

Legislative Bulletin.....May 22, 2002

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H.R. 3448— Public Health Security and Bioterrorism Preparedness and Response Act—Conference Report

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Order of Business: The Conference Report is scheduled to be considered on Wednesday, May 22, 2002, subject to a rule.

Summary: According to RSC calculations, the Conference Report would explicitly authorize (not including “such sums” likely to amount to billions of dollars in subsequent fiscal years) a minimum of **\$2.364 billion** (mostly in FY2002, but some in FY2003).

HHS Emergency Health Provisions:

Requires the Secretary of HHS to establish a National Preparedness Plan and make periodic reports to Congress.

Establishes the position of Assistant Secretary for Public Health Emergency Preparedness within HHS.

Requires the establishment of a National Disaster Medical System – a federally led coordinated effort with state and other appropriate entities to provide health services, health-related social services, and other appropriate human services to respond to a public health emergency. Authorizes such sums as may be necessary to implement the program for each of fiscal years 2002 through 2006.

Authorizes such sums as may be necessary (for each of fiscal years 2002 through 2006) for grants, contracts, or other agreements to establish a coordinated network of public health laboratories and to establish an integrated public health communications and surveillance networks.

Authorizes \$300 million for each of fiscal years 2002 and 2003 (and such sums afterwards through FY2006) for the improvement of CDC facilities (includes renovation and new construction).

Establishes Advisory Committees on Children and Terrorism and Public Information and Communications.

Recommends the establishment of a federal Internet site on bioterrorism.

Requires the development of materials for teaching a core curriculum (to health care personnel) related to bioweapons.

Authorizes such sums as may be necessary (for each of fiscal years 2002 through 2006) to provide grants and establish cooperative agreements with public and private non-profit health or education entities for low-interest loans, scholarships, and other assistance for the education and training of health professions for which there is a shortage that the Secretary of HHS determines should be alleviated in order to prepare for public health emergencies.

Requires the establishment of a system to verify the credentials of individuals who volunteer to serve as health professionals during public health emergencies. Authorizes appropriations of \$2 million for FY2002 and such sums as may be necessary for each of fiscal years 2003 through 2006.

Requires the establishment of a working group (among various appropriate federal agencies) on bioterrorism and other public health emergencies.

Authorizes \$25 million for each of fiscal years 2002 and 2003 and such sums as may be necessary afterwards through FY2006 for grants to conduct research into antimicrobial resistance (i.e. manipulating DNA to increase resistance to biological agents).

Authorizes \$1.15 billion in FY 2002 (\$509 million specifically for the development of smallpox vaccine) and such sums afterwards through FY2006 to maintain stockpiles of drugs (including potassium iodide), vaccines (including that for smallpox), etc for responding to public health emergencies.

Permits the fast-tracking of the approval of drugs to treat, identify, or prevent infection by a biological agent or toxin.

Directs the Secretary of HHS to give research priority to the pathogens most likely to be used in a biological attack (and the related countermeasures to such attacks). Also directs the Secretary to periodically evaluate new and emerging technologies regarding bioterrorist attacks and other public health emergencies.

Authorizes \$1.6 billion for FY2003 (subject to increase if deemed necessary) and such sums afterwards through FY2006 for the Secretary of HHS to award grants to improve state, local, and hospital preparedness for and response to bioterrorism.

Authorizes such sums as may be necessary for fiscal year 2004 through 2006 for the Secretary of HHS to award grants for partnerships for community and hospital preparedness.

Streamlines the process for issuing quarantine rules (eliminates the requirement for a National Advisory Health Council Recommendation prior to issuance).

Permits the Secretary of HHS to temporarily waive requirements related to deadlines, participation by individuals and health care providers, and sanctions under the Medicare, Medicaid, and SCHIP programs during public health emergencies.

Authorizes such sums as may be necessary for each of fiscal years 2002 through 2006 for the Secretary of Energy to conduct research related to pathogens that might be used in a biological attack.

Authorizes \$100 million for FY2002 and such sums afterwards through FY2006 for the enhancement of the readiness of VA medical centers for chemical and biological attacks.

Authorizes \$33 million for FY2002 and such sums afterwards through FY2006 for the evaluation of security at VA medical and research facilities, the development of a centralized system for tracking pharmaceuticals and medical supplies, the training of VA medical center personnel, the participation in a national disaster medical system, and the provision of mental health counseling.

Authorizes \$25 million for FY2003 and such sums as may be necessary afterwards through FY2006 for grants to states to implement public access defibrillation programs. Authorizes \$5 for each of fiscal years 2002 through 2006 for public access defibrillation demonstration projects.

