



## CRS Report for Congress

# Public Health and Medical Preparedness and Response: Issues in the 110th Congress

Sarah A. Lister  
Specialist in Public Health and Epidemiology  
Domestic Social Policy Division

### Summary

The nation's systems to detect and respond to public health threats such as bioterrorism gained renewed interest following the 2001 terrorist attacks. Federal authorities enacted comprehensive public health preparedness legislation in 2002 were reauthorized in the 109th Congress, building upon lessons learned from the response to Hurricane Katrina, and growing concerns about a flu pandemic. The 109th Congress also completed a statutory reorganization of the Federal Emergency Management Agency (FEMA). The 110th Congress is likely to study the implementation of these two laws, and to remain interested in other issues in public health and medical preparedness and response.

### Background and Legislation in the 109<sup>th</sup> Congress

In December 2006, Congress passed the Pandemic and All-Hazards Preparedness Act (P.L. 109-417), which extends programs for bioterrorism and other public health emergency preparedness and response activities within the Department of Health and Human Services (HHS), and establishes a Biomedical Advanced Research and Development Authority (BARDA) within HHS for advanced research and development of medical countermeasures (e.g., diagnostic tests, drugs, vaccines, and other treatments). In October 2006, Congress passed the Department of Homeland Security Appropriations Act, 2007 (P.L. 109-295). Title VI of the act incorporated the Post-Katrina Emergency Management Reform Act of 2006 (the Post-Katrina Act), which reorganizes the Department of Homeland Security (DHS) and, within it, the Federal Emergency Management Agency (FEMA). The act also codifies the position of Chief Medical Officer, with primary responsibility within DHS for medical issues related to natural and man-made disasters and terrorism.<sup>1</sup>

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<sup>1</sup> See CRS Report RL33589, *The Pandemic and All-Hazards Preparedness Act (P.L. 109-417): Provisions and Changes to Preexisting Law*, by Sarah A. Lister and Frank Gottron (hereafter (continued...))

The 110<sup>th</sup> Congress is likely to be keenly interested in implementation of these laws, and others, that address the readiness of the nation's public health and medical systems. This report, which will be updated, discusses key issues in public health and medical preparedness and response, and cites additional CRS reports and other resources.

## Issues in the 110<sup>th</sup> Congress

**Federal Coordination.** In planning for public health and medical emergencies, the roles of the Secretaries of HHS and DHS are not always clear. This was evident in the response to Hurricane Katrina. Activities in the two departments dovetail in biodefense research and development, state and local disaster preparedness and response, domestic and global infectious disease surveillance, the deployment of medical response assets, mental health counseling for disaster victims, and other areas. The Assistant Secretary for Preparedness and Response leads HHS's efforts in public health and medical preparedness and response. The Chief Medical Officer coordinates comparable activities in DHS. Certain issues regarding these positions and their respective roles were addressed in legislation in the 109<sup>th</sup> Congress.<sup>2</sup> The 110<sup>th</sup> Congress is likely to be interested in how statutory directives are carried out.

**HHS Response Capability.** Given the disaster response obligations of HHS, many question whether the department has the resources — financial, logistical, technical, and otherwise — to effectively carry out its responsibilities. The 110<sup>th</sup> Congress may consider the adequacy of permanent authorities of the HHS Secretary for responding to public health threats, including authority to declare a public health emergency. Members of Congress may also consider how HHS funds disaster response activities that are not reimbursable by FEMA.<sup>3</sup> Though the HHS Secretary has authority for a no-year emergency fund, Congress has not appropriated monies to the fund for many years. Finally, Congress may consider the permanent authority of the President — acting through the FEMA Director, in consultation with HHS — to deliver mental health counseling services to disaster victims, and whether these services are effective and well targeted.<sup>4</sup>

**State Grants for Public Health and Hospital Preparedness.** Since 2002, Congress has provided about \$7 billion in grants to states to strengthen public health and hospital preparedness for public health threats. Presumably due to national security

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<sup>1</sup> (...continued)

RL33589), and CRS Report RL33729, *Federal Emergency Management Policy Changes After Hurricane Katrina: A Summary of Statutory Provisions*, Keith Bea, Coordinator (hereafter CRS Report RL33729).

<sup>2</sup> Ibid. See also CRS Report RL33579, *The Public Health and Medical Response to Disasters: Federal Authority and Funding*, by Sarah A. Lister (hereafter CRS Report RL33579); and CRS Report RL33738, *Gulf Coast Hurricanes: Addressing Survivors' Mental Health and Substance Abuse Treatment Needs*, by Ramya Sundararaman, Sarah A. Lister, and Erin D. Williams (hereafter CRS Report RL33738).

