



## **CRS Report for Congress**

# **Public Health and Medical Preparedness and Response: Issues in the 110<sup>th</sup> Congress**

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### **Summary**

The 2001 terrorist attacks, Hurricane Katrina, and concerns about an influenza (“flu”) pandemic have sharpened congressional interest in the nation’s systems to track and respond to public health threats. The 109<sup>th</sup> Congress passed laws that reauthorized public health and medical preparedness and response programs in the Department of Health and Human Services (HHS), and reorganized parts of the Department of Homeland Security (DHS), including the establishment of an Office of Health Affairs (OHA). In its second session, the 110<sup>th</sup> Congress has continued its oversight of the implementation of these laws, focusing in particular on (1) how well equipped HHS and DHS are — in terms of authority, funding, policies, and workforce — to respond to complex health emergencies; (2) how well they and other federal agencies coordinate their efforts with each other; (3) the status of major federal initiatives, such as pandemic flu preparedness, biodefense research and development, and disaster planning for at-risk populations; and (4) the effect of the impending presidential transition on authorities and programs that were established during the current administration. This report, which will be updated, discusses key issues in public health and medical preparedness and response, citing additional CRS reports and other resources.

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

In December 2006, Congress passed the Pandemic and All-Hazards Preparedness Act (PAHPA, P.L. 109-417), extending programs for public health emergency preparedness and response activities in HHS, and establishing a Biomedical Advanced Research and Development Authority (BARDA) in HHS to develop medical countermeasures (e.g., diagnostic tests, drugs, and vaccines). In October 2006, Congress passed the Post-Katrina Emergency Management Reform Act of 2006 (PKA, Title VI of P.L. 109-295), which reorganized DHS and, within it, the Federal Emergency Management Agency (FEMA). The act also codified the position of Chief Medical Officer, with primary responsibility within DHS for medical issues related to natural and man-made disasters and terrorism. Pursuant to these laws, HHS’s efforts in public health and medical preparedness and response are led by the Assistant Secretary for

Preparedness and Response (ASPR, currently RADM W. Craig Vanderwagen), and related activities in DHS are coordinated by the Assistant Secretary for Health Affairs and Chief Medical Officer (currently Jeffrey W. Runge).<sup>1</sup>

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

**Federal Leadership and Coordination.** The PKA provided that the DHS Chief Medical Officer “shall have the primary responsibility *within the Department* for medical issues related to natural disasters, acts of terrorism, and other man-made disasters,” while the PAHPA provided that the “Secretary of [HHS] shall lead all *Federal* public health and medical response to public health emergencies and incidents....”<sup>2</sup> (Emphasis added.) The Government Accountability Office (GAO) noted, in the context of pandemic flu planning, that “... these leadership roles involve shared responsibilities, and it is not clear how these would work in practice.”<sup>3</sup> GAO recommended that DHS and HHS conduct training and exercises to ensure that federal leadership roles are clearly defined and understood.

**The Presidential Transition.** The transition to a new administration in January 2009 will mark the first such transition for agencies and programs that were established following the 2001 terrorist attacks. These include the Office of the HHS ASPR and all of the newly established (versus “legacy”) agencies and programs in DHS, including the Office of Health Affairs (OHA). The transition may be especially challenging for OHA, which is in the midst of rapid growth in funding and staffing. OHA was established (first as the office of the Chief Medical Officer) in 2005, received \$2 million in FY2006, and grew to \$117 million in FY2008, with \$161 million requested for FY2009. OHA is in the process of hiring permanent staff to carry out a variety of new responsibilities.

**HHS Response Capability.** 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. Though the HHS Secretary has authority for a no-year Public Health Emergency Fund, Congress has not appropriated monies to the fund for many years.<sup>4</sup>

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<sup>1</sup> See HHS, Assistant Secretary for Preparedness and Response, at [<http://www.hhs.gov/aspr>], and DHS, Office of Health Affairs, at [[http://www.dhs.gov/xabout/structure/editorial\\_0880.shtm](http://www.dhs.gov/xabout/structure/editorial_0880.shtm)]. See also 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 CRS Report RL33589), and CRS Report RL33729, *Federal Emergency Management Policy Changes After Hurricane Katrina: A Summary of Statutory Provisions*, by Keith Bea, Coordinator (hereafter CRS Report RL33729).

<sup>2</sup> P.L. 109-295, 120 Stat. 1409; P.L. 109-417, §101, 120 Stat. 2832.

<sup>3</sup> GAO, “Influenza Pandemic: Opportunities Exist to Clarify Federal Leadership Roles and Improve Pandemic Planning,” GAO-07-1257T, September 26, 2007. 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).

