THE CSTE WASHINGTON REPORT

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INSIDE THIS ISSUE

EDITOR'S NOTE: A new study finds that women who take folic acid supplements early in their pregnancy can substantially reduce their baby's chances of being born with a facial cleft. Researchers at the National Institute of Environmental Health Sciences (NIEHS), part of the National Institutes of Health, found that 0.4 milligrams (mg) a day of folic acid reduced by one third the baby's risk of isolated cleft lip (with or without cleft palate). Folic acid is a B vitamin found in leafy vegetables, citrus fruits, beans, and whole grains. It can also be taken as a vitamin supplement, and it is added to flour and other fortified foods. The recommended daily dietary allowance for folate for adults is 400 micrograms or 0.4 mg -- additional 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 PASSES YEAR LONG CONTINUING RESOLUTION – Yesterday, The U.S. House of Representatives passed legislation (H.J. Res. 20) that will fund most of the federal government through September 30, 2007. Fully 9 of the 11 FY 2007 Appropriations measures, including the Labor, Health and Human Services and

Education Appropriations bill which funds all of the CDC programs, were not enacted by the 109th Congress. The in-coming House and Senate Appropriations Chairmen decided to dispense with the unfinished bills by passing a year-long continuing resolution that would fund most agencies and programs at the FY 2006 level. A few exceptions were made, notably for many programs under the Labor-HHS-Education Appropriations bill. Sen. Harkin (D-IA), the current Chairman of the Labor-HHS-Education Appropriations Subcommittee and Sen. Specter (R-PA), current Ranking Minority Member, worked throughout last year, with the broad support of a large coalition of health and education groups, to try and add a full $7 billion over the President's FY 2007 budget request to their bill. They were successful in their negotiations. The House-passed bill includes an increase of about $1 billion for health programs. Details from the bill language for health programs/agencies are below. The Senate expects to take up the bill the week of February 12th. However, time is running out; the current continuing resolution expires on Feb. 15th.

- A $100 million increase for CDC to prepare for and respond to an outbreak of pandemic influenza and other emerging infectious diseases. These funds are appropriated as part of the Public Health and Social Services Emergency Fund.
- A $1.3 billion increase to the President's Emergency Plan for AIDS Relief (PEPFAR). Based on past appropriations, a significant portion of these funds will likely be transferred to CDC. In FY 2006, CDC received approximately $607 million in PEPFAR funds (approximately 32% of the total PEPFAR funding).
- An increase of approximately $30 million for the Section 317 immunization program. Language rescinds the funds previously available for purchasing bulk monovalent influenza vaccine and makes these funds available for other immunization purposes.
- A reduction of Buildings and Facilities funding by approximately $24 million below the FY 2006 level. Total funding is $134.4 million.
- Prohibits CDC from using HIV funding for new activities authorized under the reauthorized Ryan White Care Act.
- A $76 million increase for the Ryan White CARE State Grant program. This increase will help states who are disadvantaged by the new formula in the reauthorized program.
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HHS FUNDS ADVANCED DEVELOPMENT OF H5N1 INFLUENZA VACCINES

-- HHS Secretary Mike Leavitt announced January 17 that the department has awarded contracts totaling $132.5 million to three vaccine makers for the advanced development of H5N1 influenza vaccines using an immune system booster called an adjuvant. An adjuvant is a substance that may be added to a vaccine to increase the body's immune response to the vaccine's active ingredient, called antigen.

"In the event of an influenza pandemic, a vaccine that uses adjuvant could provide a way to extend a limited vaccine supply to more people," Secretary Leavitt said. "These contracts are a continuation of our aggressive multi-pronged approach to a potentially critical public health challenge."

