

THE CSTE WASHINGTON REPORT

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EDITOR'S NOTE: Last week, HHS Secretary Tommy G. Thompson introduced a strategy for developing a national health care system that addresses the prevention and treatment of heart disease and stroke. The strategy, "*A Public Health Action Plan to Prevent Heart Disease and Stroke*," provides health practitioners and policymakers a framework to prevent and treat heart disease and stroke, the nation's first and third leading causes of death. "These leading causes of death for men and women are largely preventable, yet we as a nation are not taking the steps necessary for us to lead healthier, longer lives," said Secretary Thompson. "Our nation is facing one of its most challenging health crises where the cost of failure is too high. We must start emphasizing prevention of this epidemic. " The action plan, which was unveiled at HHS' "Steps to a HealthierUS:

Putting Prevention First" conference in Baltimore, estimates that heart disease and stroke will have an economic cost of more than \$351 billion in 2003. 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. Legislation cited in the report can be accessed via <http://www.thomas.loc.gov> Regulations cited can be accessed via <http://www.gpo.gov>

CONGRESS ACTS ON BUDGET RESOLUTION – Congress finished work on the Budget Resolution before adjourning for its planned two week Easter recess. As expected the final number for Function 550, which contains all funding for public health programs, was the President's request level: .03 percent increase (+\$152 million) over FY 2003 final appropriations. This is close to a zero increase and means the competition for funding among all public health agencies and programs is likely to be intense for FY 2004. The next step in the budget and appropriations process is the allocation to each of the 13 appropriations subcommittees, known as the 302b allocation. Public health programs, except for the FDA and Indian Health Service, are the jurisdiction of the Labor, Health and Human Services, and Education Subcommittee on Appropriations. A broad array of public health organizations are working to try and get the highest possible allocation for the L-HHS-Ed Subcommittee. The determination is made by the Chairmen of the House and Senate Appropriations Committees, in consultation with each of the Chairs of the 13 Subcommittees. The Budget Resolution is viewed as a guiding outline for this process, but the appropriators fill in the details. The 302b allocations will likely be determined in the next 1-2 weeks, when Congress returns from its Easter recess.

SMALLPOX UPDATE – On April 11, the House and Senate passed a compromise smallpox compensation bill (H.R. 1770) that provides more generous benefits to those injured by the smallpox vaccine, including those accidentally inoculated with vaccinia, than had been proposed by the Administration. The compromise bill provides \$50,000 in lost wages with no cap on the amount of damages for those who are permanently disabled. Partially disabled recipients are also eligible for up to \$50,000 per year in lost wages, with a cap of \$262,100. Payment for lost wages is provided after five days of lost work, but if ten or more days of work are lost, the first five days of lost wages may be reimbursed, but only after all other sources of compensation for lost wages have been exhausted. Spouses of recipients killed by the vaccine receive \$262,100, while spouses with children choose between a \$262,100 lump sum or \$50,000 annually until the youngest child turns age 18. Federal payments for medical care costs are provided, but only after all other sources, including health insurance and workers compensation, are exhausted. The bill arrived at the White House today for expected signature by President Bush shortly.

The legislation will be funded by \$42 million that was included in the FY 2003 supplemental appropriations bill that was signed by President Bush on April 16. Also

included in the supplemental appropriation bill is \$100 million to reimburse state and local health departments for costs incurred to implement the smallpox vaccination program. The report language specifies: *“Because many State and local health departments have already devoted substantial resources to the smallpox vaccination program, often at the expense of other important public health and bioterrorism preparedness tasks, the conferees intend that these funds be available to assist health departments in covering costs already incurred as well as to assist with costs that will be incurred in the future.”*

CONGRESSIONAL FOOD SAFETY CAUCUS ESTABLISHED – On April 8th, Representatives Rosa DeLauro (D-RI), Sherrod Brown (D-OH), and Tom Latham (R-IA) announced the creation of a Congressional Food Safety Caucus. The caucus will address the incidence of food borne illness and emerging challenges in food safety, such as globalization and the susceptibility of the U.S. food supply to a bioterrorist attack. The caucus will hold regular educational briefings on topics such as contamination of foods, protecting the U.S. food supply from bioterrorism, bio-engineered foods, risk-based management of food safety and sustainable farming. One of the goals of the caucus is to enhance legislative efforts toward improving the safety of the U.S. food supply.

