THE CSTE WASHINGTON REPORT

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INSIDE THIS ISSUE

… PRESIDENT'S FY 2004 BUDGET RELEASED AND CONGRESS FINALLY FINISHES FY 2003 APPROPRIATIONS

…CDC RELEASES MOST EXTENSIVE ASSESSMENT EVER OF AMERICANS' EXPOSURE TO ENVIRONMENTAL CHEMICALS

…PRESIDENT'S BUDGET INCLUDES VITAL FOOD SUPPLY PROTECTIONS

…FDA RECOMMENDS TEMPORARY ADDITIONAL BLOOD INSPECTION MEASURES

…DR. SLATER ANNOUNCES SHE IS STEPPING DOWN AS HHS ASSISTANT SECRETARY FOR HEALTH

EDITOR'S NOTE: The Bush Administration continues to expand preparations for bioterrorism by proposing significant expansions of protections for the U.S. food supply. Of the $116.8 million in FDA's fiscal year 2004 budget for bioterror-related food safety programs, $20.5 million will be directed toward activities that implement the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, as well as related activities to protect the food supply. The FDA request directs: $5 million toward improving laboratory preparedness by expanding federal, state and local involvement in the Electronic Laboratory Exchange Network, which enables laboratories across the country to exchange information on pathogens in food.; $5 million to improve the quality of food monitoring and inspections through state contracts and grants; and $10.5 million to implement a registration system for domestic and foreign food production, handling and storage facilities, as well as a prior notice system for imported food shipments. All these additions must be approved by Congress and many questions remain as to the final funding levels of such programs in the coming year.

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'S FY 2004 BUDGET RELEASED AND CONGRESS FINALLY FINISHES FY 2003 APPROPRIATIONS – President Bush released his FY 2004 budget on February 3rd. The budget compares the President's request for FY 2004 to his request level for FY 2003 because Congress had not yet finished FY 2003 appropriations for all non-defense areas of the federal budget. The budget provides an overall increase for public health programs of 2.6 percent – just barely above regular inflation, but several points below medical inflation – compared not against FY 2003 funding, but the President's FY 2003 funding request. Within this increase, however, many programs were cut to accommodate a few areas of significant investment. The National Institutes of Health is not among the winners, this time with only a 1.8 percent overall increase, but the White House contends that when reductions in one-time construction costs are factored out research functions at NIH actually receive a 7.4 percent increase over the President's FY 2003 request, which was a 15 percent increase over FY 2002. CDC receives a slight decrease, when a new proposal for childhood immunization is factored in which creates a much needed vaccine stockpile, but appears to do so at the expense of support under 317 for state operations. Other highlights are increased funding for the President's chronic disease initiative, "Steps to a Healthier U.S."—which moves from $25 million in the FY 2003 request to $125 million in the FY 2004 request. CDC is the lead agency for this initiative which has components in several other HHS agencies. The budget also increases Breast and Cervical Cancer Screening by $10 million over the FY 2003 request. Bioterrorism funding for State and Local Health Departments is funded in the President's FY '04 request, once again, at a level of $940 million. You can read the HHS section of the President's FY 2004 budget request at the HHS web site: www.hhs.gov

Congress finally reached agreement on FY 2003 non-defense appropriations on Wednesday and the House passed the conference report on H.J. Res. 2 yesterday. The Senate will take it up today, 2/14. Below are some numbers from the conference report for selected public health programs.

SMALLPOX UPDATE – Both Senator Kennedy (D-MA) and Rep. Waxman (D-CA) have finished drafting legislation addressing smallpox vaccination costs and compensation, and liability. Rep. Waxman has introduced his bill, H.R. 865, but Senator Kennedy has not in the expectation that there will be significant negotiations with Senators Gregg (R-NH) and Frist (R-TN) who, respectively, chair and senior Member of the Health, Education, Labor and Pensions Committee. Senators Gregg and Frist appear to be waiting for an expected Administration proposal to create a smallpox compensation

fund. Members of the ASTHO-NACCHO working group on smallpox liability and compensation, which includes CSTE representation, are currently evaluating the bills.

CENTERS FOR DISEASE CONTROL AND PREVENTION (CDC)

Chronic Disease Prevention and Health Promotion

FY 2002	$ 747,000,000
FY 2003	$ 795,140,000
FY 2004	$ 834,000,000
Difference 04/03	+ $ 38,860,000

Environmental Health

FY 2002	$ 153,000,000
FY 2003	$ 184,205,000
FY 2004	$ 150,000,000
Difference 04/03	- $ 34,205,000

HIV/AIDS, STDS

FY 2002	$ 1,157,000,000
FY 2003	$ 1,194,150,000
FY 2004	$ 1,281,000,000
Difference 04/03	+ $ 86,850,000

Immunization – Current Law

FY 2002	$ 627,000,000
FY 2003	$ 640,751,000
FY 2004	$ 621,000,000
Difference 04/03	- $ 19,751,000

