THE CSTE WASHINGTON REPORT

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EDITOR'S NOTE: In observance of Africa Malaria Day on April 25, 2004, the Centers for Disease Control and Prevention (CDC) launched a new Web site with updated information on global and domestic malaria prevention and control (www.cdc.gov/malaria). Approximately one million malaria deaths occur annually worldwide. About 90 percent of these deaths occur in Africa where every 30 seconds a child dies from malaria. "Malaria remains one of the world's most serious reemerging infectious diseases, causing suffering and death for millions each year," said Dr. James Hughes, director of CDC's infectious disease program. "CDC is heavily involved in global malaria efforts, working with many partners to find new ways to prevent and control the disease in endemic countries and to ensure that American travelers and other at-risk individuals have the information they need to protect themselves" -- 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

BUDGET UPDATE – House and Senate negotiations are continuing on the conference report on the FY 2005 Budget Resolution. Four Senate Republican Moderates are still insisting on applying the PAYGO rules (offsets) to all tax cuts, even three popular measures addressing the marriage penalty tax, child tax credit and expanded tax brackets for lower and middle income taxpayers. However, various compromises are being discussed and it is still expected an agreement will be reached by the end of this week. The overall discretionary spending limit for FY 2005 has been agreed to and is 3 percent below the overall FY 2004 appropriations level. Appropriations Subcommittees are waiting for the Budget Resolution to conclude and for their respective 302b spending allocations to be awarded. The Labor-HHS-Education Subcommittee, which funds most of the federal public health service, including all of CDC, and needs an additional $4.5 billion over the FY 2004 final allocation to meet the President's budget request level of about $142 million for the agencies the Subcommittee funds in its annual appropriations bill. The situation is as bleak as many experienced public health advocates have ever witnessed with deep cuts in a number of health programs likely. Advocates are currently circulating a sign on letter urging the House and Senate Appropriations principals and leadership to award the Labor-HHS-Education Subcommittees the highest possible 302b allocation. Nearly 300 health groups have already signed the letter.

CSTE TESTIFIES BEFORE HOUSE COMMITTEE – CSTE Executive Committee Member, Matthew Boulton, MD, MPH (Michigan), testified before the House Labor-HHS-Education Subcommittee on Appropriations on April 20th. He presented CSTE's funding priorities for FY 2005, including a new epidemiology-public health laboratory workforce initiative.

OTHER LEGISLATIVE NEWS -- The week of April 19th, a number of bills to increase access to pregnancy prevention and health screening services for adult women and adolescents were introduced just prior to the enormous March for Women's Lives in Washington last weekend (H.R. 4182, H.R. 4192, S. 2336). In introducing his bill, Putting Prevention First Act, Sen. Harry Reid (D-NV) stated,

The Putting Prevention First Act will help reduce the staggering rates of unintended pregnancies in America. It will reduce the rate of infection with sexually transmitted diseases, reduce the number of abortions, and improve access to health care for women.

Specifically, the Putting Prevention First Act will: No. 1, end insurance discrimination against women; No. 2, improve awareness and understanding of emergency contraception; No. 3, ensure that rape victims have information about emergency contraception and access to emergency contraception; No. 4, increase funding for the National Family Planning Program; No. 5, provide funding to allow States to implement a comprehensive approach to sexuality education that includes information about both abstinence and contraception; No. 6, expands teen pregnancy prevention programs; and, No. 7 allows States to expand Medicaid family planning services to low-income women without having to apply for a waiver from the Federal Government.

On April 22nd, Sen. Chris Bond (R-MO) introduced the "Arthritis Prevention, Control, and Cure Act of 2004" (S. 2338). Noting that various kinds of arthritis affects 70 million Americans and is the leading cause of adult disability, the bill requires the HHS Secretary to develop a national arthritis action plan. The plan would delineate federal and state prevention and control activities and establishment of a national arthritis education and outreach program. State surveillance and epidemiological activities relating to the prevalence of arthritis and assessment of disparities in arthritis prevention, diagnosis, management and care are key provisions in the bill which does not provide a specific authorization for appropriations level.

