# THE CSTE WASHINGTON REPORT

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October 6, 2005 Volume 9, Number 19

**INSIDE THIS ISSUE**



**EDITOR'S NOTE:**. HHS Secretary Mike Leavitt September 28 announced that the National Institute of Allergy and Infectious Diseases (NIAID) and MedImmune Inc. have signed a cooperative research and development agreement for the development of vaccines against avian influenza viruses that have the potential to cause pandemics. Under the agreement, NIAID, part of the National Institutes of Health, and MedImmune of Gaithersburg, Md., will produce and test multiple vaccines against potential pandemic flu strains, including the H5N1 avian influenza virus."The threat of pandemic flu is an urgent health challenge," Secretary Leavitt said. "This agreement will help speed the process of developing vaccines we will need to fight an outbreak if the avian flu starts to spread rapidly through the human population." -- additional details are provided 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

**BUDGET UPDATE** -- Pressure is mounting to provide offsets for Hurricane Katrina and Rita relief spending totaling over $70 billion when tax breaks are included. On Tuesday, President Bush reiterated his call for deeper cuts in mandatory spending and in non-defense discretionary spending, which would include public health programs and agencies. He cited his budget request to eliminate or streamline 150 programs for a savings of $20 billion. In response to the President's urging, yesterday (10/4) Rep. Jim Nussle (R-IA), Chairman of the House Budget Committee, announced his plan to re-open the Budget Resolution, passed by Congress earlier this year, and find additional cuts, including a two percent across-the-board cut for all discretionary spending for FY 2006. Total discretionary spending is about $840 billion; a two percent cut would yield just $16.8 billion in offsets. It is not likely that the Senate will go along with Nussle's approach, however, others throughout Congress have been calling for at least a one percent cut for non-defense discretionary programs.

In response to the budget-cutting climate, yesterday a broad coalition of public health groups sent a letter to the entire Congress, President Bush, HHS Secretary Leavitt and OMB Director Bolten with a heading stating: "This is not the time to cut public health programs: Chronically underfunded, the nation relies on them every single day – not just in times of emergency." Attached to the letter was a selection of examples of what public health programs are doing to assist hurricane victims and how their needs are swamping already short-changed programs. The first example cites what state and local health departments do to assure the health, safety and well-being of evacuees in an emergency, such as Hurricane Katrina, and then criticizes the President's proposed cut to the CDC State and local terrorism preparedness grants.

**APPROPRIATIONS UPDATE** -- Last week, Congress adopted a Continuing Resolution (CR) to keep the government funded through November 18th while Congress finishes work on the FY 2006 Appropriations bills. Only two of ten appropriations bills have been passed and signed into law. In a new twist, rather than simply funding programs at the current year's level, in this case FY 2005, this year's CR funds programs at either the FY 2006 House-passed level, FY 2006 Senate-passed level or the FY 2005 (current year) level, whichever is lowest. For many programs, the lowest level is the House-passed bill.

**PANDEMIC FLU UDPATE** – Last Thursday morning (9/29) Members of Congress were provided a closed door briefing by HHS Secretary Leavitt, accompanied by Dr. Julie Gerberding, Director of CDC, as well as others, on pandemic flu and the Administration's preparation activities. The briefing appeared to frighten a number of Senators, resulting in a Democratic-led amendment to the FY 2006 Department of Defense Appropriations bill, then being debated on the Senate floor. The amendment, sponsored by Sen. Tom Harkin (D-IA), and co-sponsored by Sens. Obama (D-IL), Kennedy (D-MA), Reid (D-NV), Bayh (D-IN), Durbin (D-IL) and Dodd (D-CT), would provide $3.9 billion to support a number of pandemic flu preparedness activities, including $600 million ".. for additional grants to state and local public health agencies for

emergency preparedness, to increase funding for emergency preparedness centers, and to expand hospital surge capacity." The amendment was adopted on a voice vote with Senator Stevens (R-AK), lead sponsor of the DoD Appropriations bill, speaking in favor of the amendment while also signaling his preference for waiting for the Administration's pandemic flu plan. Stevens' vacillation implies he is not likely to support the amendment in conference with House counterparts to resolve differences between House and Senate versions of the bill. Without Stevens' support, it will be very difficult for the amendment to survive likely House opposition. The amendment is provided below.

