THE CSTE WASHINGTON REPORT

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EDITOR'S NOTE:. HHS Secretary Tommy G. Thompson July 3 announced a new effort to expand and strengthen the Public Health Service Commissioned Corps by recruiting more health care professionals and better preparing those professionals to respond quickly and effectively to emergency health needs around the country. The Secretary's plan to revitalize the Commissioned Corps represents its most sweeping transformation since its creation in 1889 as the corps will become a more effective medical health unit, prepared to assist in public health needs anywhere the Secretary believes help is needed. The revitalization focuses on creating an effective, flexible, and truly deployable force that is ready to respond to public health and emergency needs across the country or around the world. 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

HOUSE ACTS ON APPROPRIATONS – The full House of Representatives passed H.R. 2660, the FY 2004 Labor, Health and Human Services and Education Appropriations bill on July 10th. The bill funds most public health agencies and programs. The report accompanying the bill (108-188) can now be read at: http://thomas.loc.gov/cgi-bin/cpquery The House vote was 215 to 208, with 9, mostly conservative, Republicans voting against the bill along with every Democrat. Two amendment battles were over altering the Labor Department's structure for overtime pay that would have eliminated eligibility for extra compensation for a number of white collar workers, while permitting overtime for lower pay workers. The amendment opposing the restructuring and opposed by unions was defeated 210-213. Another amendment offered by Rep. Patrick Toomey (R-PA), would have stripped funding for four NIH sexual behavior studies. Subcommittee Chairman Ralph Regula (R-OH) urged Members not to interfere with NIH's peer reviewed process. The amendment failed by a mere two votes. It was watched closely by many in the health community as Rep. Toomey, a conservative, is running against Senator Arlen Specter (R-PA), Chairman of the Senate Labor-HHS-Education Appropriations, a moderate, and an NIH champion, in the 2004 election.

The action now switches to the Senate where the FY 2004 Labor-HHS-Education Appropriations bill (S. 1356) may be taken up on the floor before the week ends. The report accompanying the bill may be read at:http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=108_cong_reports&docid=f:sr081.108.pdf The Senate bill has a $445 million lower allocation that the House bill, the reverse has been true for the last decade, and funds many health programs below the House numbers. A number of amendments to increase funding for various health programs, chief among them the NIH, are expected to be offered. One possible amendment could increase funding in targeted areas to support public health workforce training.

SERIES OF BILLS IMPROVING SCHOOL NUTRITION INTRODUCED -- At least four bills have been introduced over the past several weeks that would amend the Richard B. Russell National School Lunch Act and the Child Nutrition Act of 1966, which are scheduled for reauthorization this year, to make food provided under these programs more nutritious (S. 1392 and 1393; S. 1367, and H.R. 2626). In introducing his bills (S. 1392 and 1393), Senator Harkin (D-IA) stated the following:

"I still believe that, given the chance, our kids can and will make good choices about the foods they eat. We just don't give them these choices. To test this hypothesis that, given the opportunity, kids would make good choices about the food they eat, I proposed and got adopted in the Farm Security and Rural Investment Act of 2002 a pilot program that provides grants to schools for the simple purpose of allowing them to use the money to purchase fresh fruits and vegetables for their students. Some schools use the grants to deliver bins of fruits and vegetables to their classrooms every day. Others set up kiosks in the halls. A few schools even put free fruits and vegetables in their vending machines.

Not long ago the Department of Agriculture released its assessment of the pilot program. Not surprisingly, it received high marks. Schools reported that 98 percent of students were interested in the program. Schools also reported that, over the course of the program, 71 percent of students grew more, not less, interested in the program. Most importantly, students told program evaluators that the pilot made them much more conscious about the junk food that they eat. …

Today I am introducing legislation, S. 1392, to do just that and to expand the program to all 50 States. Under this legislation, the pilot program would expand from its current 4 states and tribal schools and 60,000 students to 50 states and over 1 million children. It would also expand the pilot to ensure that additional Indian tribal schools are able to participate in the program.

