THE CSTE WASHINGTON REPORT

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INSIDE THIS ISSUE

EDITOR'S NOTE: HHS Secretary Thompson has announced an important new initiative designed to prevent diabetes, obesity and asthma. To be funded with $100 million, "Steps to a Healthier US" includes specific prevention goals for the fiscal year -- preventing diabetes for at least 75,000 Americans, preventing obesity for at least 100,000 Americans and preventing asthma-related hospitalizations for at least 50,000 Americans. HHS will rely on existing and expanded surveillance efforts to assess the new initiative's effectiveness at helping Americans to prevent disease and achieve good health.

In addition, in his fiscal year 2004 budget request, President Bush will propose a series of improvements in the financing of childhood vaccines to meet three goals -- improve

vaccine access, restore tetanus and diphtheria toxoid vaccines (Td, DT) to the Vaccine for Children (VFC) program, and build a national stockpile of childhood vaccine. President's budget calls for spending a total of an estimated $707 million between fiscal year 2003 and fiscal year 2006 to build up a national stockpile of childhood vaccines to ensure that shortages of these vaccines do not recur.

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

APPROPRIATIONS UPDATE – The Senate finished its work on the giant FY 2003 omnibus appropriations bill, which wraps together 11 non-defense spending bills, last week. During the debate a total of 2.9 percent in across-the-board cuts were adopted to fund increases in drought relief, education funding and other non-health initiatives. This has slowed the availability of final Senate numbers for programs as Congress and the White House disagree regarding what the across-the-board cuts can be applied to and whether advance funding gimmicks should be counted against FY 2003. In addition, Senator Stevens (R-AK), Chairman of the Senate Appropriations Committee, has been working to apply accounting methods that will reduce the across-the-board cuts. Nevertheless, the House and Senate appropriators have been actively negotiating differences between the House and Senate versions of the omnibus bill, although the House has never actually produced an omnibus package. Negotiations are taking place only among the principal appropriators. The target date for passing the resulting conference report by both chambers is Wednesday, February 5th, but the outlook for actually finishing the FY 2003 appropriations by this date is still very uncertain.

Meanwhile, the President's FY 2004 budget request will be presented on Monday, February 3rd. HHS Secretary Thompson has been releasing preview statements about a few select programs that will receive increases: $100 million for a chronic disease prevention program targeting obesity, fitness, and smoking, $707 million over four years to strengthen CDC's childhood immunization program largely by creating a stockpile for vaccines, and an increase of $10 million for CDC's breast and cervical cancer screening program. While public health groups welcome these developments, and a major international AIDS investment of $15 billion, they anticipate that these increases will come at the expense of other health programs.

SMALLPOX UPDATE – During debate on the Senate FY 2003 omnibus appropriations bills (H.J. Res. 2), Senator Robert Byrd (D-WV) proposed an amendment that would have added billions more for homeland security. Included in the package was $850 million for state and local health departments to offset the costs they are incurring to administer the smallpox vaccine. The amendment failed. Then Sen. Kennedy (D-MA) prepared to offer an amendment that would have added the $850 million to defray smallpox costs and $750 million to create a no-fault smallpox vaccine compensation fund for those who suffer adverse effects from the vaccine. However, rather than offer the

amendment, Kennedy worked a deal with Senators Frist (R-TN) and Gregg (R-NH) that committed them, in a colloquy on the Senate floor, to quick action on legislation that would address these issues, as well as liability gaps for entities involved in smallpox vaccination. Sen. Kennedy hopes to introduce his bill early next week and then seek agreement with Senators Frist and Gregg, and other Republicans on the Senate HELP Committee. Meanwhile HHS Sec. Thompson has publicly expressed the Department's interest in addressing compensation issues and noted his budget staff are working on a proposal.

HHS BUDGET PROPOSAL TO INCLUDE $100 MILLION INCREASE TO PREVENT DIABETES, OBESITY AND ASTHMA ACROSS THE COUNTRY

--President Bush's fiscal year 2004 budget plan will include an increase of $100 million -- to $125 million -- for a new initiative to prevent diabetes, obesity and asthma through community initiatives to achieve healthier lifestyles for hundreds of thousands of Americans, HHS Secretary Tommy G. Thompson announced January 22.

"To truly stem the epidemic of preventable diseases that threaten too many Americans, we need to move from a health care system that treats disease to one that avoids disease through wiser personal choices," Secretary Thompson said. "This new initiative will support community programs aimed at getting results and helping those at risk to avoid these diseases through proven prevention methods."

