THE CSTE WASHINGTON REPORT

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EDITOR'S NOTE:. The U.S. Food and Drug Administration (FDA) October 30 cleared a new test developed by the U.S. Centers for Disease Control and Prevention (CDC) to diagnose human influenza infections and the highly pathogenic influenza A (H5N1) viruses.The device, called the Human Influenza Virus Real-Time RT-PCR Detection and Characterization Panel (rRT-PCR Flu Panel), uses a molecular biology technique to detect flu virus and differentiate between seasonal and novel influenza.-- 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.

PRESIDENT SIGNS CONTINUING RESOLUTION -- On Tuesday, September 30th, President Bush signed into law the, "Consolidated Security, Disaster Assistance, and Continuing Appropriations Act" (H.R. 2638). The measure provides full year funding for the Departments of Defense, Veterans Affairs and Homeland Security and funds the majority of all other departments, agencies and programs, including all CDC programs, at FY 2008 levels through March 6, 2009. House Appropriations Chairman, David Obey (D-WI) stated that if Barack Obama is elected President, the new Administration is likely to honor the funding levels provided by the House and Senate Appropriations Committee's for unfinished bills, such as the Labor-HHS-Education Appropriations bill. The House Appropriations Committee provided a nearly $100 million increase, overall, for CDC while the Senate provided an increase of $76 million. The President's Budget request for FY 2009, by contrast, cut CDC programs by nearly $48 million.

DOMESTIC TB AUTHORIZATION BILL PASSES CONGRESS AND ON ITS WAY TO PRESIDENT'S DESK – After a unanimous vote of approval in the House on September 24th for the, "Comprehensive TB Elimination Act," (H.R. 1532) the Senate followed suit with a unanimous vote in favor on September 27th. The bill provides a 43 percent increase in funding, including authorizing $200 million for CDC's Division of Tuberculosis Elimination in FY 2009 and 5 percent increases for years 2010-2013. This funding will largely flow to states for their TB efforts, with other funding committed to expand research on TB diagnostic, treatment and prevention tools at the CDC and the National Institutes of Health. The bill will also intensify targeted efforts to prevent, detect and treat the disease among African Americans and other minorities and expand detection of TB at the U.S.-Mexico border and treatment of bi-national TB cases. The President is expected the sign the bill into law this week.

HHS ANNOUNCES NEW STEPS IN ANTHRAX PREPAREDNESS -- HHS Secretary Mike Leavitt October 1 announced two new actions in the department's ongoing activities to bolster the nation's preparedness for a potential outdoor anthrax attack. In development since March of this year, the steps being implemented today build upon more than a decade of preparedness efforts across HHS and other agencies of the federal government.

The first of today's actions focuses on United States Postal Service letter carriers who volunteer to deliver medicines directly to residences in their communities during an emergency.

Homeland Security Secretary Michael Chertoff and HHS Secretary Leavitt have invoked their authority under section 564 of the Federal Food, Drug, and Cosmetic Act to make the determination and declaration of emergency required by law in order for HHS' Food and Drug Administration (FDA) to consider issuing an Emergency Use Authorization (EUA) allowing eligible letter carriers to receive kits containing small quantities of antibiotics for future use by them and other members of their households during an anthrax emergency. The Biomedical Advanced Research and Development Authority within HHS requested that FDA issue a EUA for this purpose.

These antibiotics would help protect volunteers against contracting anthrax if, following an outdoor anthrax attack, the Postal Service was called upon to deliver the same life-saving antibiotics directly to homes across their community where people may have been exposed to the bacterium that causes anthrax. Although no imminent threat currently exists, these legal actions would enable FDA to issue a EUA.

"In an anthrax attack, time is of the essence in preventing illness and death by getting antibiotics to those who may have been exposed," Secretary Leavitt said. "By providing advance protection to letter carriers who volunteer to deliver antibiotics in an affected community, we can gain the benefits of the unique capabilities of the Postal Service to get much needed medicines to those who need it quickly. This is one part of our strategy to encourage preparedness at all levels of government to enable our nation to respond effectively in the event of an anthrax emergency."

Over the past several years, under the Cities Readiness Initiative (CRI), HHS and the Postal Service have successfully developed and tested in three U.S. cities -- Seattle, Philadelphia and Boston --the ability of letter carriers to quickly deliver door-to-door quantities of antibiotics from the Strategic National Stockpile to residential addresses. This quick-strike capability is intended to buy time for local and State public health authorities to set up points of dispensing for further provision of antibiotics across the community.

