THE CSTE WASHINGTON REPORT

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INSIDE THIS ISSUE

EDITOR'S NOTE:. A just released new federal report, "Physical Activity Among Adults: United States, 2000," is the first HHS report to focus on the amount of physical activity during a person's usual daily activities, including work, leisure time, or some combination of the two. The data comes from about 32,000 interviews conducted in 2000 and provides important insight into Americans' exercise routines. Other recent studies have focused exclusively on leisure time activity, including one last year that showed 7 in 10 Americans were not regularly active during their leisure time in 1997-98. Today's new

report for 2000 did not find any significant change in the percentage of adults who are physically active in their leisure time and found that one in four engage in low level daily activities or are not active at all. This finding raises troubling concerns about diseases directly resulting from the lack of exercise and its long term impact on the health status of Americans. 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

SENATE PASSES GLOBAL AIDS BILL – On May 16TH the Senate passed H.R. 1298, the U.S. Leadership Against HIV/AIDS, Tuberculosis, and Malaria Act of 2003, which provides $15 billion from FY 2004-2008 to combat the global spread of these diseases, but particularly HIV/AIDS in sub-Sahara Africa and the Caribbean. The bill earmarks one-third of the total funds for programs that emphasize sexual abstinence before marriage – a focus that many advocates, as well as many Members of Congress, are skeptical about. While the bill has already passed the House, the Senate added one change, an amendment to increase funding for debt-relief for particularly poor, AIDS-ravaged nations. The House is expected to pass the Senate version this week. The President has said he will sign the legislation.

SENATE IMPACT BILL IS READIED FOR INTRODUCTION – Senators Frist (R-TN), Bingaman (D-NM) and Dodd (D-CT) have drafted a bill that addresses overweight and obesity in an effort to prevent related chronic conditions such as cardiovascular diseases, cancer, and diabetes. The authors had planned to introduce the bill this week, but now expect to introduce it on June 3rd. The "Improved Nutrition and Physical Activity Act," or IMPACT, was introduced last Congress in both the Senate and House and achieved significant bipartisan support, but ran out of legislative time for enactment. Earlier this year, the House introduced a similar bill (H.R. 716). Both bills authorize CDC demonstration grants to states and community based organizations, including schools, to improve nutrition and physical activity; authorize NHANES to collect and assess fitness levels among children; authorize a study by the Institute of Medicine of the nutritional value of the Department of Agriculture's food supplement programs with regard to obesity prevalence among low-income populations; adds obesity prevention to the list of authorized state uses of Preventive Health and Health Services Block Grant funds. The bills differ in that the Senate bill also provides a small grant focus for eating disorders ($5 million versus $55 million for overweight and obesity), while the House bill authorizes a Medicare demonstration project to reduce obesity as well as other chronic disease risks such as cancer. After establishing that the IMPACT bill largely authorizes activities CDC is already undertaking, would not harm current CDC grants to states to address nutrition and physical activity, and is viewed favorably by CDC, CSTE forwarded letters of support to each of the Senate authors.

PROJECT BIOSHIELD PASSES ENERGY AND COMMERCE COMMITTEE -- The House Energy and Commerce Committee marked up and voted out Project BioShield Act of

2003 (H.R. 2122) on May 15th. The bill authorizes funds for the development of drugs and other countermeasures to chemical, biological, or radiological terrorist weapons. As expected, no amendments were offered addressing mandating completion of an electronic national public health surveillance system. However, the bill has also been referred to the House Government Reform Committee some of whose Members expressed interest in offering such an amendment. The Senate HELP Committee voted out its version of Project BioShield Act of 2003 in March and it has been placed on the Senate calendar. A Congressional Research Service summary of the Senate version of the bill is as follows:

Amends the Public Health Service Act to declare that the National Institute of Allergy and Infectious Diseases shall be the lead institute for performing, administering, or supporting biomedical countermeasure research and development. Defines a biomedical countermeasure as a drug, biological product, or device that is used to treat, identify, or prevent harm from: (1) a biological, chemical, radiological, or nuclear agent that may cause a public health emergency affecting national security; or (2) a potentially harmful condition arising from the administering of a drug, biological product, or device in response to such an agent.

