THE CSTE WASHINGTON REPORT

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INSIDE THIS ISSUE

EDITOR'S NOTE: The President's just released budget for Fiscal Year 2006 has more than a few disappointments for public health professionals, with cuts totalling $1 billion across the agencies of the U.S. Public Health Service. Within CDC, which suffers more than $500 million in cuts, the Preventive Health and Health Services Block Grant is eliminated completely and $130 million is cut from the Bioterrorism grants to improve state and local capacity. Other large cuts are in the Health Resources and Services Administration where the health professions program is eliminated, raising real questions about how the expanded community health centers will be staffed as they are expanded under the budget. Even the National Institutes of Health is held to a fractional increase. In any event, the proposed budget misses many important opportunities to improve the health and well being of Americans through the infrastructure of federal, state and local public programs. Let's hope that many of these proposed cuts will not stand in Congress.

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 – On February 7th the President presented his FY 2006 budget. Overall, the budget cuts public health funding by close to $1 billion below FY 2005 levels and zeros out 14 programs, among them CDC's Preventive Health and Health Services Block Grant. Other key cuts for state and local health departments include $130 million for the CDC State and Local Bioterrorism grant program. Part of this funding cut will be shifted to the National Stockpile where a new $50 mass casualty initiative will be housed, and it appears other uses of the state funding cuts will go to purchase vaccine and treatment items for the Stockpile. Chronic disease was cut $58 million, primarily due to elimination of the VERB program, a youth targeted five year demonstration project to address obesity and other risk factors. Other chronic disease programs received very slight, on the order of $10,000, increases. Nearly all other non-global programs in the CDC budget were flat-lined. Selected information is provided below and you can get additional details by viewing the budget page on CDC web site:

http://www.cdc.gov/fmo/fmofybudget.htm

CDC Program Level

FY 2004	$ 7,213,000,000
FY 2005	$ 8,034,000,000
President FY 2006	$ 7,543,000,000

Infectious Diseases

FY 2004	$ 221,000,000
FY 2005	$ 226,000,000
President FY 2006	$ 225,000,000

HIV/AIDS, STDs and TB Prevention

FY 2004	$ 964,000,000
FY 2005	$ 960,000,000
President FY 2006	$ 956,000,000

Immunization – Section 317 Discretionary Program-Current Law

FY 2004	$ 469,000,000
FY 2005	$ 479,000,000
President FY 2006	$ 529,000,000

VFC Stockpiles and Catchup Immunizations

FY 2004	$ 40,000,000
FY 2005	$ 488,000,000
President FY 2006	$ 322,000,000

Global Health

FY 2004	$ 280,000,000
FY 2005	$ 294,000,000
President FY 2006	$ 306,000,000

Bioterrorism – State and Local Capacity

FY 2004	$ 918,000,000
FY 2005	$ 927,000,000
President FY 2006	$ 797,000,000

State Grant Program

FY 2004	$ 871,000,000
FY 2005	$ 871,000,000
President FY 2006	$ 741,000,000

Bioterrorism – Upgrading CDC Capacity-Anthrax Research

FY 2004	$ 169,000,000
FY 2005	$ 157,000,000
President FY 2006	$ 140,000,000

Bioterrorism – Strategic National Stockpile

FY 2004	$ 398,000,000
FY 2005	$ 397,000,000
President FY 2006	$ 600,000,000

Bioterrorism – Biosurveillance Initiative

FY 2004	$ 22,000,000
FY 2005	$ 79,000,000
President FY 2006	$ 79,000,000

Subtotal Bioterrorism

FY 2004	$ 1,507,000,000
FY 2005	$ 1,560,000,000
President FY 2006	$ 1,616,000,000