Meanwhile, the Administration is readying its long-awaited pandemic flu plan and is expected to release it at the end of October. Rumors abound that the plan will be accompanied by a budget amendment that is more generous than the Senate DoD amendment – in the area of $6-$10 billion. Most of the funding will be devoted to purchase of antivirals and H5N1 vaccine. Rumors also abound that the current targets of stockpiling for 20 million Americans is likely to be closer to professional advisory council recommendations of upwards of 75 million. In addition, as the President signaled in his Tuesday press briefing, there may be new authority provided for use of the military to enforce quarantine laws and also significantly expanded federal authority on use of quarantine. State and local public health groups are increasingly skeptical that the plan will provide additional resources for state and local health department preparedness efforts.

AMENDMENT NO. _1886___ Calendar No. ___

Purpose: To make available emergency funds for pandemic flu preparedness.

IN THE SENATE OF THE UNITED STATES_109th Cong., 1st Sess.

H.R. 2863

Making appropriations for the Department of Defense for the fiscal year ending September 30, 2006, and for other purposes.

Referred to the Committee on _____ and ordered to be printed

Ordered to lie on the table and to be printed

Amendment intended to be proposed by Harkin (for himself, Senator Obama, Senator Reid, Senator Kennedy, Senator Durbin, Senator Bayh and Senator Dodd)

Viz:

On page ___, at the appropriate place at the end of Title 9, insert the following:

Title ____.

Section 101.

(a) From the money in the Treasury not otherwise obligated or appropriated, there are appropriated to the Centers for Disease Control and Prevention $3,913,000,000 for activities relating to the avian flu epidemic during the fiscal year ending September 30, 2006, which shall be available until expended.

(b) Of the amount appropriated under subsection (a) –

(1) $3,080,000,000 shall be for the stockpiling of antivirals and necessary medical supplies

(2) $33,000,000 shall be for global surveillance relating to avian flu

(3) $125,000,000 shall be to increase the national investment in domestic vaccine infrastructure including development and research

(4) $600,000,000 shall be for additional grants to state and local public health agencies for emergency preparedness, to increase funding for emergency preparedness centers, and to expand hospital surge capacity

(5) $75,000,000 shall be for risk communication and outreach to providers, businesses, and to the American public

(c) The amount appropriated under subsection (a)

(1) is designated as an emergency requirement pursuant to section 402 of H. Con. Res. 95 (109th Congress); and

(2) shall remain available until expended.

(d) This title shall take effect on the date of enactment of this Act.

**ESTIMATES SHOW MORE THAN 40 PERCENT OF HURRICANE EVACUEES NOW RECEIVING HHS BENEFITS OR SERVICES --** HHS Secretary Mike Leavitt announced September 29 that in the month since Hurricane Katrina struck the Gulf Coast, an estimated more than 20 percent of all those affected by the storms and who have filed for FEMA assistance are now receiving HHS benefits and services. Furthermore, 41 percent of the 857,000 evacuees living in a different zip code from the damaged areas are receiving help from HHS.

Because many victims of the hurricane no longer have the records or legal documents to help prove their eligibility for benefits from various government programs, HHS has given states the flexibility to enroll evacuees without requiring documents such as tax returns or proof of residency. This action permits evacuees to apply to the full range of

federal benefits administered by the states, including HHS programs that provide services through Medicaid, family assistance through Temporary Assistance to Needy Families (TANF), child care support, foster care assistance, mental health services and substance abuse treatment services.

