

THE CSTE WASHINGTON REPORT

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EDITOR'S NOTE: The U.S. Department of Health and Human Services (HHS) and Institut Pasteur (IP) February 6 agreed to carry out joint activities, beginning in Southeast Asia, to strengthen global capacity to detect influenza viruses that could have the potential to trigger a human pandemic. The Memorandum of Understanding (MOU), signed by HHS Deputy Secretary Alex M. Azar and IP President Professor Alice Dautry, establishes a Joint HHS-IP Working Group to oversee the development of collaborative projects, to include the following:

- * Building capacity in terms of surveillance, epidemiological investigation, testing, diagnosis, and control of infectious disease in countries affected by and at-risk for the spread of the H5N1 influenza strain;
- * Exchanging technical expertise to foster rapid response to disease threats; and
- * Disseminating effective and accurate public information on infectious disease, including in local languages in developing countries – additional information is included in this Washington Report.

The *CSTE Washington Report* is provided as an information resource for members of the Council of State and Territorial Epidemiologists on federal legislation and regulation affecting public health and epidemiology in the U.S. Legislation cited in the report can be accessed via <http://www.thomas.loc.gov> Regulations cited can be accessed via <http://www.gpo.gov>

PRESIDENT RELEASES 2007 BUDGET – President Bush presented his FY 2007 budget request to Congress on February 6th. Overall, the budget cuts public health agencies and programs by more than \$600 million, or about 1.2 percent. However, this comes on top of over \$1 billion in cuts for health programs in FY 2006. In addition, many programs have been flat-funded for several years resulting in erosion of purchasing power. The Centers for Disease Control and Prevention's core programs suffered a 4.7 percent cut in FY 2006 and the President's budget proposes cutting another 4 percent in FY 2007.

One bright area in the budget for CDC is an increase of \$93 million for HIV/AIDS prevention activities, including \$85 million for State and Local health departments. The increase comes after nearly 5 years of flat budgets. The President also requested the second installment, \$2.3 billion of his \$7.1 billion overall budget for pandemic flu preparedness. Congress provided \$3.8 billion in FY 2006, with \$350 million allotted for state and local pandemic preparedness.

A detailed table of the President's FY 2007 budget request for CDC and how it compares with program funding levels in FY 2005 and FY 2006 can be viewed at: <http://healthyamericans.org/reports/budget06/FY2007BudgetLatest.pdf>

HHS AWARDS BIOSHIELD CONTRACT FOR TWO ADDITIONAL MEDICAL COUNTERMEASURES FOR RADIOLOGICAL OR NUCLEAR INCIDENTS --

The Department of Health and Human Services (HHS) February 13 awarded a \$21.9 million contract to Akorn, Inc. of Buffalo Grove, Ill., for the manufacture and delivery of two medical countermeasures for radiological or nuclear incidents. Akorn, Inc. will deliver 390,000 doses of Ca-DTPA (Pentetate Calcium Trisodium Injection Sterile Solution) and 60,000 doses of Zn-DTPA (Pentetate Zinc Trisodium Injection Sterile Solution).

The initial number of doses being purchased under the new contract is based on the Department of Homeland Security's threat assessment and the interagency Weapons of Mass Destruction Medical Countermeasures Subcommittee's evaluation of medical consequences of a radiological or nuclear incident. Under the terms of the five-year contract HHS has the option to purchase up to 500,000 additional doses of Ca-DTPA and 500,000 additional doses of Zn-DTPA.

"Protecting the American public in a radiological or nuclear incident is a major priority of my office and Project BioShield in particular," said HHS Assistant Secretary for Public Health Emergency Preparedness Stewart Simonson. "Today's contract award is

part of our effort to expand the nation's stockpile of medical countermeasures against this threat."

Akorn, Inc. has an exclusive marketing and distribution license agreement for the United States with Hameln Pharmaceuticals, GmbH, of Hameln, Germany. Hameln Pharmaceuticals is the only manufacturer with Food and Drug Administration (FDA) approval for Ca-DTPA and Zn-DTPA to treat internal contamination from radioactive elements. FDA granted Hameln Pharmaceuticals orphan drug exclusivity for seven years beginning Aug. 11, 2004, the date of approval of its New Drug Application.

Ca-DTPA and Zn-DTPA are chelators used to treat internal contamination with radioactive isotopes of plutonium, americium, or curium. Chelators are compounds that react with metals and form stable ionic complexes, allowing the body to safely expel the metal-chelator complex. Ca-DTPA and Zn-DTPA will be used to treat those exposed through contamination from the detonation of a radiological dispersal device ("dirty bomb"), improvised nuclear device, or terrorist attack against stored radioactive material.

HHS' Office of Public Health Emergency Preparedness, which oversees the research and procurement efforts under the Project BioShield program through its Office of Research and Development Coordination, will manage the DTPA contract.