"The letter carrier has long been a reliable presence in America's neighborhoods. This important and potentially life saving undertaking is a natural extension of what the carriers see as a service to their community," Postmaster General John E. Potter said.

Begun in 2004, CRI is a federally funded effort to prepare 72 major U.S. cities and metropolitan areas to effectively respond to a large scale bioterrorist event by dispensing antibiotics to their entire identified population within 48 hours of the decision to do so. With today's actions, CRI cities will now have another distribution tool at their disposal when crafting their plans to protect their populations. Such innovations have been encouraged by the National Academy of Sciences' Institute of Medicine, which earlier this year conducted an evaluation of medical countermeasure distribution capabilities.

In a related action, Secretary Leavitt today issued a declaration under the Public Readiness and Emergency Preparedness Act (PREP Act) that provides liability protection for activities related to developing, manufacturing, distributing, prescribing, dispensing, administering and using anthrax countermeasures in preparation for, and in response to, a potential anthrax attack. This includes entities, such as large "big-box" retail stores, retail pharmacies, and other private sector businesses, that help to deliver and distribute medicines. Providing liability protection to all involved in such efforts will help ensure their full participation and bolster response efforts.

"Preparedness is a shared responsibility that must involve all sectors of society, including the private sector, community groups, families and individuals," Secretary Leavitt said. "We are using the authorities available to us to do all we can to support preparedness at

all levels."

The DHS Determination of an Emergency (under Section 564(b) of the Federal Food, Drug and Cosmetic Act) is available at http://www.dhs.gov/xlibrary/assets/ofsec_signed_determination092308.pdf; the HHS Declaration of an Emergency (under Section 564(b) of the Federal Food, Drug and Cosmetic Act) is available at http://www.hhs.gov/disasters/emergency/manmadedisasters/bioterorism/564anthrax-declaration.html; and the HHS PREP Act Declaration available at http://www.hhs.gov/disasters/emergency/manmadedisasters/bioterorism/prepact-081001.html.

FDA CLEARS NEW CDC TEST TO DETECT HUMAN INFLUENZA -- The U.S. Food and Drug Administration (FDA) October 30 cleared a new test developed by the U.S. Centers for Disease Control and Prevention (CDC) to diagnose human influenza infections and the highly pathogenic influenza A (H5N1) viruses.

The device, called the Human Influenza Virus Real-Time RT-PCR Detection and Characterization Panel (rRT-PCR Flu Panel), uses a molecular biology technique to detect flu virus and differentiate between seasonal and novel influenza.

The device is used to isolate and amplify viral genetic material present in secretions taken from a patient's nose or throat. The viral genetic material is labeled with fluorescent molecules, which are then detected and analyzed by a diagnostic instrument called the Applied Biosystems 7500 Fast Dx, also cleared today by the FDA for diagnostic use simultaneously with the CDC's rRT-PCR Flu Panel.

The test panel and diagnostic system can detect and identify commonly circulating human influenza viruses as well as influenza A (H5N1) viruses. Results can be available within four hours and the system can test multiple samples at once.

"This is a significant achievement for public health surveillance," HHS Secretary Mike Leavitt said. "The test allows us to better support laboratories on the front line of influenza testing in the United States and abroad."

"The application of the test to detect an emergent influenza virus would be especially important in the early stages of a pandemic," Secretary Leavitt added. "This breakthrough allows for a more timely detection of a pandemic virus, which helps in determining when to begin broad control strategies as well as life-saving mitigation measures, such as closing schools, cancelling social gatherings and informing businesses to begin work-at-home policies."

The test will be available to CDC-qualified laboratories for diagnosing influenza this fall, and some laboratories will be able to obtain reagents (certain substances used in the testing process) at no cost. This test should help ensure the accuracy of influenza testing

results among the different qualified laboratories that conduct influenza subtype testing.

“This new test provides us another tool in our toolbox to fight seasonal influenza, a virus that unfortunately kills thousands of people each year in the United States,” said CDC Director Dr. Julie Gerberding. “We’ll now be able to detect influenza in the community faster, which allows us to take steps more quickly to protect and save lives.”

Since influenza viruses are always changing, test reagents need to be evaluated regularly against circulating viruses to ensure the sensitivity and specificity of the test to diagnose current influenza viruses.

“Because the test can tell the difference between seasonal human influenza viruses and novel viruses, it will also provide qualified laboratories with a means to rapidly detect new influenza viruses that have not been identified yet and that could pose a pandemic risk," said FDA Principal Deputy Commissioner and Chief Scientist Dr. Frank Torti, M.D., M.P.H.