<sup>3</sup> Pursuant to the Robert T. Stafford Disaster Relief and Emergency Assistance Act (the Stafford Act, administered by DHS), FEMA may reimburse other federal agencies for activities carried out in response to presidentially declared emergencies and major disasters.

<sup>4</sup> See CRS Report RL33579 and CRS Report RL33738.

concerns, HHS has not published comprehensive or state-specific information regarding grantees' performance. Congress has been interested in the management of these grants, on topics ranging from the relevance of program goals in achieving national preparedness, to the rigor of fiscal accounting mechanisms, to the balance of federal vs. state funding shares, to issues of program transparency. The Pandemic and All-Hazards Preparedness Act extends the programs, adding certain new elements including federal authority to withhold funds for failure to meet program requirements, a state matching requirement, and a requirement that the Secretary of HHS publish certain information about program activities and performance on a federal Internet website available to the public.<sup>5</sup>

**Biodefense Research and Development.** Several federal agencies conduct or fund research on potential biological weapons, the detection of bioterrorist incidents and outbreaks of naturally occurring infections, and potential tests and treatments for use on affected individuals. The two principal agencies involved in civilian research are the Science and Technology Directorate in DHS, for research to address vulnerabilities and assess risks to the civilian population and infrastructure related to biological, chemical, radiological and nuclear threats, and high explosives; and the National Institutes of Health in HHS, for biomedical research and the development of medical countermeasures.<sup>6</sup> The National Biodefense Analysis and Countermeasures Center (NBACC) was recently established as the first DHS laboratory specifically focused on biodefense. The mission of the NBACC program is to understand current and future biological threats, assess vulnerabilities and determine potential consequences, and provide a national capability for conducting forensic analysis of evidence from bio-crimes and terrorism.<sup>7</sup>

**Project BioShield.** The private sector is reluctant to invest in the development of drugs, vaccines and other medical countermeasures for threats such as bioterrorism that may not materialize. To assure the availability of these products, the 108<sup>th</sup> Congress launched Project BioShield to encourage the development of countermeasures that lack commercial markets. To address problems with the program's early implementation, the 109<sup>th</sup> Congress incorporated in Title IV of the Pandemic and All-Hazards Preparedness Act a requirement for the HHS Secretary to develop and make public a strategic plan to guide HHS research, development and procurement of countermeasures. The act also creates the Biodefense Advanced Research and Development Authority (BARDA) in HHS, to help implement the strategic plan, directly support countermeasure development, and facilitate communication between the government and developers. The 110<sup>th</sup> Congress is likely to remain interested in the progress of Project BioShield, and, depending on appropriations, to oversee the creation and effectiveness of BARDA.<sup>8</sup>

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<sup>5</sup> See CRS Report RL33589.

<sup>6</sup> Also, the Department of Defense conducts and funds research in, and the development of, the relevant sciences, technologies, equipment, and systems to ensure that U.S. military forces are able to detect, protect, treat and remediate against chemical and biological threats.

<sup>7</sup> See CRS Report RL32891, *The National Biodefense Analysis and Countermeasures Center: Issues for Congress*, by Dana A. Shea.

<sup>8</sup> See CRS Report RS21507, *Project BioShield: Purposes and Authorities*, by Frank Gottron; CRS Report RL33907; *Project BioShield: Appropriations, Acquisitions, and Policy Implementation Issues for Congress*, by Frank Gottron; and CRS Report RL33589.

**Liability, Compensation, and Intellectual Property Issues.** Project BioShield is intended to address obstacles to countermeasures development associated with commercial attractiveness. Additional factors may affect the availability of countermeasures, the willingness of officials to deploy them, or the willingness of citizens to accept them. In December 2005, Congress passed Department of Defense Emergency Supplemental Appropriations, 2006 (P.L. 109-148). Division C of the law would eliminate liability, except in the case of willful misconduct, for manufacturers and others involved in the production and use of countermeasures, upon a declaration of emergency by the HHS Secretary. The law also requires the HHS Secretary to develop a compensation mechanism for those who may be injured by an indemnified countermeasure. Finally, intellectual property protections may affect the availability of countermeasures by making them more commercially attractive to developers, or more costly to purchasers, including governments.<sup>9</sup>

