Federal update

From the FDA

FDA approves tolterodine tartrate for overactive bladder

The Food and Drug Administration has approved tolterodine tartrate (Detrol LA) extended-release capsules, a once-daily therapy for overactive bladder.

An international study involved 1500 people randomly assigned to groups who received tolterodine 4 mg/d, 2 mg twice daily, or placebo. Patients treated with 4 mg/d had a 71% improvement in the number of incontinence episodes per week compared with the group receiving placebo. The most common adverse events reported were dry mouth, headache, and constipation.

Overactive bladder affects 17 million people in the United States, yet only 20% are under physician care.

The report was presented at the annual meeting of the American Urological Association.

FDA approves medical device for hypertension

The Food and Drug Administration has approved a medical device that helps lower blood pressure by using sound patterns to guide patients' breathing to a lower rate. Deep breathing stimulates stretch receptors in the cells of lungs, which leads to lower blood pressure. A processing unit in the device analyzes patients' patterns of breathing and issues breathing exercises customized for each patient. RespeRate, manufactured by InterCure, Inc., is used under the direction of a physician and is currently available by prescription exclusively in Chicago, Illinois.

Results of three randomized clinical studies indicate that the device—used with hypertension drugs—caused a reduction of 12 mm Hg systolic and 8 mm Hg diastolic pressure in 6 weeks of daily treatment.

The prescription for the device includes computer link cables that enable patients to connect their computer to the RespeRate device and, ultimately, transfer blood pressure readings to a secure InterCure Web site.

FDA approves letrozole as first-line treatment for breast cancer

The Food and Drug Administration has approved letrozole (Femara) for new use as a first-line treatment for postmenopausal women with advanced breast cancer who have not improved following antiestrogen therapy. In the Phase III trial, letrozole was more effective than tamoxifen in time to progression, response rates, and clinical benefit. Letrozole blocks the aromatase enzyme, which is involved in tumor growth, while tamoxifen prevents estrogen from binding to tumor receptors.

The manufacturer-funded, randomized study involved 916 postmenopausal women with advanced cancer in the breast, cancer spread to other parts of the body, or recurrences that failed to respond to surgery or radiotherapy. Results indicate that women who received letrozole had 9.4 months before disease progression compared with 6 months for women who received tamoxifen, with similar incidence of side effects.

FDA approves peginterferon alfa-2b for hepatitis C

The Food and Drug Administration has approved peginterferon alfa-2b (Peg-Intron) powder as once-weekly monotherapy for patients aged 18 years and older with chronic hepatitis and compensated liver disease who were not previously treated with alpha interferon. Peginterferon alfa-2b is administered once weekly for 1 year and may be self-administered by patients.

A total of 1219 patients with chronic hepatitis C who were not previously treated with alfa interferon were randomly assigned to groups who received peginterferon alfa-2b at dosages of 0.5μg/kg, 1.0 μg/kg, or 1.5 μg/kg administered subcutaneously once per week for 48 weeks or interferon alfa-2b, recombinant (Intron A) at a dosage of 3 mIU administered subcutaneously 3 times per week for 48 weeks.

Patients who received 1.0 μg/kg of peginterferon alfa-2b had a 24% response rate of sustained virologic response and normal alanine aminotransferase compared with a 12% response rate in patients who received interferon alfa-2b, recombinant.

Twelve percent of patients in all groups had one or more adverse events, including symptoms similar to those of influenza, injection site irritation, and depression. Peginterferon alfa-2b, like other alpha interferons, causes or aggravates fatal or life-threatening neuropsychiatric, autoimmune, ischemic, and infectious disorders. Patients should be monitored closely and withdrawn from treatment if symptoms worsen.

Four million people in the United States are infected with the hepatitis C virus, and 70% of infected patients have chronic liver disease. The current death rate of 8000 to 10,000 per year is expected to triple by 2010.

From the CDC

CDC releases cervical cancer rates by race and ethnicity

The Centers for Disease Control and Prevention released the first rates of cervical cancer detection according to race and ethnicity from its national screening program for uninsured women.

Of the women in the program who received their first Papanicolau test between 1991 and 1998, American Indian and Alaskan native women had the highest proportion of abnormal test results (4.4%), followed by African American women

(3.2%), whites (3.0%), Hispanics (2.7%), and Asians and Pacific Islanders (1.9%). White women had the highest rate of serious cervical lesions detected by biopsy (9.9 per 1000 Pap tests), followed by Hispanics (7.6), African Americans (7.1), American Indian and Alaskan native (6.7), and Asians and Pacific Islanders (5.4).

American Indian and Alaskan native women were more likely to report never having had a Pap test, and African American women were more likely not to receive follow-up after diagnosis of a lesion.

The screening and early detection program was established following passage of the Breast and Cervical Cancer Mortality Prevention Act of 1990. The program provides breast and cervical cancer screening to older women, women with low incomes, and underserved women of racial and ethnic minority groups.

The data were published in the January issue of *Cancer Causes and Control.*

From the NIH

NIAID releases updated HIV treatment guidelines

The *Guidelines for the Use of Antiretroviral Agents in HIV-Infected Adults and Adolescents* has been updated to include recommendations regarding initiation of anti-HIV therapy and the benefits and risks of available modes of therapy, according to the National Institute of Allergy and Infectious Diseases, National Institutes of Health. The guidelines acknowledge the inability of current available medications to eradicate HIV infection.

