THE CSTE WASHINGTON REPORT

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EDITOR'S NOTE: In preparation for the fall and winter season, the Centers for Disease Control and Prevention (CDC) has posted the working draft version of its "Public Health Guidance for Community-Level Preparedness and Response to Severe Acute Respiratory Syndrome (SARS)," on its web site. The SARS Plan is a working document that outlines the concepts and strategies that would guide the U.S. response in the event of a SARS outbreak. It also describes many of the activities needed at the federal, state, and local levels to prepare for and respond rapidly and decisively to a reemergence of SARS. State and local health departments, hospitals and other public health providers will have an opportunity to comment on the draft and provide input to an effective SARS preparedness plan for the United States. The plan is designed to assist federal, state, and local public health partners in developing or coordinating their own SARS preparedness and response

planning activities, while taking into account available healthcare and public health resources, and other factors that are unique at each level. 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

HOUSE PASSES CONTINUING RESOLUTION – Earlier this week the House passed another Continuing Resolution (CR) that is designed to serve as a mechanism for including an omnibus appropriations bill that wraps together six unfinished appropriations bills. The CR extends funding for the federal government at the FY 2003 level until November 7th. The current CR expires on October 31st. The short time frame for the November 7th CR is designed to also pressure conferees working on four appropriations bills that have passed both the House and Senate to finish up quickly. The latter includes the FY 2004 Labor-HHS-Education Appropriations bill which funds most public health programs including all of CDC. The largest stumbling block to successful conference of the Labor-HHS-Ed bill is a provision prohibiting implementation of proposed new overtime rules in the Labor Department. The President has stated he will veto a bill that contains the prohibition and it is unlikely there are enough votes in the House and Senate to override his veto. Sen. Specter (R-PA) proposed a compromise yesterday to the impass, but House Republican conferees rejected it.

BILLS ADDRESSING GROWING NUMBERS OF PREMATURE INFANTS INTRODUCED -- Four bipartisan bills were introduced on October 14th and 15th addressing the growing numbers of infants that are born prematurely: from a rate of 9.4 percent in 1981 to 11.9 percent in 2001. S. 1726 introduced by Sen. Alexander (R-TN) and Dodd (D-CT) and H.R. 3350 introduced by Rep. Upton (R-MI) and several Democrats expands NIH research into the causes of pre-term and low birthweight infants; expands CDC research into the relationship between prematurity, birth defects and developmental disabilities, and requires the CDC to review the Pregnancy Risk Assessment Monitoring Survey to ensure the survey includes information relative to medical care and intervention received; calls for NIH and CDC to jointly contract with the Institute of Medicine to review the epidemiology of premature birth and low birthweight, quality of life issues, associated costs, options for preventive interventions and best practices; creates a grant program to improve public and health care provider education about prematurity; and establishes an interagency coordinating council on prematurity and low birthweight. No specific authorization for appropriations is provided; just such sums as necessary.

S. 1734, introduced by Sen. Lincoln (D-AR) and Senators Lugar (R-IN) and Bingaman (D-NM) and H.R. 3293, introduced by Rep. DeGette (D-CO) amends Medicaid and the S-CHIP programs to provide states with the option to expand or add coverage of pregnant women. In introducing her bill, Sen. Lincoln made the following remarks:

"This legislation I introduced today gives States increased flexibility and the Federal resources needed to improve access to prenatal care for low-income pregnant women. Specifically, it will give States new options to cover pregnant women under the State Children's Health Insurance Program (SCHIP) and to cover low-income legal immigrant pregnant women and children under Medicaid and SCHIP…Additionally, this bill tackles a major prematurity risk factor--maternal smoking--by improving and expanding coverage for pharmaceuticals and counseling that will help income-eligible pregnant women enrolled in the program quit smoking. Almost 20 percent of pregnant women ages 15 to 44 smoke, according to the Centers for Disease Control and Prevention. …For some pregnant women, counseling is not enough and a physician may prescribe pharmaceuticals. At least 35 States already include at least one type of smoking cessation pharmaceutical in their Medicaid programs. This bill will require all States to include these drugs that, when prescribed by a physician, can help pregnant women stop smoking.