Chronic Disease Prevention and Health Promotion

FY 2004	$ 818,000,000
FY 2005	$ 899,000,000
President FY 2006	$ 840,000,000

Birth Defects Disability and Health

FY 2004	$ 114,000,000
FY 2005	$ 125,000,000
President FY 2006	$ 124,000,000

Health Statistics

FY 2004	$ 90,000,000

FY 2005	$ 109,000,000
President FY 2006	$ 109,000,000

Environmental Health

FY 2004	$ 146,000,000
FY 2005	$ 148,000,000
President FY 2006	$ 147,000,000

Health Track

FY 2004	$ 24,147,000
FY 2005	$ 24,438,000
President FY 2006	$ 24,356,000

Injury Prevention and Control

FY 2004	$ 137,000,000
FY 2005	$ 138,000,000
President FY 2006	$ 138,000,000

Occupational Safety and Health

FY 2004	$ 277,000,000
FY 2005	$ 286,000,000
President FY 2006	$ 286,000,000

Public Health Research

FY 2004	$ 29,000,000
FY 2005	$ 31,000,000
President FY 2006	$ 31,000,000

Preventive Health and Health Services Block Grant

FY 2004	$ 132,000,000
FY 2005	$ 131,000,000
President FY 2006	$ 0

ATSDR

FY 2004	$ 73,000,000
FY 2005	$ 76,000,000
President FY 2006	$ 76,000,000

CDC COALITION MEETING WITH CDC BUDGET STAFF – On February 10th, the CDC Coalition held a meeting with the CDC budget staff. Below are some questions raised by advocacy organizations and the written responses provided by the CDC budget staff. They help clarify some of the Bioterrorism budget items in the President's FY 2006 budget.

1. Is it possible for the stockpile increase to be used to purchase reagents?

Of the $203.2 million increase $50 million has been designated for enhancing HHS's Federal Medical Contingency Station project. The remaining $153.2 is specifically targeted to cover the costs of BioShield acquisitions, and the FY 2006 commitment for purchase of additional anthrax antibiotics. The expected cost to fund both the BioShield and anthrax initiatives is not expected to exhaust all of the additional funding thereby leaving funds for the rotation and purchase of reagents. However, CDC has not used SNS funding for reagents in the past and would be a very big change to the management and mission of the SNS.

2. Will the cuts to Preparedness impact cities readiness?

This is still undecided. CDC in partnership with its initial 21 city partners is currently evaluating the early progress of this program. The results of this study will hopefully show the advances and successes that have occurred as well as show more efficient ways to implement this programs expansion. Until this process has been sufficiently determined, and in light of the current budget reduction, CDC cannot definitively state whether or not the Cities Readiness Initiative will be impacted.

3. Please provide more information on the mass casualty funding.

The $50 million will go to enhance HHS's Federal Medical Contingency Station program. The funding will increase the number of deployable units designed for flexible response through its scaleable and modular design. This project allows for the deployment of as few as 50 beds and as many as 250 beds and will be configured as a quarantine operation, a non-acute care operation, or a combination of these operations. The goal is to provide a quick, flexible and transportable bed surge capability within any region of the nation, and the FY 2006 funding will allow for the enhancement and expansion of this goal.

HOUSE APPROPRIATIONS COMMITTEE ADOPTS REORGANIZATION – The House Appropriations Committee has formally reorganized eliminating three Subcommittees: Veterans Affairs, Housing and Urban Development, and Independent Agencies (VA-HUD); Legislative Branch; District of Columbia. Funding for a key public health agency, Agency for Toxic Substances and Disease Registry (ATSDR) will be moved from VA-HUD to Interior and Related Agencies Subcommittee. The Labor-HHS-Education Subcommittee, which funds most public health agencies including CDC, NIH, and HRSA, has not been affected by the reorganization, except that it lost a very helpful Member, Rep. Mike Simpson (R-ID) who will now move to the Interior Subcommittee. His place has been taken by Rep. Jim Walsh (R-NY), a moderate Republican who used to chair the VA-HUD Subcommittee. Rep. Walsh had reached his six year term as Chairman of that Subcommittee – now eliminated. The Senate Appropriations Committee continues to reject the House plan which is predicted to cause a very chaotic conference situation between House and Senate appropriations bills practically ensuring there will be a giant omnibus bill, once again.

NIDA-FUNDED STUDIES SHOW EXPANDING HIV SCREENING IS COST EFFECTIVE -- Two multicenter research teams supported in part by the National Institute on Drug Abuse, National Institutes of Health, have independently determined

through the development of computer models that routine screening for HIV in health care settings is as cost effective as screening for such other conditions as breast cancer and high blood pressure, and can provide important health and survival benefits. The studies also suggest that screening that leads to a diagnosis of HIV infection may further lower health care costs by preventing high-risk practices and decreasing virus transmission.