Under the "Steps to a Healthier US" initiative, HHS would fund specific projects at the state and community level that would use proven medical and public health strategies to reduce the burden of diabetes, obesity and asthma among their populations. The initiative includes target goals for disease reduction. Projects under the initiative would include:

* State programs to motivate and support responsible health choices that would reduce the burden of preventable disease;
* Community initiatives to promote and enable healthful choices, especially those focused on youth and older Americans;
* Health care and insurance systems that put prevention first and reduce people's risk factors for chronic disease and reduce potential health care complications.

The incidence of diabetes and obesity among Americans are up sharply in the past decade, putting millions more Americans at higher risk for heart disease, stroke and other related medical conditions. Diabetes alone costs the nation nearly $100 billion each year in direct medical costs as well as indirect economic costs, including disability, missed work and premature death. Medical studies have shown that modest lifestyle changes -- such as getting more exercise and losing weight -- can reduce an individual's risks for developing these serious health conditions.

"Not only do these preventable diseases take a terrible toll on the lives of individual Americans, but they also contribute to skyrocketing health care costs affecting our nation as a whole," Secretary Thompson said. "We must do more to encourage individual

Americans to take personal responsibility for their health choices and to create a sense of social responsibility to ensure that policymakers support the kinds of programs that foster healthy activity and prevention."

"Steps to a Healthier US" includes specific prevention goals for the fiscal year -- preventing diabetes for at least 75,000 Americans, preventing obesity for at least 100,000 Americans and preventing asthma-related hospitalizations for at least 50,000 Americans. HHS will rely on existing and expanded surveillance efforts to assess the new initiative's effectiveness at helping Americans to prevent disease and achieve good health.
"It's disturbing to see that the number of Americans suffering from chronic diseases continues to go up each year," Secretary Thompson said. "The reason they are going up is very simple: We don't take care of ourselves. And by not taking care of ourselves, we are paying for it, both with our health and from our pocketbooks."

The initiative represents an expansion of HHS' $25 million Healthy Communities initiative, which President Bush and Secretary Thompson proposed as part of the fiscal year 2003 budget request. This increase, included in the request for the Centers for Disease Control and Prevention (CDC), will be closely coordinated with existing diabetes, asthma, and obesity prevention programs at CDC. The expanded effort will involve five HHS agencies -- CDC, the Health Resources and Services Administration (HRSA), the Administration for Children and Families (ACF), the Administration on Aging (AoA) and the Agency for Healthcare Research and Quality (AHRQ).

PRESIDENT TO PROPOSE IMPROVEMENTS IN CHILDHOOD VACCINE PROGRAMS -- In his fiscal year 2004 budget request, President Bush will propose a series of improvements in the financing of childhood vaccines to meet three goals -- improve vaccine access, restore tetanus and diphtheria toxoid vaccines (Td, DT) to the Vaccine for Children (VFC) program, and build a national stockpile of childhood vaccine. The proposed improvements are part of HHS' fiscal year 2004 budget request and will expand on the department's efforts to improve access to health care for all Americans.

"The President's proposal will expand access to preventive health care for some of our most vulnerable citizens, our children," Secretary Thompson said. "Vaccines are one of the most successful tools we have available today to prevent an array of childhood diseases, so we must do all we can to ensure that our children can get the vaccines they need."

The proposed budget includes three important immunization initiatives.
First, the President will propose legislation that will expand the number of clinics that can provide VFC vaccines at no cost to underinsured children. The VFC program is managed by the Centers for Disease Control and Prevention (CDC), and it provides vaccines at no cost for children covered under Medicaid, for American Indian and Alaska Native children, for those with no insurance, and for underinsured children (those whose private

insurance does not cover immunizations) seeking services at a community health center or other federally qualified health center. Currently, state and local public health clinics can only provide VFC vaccines to Medicaid or uninsured children but not to underinsured children.
The proposed legislation will allow state and local public health clinics to provide VFC vaccine to underinsured children at no cost. The legislation will make it easier for these underinsured children to get recommended vaccines for which they are already entitled by expanding access to health care. HHS estimates that the net cost of this reform is $50 million, which would cover the additional number of vaccinations expected as a result of increased access to immunization clinics.

"By letting underinsured children go to local public health clinics to get their VFC vaccines, we're making it easier than ever for these children to get their recommended shots," Secretary Thompson said.

The second key element of the President's budget request includes legislation to restore tetanus and diphtheria vaccines (Td and DT) to the VFC program. Since 1993 the VFC program has had a price cap on Td and DT vaccines. The cap has been so low that vendors have concluded it is not economically feasible to sell, and in 1998, Td and DT vaccines were removed from the VFC program. The President will propose legislation lifting these price caps and enable the VFC program to procure an estimated 2.5 million doses in FY 2004.