On April 22nd, the Senate took up, but failed to reach the required 60 votes to invoke cloture, or termination of filibuster on the Fairness in Asbestos Injury Resolution Act of 2004 (S. 2290). The bill would establish a federal claimant process for compensating victims of asbestos-related disease and injury funded by asbestos defendants.

OTHER NEWS -- On April 8, HHS Secretary Tommy Thompson announced the appointment of Stewart Simonson as Assistant Secretary for Public Health Preparedness. Mr. Simonson previously served as Special Counsel to the Secretary within the Office of the Assistant Secretary for Public Health Emergency Preparedness.

HHS ANNOUNCES NEW INITIATIVE TO IMPROVE QUALITY OF CARE FOR MEDICARE BENEFICIARIES WITH CHRONIC ILLNESSES -- HHS Secretary Tommy G. Thompson April 20 announced a new Medicare initiative to improve the quality of care for people living with multiple chronic illnesses by helping them manage their conditions and encouraging better coordinated care.

"This initiative will help hundreds of thousands of seniors and disabled Americans with chronic illnesses to stay healthier and receive higher quality care," Secretary Thompson said. "Too often, seniors with serious chronic illnesses move from doctor to doctor for their specific health problems without any single doctor getting a full picture of their needs. This new program will give them the support they need to better manage their conditions and stay healthy."

The initiative, known as the Voluntary Chronic Care Improvement Program, will reach about 150,000 to 300,000 beneficiaries who are enrolled in traditional fee-for-service Medicare and who have multiple chronic conditions, including congestive heart failure, complex diabetes and chronic obstructive pulmonary disease. It was authorized by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), the legislation that also added a prescription drug benefit to Medicare.

Beneficiaries who agree to participate will receive help in managing their conditions, following their physicians' plan of care and ensuring that they know about, and can take advantage of, Medicare-covered benefits that will help to reduce their health risks. Similar strategies have been widely and successfully adopted across the health care system.

Chronic conditions are a leading cause of illness, disability, and death among Medicare beneficiaries and account for a disproportionate share of health care expenditures. For example, about 14 percent of Medicare beneficiaries have congestive heart failure but account for 43 percent of Medicare spending. About 18 percent of Medicare beneficiaries have diabetes, accounting for 32 percent of Medicare spending.

"This new program creates a new business platform that will encourage innovation in addressing deficiencies in chronic care in the fragmented fee-for-service health care delivery system," said Centers for Medicare & Medicaid Services Administrator Mark B. McClellan, M.D., Ph.D. "The Chronic Care Improvement Program demonstrates this Administration's commitment to improving and strengthening the traditional fee-for-service Medicare program. This program is designed to support and improve physician/patient relationships. Physicians will appreciate the timely, accurate information these services can provide."

To launch the new initiative, HHS' Centers for Medicare & Medicaid Services (CMS) is seeking innovative proposals from qualified organizations to run large-scale chronic care improvement projects to help beneficiaries with congestive heart failure, complex diabetes and chronic obstructive pulmonary disease. To qualify, organizations must have demonstrated success in population-based chronic care improvement services.

CMS will choose about 10 projects, each of which will serve about 15,000 to 30,000 beneficiaries in specific regions around the country over a three-year period. Each project will provide participating beneficiaries with information and support to help them better care for their conditions. In addition, organizations will work with physicians to ensure that the patient care is coordinated appropriately with other physicians. Elements of the projects that succeed in improving quality of care, reducing Medicare costs and promoting patient satisfaction could be expanded to reach more Medicare beneficiaries with chronic health conditions.

The chronic care improvement services will supplement the benefits already provided under fee-for-service Medicare. Beneficiary participation will be completely voluntary and will not affect beneficiaries' access to services or their ability to choose their doctors and other health care providers. Their Medicare benefits will not change as a result of receiving these additional services.

CMS, which will oversee the new program, will publish a notice in the April 23 Federal Register soliciting proposals from organizations to provide care support services for beneficiaries with multiple chronic conditions, including congestive heart failure, complex diabetes, and chronic obstructive pulmonary disease (COPD). More information, including the solicitation for the program, is available http://www.cms.hhs.gov/medicarereform/ccip.