It would do this at a reasonable price tag--only $75 dollars per student per year. This means that at a cost of just over $75 million per year, we can make fresh fruits and vegetables a constant presence in the life of over 1 million American schoolchildren. It is difficult for me to imagine a more effective use of taxpayer dollars.

Today I am also introducing companion legislation, S. 1393, to the fruit and vegetable pilot program expansion. The first piece of legislation seeks to provide kids with healthier food, and the second complements that by improving the overall nutritional environment of American schools. It seeks to give kids more choices and the ability to choose healthy foods."

PROJECT BIOSHIELD PASSES THE HOUSE -- The House passed Project BioShield (H.R. 2122) on July 16th by an overwhelming margin. The Senate is expected to take up the bill before the August recess. The following is a Congressional Research Service summary of the bills provisions:

"Project BioShield Act of 2003 - (Sec. 2) Amends the Public Health Service Act regarding preparations for public health emergencies affecting national security, including a bioterrorist attack.

Makes biocontainment laboratories and specialized research facilities available as needed to the Secretary of Health and Human Services (the Secretary) in public health emergencies affecting national security if the owners of such a facility have entered into a grant or cooperative agreement with the Secretary under the provisions of this Act pertaining to biomedical countermeasure research and development.

Grants the Secretary certain authority with respect to the research and development of qualified countermeasures, including: (1) expedited procurement authority; (2) expedited peer review authority; (3) authority for personal services contracts; and (4) streamlined personnel authority. Defines a qualified countermeasure as a priority countermeasure that affects national security. Declares that nothing in this section shall affect the authority of interested parties to protest contracting decisions to the contracting agency, the General Accounting Office, or the Federal Court of Claims.

(Sec. 3) Directs the Secretary of Homeland Security, in coordination with the Secretary and the Secretary of Veterans Affairs, to maintain a stockpile of drugs, vaccines (including smallpox vaccine), and other supplies to provide for the emergency health security of the United States in the event of a bioterrorist attack or other public health emergency. Directs the Secretary to: (1) review and revise the contents of the stockpile on a regular basis; (2) award grants to ensure that the stockpile contains an adequate amount of smallpox vaccine; and (3) assess, on an ongoing basis, the potential public health consequences from the use of chemical, biological, radiological, and nuclear agents and determine the agents for which countermeasures are necessary. Permits the Secretary and the Secretary of Homeland Security to jointly submit to the President proposals for the development of needed security countermeasures (qualified countermeasures approved or likely to be approved under the Federal Food, Drug, and Cosmetic Act as countermeasures against a chemical, biological, radiological, or nuclear agent).

Amends the Homeland Security Act of 2002 to authorize appropriations for the procurement of security countermeasures.

(Sec. 4) 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 for use in an emergency. Directs the Secretary to impose requirements on the authorization, including ensuring 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. Allows the President, with regard to the Armed Forces, to waive the requirement that individuals be allowed to refuse administration of a countermeasure if complying with such requirement is: (1) not feasible; (2) contrary to the best interests of such individuals; or (3) not in the interests of national security. Allows the Secretary to withhold from members of the Armed Forces information about the benefits and risks of a countermeasure and alternatives to its use if such information is provided to such individuals within 30 days of the administration of the countermeasure and is recorded in the medical records of such members.

(Sec. 5) Requires: (1) reports from the Secretary regarding authorities under this Act; (2) the Secretary to request the National Academy of Sciences to review biomedical countermeasure research and development activities under this Act; and (3) review by the General Accounting Office."

SECRETARY THOMPSON TO INCREASE NUMBERS AND FLEXIBILITY OF PUBLIC HEALTH SERVICE COMMISSIONED CORPS -- HHS Secretary Tommy G. Thompson July 3 announced a new effort to expand and strengthen the Public Health Service Commissioned Corps by recruiting more health care professionals and better preparing those professionals to respond quickly and effectively to emergency health needs around the country.

The Secretary's plan to revitalize the Commissioned Corps represents its most sweeping transformation since its creation in 1889 as the corps will become a more effective medical health unit, prepared to assist in public health needs anywhere the Secretary believes help is needed. The revitalization focuses on creating an effective, flexible, and truly deployable force that is ready to respond to public health and emergency needs across the country or around the world.