The guidelines recommend consideration of initiating antiretroviral therapy when an asymptomatic HIV-infected person's CD4+T-cell count is less than 350 cells/mm^3, whereas previous guidelines had recommended consideration of therapy at a CD4+T-cell count less than 500 cells/mm^3.

For asymptomatic HIV-infected patients with CD4+T-cell counts greater than 350 cells/mm^3, treatment should be considered when the level of HIV in plasma is more than 30,000 copies/mL using the branched-chain DNA assay, or more than 55,000 copies/mL using the reverse transcriptase polymerase chain reaction test, while previous guidelines recommended consideration at lower levels of plasma HIV. The guidelines recommend antiretroviral therapy for all patients with acute HIV syndrome, all patients with symptoms ascribed to HIV infection, and those within 6 months of HIV seroconversion.

The updated guidelines include two new entries in the category of *strongly recommended* anti-HIV drug treatments: the protease inhibitor Kaletra—a combination of ritonavir and lopinavir—and a combination of ritonavir and indinavir.

Drug toxicity associated with long-term use is also addressed by the guidelines, particularly the alteration of fat metabolism, which may lead to high levels of cholesterol and triglycerides and subsequent premature coronary disease.

Finally, the importance of adherence to therapy once the decision is made to begin is emphasized in the guidelines.

The updated guidelines are available at *www.hivatis.org*, by calling 800-448-0440, or by sending an e-mail request to *atis@hivatis.org.*

Three government agencies and AMA raise awareness of foodborne illness

The Centers for Disease Control and Prevention, Food and Drug Administration, USDA Food Safety and Inspection Service, and American Medical Association released a new physician/patient information kit to raise awareness of emerging food-related diseases as a serious health problem.

Although many foodborne illnesses have faded, new and reemerging ones have appeared. The *Diagnosis and Management of Foodborne Illness: A Primer for Physicians* kit is designed to update physicians and contains patient information for physicians to distribute.

There are 76 million cases of food-related illness in the United States each year resulting in more than 5000 deaths. The kit allows physicians to educate patients, especially at-risk populations such as young children, pregnant women, older adults, and those with weakened immune systems. People who have liver disease, alcoholism, or increased stomach acidity are also at higher risk for foodborne illness.

Information regarding the kit is available at *www.ama-assn.org/foodborne/.*

Lowering children's fat intake safe and beneficial

A long-term reduction of fat, saturated fat, and cholesterol in the diets of children with high blood-cholesterol levels offers benefit without adversely affecting development, according to the National Heart, Lung, and Blood Institute, National Institutes of Health.

A total of 650 children between the ages of 8 and 10 years was randomly assigned to an intervention group or usual care group. Children in the intervention group met with nutrition counselors periodically and maintained a diet of 28% calories from total fat, less than 8% from saturated fat, 9% from polyunsaturated fat, and fewer than 150 mg/d of cholesterol. Children in the usual care group received dietary recommendations without counseling intervention.

Blood tests to measure total cholesterol and LDL-cholesterol levels were given at 1, 3, 5, and 7 years. Cholesterol levels in the intervention group were lower compared with levels in the usual care group, particularly at 1 year and 3 years. Differences between the groups in total blood cholesterol and LDL-cholesterol levels narrowed and were no longer significant at 5 years and 7 years.

Scientists attribute the narrowing of levels between the groups to improvements in the dietary habits of the usual care group or lower adherence to dietary recommendations by intervention group participants.

NIH course on protection of human research participants available online

The National Cancer Institute, National Institutes of Health, developed an interactive Web-based course in response to the mandate that requires education on human subjects' protection for all investigators who receive funds from the National Institutes of Health for research involving people. The program offers up to 2 hours of category 1 continuing medical education credit.

The course, *Human Participant Protection Education for Research Teams*, is now available at *http://cme.nci.nih.gov.*

Peer pressure influences girls' decision to drink

The National Institutes of Health has released study results that indicate girls are more swayed by the influence of friends to drink alcohol than boys.

In the study, confidential surveys were given to 4200 teenagers in junior high schools in Maryland.

The study showed that the leading indicator of whether either gender decides to drink or smoke is if they have friends who do, regardless of whether the friends exert pressure. Also, most teenagers who drink and smoke think their parents do not care.

From the EPA

EPA reports on environmental health threats to children

A report issued by the Environmental Protection Agency assesses environmental factors affecting the health of children.

Trends in curbing environmental health threats to children include a decline in the number of children who live in areas where one or more key air pollutants exceed air quality standards (28% in 1990 vs. 23% in 1998). The number of children who live in areas with recorded violations of drinking water standards also declined, from 19% in 1993 to 8% in 1998. Finally, the number of children 7 years of age and younger who live in homes with a person who smokes tobacco declined from 29% in 1994 to 19% in 1999.

Asthma rates among African American children, however, remain higher than rates of other groups, and the prevalence of asthma among all children in the United States increased from 5.8% in 1990 to 7.5% in 1995. ◆