NEW CDC INITIATIVE WOULD INCREASE HIV TESTING AND ENHANCE PREVENTION FOR PERSONS LIVING WITH HIV -- The Centers for Disease Control and Prevention (CDC) April 17 announced an initiative aimed at reducing the number of new infections caused by Human Immunodeficiency Virus (HIV) each year in the United States. The initiative, while new involves \$35 million in redirected rather than new funding, expands on current HIV prevention strategies and it models other approaches that have proven effective in preventing infectious diseases.

The initiative, described in the April 17 issue of CDC's *Morbidity and Mortality Weekly Report*, has four parts and will be implemented by several agencies working together within the Department of Health and Human Services. It includes: making HIV testing a routine part of medical care; creating new models for diagnosing HIV infections outside medical settings; preventing new infections by working with people diagnosed with HIV and their partners; and further decreasing mother-to-child HIV transmission by incorporating HIV testing in the routine battery of prenatal tests.

“We can no longer accept the status quo when it comes to HIV/AIDS prevention,” said HHS Secretary Tommy G. Thompson. “The nature of this epidemic is changing and it is time to expand our prevention strategies in order to more effectively reduce the number of HIV infections in the United States.”

Experts estimate that 850,000 to 950,000 persons are currently living with HIV in the United States and many of these individuals don't know they are infected. In addition, an estimated 300 infants contract HIV from their mothers each year.

"It's simply unacceptable that 40,000 people in this country become infected with HIV each year, and it's intolerable that about one fourth of those infected with HIV don't know they're infected and therefore are not receiving appropriate medical care," said Julie Gerberding, M.D., M.P.H., director of CDC. "This new initiative will go a long way to help frontline clinicians help people overcome some of the barriers they face getting diagnosed and treated for HIV."

Implementing the strategies will require extensive involvement and coordination among a broad range of federal agencies, non-governmental providers and professional organizations. CDC is conducting meetings with state health departments and other partners to introduce the new initiative and the agency will also work with the Health Resources and Services Administration (HRSA) and other HHS agencies to reach persons who have been diagnosed with HIV but who are not receiving ongoing treatment and preventive care services.

"This new initiative is exciting and it capitalizes on new, rapid testing technologies; provides us the opportunity to reduce barriers to testing; enhances prevention services; and continues to prevent mother-to-child HIV infections," said Harold Jaffe, M.D., director of CDC's National Center for HIV, STD, and TB Prevention (NCHSTP). The initiative utilizes the strengths of the public health community and engages clinicians as well. It calls for continued cooperation between the federal government and state and local health departments, and it continues to involve professional associations, individual healthcare professionals, community-based organizations and people living with HIV.

HHS AWARDS \$1 BILLION TO HELP STATES PROVIDE HEALTH CARE, SERVICES AND PRESCRIPTION DRUGS FOR PEOPLE WITH HIV/AIDS --
HHS Secretary Tommy G. Thompson April 10 announced \$1 billion in grants to states and territories to provide medical care, support services and prescription drugs for people living with HIV/AIDS.

"Poverty, unfortunately, is a common symptom of AIDS, but these grants to states will help us ensure that people with AIDS can get needed care and services," Secretary Thompson said. "When insurance runs out, when savings are depleted, or when disability checks are needed to buy groceries instead of prescriptions, patients can turn to the programs funded by these grants to get life-sustaining medical treatment."