"As we face an uncertain future of possible terrorist attacks, emerging infectious diseases, natural disasters, and other prevention or public health needs, this transformation will help us strengthen our public health infrastructure and response system to better serve the American people," Secretary Thompson said. "That is why this transformation is so vital."

The transformation will forge the Commissioned Corps into a more highly trained, fully deployable force that is prepared to respond to emergency situations. The new structure will put in place a modern force management system that provides for the recruitment and retention of the highest quality health professionals in a uniformed service and assures the capacity for immediate response and deployment.

"This is an exciting time for the Public Health Service Commissioned Corps," U.S. Surgeon General and Commander of the Commissioned Corps Richard H. Carmona said. "This first step will lead to a stronger and more versatile corps that will be able to respond to any public health emergency. I thank Secretary Thompson for his continued leadership and vision and look forward to helping implement his plan over the coming weeks and months."

As part of the transformation, the Commissioned Corps will:

* Work to create scholarships to recruit as many as 1,000 nurses and 100 doctors per year to work in medically underserved areas.
* Identify PHS officers who can assist in reducing staffing shortages in clinical settings in the Indian Health Service (IHS) and the National Health Service Corps, as well as assist with President Bush's plan to increase Community Health Center capacities throughout the nation.
* Recruit at least 275 new officers to support the IHS by September 30, 2004.
* Improve and expand training and deployability of PHS officers into areas where primary care services are lacking.
* Phase out the existing Commissioned Corps Readiness Force structure, and replace it with a revised system designed to bring the status of the Commissioned Corps to 100 percent deployability by the end of 2005.
* Create additional short term duty missions and "rolling deployments" to address Presidential and Secretarial initiatives directed toward serving critical needs through the use of active duty and reserve officers who will be called to temporary active duty.
* Provide a modernized reserve component system that can marshal resources for deployment at the local level for needed public health initiatives.

* Establish a ready reserve corps that will supplement the efforts of the Commissioned Corps.
* Open new opportunities for registered nurses and other credentialed health personnel who hold an associate degree and appropriate credentials.

This transformation will unfold over the next several months and under the leadership provided by the Assistant Secretary for Health and the Surgeon General.
As one of the seven Uniformed Services of the United States, the United States Public Health Service Commissioned Corps is a specialized career system designed to attract, develop, and retain health professionals who may be assigned to federal, state, or local agencies or international organizations to accomplish its mission.

REPORT RECOMMENDS STEPS TO REDUCE DIETARY DIOXIN EXPOSURE-- A federal interagency group should develop and implement an integrated risk-management strategy and action plan to reduce human exposure to dioxins in foods, says a new report from the Institute of Medicine of the National Academies. Government officials should collaborate with the private sector to identify and pursue voluntary interventions to further minimize levels of these toxic compounds in human foods and animal feeds. However, the health risks posed by the levels of dioxins in foods have yet to be ascertained, so the report does not recommend regulatory limits on dioxins or dioxin-like compounds (DLCs) in food or feed.

Since fetuses and infants are especially sensitive to the effects of toxic compounds, one part of the government's action plan should be an effort to reduce girls' and women's exposure to dioxins in foods during the years well before childbearing, so that less of these compounds accumulate in their bodies and are passed on through the placenta and breast milk, the report adds. By promoting compliance with current dietary recommendations to consume less animal fat -- where dioxins primarily collect -- the government could help all Americans reduce their exposure to these compounds.

"Because the risks posed by the amount of dioxins found in foods have yet to be determined, we are recommending simple, prudent steps to further reduce dioxin exposure while data are gathered that will clarify the risks, " said Robert Lawrence, associate dean for professional practice and programs, Bloomberg School of Public Health, Johns Hopkins University, Baltimore, and chair of the committee that wrote the report.

