THE CSTE WASHINGTON REPORT

Marcia S. Mabee, MPH, PhD
Editor
11479 Waterview
Reston, Virginia 20190
mmabee@ix.netcom.com
703-709-3001

June 23, 2006 Volume 10, Number 13

INSIDE THIS ISSUE

EDITOR'S NOTE -- The Department of Health and Human Services (HHS) announced June 20 it will purchase 20,000 treatment courses of ABthrax, an anthrax therapeutic treatment, from Human Genome Sciences of Rockville, Md. for $165,205,217. Delivery is expected to begin in 2009. Under the terms of the agreement, full payment to Human Genome Sciences is contingent on the product receiving licensure from the Food and Drug Administration. "This important addition to the Strategic National Stockpile will provide physicians a way to neutralize the deadly toxin anthrax bacteria produces," said Dr. Gerald Parker, HHS Acting Assistant Secretary for Public Health Emergency Preparedness. "And we found it is the toxin which accounted for the majority of anthrax-related deaths during the anthrax attacks of 2001"-- 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

CSTE COMMENTS ON SENATE BILL -- Last week the Senate Subcommittee on Bioterrorism and Public Health Preparedness provided stakeholder groups with a discussion draft of legislation reauthorizing the 2002 Public Health Security and Bioterrorism Response Act, and provided a forum for comments on the draft bill. CSTE provided an extensive set of comments in writing and verbally. CSTE is currently reviewing a second discussion draft. The Subcommittee expects to mark up the bill sometime in June and hopes to finish the Senate process during July. Meanwhile the corresponding House Energy and Commerce Committee has not produced a similar comprehensive bill, but did vote out a bill in May, the "Public Health and Medical Emergency Coordination Act, H.R. 5438, which incorporate two key provisions in the draft Senate bill: designates HHS as responsible for coordinating the federal government's response to medical emergencies, including bioterrorist attacks, and returns the National Disaster Medical System (NDMS) to HHS from its current home in the Department of Homeland Security.

Bills of interest recently acted on or introduced -- S. 1741/H.R. 3850, the "Disaster Area Health and Environmental Monitoring Act," sponsored in the Senate by Senators Voinovich (R-OH) and Clinton (D-NY) was recently voted out of the Senate Committee on Homeland Security and Governmental Affairs. There has been no action, thus far, in the House. Below is a CRS summary of the bill:

> Disaster Area Health and Environmental Monitoring Act of 2005 - Amends the Robert T. Stafford Disaster Relief and Emergency Assistance Act to authorize the President to carry out a program for the protection, assessment, monitoring, and study of the health and safety of individuals if chemicals or substances associated with potential acute or chronic human health effects (substances of concern) are being or have been released in a disaster area.
>
> Makes participation in any registry or study that is part of the program voluntary. Requires the President to take appropriate measures to protect the privacy of registry or study participants. Authorizes the President to carry out such a program through a cooperative agreement with a medical institution (including a local health department) or a consortium of medical institutions. Requires the President to carry out such a program in accordance with certain privacy regulations promulgated under the Health Insurance Portability and Accountability Act of 1996. Directs the Secretary of Homeland Security, the Secretary of Health and Human Services, and the Administrator of the Environmental Protection Agency to enter jointly into a contract with the National Academy of Sciences to study and report on disaster area health and environmental protection and monitoring. Amends the Robert T. Stafford Disaster Relief and Emergency Assistance Act to extend through September 30, 2007, the President's authority to establish a program to provide technical and financial assistance to state and local governments for the implementation of cost-effective predisaster hazard mitigation measures.

H.R. 5608, "Keeping Seniors Safe From Falls Act of 2006" -- Introduced on June 14th by Reps. Hall (R-TX) and Pallone (D-NJ), the bill amends the Public Health Service Act to direct the Secretary of Health and Human Services to intensify programs with respect to research and related activities concerning falls among older adults. It has been referred to the Energy and Commerce Committee.

S. 3484/H.R. 5563, the "Menu Education and Labeling Act' or the `MEAL Act" -- the bill was introduced on June 6th by Senators Harkin (D-IA) and Cantwell (D-WA) and Rep. DeLauro (D-CT). It amends the Federal Food, Drug, and Cosmetic Act to extend the food labeling requirements of the Nutrition Labeling and Educatin Act of 1990 to enable customers to make informed choices about the nutritional content of standard menu items in large chain restaurants. The bill has been referred to the Senate Committee on Health, Education, Labor, and Pensions and the House Committee on Energy and Commerce.

S. 3128, the "National Uniformity for Food Act" -- the bill was introduced on May 25th by Senators Burr (R-NC), Nelson (R-NE) and Roberts (R-KS). It amends the Federal Food, Drug, and Cosmetic Act to provide for uniform food safety warning notification requirements, and for other purposes. A similar bill, H.R. 4167, sponsored by Rep. Mike Rogers (R-MI) passed the House on March 8th. Both the House and Senate bills have been referred to the Committee on Health, Education, Labor, and Pensions. The excerpt below provides the key content of the Senate bill of interest to states:

> "(a) Uniformity Requirement-
>
> > `(1) IN GENERAL- Except as provided in subsections (c) and (d), no State or political subdivision of a State may, directly or indirectly, establish or continue in effect under any authority any notification requirement for a food that provides for a warning concerning the safety of the food, or any component or package of the food, unless such a notification requirement has been prescribed under the authority of this Act and the State or political subdivision notification requirement is identical to the notification requirement prescribed under the authority of this Act."