Finally, the President's budget calls for spending a total of an estimated $707 million between fiscal year 2003 and fiscal year 2006 to build up a national stockpile of childhood vaccines to ensure that shortages of these vaccines do not recur. HHS plans to have a vendor?managed, six month supply of all childhood vaccines by 2006. HHS will begin these procurements later this year.

"All of these improvements will ensure that all VFC-eligible children have rapid access to all new and improved vaccines that become available," Secretary Thompson said.
The fiscal year 2004 budget includes a total of $1.6 billion for CDC's immunization programs.

CDC DIRECTOR ANNOUNCES NEW EXECUTIVE LEADERSHIP TEAM
-- Centers for Disease Control and Prevention (CDC) Director Dr. Julie Gerberding January 17 announced her executive leadership team. The announcement was made during a meeting with CDC employees at the main headquarters on Clifton Road in Atlanta.

Named to the executive leadership team are William H. Gimson, chief operating officer; David Fleming, MD, deputy director for public health science; Ed Thompson, MD, deputy director for public health services; Kathy Cahill, senior advisor for strategy and innovation; and Verla Neslund, acting chief of staff.

"CDC is a vital component of HHS, and strong leadership is essential for the agency to fulfill its core mission of protecting the public health," said Tommy G. Thompson, Secretary of the Department of Health and Human Services. "Dr. Gerberding has assembled an impressive team to guide the agency as it continues to tackle complex and important public health issues like terrorism preparedness and disease prevention." Gerberding chose a corporate executive team model to manage CDC and its sister agency, the Agency for Toxic Substances and Disease Registry (ATSDR), after consulting with corporate executives and seeing how the model could improve the agency's effectiveness, accountability and impact. The corporate team approach allows for more flexible integration of CDC's diverse operating components as well as greater integration within the Department of Health and Human Services.

"Within the past decade CDC has been charged with increasingly varied responsibilities for the nation, including public health terrorism preparedness and response. This kind of growth requires a new approach to leadership and management that allows the agency to balance emerging issues with its long-term vision for safer, healthier people in every community," said Dr. Gerberding.

FDA ISSUES GUIDANCE FOR COLLECTION OF RACE AND ETHNICITY DATA IN CLINICAL TRIALS FOR FDA REGULATED PRODUCTS—The Food and Drug Administration (FDA) has published a draft Guidance for Industry to recommend categories for collecting effectiveness and safety data during clinical trials for ethnic and racial demographic groups.

FDA regulations require drug sponsors to present an analysis of data according to age, gender and race. An analysis of modifications of dose or dosage intervals for specific groups is also required when manufacturers submit a new drug application for approval by FDA. To accomplish this, FDA recommends that the drug manufacturers use the OMB race and ethnicity categories during clinical trial data collection to ensure consistency in evaluating potential differences in drug response among racial and ethnic groups.

Some differences in response to medical products have already been observed in distinct groups of the U.S. population. These differences may be attributable to intrinsic factors such as genetic differences; to extrinsic factors like diet, environmental exposure, socio-cultural issues, or to interactions between these factors. For example, in the United States, whites are more likely than people of African or Asian heritage to have low levels of an important enzyme (CYP2D6) that metabolizes antidepressants, antipsychotics, and beta blockers. Additionally, of some drugs in the psychotherapeutic class, slower enzyme metabolism has been observed in persons in the United States of Asian descent as compared to Whites and Blacks.

Other studies have shown that Blacks respond less to several classes of antihypertensive agents (beta blockers and angiotensin converting enzyme (ACE) inhibitors). Racial differences in skin structure and physiology have been noted that can affect response to dermatologic and topically applied products. Clinical trials have demonstrated lower

responses to interferon-alpha used in the treatment of hepatitis C among Blacks when compared to other racial groups.

Collecting race and ethnicity data using standardized categories will enhance the early identification of differences in response among racial and ethnic groups during the evaluation of safety and effectiveness of FDA-regulated products.
Furthermore, collection of this data using standardized categories will facilitate comparisons across studies analyzed by FDA and with data collected by other Federal agencies.

The draft guidance does not discuss increasing the number of studies in which certain groups are exposed to a product, nor does it discuss increasing the total number of participants involved in clinical trials.

