, to better coordinate the development, manufacture, or distribution of countermeasures.

Sec. 13 Procurement

- Allows HHS to enter into an exclusive sales contract with a particular manufacturer for a particular product.
- Allows BioShield contracts to support the cost of establishing domestic manufacturing capacity; and to include 3 additional advance payments for meeting specified milestones.
- Allows other executive agencies (DoD, USDA) to order countermeasures through HHS.

Sec. 14 National Pathology Center

- Transfers the functions of the Armed Forces Institute of Pathology, which will be closed due to BRAC realignment, to the NIH.
- Requires that the Secretary report back to Congress within 12 months on areas where transferred functions and duties overlap with the functions and duties of the National Institutes of Health; and provide recommendations concerning necessary modifications to the National Pathology Center.