The fiscal year 2003 awards include \$289 million in basic awards based on the number of people living with AIDS in each state or territory and \$693 million for the purchase of medications through state-run AIDS Drug Assistance Programs (ADAPs). In addition, the award includes \$7 million under the Minority AIDS Initiative (MAI) and \$10 million for states with "emerging communities" -- metropolitan areas with significant populations of people living with AIDS. An additional \$21.4 million in grants for the Supplemental Drug Treatment Program will be awarded later. The grants are funded under Title II of the Ryan White CARE Act.

"With this year's increase in ADAP funds, we expect to help 159,000 low-income people living with HIV/AIDS obtain the medications they need to stay healthy," said Elizabeth M. Duke, administrator of HHS' Health Resources and Services Administration. Title II grants are awarded to every state, the District of Columbia, Puerto Rico, Guam, the Virgin Islands, American Samoa, Federated States of Micronesia, Marshall Islands, Northern Mariana Islands, and Republic of Palau.

Basic grants are awarded based on the estimated number of people living with AIDS in a state or territory. Since fiscal year 1996, separate funds have been earmarked under Title II to help state ADAPs buy pharmaceuticals for people living with HIV/AIDS. States also may designate a portion of their Title II basic allotment to support ADAPs. The MAI award is based on the number of minorities living with HIV/AIDS in the area over a two-year period. The emerging communities funds go to metropolitan areas that report between 500 and 1,999 cases of AIDS but did not receive Title I grants awarded last month. (A list of the Title I grantees is available at <http://www.hhs.gov/news/press/2003pres/20030319.html>).

Emerging communities funds are used to bolster HIV-related health care and services for these individuals.

CARE Act programs help an estimated 530,000 poor and uninsured individuals with HIV/AIDS obtain primary health care, support services and life-sustaining medications each year. Since the Act was first funded in fiscal year 1991, \$13.6 billion has been awarded to provide needed health care and associated services for people living with HIV/AIDS.

KEY TO HEPATITIS VIRUS PERSISTENCE FOUND -- Scientists at two Texas universities have discovered how hepatitis C virus thwarts immune system efforts to eliminate it. The finding, published online April 17 in *ScienceExpress*, could lead to more effective treatments for liver disease caused by hepatitis C virus, says author Michael Gale, Jr., Ph.D., of University of Texas Southwestern Medical Center at Dallas. Dr. Gale and coauthor Stanley Lemon, M.D., of University of Texas Medical Branch at Galveston, are grantees of the National Institute of Allergy and Infectious Diseases (NIAID).

"Persistent hepatitis C virus (HCV) infection is a major cause of liver disease worldwide and is the leading reason for liver transplants in this country," notes NIAID Director Anthony S. Fauci, M.D. "The most prevalent form of HCV in the United States is, unfortunately, the least responsive to available treatments. Moreover, African Americans are even less responsive to therapy than Caucasians," he adds.

The immune system has many ways to detect and fight off invading microbes, and microbes have just as many ways to elude and disarm immune system components. Through a series of experiments on cells grown in the laboratory, Drs. Gale and Lemon defined the strategy HCV uses to evade the host's immune response. As HCV begins to replicate in its human host, it manufactures enzymes, called proteases, which it requires to transform viral proteins into their functional forms. The Texas investigators

determined that one viral protease, NS3/4A, specifically inhibits a key immune system molecule, interferon regulatory factor-3 (IRF-3). IRF-3 orchestrates a range of antiviral responses. Without this master switch, antiviral responses never begin, and HCV can gain a foothold and persist in its host.

Next, the scientists searched for ways to reverse the IRF-3 blockade. They applied a protease inhibitor to human cells containing modified HCV. This prevented the virus from making functional NS3/4A and restored the cells' IRF-3 pathway. Follow-up studies have shown that once restored, the immune response reduced viral levels to nearly undetectable levels within days, according to Dr. Gale.

The identification of this viral protease-regulated control of IRF-3 opens new avenues in both clinical and basic research on hepatitis C, notes Dr. Gale. Until now, scientists had not considered the possibility that inhibiting this protease did anything more than halt viral replication. "Now that we know NS3/4A inhibition essentially restores the host's immune response to the virus, we can assess hepatitis drug candidates for this ability as well," Dr. Gale says.

