

THE CSTE WASHINGTON REPORT

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EDITOR'S NOTE:. HHS Secretary Tommy G. Thompson and Agriculture Secretary Ann M. Veneman January 12 announced the release of the Dietary Guidelines for Americans 2005, the federal government's science-based advice to promote health and reduce risk of chronic diseases through nutrition and physical activity. The sixth edition of Dietary Guidelines for Americans places stronger emphasis on reducing calorie consumption and increasing physical activity. This joint project of the Departments of Health and Human Services and Agriculture is the latest of the five-year reviews required by federal law. It is the basis of federal food programs and nutrition education programs and supports the nutrition and physical fitness pillars of President Bush's HealthierUS Initiative. Additional details are included 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 APPROPRIATIONS COMMITTEE CHAIR AGAINST

REORGANIZING – Incoming, new Chairman of the Senate Appropriations Committee, Sen. Thad Cochran (R-MS), has expressed strong skepticism about reorganizing the Senate Appropriations Committee. The Senate approved a resolution last October creating a new Intelligence Subcommittee on Appropriations, but left it up to the Chairman to decide whether and how to implement the recommendation while keeping the total number of Appropriations subcommittees at 13. Sen. Cochran does not favor creating an Intelligence Subcommittee, but prefers to keep it within the jurisdiction of the Defense Appropriations Subcommittee. He also does not favor reducing the number of Subcommittees as House Majority Leader Tom DeLay has proposed. He remains open to other Senators' suggestions, but is strongly inclined to the status quo. The House is considering, at the very least, realigning Subcommittee jurisdictions, including, potentially, moving NIH out of the Labor-HHS-Ed bill and into a bill and Subcommittee that would handle all major domestic federal research endeavors. It is not clear that the Republican Majority would follow through on a House reorganization plan if the Senate does not follow through. The result would be considerable chaos during efforts to conference differing versions of differing appropriations bills.

BUDGET UPDATE – Senate Appropriations Chairman Cochran also expressed his desire to honor the President's FY 2006 budget request and to rein in domestic discretionary spending for the third year in a row. According to Congressional Quarterly, he stated, "Keeping better control over the spending side of the budget is important for our continued economic growth. We're just going to have to learn to say no to those who want to spend more." Rumors abound about what the President's budget will recommend for health programs. A recent New York Times article indicated that NIH will receive a 2 percent increase instead of the 1 percent cut that OMB had initially proposed. HHS Sec. Thompson appealed that decision and reportedly won an increase. Rumors about non-NIH health programs range from a hard freeze from FY 2005 levels, to cuts as deep as 4 percent on average. Another rumor is that the Preventive Health and Health Services Block Grant is slated for elimination. The budget will be presented on February 7th. Public Health groups are circulating a sign on letter urging that public health programs be increased by \$3.5 billion, or 7 percent, in the FY 2006 budget resolution. Last year, nearly 400 organizations signed onto a similar letter. Many are also poised to send out press releases, and letters to the editor around the nation. A Congressional Briefing on Public Health 101 – an effort to educate new Members of Congress, and non-health oriented Members and their staffs about the importance of a range of public health programs in their Districts and States – is planned for March 4th.

OTHER NEWS – Bush HHS Secretary nominee, Michael Leavitt, former Environmental Protection Agency Administer, and former Governor of Utah, appeared before the Senate Finance Committee in a confirmation hearing yesterday. He would not rule out cutting the budget for Medicaid and stated that the whole U.S. health care system was inefficient and needed overhaul. Expectation of Medicaid cuts and a block grant proposal in the President's FY 2006 budget has alarmed many health groups and their need to attend to this major fire complicates efforts to get attention to discretionary health program freezes and cuts.

Washington FAX, a widely read Washington trade publication, reported on the Jan. 18th release of CSTE's 2004 National Assessment of Epidemiologic Capacity: Findings and Recommendations today (1/20/05). The headline reads: "Bioterrorism Readiness Dominates State and Territorial Epidemiology Efforts, Council Reports." The article noted that while the number of epidemiologists working in state and territorial health departments had increased since bioterrorism preparedness funding went from \$180 million to nearly \$1 billion in FY 2002, FY 2003, and FY 2004, the increase had come at the expense of epidemiologists practicing in other areas of public health: environmental health, injury, and occupational health. In addition, the number of infectious disease stayed stagnant and insufficient, and the report concludes that flexibility to address local health challenges such as West Nile Virus, flu, and SARS is being compromised in favor of federal preparedness activities. The Washington FAX article also stressed the problem of training, noting that only 52 percent of epidemiologists have a degree in epidemiology. The article quoted a recommendation in the report for, "A national standard for competency-based, on-the-job training and/or a certificate program should be established to ensure appropriate training for epidemiologists."