“Based on preliminary reports, we estimate that more than 40 percent of hurricane evacuees who have been displaced from their homes are getting help from HHS,” Secretary Leavitt said. “Working with our partners at the state and local level, we have streamlined the process for all evacuees who may need access to the range of benefits we can provide to get back on their feet.”

In the days following Katrina’s landfall, HHS provided:

* Waivers to a number of states, including Texas, Mississippi, Florida, Alabama and Idaho, to make it easier for eligible evacuees to receive services through the state’s Medicaid and State Children’s Health Insurance Programs (SCHIP), and to make states whole for their generosity.
* Uncompensated care pools to Texas, Mississippi, Florida, Alabama and Idaho to help compensate physicians, hospitals and other health care providers who provide needed medical treatment to evacuees who do not currently have health insurance and are ineligible for Medicaid or SCHIP.
* $2.3 million in accelerated grants to establish 26 new health center sites in states impacted by Hurricane Katrina.
* $15 million in emergency funding to assist Head Start and Early Head Start grantees in providing services to children and families displaced by Hurricane Katrina.
* $600,000 in emergency grants to Louisiana, Alabama, Texas and Mississippi to insure that mental health assessment and crisis counseling are available in areas impacted by Hurricane Katrina.
* $750,000 in disaster relief funds to Alabama, Louisiana, and Mississippi to reestablish the service capacity of state and local entities that deliver services to the aging and elderly.
* Free vaccines through the federally-run Vaccines for Children program to all children from birth to 18 years old displaced by Hurricane Katrina, regardless of whether they are staying at shelters, hotels, or with family and friends and regardless of previous health insurance coverage status.
* $27.25 million in emergency energy assistance to Alabama, Florida, Louisiana and Mississippi from the Low Income Home Energy Assistance Program.

In addition to expediting access to the department’s benefits and services following the storm, HHS began providing assistance to the region before Katrina made landfall, and has been augmenting medical care in affected hospitals and shelters, providing human and mental health services to the evacuee population since the storm passed.

“Before Hurricane Katrina hit, HHS had 38 U.S. Public Health Service officers and more than 30 tons of medical supplies prepositioned in Mississippi and Louisiana and ready to deploy immediately after the storm passed. Ever since, we have continued to provide the

Gulf Coast region with needed health care assistance and medical equipment and supplies," Secretary Leavitt said.

In response to the health care needs in affected states, the U.S. Public Health Service Commissioned Corps, one of the nation's seven uniformed services, carried out the largest mobilization in its 207-year history. More than 1,400 officers from more than 40 states came together over the last month to work with state, local and private agencies in Alabama, Arkansas, Florida, Georgia, Louisiana, Mississippi and Texas. One month after Katrina hit, the Corps still has 700 officers providing relief services along the Gulf Coast and in areas with evacuees.

"The selfless dedication of these officers has made a difference in the lives of thousands of Americans in the aftermath of Hurricanes Katrina and Rita," said Vice Admiral Richard Carmona, U.S. Surgeon General and commander of the Public Health Service. "Their contributions to the relief effort have been as diverse as their professions and training, and I could not be prouder of their efforts than I am at this defining moment."

In addition to the Commissioned Corps, the PHS for the first time deployed the Medical Reserve Corps (MRC), a cadre of civilian volunteers across the country who are trained and ready to help with emergencies and ongoing public health activities. President Bush created the MRC in 2002 as a way to strengthen local public health infrastructures and improve emergency preparedness at the community level. More than 6,500 members of the MRC have been activated to help with Hurricanes Katrina and Rita.

