THE CSTE WASHINGTON REPORT

Marcia S. Mabee, MPH, PhD
Editor
11479 Waterview
Reston, Virginia 20190
mmabee@ix.netcom.com
703-709-3001

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INSIDE THIS ISSUE

EDITOR'S NOTE:. The Centers for Disease Control and Prevention (CDC), in collaboration with more than 35 federal, public and private partners, April 20 released national recommendations designed to encourage women to take steps toward good health before becoming pregnant. The recommendations for preconception care were published in the Morbidity and Mortality Weekly Report (MMWR) Recommendations and Reports. "The child-bearing years are an exciting time in a woman's life and there are a number of steps they can take to be healthy, benefiting both them and their future child," said Dr. Julie Gerberding, CDC director. "For instance, even before pregnancy, women of child-bearing age should see their doctor about controlling existing medical conditions, such as diabetes, high blood pressure and eating disorders. They should take 400 micrograms of folic acid to help prevent neural tube defects and avoid smoking or drinking alcohol." -- additional information is 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

BUDGET DISCUSSIONS CONTINUE IN HOUSE – Negotiations between the House Republican leadership and House Republican Moderates are continuing today in an effort to garner enough votes to pass the House Budget Resolution (H. Con. Res. 376). At stake is the effectiveness of the new Majority Leader, John Boehner (R-OH), who replaced Rep. Tom DeLay when he stepped down in the wake of campaign finance-related legal troubles. Also at stake is a strong joint effort by the health and education communities to pressure Moderates to vote against the budget resolution unless $7 billion is added for health and education programs. Bowing to that pressure, last week House Appropriations Chairman Lewis (R-CA) shifted $4.1 billion in funding from the Defense and Foreign Operations Subcommittees to the Labor, Health and Human Services and Education Subcommittee. However, health and education groups, and the Moderates they are working with, want the full $7 billion, which the Senate agreed to on a 73-27 vote in March. They sent a letter stating that on May 8th to the House and Senate leaderships and Appropriations principals that was signed by over 800 organizations. The $4.1 billion increase, while welcome, flat-funds all programs from the FY 2006 level, and so builds in deep cuts that occurred last year.

OBESITY UPDATE – On May 2nd, the Center for Science in the Public Interest (CSPI), which coordinates a national coalition, including CSTE, to battle obesity announced that a new Federal Trade Commission and U.S. Department of Health and Human Services report on marketing to children has been released and can be found at: http://ftc.gov/opa/2006/05/childhoodobesity.htm. CSPI states: "The report makes welcome recommendations on improving food marketing aimed at kids. Importantly, the agencies recommend that food companies and the Children's Advertising Review Unit (CARU) set nutrition standards for foods that can be marketed to children through television, schools, via cartoon characters on food packages, etc."

On May 3rd, CSPI reported that soft drink companies will pullall sugary sodas from schools: "Today's announcement that soft drink companies will pull all sugary sodas from schools is great step toward improving school foods. CSPI applauds the soft drink industry and the Alliance for a Healthier Generation. This agreement is the culmination of the tremendous national momentum on improving school foods -- from the local policies (in LA, NYC, Chicago, Philadelphia, DC, etc.), state bills (in 2005, 200 bills were introduced in 40 states to get soda and junk foods out of schools), the strong bipartisan bill pending in the U.S. Congress, and threats of litigation against soda companies.

While today's agreement is a huge step forward, it is by no means the last step. As nutrition professionals, advocates and parents, we still have a lot of work to do to improve school foods.

The soft drink companies have agreed to remove soda and all sugary drinks from elementary and middle schools. In high schools, they will not sell sugary sodas but will continue to sell sports drinks and many sugary fruit drinks (though portion sizes and calories are capped). Importantly, the agreement doesn't address the sale of chips, candy, snack cakes, ice cream, or any of the other high-fat, high-calorie, high-salt foods that are sold widely in schools.

This is a voluntary agreement and is not enforceable, while Senator Harkin's school foods bill would have the force of law."

Senator Harkin's bill is supported by CSTE: "Child Nutrition Promotion and School Lunch Protection Act" (S. 2592/H.R. 5167) calls on USDA to update its nutritional standards for foods outside of school meals and extend them to cover the entire campus and whole school day.