Grants the Secretary of Health and Human Services (the Secretary): (1) expedited procurement authority regarding property or services for use in performing, administering, or supporting biomedical countermeasure research or development; (2) the authority to expedite peer review under this section as deemed necessary to obtain a likely contribution to the field of biomedical countermeasure research; and (3) the authority to secure the personal services of experts or consultants with relevant qualifications for the purpose of performing, administering, and supporting biomedical countermeasure research and development.

Classifies a person carrying out a contract under this section, and an officer, employee, or governing board member of such person, to be deemed an employee of the Department of Health and Human Services for purposes of claims under specified law for money damages for personal injury, including death.

Directs the Secretary of Homeland Security, on an ongoing basis, to assess threats of use of chemical, biological, radiological, and nuclear agents and determine which threats pose a material risk of use against the United States population. Requires the Secretary of Homeland Security to assess the public health consequences of such potential uses and to determine the agents for which countermeasures are necessary to protect the public health. Authorizes the Secretary and the Secretary of Homeland Security to jointly submit to the President for approval proposals to call for needed countermeasures. Directs the Secretaries to inform persons who may respond to each approved call. Requires the Secretary, in consultation with the Secretary of Homeland Security, to determine countermeasures appropriate for procurement and inclusion in the stockpile under the Public Health and Bioterrorism Preparedness and Response Act of 2002. Directs the Secretary to annually determine and report to the President whether there is a significant commercial market for products identified as appropriate for procurement other than as

biomedical countermeasures. Directs the Secretary to procure countermeasures that have been approved by the President.

Authorizes appropriations.

Amends the Federal Food, Drug, and Cosmetic Act to allow the Secretary to declare a national emergency under specified conditions and authorize the release of a drug or device intended solely for use in an emergency. Directs the Secretary to impose requirements on the authorization to ensure that health care professionals administering the product and persons to whom the product is administered are fully informed about the benefits and risks involved and other alternatives. Requires the Secretary to periodically review an authorization under this Act, and authorizes the Secretary to revoke such an authorization if circumstances so warrant. Imposes civil monetary penalties for violation of this section. Allows the President, under specified circumstances in cases involving the Armed Forces, to waive the requirement that individuals be allowed to refuse administration of a countermeasure. Applies record keeping requirements under the Act to products authorized under this Act for use in emergencies.

MOSQUITO ABATEMENT BILLS CLEAR KEY HEALTH COMMITTEES – As of May 14th, both House and Senate versions of bills authorizing $100 million in FY 2003, and such sums as necessary in FY 2004-07, for CDC-provided grants to states and political subdivisions of states for mosquito abatement had cleared the House Energy and Commerce and Senate Health, Education, Labor and Pension Committees and are awaiting floor consideration. The bills (H.R. 342/S.1015) are exactly alike except that the Senate bill includes provisions mandating that 50 percent funds providing in FY 2004 must be provided to political subdivisions of states; permits two or more political subdivisions to form consortiums and receive $110,000 in grants; and requires a report to Congress from the HHS Secretary, in consultation with the EPA Administrator, on blood supply screening for West Nile Virus, and surveillance of the virus in the blood supply, and other related issues. To qualify for a grant, states must develop a plan for coordinating control programs taking into account any available needs assessments, agree to monitor control programs, and submit a report to the Secretary describing control activities and an evaluation of their effectiveness. Political subdivisions of states may apply for grants directly, but must have conducted a needs assessment, and must match every $2 in federal funds with $1 in locally derived contributions.

U.S., CHINA DEVELOP PLAN FOR IMPROVED DISEASE SURVEILLANCE -- HHS Secretary Tommy G. Thompson May 6 announced agreement with Chinese Vice Premier and Health Minister Wu Yi to increase collaboration with China toward improved detection and management of infectious diseases. The agreement stems from President Bush's pledge to Chinese President Hu Jintao to provide resources necessary to help stem the SARS epidemic in China.