Other highlights of HHS' hurricane response include:

* HHS Secretary's Emergency Response Teams (SERTs) are working in the three most critical states -- Louisiana, Mississippi and Texas. Each SERT is led by a U.S. Public Health Service (USPHS) Rear Admiral, who reports directly to HHS Headquarters in Washington, D.C.
* Secretary Leavitt activated the entire USPHS Commissioned Corps to respond to Hurricane Katrina. Since landfall, nearly 1,500 USPHS officers have served as part of the response effort.
* HHS now has the equipment and supplies for 18 Federal Medical Shelters, each with a 250-bed capability.
* A new volunteer health care worker disaster response hotline and Web site received more than 30,000 applications. As a result, HHS has been able to credential more than 3,800 health care professionals who are now ready to be sent to help, if needed, as temporary federal employees.
* The Strategic National Stockpile (SNS) has sent more than $38 million worth of pharmaceuticals and other medical supplies to areas impacted by Hurricane Katrina. Many of the basic pharmaceuticals were in place within hours of the hurricane's passage.

**NIAID AND MEDIMMUNE JOIN FORCES TO DEVELOP POTENTIAL PANDEMIC INFLUENZA VACCINES --** HHS Secretary Mike Leavitt September 28 announced that the National Institute of Allergy and Infectious Diseases (NIAID) and

MedImmune Inc. have signed a cooperative research and development agreement for the development of vaccines against avian influenza viruses that have the potential to cause pandemics. Under the agreement, NIAID, part of the National Institutes of Health, and MedImmune of Gaithersburg, Md., will produce and test multiple vaccines against potential pandemic flu strains, including the H5N1 avian influenza virus.

“The threat of pandemic flu is an urgent health challenge,” Secretary Leavitt said. “This agreement will help speed the process of developing vaccines we will need to fight an outbreak if the avian flu starts to spread rapidly through the human population.”

Kanta Subbarao, M.D. M.P.H, and Brian Murphy, M.D., of NIAID’s Laboratory of Infectious Diseases will lead NIAID’s part in this collaboration. The agreement specifies that the scientists will add selected genes from avian flu viruses with pandemic potential into a weakened human flu virus to create several attenuated, live virus vaccines candidates.

“Our agreement with MedImmune coordinates public and private resources and brings a deeper pool of talent to bear on the urgent need for vaccines to combat the threat of an influenza pandemic,” said NIAID director Anthony S. Fauci, M.D. “It is an example of the many productive public-private partnerships upon which we depend in our quest to develop vaccines, drugs and diagnostics for myriad infectious disease threats.”

Infectious disease experts worry that avian influenza viruses, which until recently have rarely infected people, could trigger a devastating global flu outbreak. The H5N1 avian influenza is especially troubling as it has spread rapidly among birds and other animals in Asia since late 2003, and more recently has been found in birds in Russia and Kazakhstan. According to the World Health Organization, of the 115 people in four Asian countries who have been infected with H5N1 from late 2003 through 2005, 59 have died. While this virus currently is not known to spread efficiently from person to person, it could trigger a human influenza pandemic if it acquires that ability.

NIAID and MedImmune will develop at least one vaccine for each of the 16 variations of a key influenza surface protein known as hemagglutinin (represented by the letter “H” in the names of influenza strains, such as H5N1). NIAID and MedImmune will develop vaccines for the highest priority hemagglutinin subtypes first. The researchers say it will take years to systematically develop vaccines for all the hemagglutinin subtypes. Having effective vaccines against all subtypes will help us prepare for influenza pandemics in the future, explains NIAID’s Dr. Subbarao.

Human influenza viruses that have circulated in the last century contain one of three possible hemagglutinin proteins (H1, H2 and H3); potential pandemic viruses contain one of the others to which humans have never been exposed. Not having any prior exposure to the hemagglutinin in H5N1 avian influenza virus currently spreading in Asia, the human immune system is unprepared to fight it. For that reason, developing an H5N1 vaccine is a high priority for the NIAID/MedImmune collaboration.

