




REPORT TO CONGRESS

Pandemic Influenza Preparedness Spending

The Department of Health and Human Services

Conference Report 109-359

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“The conferees direct the Secretary to provide on a semi-annual basis to the House and Senate Appropriations Committees a report identifying the disbursements of funds received under this heading and a listing of the governments, companies and organizations that received funding. The report should include the amount and purpose of each grant or other form of assistance. Finally, the report should include the cumulative obligations by activity of the funds made available under this heading for pandemic preparedness, as well as any remaining unobligated balances.”

AND

“The conferees direct the Secretary of Health and Human Services to provide the Committees on Appropriations with quarterly reports on the expenditure of the funds provided for the Food and Drug Administration in this Act for pandemic influenza preparedness. The reports shall also include details on any reimbursements received by the agency from any other federal agencies for expenses incurred for pandemic influenza preparedness. The first report shall be transmitted no later than February 15, 2006.”

Introduction

The current pandemic influenza threat stems from outbreaks of avian influenza in Asia and Europe. The ability of the H5N1 virus to infect a wide range of hosts, including birds and humans, is of great concern to the public health and medical community. Although the virus has not yet shown an ability to transmit efficiently between humans, it has the potential to acquire this capability. Once a pandemic begins, time will be a critical factor in our ability to accomplish the necessary production and delivery of vaccines and other medical countermeasures required to mitigate the pandemic.

To prepare for the possibility of a pandemic, the President requested a total of \$7.1 billion to fund a three-year strategy to enhance the Nation’s pandemic influenza preparedness, of which \$6.7 billion was designated for the Department of Health and Human Services (HHS). HHS is responsible for the public health and medical response for a pandemic of human influenza. On November 2, 2005, HHS released the *HHS Pandemic Influenza Plan*, which defines the HHS strategy for preparedness and response to this threat and provides a detailed framework for the operational plans being developed by HHS agencies and State, local, and tribal health authorities.

In December 2005, Congress appropriated \$3.3 billion for HHS, the first year of funding for the *HHS Pandemic Influenza Plan*. With this funding, HHS is implementing the first stage of activities of the *HHS Pandemic Influenza Plan*, which include: expanding domestic production and surge capacity of vaccine and antiviral drugs; enlarging H5N1 vaccine and antiviral drug stockpiles; supporting advanced development of cell culture vaccines, antigen-sparing technologies, and new or improved antiviral drugs; stockpiling of medical supplies, masks, and ventilators; improving State and local preparedness; enhancing Food and Drug Administration’s (FDA) regulatory science base; and expanding surveillance, research, and international

collaboration efforts of Centers for Disease Control and Prevention (CDC), National Institutes of Health (NIH), and the Office of Global Health Affairs (OGHA).

These allocations of funding by category are HHS decisions made with the best scientific evidence available. HHS may reallocate these funds in the future if new science or contracting realities necessitate modification in order to best protect the Nation against a pandemic threat. The attached table provides detailed information on obligations to date by category area.

Vaccine

A key goal of the *HHS Pandemic Influenza Plan* is to provide pandemic influenza vaccine to every American within six months of detection of sustained human-to-human transmission of pandemic influenza. To achieve this goal, HHS is investing in the expansion of vaccine manufacturing capacity (egg- and cell-based), the advanced development of new cell-based vaccines, antigen-sparing technologies, and the establishment and maintenance of pre-pandemic vaccine stockpiles.

Accomplishments to Date:

- On May 4, 2006, HHS awarded \$1 billion in cell-based advanced research and development contracts to five new manufacturers to enable U.S. production of at least 240 million courses of cell-based pandemic vaccine within six months of the emergence of a pandemic virus. Contracts were awarded to Glaxo SmithKline, MedImmune, Novartis, Solvay, and Dynport (with Baxter).
- In fall 2005, HHS awarded \$80 million to purchase approximately 2.6 million courses of H5N1 bulk vaccine from U.S. licensed influenza vaccine manufacturers (Sanofi Pasteur and Chiron). HHS plans to purchase additional vaccine in fall 2006.
- HHS issued a Request for Proposals (RFP) for Antigen-Sparing Technologies on March 17, 2006 and plans to award contracts by September 2006.
- HHS issued a Request for Information on enhancing domestic egg-based and other influenza vaccine production capacity through new and converted facilities on January, 30, 2006 and plans to issue RFPs in the summer of 2006.
- FDA is providing technical support for the above mentioned HHS activities. FDA is also actively engaged in efforts to build and enhance its infrastructure, by hiring personnel with expertise in essential clinical, product safety, and manufacturing areas to support new vaccine development and licensure for pandemic influenza. FDA is currently advertising for experts, interviewing, and proceeding with hiring staff to be on board by the end of the fiscal year.