Both studies — one led by Dr. Gillian Sanders at Duke Clinical Research Institute at Duke University and Dr. Douglas Owens at the Veterans Affairs Palo Alto Health Care System; and one led by Dr. A. David Paltiel at Yale School of Medicine — are published in the February 10, 2005 issue of the *New England Journal of Medicine*.

"Of the nearly 1 million people in the United States infected with HIV, about 280,000 are unaware of their status," says NIDA Director Dr. Nora D. Volkow. "Current patterns of screening are inconsistent, and people generally are diagnosed late in their disease. There is the possibility that by expanding screening, people identified with HIV can begin highly effective and lifesaving medical therapy early on and improve their quality of life. And, by realizing their HIV status sooner, people may reduce high-risk behaviors and decrease transmission of this virus."

In the first study, the scientists developed a computer model to follow a hypothetical group of 43-year-old men and women whose HIV status was unknown, to estimate the health costs and benefits associated with voluntary HIV screening in health care settings.

"As part of the study, we analyzed the costs associated with HIV testing, counseling, followup, and treatment," says Dr. Sanders. "While no computer model is a perfect representation of reality, the results suggest that a one-time HIV screening program provides a very important health benefit and is a good value, even in populations with a relatively low proportion of people with HIV. In the end, a one-time screening costs about $15,078 for every year of life gained, a figure that takes into account the resulting reduction in virus transmission and benefits to partners."

"An intervention that costs under $20,000 per quality-adjusted life year gained would definitely be recognized as providing good value," notes Dr. Sanders. A quality-adjusted life year is a standard health outcome measure used by many researchers. It is a way to account for both longevity and health-related quality of life.

In addition, the researchers found that implementing a one-time screening program could reduce the annual HIV transmission rate over these patients' lifetimes by 21 percent compared to current practice.

In the second study, researchers developed a computer model that compared costs associated with HIV screening and current voluntary HIV diagnostic and counseling practices in three populations: a "high-risk" population in which 3 percent had undiagnosed HIV infection, a population in which 1 percent had undiagnosed HIV, and the general population in which the prevalence of undiagnosed HIV was 0.1 percent.

They found that routine, voluntary HIV screening every 3 to 5 years provides clinical benefits and is cost effective in all but the lowest-risk populations. One-time screening in the general U.S. population also may be cost effective.

“Our study suggests that routine HIV counseling, testing, and referral should be extended,” says Dr. Paltiel. “In populations barely meeting a 1 percent prevalence of undiagnosed HIV infection, the costs per quality-adjusted life year gained of HIV testing every 3 to 5 years compare favorably with those of many commonly used screening interventions in chronic conditions, including breast cancer, colorectal cancer, diabetes, and high blood pressure.”

Data from other cost-effectiveness studies show that screening for type 2 diabetes costs approximately $56,600 per quality-adjusted life year gained, while screening costs for high blood pressure and colorectal cancer cost $48,000 and $51,200, respectively.

Further research might reveal the best ways to implement HIV screening programs, how to reduce existing barriers to screening, how to increase the effects of counseling on patient knowledge, and the cost-effectiveness of HIV screening in the elderly.

“These studies suggest that voluntary screening for HIV is justified in certain populations and may offer significant benefits on both clinical and cost-effectiveness grounds,” says Dr. Volkow. “Additional research is needed to determine if one-time screening for undiagnosed HIV in the general population also is warranted.”

HHS ANNOUNCES SIMPLIFIED SYSTEM FOR RESEARCH PROTECTION ASSURANCES -- The U.S. Department of Health and Human Services (HHS) February 9 announced a new simplified mechanism for all research institutions that receive HHS funding or support to obtain an assurance of compliance with HHS regulations for the protection of human subjects. A single Web-based "Federalwide Assurance" (FWA) will replace the several types of assurances under which research institutions had operated in the past.

"We are pleased to provide this robust and flexible simplification to our assurance system," said Bernard A. Schwetz, D.V.M., Ph.D., director of the Office for Human Research Protection. "It reduces the burden of regulatory compliance while strengthening the research community's ability to focus on protections for research subjects."