REPORT ASSESSES HEALTH IMPLICATIONS OF PERCHLORATE

EXPOSURE-- A new report by the National Academies' National Research Council on the health effects of perchlorate, a chemical that in high doses can decrease thyroid function in humans and that is present in many public drinking-water supplies, says daily ingestion of up to 0.0007 milligrams per kilogram of body weight can occur without adversely affecting the health of even the most sensitive populations. That amount is more than 20 times the "reference dose" proposed by the U.S. Environmental Protection Agency in a recent draft risk assessment.

Environmental releases of perchlorate -- a component of rocket fuel and fireworks -- have been discovered in 35 states, and more than 11 million people have perchlorate in their drinking water at concentrations of 4 parts per billion or higher. As it considers a first-ever national standard for acceptable levels of perchlorate in drinking water, EPA has issued a series of draft risk assessments, each containing a reference dose upon which a standard could be based. Controversies over the scientific conclusions reached in the risk assessments, however, led the federal government to request that the National Research Council review the issue.

The most recent EPA risk assessment, published in 2002, proposes a daily reference dose of 0.00003 milligrams per kilogram (mg/kg) of body weight, which the agency said

would correspond to a drinking-water concentration of 1 part per billion based on certain assumptions about body weight and daily water consumption. The committee that wrote the Research Council report did not include a corresponding drinking-water concentration with its reference dose because the assumptions that are used to derive drinking-water standards involve public-policy choices that were beyond the committee's charge.

Perchlorate inhibits the thyroid's uptake of iodide, which is essential for the production of thyroid hormones. One potential consequence of that effect is low thyroid hormone production, or hypothyroidism. EPA has predicted that an ultimate consequence of that effect is the development of thyroid tumors -- a conclusion the agency based on the occurrence of a few thyroid tumors in rats exposed to perchlorate. The committee disagrees with EPA's conclusion and thinks that perchlorate exposure is unlikely to lead to thyroid tumors in humans. Humans are much less susceptible to disruption of thyroid function or formation of thyroid tumors than rats, and therefore the way rats responded to perchlorate exposure is not a good indicator of how humans would react.

In the past, high doses of perchlorate were used to treat patients with hyperthyroidism, or excessive thyroid hormone production, but a few patients had serious adverse reactions, and the use of perchlorate in this manner was largely abandoned. More recently, patients with hyperthyroidism have been treated effectively and safely with moderate doses of perchlorate for up to two years. Perchlorate has been administered to healthy subjects in doses ranging from 0.007 mg/kg to 9.2 mg/kg per day with no changes in thyroid hormone production to suggest any adverse effect on thyroid function. On the basis of these and other studies, the committee concluded that a perchlorate dose of more than 0.4 mg/kg per day would be required to adversely affect thyroid hormone production and cause hypothyroidism. However, the dose required to cause hypothyroidism in pregnant women, infants, children, and people with low iodide intake or pre-existing thyroid dysfunction might be lower.

There have been studies on the health effects of human populations exposed to perchlorate, but they were studies in which data were available for geographic areas, not for individuals. Relationships observed at the geographic level may not apply at the individual level, and therefore such studies cannot provide direct evidence of causation. They can support a possible association between two events, however, which allowed the committee to reach some conclusions based on those studies. In particular, the committee found that the available evidence is not consistent with an association between exposure to perchlorate in the drinking water at concentrations up to 120 parts per billion during pregnancy and changes in thyroid hormone production in normal-birth weight, full-term newborn infants. The evidence is insufficient to determine whether or not there is an association between perchlorate exposure and adverse neurodevelopmental outcomes in children.

Because of the weaknesses in the studies of the health effects in human populations exposed to perchlorate in the environment, the committee recommended against using them to determine a reference dose. Rather, it recommended using a 2002 clinical study

in which groups of healthy men and women were administered perchlorate in daily doses ranging from 0.007 mg/kg to 0.5 mg/kg for 14 days. The study found no statistically significant inhibition of iodide uptake by the thyroid at the 0.007 mg/kg daily dose. The findings in this study are supported by the results in four other studies of healthy subjects, including a six-month study. The committee recommended that an uncertainty factor of 10 be applied to the 0.007 mg/kg per day level to protect the fetuses of pregnant women who might have hypothyroidism or iodide deficiency. This results in the 0.0007 mg/kg per day reference dose recommended in the report.