Under the agreement, NIAID and MedImmune will use methods such as reverse genetics and classical reassortment to place hemagglutinin genes with pandemic potential into an attenuated human flu virus. Reverse genetics is a laboratory method by which researchers can custom make a flu vaccine by assembling genes that code for the desired features. Reassortment is the swapping and mixing of gene segments between two different viral strains inside a chicken cell to create a new vaccine.

The NIAID/MedImmune agreement builds on research pioneered by NIAID's Dr. Murphy beginning in the 1970s. Working with the developer of the attenuated influenza virus -- John Maassab, Ph.D., of the University of Michigan School of Public Health -- Dr. Murphy and colleagues created a flu vaccine from a live flu virus weakened so that it would not cause disease. As an extra measure of safety, the researchers grew the live virus vaccine in progressively colder temperatures to prevent it from spreading beyond the relatively cool upper respiratory tract. This "cold-adapted" virus is proprietary to MedImmune and is the basis of MedImmune's FluMist® flu vaccine, also a product of a public-private partnership between NIAID and MedImmune. The researchers will use the same cold-adapted virus as the backbone for the pandemic influenza vaccines.

NIAID and MedImmune will generate many of the vaccines in NIAID's Bethesda, Md., labs. Both NIAID and MedImmune will initially conduct laboratory studies of the vaccines. MedImmune then will manufacture the vaccines for human clinical trials, which NIAID will run through a contract facility, pending Food and Drug Administration approval. These studies will assess vaccine safety and immunogenicity.

**CDC WORKING TO IMPROVE ABILITY TO USE TECHNOLOGY AND COMMUNICATION TO IMPROVE HEALTH; FIRST GRANTS TO ESTABLISH CENTERS OF EXCELLENCE ARE AWARDED** --The Centers for Disease Control and Prevention (CDC) has awarded nearly $5.2 million to fund two new Centers of Excellence in Health Marketing and Health Communication and two Centers of Excellence in Public Health Informatics. With these grants, CDC is hoping to foster scientific advances that improve the ability of health care professionals to communicate health recommendations to consumers and to more easily use electronic information systems.

"We know that our ability to effectively communicate, along with our skills in using computers and other information technologies, are very important in our efforts to improve people's health and well being," said CDC Director Dr. Julie Gerberding. "With these initial investments in four new Centers of Excellence, we hope to identify new tools, approaches, and strategies for managing health records, bringing together disease information from different places, understanding the questions and concerns of patients, and educating people about ways to improve their health. The more we learn about when and how to use health communication and electronic informationsystems, the better able we'll be to meet the needs of people in the community."

The grants are part of a larger CDC research program, the "Health Protection Research Initiative," that is designed to discover strategies and tools that increase the ability of

health departments, physicians, and other health care providers to promote health and prevent diseases, injuries, or disabilities. Projects funded under CDC's research initiative are designed to speed the detection of infectious diseases and environmental hazards, improve health education and communication efforts, lead to better and wider use of information systems, and promote greater collaboration among organizations working to protect the health and well being of the public.

**Centers of Excellence in Health Marketing and Health Communication**
The focus of CDC's two new Centers of Excellence in Health Marketing and Health Communication is on finding ways to effectively provide information and educational materials to help people make sound health decisions. Often, websites, brochures, posters, and videos are used to provide health information and advice. These two Centers of Excellence will be looking for ways to best use these and other tools, as well as doing research designed to determine how to measure the effectiveness of communication materials. The Centers will also begin placing special emphasis on projects designed to improve the health and well being of people who are at higher risk for disease and illness as well as people living in rural areas (i.e., areas that have less access to medical care). Projects at the new Center at the University of Connecticut are designed to promote abstinence, safer sex, and reduce drug and alcohol use among youth and young adults. Projects at the new Center at the University of Georgia will focus on improving the health of the poor and near-poor in the South and will examine how they understand and respond to health risks. One major research study focuses on understanding how people process personalized genetic risk information. In another study adolescents' attitudes toward smoking are examined to improve the effectiveness of anti-smoking media messages.