BILL INTRODUCED TO PROVIDE GRANTS TO HOSPITALS FOR INFORMATION TECHNOLOGY PURCHASES – Senators Graham (D-FL) and Snowe (R-ME) have introduced the "Medication Errors Reduction Act" (S. 1729) which would provide grants to hospitals and skilled nursing homes for start-up costs associated with purchasing and implementing computerized information systems. The bill provides a total of $93 million in each of Fiscal Years 2004-13 for hospitals funded out of the Federal Hospital Insurance Trust Fund under Medicare. Hospitals with a large share of publicly-insured patients will receive preference and 20% of the funds will be set aside for rural hospitals. Grants will total no more than $750,000 per hospital. The bill is supported by a broad array of national, state and local hospital and other organizations such as the Association of American Medical Colleges, the American Hospital Association, and the eHealth Initiative. In introducing the legislation, Sen. Graham stated the following:

"The legislation we are introducing today would bring the solution within our reach. It would address the causes of medication errors--which are systems breakdowns--and the solutions--use of clinical computerized information systems that can save lives….

The grants could be used to improve patient safety at every stage of the medication delivery process. For example, a hospital or nursing home could use the funds to implement 1. electronic prescribing systems that can intercept errors at the time medications are ordered, 2. electronic medical records to alert doctors to possible drug interactions and complications related to the patient's medical history, 3. automated pharmacy dispensing to make sure the nurse receives the correct medication in the correct dosage for the correct patient, and 4. bedside verification--using bar codes on patient wristbands and the medications to ensure that the right medication is administered to the right patient at the right time."

A related bill, the Patient Safety and Quality Improvement Act (H.R. 663) that includes a similar grant program was passed by the House earlier this year, and a similar bill to H.R. 663, but minus the information technology grant program, was reported out of the Senate HELP Committee several months ago (S. 720). Both of these bills include provisions requiring the Secretary of Health and Human Services to develop or adopt voluntary national standards promoting the integration of health care information technology systems.

HHS ISSUES NEW RULES TO ENHANCE SECURITY OF THE U.S. FOOD SUPPLY -- HHS Secretary Tommy G. Thompson October 9 announced the issuance of two Food and Drug Administration regulations that will bolster the safety and security of America's food supply. The new regulations will enable better targeted efforts to monitor and inspect imported foods and will allow quick identification and notification of food processors and other establishments involved in any deliberate or accidental contamination of food.

"By requiring advance notice for imported food shipments and registering domestic and foreign food facilities, we are providing critical new tools for the FDA to identify potentially dangerous foods and better keep our food supply safe and secure," Secretary Thompson said. "These new requirements represent the latest steps in our ongoing efforts to respond to new threats and improve the safety of all the foods that we eat in this country."

The two new regulations will implement key provisions of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, which provided FDA new authority to protect the nation's food supply against actual or threatened terrorist acts and other food-related emergencies.
"With input from the private sector, our partners in the federal government and the governments of our trading partners, we will use these regulations to work more effectively than ever to protect America's food supply, while maintaining the regular, free flow of commerce that is so vital to the well being of our citizens," said FDA Commissioner Mark B. McClellan, M.D., Ph.D. "Coupled with other counter-terrorism initiatives, these regulations mark a new era of international collaboration, one that strengthens the free market and free trade even as we face new threats to our security. We will keep working to build on these important regulations to fulfill our mission of helping Americans get diverse, affordable food products that are as safe and secure as possible."

The first regulation requires food importers to provide the FDA with advance notice of human and animal food shipments imported or offered for import on or after Dec. 12, 2003. This will allow FDA to know, in advance, when specific food shipments will be arriving at U.S. ports of entry and what those shipments will contain. This advance information will allow the FDA, working with U.S. Customs and Border Protection (CBP), to more effectively target inspections and ensure the safety of imported foods. The FDA expects to receive about 25,000 notifications about incoming shipments each day.

