Emergency Use Authorization Toolkit

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ASTHO LEGAL PREPAREDNESS SERIES
EMERGENCY USE AUTHORIZATION TOOLKIT

Project BioShield Act

Fact Sheet

Overview

With the anthrax and other terrorist attacks of 2001, the federal government determined that it would need new medical countermeasures, such as diagnostic tests, drugs, and vaccines, to respond to an attack using chemical, biological, radiological, or nuclear (CBRN) agents.1 The lack of a significant commercial market for CBRN countermeasures was identified as a reason for the dearth of such countermeasures.1 Since diseases and conditions caused by CBRN agents occur infrequently, the private sector did not have an economic incentive to invest the millions of dollars necessary to research and develop such measures.1 The Project BioShield Act of 20042 was enacted to accelerate the research, development, purchase, and availability of effective medical products against CBRN agents.3 Project BioShield provided the government with the authority and funding to develop, acquire, stockpile, and distribute the medical products needed to protect the United States against weapons of mass destruction.3

Note: As of March 2012, Congress is in the process of reauthorizing the Pandemic and All-Hazards Preparedness Act (PAHPA), which may impact some provisions of the Project BioShield Act. Please see ASTHO EUA Current Issues Winter 2012 for more information about reauthorization and its potential impact on EUAs and related issues. (Download a printable PDF.)

What the Law Does

The Project BioShield Act authorizes expedited procurement, streamlined personnel appointments, expedited peer review, biomedical countermeasures procurement, emergency use of medical countermeasures, and other biodefense activities.

Liability Protections
The Project BioShield Act does not contain any explicit immunity or other liability protections. The absence of such protections in the act was an ongoing concern for potential developers of CBRN countermeasures. To address these and other concerns, the Public Readiness and Emergency Preparedness (PREP) Act was enacted to, among other things, provide liability protections to persons and entities involved in the development, sale, distribution, and administration of countermeasures.4 (See ASTHO Fact Sheet on the PREP Act.)

How the Law Works

The act has three primary provisions: (1) expedited procurement and grant making; (2) guaranteed government purchasing of countermeasures; and (3) authority to temporarily use medical countermeasures under Emergency Use Authorization (EUA) authority. The act vests authority and implementation with the Secretary of the Department of Health and Human Services (HHS) and agencies within HHS. Congress created the Biomedical Advanced Research and Development Authority (BARDA) in the HHS Office of the Assistant Secretary for Preparedness and Response (ASPR)5 through the Pandemic and All-Hazards Preparedness Act6 to create an infrastructure to manage Project BioShield's countermeasures development and purchasing.1 The FDA is responsible for issuing EUAs. The Project BioShield Act requires the HHS to issue annual reports about its use of the authorities granted under it.1,7 The HHS has contracted for anthrax vaccine and treatment, botulinum antitoxin, pediatric potassium iodide, treatments for internal radioactive particle contamination, and a new smallpox vaccine.1,7 Countermeasures against anthrax, viral hemorrhagic fevers, and radiation are planned.1

Expedited Procurement
The act streamlines Federal Acquisition Regulation (FAR) rules for the HHS in procuring property or services used in CBRN countermeasure development.1 Expedited FAR procedures decrease the amount of paperwork required for CBRN expenditures,

increase the maximum dollar amount for contracts awarded under simplified acquisition rules from $100,000 to $25 million, and allow for noncompetitive purchasing under FAR.1 The act also authorizes the HHS secretary to use an expedited process for awards up to $1.5 million for grants, contracts, and cooperative agreements related to CBRN countermeasure research and development if an urgent need exists for an expedited award.1 The expedited award process replaces the normal peer review process associated with research awards.1

Guaranteed Government Purchasing

The Project BioShield Act was intended to guarantee that the government will buy new, successful CBRN countermeasures for the Strategic National Stockpile (SNS). The act allows the HHS secretary, with the concurrence of the secretary of Homeland Security and upon the approval of the president, to promise to buy a product up to eight years before it is reasonably expected to be delivered.1 The Project BioShield Act allows the HHS to purchase unapproved and unlicensed countermeasures upon a determination that sufficient satisfactory clinical experience or research data exists to reasonably conclude that the proposed countermeasure will qualify for FDA approval within eight years.1 The Pandemic and All-Hazards Preparedness Act amended the Project BioShield Act to give countermeasure developers milestone-based payments of up to half of the total award before the final product is delivered.1

Emergency Use Authorization

The Project BioShield Act also amended §564 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) to create Emergency Use Authorization (EUA) authority. This authority allows for the temporary use of an unapproved medical product (drugs, biologics [e.g., vaccines], and devices [e.g., diagnostics]) or an unapproved use of an approved medical product during certain types of emergencies. FDA may issue an EUA for specific countermeasures if statutory and other criteria regarding emergency conditions are satisfied. (See ASTHO Fact Sheet on EUA Authority for more information about the EUA.)

How the Law Affects States

The Project BioShield Act primarily affects states through the act's EUA provisions allowing the FDA to temporarily authorize the use of unapproved medical products, or the unapproved use of FDA-approved medical products, in an emergency.

Sources

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Note: This document was compiled from June–December 2011 and reflects the laws and programs current then. It reflects only portions of the laws relevant to public health emergencies and is not intended to be exhaustive of all relevant legal authority. This resource is for informational purposes only and is not intended as a substitute for professional legal or other advice. The document was funded by CDC Award No. 1U38HM000454 to the Association of State and Territorial Health Officials; Subcontractor PI Elliott, Logan Circle Policy Group LLC.