The Department has awarded five-year contracts to GlaxoSmithKline for $63.3 million and to Novartis Vaccines and Diagnostics, Inc. for $54.8 million. In addition, HHS is funding IOMAI Corporation for $14.4 million for 15 months to complete Phase 1 clinical trials of their candidate vaccine. IOMAI may receive an additional $114 million in funding upon successful completion of the Phase 1 trials. Phase I trials are the first stage of testing in people and normally include a small (usually less than 100) group of healthy volunteers. Overall the three contracts support advanced development work through Phase 3 clinical trials in the U.S. that are aimed at obtaining U.S. licensure for the product. In addition, the contracts support the establishment of U.S.-based manufacturing capabilities.

Under the contracts each company will build up its capacity to produce within six months after the onset of an influenza pandemic either 150 million doses of an adjuvant-based pandemic influenza vaccine or enough adjuvant for 150 million doses of a pandemic influenza vaccine. In addition to supporting the development of each company's antigen-sparing vaccine candidate, the contracts also require each company to provide its proprietary adjuvant for U.S. Government-sponsored, independent evaluation with influenza vaccines from other manufacturers.

Initial clinical studies of H5N1 vaccine in humans have shown that two 90-microgram doses of the vaccine are required to stimulate a level of immune response that researchers anticipate would provide protection for an individual against the H5N1 strains that have been spreading among birds in Asia. However, the addition of adjuvant to these candidate vaccines may reduce the amount of antigen (active ingredient) per dose needed to achieve effective individual protection.

HHS' effort to pursue adjuvant-based vaccine is part of a broader effort by the department to accelerate the development and production of new technologies for influenza vaccines within the U.S. For example, in May 2006 HHS announced a $1 billion investment to support the advanced development of cell-based production technologies for influenza vaccines and will help to modernize and strengthen the nation's influenza vaccine production by creating an alternative to producing influenza vaccines in eggs.

The H5N1 strain of avian flu has spread to more than 40 countries and has led to the deaths of hundreds of millions of additional birds, which has heightened concern about the possibility of a human flu pandemic. Furthermore, the number of avian flu cases in humans has reached more than 260 cases in 10 countries. More than half of those persons infected have died. To date, H5N1 avian influenza has remained primarily an animal disease, but should the virus acquire the ability for sustained transmission among humans, the potential for an influenza pandemic would have grave consequences for global public health.

More information on pandemic preparedness including information on vaccines can be found online at http://www.pandemicflu.gov/vaccine/index.html.

FOLIC ACID MAY PREVENT CLEFT LIP AND PALATE --A new study finds that women who take folic acid supplements early in their pregnancy can substantially reduce their baby's chances of being born with a facial cleft.

Researchers at the National Institute of Environmental Health Sciences (NIEHS), part of the National Institutes of Health, found that 0.4 milligrams (mg) a day of folic acid reduced by one third the baby's risk of isolated cleft lip (with or without cleft palate). Folic acid is a B vitamin found in leafy vegetables, citrus fruits, beans, and whole grains. It can also be taken as a vitamin supplement, and it is added to flour and other fortified foods. The recommended daily dietary allowance for folate for adults is 400 micrograms or 0.4 mg.

"These findings provide further evidence of the benefits of folic acid for women," said Allen J. Wilcox, M.D., Ph.D., lead NIEHS author on the new study published online in the *British Medical Journal*. "We already know that folic acid reduces the risk of neural tube defects, including spina bifida. Our research suggests that folic acid also helps prevent facial clefts, another common birth defect." In the United States, about one in every 750 babies is born with cleft lip and/or palate.
"Folic acid deficiency causes facial clefts in laboratory animals, so we had a good reason to focus on folic acid in our clefts study," said Wilcox. "It was one of our main hypotheses."

The researchers examined the association between facial clefts and mothers' intake of folic acid supplements, multivitamins, and folates in diet. The researchers found that folic acid supplementation of 400 micrograms or more per day reduced the risk of isolated cleft lip with or without cleft palate by one-third, but had no apparent effect on the risk of cleft palate alone.