LEGISLATIVE UPDATE – Senator Kennedy's amendment to the emergency supplemental appropriations bill, which is working its way through Congress, provides $289 million for a flu vaccine compensation fund and was adopted on a vote of 53-46 on May 3rd. CSTE urged Congress to establish such a fund in conjunction with development of a pandemic flu vaccine. Below is Senator Kennedy's statement on the amendment:

"Today's vote by the Senate is a show of support and respect for America's first responders, the courageous and highly trained men and women who protect us all in the case of emergencies.

In the event of a pandemic flu crisis, they deserve a clear commitment from the government that they and their families will be compensated if they're taken ill by a vaccine while caring for others.

The passage of this obvious but essential amendment is a step in the right direction, but we are still far behind where we should be in planning for such a pandemic. Other nations have been implementing their plans for years, but the Bush Administration has only just announced its plan today. We're far behind, and time is not on our side."

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FACT SHEET
KENNEDY AMENDMENT ON COMPENSATION

Background

Last December, a provision was inserted into a major spending bill to provide sweeping immunity from liability for manufacturers of experimental flu vaccines – as well as a broad range of other vaccines, drugs, and medical devices. The provision purported to provide compensation for first responders and others who might be injured by the products to which the legal immunity applied – but the promise of compensation was an empty one. Even though the provision was enacted as part of an appropriations bill, no funding was provided for the compensation program. As a result of this provision, drug companies can receive legal immunity even when they ignore basic safety precautions in the manufacture of their products, but injured patients have no access to compensation.

This provision ignores the lessons of the botched smallpox vaccination campaign. Despite the advice of public health experts and representatives of first responders and health care workers, no compensation fund was provided at the outset of that campaign. The absence of compensation was a major reason that few decided to accept the vaccinations.

We should not repeat the mistakes of the past. A compensation program with no funding is an empty gesture, and the wrong course to take.

The Kennedy Amendment

The Kennedy amendment provides $289 million in funding available this year for the compensation program. These funds would give the assurance needed to health professionals, first responders, and others who will be first to receive experimental flu vaccines that they will be compensated if they are injured. If funds are not provided as part of this supplemental appropriation, there will be no further opportunity to assure that funds are available for the compensation program until next fiscal year. We should not ask nurses, doctors, health workers, and other first responders to wait for uncertain compensation if they are injured.

RECENTLY INTRODUCED LEGISLATION OF INTEREST : THE NEWBORN SCREENING SAVES LIVES ACT OF 2006 (S. 2663) WAS INTRODUCED ON APRIL 27TH BY SENATOR CHRISTOPHER DODD (D-CT) AND IT IS CO-SPONSORED BY SENATOR MIKE DEWINE (R-OH). THE BILL AMENDS THE PUBLIC HEALTH SERVICE ACT TO ESTABLISH GRANT PROGRAMS TO PROVIDE FOR EDUCATION AND OUTREACH ON NEWBORN SCREENING AND COORDINATED FOLLOWUP CARE ONCE NEWBORN SCREENING HAS BEEN CONDUCTED AND REAUTHORIZES TITLE XI OF THE PHS ACT. A TOTAL OF $5 MILLION IN GRANTS IN FY 2007 AND SUCH SUMS FOR FY 2008-2011 IS PROVIDED FOR IMPROVING LABORATORY QUALITY IN SCREENING NEWBORNS AND CHILDREN FOR HERITABLE DISORDERS AND $15 MILLION IN GRANTS IN FY 2007 AND SUCH SUMS FOR FY 2008-2011 IS PROVIDED FOR SURVEILLANCE PROGRAMS FOR HERITABLE DISORDERS. THE DETAILS OF THESE ASPECTS OF THE BILL ARE BELOW:

`SEC. 1112. LABORATORY QUALITY.