Because of the multiple types of assurances in use, HHS will allow research institutions to transition to the new system over the next 11 months. By Dec. 31, 2005, all institutions conducting HHS-funded human subjects research must hold an FWA approved by HHS' Office for Human Research Protections (OHRP). For more information, visit the OHRP assurance Web page at http://www.hhs.gov/ohrp/assurances/assurances_index.html.

Nearly all federal departments and agencies that conduct or fund human subject research adhere to the Federal Policy for the Protection of Human Subjects, a set of identical regulations adopted by 16 departments and agencies in 1991 that is known informally as

the "Common Rule." The Common Rule is based on the HHS regulations in force since 1974 and requires that federally supported research involving human subjects be covered by an assurance. The other Common Rule agencies now have the option of using -- or directing their grantees to use -- the HHS FWA, rather than operating their own assurance systems, and a large majority of the agencies are expected to rely on the FWA.

The Common Rule signatories group includes the Departments of Agriculture, Energy, Commerce, Defense, Education, HHS, Housing and Urban Development, Justice, Transportation, Veterans Affairs, the Agency for International Development, the Central Intelligence Agency, the Consumer Products Safety Commission, the Environmental Protection Agency, the National Aeronautics and Space Administration and the National Science Foundation.

OHRP is a component of the Office of the Secretary, Office of the Assistant Secretary for Health, Office of Public Health and Science. OHRP works to support and strengthen the nation's system for protecting those who volunteer to participate in research that is conducted or supported by HHS agencies.

INTERNATIONAL TRIAL OF TWO MICROBICIDES BEGINS -- A large, multisite trial designed to examine the safety and preliminary effectiveness of two candidate topical microbicides to prevent HIV infection has opened to volunteer enrollment. The trial, sponsored by the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health, represents a partnership among various research institutions in Africa and the United States.

Although no licensed microbicides are available to the public currently, scientists hope these agents — designed to be applied to the surface of the vagina to prevent sexually transmitted infections (STIs) — will one day be a key tool in the fight against HIV/AIDS.

Women make up nearly half of all people living with HIV worldwide. “The majority of new cases of HIV infection in women result from heterosexual intercourse, but women may not always be able to insist that their male partners use measures to prevent HIV transmission,” notes NIAID Director Anthony S. Fauci, M.D. “If effective, microbicides would be a valuable woman-controlled means of slowing the pace of the HIV/AIDS epidemic,” Dr. Fauci adds.

The first volunteers were enrolled this week at sites in Durban, South Africa, and at the University of Pennsylvania in Philadelphia. Enrollment will begin shortly at sites in four additional African countries — Malawi, Tanzania, Zimbabwe and Zambia. Approximately 3,220 women will be enrolled in the trial, which is expected to last approximately 30 months.

“This is the first microbicide safety and effectiveness trial of this magnitude to be conducted by NIAID,” says Roberta J. Black, Ph.D., Topical Microbicide Team Leader in NIAID’s Division of AIDS. “It is a critical trial evaluating two topical microbicides with differing mechanisms of action,” she adds.

The microbicides to be tested are PRO 2000 and BufferGel. Produced by Indevus Pharmaceuticals, Lexington, MA, PRO 2000 has shown activity against HIV and other STIs in both laboratory and animal testing. It is believed to act by inhibiting the entry of HIV and other pathogens into body cells. BufferGel, a product of ReProtect, Inc., Baltimore, MD, boosts the natural acidity of the vagina in the presence of seminal fluid that neutralizes the vaginal environment. An acidic environment inactivates HIV as well as other pathogens.

Each woman in the trial will be placed at random into one of four equally sized groups. One group will use BufferGel before each act of sexual intercourse, one group will use PRO 2000, one group will use a placebo gel, and the final group will not use any gel. In addition, all participants will receive condoms and extensive prevention counseling at each clinic visit.

The trial is one of numerous studies conducted through NIH's HIV Prevention Trials Network (HPTN), which is funded by NIAID, the National Institute of Child Health and Human Development, the National Institute on Drug Abuse and the National Institute of Mental Health. More information about this study (HPTN 035) is available at www.hptn.org/index.htm. The protocol chair of the study is Salim Abdool Karim, MBChB, Ph.D., of the University of KwaZulu-Natal in Durban, South Africa.

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