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FOLIC ACID AND PREVENTION OF SPINA BIFIDA AND ANENCEPHALY, 10 YEARS AFTER THE US PUBLIC HEALTH SERVICE RECOMMENDATION

To reduce the risk of spina bifida and anencephaly (NTDs), the US Public Health Service (USPHS) recommended in September 1992, that women of childbearing years consume 400mg of folic acid/day. Moreover, USPHS recommended that women with high risk consume 400 mg/day when not trying to get pregnant. In addition, in 1991, the Centers For Disease Control (CDC) recommended that high-risk women with past pregnancies affected by NTDs consume 4,000 mg/day of folic acid from the initial stages of getting pregnant through their first trimester. The recommendations were based on scientific

research results involving both controlled and randomized studies that demonstrated increased folic acid consumption reduced the risk for having a pregnancy affected by a NTD.

The 1992 USPHS recommendation stated that increased folic acid consumption could be achieved in three ways: by increasing consumption of foods rich in naturally occurring folate, by increasing use of folic acid containing dietary supplements, and by fortification of a staple foodstuff.

To help achieve this goal, in 1998, the Food and Drug Administration (FDA) initiated a requirement that producers of cereal grain products enrich their products with 140 mg/100 grams of grain. This level of fortification was chosen with the desired result that women of reproductive age would increase their consumption by an average of 100 mg of folic acid/day.

Blood folate levels for US women of reproductive years were substantially higher according to data from the National Health and Nutrition Examination Survey (NHANES) (1999 and 2000) than that from NHANES III (1987-1994) (1). It is assumed that the rise in blood folate levels is due to increased consumption of fortified cereal grain products and fortified ready-to eat breakfast cereals rather than folic-acid dietary supplements based on data from the March of Dimes National Survey of pre-pregnancy awareness and behavior among women of child-bearing years. However, certain subgroups have experienced more limited success in increasing folic acid consumption than the national average.

Neural tube defect (NTD) rates have declined by approximately 20-30 percent since the institution of folic acid fortified cereal grains (2). The decrease in NTD rates is not the 50-70 percent decrease predicted by USPHS if all women of reproductive age consume 400 mg of folic acid/day. The decrease is also lower than predictive values based on the substantial rise in blood folate levels among US women of childbearing years.

It is possible that since the data is aggregate, the subpopulations of women who are considered high-risk for NTDs might not have access to fortified food products, they may not absorb as much folic acid, or they do not consume as much folic acid food products. This population could benefit from targeted interventions.

Between 1995 and 2002, awareness of the term folic acid increased from 52 percent to 80 percent within the reproductive-age women population (3). Yet, just 20 percent of the women knew that folic acid could prevent birth defects. This finding indicates that educational efforts directed towards this population might positively influence knowledge between the link of folic acid consumption and decreased NTDs.

More alarming is that 90 percent of physicians who responded to a survey conducted in Florida (CDC, unpublished data, 2002) knew that folic acid consumption is linked to NTDs, but only a limited proportion could identify the recommended daily intake of 400mg for the general population; moreover, an even smaller percentage could state the

recommended dose of 4,000 mg for women of high risk. This points to a need for more educational efforts directed towards physicians.

References:

1. CDC. Folate status in women of childbearing age by race/ethnicity, United States, 1999-2000. MMWR 2002 (in press).
2. Mathews TJ, Honein MA, Erickson JD. Spina bifida and anencephaly prevalence, United States, 1991-2000. MMWR; September 13, 2002; 51 (No.RR-13):8-10.
3. March of Dimes Birth Defects Foundation. Folic acid and the prevention of birth defects: a national survey of pre-pregnancy awareness and behavior among women of childbearing age, 1995-2002. Conducted by the Gallup Organization. White Plains, NY: March of Dimes Foundation, May 2002. Publication No. 31-1677-02.

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FDA ANNOUNCES INITIATIVE TO PROVIDE BETTER HEALTH INFORMATION FOR CONSUMERS

Commissioner of Food and Drugs Mark B. McClellan, MD, recently announced a bold major new initiative to make available more and better information about foods and dietary supplements, to improve the public health and to help American consumers prevent a host of diseases and improve their health by making sound dietary decisions.

The Consumer Health Information for Better Nutrition initiative is designed to foster two complementary goals concerning the labeling of food and dietary supplements: to encourage makers of conventional foods and dietary supplements to make accurate, science-based claims about the health benefits of their products, and to help eliminate bogus labeling claims by taking on those dietary supplement marketers who make false or misleading claims, and to encourage makers of conventional foods and dietary supplements to make accurate, science-based claims about the health benefits of their products.

"By putting credible, science-based information in the hands of consumers, we hope to foster competition based on the real nutritional value of foods rather than on portion size or spurious and unreliable claims," Health and Human Services Secretary Tommy G. Thompson said. "Such labeling can help empower consumers to make smart, healthy choices about the foods that they buy and consume.