As of May 15, 2006, HHS has obligated \$1.085 billion out of the \$1.79 billion allocated for vaccine-related activities.

Antivirals

Another key goal in the HHS Pandemic Influenza Plan is to ensure the availability of antiviral treatment courses for 25 percent of the population, or 75 million individuals. By FY 2008 and with full funding of the President's plan, the Federal government will complete the 20 million course antiviral stockpile purchase to maintain the function of the health care system and protect first responders, and stockpile an additional 24 million treatment courses for treatment of pandemic influenza, for a total of 44 million treatment courses. State and local jurisdictions may purchase up to 31 million treatment courses of antivirals through leveraging Federal contracting and a subsidy of up to 25 percent of the Federal contract price. In addition, the Federal government will stockpile 6 million treatment courses to attempt to quench up to two local outbreaks of pandemic influenza in the U.S., if the disease were to manifest itself in this very limited way as distinct from numerous simultaneous outbreaks in geographically separated communities. The Federal government and the States will together purchase a total of 81 million courses of antivirals. HHS will also invest in the advanced development of new antiviral drugs.

Accomplishments to Date:

- HHS procured 20.2 million courses of Tamiflu and Relenza to fulfill the plans to purchase 20 million treatment courses of antivirals and six million courses for prophylactic usage for a Federal total of 26 million courses.
- HHS issued a RFP for the Advanced Development of Influenza Antiviral Drugs on June 13, 2006 and plans to award contracts by fall 2006.
- Federal contracts for States to utilize for the purchase of federally-subsidized and unsubsidized purchases of influenza antiviral drugs are expected in summer 2006 for State usage.

As of May 15, 2006, HHS has obligated \$280 million out of the \$721 million allocated for antivirals-related activities.

Medical Supplies

HHS is expanding medical infrastructure and response capacity during an influenza pandemic by stockpiling medical supplies for distribution to States in the event of a pandemic. HHS' plan is to purchase personal protective equipment (e.g., masks) to prevent direct contact with the pandemic influenza virus and to reduce the spread of the disease. In addition, HHS plans to purchase and stockpile ventilators to provide assistance in patient breathing to the critically ill. Other purchases include intravenous antibiotics, syringes and needles, and non-pharmaceuticals.

Accomplishments to Date:

- HHS has purchased over 150 million masks. This includes 94.8 million N95 masks and 63.7 million surgical masks.

As of May 15, 2006, HHS has obligated \$50 million out of the \$162 million allocated for other medical supplies.

State and Local Funding

States and local governments will play a key role in responding to a pandemic. HHS is working with State and local communities to complete their pandemic influenza plans and to exercise those plans. HHS is also conducting a pandemic influenza summit in every State and Territory. These summits bring together HHS leadership with State leadership, health professionals, schools, and the private sector to discuss State and community preparedness issues.

Accomplishments to Date:

- HHS awarded \$100 million for State and local preparedness and conducted over 50 State pandemic influenza summits by May 31. The remaining \$250 million will be awarded to States this summer following a review of State applications.

As of May 15, 2006, HHS has obligated \$100 million out of the \$350 million available for State and Local preparedness.

International Collaboration

HHS is actively engaged with countries around the world to help them prepare for the possibility of a pandemic influenza outbreak and help to minimize and contain the impact of an outbreak should one occur. HHS is collaborating with the Department of State and the U.S. Agency for International Development to enhance preparedness in other countries by providing training, direct assistance, supplies, reagents and technical support to Ministries of Health (MoH) and non-governmental organizations (NGO).