CDC DEBUTS NEW MALARIA WEB SITE -- In observance of Africa Malaria Day on April 25, 2004, the Centers for Disease Control and Prevention (CDC) launched a new Web site with updated information on global and domestic malaria prevention and

control (www.cdc.gov/malaria). Approximately one million malaria deaths occur annually worldwide. About 90 percent of these deaths occur in Africa where every 30 seconds a child dies from malaria.
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CDC was created in 1946 to fight malaria in the United States. Nearly 60 years later, CDC participates actively in the worldwide battle against malaria abroad and at home, where reintroduction of the disease by travelers arriving or returning from malaria-endemic countries is a constant threat.

Features of the new malaria Web site include:

* How to prevent and control malaria in the United States and abroad
* Facts and figures on the impact of malaria
* CDC malaria activities nationally and globally
* Interactive training using clinical and epidemiologic case studies
* Malaria treatment information for U.S. clinicians
* Expanded information on malaria for travelers
* Malaria's biology, epidemiology, geographic distribution, and health impact
* Extensive list of references and resources

Additional information about Africa Malaria Day is available at http://www.afro.who.int/amd2004/ and http://rbm.who.int.

AHRQ EVIDENCE REPORTS CONFIRM THAT FISH OIL HELPS FIGHT HEART DISEASE -- Fish oil can help reduce deaths from heart disease, according to new evidence reports announced April 22 by the Agency for Healthcare Research and Quality. The systematic reviews of the available literature found evidence that long chain omega-3 fatty acids, the beneficial component ingested by eating fish or taking a fish oil supplement, reduce heart attack and other problems related to heart and blood vessel disease in persons who already have these conditions, as well as their overall risk of death. Although omega-3 fatty acids do not alter total cholesterol, HDL cholesterol, or LDL cholesterol, evidence suggests that they can reduce levels of triglycerides—a fat in the blood that may contribute to heart disease.

The review also found other evidence indicating that fish oil can help lower high blood pressure slightly, may reduce risk of coronary artery re-blockage after angioplasty, may increase exercise capability among patients with clogged arteries, and may possibly reduce the risk of irregular heart beats—particularly in individuals with a recent heart attack.

"These findings will help health care professionals and the public understand which benefits of omega-3 fatty acids have been scientifically proven and pinpoint areas where additional evidence is needed," said Carolyn M. Clancy, M.D., AHRQ's Director. "Translating scientific evidence into information that can be used to improve health and heath care is key to AHRQ's mission."

The evidence reports of the health effects of omega-3 fatty acids are part of a series conducted by AHRQ-supported Evidence-based Practice Centers at the request of the National Institutes of Health's Office of Dietary Supplements, which plans to use the findings to develop research agendas on the issues. Five reports are currently being issued, and an additional six reports will be issued next year.

Paul M. Coates, Ph.D., Director of NIH's Office of Dietary Supplements, said, "The reports describe some positive findings as well as a number of areas where data are insufficient to draw conclusions about the efficacy and safety of omega-3 fatty acids. The Office of Dietary Supplements, in collaboration with other NIH institutes, will use these reports to develop appropriate research agendas for omega-3 fatty acids that will fill these gaps in knowledge."

Findings from the three other AHRQ evidence reviews indicate that:

* Omega-3 fatty acids do not affect fasting blood sugar or glycosylated hemoglobin in people with type II diabetes, nor do they appear to affect plasma insulin levels or insulin resistance.
* Alpha-linolenic acid (ALA), a type of omega-3 fatty acid from plants such as flaxseed, soybeans, and walnuts, may help reduce deaths from heart disease, but to a much lesser extent than fish oil.
* Based on the evidence to date, it is not possible to conclude whether omega-3 fatty acids help improve respiratory outcomes in children and adults who have asthma.
* Omega-3 fatty acids appear to have mixed effects on people with inflammatory bowel disease, kidney disease and osteoporosis, and no discernible effect on rheumatoid arthritis.