**Centers of Excellence in Public Health Informatics**
The CDC's two new Centers of Excellence in Public Health Informatics will improve the public's health through discovery, innovation, and research related to health information and information technology (e.g., better use of electronic or computerized information systems). The new Center at Harvard Medical School will be developing a computer-based system designed to rapidly identify disease outbreaks using patient and other medical records. The new Center at the University of Washington will work on two major research projects that focus on improving public health surveillance and epidemic detection methods and the development of an interactive digital knowledge management system including concept mapping services that will provide rapid access to answers from a variety of key resources.

For more information visit www.cdc.gov/od/ophr

**LARGE TULAREMIA VACCINE CONTRACTS AMONG NEW NIAID BIODEFENSE AWARDS** -- The National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health, October 3 announced that it has recently made several dozen awards to further strengthen the nation's biodefense and emerging disease research capabilities. The new awards include grants totaling

approximately $87 million for the construction of four biosafety level-3 (BSL-3) laboratories as well as two five-year contracts totaling approximately $60 million to support the development of a vaccine against tularemia, a potential agent of bioterror.

“Devising medical countermeasures against biological threats, whether they arise naturally or are the result of deliberate human action, is a top priority for NIAID,” says NIAID Director Anthony S. Fauci, M.D. “These new awards support research needed to better understand and defend against disease-causing microbes and provide funds to construct facilities where such research can be performed safely.”

**Regional Biocontainment Laboratories**
The four new labs will join nine other NIAID-funded BSL-3 labs in the Institute’s Regional Biocontainment Laboratory (RBL) program. In 2002, a panel of experts convened to provide guidance to NIAID on its biodefense agenda cited insufficient BSL-3 and BSL-4 space as a major barrier to research progress. As part of its response, NIAID established the RBL program to fund the design, construction and commissioning of state-of-the-art BSL-3 labs at sites spanning the country. The institutions receiving the new awards and the principal investigators are as follows

* George Mason University, Manassas, VA/ Charles Bailey, Ph.D.

* Tufts University, North Grafton, MA/ Sawkat Anwer, DMVH, Ph.D.

* University of Louisville, KY/ Nancy Martin, Ph.D.

* University of Hawaii at Manoa/ James Gaines, Ph.D.

More information about NIAID’s biocontainment facility construction program and a map of the previously awarded sites is at http://www2.niaid.nih.gov/Biodefense/Research/RBL.htm.

**Tularemia Vaccine Contracts**
Two contracts totaling approximately $60 million have been awarded to the University of New Mexico (C. Rick Lyons, M.D., principal investigator) and to DVC LLC, Frederick, MD (Robert House, Ph.D., principal investigator) to support research to identify and evaluate new tularemia vaccine candidates. Tularemia, a bacterial disease, is also known as rabbit fever; symptoms include high fever, chills, aches and swollen lymph glands. Tularemia usually can be successfully treated with antibiotics. However, the bacterium that causes tularemia is regarded by experts as a potential agent of bioterror because, if aerosolized, it could cause widespread cases of more serious disease, including severe respiratory illness and systemic infections, and even death.

**Additional Biodefense Research Awards**
In addition to those described above, NIAID’s Fiscal Year 2005 biodefense awards include

* Challenge Grant program awards to support further development of previously identified therapeutics, vaccines, and diagnostics against NIAID Category A, B and C priority pathogens including anthrax, smallpox and viruses that cause pandemic influenza

* Cooperative Research program awards to stimulate research requiring multidisciplinary effort to advance promising candidate vaccines, therapeutics and other products through the product development pathway

* Small Business Biodefense program awards

* BioShield
http://www3.niaid.nih.gov/news/newsreleases/2005/27million_bioshield.htm

* Regional Centers of Excellence for Biodefense and Emerging Infectious Diseases
http://www3.niaid.nih.gov/news/newsreleases/2005/rce_05.htm