`(a) In General- The Secretary, acting through the Director of the Centers for Disease Control and Prevention and in consultation with the Advisory Committee on Heritable Disorders in Newborns and Children established under section 1111, shall provide for--

`(1) quality assurance for laboratories involved in screening newborns and children for heritable disorders, including quality assurance for newborn-screening tests, performance evaluation services, and technical assistance and technology transfer to newborn screening laboratories to ensure analytic validity and utility of screening tests; and

`(2) population-based pilot testing for new screening tools for evaluating use on a mass scale.

`(b) Authorization of Appropriations- For the purpose of carrying out this section, there are authorized to be appropriated $5,000,000 for fiscal year 2007 and such sums as may be necessary for each of the fiscal years 2008 through 2011.

`SEC. 1113. SURVEILLANCE PROGRAMS FOR HERITABLE DISORDERS SCREENING.

`(a) In General- The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall carry out programs--

`(1) to collect, analyze, and make available data on the heritable disorders recommended by the Advisory Committee on Heritable Disorders in Newborns and Children established under section 1111, including data on the causes of such disorders and on the incidence and prevalence of such disorders;

`(2) to operate regional centers for the conduct of applied epidemiological research on the prevention of such disorders;

`(3) to provide information and education to the public on the prevention of such disorders; and

`(4) to conduct research on and to promote the prevention of such disorders, and secondary health conditions among individuals with such disorders.

`(b) Grants and Contracts-

`(1) IN GENERAL- In carrying out subsection (a), the Secretary may make grants to and enter into contracts with public and nonprofit private entities.

`(2) SUPPLIES AND SERVICES IN LIEU OF AWARD FUNDS-

`(A) IN GENERAL- Upon the request of a recipient of an award of a grant or contract under paragraph (1), the Secretary may, subject to subparagraph (B), provide supplies, equipment, and services for the purpose of aiding the recipient in carrying out the purposes for which the award is made and, for such purposes, may detail to the recipient any officer or employee of the Department of Health and Human Services.

`(B) REDUCTION- With respect to a request described in subparagraph (A), the Secretary shall reduce the amount of payments under the award involved by an amount equal to the costs of detailing personnel and the fair market value of any supplies, equipment, or services provided by the Secretary. The Secretary shall, for the payment of expenses incurred in complying with such request, expend the amounts withheld.

`(3) APPLICATION FOR AWARD- The Secretary may make an award of a grant or contract under paragraph (1) only if an application for the award is submitted to the Secretary and the application is in such form, is made in such manner, and contains such agreements, assurances, and information as the Secretary determines to be necessary to carry out the purposes for which the award is to be made.

`(c) Biennial Report- Not later than February 1 of fiscal year 2007 and of every second such year thereafter, the Secretary shall submit to the Committee on Energy and Commerce of the House of Representatives, and the Committee on Health, Education, Labor, and Pensions of the Senate, a report that, with respect to the preceding 2 fiscal years--

`(1) contains information regarding the incidence and prevalence of heritable disorders and the health status of individuals with such disorders and the extent to which such disorders have contributed to the incidence and prevalence of infant mortality and affected quality of life;

`(2) contains information under paragraph (1) that is specific to various racial and ethnic groups (including Hispanics, non-Hispanic whites, Blacks, Native Americans, and Asian Americans);

`(3) contains an assessment of the extent to which various approaches of preventing heritable disorders and secondary health conditions among individuals with such disorders have been effective;

`(4) describes the activities carried out under this section;

`(5) contains information on the incidence and prevalence of individuals living with heritable disorders, information on the health status of individuals with such disorders, information on any health disparities experienced by such individuals, and recommendations for improving the health and wellness and quality of life of such individuals;

`(6) contains a summary of recommendations from all heritable disorders research conferences sponsored by the Centers for Disease Control and Prevention; and

`(7) contains any recommendations of the Secretary regarding this section.

`(d) Applicability of Privacy Laws- The provisions of this section shall be subject to the requirements of section 552a of title 5, United States Code. All Federal laws relating to the privacy of information shall apply to the data and information that is collected under this section.

`(e) Coordination-

`(1) IN GENERAL- In carrying out this section, the Secretary shall coordinate, to the extent practicable, programs under this section with programs on birth defects and developmental disabilities authorized under section 317C.