"A mother's nutrition during pregnancy is clearly an environmental factor that can affect the health of her fetus," said NIEHS Director David A. Schwartz, M.D. The NIEHS researchers are continuing to analyze their data for evidence of other environmental exposures that increase the risk of facial clefts.

This population-based study was conducted in Norway, which has one of the highest rates of facial clefts in Europe and does not allow foods to be fortified with folic acid. The investigators contacted all families of newborn infants with clefts (either cleft lip with or without cleft palate (CLP) or cleft palate only (CPO)) born between 1996 and 2001 in Norway. The study included 377 babies with CLP and 196 with CLO; as well as 763 control babies randomly selected from all live births in Norway.

The researchers mailed two questionnaires to each of the mothers participating in the study. The first questionnaire mailed soon after delivery focused on general health information, including demographics, reproductive history and information about

environmental exposures including smoking, alcohol and vitamins; whereas the second questionnaire focused on nutrition and diet during the pregnancy. Mothers who reported taking folic acid supplements and or multivitamins were asked to send in their empty bottles or labels to confirm dosage.

The nutrition questionnaire included questions on mothers' fruit and vegetable consumption during the first three months of pregnancy.
The researchers estimated that 22 percent of isolated CLP cases in Norway could be averted if all pregnant women took 0.4 mg of folic acid per day.

In addition to funding from NIEHS, this research was supported by the Johan Throne Holst Foundation for Nutrition Research, and the Thematic Perinatal Nutrition at the Medical Facility of University of Oslo, Norway. Researchers at the University of Bergen, the University of Oslo, and the Departments of Plastic Surgery in Oslo and Bergen, Norway, also contributed to this study.

DAMAGE TO SPECIFIC PART OF THE BRAIN MAY MAKE SMOKERS 'FORGET' TO SMOKE -- Preliminary research supported by the National Institute on Drug Abuse (NIDA), a component of the National Institutes of Health, has found that some smokers with damage to a part of the brain called the insula may have their addiction to nicotine practically eliminated. The study is published in the January 26, 2007 issue of the journal *Science*.

"The researchers found that smokers with insula lesions were 136 times more likely to have their addiction to nicotine erased than smokers with other brain injuries," says NIDA Director Dr. Nora Volkow. "Research that identifies a way to alter the function of this area could have major implications for smokers and addiction treatment in general." Dr. Antoine Bechara of the University of Southern California and his colleagues identified 19 smokers who had experienced some degree of brain damage, resulting in lesions on the insula. Of these, 13 quit smoking. The scientists also identified 50 smokers whose brain injuries did not include damage to the insula. Of these, 19 quit smoking. The scientists recognized that individuals from both groups — those with damage to the insula or damage to other brain regions — were able to quit smoking. However, some smokers experienced a greater ease in quitting. The scientists developed four behavioral criteria for determining who fell into this group; those who reported: (1) quitting smoking less than one day after the brain injury; (2) their difficulty of quitting was less than three on a scale of one to seven; (3) that they did not smoke again after quitting; and (4) no urge to smoke since quitting.

The researchers found that twelve of the 13 participants who quit smoking following damage to their insula met these criteria as compared to only four of 19 participants who quit smoking after sustaining damage to other brain areas.

"Participants with damage to the insula were overwhelmingly more likely to experience a true disruption of the urge to smoke, characterized by an almost immediate cessation of smoking with no reported struggles to maintain their abstinence," said Dr. Bechara. "We

know that the insula plays a role in the desire to smoke by anticipating physical effects brought on by emotions such as those induced by environmental cues. Thus, damage to the insula could lead smokers to feel that their bodies have ’forgotten‘ the urge to smoke.”

“Cigarette smoking is the most common preventable cause of illness and death in the modern world, and it is an addictive behavior,” says Dr. Volkow. “While additional research is needed to replicate these findings, the current study suggests that damage to the insula can impact the conscious ’urge‘ to smoke, making it easier for smokers to quit and remain abstinent. Medications that target receptors within the insula may offer promise in developing more effective smoking cessation therapies in the future.”