The second regulation requires domestic and foreign food facilities that manufacture, process, pack or hold food for human or animal consumption in the United States to register with the agency by Dec. 12, 2003. As a result, FDA will have for the first time a complete roster of foreign and domestic food facilities. The requirements will enable the FDA to quickly identify and locate affected food processors and other establishments in the event of deliberate or accidental contamination of food. The FDA expects about 420,000 facilities to register under this requirement.

The FDA worked closely with CBP to ensure the new regulations promote a coordinated strategy for border protection. "Using the electronic data required under these regulations and a sophisticated automated targeting system, CBP and the FDA will be working side-by-side to make joint decisions about food shipments that could pose a potential threat to the United States," said Commissioner Robert C. Bonner, U.S. Customs and Border Protection, Department of Homeland Security. "This integrated risk-management process will increase our security and facilitate the movement of legitimate commerce -- objectives shared by both agencies. We look forward to continuing our work with the FDA to implement the regulations in a manner that meets these shared objectives."

The regulations reflect comments from a broad array of law enforcement, national security, industry and other experts as the FDA worked to effectively improve food safety and security without adding unnecessary costs to domestic or international trade. "We have listened carefully to what stakeholders said about the proposals, in order to develop rules that are both workable and feasible," said Dr. McClellan. "The rules we are announcing today are intended to fulfill our goal of making the food supply safer and more secure without hindering trade."

Under the prior notice regulation, prior notice of imported foods must be received and confirmed electronically by FDA no more than five days before its arrival and no fewer than:

* two hours before arrival by land via road;
* four hours before arrival by air or by land via rail; or
* eight hours before arrival by water.

In addition, for international mail shipments, notifications must be made before the shipment is mailed. Also, when an individual carries or otherwise transports foods subject to the new requirement, advance notice of two, four or eight hours is required -- depending on the mode of transportation. The food must also be accompanied by confirmation of receipt for FDA review.

The regulation's timeframes reflect the FDA's work, in collaboration with other agencies, to reduce substantially the required time for advance notice to minimize unnecessary costs. For example, the proposed rule issued earlier this year would have required that importers give notice by noon the day before the arrival of a shipment of food into the United States for all modes of transportation, including by land by road. The final regulation requires only two hours notice before arrival of food by land by road and could be reduced further in the future as part of FDA-CBP plan to coordinate border-management activities more efficiently.

The advance notice to the FDA may be submitted electronically in most circumstances using Customs' existing ABI/ACS system, making it easier for importers to comply with the new law. In addition, the FDA will operate a new Prior Notice System Interface that can receive such notifications.

The second regulation requires the owner, operator, or agent in charge of a domestic or foreign food facility to register with FDA, providing information about the name and address of each facility at which, and all trade names under which, the registrant conducts business, and information about certain categories of food the facility produces. For a foreign facility, the registration must include the name of the U.S. agent for the facility. Registration is required for domestic facilities whether or not food from the facility enters interstate commerce. Domestic facilities are also required to provide emergency contact information. All changes to such information must be reported within 60 days.
Except for specific exemptions, the registration requirements apply to all facilities that manufacture, process, pack or hold food regulated by FDA, including animal feed, dietary supplements, infant formula, beverages (including alcoholic beverages) and food additives.
Registration would not be required for private residences of individuals; certain food transport vehicles; facilities that manufacture food contact substances and pesticides; farms; restaurants; other retail food establishments; nonprofit food establishments in which food is prepared for or served directly to the consumer; non-processing fishing vessels; and facilities (such as meat and poultry slaughterhouses) that are regulated exclusively by the U.S. Department of Agriculture. Also exempt are foreign facilities if the food from the facility is to undergo further processing or packaging by another facility before it is exported to the U.S.

The registration may be submitted electronically, via the Internet, or by paper through surface mail or by fax. Registrations may also be submitted on CD-ROM by mail. The FDA will be able to accept electronic registration from anywhere in the world 24 hours a day, 7 days a week, beginning Oct. 16. Filling out registration online should take about 15 minutes if a facility has its paperwork ready. A registering facility will receive confirmation of electronic registration and its registration number instantaneously once all the required fields on the registration screen are filled in. There is no fee associated with registration.