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

**State Grants for Public Health and Hospital Preparedness.** Since 2002, Congress has provided more than \$9 billion in grants to states to strengthen public health and hospital preparedness for public health threats. The PAHPA extended the programs, adding 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 public website.<sup>5</sup>

**Biodefense Research.** Several federal agencies support biodefense research. These include the Science and Technology Directorate in DHS, the National Institutes of Health in HHS, the Department of Defense, and the U.S. Department of Agriculture (USDA). The National Biodefense Analysis and Countermeasures Center (NBACC) was recently established by DHS to study biological threats, assess vulnerabilities and potential consequences, and establish a national capability for forensic analysis of evidence from bio-crimes and terrorism. DHS has also requested funding to build a new facility, the National Bio- and Agro-Defense Facility (NBAF), to house high-containment laboratories for the study of foreign animal diseases, such as Foot and Mouth Disease.<sup>6</sup>

**Project BioShield.** The 108<sup>th</sup> Congress launched Project BioShield to encourage the development of countermeasures that lack commercial markets. The 109<sup>th</sup> Congress required, in PAHPA, that the HHS Secretary develop and publish a strategic plan to guide HHS countermeasures research, development, and procurement. PAHPA also established the Biodefense Advanced Research and Development Authority (BARDA) in HHS to help implement the strategic plan, support countermeasure development, and facilitate communication between the government and developers. The 110<sup>th</sup> Congress has remained interested in the progress of Project BioShield and the establishment and effectiveness of BARDA.<sup>7</sup>

**Vulnerable Populations.** The terrorist attacks of 2001 and the hurricanes of 2005 showed that some people may be at greater risk, or more in need of special services, during and following a disaster. The PAHPA required the Secretary of HHS to consider, in planning, the needs of *at-risk individuals*, defined as children, pregnant women, senior citizens, and others as determined by the Secretary. The PKA required the head of FEMA to appoint a Disability Coordinator, charged, among other things, with coordinating emergency management policies and practices for individuals with disabilities.<sup>8</sup>

**Pandemic Influenza Preparedness.** To prepare for the threat of a human flu pandemic, 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,

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

<sup>6</sup> See CRS reports on homeland security research and development at [[http://apps.crs.gov/cli/cli.aspx?PRDS\\_CLI\\_ITEM\\_ID=589&from=3&fromId=19](http://apps.crs.gov/cli/cli.aspx?PRDS_CLI_ITEM_ID=589&from=3&fromId=19)].

<sup>7</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.

<sup>8</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.

Congress may be interested in other matters, such as (1) federal coordination of pandemic preparedness and response; (2) state, local, and private sector pandemic preparedness; (3) the impact of avian flu on affected countries; and (4) the possible effects of a flu pandemic on global trade and commerce.<sup>9</sup>

**Disaster Victims and Health Care.** The United States lacks a comprehensive health insurance system to pay for medical and supportive services for all persons who might be victims of a natural disaster, terrorist incident, or other public health emergency. As of 2006, about 47 million persons in the United States were uninsured. In the face of a catastrophic incident, enormous pressure would likely be placed on hospitals, physicians, and other providers to deliver care to these individuals without a clear source of reimbursement. Consensus has not been reached about the role of the federal government in addressing these barriers to coverage.<sup>10</sup> Several bills in the 110<sup>th</sup> Congress would address the health care 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>11</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 affected areas.<sup>12</sup> The Louisiana Health Care Redesign Collaborative, a federal, state, local, and private partnership, was developed to propose options for rebuilding the healthcare system in southern Louisiana through a Medicaid waiver and Medicare demonstration proposal.<sup>13</sup>

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<sup>9</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 RL34190, *Pandemic Influenza: An Analysis of State Preparedness and Response Plans*, by Sarah A. Lister and Holly Stockdale; 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*, by Emma Chanlett-Avery, Coordinator; and CRS Report RS22453, *Avian Flu Pandemic: Potential Impact of Trade Disruptions*, by Danielle Langton.

<sup>10</sup> See "Federal Assistance for Disaster-Related Healthcare Costs," in CRS Report RL33579, and CRS Report RL33927, *Selected Federal Compensation Programs for Physical Injury or Death*, by Sarah A. Lister and C. Stephen Redhead.

<sup>11</sup> See, for example, H.R. 1414/S. 201, H.R. 1247, and H.R. 3543.

<sup>12</sup> See Government Accountability Office, *Hurricane Katrina: Allocation and Use of \$2 Billion for Medicaid and Other Health Care Needs*, GAO-07-67, February 28, 2007.

<sup>13</sup> See 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, March 13, 2007, and the Louisiana Healthcare Redesign Collaborative, at [<http://www.dhh.louisiana.gov/offices/?ID=288>]. See also CRS Report RL33579; CRS Report RL33083, *Hurricane Katrina: Medicaid Issues*, by Evelyne P. Baumrucker et al.; 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).