Accomplishments to Date:

- HHS' Office of Public Health Emergency Preparedness (OPHEP) and OGHA in partnership with the CDC obligated \$13 million to award (and/or supplement) grants/cooperative agreements to 25 countries and/or multilateral organizations.

As of May 15, 2006, HHS has obligated \$14 million out of the \$125 million allocated for international collaboration.

Other Domestic (Surveillance, Risk Communications, Laboratory Capacity, Quarantine Stations, Rapid Testing)

HHS is working on the domestic front to enhance surveillance through BioSense, increase and expand the capacity of quarantine stations, improve diagnostic tools, develop risk communications materials, and enhance laboratory capacity at the Centers for Disease Control and Prevention. These activities will allow HHS to build the domestic capacity needed to detect and respond to a pandemic early and effectively.

Accomplishments to Date:

- The Office of the Assistant Secretary of Public Affairs (ASPA) has developed an extensive array of projects focusing on avian and pandemic flu communications. ASPA has completed twelve preparedness checklists and designed the government Web site, www.pandemicflu.gov.
- CDC has obligated funds to facilitate the implementation of a Laboratory Information Management System (LIMS) that will facilitate the rapid, real time transmission of laboratory information regarding influenza tests and results between CDC, State and local area health departments, and international laboratory partners. Funds have also been obligated to develop advanced mass spectrometry techniques.
- HHS issued a Request for Proposals on Point-of-Care Diagnostics on May 19, 2006 and expects to make awards in fall 2006.

As of May 15, 2006, HHS has obligated \$7 million out of the \$171 million allocated for these domestic activities.

FDA

In order to provide a comprehensive depiction of the how all operating divisions of HHS are working together to prepare for a pandemic of human influenza, FDA obligations and activities are included in this report. FDA's efforts to enhance its infrastructure and provide personnel and expertise in the essential clinical, product and manufacturing areas are vital to support new vaccine development.

From February 15, 2006 to May 15, 2006, FDA expended \$849,000 of the \$20 million in emergency supplemental funds on pandemic influenza activities. At this time, FDA has not received, nor does it anticipate the receipt of any reimbursements from any other federal agencies for pandemic influenza preparedness. Within these funds, FDA has obligated \$375,000 for information technology systems such as the Lot Release System Development, which supports the testing and release of vaccines to ensure that they are safe and effective for the American public. These funds will expand capacity to accommodate future pandemic influenza vaccine products.

FDA has also expended funds to upgrade surge capacity and Biosafety Level 3 (BSL3) laboratories and prepare for additional personnel to be hired to meet the growing demand for intensive and quick interactions with manufacturers, HHS partners, and other agencies to achieve high-priority influenza vaccine development and licensure. This capability is critical to enhancing product availability, assuring timely and expert evaluation of product quality, supporting national preparedness and response capacities for pandemic influenza, and maintaining public confidence in vaccine products.

FDA has published new guidances and held meetings for industry on facilitating development, manufacturing and evaluation of influenza vaccines, including using new technologies. FDA has initiated a global pandemic vaccine regulatory harmonization effort, working closely with WHO, Health Canada and other regulatory agencies. FDA continues to work closely with HHS partners and industry to advance production, evaluation, and stockpiling of pandemic vaccines.

FDA is also fully engaged in building and enhancing its critical infrastructure to gain personnel and expertise in essential clinical, product safety, and manufacturing areas necessary to support vaccine development, manufacturing and preparedness for pandemic influenza. Of the 75 Center for Biologic Evaluation and Review positions FDA is expecting to hire with the emergency supplemental funds, 43 have recruitment actions in process, 22 names with hiring dates have been identified and 10 people have been hired. Facilities have been secured to house the hired staff and contracts are being initiated to ensure facilities, including laboratories critical for vaccine testing, have needed surge capacity. All of these investments are an integral part of the *HHS Pandemic Influenza Plan*.