Dioxins and DLCs are long-lasting compounds that accumulate in the body fat of animals and people. Although dioxins are ubiquitous in the environment, the fats in meat, poultry, fatty fish, whole milk, and full-fat dairy products are the principal source of most people's exposure. However, fetal and infant exposure depends on the amount in the mother's body because these compounds can cross the placenta and also collect in the fat in breast milk.

High levels of dioxins have been linked to endocrine-related conditions, developmental problems, and susceptibility to cancer, among other health hazards. However, more research is needed to discern whether small amounts of dioxins are toxic and at what levels they begin to pose risks. Further improvements in analytical tools and methods will enable researchers to better characterize any possible risks associated with low-level exposure. Dioxin levels in the environment have declined dramatically in recent decades -- by as much as 76 percent since the 1970s, according to some measurements. Dioxin levels in foods have decreased greatly as well.

The committee was not asked to offer any judgments about the risks of human exposure through foods, but rather to recommend risk-management options that would further reduce dioxin exposure among the general population and vulnerable groups until the health risks are defined. The report recommended no mandatory limits on dioxins, given the current lack of precise data on both the risks and the current amounts of the compounds in foods and feeds.

Minimizing girls' and young women's intake of dioxins during the years before pregnancy is the only practical way to reduce dioxin exposure in fetuses and breast-feeding infants, the report says. Given the health and social benefits of breast-feeding, the committee recommended strategies to reduce accumulated body levels of dioxin, rather than to discourage breast-feeding.

To reduce dioxin exposures in all children -- especially girls -- government-sponsored food programs, such as the National School Lunch Program, should increase the availability of foods low in animal fat. For example, low-fat milk should be made more widely available in the school lunch program. Also, the U.S. Department of Agriculture should analyze the impact of setting limits on the amount of saturated fat that can be present in meals served in the school breakfast and lunch programs. Except for children under age 2, participants in the Special Supplemental Food Program for Women, Infants, and Children should be encouraged to choose low-fat milk and foods.

Promoting compliance with the Dietary Guidelines for Americans on consumption of saturated fats and fats in general would minimize people's dioxin exposure without compromising their intake of nutrients. Because of the health benefits associated with omega-3 fatty acids in fish and the difficulty of trimming fat from fish, the committee did not recommend that people reduce their consumption of fatty fish below the currently recommended two servings per week.

The committee also urged the government to give priority to reducing dioxin contamination of animal feed, and to curtailing the recycling of dioxins that occurs when contaminated grass forage and animal fat are included as ingredients in feed. Federal agencies should work with food producers to develop voluntary guidelines for animal feeding and food-production practices that would minimize animals' exposure to dioxins.

The report was sponsored by the U. S. Department of Health and Human Services, Food and Drug Administration, and agencies within the U. S. Department of Agriculture. 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 **Dioxins and Dioxin-like Compounds in the Food Supply: Strategies to Decrease Exposure** will be available later this year from the National Academies Press; tel. (202) 334-3313 or 1-800-624-6242 or on the Internet at **http://www.nap.edu**.

HHS TO REQUIRE FOOD LABELS TO INCLUDE TRANS FAT CONTENTS --
HHS Secretary Tommy G. Thompson announced July 9 that food labels will be required to list the amount of unhealthy trans fatty acids, or trans fat, to give consumers better information when choosing their foods. The new requirement through the Department's Food and Drug Administration (FDA) will mean that manufacturers of most conventional foods and some dietary supplements will have to list in the Nutrition Facts panel the trans fat content of the product, in addition to the information about its overall fat content and saturated fat content.

The additional information will give consumers a more complete picture of fat content in foods -- allowing them to choose foods low in trans fat, saturated fat and cholesterol, all of which are associated with an increased risk of heart disease. Reducing the intake of trans fat and saturated fats is recommended by the Federal Dietary Guidelines for Americans.

"We are empowering Americans to make healthier choices about the foods they eat," Secretary Thompson said. "By putting trans fat information on food labels, we are making it possible for consumers to make better educated choices to lower their intake of these unhealthy fats and cholesterol. It's just one more way we're helping consumers lead healthier lives."