CDC UNVEILS NEW TOOLKIT TO HELP PHYSICIANS PREVENT AND TREAT BRAIN INJURIES -- The Centers for Disease Control and Prevention (CDC) January 22 unveiled Heads Up Brain Injury in your Practice, a tool kit for physicians. The tool kit is designed to raise physicians' awareness about the public health problem of mild traumatic brain injury (MTBI) and to improve treatment for patients with MTBI. MTBI, also known as concussion, is one of the most common neurological disorders. The kit is part of a larger initiative directed by CDC's Injury Center**.**

"Physicians can play a key role in helping to prevent concussions and in helping patients who experience one, when it does occur," Health and Human Services Secretary Tommy G. Thompson said. "This tool kit will help physicians communicate with their patients and their family members about brain injury and prevention."

Approximately 1.5 million people sustain traumatic brain injuries in this country every year. Of those, approximately 1.1 million, or 75 percent sustain a MTBI. Yet, many are released from medical care without hospitalization or never receive medical care at all. An unknown proportion of those who are not hospitalized may experience long-term disability such as persistent headache, confusion, pain, memory problems, fatigue, difficulties with sleep patterns, mood changes, or vision or hearing problems.

"It is our hope that we can foster better treatment, and provide better follow-up care of patients with MTBI," said Dr. Julie Louise Gerberding, Director of CDC.
The kit provides doctors clinical information on incidence, prevention strategies, diagnosis, and treatment, patient education materials, including tips on preventing brain injuries, and a booklet for patients already diagnosed with a brain injury, *Facts about Concussion and Brain Injury* (English and Spanish versions), and a CD-ROM with relevant scientific articles and downloadable kit materials.

HHS IDENTIFIES DRUGS FOR PEDIATRIC TESTING AND ANNOUNCES $93 MILLION IN FY 2003 AND FY 2004 FUNDING -- HHS Secretary Tommy G. Thompson January 21 named 12 commonly-prescribed drugs that need to be tested for

use in children. He said government-supported tests of the drugs will begin this year, with up to $25 million available to launch the tests in fiscal year 2003 and up to $50 million to be included in the President's FY 2004 budget proposal next month for the testing. An additional $18 million will also be provided for review by the Food and Drug Administration (FDA).

The testing is called for in the Best Pharmaceuticals for Children Act (BPCA), which was signed into law by President Bush last year. The law provides for HHS agencies to sponsor pediatric tests of certain drugs already approved for marketing but never tested specifically for their effects in children. The list released today identifies the dozen highest-priority drugs needing pediatric review.

"Children often react differently to drugs than adults do," Secretary Thompson said. "The drugs we are naming today have long been approved for marketing and are often prescribed for children, yet they have only been tested in adults. We need to conduct testing now to fully understand the effects of these medications in children."

The list of drugs released January 21 was developed by the National Institute of Child Health and Human Development (NICHD), part of HHS' National Institutes of Health (NIH), in consultation with FDA and experts in pediatric research. The list will be updated each year.

Once a drug has been approved for a particular use, physicians may prescribe it for other uses, as they deem necessary. Many commonly available drugs, although approved for use in adults, have never been tested specifically for use in children. The 12 drugs on the list are currently prescribed for children, but their safety and effectiveness has been established only in adults:
Azithromycin-An antibiotic used to treat many different types of bacterial infection
Baclofen-A muscle relaxant used to relieve the spasms, cramping, and tightness of muscles caused by medical problems such as multiple sclerosis or certain injuries to the spine.
Bumetanide-Used to reduce the swelling and fluid retention caused by various medical problems, including heart or liver disease. It also is used to treat high blood pressure. It causes the kidneys to get rid of unneeded water and salt from the body into the urine.
Dobutamine-A heart stimulating drug.
Dopamine-Used to treat Parkinson's disease and Schizophrenia.
Furosemide-Used to treat swelling and water retention.
Heparin-Decrease the clotting ability of the blood and help prevent harmful clots from forming in the blood vessels
Lithium-Treatment for bipolar disorder (extreme mood changes from depression or anger to elation).
Lorazepam-Treatment for anxiety.
Rifampin-Used in combination with other medications to treat tuberculosis, and to treat carriers of meningitis-causing bacteria.
Sodium Nitroprusside-A treatment for high blood pressure.

Spironolactone-A treatment for high blood pressure.
Each drug will undergo about two years of testing, followed by evaluation of test results by the FDA. NICHD will oversee the testing process, consulting closely with other NIH institutes and the FDA.

Following enactment of BPCA last January, NIH set aside $25 million to launch tests this year. In his budget proposal next month, President Bush will propose doubling this amount in FY 2004. In addition, another $6.6 million is available for FDA support this year, increasing to $11.5 million in the President's FY 2004 budget. Requests for proposals to carry out the research will be developed immediately, and contracts will be awarded later this year.