The rules take effect Dec. 12, 2003, in accordance with the Bioterrorism Act. To assure that the regulations can be implemented efficiently and with minimal disruption, FDA intends to exercise broad enforcement discretion for the prior notice rule for the first four months after implementation. During this time, FDA and CBP will educate importers about how they can comply with the regulations, and will work with trade associations and foreign governments to make sure all importers are well informed of the new requirements. Thereafter, FDA will phase in full implementation of the prior notice requirements.

FDA has already conducted extensive domestic and international outreach and education about the new rules. In the coming weeks, FDA will conduct national and international meetings and other programs to provide full information about the rules. FDA also will hold a satellite downlink public meeting on Oct. 28 to discuss the two regulations. Information about this meeting, including domestic and international viewing

opportunities and registration, is available at http://www.fda.gov/OHRMS/DOCKETS/98fr/03-24921.htm.
Both the new regulations were published as interim final rules in the Oct. 10 issue of the Federal Register. The FDA is requesting further public comment on the rules. The regulations are available at http://www.cfsan.fda.gov

CDC RELEASES DRAFT VERSION OF NEW SARS PLAN --The Centers for Disease Control and Prevention (CDC) has posted the working draft version of its "Public Health Guidance for Community-Level Preparedness and Response to Severe Acute Respiratory Syndrome (SARS)," on its web site.

The SARS Plan is a working document that outlines the concepts and strategies that would guide the U.S. response in the event of a SARS outbreak. It also describes many of the activities needed at the federal, state, and local levels to prepare for and respond rapidly and decisively to a reemergence of SARS. State and local health departments, hospitals and other public health providers will have an opportunity to comment on the draft and provide input to an effective SARS preparedness plan for the United States. The plan is designed to assist federal, state, and local public health partners in developing or coordinating their own SARS preparedness and response planning activities, while taking into account available healthcare and public health resources, and other factors that are unique at each level.

The plan was prepared in close collaboration with domestic and international partners, and incorporates many of the concepts and approaches that were successfully used to contain SARS outbreaks in the United States and other counties with more widespread outbreaks. In addition, it integrates and builds on other preparedness and response plans for SARS (e.g., U.S. Government Interagency SARS Concept of Operations Plan) and for other public health emergencies, such pandemic influenza and bioterrroism. The plan will be updated regularly and can be implemented immediately should SARS reemerge.
For more information about the SARS Plan, visit CDC's web site at http://www.cdc.gov/ncidod/sars/ or contact the Office of Communication at 404-639-3286.

TEXAS JOINS CDC'S EMERGING INFECTIONS PROGRAM NETWORK--
Texas has become the 11th Emerging Infections Program (EIP) site in the United States. The Centers for Disease Control and Prevention (CDC) established EIP sites in 1995 as part of the agency's strategy to address the ongoing threat of emerging infectious diseases. EIPs are a population-based network of state and local health departments, healthcare providers, and academic institutions. Sites within the network monitor and track infectious diseases, and perform epidemiologic and laboratory research for emerging infectious disease threats.

"The EIP sites are key components in strengthening the national public health structure to prevent and control emerging infectious diseases," said CDC Director Julie L. Gerberding, M.D. "Over the past few years, the EIPs have been a national resource for

monitoring the impact of a new vaccine against pneumonia in young children, and evaluating and helping to improve guidelines for preventing group B streptococcal disease which is a life-threatening infection in newborns, and measuring the burden of foodborne diseases."

There are 11 EIP sites: California (San Francisco Bay area), Colorado, Connecticut, Georgia, Maryland, Minnesota, New Mexico, New York, Oregon, Tennessee, and Texas. The study population for these sites is representative of approximately 36 million people. In fiscal year 2003, EIP sites received nearly $20 million in funding.
Select EIP projects include:

Active Bacterial Core Surveillance (ABCs). Tracking invasive diseases caused by emerging, vaccine-preventable, or drug-resistant pathogens such as Neisseria meningitides and Streptococcus pneumoniae.