NS3/4A will be a valuable tool in further dissecting the roles of viral proteases and their host cell targets, says Dr. Gale. For example, the scientists plan to use NS3/4A to hunt for the still unknown host cell enzyme responsible for activating IRF-3. Conceivably, Dr. Gale explains, future therapeutic approaches to viral disease could involve boosting the activity of any key host enzymes that are found. "Understanding the tricks that the hepatitis C virus employs to impair the immune system represents an important advance with potential implications for successful cure of those suffering from liver disease," says Leslye Johnson, Ph.D., chief of NIAID's enteric and hepatic diseases branch.

NIAID is a component of the National Institutes of Health (NIH), which is an agency of the Department of Health and Human Services. NIAID supports basic and applied research to prevent, diagnose, and treat infectious and immune-mediated illnesses, including HIV/AIDS and other sexually transmitted diseases, illness from potential agents of bioterrorism, tuberculosis, malaria, autoimmune disorders, asthma and allergies.

HHS ANNOUNCES PUBLIC HEALTH ACTION PLAN FOR PREVENTION AND TREATMENT OF HEART DISEASE AND STROKE --HHS Secretary Tommy G. Thompson April 15 introduced a strategy for developing a national health care system that addresses the prevention and treatment of heart disease and stroke. The strategy, "*A Public Health Action Plan to Prevent Heart Disease and Stroke*," provides health practitioners and policymakers a framework to prevent and treat heart disease and stroke, the nation's first and third leading causes of death.

"These leading causes of death for men and women are largely preventable, yet we as a nation are not taking the steps necessary for us to lead healthier, longer lives," said Secretary Thompson. "Our nation is facing one of its most challenging health crises

where the cost of failure is too high. We must start emphasizing prevention of this epidemic. "

The action plan, which was unveiled at HHS' "Steps to a HealthierUS: Putting Prevention First" conference in Baltimore, estimates that heart disease and stroke will have an economic cost of more than \$351 billion in 2003. In addition, certain racial and ethnic populations are at increased risk of heart disease and stroke, as are people with lower income and educational levels.

"While we know the federal government has an important role to play in this action plan, we also will draw on the strengths of our partners -- state, local and tribal governments, community and faith-based organizations, the private sector and individuals -- to help develop new and creative approaches to solving this nation's biggest health challenge -- heart disease and stroke," says Dr. Julie Gerberding, director of HHS' Center for Disease Control and Prevention (CDC).

As we work with these partners, we hope to increase both the quality and years of healthy life for all Americans," said Dr. Elias Zerhouni, director of HHS' National Institutes of Health. "This action plan will be guided by new advances in science. We are committed to supporting research on the prevention, detection, and control of cardiovascular disease and its risk factors."

Throughout the conference, Secretary Thompson underscored his priorities and programs for "Steps to a HealthierUS," the department's initiative to advance the President's HealthierUS Initiative. The action plan announced today embraces this national initiative by highlighting the need for urgent action to prevent and treat heart disease and stroke. The plan's five main recommendations are:

- * Taking action to prevent and treat heart disease and stroke by using the latest scientific findings;
- * Ensuring a clear focus at public health agencies;
- * Evaluating the impact of policy and program interventions;
- * Advancing prevention policies; and
- * Collaborating with regional and global partners to share knowledge and practices.

"This plan will help the public health community make the nation's number one health threat a number one priority," said American Heart Association President Robert O. Bonow. "We already have much science and knowledge to help prevent and treat heart disease and stroke. Now we have a national vision and roadmap for the public health community to help guide its efforts, and strategies to give Americans a healthier future." Joining Secretary Thompson at the conference were representatives from the national organizations working with HHS to implement the action agenda. They include the American Heart Association (AHA), the American Stroke Association (ASA) and the Association of State and Territorial Health Officials (ASTHO).