`(2) PRIORITY IN GRANTS AND CONTRACTS- In making grants and contracts under this section, the Secretary shall give priority to entities that demonstrate the ability to coordinate activities under a grant or contract made under this section with existing birth defects surveillance activities.

`(f) Authorization of Appropriations- For the purpose of carrying out this section, there are authorized to be appropriated $15,000,000 for fiscal year 2007 and such sums as may be necessary for each of the fiscal years 2008 through 2011.'.

HHS AWARDS CONTRACTS TOTALING MORE THAN $1 BILLION TO DEVELOP CELL-BASED INFLUENZA VACCINE -- As part of the President's plan to prepare for a pandemic, HHS Secretary Mike Leavitt May 5 awarded more than $1 billion to accelerate development and production of new technologies for influenza vaccines within the U.S. These five contracts 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. These funds are part of $3.3 billion proposed by the President and appropriated by Congress to HHS for fiscal year 2006 to help the nation prepare for a pandemic.

"Today, we're taking a step closer to preparedness by investing more than $1 billion to develop vaccines more quickly and to produce them here in the United States," Secretary Leavitt said.

He added, “We have the opportunity to be the first generation that prepares for pandemic. Our current capacity of egg-based influenza vaccine production is not sufficient to meet increased demands during an emergency. Accelerating the development of this vaccine technology and creating domestic capacity are critical to our preparedness efforts.”

Cell-based vaccine manufacturing -- a technology that is used in many other modern vaccines -- holds the promise of a reliable, flexible and scalable method of producing influenza vaccines. Currently licensed influenza vaccines are produced in specialized chicken eggs in a technique that has changed little in over 50 years. With increasing demand for seasonal influenza vaccine and with the looming threat of a pandemic, a system that allows surge capacity in an emergency is needed.

Using a cell culture approach to producing influenza vaccine offers a number of benefits. Vaccine manufacturers are able to bypass the steps needed to adapt the virus strains to grow in eggs. In addition, cell culture-based influenza vaccines will help meet surge capacity needs in the event of a shortage or pandemic, since cells may be frozen in advance and large volumes grown quickly. Licensure and manufacture in the U.S. of influenza vaccines produced in cell culture also will provide security against risks associated with egg-based production, such as the potential for egg supplies to be unavailable as a result of various poultry-based diseases. Finally, the new cell-based influenza vaccines will provide an option for people who are allergic to eggs and therefore unable to receive the currently licensed vaccines.

The following awards were announced today:
Company Funding Amount

GlaxoSmithKline -- $274.75 million

MedImmune -- $169.46 million

Novartis Vaccines & Diagnostics -- $220.51 million

DynPort Vaccine -- $40.97 million

Solvay Pharmaceuticals -- $298.59 million

Total $1.004 billion

Previously, HHS awarded Sanofi Pasteur a $97 million contract for development of a cell-based vaccine in April 2005. This company was the first to be awarded a federal contract for commercial scale production of newer influenza vaccine methodology.

Developing improved vaccines and enhanced vaccine production capacity are top objectives laid out in the President’s National Strategy for Pandemic Influenza. That plan and additional information are available at www.pandemicflu.gov.

CDC RELEASES NATIONAL RECOMMENDATIONS TO IMPROVE HEALTH OF BABIES AND MOMS -- The Centers for Disease Control and Prevention (CDC), in collaboration with more than 35 federal, public and private partners, April 20 released national recommendations designed to encourage women to take steps toward good health before becoming pregnant. The recommendations for preconception care were published in the Morbidity and Mortality Weekly Report (MMWR) Recommendations and Reports.

"The child-bearing years are an exciting time in a woman's life and there are a number of steps they can take to be healthy, benefiting both them and their future child," said Dr. Julie Gerberding, CDC director. "For instance, even before pregnancy, women of child-bearing age should see their doctor about controlling existing medical conditions, such as diabetes, high blood pressure and eating disorders. They should take 400 micrograms of folic acid to help prevent neural tube defects and avoid smoking or drinking alcohol."

The recommendations on preconception health and health care identify more than a dozen risk factors and conditions that require interventions before pregnancy to be effective. Among developed nations, the United States is ranked 26th in infant mortality. If implemented, the recommendations can help improve the health of babies and moms.