In a phone call, Vice Premier Wu and Secretary Thompson agreed to proceed with planning for expanded collaborative efforts in epidemiological training and development

of greater laboratory capacity in China. The new efforts, which would expand the number of HHS personnel working in China, were spurred by the current SARS epidemic, but would be important for all other infectious diseases, especially newly emerging infectious diseases, Secretary Thompson said.

"The SARS epidemic has made clear that every serious infectious disease today is a potential issue of global importance," he said. "We need a strong global network to quickly identify and manage disease outbreaks, and this network will depend on the strength of each nation's epidemiological capacity, as well as on cooperation between nations. I am encouraged by Vice Premier Wu's desire for new collaboration, and for her country's increasing openness to the global health community."

Secretary Thompson said his department will develop a plan with Chinese officials this month for increased technical assistance, including training, lab capacity and improved health information technology. In the call, he emphasized the importance of rapid sharing among nations of human and animal biomedical specimens needed to understand new disease outbreaks.

His call followed a conversation on April 27 in which President Bush told Chinese President Hu that the United States stood ready to provide short and long-term assistance to China in public health and control of infectious diseases.
Secretary Thompson also spoke by phone this morning with Hong Kong Health Secretary Yeoh Eng-kiong and offered congratulations on apparent progress against SARS in Hong Kong.

HHS ISSUES NEW REPORT ON AMERICANS' OVERALL PHYSICAL ACTIVITY LEVELS -- HHS' Centers for Disease Control and Prevention (CDC) May 14 released a new report that shows about 1 in 5 American adults engage in a high level of overall physical activity, including both activity at work and during leisure time. At the other end of the spectrum, about 1 in 4 American adults engage in little or no regular physical activity. "Physical activity -- whether it's walking the dog or simply taking the stairs at work -- is essential to good health," HHS Secretary Tommy G. Thompson said. "This study helps give us an even fuller picture of our physical activity status. It confirms that we need to pay more attention to getting adequate physical activity and reversing the alarming rise in obesity that we've experienced nationally during the past decade."

The report, "Physical Activity Among Adults: United States, 2000," is the first HHS report to focus on the amount of physical activity during a person's usual daily activities, including work, leisure time, or some combination of the two. The data comes from about 32,000 interviews conducted in 2000.

Other recent studies have focused exclusively on leisure time activity, including one last year that showed 7 in 10 Americans were not regularly active during their leisure time in 1997-98. Today's new report for 2000 did not find any significant change in the percentage of adults who are physically active in their leisure time.

Usual daily activity, in addition to work, includes commuting, running errands, performing household chores, or any other activities not performed during leisure time. The level of physical activity is determined by how much "moving around and lifting or carrying things" occurs during these usual daily activities.

Regular leisure time physical activity consists of exercise, sports or active hobbies that cause light sweating or a slight to moderate increase in breathing or heart rate occurring five or more times per week for at least 30 minutes each time. Regular leisure time physical activity also could include a vigorous activity that causes heavy sweating or large increases in breathing or heart rate three or more times a week for at least 20 minutes each time.

The new report shows that 19 percent of adults engage in a high level of physical activity (defined as "very active during usual daily activities and engaged in regular leisure time physical activity"). In general, men are more likely than women to engage in a high level of overall physical activity, and these rates decline with age.
Meanwhile, another 1 in 4 adults either engage in a low level of activity (i.e. moderately active during usual daily activities and completely inactive during leisure-time) or are never active at all.

The study reports that those who are more active in their usual daily activities -- walking or lifting or carrying moderate to heavy loads -- are more likely to engage in regular physical activity in their leisure time compared to those who mostly sit, stand or lift only light loads.

The report also shows that about one half of all adults usually walk during their normal daily activities, while more than a third usually sit, and about 14 percent usually stand. Almost three-quarters of adults lift or carry light to heavy loads during their usual activities.

The report also documents physical activity among different population groups. About 15 percent of Hispanic adults of all races engage in a high level of physical activity, about the same as African American adults (14 percent) and slightly less than white adults (20 percent).