For more information or for free copies of *A Public Health Action Plan to Prevent Heart Disease and Stroke*, write to the CDC's National Center for Chronic Disease Prevention and Health Promotion, Division of Adult and Community Health, 4770 Buford Highway NE, MS K-45, Atlanta, GA 30341-3717; call 1-888-232-2306 (toll free inside the United States); e-mail: ccdinfo@cdc.gov; or visit the Web site www.cdc.gov/cvh.

HEALTH PROFESSIONALS' EDUCATION MUST BE OVERHAULED TO ENSURE SAFETY, QUALITY OF CARE --

Doctors, nurses, and other health professionals are not being adequately prepared to provide the highest quality and safest medical care possible, and there is insufficient assessment of their ongoing proficiency, says a new report from the Institute of Medicine of the National Academies. The report is part of the IOM series on improving the quality and safety of health care, which includes a 1999 landmark study on reducing the high rate of medical errors.

"Reforming the education of health professionals will require a collective effort across all the health care disciplines, focusing on a set of core competencies that they all embrace," said Edward Hundert, M.D., co-chair of the committee that wrote the report, and president, Case Western Reserve University, Cleveland. "We owe it to our patients to change the way we are educated in order to improve quality and safety."

All programs that educate and train health professionals should adopt five core competencies: the abilities to deliver patient-centered care, work as a member of an interdisciplinary team, engage in evidence-based practice, apply quality improvement approaches, and use information technology. The report calls on accreditation, licensing, and certification organizations to ensure that students and working professionals develop and maintain proficiency in these core areas.

These oversight groups should take the lead in improving health professionals' education because they can implement change at the national and state levels, the report notes. In particular, organizations that accredit health education programs should assess what students know and are able to do in a clinical setting -- not, for example, the number of semester hours they take of a particular subject. And all licensing boards should require doctors, nurses, and other health care workers to demonstrate their clinical skills and understanding of medical advances, rather than allow them simply to take a class and pay a fee to renew their licenses. In addition, all certifying organizations should use rigorous tests to evaluate the ongoing proficiency of health professionals instead of just requiring continuing medical education, which is not a reliable way to measure ongoing competency. Consensus on what constitutes evidence of proficiency and the most effective methods to assess competence will have to be reached, the committee acknowledged.

In addition, report cards on the quality of health professions training programs should be issued to give policy-makers and educational leaders a way to assess and compare academic institutions. Also, leaders from different health disciplines should meet at biennial summits to promote reforms in health education and evaluate the progress of

these reforms, said the committee, whose own work was informed by more than 150 leaders from medicine, nursing, pharmacy, and allied health who attended an IOM forum in June 2002. Their ideas for how to integrate the core competencies into health professions education are included in the report.

"Schools for health professionals generally are not interdisciplinary, but practice environments increasingly are, which poses a serious disconnect," said Mary Wakefield, Ph.D., R.N., committee co-chair and director, Center for Rural Health, University of North Dakota, Grand Forks. "Ideally, collaboration among clinicians in practice settings draws upon each profession's strength and optimizes care for patients. We believe that the same can be true for health professions education and that it's high time to embrace a collaborative approach to reform."

Significant funds and other resources will be necessary to develop and implement this new evidence-based approach to evaluation. The new evaluations may need to be phased in, the report says.

The study was sponsored by the Health Resources and Services Administration, Agency for Health Care Research and Quality, ABIM Foundation, and California HealthCare Foundation. The Institute of Medicine is a private, nonprofit institution that provides health policy advice under a congressional charter granted to the National Academy of Sciences. A committee roster follows.

Read the full text of **[Health Professions Education: A Bridge to Quality](#)** for free on the Web, as well as more than 2,500 other publications from the National Academies. Printed copies are available for purchase from the National Academies Press; tel. (202) 334-3313 or 1-800-624-6242 or on the Internet at **<http://www.nap.edu>**.