The consumer health information initiative comprises three related actions:

- Issuing guidance on qualified health claims for conventional foods and dietary supplements. Any such claims must be pre-approved by FDA and meet the "weight of the scientific evidence" standard, including support by a credible body of scientific evidence.
- Strengthening enforcement of dietary supplement rules, FDA is emphasizing its commitment to carrying out the intent of Congress in the Dietary Supplement Health and

Education Act of 1994 by outlining its enforcement strategy against false or misleading claims about dietary supplements. As an example of its commitment to strong enforcement, FDA is also announcing a seizure of a dietary supplement making unapproved drug claims.

· Establishing an FDA Task Force on Consumer Health Information for Better Nutrition. This task force will develop a framework to help consumers obtain accurate, up-to-date, and science-based information about conventional food and dietary supplements.

This includes the development of additional scientific guidance on how the "weight of the evidence" standard will be applied, as well as the development of regulations that will give these principles the force and the effect of law. "Our mission at FDA is to improve health outcomes for the nation, and some of the best opportunities for improving health involve informed choices by consumers," said Dr. McClellan. "Through this Better Health Through Better Information initiative, we are committed to improving opportunities for consumers to get scientifically accurate information about the health consequences of the foods they consume, and to enhancing our enforcement efforts against those who would make false or misleading claims for their products."

The guidance on health claims FDA issued sets forth the conditions under which the agency intends to exercise enforcement discretion for qualified health claims about conventional foods and dietary supplements. FDA currently permits such claims for dietary supplements under certain circumstances but not for conventional foods - even though in general much more scientific data is available to support the health benefits of foods. To meet the criteria for making a new, qualified claim on a conventional food, the manufacturer would need to provide a credible body of scientific data supporting the claim. The company would need to demonstrate, based on a fair review by scientific experts of the totality of information available, that the "weight of scientific evidence" supports the proposed claim.

All qualified health claims will require review by FDA before they may be used on the food label. In the enforcement action recently announced, FDA revealed that United States Marshals on Monday, December 16, 2002, seized approximately 3000 bottles, valued at more than \$100,000, of EverCLR, a dietary supplement. EverCLR is marketed by Halo Supply Company of San Diego, Calif., as a "natural" treatment for viruses, including the herpes virus, and for "cold and flu protection." None of these claims has been substantiated. In court documents, FDA charges that EverCLR is an unapproved and therefore illegal new drug because it is promoted to treat or prevent specific diseases and conditions. FDA also charges that EverCLR is misbranded because its labeling lacks adequate directions for use. In addition, FDA released a report on its strengthened enforcement actions over the past year against dietary supplements that make false or misleading claims. FDA's report also outlines an aggressive enforcement strategy against such claims and outlines enforcement priorities so that manufacturers will be on notice. A Notice of Availability about FDA's guidance on qualified health claims went on display recently at the office of the Federal Register. Both the notice and the guidance itself are available online at <http://www.fda.gov/ohrms/dockets/default.htm>. FDA's Dietary Supplement Enforcement Report is available on FDA's website,

<<http://www.fda.gov/>>, as is the document "FDA's Consumer Health Information for Better Nutrition Initiative," a brief, descriptive summary of FDA's entire consumer health information initiative.

FDA advises consumers to consult a health professional before taking dietary supplements. Information about dietary supplements is available on FDA's website at <http://www.cfsan.fda.gov/~dms/supplmnt.html>. Consumer advice from FDA about purchasing medicines on line may be found at <http://www.fda.gov/oc/buyonline/default.htm>.

Source: FDA Press Release; December 18, 2002.

NEW GUIDELINES FOCUS ON FISH, FISH OIL, OMEGA-3 FATTY ACIDS

Healthy people should eat omega-3 fatty acids from fish and plant sources to protect their hearts, according to updated American Heart Association recommendations (1).

"Omega-3 fatty acids are not just good fats; they affect heart health in positive ways," says Penny Kris-Etherton, PhD, RD, lead author of the report. They make the blood less likely to form clots that cause heart attacks and protect against irregular heartbeats that cause sudden cardiac death.

The comprehensive report examines the health benefits of omega-3 fatty acids in the context of cardiovascular disease (CVD) risk reduction and considers the recent Environmental Protection Agency and the Food and Drug Administration (FDA) guidance about the presence of contaminants in certain species of fish.

Since 2000, the American Heart Association's dietary guidelines have recommended that healthy adults eat at least two servings of fish per week, particularly fish such as mackerel, lake trout, herring, sardines, albacore tuna and salmon. These fish contain two omega-3 fatty acids, eicosapentaenoic and docosahexaenoic acids (EPA and DHA). A third kind is less potent, alpha-linolenic acid and comes from plants, including tofu and other forms of soybeans, canola, walnut and flaxseed and oils made from those nuts and seeds.