Bioterrorism State and Local Capacity

FY 2002	$ 940,000,000
FY 2003	$ 940,000,000
FY 2004	$ 940,000,000
Difference 04/03	$ 0

Health Statistics

FY 2002	$ 127,000,000
FY 2003	$ 126,000,000
FY 2004	$ 125,899,000
Difference 04/03	- $ 101,000

Injury Prevention and Control

FY 2002	$ 150,000,000

FY 2003	$ 149,385,000
FY 2004	$ 145,000,000
Difference 04/03	- $ 4,385,000

Infectious Disease Control

FY 2002	$ 348,000,000
FY 2003	$ 345,371,000
FY 2004	$ 332,000,000
Difference 04/03	- $ 13,371,000

Occupational Safety and Health

FY 2002	$ 276,000,000
FY 2003	$ 274,899,000
FY 2004	$ 246,000,000
Difference 04/03	- $ 28,899,000

Preventive Health and Health Services Block Grant

FY 2002	$ 135,000,000
FY 2003	$ 134,966,000
FY 2004	$ 135,000,000
Difference 04/03	+ $ 34,000

HEALTH RESOURCES AND SERVICES ADMINISTRATION

Maternal and Child Health Block Grant

FY 2002	$ 731,000,000
FY 2003	$ 734,741,000
FY 2004	$ 751,000,000
Difference 04/03	+ $ 16,259,000

CDC RELEASES MOST EXTENSIVE ASSESSMENT EVER OF AMERICANS' EXPOSURE TO ENVIRONMENTAL CHEMICALS --The Centers for Disease Control and Prevention (CDC) has released the second National Report on Human Exposure to Environmental Chemicals, the largest and most extensive assessment of the U.S. population's exposure to environmental chemicals. The report presents exposure information for 116 environmental chemicals measured in blood and urine specimens. The blood and urine specimens came from a sample of people who represent the U.S. population for the years 1999 and 2000.

"This report is by far the most extensive assessment ever of exposure of the U.S. population to environmental chemicals," said CDC Director Dr. Julie Gerberding, "This kind of exposure information is essential, it helps us to lay the critical groundwork for future research in ensuring that exposures to chemicals in our environment are not at levels that affect our health."

The report contains new data on declines in blood lead levels in children; decreases in adults' exposure to environmental tobacco smoke, and for the first time, extensive data on many other chemicals that will help public health physicians and scientists identify and prevent health problems from exposure.

Blood and urine samples were collected from some 2,500 participants for each chemical tested in CDC's National Health and Nutrition Examination Survey (NHANES)—an ongoing national health survey of the U.S. population. CDC's Environmental Health Laboratory developed special analytical methods and measured the chemicals and their metabolites (breakdown products) in these blood and urine samples.

Selected Findings -- Some Progress, Some Concern

Lead

New data on blood lead levels in children aged 1-5 years allow us to estimate the number of children with elevated levels. For 1999-2000, 2.2 percent (95 percent confidence interval of 1.0 to 4.3 percent) of children aged 1-5 years had elevated blood lead levels (levels greater than or equal to 10 micrograms per deciliter). This percentage has decreased from 4.4 percent for the period 1991-1994. "The continued decline of elevated blood lead levels in America's children is a public health success story. However, exposure of children to lead in homes containing lead-based paint and lead-contaminated dust remains a serious public health concern," said Dr. Richard Jackson, Director, National Center for Environmental Health.

Exposure to environmental tobacco smoke

Compared with levels measured during the period 1991-1994 for nonsmokers, cotinine levels have decreased 58 percent for children, 55 percent for adolescents, and 75 percent for adults. These declines support the effectiveness of public health efforts to reduce environmental tobacco smoke (ETS) exposure during the 1990s, which have mostly targeted adults," Dr. Jackson said. "However, continued efforts to reduce exposure to environmental tobacco smoke are warranted, especially for children, adolescents, and non-Hispanic blacks."

The second report presents extensive data for many other chemicals that include mercury, uranium, cadmium, thallium, and other metals; phthalates; organochlorine pesticides, herbicides, polycyclic aromatic hydrocarbons; carbamate insecticides; organophosphate pesticides, phytoestrogens. The report and an executive summary are available online at the following web site: http://www.cdc.gov/exposurereport. The report will continue to be released every two years, expanding the number of chemicals covered, providing physicians with reference levels of exposure so that they can recognize unusually high levels of exposure in patients and assessing the effectiveness of efforts to reduce chemical exposure.

PRESIDENT'S BUDGET INCLUDES VITAL FOOD SUPPLY PROTECTIONS -- HHS Secretary Tommy G. Thompson announced February 4 that President Bush's fiscal year 2004 budget request builds on the department's commitment to protect the nation's food supply by seeking $116.8 million -- an increase of $19 million, or 19 percent -- for bioterror-related food safety programs at the Food and Drug Administration (FDA). Overall, the President is requesting $3.6 billion for bioterrorism funding at HHS to enhance the significant steps that HHS has taken since Sept. 11, 2001 to better prepare America for a bioterror attack. Between fiscal year 2002 and fiscal year 2004, HHS has spent or requested $9.2 billion for research, prevention and preparedness.