The report also indicates several of other factors are associated with physical activity:

* **Education.** About 1 in 4 adults with an advanced degree engage in a high level of overall physical activity, compared to 1 in 7 of those with less than a high school diploma.
* **Income.** Adults with incomes below the poverty level are three times as likely to be physically inactive as adults in the highest income group.
* **Marital Status.** Married women are more likely than never married women to engage in a high level of overall physical activity.

* **Geography.** Adults in the South are more likely to be physically inactive than adults in any other region.

The report is based on approximately 32,000 interviews with adults ages 18 and over, regardless of employment status from the National Health Interview Survey, conducted by CDC's National Center for Health Statistics (NCHS). "Physical Activity Among Adults: United States, 2000," is available at www.cdc.gov/nchs.

HHS TO AWARD HEALTHY COMMUNITY GRANTS TO SUPPORT LOCAL PROGRAMS TO PREVENT DIABETES, ASTHMA AND OBESITY --HHS Secretary Tommy G. Thompson May 9 encouraged states, cities and other local government agencies to propose innovative, community-based programs to prevent diabetes, asthma and obesity as part of a new grants program. The grants will be awarded to support local projects that will demonstrate approaches to reduce the prevalence and impact of the three common chronic health conditions in local communities.

The grants are being made available as part of the department's $15 million Steps to a HealthierUS initiative, which advances President Bush's HealthierUS goal of helping Americans live better, longer, and healthier lives. The President's fiscal year 2004 budget proposal would substantially increase the investment in this initiative to a total of $125 million, $110 million more than the amount appropriated by Congress in the current fiscal year.

"To truly change our attitudes to focus on preventing chronic diseases rather than simply treating them, we need to reach Americans in their homes and neighborhoods with innovative programs that prevent diabetes and obesity and improve asthma management," Secretary Thompson said. "We've all got to think outside the box. The communities awarded the grants will help lead the country in changing our healthcare model from one that only treats the sick to one that successfully promotes better health."
The competitively awarded grants will fund more than a dozen demonstration projects in communities across the country. Local health departments, state health departments and tribal governments are eligible to apply for the grants.

Under the grants program, HHS will award about $13.7 million to communities with the strongest proposals to enhance access to health services, encourage preventive behaviors and improve the overall health of the community by targeting those populations with the greatest needs. Communities selected for grant awards will use federal resources to build partnerships between public and private organizations working in the areas of prevention, medical, social, educational, business, religious and civic services.

Diabetes, asthma and obesity were chosen as targets not only because of their debilitating effects and their rapidly increasing prevalence in the United States but also because of their responsiveness to prevention measures. The number of people with diabetes in the United States has nearly doubled in the past decade to 17 million. An estimated 10 million adults and 5 million children suffer from asthma, and the number of cases of

obesity in the United States has increased more than 50 percent over the past two decades.
HHS today published a Request for Applications for the new program in Federal Register. Applications must be submitted by July 15.

The request for applications and other information about the initiative is available at http://www.healthierUS.gov. In addition, HHS will host an interactive satellite broadcast to explain the Steps to a HealthierUS initiative to potential applicants and provide assistance to help them develop proposals. More information about this program is available at www.phppo.cdc.gov/phtn/RFA.

NATIONAL QUALITY FORUM FINDS CONSENSUS ON 30 PATIENT SAFETY PRACTICES --Representatives of the nation's leading health care and consumer groups have endorsed 30 patient safety practices that should be universally used in health care settings to reduce the risk of harm resulting from processes, systems, or environments of care, according to a consensus report released May 15 by the National Quality Forum and funded in part by the Agency for Healthcare Research and Quality**.**

Informing patients that they are likely to fare better if they have certain high-risk, elective surgeries at facilities that have demonstrated superior outcomes; specifying explicit protocols for hospitals and nursing homes to ensure adequate nurse staffing; hiring critical care medicine specialists to manage all patients in hospital intensive care units; making sure hospital pharmacists are more actively involved in the medication use process; and creating a culture of safety in all health care settings are among the 30 patient safety practices in the new report, *Safe Practices for Better Healthcare: A Consensus Report*.

