



## *Improving Pandemic Preparedness*

### **FY 2010 Labor HHS Appropriations Bill: Department of Health and Human Services**

	<b>2007</b>	<b>2008</b>	<b>2009 Omnibus</b>	<b>2010 TFAH</b>
State & Local Pandemic Preparedness	\$0	\$0	\$0	\$350,000,000*
CDC	\$70,000,000	\$154,981,335	\$156,046,000	\$157,000,000
FDA	\$33,000,000	\$38,000,000	TBD	\$42,000,000
NIH	\$35,000,000	\$34,000,000	TBD	\$35,000,000
Office of the Secretary	\$0	\$74,808,852	\$78,091,000	\$78,091,000
No-Year Funding	\$0	\$0	\$507,000,000	\$870,000,000**
BARDA	\$104,000,000	\$102,106,000	\$275,000,000	\$500,000,000

\*Congress appropriated \$600 million in FY 2006 for state and local pandemic preparedness activities.

\*\*This includes no-year funds from the Bush Administration's FY 2008 request.

**Pandemic Influenza Preparedness:** The H5N1 influenza virus has infected millions of birds and resulted in over 250 deaths in humans, with a human case fatality rate of over 60 percent. It is estimated that a moderate to severe pandemic could cause between 900,000 and almost 10 million hospitalizations, and an estimated 200,000 to 2 million deaths in the U.S.

In November 2005, President Bush requested \$7.1 billion over three years for emergency funding for pandemic influenza preparedness. In FY 2006, Congress appropriated \$5.6 billion in emergency funding. Emergency funding was not appropriated in FY 2007 or FY 2008, though funding was provided to support ongoing preparedness activities at CDC, FDA, NIH and the Office of the Secretary. HHS has achieved the following with these funds:

#### HHS Pandemic Influenza Accomplishments:

- HHS has procured 12.2 million courses of H5N1 pre-pandemic influenza vaccine to help meet the first wave of a pandemic. This stockpile is available to protect healthcare workers, first responders, and other critical workers in the early stages of a pandemic and to support clinical trials.
- HHS has reached its goal of stockpiling enough pandemic influenza antivirals to cover 44 million people. HHS has completed the purchase of 50 million courses of antiviral drugs for the Federal portion of the antiviral stockpile goal. As of February 8, 2008, the SNS contains 39.4 million regimens of Oseltamavir capsules, with 409,000 on order; and 9.9 million regimens of Zanamivir with 0 regimens on order.
- As of September 2008, States have purchased 22 million courses of antivirals. (The goal is for States to purchase 31 million courses).
- HHS has purchased medical supplies for the Strategic National Stockpile, including:
  - 104 million N95 respirators
  - 51.6 million surgical masks
  - 20 million syringes for pre-pandemic vaccine
  - 4,000 ventilators
- With over \$1 billion of HHS funding, six companies are in various stages of implementing commercial-scale production of cell-based methods and/or expanding their vaccine capacity using eggs. By 2011, U.S. based vaccine production capacity is expected to be at a point in which it can generate enough pandemic influenza vaccine for every American within six months of the time that the pandemic virus is identified, according to the most recent Pandemic Planning Update from HHS.

- HHS has completed clinical evaluation of a new rapid diagnostic test for avian and seasonal influenza that will be used in U.S. public health labs and at World Health Organization reference laboratories.
- HHS has deployed teams to help investigate suspected cases of human transmission of infection of influenza A in 12 countries and supported pandemic influenza preparedness activities in 40 countries, including helping countries to improve their lab capacities, develop and strengthen disease-surveillance systems, develop preparedness plans, and train health workers to respond rapidly to outbreaks.

A GAO report, while detailing some of the successful pandemic-related efforts by HHS, points out that “while these approaches have been significant, considerable more work needs to be done.” Former HHS Secretary Leavitt also underscored the need for continued preparedness in his final Pandemic Planning Update, noting that “This is a never-ending task. The media buzz has died down, but the ‘bird flu’ virus has not.” With that in mind, TFAH recommends continued funding for pandemic preparedness.

### **Recommendations:**

#### *No Year Funding:*

- \$870 million (no-year) requested by the Bush Administration for FY 2008. This money will be used for expanding cell and egg-based vaccine capacity, purchasing antivirals, and accelerating research and development of rapid diagnostic tests that can be used to enable doctors and field epidemiologists to quickly test patients for influenza viruses.

#### *Annual Funding:*

- \$350 million for state and local pandemic preparedness activities. “Local preparedness is the foundation of pandemic readiness” according to HHS (Pandemic Planning Update VI). In FY 2006, Congress provided \$600 million for state and local pandemic preparedness grants. Since then, grantee activities have included: conducting statewide pandemic influenza preparedness summits and assessing preparedness gaps; conducting exercises at the state and local levels (mass vaccinations, community-based school closures, and medical surge); developing antiviral distribution plans; reviewing state pandemic plans; and filling identified gaps. All of this funding has been allocated and must be reinstated. According to Richard Besser, MD, Acting CDC Director, “What is learned from these projects can benefit everyone because it could improve national, regional and local public health detection and response to a pandemic involving influenza.”<sup>1</sup> Further funding is necessary for states and localities to continue updating and exercising pandemic response plans, building medical surge capacity, and learning lessons from one another.
- \$157 million for CDC to reduce the time between detection of a pandemic and the development of a vaccine; develop better tests to detect influenza virus; develop and maintain international surveillance, diagnostic and rapid response capabilities; strengthen risk communications; and develop and test plans to distribute countermeasures at the outset of a pandemic.
- \$42 million for FDA to inspect flu vaccine manufacturers; identify counterfeit flu products; review new applications; conduct drug reviews; and develop agency response plans.
- \$35 million for NIH to conduct international and domestic animal surveillance programs and support research into the development of new vaccines, therapeutics and diagnostics.
- \$78 million for the Office of the Secretary for risk communications, international surveillance and other activities.

**The Biomedical Advanced Research and Development Authority (BARDA)** was established in 2006 to help jumpstart a new cycle of innovation in vaccines, diagnostics and therapeutics in order to combat health threats. BARDA provides incentives and guidance for research and development of products to counter bioterrorism and pandemic flu and manages Project BioShield, which includes the procurement and advanced development of medical countermeasures for chemical, biological, radiological, and nuclear agents. According to an analysis by the Center for Biosecurity, BARDA’s current level of funding has allowed The Assistant Secretary for Preparedness and Response (ASPR) to establish the infrastructure necessary to support advanced research and development of medical countermeasures. However, funding has been insufficient to support the successful development of a whole range of medical countermeasures.

To achieve the goals identified in HHS' Public Health Emergency Medical Countermeasures Enterprise Implementation Plan, BARDA would need \$3.39 billion in FY 2009 to have a 90 percent chance of developing successful medical countermeasures for each biodefense requirement set forth in the plan. This investment would need to be sustained.

Recommendation: Provide \$500 million for BARDA, within the Office of the ASPR, as a starting point to build toward higher levels of funding that must ultimately be allocated and sustained. These funds are requested with two years of fiscal availability and would support research on additional countermeasures for biological threat agents, volatile nerve agents and radiological and nuclear threats.

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<sup>1</sup> <http://www.cdc.gov/media/pressrel/2008/r080924.htm>