The announcement is another step in Secretary Thompson's efforts to give consumers better health information that allows them to take the right steps to reduce their risk of disease, including making sound dietary choices.

Under the new FDA regulations, by Jan. 1, 2006, consumers will be able to find trans fat listed on food nutrition labels directly under the line for saturated fat. The new information is the first significant change on the Nutrition Facts panel since it was established in 1993.

The new labeling reflects scientific evidence showing that consumption of trans fat, saturated fat and dietary cholesterol raises low-density lipoprotein (LDL) cholesterol ("bad" cholesterol) levels that increase the risk of coronary heart disease. Nearly 13 million Americans suffer from coronary heart disease, and more than 500,000 die each year from causes related to coronary heart disease.

Trans fat occurs in foods when manufacturers use hydrogenation, a process in which hydrogen is added to vegetable oil in order to turn the oil into a more solid fat. Trans fat is often but not always found in the same foods as saturated fat, such as vegetable shortening, some margarines, crackers, candies, cookies, snack foods, fried foods, baked goods, salad dressings, and other processed foods.

"Our choices about our diets are choices about our health, and those choices should be based on the best available scientific information. This label change means that trans fat can no longer lurk, hidden, in our food choices," said Mark B. McClellan, M.D., Ph.D., commissioner of FDA. "Americans will now be armed with better information to reduce their intake of saturated fat, trans fat and cholesterol - which could significantly lower the risk of heart disease, the leading cause of death in America today."

By providing more useful information to consumers seeking a healthy diet, the new labels are expected to reduce the costs of illness and disease for Americans. The FDA estimates that the changes in regulations will save between $900 million and $1.8 billion each year in medical costs, lost productivity and pain and suffering.
The new label is part of the department's broader efforts to more effectively inform consumers about the health consequences of their dietary choices. The agency hopes to improve the nutrition label to provide clearer, up-to-date guidance on a healthy overall diet. FDA is also working to increase the focus on health in food product development and promotion, as well as encouraging research that would foster greater science-based competition among food producers to improve health.

The National Heart, Lung and Blood Institute (NHLBI) at HHS' National Institutes of Health (NIH) supports the new labeling. "Trans fat, like saturated fat and dietary cholesterol, raises LDL "bad" cholesterol levels in the blood, which increases the risk for heart disease," said Dr. Claude Lenfant, director of NHLBI. "It is therefore desirable to have food labels display all the information that can help consumers choose foods low in saturated fat, trans fat and cholesterol as part of a healthy diet."

Although some food products already list trans fat on the food label, food manufacturers have until Jan.1, 2006, to add it to the nutrition label. This phase-in period minimizes the need for multiple labeling changes and allows small businesses to use up current label inventories. The FDA will allow manufacturers to implement the change more quickly, and in fact expects many manufacturers to start listing trans fat content soon.
In addition, dietary supplement manufacturers will now need to list trans fat, as well as saturated fat and cholesterol, on the Supplement Facts panel when their products contain more than trace amounts (0.5 gram) of trans fat. Examples of dietary supplements that may contain trans fat are energy and nutrition bars.
The new requirements are included in final FDA regulations were published in the Friday, July 11, Federal Register.

FDA also is issuing an advanced notice of proposed rulemaking to solicit information and data that could lead to further changes in nutrition and product labels related to trans fat, saturated fat, and cholesterol.
"While giving consumers accurate information about the trans fat content of their foods is an important step forward, we must do more to help consumers improve their nutrition," said Dr. McClellan. "Consequently, we are also giving notice that we intend to take further steps to increase consumer understanding of the importance of limiting consumption of trans fat, saturated fat, and cholesterol in their diet."
In particular, comments in response to FDA's notice could assist the agency in further action to establish:

* new nutrient content claims about trans fat, for example, claims that a product is "low in trans fat" on its label;
* qualifying criteria for trans fat in current nutrient content claims for saturated fat and cholesterol, lean, and extra lean claims, because the claims currently allowed by FDA in these areas may not appropriately reflect trans fat content; and
* health claims that contain a message about cholesterol-raising fats.