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(\$ in millions)

Activities Funded with FY 2006 Emergency Funding: **FY 2006**

Vaccine Funding **\$1,791.0**

FDA -- Contract with PSI International	\$0.4
Purpose - This contract was issued for the purpose of IT support such as Lot Release System Development	
FDA -- Additional Contracts - XL Assoc. and Professional & Scientific Assoc.	\$0.2
Purpose - Administrative support-Events Mgmt. and Procurement Support	
FDA -- Program Management Costs - Salaries and Benefits, Office furniture purchases and miscellaneous	\$0.2
OPHEP -- Task orders on contract issued (10/5/05) to sanofi pasteur and Chiron by OPHEP.....	\$80.0
Purpose - Contract issued for the acquisition of H5N1 vaccine for pre-pandemic stockpile.	
OPHEP -- Contract awarded (5/1/06) to Glaxo SmithKline/MedImmune/Novartis/Solvay/DynPort by OPHEP.....	\$1,004.0
Purpose - Contract issued for the advanced develop. of cell-based pan flu vaccines for domestic licensure & mfg	

Cumulative Obligations, Vaccine **\$1,084.8**
Unobligated Balances, Vaccine..... *\$706.2*

Antivirals Funding **\$721.0**

OPHEP -- Task order on contract awarded to Roche and Glaxo SmithKline by OPHEP.....	\$280.0
Purpose - Contract issued for the acquisition of Tamiflu and Relenza antivirals for federal pandemic stockpile.	

Cumulative Obligations, Antivirals **\$280.0**
Unobligated Balances, Antivirals..... *\$441.0*

Medical Supplies (PPE, ventilators, etc.) Funding **\$162.0**

CDC -- Surgical Masks and N-95 respirators.....	\$50.0
Purchase of 62.5 million N-95 respirators for potential distribution to affected areas in case of an influenza pandemic.	

Cumulative Obligations, Medical Supplies **\$50.0**
Unobligated Balances, Medical Supplies..... *\$112.0*

State and Local Preparedness Funding **\$350.0**

CDC -- Cooperative Agreements for special projects of national significance.	
ALASKA DEPT OF HEALTH & SOCIAL SERVICES.....	\$0.7
OREGON DEPT OF HUMAN SERVICES, HLTH SRVC.....	\$1.4
WASHINGTON STATE DEPARTMENT OF HEALTH.....	\$2.0
IDAHO DEPT. OF HEALTH AND WELFARE.....	\$0.8
VERMONT DEPARTMENT OF HEALTH.....	\$0.7
MAINE DEPT OF HUMAN SERVICES.....	\$0.8
CONNECTICUT DEPT OF PUBLIC HEALTH.....	\$1.3
MASSACHUSETTS DEPARTMENT OF PUBLIC HLTH.....	\$2.1
RHODE ISLAND DEPARTMENT OF HEALTH.....	\$0.8
NH DIVISION OF PUBLIC HEALTH SERVICES.....	\$0.8
NY STATE DOH/HEALTH RESEARCH, INC.....	\$3.2
NEW JERSEY DEPT OF HEALTH/SENIOR SERVICE.....	\$2.6
MHRA/NYC DOH.....	\$2.5
VIRGIN ISLANDS DEPARTMENT OF HEALTH.....	\$0.1
PUERTO RICO DEPARTMENT OF HEALTH.....	\$1.4