One committee member, concerned over the adequacy of the data, dissented and thought that an additional uncertainty factor of three should be applied. The rest of the 15-member committee responded by pointing out that the key study examined the effects of four dose levels in a total of 37 subjects, and that four other studies had remarkably similar results. The committee was unanimous in all other findings and recommendations.

The committee emphasized that the reference dose should be based on inhibition of iodide uptake by the thyroid in humans, which is not an adverse effect but the key biochemical event that precedes any health effects caused by perchlorate exposure. The committee called this a "conservative, health-protective approach to perchlorate risk assessment." It also suggested studies that have the potential to more precisely define "safe" perchlorate exposures. Future findings could result in the need to adjust the reference dose recommended in the report, the committee acknowledged.

The study was sponsored by the U.S. Environmental Protection Agency, the U.S. Department of Defense, the U.S. Department of Energy, and NASA. The National Research Council is the principal operating arm of the National Academy of Sciences and the National Academy of Engineering. It is a private, nonprofit institution that provides science and technology advice under a congressional charter. A committee roster follows.

Copies of [Health Implications of Perchlorate Ingestion](#) will be available later this winter from the National Academies Press; tel. 202-334-3313 or 1-800-624-6242 or on the Internet at <http://www.nap.edu>.

NEW DIETARY GUIDELINES WILL HELP AMERICANS MAKE BETTER FOOD CHOICES, LIVE HEALTHIER LIVES -- HHS Secretary Tommy G. Thompson and Agriculture Secretary Ann M. Veneman January 12 announced the release of the *Dietary Guidelines for Americans 2005*, the federal government's science-based advice to promote health and reduce risk of chronic diseases through nutrition and physical activity.

The sixth edition of *Dietary Guidelines for Americans* places stronger emphasis on reducing calorie consumption and increasing physical activity. This joint project of the Departments of Health and Human Services and Agriculture is the latest of the five-year reviews required by federal law. It is the basis of federal food programs and nutrition

education programs and supports the nutrition and physical fitness pillars of President Bush's *HealthierUS* Initiative.

"These new *Dietary Guidelines* represent our best science-based advice to help Americans live healthier and longer lives," Secretary Thompson said. "The report gives action steps to reach achievable goals in weight control, stronger muscles and bones, and balanced nutrition to help prevent chronic diseases such as heart disease, diabetes and some cancers. Promoting good dietary habits is key to reducing the growing problems of obesity and physical inactivity, and to gaining the health benefits that come from a nutritionally balanced diet."

"The new *Dietary Guidelines* highlight the principle that Americans should keep their weight within healthful limits and engage in ample physical activity," said Secretary Veneman. "The process we used to develop these recommendations was more rigorous and more transparent than ever before. Taken together, the recommendations will help consumers make smart choices from every food group, get the most nutrition out of the calories consumed and find a balance between eating and physical activity."

Eating a healthy balance of nutritious foods continues as a central point in the *Dietary Guidelines*, but balancing nutrients is not enough for health. Total calories also count, especially as more Americans are gaining weight. Because almost two-thirds of Americans are overweight or obese, and more than half get too little physical activity, the 2005 *Dietary Guidelines* place a stronger emphasis on calorie control and physical activity.

The *Dietary Guidelines*, based on the latest scientific information including medical knowledge, provides authoritative advice for people two years and older about how proper dietary habits can promote health and reduce risk for major chronic diseases. The 2005 *Dietary Guidelines* were prepared in three stages. In the first, a 13-member Dietary Guidelines Advisory Committee prepared a report based on the best available science. In the second stage, government scientists and officials developed the *Dietary Guidelines* after reviewing the advisory committee's report and agency and public comments. In the third stage, experts worked to translate the *Dietary Guidelines* into meaningful messages for the public and educators.

The report identifies 41 key recommendations, of which 23 are for the general public and 18 for special populations. They are grouped into nine general topics:

- * Adequate Nutrients Within Calorie Needs
- * Weight Management
- * Physical Activity
- * Food Groups to Encourage
- * Fats
- * Carbohydrates
- * Sodium and Potassium
- * Alcoholic Beverages

* Food Safety

The *Dietary Guidelines* provide health education experts, such as doctors and nutritionists, with a compilation of the latest science-based recommendations. Consumer-friendly materials such as brochures and Web sites will assist the general public in understanding the scientific language of the 2005 *Dietary Guidelines* and the key points that they can apply in their lives. To highlight those points, a consumer-oriented brochure accompanies the 2005 *Dietary Guidelines*. USDA's Food Guidance System also will serve as a tool to educate consumers on the *Dietary Guidelines for Americans*. The Food Guidance System, currently called the Food Guide Pyramid, is undergoing revision and will be released in the spring of 2005.