People who have elevated triglycerides may need 2 to 4 grams of EPA and DHA per day provided as a supplement. Even the 1 gram/day dose recommended for patients with existing CVD may be more than can readily be achieved through diet alone. These people should consult their physician to discuss taking supplements to reduce heart disease risk. Patients taking more than 3 grams of omega-3 fatty acids from supplements should do so only under a physician's care.

The FDA has noted that high intakes could cause excessive bleeding in some people. Depending on their stage of life consumers need to be aware of both the benefits and risks of eating fish. Children, pregnant and nursing women may be at increased risk of exposure to excessive mercury from fish but also are generally at low risk for CVD. Thus, avoiding potentially contaminated fish is a higher priority for these groups, says Kris-Etherton.

For middle aged and older men, and postmenopausal women, the benefits of eating fish far outweigh the risks within the established guidelines.

"This is hopeful news as we have found that the effects of omega-3 fatty acids on heart disease risk is seen in relatively short periods of time," Kris-Etherton says. "The research shows that all omega-3 fats have cardio-protective benefits, especially those in fish."

Although the mechanisms responsible for omega-3 fatty acids' reduction of CVD risk are still being studied, research has shown:

- Decreased risk of sudden death and arrhythmia.
- Decreased thrombosis (blood clot).
- Decreased triglyceride levels.
- Decreased growth of atherosclerotic plaque.
- Improved arterial health.
- Lowered blood pressure.

Reference:

1. Kris-Etherton PM, Harris WS, Appel LJ. Fish consumption, fish oil, omega-3 fatty acids, and cardiovascular disease. *Circulation*; November 19, 2002; 106(21); pp. 2747-57.

Source: AHA Press Release; November 18, 2002;

http://www.eurekalert.org/emb_releases/2002-11/aha-ngf111302.php.

IOM REPORTS NEW EATING AND PHYSICAL ACTIVITY TARGETS

The National Academies' Institute of Medicine (IOM) recently released the newest recommendations for healthy eating. This report was focused mainly on macronutrients, carbohydrates, fats, and proteins, and physical activity. The scientists on the IOM Food and Nutrition Board report macronutrient targets based on the daily energy and nutrition needs, while minimizing the risks of chronic disease.

The current report includes Dietary Reference Intakes, which include upper limits, "levels at which no adverse consequences occur, nutrition for optimum health," said Alice Lichtenstein, DSc, professor of nutrition at the Friedman School of Nutrition Science and Policy at Tufts University.

For the first time in a report of this kind, the IOM has recommended percentage ranges for the macronutrients, which are as follows for adults and children (percentages vary for infants to young children):

- 45 percent-65 percent calories from carbohydrates
- 20 percent-35 percent calories from fat
- 10 percent-35 percent calories from protein

Prior to this report, the upper limits had not been recommended for macronutrients, but these changes come at a time when public health officials are concerned about the prevalence of overeating and the increasing number of obesity cases in the United States, and feel it is necessary to recommend upper limits.

In this report, the IOM report states adults and children should be physically active (at a moderate intensity) for at least one hour each day, which is twice the amount of physical activity the IOM recommended six years ago. "The recommendation for at least one hour of moderate physical activity is a good one," said Lichtenstein.

The IOM also recommends limiting:

- Added sugars to 25 percent total calories per day
- Consumption of saturated fats (meats, baked goods, full-fat dairy products) to a minimum

Further, the IOM has made the following unprecedented recommendations for the nine essential amino acids, as well as the omega-3 and omega-6 fatty acids:

- The recommended daily intake of omega-6 fatty acids (safflower, corn oil) is 17 grams for men, 12 grams for women
- The recommended daily intake of omega-3 fatty acids (soybean, flaxseed oils) is 1.6 grams for men, 1.1 grams for women

Go to www.iom.edu/iom/iomhome.nsf/Pages/Recently+released+Reports to view the IOM report.

Source: Nutrition Week; Vol. XXXII(17); September 16, 2002; p. 2.

HOW TO DEAL WITH THE HAZARDS OF LEAD

Lead is a highly toxic metal that was used for many years in paints and other household products, especially in houses built before 1978. Lead has been linked to a range of adverse health effects, from behavioral problems to learning disabilities, and even seizures and death. At greatest risk are children under age 6.

To help explain lead contamination, the Environmental Protection Agency has created a Web site at www.epa.gov/lead that tells how to determine if your home has lead and what to do if it is found. Typically, household environmental lead contamination is found in deteriorating lead-based paints and lead-contaminated dust and soil. The EPA site suggests some simple steps to help protect your family from these hazards.

For those who want to delve deeper into the science of environmental lead, the site includes a number of technical reports, including ones that examine the extent of lead hazards, lead removal, and the link between blood lead and environmental lead exposure. **Source:** John Henkel; FDA Consumer; November-December 2002; p. 37.

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