"We are building on the largest investment in our public health infrastructure in history by making America healthier, safer and better prepared," Secretary Thompson said. "We are ensuring that our food supply is safe by making it easier for state, local and federal authorities to exchange information about pathogens in food, and we will be able to improve food monitoring and inspections throughout America."

Of the $116.8 million in FDA's fiscal year 2004 budget for bioterror-related food safety programs, $20.5 million will be directed toward activities that implement the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, as well as related activities to protect the food supply. The FDA request directs:

* $5 million toward improving laboratory preparedness by expanding federal, state and local involvement in the Electronic Laboratory Exchange Network, which enables laboratories across the country to exchange information on pathogens in food.
* $5 million to improve the quality of food monitoring and inspections through state contracts and grants.
* $10.5 million to implement a registration system for domestic and foreign food production, handling and storage facilities, as well as a prior notice system for imported food shipments.

These new initiatives complement the steps HHS already has taken to protect the nation's food supply. FDA has hired more than 800 new food safety employees, the vast majority of whom are involved in inspecting food imported into the country. FDA now can conduct 48,000 on-site import inspections per year.

Additionally, FDA last week proposed a new regulation that would require notice be given to the FDA before food is imported into the United States, allowing inspectors to target inspections more effectively to help ensure the safety of food. The FDA also proposed a regulation that would require domestic and foreign food facilities that manufacture, process, pack or hold food in the United States to register with the agency by Dec. 12 of this year, bolstering FDA's ability to regulate the more than 400,000 facilities that deal with food within the United States.
HHS works closely with the United States Department of Agriculture (USDA) to protect the nation's food supply. President Bush's fiscal year 2004 budget request includes a $112

million increase for food safety, homeland security and agricultural protection systems at USDA.

FDA RECOMMENDS TEMPORARY ADDITIONAL BLOOD INSPECTION MEASURES AS IT CONTINUES INVESTIGATION OF REPORTS OF WHITE PARTICULATE MATTER IN SOME UNITS OF BLOOD AND BLOOD COMPONENTS --The Food and Drug Administration (FDA) announced that it has issued recommendations to the blood industry for additional blood inspection measures and will shortly issue interim guidance recommending enhanced visual inspection of all blood and blood components. This interim guidance is a precautionary measure as the FDA continues to actively investigate reports of units of blood and blood components containing white particulate matter**.**

Most of the reports of particulates have, to date, been associated with blood and blood components contained in bags with a sampling port manufactured by Baxter Healthcare Corporation, and have come from Red Cross blood centers in the southeastern United States, including parts of Tennessee and Georgia.

The exact nature of the particulate matter is under investigation. Preliminary results reported to FDA suggest that some particles represent clumping of platelets, which are a normal blood cell. Testing completed to date by the Centers for Disease Control and Prevention (CDC) has found no evidence of infectious agents.

FDA has also received a smaller number of preliminary reports of possible particulates involving some other bag types, locations, and blood banks. It is unclear at this time whether all reported observations are similar, or whether all represent abnormalities. Blood is a complex substance and some units may, at times, contain small numbers of particles composed of clumped cells or globules of normal substances. Some clearly abnormal particles and increased numbers of particles have recently been noted in some blood units by experienced observers. However, the recently increased intensity and enhanced methods of inspections are likely contributing to reporting of some particles that may, in fact, be normal occurrences. Ongoing clinical and laboratory studies are in progress to help evaluate these observations.

As a precautionary measure while FDA's investigation continues, FDA is asking all blood establishments to implement enhanced visual inspection procedures. If abnormalities are detected, FDA is requesting that blood establishments quarantine the products and report their findings expeditiously to FDA by sending an e-mail message to BP_Deviations@cber.fda.gov or by calling FDA at 800-835-4709. Adverse events potentially related to the presence of particulate matter should also be reported to FDA using the aforementioned e-mail address or phone number.

DR. SLATER ANNOUNCES SHE IS STEPPING DOWN AS

HHS ASSISTANT SECRETARY FOR HEALTH -- Eve E. Slater, M.D., announced February 4 that she is stepping down as assistant secretary for health to pursue other opportunities.

"Eve Slater is a relentless advocate for the health and well-being of all Americans," Secretary Tommy G. Thompson said. "Her tireless work on building the issues of women's health, HIV/AIDS, reducing health disparities, vaccinations, patient safety, quality of health care and the use of information technology in health care reform will leave a lasting legacy at HHS."

President Bush nominated Dr. Slater to be assistant secretary for health in October 2001. The assistant secretary for health serves as the Secretary's primary advisor on matters involving the nation's public health and oversees HHS' U.S. Public Health Service (PHS) for the Secretary. The PHS is comprised of the eight health agency divisions of HHS and the Commissioned Corps, a uniformed service of more than 6,000 health professionals who serve at HHS and other federal agencies.

Surgeon General Richard Carmona will be the acting assistant secretary for health while the search for a new assistant secretary takes place.