S. 3482, the "Volunteer Vaccine and Countermeasure Corps Development Act" -- Introduced on June 8th by Senators Harkin (D-IA) and Clinton (D-NY), the bill provides for the establishment of a volunteer corps to aid in the dissemination and distribution of vaccines and other countermeasures during a public health emergency. The bill has been referred to the Committee on Health, Education, Labor, and Pensions.

Introduced 6/8/06 -- By Mr. HARKIN (for himself and Mrs. CLINTON):

S. 3482. Volunteer Vaccine and Countermeasure Corps Development Act A bill to provide for the establishment of a volunteer corps to aid in the dissemination and distribution of vaccines and other countermeasures during a public health emergency; to the Committee on Health, Education, Labor, and Pensions.

HHS ISSUES FINAL RULE FOR SMALLPOX VACCINE INJURY COMPENSATION PROGRAM --HHS Secretary Mike Leavitt June 16 announced final rules for the Smallpox Vaccine Injury Compensation Program. The rules strengthen the smallpox vaccination compensation program, which provides benefits to public health and medical response team members and others who are injured as a result of receiving the smallpox vaccine.

The final rules supersede and update the Smallpox Vaccine Injury Table and the Administrative Implementation interim final rules that were published in the Dec. 16, 2003, Federal Register.

"By offering compensation to first responders and others injured by the vaccine, the program protects those pledged to protect us in the event of a smallpox outbreak," Secretary Leavitt said. The final rules also clarify the definition of a child survivor, extend the effective period in which an individual may receive a smallpox vaccination and be considered for benefits, and address which individuals may be considered for benefits. The final rules were published in the May 24, 2006, edition of the *Federal Register* and are effective immediately.

The department's Health Resources and Services Administration administers the program, which provides medical benefits and lost employment income to eligible members of an HHS-approved smallpox emergency response plan and others injured by a smallpox vaccine or death benefits to survivors.

In addition to smallpox vaccine recipients, unvaccinated individuals injured after coming into contact with a vaccinated member of an emergency response plan, or with a person with whom the vaccinated person had contact, or their survivors may be eligible for the same program benefits.

Based on a Jan. 30, 2006, amendment to the Secretary's Declaration, the date by which an individual in an HHS-approved smallpox emergency response plan may receive a smallpox vaccination and still be considered for benefits under the program has been extended to Jan. 23, 2007.

Anyone interested in eligibility or application information can contact the Smallpox Vaccine Injury Compensation Program at 1-888-496-0338 or by sending an email to smallpox@hrsa.gov. Those who wish to file a claim will find forms and information at www.hrsa.gov/smallpoxinjury.

HHS TO ACQUIRE NEW ANTHRAX THERAPEUTIC TREATMENT FOR STOCKPILE --The Department of Health and Human Services (HHS) announced June 20 it will purchase 20,000 treatment courses of ABthrax, an anthrax therapeutic treatment, from Human Genome Sciences of Rockville, Md. for $165,205,217. Delivery is expected to begin in 2009. Under the terms of the agreement, full payment to Human Genome Sciences is contingent on the product receiving licensure from the Food and Drug Administration.

“This important addition to the Strategic National Stockpile will provide physicians a way to neutralize the deadly toxin anthrax bacteria produces,” said Dr. Gerald Parker, HHS Acting Assistant Secretary for Public Health Emergency Preparedness. “And we found it is the toxin which accounted for the majority of anthrax-related deaths during the anthrax attacks of 2001.”

The Department of Homeland Security has determined that anthrax poses a threat to the U.S. population and the interagency Weapons of Mass Destruction Medical Countermeasures Subcommittee has recommended that anthrax therapeutics be acquired to improve the nation's biodefense preparedness and response capabilities and protect civilians from a potentially lethal exposure to anthrax spores.

In September 2005, HHS awarded a base contract to Human Genome Sciences for acquisition of a small amount of ABthrax, their antitoxin product, for independent government analysis and testing. The base contract included an option to acquire additional product following the testing and HHS is now exercising that option.

HHS' Office of Public Health Emergency Preparedness, which oversees the advanced research and procurement efforts under the Project BioShield program through its Office of Research and Development Coordination, manages the contract with Human Genome Sciences.

HEALTH INSURANCE FOR CHILDREN IMPROVED IN 2005; OVERALL COVERAGE VARIES BY STATE -- New estimates of health insurance coverage and other major indicators of health and health care were released today in two new reports by the Centers for Disease Control and Prevention (CDC). In addition to health insurance, the reports present the latest data on health habits, such as smoking, preventive health care including immunizations, and prevalence of diabetes, asthma and psychological distress.

Highlights of the reports include:

* In 2005, 41.2 million persons of all ages (14.2 percent) were currently without health insurance, down from 15.4 percent in 1997.

* In the same time period, children experienced the greatest increase in coverage with only 8.9 percent without insurance in 2005 compared to 13.9 percent in 1997.

* Insurance coverage varied widely among the 20 states for which data are now available, from 6 percent without health insurance in Massachusetts to over 24 percent lacking health insurance in Texas.

* Both diagnosed diabetes and asthma are on the rise, up to 7.4 percent and 7.8 percent of the population respectively.

* The 2005 estimates of influenza vaccinations reflected the shortage that occurred during the 2004-2005 flu season, but rates for those 65 years of age or older rebounded quicker than for other age groups.

The reports, which are produced on a fast track by CDC's National Center for Health Statistics to speed the release of major findings, are available on the CDC website at www.cdc.gov/nchs