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DISTRICT OF COLUMBIA DEPT OF HEALTH.....	\$0.6
PENNSYLVANIA DEPT OF HEALTH.....	\$3.5
DELAWARE HEALTH & SO. SVCS.....	\$0.7
WV DEPT OF HEALTH & HUMAN RESOURCES.....	\$0.9
VIRGINIA DEPARTMENT OF HEALTH.....	\$2.3
MARYLAND DEPT OF HEALTH & MENTAL HYGIENE.....	\$1.8
TENNESSE DEPARTMENT OF HEALTH.....	\$1.9
SO. CAROLINA DEPT OF HLTH & ENVIR CONTRL.....	\$1.5
ALABAMA DEPARTMENT OF PUBLIC HEALTH.....	\$1.6
NC DEPT OF HEALTH AND HUMAN SERVICES.....	\$2.5
MISSISSIPPI STATE DEPT OF HEALTH.....	\$1.2
FLORIDA DEPT. OF HEALTH.....	\$4.6
GEORGIA DIVISION OF PUBLIC HEALTH.....	\$2.6
KENTUCKY CABINET FOR HEALTH SCIENCE.....	\$1.5
ILLINOIS DEPT OF PUBLIC HEALTH.....	\$2.9
MINNESOTA DEPARTMENT OF HEALTH.....	\$1.7
OHIO DEPT OF HEALTH.....	\$3.3
WISCONSIN DEPARTMENT OF HLTH/FAMILY SVCS.....	\$1.8
CHICAGO DEPARTMENT OF HEALTH.....	\$1.2
MICHIGAN DEPARTMENT OF COMMUNITY HEALTH.....	\$3.0
INDIANA STATE DEPARTMENT OF HEALTH.....	\$2.0
ARKANSAS DEPARTMENT OF HEALTH.....	\$1.2
OKLAHOMA STATE DEPT OF HEALTH.....	\$1.4
NEW MEXICO DEPARTMENT OF HEALTH.....	\$1.0
TEXAS DEPT OF STATE HEALTH SERVICE.....	\$5.9
LOUISIANA DEPT OF HEALTH & HOSPITALS.....	\$1.6
IOWA DEPARTMENT OF PUBLIC HEALTH.....	\$1.2
MISSOURI DEPT OF HEALTH & SENIOR SERVICE.....	\$1.9
NE DEPT OF HHS REGULATION & LICENSURE.....	\$0.9
KANSAS DEPT OF HEALTH & ENVIRONMENT.....	\$1.2
COLORADO DEPT OF PUB HLTH & ENVIRON.....	\$1.6
MONTANA DEPT OF PUB HLTH & HUMAN SVCS.....	\$0.7
UTAH DEPARTMENT OF HEALTH.....	\$1.1
SOUTH DAKOTA DEPARTMENT OF HELTH.....	\$0.7
WYOMING DEPARTMENT OF HEALTH.....	\$0.6
ND DEPARTMENT OF HEALTH.....	\$0.7
NEVADA DEPT. OF HEALTH & HUMAN SERVICES.....	\$1.0
HA WAII DEPARTMENT OF HEALTH.....	\$0.8
ARIZONA DEPT OF HEALTH SERVICES.....	\$1.9
GUAM DEPT OF PUBLIC HEALTH/SOCIAL SVCS.....	\$0.1
LOS ANGELES CO DEPT OF HLTH SERVICES.....	\$2.9
CALIFORNIA DEPARTMENT OF HEALTH SERVICES.....	\$6.7
COMMONWEALTH OF N. MARIANA ISLANDS.....	\$0.1
REPUBLIC OF THE MARSHALL ISLANDS.....	\$0.1
REPUBLIC OF PALAU.....	\$0.1
FEDERATED STATES OF MICRONESIA.....	\$0.1
AMERICAN SAMOA GOVERNMENT DOH.....	\$0.1

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Cumulative Obligations, State and Local Preparedness	\$100.0
<i>Unobligated Balances, State and Local Preparedness.....</i>	<i>\$250.0</i>

