



Improving Pandemic Preparedness

**FY 2012 Labor HHS Appropriations Bill
Department of Health and Human Services**

Agency	Program	2010	2012 President	2012 TFAH
CDC	Pandemic Influenza	\$159,721,000	\$159,672,000	\$159,672,000
FDA	Pandemic Influenza	\$46,730,000	\$51,014,000	\$51,014,000
NIH	Pandemic Influenza	\$35,000,000	\$33,000,000	\$35,000,000
Office of the Secretary	Pandemic Influenza	\$65,000,000	\$0	\$65,000,000
ASPR	BARDA	\$320,000,000	\$665,000,000	\$665,000,000
ASPR	Strategic Investor	--	\$100,000,000	\$100,000,000

Pandemic Influenza Preparedness:

The recent H1N1 flu outbreak demonstrated how rapidly a new strain of flu can emerge and spread around the world. The sudden outbreak of this novel flu virus has tested the world’s public health preparedness. H1N1 provided a real-world test that showed the strengths and vulnerabilities in the abilities of the United States and the rest of the world to respond to a major infectious disease outbreak.

Prior pandemic preparedness investments resulted in the development of medical countermeasures that were used in the H1N1 response, as well as building the nation’s surveillance, distribution, communications, and laboratory capacity. Without ongoing investment, America’s vaccine, antiviral, and laboratory capacity would have been years behind other nations – but there is much work to be done to be fully prepared for the next outbreak. Continuing our annual pandemic flu preparedness activities at CDC, FDA, NIH and the Office of the Secretary will help strengthen our preparedness and response during any future outbreaks by supporting vaccine production, distribution and administration; surveillance; regulatory science; and community mitigation planning. As we discovered during H1N1, these programs cannot simply be funded after an outbreak hits.

Recommendation:

Provide \$160 million for CDC (which funds both seasonal and pandemic influenza activities), \$45 million for FDA, \$33 million for NIH, and \$65 million for the Office of the Secretary (OS), as proposed in the President’s budget to expand international and domestic surveillance and detection capabilities, including the identification of vaccine virus strains; identify emerging viruses with pandemic potential; accelerate research and development of rapid diagnostic tests; improve pandemic preparedness and response, as well as our ability to contain a potential pandemic; and support international efforts to strengthen vaccine manufacturing infrastructure, expand surveillance systems, and improve pandemic influenza preparedness and response capabilities. In the President’s request, NIH and OS money would come from unobligated H1N1 supplemental funds.

The Biomedical Advanced Research and Development Authority (BARDA) and Medical Countermeasure Enterprise:

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. BARDA has more than 25 product candidates in development, including anthrax vaccines and antitoxins, radiation therapeutics and diagnostics, smallpox antivirals and vaccines, ChemPaks, broad spectrum antimicrobials, and influenza vaccines and technologies. BioShield has helped build the stockpile of smallpox vaccine, radiation treatments, anthrax antitoxins, and botulism antitoxins. For example, BioShield has taken the botulism threat off the table by stockpiling enough antitoxin to last until 2026. BARDA is also using unobligated H1N1 funds to support Centers of Innovation for Advanced Development and Manufacturing, which would allow for flexible manufacturing facilities, supported the development of H1N1 and H5N1 vaccine, has built domestic manufacturing surge capacity for flu, and has supported the opening of the nation's first cell-based influenza vaccine facility.

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 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.

In August 2010, HHS released a review of the federal medical countermeasure enterprise.¹ The review called for a strategy to address key priorities to create incentives for private industry while protecting the public's interest, including advancing regulatory science, improving domestic manufacturing capacity, developing financial incentives and novel partnerships with stakeholders, and addressing roadblocks from concept development to advanced development. The President's FY2012 request includes funding for a new medical countermeasure strategic investment firm, as proposed in the review. The strategic investor would act as an independent firm to bring together small companies and private investors to advance medical products that would meet the national security needs of the nation, such as novel antimicrobials and multiuse platform technologies.

Recommendation:

Provide \$665 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 would support research on additional countermeasures for biological threat agents, volatile nerve agents and radiological and nuclear threats. Funding will be targeted to countermeasure development in the high priority areas of anthrax, broad-spectrum antimicrobials, diagnostics, chemical nerve agents, next-generation influenza vaccines, and radiation countermeasures.

We also recommend funding the HHS request for \$100 million to establish a new Medical Countermeasure Strategic Investor. The approach, modeled after successful programs such as In-Q-Tel's work with the intelligence community, represents a novel way of attracting private equity and biotechnology companies into the market for medical countermeasures.

We also urge you to include language, as included in the President's 2010 Budget Amendment request, to allow funds provided for the H1N1 response to be used to advance regulatory science at FDA.² Scientific innovation and capacity is necessary to oversee medical countermeasures, to modernize and allow for increased efficiency in the regulatory review process.

Implication of Cuts:

In FY2008, BARDA's budget was only \$150 million as the program was just getting off the ground. Reverting to these numbers would be catastrophic for America's domestic vaccine manufacturing capacity, hinder research into new flu antivirals, cancel existing contracts for biotech research, and block the potential for new countermeasures for chemical, biological, radiological, and nuclear threats.

¹ <https://www.medicalcountermeasures.gov/documents/MCMReviewFinalcover-508.pdfv>

² http://www.whitehouse.gov/sites/default/files/omb/assets/budget_amendments/amendment_08_20_10_0.pdf