The 2005 *Dietary Guidelines* and consumer brochure are available at www.healthierus.gov/dietaryguidelines.

COMPLEMENTARY AND ALTERNATIVE THERAPIES AND CONVENTIONAL MEDICAL THERAPIES SHOULD BE HELD TO SAME STANDARDS; REVISED REGULATION OF DIETARY SUPPLEMENTS IS NEEDED TO ENSURE PRODUCT QUALITY AND SAFETY -- Stating that health care should strive to be both comprehensive and evidence-based, a new report from the Institute of Medicine of the National Academies calls for conventional medical treatments and complementary and alternative treatments to be held to the same standards for demonstrating clinical effectiveness. The same general research principles should be followed in evaluating both types of treatments, although innovative methods to test some therapies may have to be devised, said the committee that wrote the report.

The committee noted in particular the escalating popularity of dietary supplements as well as the lack of consistency and quality in these products, which are an important component of several complementary and alternative approaches. Product inconsistency hinders health professionals' abilities to guide patients on the use of supplements and researchers' ability to study them. The report calls on Congress to work with stakeholders to amend the regulation of supplements to improve quality control and consumer protections and to create incentives for research on the efficacy of these products.

"Ideally, health care should be comprehensive, grounded in the best available scientific evidence, and centered on patients' needs and preferences," said committee chair Stuart Bondurant, interim executive vice president for health sciences and executive dean, Georgetown University Medical Center, Washington, D.C. "Health professionals and patients should have sufficient information about safety and efficacy to take advantage of all useful therapies, both conventional and complementary and alternative. To that end, we believe that the same research principles and standards for showing effectiveness should apply to both conventional and complementary and alternative treatments. And because evidence is a key element of prudent decision-making, we need to change the current regulation of dietary supplements in this country to encourage more studies of these widely used products and to ensure their quality," he said.

Written to assist the National Institutes of Health in developing research methods and setting priorities for evaluating products and approaches within complementary and alternative medicine (CAM), the report also assesses what is known about Americans' reliance on these therapies. Use of CAM is widespread among the U.S. public, with more than one-third of adults reporting that they have pursued some form of these treatments, which include products such as herbal remedies, techniques such as acupuncture, and schools of practice such as naturopathy. Fewer than 40 percent of CAM users have disclosed their use of such therapies to their physicians. More than half of physicians report that they would encourage patients to talk to them about using CAM and would refer them for treatments that fall into that category. However, much is still unknown about how and why people use these therapies in conjunction with or in lieu of conventional therapies.

A common set of methods and standards for generating and interpreting evidence is necessary if health care providers are to make informed decisions about the use of both conventional treatments and CAM. It has been argued that characteristics of CAM therapies -- such as customization of treatments, variations in how practitioners perform treatments, or the holistic nature of many of these practices -- make it difficult to apply traditional clinical studies to them. Randomized controlled trials (RCTs) are the gold standard for providing evidence of efficacy, the committee said, but other study designs can generate useful information on treatments that do not lend themselves to RCTs. Observational studies, case control studies, and studies that specifically measure patients' expectations, emotional states, and other self-healing processes can provide useful data. Some conventional treatments, such as psychotherapy, also have similar characteristics that make them incompatible with RCTs, but they have been successfully evaluated via other methods, the committee noted.

Because many CAM products and approaches have not undergone formal testing and because resources to conduct research are finite, the report outlined several criteria to help determine which CAM therapies to prioritize for study. These same criteria apply equally well to as-yet untested conventional treatments, the committee noted. They include the prevalence and severity of the target health condition; existing evidence that the therapy is effective or may have safety issues; whether there is a plausible biological mechanism by which the therapy might work or the likelihood that research will discover a mechanism; and the likelihood that research will yield unambiguous results. Inability to meet any one of the criteria should not necessarily exclude a therapy from consideration, the report says.

To foster more research on the effectiveness and safety of CAM -- as well as on how these therapies compare with one another or with conventional treatments -- practitioners need to be trained in research principles and methods. Studies depend on the involvement of those who understand the therapies' characteristics and goals, but CAM training programs focus on preparing students for practice, and few practitioners learn how to conduct research. At the same time, because CAM use is becoming so widespread, all doctors, nurses, and other health care providers should receive education about these treatments during their professional education, the committee urged.