<u>International Activities Funding</u>	<u>\$125.0</u>
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OPHEP -- Supplement Grant to Bangladesh.....	\$1.0
Purpose - To support preparedness, surveillance and containment activities	
OPHEP -- Supplement Grant to Central Asia Platform	\$1.4
Purpose - To support preparedness, containment and risk communication activities	
OPHEP -- Supplement Grant to China.....	\$0.4
Purpose - To support preparedness, containment and risk communication activities	
OPHEP -- Supplement Grant to India.....	\$0.4
Purpose - To support preparedness, communication and response activities	
OPHEP -- Supplement Grant to Indonesia.....	\$1.9
Purpose - To support detection, containment and communication activities	
OPHEP -- Supplement Grant to Malaysia.....	\$0.4
Purpose - To support preparedness and risk communication activities	
OPHEP -- Supplement Grant to Mongolia.....	\$0.4
Purpose - To support preparedness and risk communication activities	
OPHEP -- Supplement Grant to Pakistan.....	\$0.4
Purpose - To support preparedness and risk communication activities	
OPHEP -- Supplement Grant to Philippines.....	\$0.4
Purpose - To support risk communication, preparedness and containment activities	
OPHEP -- Grant to Ukraine.....	\$0.4
Purpose - To support preparedness and risk communication activities	
OPHEP -- Supplement Grant to WPRO (Laos, Vietnam).....	\$0.3
Purpose - To support effective risk communication activities	
OPHEP -- Supplement Grant to WPRO (Cambodia).....	\$0.8
Purpose - To support effective risk communication/containment activities	
OPHEP -- Supplement Grant to Bangkok Regional Site.....	\$1.0
Purpose - To support response and containment activities	
OPHEP -- Supplement Grant to WHO-AFRO Brazza-ville.....	\$0.5
Purpose - To support response and containment activities	
OPHEP -- Supplement Grant to WHO-AFRO Brazza-ville.....	\$0.4
Purpose - To provide expert staffing support	
OPHEP -- Supplement Grant to WHO Egypt EMRO.....	\$0.4
Purpose - To provide expert support	
OPHEP -- Grant to Kenya Regional Site.....	\$0.1
Purpose - To support preparedness and communication activities	
OPHEP -- Grant to Kenya Regional Site.....	\$1.0
Purpose - To support response and containment activities	
OGHA -- Supplement Grant to Angola.....	\$0.8
Purpose - To support surveillance and detection activities	
OGHA -- Supplement Grant to Afghanistan.....	\$0.8
Purpose - To support surveillance and detection activities	
OGHA -- Supplement Grant to Brazil.....	\$0.1
Purpose - To support surveillance and detection activities	
OGHA -- Supplement Grant to Turkey.....	\$0.3
Purpose - To support surveillance and detection activities	
CDC -- Personnel stationed at international surveillance regions.....	\$0.2
CDC -- International Travel for the Outbreak Monitoring Team and to assess preparedness.....	\$0.2
Cumulative Obligations, International Activities	13.6
<i>Unobligated Balances, International Activities.....</i>	<i>\$111.4</i>

<u>Other Domestic (Surveillance, Quarantine, Lab Capacity, Rapid Tests) Funding</u>	<u>\$133.0</u>
CDC -- Mass Spectrometer: Applied BioSystems contract.....	\$0.7

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Mass spectrometry analysis of influenza virus surface proteins.

CDC -- Mass Spectrometer: Eskigent Systems contract.....	\$0.3
HPLC system for influenza mass spectrometry project.	
CDC -- Mass Spectrometer: Thermo Electron Corp. contract.....	\$0.5
Thermo Orbitrap required for analysis of influenza proteins.	
CDC -- Pandemic Flu Operation Plan: Booz Allen Hamilton Inc. contract.....	\$0.3
Professional and technical services in support of an evaluation of the CDC's operation plan.	
CDC -- Pandemic Flu Operation Plan: MPRI, Inc. contract	\$1.3
Develop operational and tactical action plan for pandemic influenza.	
CDC -- Lab Info Management System: StarLIMS contract.....	\$0.3
Enterprise development kit for the Laboratory Information Management Systems	
CDC -- Lab Info Management System: Northrop Grumman contract.....	\$0.2
LITS Plus™ Programming and Support Services	
CDC -- Lab Info Management System: Lockheed Martin contract.....	\$0.2
Consultation, facilitation, project management and technical support services to the National Center for Infectious Diseases (NCID)	
CDC -- Various contracts under \$75,000 each.....	\$0.3
Equipment for upgrading lab capacity including hybridization system, protein array system, microtome, and freezers	
CDC -- Personnel engaged in upgrading lab capacity.....	\$2.1
Cumulative Obligations, Other Domestic	<u>\$6.2</u>
<i>Unobligated Balances, Other Domestic</i>	<i>\$126.8</i>

Risk Communications Funding **\$38.0**

CDC -- State Pandemic Summits.....	\$0.1
Travel to State Pandemic Influenza Summits	
CDC -- Phoenix Air Group Inc. contract.....	\$1.0
Pandemic Influenza State Summits	
Cumulative Obligations, Risk Communicatons	<u>\$1.1</u>
<i>Unobligated Balances, Risk Communications</i>	<i>\$36.9</i>

Total Cumulative Obligations..... **\$1,535.8**
Total Unobligated Balances..... **\$1,784.2**

Total HHS Pandemic Flu Funding from Emergency Supplemental..... **\$3,320.0**

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