HHS AND INSTITUT PASTEUR PARTNER ON PANDEMIC INFLUENZA PREPAREDNESS -- The U.S. Department of Health and Human Services (HHS) and Institut Pasteur (IP) February 6 agreed to carry out joint activities, beginning in Southeast Asia, to strengthen global capacity to detect influenza viruses that could have the potential to trigger a human pandemic.

The Memorandum of Understanding (MOU), signed by HHS Deputy Secretary Alex M. Azar and IP President Professor Alice Dautry, establishes a Joint HHS-IP Working Group to oversee the development of collaborative projects, to include the following:

- * Building capacity in terms of surveillance, epidemiological investigation, testing, diagnosis, and control of infectious disease in countries affected by and at-risk for the spread of the H5N1 influenza strain;
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- * Disseminating effective and accurate public information on infectious disease, including in local languages in developing countries.

"The looming threat of a global influenza pandemic demands global, regional and national attention, and preparation and response to a pandemic is a shared responsibility," Deputy Secretary Azar said. "This partnership will substantially strengthen the capacity to prepare for and respond to a pandemic in countries where avian influenza is now endemic in poultry and where human infections and deaths have occurred. We are very pleased to partner with the IP, an internationally respected research institute with such an impressive global network of institutes."

The working group will initially focus on activities and cooperation in Southeast Asia, where the bulk of reported cases of H5N1 avian influenza has been found. In addition, potential activities include organizing scientific conferences, conducting training exercises, and fostering exchanges among experts that will improve preparedness for and response to infectious diseases, with particular emphasis on respiratory diseases and influenza.

"The Avian Flu and respiratory diseases have been our constant concern, especially in the Pasteur Institutes in the Asian region" IP President Professor Alice Dautry said, "We have laid a heavy focus on them since 2004 and heartily welcome this new partnership with HHS to fight the potential pandemic. This is a unique opportunity to join efforts to fight infectious diseases upfront."

In October 2005, HHS Secretary Mike Leavitt led a combined U.S. and international delegation of health experts on a ten-day, five-nation trip to Southeast Asia, during which he met with officials from IP in Cambodia and other groups. The purpose of Secretary Leavitt's visit was to learn from countries that had first-hand experience in dealing with avian influenza, to emphasize to them the importance of sharing information in a timely fashion, to look at local capacity and to determine where HHS investments might make additional investments, consistent with the President's *National Strategy on Pandemic Influenza*. During this trip, and during subsequent negotiations led by HHS Assistant Secretary for Public Health Emergency Preparedness Stewart Simonson, HHS and IP set out a plan to collaborate on containment efforts in Viet Nam, Cambodia, and Laos, as well as how to enhance surveillance for H5N1 in those countries.

Health professionals are concerned that the continued and expanded spread of the highly pathogenic H5N1 avian influenza virus, now endemic in poultry populations across eastern Asia and other parts of the world, represents a significant threat to global health security. The H5N1 virus has raised concerns about a potential human pandemic because it is especially virulent; spread by migratory birds; transmitted from birds to mammals, and, in some limited circumstances to humans; and, like other influenza viruses, it continues to evolve.

Since 2003, a growing number of human H5N1 cases have been reported in Thailand, China, Viet Nam, Cambodia, Indonesia, Turkey and Iraq, and more than half of the people infected with the H5N1 virus have died. Exposure to infected poultry is believed to have caused all these cases. The concern is that H5N1 will evolve into a virus capable of sustained human-to-human transmission.

The U.S. Department of Health and Human Services is a component of the U.S. Government, which includes such agencies as the Centers for Disease Control and Prevention and the National Institutes of Health.

The Institut Pasteur is a non-profit foundation dedicated to the prevention and treatment of infectious diseases through biological research, education and public health activities.

NEW TEAMS JOIN NETWORK TO MODEL PANDEMIC FLU, OTHER INFECTIOUS OUTBREAKS --Four new scientific teams joined an international research network developing computer-based simulations of pandemic flu and other infectious disease outbreaks, the National Institute of General Medical Sciences (NIGMS), a component of the National Institutes of Health, announced February 1.

The network is part of the Models of Infectious Disease Agent Study (MIDAS), an ongoing NIGMS effort to use computer modeling techniques to better understand the spread of contagious diseases and the potential impact of public health measures. The results could aid health officials and policymakers in developing preparedness plans for outbreaks that occur naturally or deliberately.

The new research groups will receive a total of approximately \$7.8 million over the next five years and will collaborate with four existing MIDAS teams established in 2004.

“The MIDAS network has already demonstrated the power of applying computer models to the study of disease spread and the effects of various intervention strategies,” said Jeremy M. Berg, Ph.D., NIGMS director. “The new MIDAS teams expand the network’s spectrum of expertise and enhance its ability to develop robust models.”

In addition to the individual research projects described below, the new MIDAS teams will contribute to the network’s pandemic influenza modeling project. This project involves simulating outbreaks of a deadly flu strain in different regions of the world and then evaluating the effects of various intervention measures, such as vaccination or school closures, on containing or slowing disease spread.