The evidence reports and Evidence-based Practice Centers that produced them are: *Effects of Omega-3 Fatty Acids on Cardiovascular Disease*, *Effects of Omega-3 Fatty Acids on Cardiovascular Risk Factors and Intermediate Markers for Cardiovascular Disease*, and *Effects of Omega-3 Fatty Acids on Arrhythmogenic Mechanisms in Animal and Isolated Organ/Culture Studies* (Tufts-New England Medical Center EPC, Boston); *Health Effects of Omega-3 Fatty Acids on Asthma* (University of Ottawa EPC, Ottawa, Ontario); *Health Effects of Omega-3 Fatty Acids on Lipids and Glycemic Control in Type II Diabetes and the Metabolic Syndrome, and on Inflammatory Bowel Disease, Rheumatoid Arthritis, Renal Disease, Systemic Lupus Erythematosus, and Osteoporosis* (Southern California-RAND EPC, Santa Monica).

Summaries of evidence reviews are available on AHRQ's Web site at www.ahrq.gov/clinic/epcindex.htm#dietsup, and on the National Guideline

Clearinghouse™ Web site at www.guideline.gov (select "EPC reports"). Free printed copies are available from the AHRQ Publications Clearinghouse by calling 1-800-358-9295 or sending an E-mail to ahrqpubs@ahrq.gov.

SECOND NIAID SARS VACCINE CANDIDATE HELPS MICE FEND OFF SARS
-- An experimental vaccine based on a critical piece of the SARS virus protects mice from SARS infection, researchers from the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health, have found. When exposed to the SARS virus, immunized mice produced SARS-specific antibodies, and virus replication was nearly eliminated.

The new report, published last week in the *Proceedings of the National Academy of Sciences* online, is the second from NIAID in recent weeks describing a promising SARS vaccine candidate.

"We now have two candidate vaccines, based on two distinct technologies, shown to be effective against SARS infection in mice," says NIAID Director Anthony S. Fauci, M.D. "The animal model employed in both studies was developed by NIAID researchers as well. By taking various approaches to vaccine development, we are making significant research progress against a disease that was unknown little more than a year ago."
SARS is caused by a coronavirus, a family of viruses so named because spikey proteins protrude from the virus's surface, giving the microbe a crown-like appearance. The newly described vaccine is based on the spike (S) protein. Because the virus initiates infection by attaching to and entering cells using its S protein, a vaccine based on this protein should closely mimic natural infection, notes senior author, Bernard Moss, M.D., Ph.D.
Investigators inserted the gene encoding the S protein into a virus called modified vaccinia Ankara (MVA). Neither MVA nor the solitary gene from the SARS virus can cause disease. Instead, MVA simply ferries the SARS gene into the body. First developed as a vaccine against smallpox, MVA has an excellent safety record in humans, says Dr. Moss, and it efficiently stimulates both the antibody and cellular arms of the immune system.
Dr. Moss and his colleagues collaborated in this research with fellow NIAID scientist Kanta Subbarao, M.D., whose lab recently developed the mouse model of SARS infection. In the current study, two groups of eight mice received doses of the MVA/S vaccine, delivered either into nose or as an injection into muscle, four weeks apart. One month after the second immunization, the rodents were exposed to SARS coronavirus via their nasal passages, mimicking the natural route of infection. Two days later, scientists examined the animals' lungs and nasal passages for evidence of SARS coronavirus replication. Almost no virus was seen in the lungs, and virus levels in the nose were greatly diminished. The results were the same regardless of the vaccination method.

The NIAID scientists also tested the blood of immunized mice to determine the level of antibodies that neutralize the virus. Mice immunized with the MVA/S vaccine developed S-specific neutralizing antibodies. Control mice immunized with MVA alone did not develop antibodies and were not protected from SARS infection.

Finally, the investigators determined that immunity to SARS can be passively acquired. Blood serum from MVA/S immunized mice (which contained anti-SARS antibodies) was injected into non-immunized mice. The non-immunized mice could then fend off SARS infection almost as well as vaccinated mice.

Now that the essential role of S protein in a SARS vaccine has been demonstrated, says Dr. Moss, the researchers will begin to selectively modify the protein in an effort to enhance its immune-stimulating powers. Meanwhile, work is continuing in Dr. Subbarao's lab to develop improved rodent models of SARS. Currently, while mice can be infected with SARS virus, they do not become ill. Thus, the protective value of the experimental vaccine can only be inferred, not shown directly.