"By achieving consensus on this set of evidence-based, high-priority safe practices, NQF seeks to stimulate their universal implementation in applicable health care settings and, in turn, achieve substantial improvements in patient safety," said NQF President and CEO Kenneth W. Kizer, M.D. The report is being released in Los Angeles at the NQF's meeting, *Safe Practices for Better Healthcare: It's Time to Act*.

The report reflects consensus among the NQF's 173 member organizations about the need to put better systems and procedures in place to help prevent medical errors like those outlined in a landmark 1999 Institute of Medicine report. NQF's member organizations represent all sectors of health care, including health care providers, consumers, employers, insurers, and other stakeholders. Among its members are the AARP, AFL-CIO, the American Hospital Association, the American Medical Association, the American Nurses Association, the American Society of Health-System Pharmacists, the Ford Motor Company, and General Motors.

The NQF consensus report is based in part on work by a team of researchers at AHRQ's Evidence-based Practice Center at Stanford University/University of California at San Francisco who identified 73 patient safety practices for which there were varying levels of

scientific evidence in 2001. Numerous additional candidate measures were considered, and the 30 voluntary consensus standards in the NQF report were culled from a list of 220 candidate practices based on each practice's specificity, effectiveness, potential benefit, generalizability, and readiness for implementation. This report also identified 27 practices that have great promise for reducing adverse events and should have high priority for further research.

A private, non-profit public benefit corporation, NQF was created in 1999 in response to the need to develop and implement a national strategy for health care quality measurement and reporting. Established as a unique public-private partnership, NQF has broad participation from more than 170 organizations that represent all sectors of the health care industry. Additional information about NQF and its projects is available at www.qualityforum.org.

FDA ISSUES FINAL TWO PROPOSED FOOD SAFETY REGULATIONS --FDA May 6 announced publication of the final two food safety proposed regulations required by the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 ("The Act"), which gave FDA new authority to protect the nation's food supply.
The proposals are two of four proposed regulations that the Act calls upon FDA to develop regarding food safety. These two proposals deal with establishing and maintaining records among food firms, and the administrative detention of foods that may pose a risk to public health. The other two proposals, concerning the registration of food facilities and prior notice of imported foods, were published in January 2003.
"Improving FDA's food safety inspection, detention and monitoring capabilities is a top priority of the Department. We have taken strong steps to enhance FDA's ability to make our food supply safer, said Secretary of Health and Human Services Tommy G. Thompson. "This FDA effort is the latest in a series of measures to build stronger safeguards for the American people."

"These proposed regulations measures will further bolster FDA ability to protect the more than 400,000 domestic and foreign facilities that deal with food within our country," said FDA Commissioner Dr. Mark B. McClellan, M.D., PhD. "Thanks to the efforts of Senators Gregg and Kennedy, and Representatives Tauzin and Dingell, the Bioterrorism Act gives FDA this important new authority."

The recordkeeping proposal is designed to help FDA track foods implicated in future emergencies, such as terrorism-related contamination. Under the proposed rule, manufacturers, processors, packers, distributors, receivers, holders and importers of food would be required to keep records identifying the immediate source from which they received the food, as well as, the immediate subsequent recipient, to whom they sent it. This requirement would apply to almost all foreign and domestic food sources and almost all recipients of food destined for consumption in the United States. It would assist FDA in addressing credible threats of serious adverse health consequences or death to humans or animals.

To minimize the economic burden on food companies affected by the proposal, FDA's proposals would allow companies to keep the required information in any form that they prefer. Records may be kept in any format, paper or electronic, provided they contain all the required information. The proposed rule also states that existing records can be used to satisfy the requirements of the regulations if these records contain all the required information.

A comment period of 60 days will be provided on these proposals. Written comments can be submitted to FDA at: Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852. Comments can also be submitted electronically through www.fda.gov/dockets/ecomments. It is important to include docket number 02N-0277 for the recordkeeping proposal and docket number 02N-0275 for the administrative detention proposal when providing comments. These proposals can also be accessed electronically at the FDA web page on the Bioterrorism Act.