Foodborne Disease Active Surveillance Network (FoodNet). Laboratory-based monitoring for foodborne and waterborne diseases.

\Surveillance for Infectious Disease Syndromes. Active tracking for SARS and severe pneumonia, encephalitis, chronic and acute liver failure, unexplained rash illnesses, and unexplained deaths and critical illnesses.

For more information about EIP and infectious disease surveillance, visit CDC's National Center for Infectious Diseases (NCID) website: http://www.cdc.gov/ncidod/osr/.

NIEHS-FUNDED RESEARCHERS FIND LOW-LEVEL OZONE INCREASES RESPIRATORY RISK OF ASTHMATIC CHILDREN -- New evidence gathered in a study funded by the National Institute of Environmental Health Sciences suggests that asthmatic children who use maintenance medication are particularly vulnerable to the effects of ground-level ozone, even at levels well below the federal standard set by the Environmental Protection Agency.

Their research results were published Oct. 8 in the *Journal of the American Medical Association*. The study was conducted at the Yale University School of Medicine. NIEHS is one of the federal National Institutes of Health.

"Although the 1-hour average ozone levels in our study were well below the federal standard, statistical analysis revealed that for every 50 parts per billion increase in ozone, the likelihood of asthma symptoms the following day increased by more than 35 percent among asthmatic children on maintenance medication," said Brian Leaderer, Ph.D., the Susan Dwight Bliss Professor of Epidemiology at Yale University and principal investigator for the study.

Asthma, an inflammatory disorder of the airways that is characterized by periodic attacks of wheezing, shortness of breath and coughing, can be triggered by inhaled allergens such

as pet dander, dust mites, molds or pollens. But researchers have also shown that air pollutants such as ground-level ozone, an active form of oxygen that is the prime ingredient of urban smog, and fine particulate matter, which includes dust, dirt, smoke and soot from a variety of natural and man-made sources, can significantly aggravate asthma symptoms.

Repeated exposures to ozone and fine particles at or above the federal standards can irritate or damage sensitive tissue in the airways and lungs, making breathing even more difficult for asthmatics and causing more attacks, increased use of medication, and more visits to hospital emergency clinics. Children are particularly vulnerable to these exposures because their respiratory systems are still developing, and they tend to spend more time in outdoor activities than do adults.

Earlier studies of children with asthma living in highly polluted regions, such as Mexico City and Los Angeles, all concluded that exposure to ozone and fine particles in excess of 120 parts per billion (ppb) and 65 micrograms per cubic meter , respectively, greatly increased the risk for respiratory symptoms. “We wanted to design a study that examined the effects of air pollution on a particularly vulnerable population — children with active asthma — in regions where pollution levels were somewhat lower than those in major metropolitan areas,” said Leaderer.

Study participants included 271 asthmatic children living in Connecticut and the Springfield area of Massachusetts during the spring and summer of 2001. The investigators conducted monthly interviews with the mothers to obtain information on each child’s daily wheezing, coughing, shortness of breath, chest tightness, and asthma medication use. Daily measurements of ground-level ozone and fine particulate matter were provided by the Departments of Environmental Protection of Connecticut and Massachusetts.

Although mean 1-hr average ozone concentrations measured only 59 ppb, variations in daily levels had a profound effect on the respiratory symptoms of those who used maintenance medication. A 50 ppb increase in 1-hr ozone was associated with a 35 percent increase in wheezing, and a 47 percent increase in chest tightness. The highest ozone levels were associated with increased shortness of breath and rescue medication use.

However, the investigators did not find a significant relationship between the children’s exposure to fine particulate matter and daily respiratory symptoms or rescue medication use. Furthermore, no exposure-dependent outcomes were observed for either pollutant category among children who did not use maintenance medication.
“Our results suggest that ground-level ozone is strongly associated with adverse health effects in children with asthma, even at levels below the current federal standards,” said Leaderer.