**Workforce Surge Capacity.** The health workforce is aging into retirement, yet is strained by new homeland security duties. Authority for health professions programs in HHS expired in 2002. These programs are primarily geared toward alleviating shortages and maldistributions of primary care physicians and nurses. The public health workforce has, in contrast, received little federal attention until recently. The Pandemic and All-Hazards Preparedness Act authorizes a loan repayment demonstration project for individuals who serve in health professional shortage areas, or areas at high risk of a public health emergency. Efforts to increase the availability of health professionals for emergency response also include ensuring civil liability protection for volunteer health professionals, and establishing a system to verify the licenses and credentials of medical practitioners. While efforts are ongoing among states and on the federal level, a uniform system for protection of volunteer health professionals does not yet exist.<sup>10</sup>

**Vulnerable Populations.** The terror attacks of 2001 and the hurricanes of 2005 showed that some people may be at greater risk of harm or more in need of special services during and following a disaster. These may include persons with disabilities, as defined by the Americans with Disabilities Act. Children and pregnant women may not be able to safely use the same drugs as the general population during a bioterrorism incident. Those living in poverty may have fewer options in complying with a mandatory evacuation order. Those with mental health or substance abuse problems may worsen when faced with disasters, or may lose access to ongoing services. The Pandemic and All-Hazards Preparedness Act requires the Secretary of HHS, in various planning activities, to consider *at-risk individuals*, defined as children, pregnant women, senior citizens, and others who have special needs in the event of a public health emergency, as determined by the Secretary. The Post-Katrina Act requires the head of FEMA to appoint a Disability Coordinator, who is charged, among other things, with assessing the

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<sup>9</sup> See CRS Report RS22327, *Pandemic Flu and Medical Biodefense Countermeasure Liability Limitation*, by Henry Cohen; CRS Report RL32917, *Bioterrorism Countermeasure Development: Issues in Patents and Homeland Security*, by Wendy H. Schacht and John R. Thomas; and CRS Report RL33159, *Influenza Antiviral Drugs and Patent Law Issues*, by Brian T. Yeh.

<sup>10</sup> See CRS Report RL32546, *Title VII Health Professions Education and Training: Issues in Reauthorization*, by Bernice Reyes-Akinbileje (hereafter CRS Report RL32546); CRS Report RS22255, *Emergency Response: Civil Liability of Volunteer Health Professionals*, by Kathleen Swendiman and Nathan Brooks; and CRS Report RL33589.

coordination of emergency management policies and practices for individuals with disabilities, including training, physical and virtual access, transportation, media outreach, and general coordination and dissemination of best practices, including evacuation planning.<sup>11</sup>

**Pandemic Influenza Preparedness.** The spread of avian influenza (“bird flu”) and the human deaths it has caused raise concern that the virus could further evolve and cause a global human pandemic. To prepare for this threat, the 109<sup>th</sup> Congress provided \$6.1 billion in emergency supplemental funding for FY2006. Most of this funding supports an HHS initiative to expand domestic vaccine production capacity. In addition to oversight of federal spending for pandemic flu, Congress may be interested in (1) federal coordination of activities to prepare for and respond to a possible pandemic, such as integrated surveillance for avian and human flu among HHS, DHS, the Departments of Agriculture and Interior, the State Department, the U.S. Agency for International Development, and the Defense Department; (2) the impact of avian flu on affected countries; and (3) the possible effects of a flu pandemic on global trade and commerce.<sup>12</sup>

**Rationing of Scarce Healthcare Resources.** Health emergencies often involve scarcities of healthcare and public health resources, including personnel, equipment, drugs, and vaccines. Prioritizing the use of scarce resources to maximize benefit requires careful study of scientific and medical evidence, and raises complex legal and ethical questions that are best considered before emergencies arise.<sup>13</sup>

**Isolation, Quarantine, and Mandatory Vaccination.** The response to communicable disease threats may involve movement restrictions, business and school closures, compulsory treatments, and other constraints. While state and local governments have the primary authority over containment measures such as quarantine, isolation, and mandatory vaccination, a comprehensive response to a public health emergency may involve overlapping governmental authorities and attendant legal and economic issues. Constitutional and federal statutory issues may also be raised where individual liberties are restricted.<sup>14</sup>

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<sup>11</sup> See CRS Report RS22254, *The Americans with Disabilities Act and Emergency Preparedness and Response*, by Nancy Lee Jones; CRS Report RL33589; and CRS Report RL33729.

<sup>12</sup> See CRS Report RS22576, *Pandemic Influenza: Appropriations for Public Health Preparedness and Response*, by Sarah A. Lister; CRS Report RL33145, *Pandemic Influenza: Domestic Preparedness Efforts*, by Sarah A. Lister; CRS Report RL33219, *U.S. and International Responses to the Global Spread of Avian Flu: Issues for Congress*, by Tiaji Salaam-Blyther; CRS Report RL33795, *Avian Influenza in Poultry and Wild Birds*, by Jim Monke and M. Lynne Corn; CRS Report RL33871, *Foreign Countries' Response to the Avian Influenza (H5N1) Virus: Current Status*, Emma Chanlett-Avery, Coordinator; and CRS Report RS22453, *Avian Flu Pandemic: Potential Impact of Trade Disruptions*, by Danielle Langton.