FDA is also requesting comments on whether it should consider statements about trans fat, either alone or in combination with saturated fat and cholesterol; as a footnote in the Nutrition Facts panel (for example, to modify the recommended daily amount of trans and saturated fat and cholesterol to encourage limiting intake of all three); or as a disclosure statement in conjunction with claims to enhance consumers' understanding about such cholesterol-raising lipids and how to use the information to make heart-healthy food choices.

LACK OF STUDIES ON WOMEN LIMITS USEFULNESS OF RESEARCH ON CORONARY HEART DISEASE --Although coronary heart disease (CHD) is the cause of more than 250,000 deaths in women each year, much of the research in the last 20 years on the diagnosis and treatment of CHD has either excluded women entirely or included only limited numbers of women and minorities. As a result, many of the tests and therapies that are used to treat women for CHD are based on studies conducted predominantly in men**.**

Even in studies that include women, the published research often does not provide findings specific to women, according to two evidence reviews on CHD in women, conducted for the Agency for Healthcare Research and Quality and the National Institutes of Health's Office of Research on Women's Health by researchers at the University of California at San Francisco/Stanford Evidence-based Practice Center. Only 20 percent of the articles reviewed for this project provided separate findings on women.

The U.S. Department of Health and Human Services, which includes AHRQ, has been working to expand the involvement of women in research involving CHD. For example, the NIH's National Heart, Lung, and Blood Institute supports a wide range of clinical trials on heart disease that have included women, including large studies such as the

Antihypertensive and Lipid-Lowering Treatment to Prevent Heart Attack Trial (ALLHAT) and the Atrial Fibrillation Follow-up Investigation of Rhythm Management (AFFIRM). In addition, the Women's Ischemia Syndrome Evaluation (WISE) study is investigating issues related to the specific symptoms of chest pain in women and the diagnosis of CHD. The NIH also has been working with scientific journals to encourage the publication of more research data specific to women.
In reviewing studies that did publish findings specific to gender or race/ethnicity, the researchers found that:

* Fair or good evidence suggests that the use of diagnostic tests and treatments may differ by gender. Men are more likely than women to undergo diagnostic testing and treatment for CHD, but women are more likely to be treated for hypertension.
* Fair or good evidence suggests that beta-blockers, aspirin, and angiotensin-converting enzyme inhibitors reduce risk for CHD events.
* Good evidence suggests that treatment of hypertension lowers the risk for CHD events in women, and that these benefits may be greater in African-American women.
* Fair evidence suggests that smoking cessation after heart attack lowers the risk for CHD in women.
* Fair evidence suggests that women who receive glycoprotein IIb/IIIa inhibitor drugs during coronary procedures seem to benefit from this treatment, but good evidence suggests that use of glycoprotein IIb/IIIa inhibitor drugs in women with acute coronary syndromes may be associated with an increased risk of death. This was the only treatment studied for which there was evidence that the outcomes may be different between men and women. Men treated with glycoprotein IIb/IIIa inhibitor drugs during acute coronary syndromes appeared to benefit.

The researchers conclude that even though funding agencies appear to have succeeded in ensuring that some women and minorities are included in randomized trials, data about these populations often are not made clear in the published findings. They recommend that in addition to requiring participation of women and minorities in research, funding and regulatory agencies should request that outcome data by gender and race/ethnicity be published or made easily available.

Details of these findings from the following two evidence reports can be found on the AHRQ Web site: *Results of Systematic Review of Research on Diagnosis and Treatment of Coronary Heart Disease in Women* at http://www.ahrq.gov/clinic/epcsums/chdwomsum.htm; *Diagnosis and Treatment of Coronary Heart Disease in Women: Systematic Reviews of Evidence on Selected Topics* at http://www.ahrq.gov/clinic/epcsums/chdwtopsum.htm. In addition, the information can be found on the National Guideline Clearinghouse™ at http://www.guideline.gov (Select EPC Reports). Printed copies also are available from the AHRQ Clearinghouse at 800-358-9295, or ahrqpubs@ahrq.gov.