The CDC, Applied Biosystems of Foster City, Calif., and the Association of Public Health Laboratories collaborated on the development of this new test. State public health laboratories in Virginia, Iowa, California, Massachusetts, Wisconsin, and Washington performed clinical evaluations of the new flu panel.

Scientists around the world are concerned that the H5N1 virus could one day mutate and acquire the properties needed to quickly spread between people, resulting in a pandemic. H5N1 viruses circulate widely in birds in Asia, Africa and Europe and have caused human illness and death. These viruses have never been detected in the Americas.

For more information, please visit www.pandemicflu.gov, and www.cdc.gov

NIH'S GENES ENVIRONMENT AND HEALTH INITIATIVE ADDS SIX STUDIES -- The Genes, Environment and Health Initiative (GEI) of the National Institutes of Health (NIH) September 24 awarded grants estimated to be up to $5.5 million over two years for six studies aimed at finding genetic factors that influence the risks for stroke, glaucoma, high blood pressure, prostate cancer and other common disorders. The grantees will use a genome-wide association study to rapidly scan markers across the complete sets of DNA, or genomes, of large groups of people to find genetic variants associated with a particular disease, condition or trait.

"Genome-wide association studies are helping us take major strides towards identifying the genetic variants associated with common diseases," said National Human Genome Research Institute (NHGRI) Acting Director Alan E. Guttmacher, M.D., who is co-chair of the GEI coordinating committee. "This initiative will yield valuable information about the biological pathways that lead to health and disease and about how genetic variants, environmental factors and behavioral choices interact to influence disease risk. Such information is vital to our efforts to develop more personalized approaches to health

care."

GEI is collaboration between genetic researchers and environmental scientists. Six GEI-supported genome-wide association studies, overseen by NHGRI, are already under way. Two additional GEI studies, supported and managed by the National Institute of Dental and Craniofacial Research, have also begun. In addition, the National Institute of Environmental Health Sciences is overseeing GEI-supported research that seeks to develop wearable sensors and other technologies to accurately measure personal exposures to environmental agents.

Funding for the latest round of studies was contributed by all of NIH's 27 institutes and centers. The principal investigators, their approximate funding for fiscal years 2008 and 2009, and their research projects are:

Kathleen Barnes, Ph.D., Johns Hopkins University School of Medicine, Baltimore; $1.2 million. Genome-Wide Associations: Environmental Interactions in the Lung Health Study.

Myriam Fornage, Ph.D., University of Texas Health Science Center, Houston; $1.1 million. Genome-Wide Association Study of Longitudinal Blood Pressure Profiles from Young Adulthood to Middle-Age.
Christopher Haiman, Sc.D., University of Southern California, Los Angeles; $210,000. A Multiethnic Genome-Wide Scan of Prostate Cancer.

John Heit, M.D., Mayo Clinic, Rochester, Minn.; $1.1 million. Genome-Wide Association of Venous Thrombosis (Blood Clots in Veins).

Braxton Mitchell, Ph.D., University of Maryland School of Medicine, Baltimore; $1.1 million. Genetic Risk to Stroke in Smokers and Nonsmokers in Two Ethnic Groups.

Louis Pasquale, M.D., Massachusetts Eye and Ear Infirmary, Harvard Medical School, Boston, $850,000. Genes and Environment Initiative in Glaucoma.

Data from the genome-wide association studies will be deposited in the database of Genotypes and Phenotypes (dbGaP), http://view.ncbi.nlm.nih.gov/dbgap, at the National Center for Biotechnology Information, a part of the National Library of Medicine at NIH, which will manage the vast amount of genetic, medical and environmental information that emerges from GEI. To encourage rapid research advances, and in keeping with the principles pioneered by the Human Genome Project, all data generated through these initiatives will be made available to researchers, consistent with NIH's data-sharing policy for NIH-supported, genome-wide association studies, which is available on NIH's Office of Extramural Research Genome-Wide Association Studies Web page at http://grants.nih.gov/grants/gwas/.

For researchers who want to view genome-wide association data produced by GEI, dbGaP offers two levels of access. The first is open-access, which means the information will be available without restriction on the Internet, and the second is controlled-access, which requires preauthorization for the individual researcher seeking to view it. The open-access section will allow users to view study documents, such as protocols, questionnaires and summaries of phenotype data. The second is the controlled-access portion of the database, which allows approved researchers to download individual-level genotype and phenotype data from which the study participants' personal identifiers, such as names, have been removed.

More information on genome-wide association studies can be found at www.genome.gov/17516714.