Toxins and Biological Agents:

Requires the establishment of a list of each biological agent and toxin that has the potential to pose a severe threat to public health and safety; directs the HHS to issue regulations establishing standards governing the possession, use, and transfer of items on the list and the registration with HHS of those individuals and entities that possess and use biological toxins and agents (while such information would not be subject to a Freedom of Information Act request, the government is authorized to release information for the purpose of protecting the public health and safety); provides for interagency coordination; establishes civil and criminal penalties for the violation of these provisions. Authorizes such sums as may be necessary for each of fiscal years 2002 through 2007.

Food and Drug Supply:

Authorizes \$750 million for FY2002 and such sums as may be necessary for each subsequent fiscal year for the development of a food safety and security strategy by the relevant federal agencies

Authorizes \$100 million in FY 2002 and such sums through FY 2006 to study and improve testing and detection of intentionally adulterated food.

Permits the FDA to detain food that it believes may present a threat of serious adverse health consequences to humans or animals. Also permits the holding of food at ports of entry for 24 hours to permits inspection if there is credible evidence or information that food may pose a health risk

Requires registration with the Secretary of any facility engaged in manufacturing, processing, packaging, or holding of food for consumption in the U.S. The Secretary may exclude retail establishments.

Requires the prior notice of food shipments intended for import into the U.S.

Authorizes \$10 million in FY2002 and such sums as may be necessary afterwards through FY2006 for grants to states for food inspections and providing notices to the public regarding adulterated imported food.

Authorizes \$19.5 million in FY2002 and such sums as may be necessary afterwards through FY2006 for the Secretary of HHS to award grants to states to expand participation in networks to enhance food safety.

Modifies provisions related to the registration of foreign drug manufacturers, drug shipping information, and drug and device listing.

Authorizes \$30 million in FY2002 and such sums as may be necessary for each subsequent fiscal year for the expansion of animal and plant health inspection service activities.

Authorizes \$180 million in FY2002 for the Department of Agriculture to make biosecurity upgrades at existing facilities.

Authorizes such sums as may be necessary each fiscal year for grants to colleges and universities to review security standards and practices at their facilities in order to protect against bioterrorist attacks.

Authorizes \$190 million in FY2002 and such sums as may be necessary for each subsequent fiscal year for the Department of Agriculture to conduct research activities regarding agricultural bioterrorism.

Establishes penalties for the intentional physical disruption of an animal enterprise.

Drinking Water Security:

Requires each community water system serving a population greater than 3,300 to conduct a vulnerability assessment related to intentional acts designed to disrupt the supply of safe water and prepare an emergency response plan. Authorizes \$160 million in FY 2002 and such sums through FY 2005 to provide assistance to community water systems to carryout these requirements.

Requires the Administrator to review and study methods individuals may use to disrupt safe water supplies and methods to prevent such disruptions. Authorizes \$15 million for FY2002 and such sums as may be necessary through FY2005.

Additional Provisions:

Extends through FY2007 the authority for the FDA to assess and use prescription drug user fees. Directs the FDA to set such fees to generate \$222.9 million in revenue in FY2003, \$231 million in FY2004, \$252 million in FY2005, \$259.3 million in FY2006, and \$259.3 million in FY2007. Authorizes these revenues for use by the FDA.

Earmarks (within funds appropriated for the FDA) \$5 million for the Office of Drug Safety in FY2003, \$10 million in FY2004, and \$10 million plus inflation for each subsequent fiscal year.

Increases the FY2002 authorization for the Division of Drug Marketing, Advertising, and Communication (within FDA) by \$2.5 million in FY2003, \$4 million in FY2004, \$5.5 million in FY2005, \$7.5 million in FY2006, and \$7.5 million in FY2007.

Increases the FY2002 authorization for the Office of Generic Drugs (within FDA) by \$3 million in FY2003, \$6 million in FY2004, \$9 million in FY2005, \$12 million in FY2006, and \$15 million in FY2007.

Accelerates the transition to digital television by directing the FCC to assign a paired digital television channel to a requesting licensee or permittee within 90 days of this bill's enactment.

Delays by three years the implementation of the lock-in procedures for Medicare+Choice plans and changes certain deadlines for such plans.

Cost to Taxpayers: A CBO cost estimate is unavailable for the Conference Report. According to RSC calculations, the Conference Report would explicitly authorize (not including "such sums" likely to amount to billions of dollars in subsequent fiscal years) a **minimum** of **\$2.364 billion** (mostly in FY2002, but some in FY2003).

Constitutional Authority: A committee report for the Conference Report was unavailable at the time of this writing.

Does the Bill Create New Federal Programs or Rules: The bill creates numerous new programs and reporting and registration requirements, as detailed above.

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