<sup>13</sup> For further discussion, see CRS Report RL33381, *The Americans with Disabilities Act (ADA): Allocation of Scarce Medical Resources During a Pandemic*, by Nancy Lee Jones.

<sup>14</sup> See CRS Report RL33201, *Federal and State Quarantine and Isolation Authority*, by Kathleen S. Swendiman and Jennifer K. Elsea; CRS Report RL33609, *Quarantine and Isolation: Selected Legal Issues Relating to Employment*, by Nancy Lee Jones and Jon O. Shimabukuro; CRS Report

**Disaster Victims and Healthcare Costs.** The 110<sup>th</sup> Congress may consider ways to cover healthcare costs for disaster victims.<sup>15</sup> Several bills in the 109<sup>th</sup> Congress addressed the healthcare needs of responders and others who were exposed to hazards at the World Trade Center following the September 11, 2001 attack, and who are now experiencing health problems.<sup>16</sup> Following Hurricane Katrina, Congress provided \$2 billion to cover the state share of Medicaid costs associated with evacuees and individuals living in declared disaster areas (for states with approved federal waivers), and to restore access to care in impacted communities. Related issues include the healthcare, mental health and substance abuse treatment needs of hurricane victims and efforts to rebuild Louisiana's devastated healthcare infrastructure. Crisis counseling programs to address the mental health needs of the Hurricane Katrina victims may be extended. The Louisiana Health Care Redesign Collaborative, a federal, state, local, and private partnership, has been developed to propose options for rebuilding the healthcare system in southern Louisiana through a Medicaid waiver and Medicare demonstration proposal.<sup>17</sup>

**Expired and Expiring Authorities.** The 110<sup>th</sup> Congress may consider reauthorization of some expired or expiring preparedness and response programs.<sup>18</sup> These include the Select Agent Program, a program in HHS to regulate certain biological pathogens and toxins that could be used for bioterrorism. Program authority expires at the end of FY2007.<sup>19</sup> In addition, authority for HHS health professions programs expired in 2002. These programs have not focused on emergency preparedness and response in the past, though the last reauthorization in 1998 preceded heightened concerns in this area.<sup>20</sup> Finally, while authority for the Strategic National Stockpile of countermeasures has been amended several times since the terror attacks of 2001, general program authority, which expired at the end of FY2006, was not extended.<sup>21</sup>

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<sup>14</sup> (...continued)

RS22219, *The Americans with Disabilities Act (ADA) Coverage of Contagious Diseases*, by Nancy Lee Jones; and CRS Report RS21414, *Mandatory Vaccinations: Precedent and Current Laws*, by Kathleen S. Swendiman.

<sup>15</sup> See CRS Report RL33927, *Selected Federal Compensation Programs for Physical Injury or Death*, by Sarah A. Lister, Edward Rappaport and C. Stephen Redhead; and "Federal Assistance for Disaster-Related Healthcare Costs," in CRS Report RL33579.

<sup>16</sup> See, for example, S. 3918, S. 4021, S. 4022, H.R. 6046 and H.R. 6124. See also HHS, "World Trade Center Health Resources," at [<http://www.hhs.gov/wtc/>].

<sup>17</sup> See the Louisiana Healthcare Redesign Collaborative charter at [<http://www.hhs.gov/louisianahealth/collaborative/charter.html>]; and hearing on "Post Katrina Health Care: Continuing Concerns and Immediate Needs in the New Orleans Region," House Committee on Energy and Commerce, Subcommittee on Oversight and Investigations, Mar. 13, 2007. See, also, CRS Report RL33579; CRS Report RL33083, *Hurricane Katrina: Medicaid Issues*, by Evelyne P. Baumrucker, et al.; and CRS Report RL33738.

<sup>18</sup> See Congressional Budget Office, "Unauthorized Appropriations and Expiring Authorizations," Jan. 2007, at [<http://www.cbo.gov/publications/bysubject.cfm?cat=6>].

<sup>19</sup> 42 U.S.C. § 262a. See the CDC Select Agent Program page at [<http://www.cdc.gov/od/sap/>].

<sup>20</sup> See CRS Report RL32546.

<sup>21</sup> See CRS Report RL33589.