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Final Bioterrorism Preparedness Conference Report
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Provisions	Final Conference Bill (H.R. 3448/S. 1765) approved by House May 22, Senate May 23
Support for hospitals and medical schools	<p>(Sec. 131) Authorizes state block grants to improve state, local, and hospital preparedness. Similar to current HHS plan for FY 2002 funds, state plans must be submitted to Secretary, and once approved, funds will be distributed to the states based on population. Funds may be used to purchase or upgrade equipment, conduct exercises, develop trauma care components, improve training or workforce development, improve participation in communication systems, enhance training of health professionals to recognize and treat mental health consequences, enhance training to protect the safety of health care personnel, among other uses. \$1.6 billion is authorized for FY 2003, with \$520 million for the purpose of enhancing preparedness of hospitals (including children’s hospitals), clinics, health centers, and primary care facilities. Beyond FY 2003, the Secretary may continue the same approach or modify.</p> <p>Secretary will award grants to eligible entities to improve community and hospital preparedness for bioterrorism and other public health emergencies. Eligible entities consist of a partnership between one or more hospitals and a state or locality. The plans should be consistent with the state bioterrorism plan. Such sums are authorized for 2004 to 2006.</p>
Support for training and education	<p>(Sec. 105) Secretary, in collaboration with federal interagency working group and professional societies is charged with the following duties:</p> <ul style="list-style-type: none"> - develop materials for teaching the elements of a core curriculum to health care professionals for the recognition and identification of potential bioweapons and for the care of victims, recognizing the special needs of children; - develop a core curriculum for community-wide planning by state and local governments, hospitals and other health entities; - develop materials for proficiency testing of laboratory and other public health personnel for the recognition of bioweapons and other agents that may create a public health emergency - provide for dissemination

	<p>Secretary may award grants to carry out these initiatives.</p> <p>(Sec. 106) Grants to health or educational entities, including health professions schools, for the purpose of providing low-interest loans, partial scholarships, revolving loan funds, or other cost-sharing forms of assistance to increase the number of individuals entering a health profession for which there is a shortage that the Secretary determines should be alleviated to prepare for or respond effectively to bioterrorism. The Secretary may require as a condition of an award that a grantee provide non-Federal contributions. Such sums authorized for FY 2002 through 2006.</p>
Regulation of agents and persons	<p>(Sec. 201) Secretary will establish and maintain list of agents and toxins that pose serious threat to the public health and safety. The list will be reviewed and republished biennially.</p> <p>Secretary will by regulation establish and enforce safety procedures and standards for the transfer, possession, and use of biological agents and toxins to ensure: proper training to handle agents, safeguards to prevent access to agents, procedures to protect public safety in the event of violation of procedures, and the appropriate availability of biological agents and toxins for research, education and other legitimate purposes.</p> <p>Regulations will require that entities register for the possession, use, and transfer of agents, and such entities seeking to register have a lawful purpose to access such agents and toxins, and are cleared in accordance with screening process described below. Registration will include (if available to the entity registering) information regarding the characterization of agents to facilitate their identification, including their source. The Secretary will maintain a national database that includes name and locations of registered entities, the listed agents and toxins they are possessing, using, or transferring, and information regarding the characterization of such agents. Registered entities are directed to provide access to only those individuals whom the registered entity determines to have a legitimate need to handle or use such agents or toxins.</p>
Screening of individuals	<p>The entity must promptly submit the names and other identifying information of the individuals to the Secretary and Attorney General, and periodically thereafter, not less than every five years. The Attorney General will promptly use criminal, immigration, and national security databases to identify whether the entities or individuals should be denied or have limited access to agents or toxins as defined below. Regulations will allow the</p>

	Secretary to request an expedited review and will allow for a review of denials by the Secretary and subsequent judicial review.
Restricted persons	<p>Restricted persons will be denied access to agents or toxins. Restricted person, as defined in the USA PATRIOT Act [P.L. 107-56]: 1) is under indictment for a crime punishable by imprisonment for a term exceeding 1 year; 2) has been convicted in any court of a crime punishable by imprisonment for a term exceeding 1 year; 3) is a fugitive from justice; 4) is an unlawful user of any controlled substance; 5) is an alien illegally or unlawfully in the United States; 6) has been adjudicated as a mental defective or has been committed to any mental institution; 7) is an alien who is a national of a country that has repeatedly provided support for acts of international terrorism or; 8) has been dishonorably</p> <p>An individual reasonably suspected of Federal crimes of terrorism will be denied or have limited access to agents or toxins, as determined appropriate by the Secretary in consultation with Attorney General.</p>
Regulation of facilities and labs	<p>Regulations will provide for inspections of regulated entities to ensure they are following requirements and protecting the public health and safety</p> <p>Secretary may exempt clinical laboratories and other persons using the agents in these settings from these regulations only when such agents are presented for diagnosis, verification, or proficiency testing; the identification of the agents is reported to the Secretary or other public health authorities; and such agents are transferred or destroyed</p> <p>Labs or persons must notify the Secretary and law enforcement agencies when a listed agent is lost or stolen.</p> <p>Regulations shall exempt products containing the restricted agents that are cleared, approved licensed or registered under certain Federal laws, unless the Secretary determines that additional regulation is necessary to protect the public's health. Regulations may also exempt investigational products used in investigational or clinical trials.</p>
Support for research	(Sec. 125) Secretary will develop priorities for and award grants in health sciences relating to the epidemiology and pathogenesis of agents and toxins; the development of new vaccines and therapeutics; and the development of diagnostic tests to detect agents or toxins

	<p>Secretary directed to consider using the biomedical research and development capabilities of the VA, in conjunction with health professions universities</p> <p>(Sec. 122) Secretary may designate a priority countermeasure as a fast-track product under the Food, Drug, and Cosmetic Act and may make this designation based solely on evidence derived from animal trials.</p> <p>(Sec. 123) Directs Secretary to issue final rule for the use of animal trials in the approval of priority countermeasures when studies in humans cannot be ethically conducted. Rule must be issued within 90 days of enactment.</p> <p>(Sec. 152) Expanded research by the Department of Energy.</p>
Enhanced security	(Sec. 124) Authorizes funds for HHS Secretary to secure facilities where biological agents, toxins, or vaccines are housed or researched
Department of Agriculture	(Sec. 212) Using the same framework outlined in the HHS biological agents section of this bill (Sec. 201), the Agriculture Secretary is directed to establish a list of biological agents and toxins that present a serve threat to plant or animal health, or animal or plant products; register persons possessing the agents; maintain a database; and establish safety standards and procedures. For agents appearing on both lists, the HHS and USDA should coordinate their registration processes to avoid administrative burden. The Secretaries are directed to immediately enter into a memorandum of understanding providing for a single registration system for overlap agents.
Food safety	(Sec. 331) Expands APHIS activities to increase inspection capacity at international points of origin, protect against the introduction of animal and plant disease organisms by terrorists, and adopt new strategies for dealing with animal and plant disease outbreaks. Authorizes \$30 million for APHIS expansion in FY 2002 and such sums thereafter
Drug supply safety	(Sec. 321) Mandates annual registration of foreign drug manufacturers who supply drugs or devices to the U.S.
Water security	(Sec. 401) Amends the Safe Drinking Water Act to require that community water systems conduct a vulnerability assessment and prepare an emergency response plan. Each system must submit assessment to the EPA, but the information is exempt from FOIA.