Health emergencies often involve scarcities of resources, including personnel, equipment, drugs, and vaccines. Prioritizing the use of these 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>14</sup> Also, many are concerned that the nation's health care system, which is often overburdened by routine demands, would not be able to handle surges in demand that could result from some types of disasters. The PAHPA requires the HHS Secretary to assess national medical response capability in a quadrennial National Health Security Strategy, and authorizes HHS to acquire mobile medical assets, such as field hospitals.<sup>15</sup> Finally, Congress may consider the effectiveness of programs to deliver mental health counseling services to disaster victims, and whether these services are well coordinated and well targeted.<sup>16</sup>

**Authorities to Control Communicable Diseases.** 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 these domestic containment measures, a comprehensive response to a public health emergency may involve overlapping governmental authorities and attendant legal and economic issues. Recent incidents have expanded Congress's longstanding interest in the security of U.S. borders to include concerns about communicable diseases in travelers, which is a matter of federal jurisdiction. These incidents have brought into question the divisions of authority and effectiveness of coordination among federal agencies that are responsible for disease control, and for the security of the borders and the transportation infrastructure. Policy makers have noted that if these systems are unable to respond to common and expected infectious disease threats such as tuberculosis, they may also be unable to respond to more serious threats such as pandemic flu or bioterrorism. Effective solutions are elusive, but would ideally address scientific, technical, and economic constraints; the balance of individual and collective rights; and the roles of federal, state, and local authorities, and foreign governments.<sup>17</sup>

**Workforce Surge Capacity.** HHS manages several health professions programs geared toward alleviating shortages and maldistributions of physicians, nurses, and others who provide individual *health care* services. The *public health* workforce has, in contrast, received little federal attention until recently. The PAHPA authorized a loan repayment demonstration project for individuals who serve in state or local health departments in defined areas of need. Other efforts to bolster the ranks of health professionals for emergency response also include ensuring civil liability protection for

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<sup>14</sup> See CRS Report RL33381, *The Americans with Disabilities Act (ADA): Allocation of Scarce Medical Resources During a Pandemic*, by Nancy Lee Jones.

<sup>15</sup> See CRS Report RL33589.

<sup>16</sup> See CRS Report RL33738.

<sup>17</sup> See CRS Report RL33201, *Federal and State Quarantine and Isolation Authority*, by Kathleen S. Swendiman and Jennifer K. Elsea; CRS Report RL34144, *Extensively Drug-Resistant Tuberculosis (XDR-TB): Emerging Public Health Threats and Quarantine and Isolation*, by Kathleen S. Swendiman and Nancy Lee Jones; CRS Report RL33609, *Quarantine and Isolation: Selected Legal Issues Relating to Employment*, by Nancy Lee Jones and Jon O. Shimabukuro; CRS Report 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.

volunteer health professionals and establishing a system to verify their licenses and credentials. 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>18</sup>

**Liability, Compensation, and Intellectual Property Issues.** In December 2005, Congress passed Department of Defense Emergency Supplemental Appropriations, 2006 (P.L. 109-148), including Division C, titled the “Public Readiness and Emergency Preparedness Act” (PREP Act). Upon a declaration of emergency, the PREP Act eliminates liability, except in the case of willful misconduct, of manufacturers and others involved in the production and use of countermeasures.<sup>19</sup> In February 2007, HHS Secretary Leavitt made such a declaration with respect to pandemic flu vaccine.<sup>20</sup> The law also establishes, in the U.S. Treasury, a “Covered Countermeasure Process Fund,” and requires the HHS Secretary to develop a compensation mechanism for those who may be harmed by a covered countermeasure. As of FY2008, the fund has not received an appropriation; none is requested for FY2009. 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>21</sup>

**Expired Program Authorities.** The 110<sup>th</sup> Congress may consider reauthorization of some expired preparedness and response programs.<sup>22</sup> Legislation introduced in the Senate (S. 3127) would reauthorize the Select Agent Program, which is jointly managed by the Centers for Disease Control and Prevention (CDC) and USDA’s Animal and Plant Health Inspection Service (APHIS) to regulate certain biological pathogens and toxins that could be used for bioterrorism. Program authority expired at the end of FY2007.<sup>23</sup> 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>24</sup> Finally, authority for the Strategic National Stockpile of countermeasures has been amended since the terror attacks of 2001, but general program authority expired at the end of FY2006 and has not been extended.<sup>25</sup>

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<sup>18</sup> See CRS Report RS22255, *Emergency Response: Civil Liability of Volunteer Health Professionals*, by Kathleen Swendiman and Nathan Brooks; CRS Report RL32546, *Title VII Health Professions Education and Training: Issues in Reauthorization*, by Bernice Reyes-Akinbileje (hereafter CRS Report RL32546); and CRS Report RL33589.

<sup>19</sup> See CRS Report RS22327, *Pandemic Flu and Medical Biodefense Countermeasure Liability Limitation*, by Henry Cohen and Vanessa K. Burrows.

<sup>20</sup> *72 Federal Register* 4710-4711, February 1, 2007.

<sup>21</sup> See 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>22</sup> See Congressional Budget Office, “Unauthorized Appropriations and Expiring Authorizations,” January 2008, at [<http://www.cbo.gov/ftpdoc.cfm?index=8920&type=1>].

<sup>23</sup> 42 U.S.C. §262a and 7 USCS §8401. See CDC Select Agent Program, at [<http://www.cdc.gov/od/sap/>], and APHIS Agricultural Select Agent Program, at [[http://www.aphis.usda.gov/programs/ag\\_selectagent/](http://www.aphis.usda.gov/programs/ag_selectagent/)].

<sup>24</sup> See CRS Report RL32546.

<sup>25</sup> See CRS Report RL33589.