"Preconception health is important for every woman capable of having a baby, and should be tailored to each individual," said Dr. José Cordero, director of CDC's National Center on Birth Defects and Developmental Disabilities and Assistant Surgeon General. "And all couples, whether or not they are planning pregnancies, should have a reproductive life plan, which is a set of personal goals about having (or not having) children. This also includes couples who have a difficult time getting pregnant; they should discuss their options with their health care professional."

Some topics:

* Folic acid supplements to prevent neural tube defects
* Detecting and treating existing health conditions
* Reviewing medications that can affect the fetus or the mother
* Reviewing a woman's pregnancy history
* Stopping smoking to reduce the risk of low birth weight
* Eliminating alcohol consumption to prevent fetal alcohol syndrome
* Family planning counseling to avoid unplanned pregnancies
* Counseling to promote healthy behaviors such as appropriate weight, nutrition, exercise and oral health.

These recommendations will also give physicians and other health care professionals the knowledge, messages and tools to act on the scientific evidence that exists concerning about how and when to intervene for preconception care.

"I encourage all women who are thinking about getting pregnant to talk to their doctor about medications, including those bought without a prescription. They should also avoid exposure at work or at home to toxic substances or potentially infectious materials, such as chemicals or cat feces," added Dr. Cordero.

The recommendations are the result of two-years of collaborative efforts with a number of partner groups including American College of Obstetricians and Gynecologists, National March of Dimes Birth Defects Foundation, CityMatCH (Urban Maternal and Child Health Leadership), Association of Maternal and Child Health Programs, American College of Nurse Midwives, American Academy of Pediatrics, National Association of County and City Health Officials, Association of State and Territorial Health Officials, and American Academy of Family Physicians.

The full recommendations on preconception care are available at www.cdc.gov/mmwr and for more information on preconception care go to www.cdc.gov/ncbddd

FUSARIUM KERATITIS UPDATE -- The Centers for Disease Control and Prevention (CDC) is continuing its investigation on the multi-state outbreak of *Fusarium* keratitis that may be associated with contact lens use.

As of May 5, 2006, CDC has received reports of 102 confirmed cases, 12 possible cases and 81 cases still under investigation from 31 U.S. states and territories. 65 reports include insufficient evidence to classify them as cases or carry other non-*Fusarium* diagnoses. States or territories with at least 1 confirmed or possible case include: AR, AZ, CA, CT, FL, GA, IA, IL, KS, KY, LA, MA, MD, MI, MO, NC, ND, NJ, NY, OH, PA, PR, TN, TX, and VT. States where all cases under investigation include: IN, MN, NV, OK, OR, and RI.

Not all data are available for all confirmed cases. However, as of May 2, 2006, of the 58 confirmed cases for which CDC has complete data:

* 56 wear contact lenses
* 32 reported using any B&L ReNu with MoistureLoc
* 15 reported using any B&L ReNu MultiPlus
* 7 reported using any unspecified B&L ReNu
* 3 reported using any AMO product
* 3 reported using any Alcon product

* Some cases reported using more than one type of solution and therefore the solution categories are not mutually exclusive.

(Note: Updated case count numbers will be available on Tuesdays and Fridays. Updated numbers on solution use and other pertinent exposures will be available on Tuesdays.)

Summary and Clarifications

In addition, CDC would like to clarify some of the information that has appeared in a number of recent media stories on the outbreak. The following information is known related to this outbreak:

* Since the first report on this outbreak in the April 10, 2006 *Morbidity and Mortality Weekly Report* (MMWR), CDC has noted that patients have reported using multiple products, including those manufactured by Bausch & Lomb, Alcon, and Advanced Medical Optics, Inc.

* At this point, it is too early in the investigation to say whether a particular product or solution may be responsible for the outbreak.

* Throughout the investigation, the proportion of patients who reported using Bausch & Lomb's ReNu with MoistureLoc has remained relatively consistent, at around 50-60 percent of confirmed cases.

* ReNu with MoistureLoc was used by approximately 2.3 million contact lens wearers in the United States, while MultiPlus was used by nearly 11 million contact lens wearers (branded or private label).