Dietary supplements, such as herbal products and vitamin pills, are among the most widely and increasingly used forms of CAM; use of herbal products jumped 380 percent between 1990 and 1997, for example. The Dietary Supplement Health and Education Act (DSHEA) mandates that supplements be regulated as foods rather than drugs, which means that supplement manufacturers are not required to conduct safety or efficacy tests on their products. Given that manufacturers are not required to conduct testing and are unable to patent many supplements, there is little incentive for supplement makers to invest in research on the effectiveness of these products. Moreover, the general lack of quality control for dietary supplements is problematic because researchers need consistent samples to conduct studies that could further elucidate these products' effectiveness and potential uses, the report says.

The committee also noted that although there are some restrictions on what information and claims can be included on labels, officials at the Federal Trade Commission have described a proliferation of unfounded and exaggerated claims for supplements. This is of concern because many consumers use these products without consulting a health care professional.

To remedy this situation, the report calls on Congress and the appropriate federal agencies to work with industry representatives, researchers, consumers, and other stakeholders to amend DSHEA to implement quality-control standards for each step of the manufacturing process and to enforce more accurate labeling and disclosures and other consumer protections. In addition, the broader regulatory scheme for supplements should be revised to create incentives for privately funded research on the effectiveness of products and brands and on how consumers use these products.

The study was sponsored by the National Institutes of Health and Agency for Health Care Research and Quality. 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.

Pre-publication copies of **Complementary and Alternative Medicine in the United States** are available from the National Academies Press; tel. 202-334-3313 or 1-800-624-6242 or on the Internet at <http://www.nap.edu>.

MORE RESEARCH NEEDED TO EXPLORE LINKS BETWEEN PHYSICAL ACTIVITY AND BUILT ENVIRONMENT-- Research increasingly shows a link between physical activity and the "built" environment -- buildings, roads, parks, and other structures that physically define a community -- but more research is needed to assess whether the built environment affects people's actual levels of physical activity, says a new report from the National Academies' Transportation Research Board and Institute of Medicine. This additional research could help clarify whether and to what extent the physical environment where Americans live and work contributes to the fact that more than half of the U.S. adult population falls short of meeting the U.S. surgeon general's guidelines for physical activity, said the committee that wrote the report.

"Inadequate physical activity is a major and largely preventable public health problem," said committee chair Susan Hanson, Landry University Professor, Clark University, Worcester, Mass. "We know from empirical evidence that the built environment can encourage some forms of physical activity, such as walking and cycling, for some population groups. But we don't know yet how important it is to meeting recommended levels of physical activity -- at least 30 minutes of moderate activity on five or more days per week -- or how much of a person's decision to be physically active depends on physical surroundings as opposed to personal inclination."

The well-established connection between physical activity and health justifies a continuing and more interdisciplinary research effort to study causal relationships between the built environment and physical activity, the committee said. The results of this research could provide guidance to policy-makers about cost-effective strategies for increasing physical activity, the committee said. Additional federal funds are needed to support multiyear studies to assess people's behavior over time as their environment changes, evaluations of how interventions that change the built environment affect physical activity levels, and additions to national travel and health databases. A collaborative effort to develop and fund an appropriate research agenda should be conducted by an interagency working group led by the U.S. Department of Health and Human Services and the U.S. Department of Transportation, the committee said.

National public health and travel surveys, such as the Behavioral Risk Factor Surveillance System and the National Household Travel Survey, should be expanded to provide more detailed information about where people exercise and travel, not only in their neighborhoods but also in their homes, at work, and at school, where people spend the majority of their time, the report says. These surveys should also consider various settings that may encourage or deter physical activity. For instance, the deteriorated physical condition of poor inner-city neighborhoods may discourage outdoor physical activity except for necessary trips. In other neighborhoods, people may feel encouraged to increase their daily physical activity by readily available facilities for recreational walking and cycling.

The study was sponsored by the Robert Wood Johnson Foundation and the Centers for Disease Control and Prevention. The Transportation Research Board is a division of the National Research Council, the principal operating arm of the National Academy of Sciences and the National Academy of Engineering. The Research Council is a private, nonprofit institution that provides science and technology advice under a congressional charter. 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.

Copies of **Does the Built Environment Influence Physical Activity? Examining the Evidence** will be available in the early spring from the TRB Business Office; tel. 202-334-3213 or on the Internet at <http://www.trb.org>