The new MIDAS awards will support researchers at:

- * The University of California, Irvine, and the Centers for Disease Control and Prevention in Atlanta, Ga. This group will analyze past transfers of flu from birds to people and model the effects of rapid pathogen evolution on strategies for disease surveillance, prediction, and control.
- * The Harvard School of Public Health in Boston, the University of Hong Kong, the National Institute of Public Health and the Environment in the Netherlands, and the University of Washington in Seattle. This team will use mathematical models to explore mechanisms of transmission, evaluate public health measures, and design methods for monitoring the early stages of an outbreak in real time.
- * The University of Pennsylvania School of Veterinary Medicine in Philadelphia and the University of Warwick in the United Kingdom. This team will develop spatial and temporal models of infectious animal diseases, particularly those like avian influenza that can cross species barriers to infect people.
- * Harvard Pilgrim Health Care, Harvard School of Public Health, and Brigham & Women’s Hospital, all in Boston; Kaiser Permanente Northern California in Oakland;

and the National Institute of Infectious Diseases in Argentina. This group will develop ways to identify new clusters of emerging infectious diseases and track antimicrobial resistance in hospitals and ambulatory settings. It also will optimize strategies for using patient care data from large health systems in infectious disease models.

FDA APPROVES NEW LABORATORY TEST TO DETECT HUMAN INFECTIONS WITH AVIAN INFLUENZA A/H5 VIRUSES -- HHS' Food and Drug Administration (FDA) February 3 announced the approval of a new laboratory test to diagnose H5 strains of influenza in patients suspected to be infected with the virus. The test was developed by another HHS agency, the Centers for Disease Control and Prevention (CDC).

The product approved today is called the Influenza A/H5 (Asian lineage) Virus Real-time RT-PCR Primer and Probe Set. The test provides preliminary results on suspected H5 influenza samples within four hours once a sample arrives at the lab and testing begins. Previous testing technology would require at least two to three days to render results. If the presence of the H5 strain is identified, then further testing is conducted to identify the specific H5 subtype (e.g., H5N1).

"This laboratory test is a major step forward in our ability to more quickly detect cases of H5 avian influenza and provides additional safeguards to protect public health," HHS Secretary Mike Leavitt said. "Thanks to the expeditious and collaborative efforts of CDC and FDA, the availability of this new test gives us one more tool to keep up with the ever changing nature of influenza viruses."

Since December 2003, more than 160 human cases of avian flu caused by the H5N1 strain of influenza have been reported in Thailand, China, Vietnam, Cambodia, Indonesia, Turkey and Iraq. More than half of the people infected with the H5N1 virus have died. Nearly all of these cases are believed to have been caused by exposure to infected poultry. The concern is that H5N1 will evolve into a virus capable of human-to-human transmission and lead to an influenza pandemic.

"Preparing for a possible flu pandemic is a top priority for our nation, and FDA acted quickly to evaluate and expedite CDC's request for approval of this test," Acting FDA Commissioner Dr. Andrew von Eschenbach said. "Using flexible regulatory authorities, FDA was able to prioritize this expedited approval based on the clear critical need without compromising the quality or integrity of the FDA review process."

A flu pandemic occurs when a new influenza virus emerges for which people have little or no immunity and for which there is no vaccine. In an influenza pandemic, the disease spreads easily from person to person in a sustained manner, causes serious illness, and can sweep across the country and around the world in very short time. It is difficult to predict when the next influenza pandemic will occur or how severe it will be.

This test will be distributed to Laboratory Response Network (LRN)-designated laboratories to enhance early detection and surveillance activities as well as increase

laboratory response capacity associated with a potential pandemic. Domestically the LRN is a system of about 140 labs in all 50 states. LRN labs have special experience and training in molecular testing methods, special bio-safety facilities and containment procedures as well as communication networks connected to public health programs across the country. The testing kits will be distributed by CDC beginning next week. CDC has also shared the test technology with the World Health Organization and its collaborating centers around the world.

“The use of this test by laboratories that are part of the LRN, in conjunction with other laboratory testing and clinical observations, may enable earlier detection of influenza cases caused by this specific virus and allow public health agencies to investigate sources of infection and more quickly respond with control and prevention activities,” said CDC Director Dr. Julie Gerberding.

Information obtained from this test will be used to track cases of illness with this strain of virus. Testing for this virus is indicated when a patient has symptoms of severe respiratory illness and a risk of exposure (e.g., direct contact with sick, dead or infected poultry in a country with outbreaks of influenza H5N1 among poultry).

CDC recommends that testing for influenza A/H5 (Asian lineage) should be considered on a case-by-case basis in consultation with local or state health departments. If a clinician suspects a patient may be infected with an avian influenza virus, they should contact their state or local health department. CDC's full recommendations are available at <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm55e203a1.htm>. Further information on the expedited review process used by FDA for this approval can be found at: <http://www.fda.gov/oc/opacom/hottopics/avianflu/process.html>.