* *Fusarium* keratitis is naturally occurring disease in the United States. It is not a disease that healthcare providers must report so it is unclear how many cases occur each year in the United States.

* Disease outbreaks and increased media coverage often raise awareness about particular infections, which, in turn, may 1) increase reports of a disease and 2) result in additional information being identified and collected. Thus, it is possible that some of the cases currently being investigated represent infection which might normally occur and, as a result, are not related to the outbreak.

* The risk of getting fungal keratitis from contact lenses remains extremely low. Contact lens wearers who experience unusual redness, pain, tearing, light sensitivity, blurry vision, discharge or swelling should consult their doctor immediately.

CDC is continuing its investigation into identifying whether there are specific factors that may have placed people at risk for developing fungal keratitis, including hygiene practices, overnight contact lens wear and specific solutions used. The CDC will provide more information as it becomes available.

For more information on fungal keratitis and advice to doctors and consumers, please visit http://www.cdc.gov/ncidod/dhqp/fungal_fusariumKeratitis.html or http://www.fda.gov/oc/opacom/hottopics/contacts.html.

GENETIC AND ENVIRONMENTAL FACTORS IMPACT CFS PATIENTS -- People who suffer from chronic fatigue syndrome (CFS) have a genetic make up that

affects the body's ability to adapt to change, according to a series of papers released today by the Centers for Disease Control and Prevention (CDC). These papers, which analyze the most detailed and comprehensive clinical study on CFS to date, are published in the April issue of Pharmacogenomics.

Over the past year, CDC scientists have worked with experts in medicine, molecular biology, epidemiology, genomics, mathematics, engineering, and physics to analyze and interpret information gathered from 227 CFS patients. The information was gathered during a study in which volunteers spent two days in a hospital research ward. During this time, they underwent detailed clinical evaluations, measurement of sleep physiology, cognitive function, autonomic nervous system function, and extensive blood evaluations, including an assessment of the activity of 20,000 genes, in an attempt to identify factors that potentially cause or are related to CFS.

"This study demonstrates that the physiology of people with CFS is not able to adapt to the many challenges and stresses encountered throughout life, such as infection, injury and other adverse events during life," said Dr. William C Reeves, who heads CDC's CFS public health research program. "These findings are important because they will help to focus our research efforts to identify diagnostic tools and more effective treatments which ultimately could alleviate a lot of pain and suffering."

The multidisciplinary approach to this study, which has been termed C3 or the CFS Computational Challenge, was developed by the CDC's Dr. Suzanne Vernon, Molecular Epidemiology Team Leader for the CFS Research Laboratory. It is an approach that could lead to advances with other diseases and disorders. "We put together four teams of different experts and challenged them to develop ways to integrate and analyze a wide range of medical data so as to identify those things that could improve the diagnosis, treatment, or understanding of CFS," Dr. Vernon said. "There is a clear biologic basis for CFS, and knowing the molecular damage involved will help us devise effective therapeutic intervention and control strategies."

It's estimated that over one million people in the United States alone are sick with CFS. The condition takes a tremendous personal and social toll - approximately $9 billion a year to the nation and $20,000 per family. It occurs most frequently in women ages 40-60 and can be as disabling as multiple sclerosis and chronic obstructive pulmonary disease.

The CDC is the principal agency in the United States for protecting the health and safety of all Americans. CDC is promoting CFS awareness through a national media and education campaign set to kick off later this spring.

The April issue of Pharmacogenomics, published by Future Medicine, includes 14 research papers, the culmination of C3. The journal Pharmacogenomics is dedicated to the rapid publication of original research on basic pharmacogenomics research and its clinical applications. Published eight times a year, the journal covers the effects of genetic variablity on drug toxicity and efficacy, the characterization of genetic mutations

relevant to drug action, and the identification of novel genomic targets for drug development.

For additional information about the CFS Computational Challenge, including a list of participants, visit www.cdc.gov/ncidod/diseases/cfs/meetings/2005_09.htm

For additional information about CFS visit www.cdc.gov/ncidod/diseases/cfs/

For a list of articles in the April issue of Pharmacogenomics visit www.futuremedicine.com/toc/pgs/7/3