Federal update

From the FDA

FDA approves laser for LASIK procedures
The Food and Drug Administration (FDA) approved an eye laser for use in laser in situ keratomileusis (LASIK) procedures to correct nearsightedness with or without astigmatism in adults.

LASIK is a nonreversible procedure in which the surgeon uses a knife called a microkeratome to precisely cut a flap in the outer layers of the cornea, removes a small amount of the targeted tissue beneath it with the laser, and then replaces the flap.

The laser, made by Summit Technology of Waltham, Mass., was approved for treating nearsightedness (0.0 to –14.0 diopters) with or without astigmatism (–0.5 to 5.0 diopters) in people 18 and older whose vision has been stable for the past year.

Approval of the laser was based on a review of clinical studies on safety and effectiveness submitted by Summit and on the recommendation of the Ophthalmic Devices Panel of FDA’s medical devices advisory committee.

In the studies, LASIK procedures were performed on 1013 eyes at 13 medical centers in the United States. Patients were followed up for 6 months.

Of the 1013 eyes treated, 92% were corrected to 20/40 or better, and 47% were corrected to 20/20 or better without glasses or contact lenses.

Short-term side effects included pain (for 24 to 48 hours), corneal swelling, double vision, and light sensitivity. Side effects 6 months after treatment included under-correction (11.9%), overcorrection (4.2%), severe halo (3.5%), loss of best corrected vision with eyeglasses (3%), severe visual fluctuations (2.6%), and severe glare (1.7%).

Pregnant or nursing women; or people who have a vascular, autoimmune, or immunodeficiency disease; who have a herpes simplex virus or herpes zoster infection in their eyes; or people taking isotretinoin (Accutane) for acne or amioderone hydrochloride (Cordarone) to control heart rhythm are not candidates for this treatment.

FDA approves Tamiflu for influenza
The FDA approved oseltamivir phosphate (Tamiflu), an antiviral drug administered orally for treatment of type A and B influenza.

In two clinical trials, treatment with oseltamivir was started within 40 hours of onset of symptoms. Participating subjects were asked to self-assess their influenza-associated symptoms. The time to improvement of symptoms was calculated from the time treatment started to the time when all symptoms decreased to none or mild. In both studies, there was a little more than a 1-day reduction in time to improvement of symptoms for influenza-infected patients treated with oseltamivir compared with the placebo group.

The most common side effects were nausea, vomiting, bronchitis, insomnia, and dizziness.

Abbott agrees to correct manufacturing deficiencies
Abbott Laboratories has signed a consent decree of permanent injunction agreeing to stop manufacturing and distributing many of its in vitro diagnostic tests until it corrects manufacturing problems in its Diagnostics Division.

During the past 6 years, Abbott has failed to comply with FDA’s Good Manufacturing Practice and Quality System (GMP/QS) regulation. Despite warnings, Abbott has failed to correct its problems.

The FDA is not recommending that diagnostic tests be repeated for those patients whose initial testing was performed using Abbott’s in vitro diagnostic test kits.

Abbott’s manufacturing practices first raised FDA concern in 1993, when deficiencies in good manufacturing practice were found during FDA inspections of the firm’s Abbott Park, III, and North Chicago, Ill, manufacturing facilities. Violations were found in process validation, production, and process control, and corrective and preventive action.

After these inspections, the FDA sent a warning letter to Abbott in March 1994. Subsequent FDA inspections during 1995, 1996, 1997, and 1998 found the same types of deficiencies. When the firm failed to meet promised completion dates and failed to correct problems adequately, FDA sent another warning letter in March 1999 and reinspected the facilities during May, June, and July. During that inspection, FDA found continuing deficiencies.

Under the consent decree, FDA will allow the firm to continue distributing certain medically necessary tests for screening blood donors for infectious bloodborne diseases such as the human immunodeficiency virus, hepatitis B, and hepatitis C.

Abbott will continue distributing a number of tests to laboratories. These include tests for identifying tumors, tests to detect heart attacks, and tests to monitor levels of therapeutic drugs.

The FDA will notify the medical community by letter about specific precautions that may be taken regarding continued use of these products.

Information will also be available via the Internet at www.FDA.gov/cedr/ and www.FDA.gov/cber/.

FDA allows soy health claim on food labels
Food products containing at least 6.25 g of soy protein per serving are now permit-
From the CDC

Flu, pneumonia shots urged

The CDC is urging Americans to have a flu vaccination and a protective shot against pneumonia. It estimates that without shots 1 in 10 Americans will suffer.

This strong urging follows an unusual outbreak of influenza during the summer months. Tourists in Alaska were sickened by an outbreak, and there were also outbreaks in Louisiana, Florida, Oklahoma, and Texas.

Vaccinations are particularly recommended for everyone older than 64 years; younger people with chronic heart or lung disorders, including asthma, or who have diabetes, kidney disease, or a weakened immune system; and anyone in close contact with those high-risk patients.

Obesity increases dramatically in the United States

Obesity has increased to 17.9% in 1998 from 12% in 1991, and has spread rapidly throughout the United States, according to CDC research published in the October 27 issue of JAMA.

The highest increase occurred among 18-to-29 year olds with some college education and people of Hispanic ethnicity. There was a 67% increase in the number of obese people in the South.

To abate the epidemic, the CDC is recommending that healthcare providers counsel their obese patients, workplaces offer healthy food choices and opportunities to be physically active, and schools must offer more physical education to encourage lifelong physical activity.

For more information about nutrition and physical activity, call the CDC at 888-CDC-4NRG or visit the agency’s Web site at www.cdc.gov/nccdphp/dnpa.

Rotavirus vaccine withdrawn from market

The RotaShield rotavirus vaccine was voluntarily withdrawn from the market by its manufacturer, Wyeth Lederle Vaccines unit of American Home Products. It has also requested an immediate return of all doses.

The CDC, following reports associating the vaccine with intussusception in some infants, had previously requested that healthcare providers and parents postpone use of the vaccine. The vaccine was approved by the FDA in August 1998.

Guidelines modified for meningitis vaccination

The Advisory Committee on Immunization Practices (ACIP) is recommending that physicians who provide care to freshman dormitory residents give information about the benefits of vaccination for meningococcal disease to this at-risk group.

Vaccination should be provided or made easily available to those freshman wishing to reduce their risk of disease.

The currently available vaccine protects against some types of the bacterium Neisseria meningitidis. A single dose of the vaccine is recommended, and vaccination will decrease the risk of disease caused by N meningitidis serogroups A, C, Y, and W-135.

From the NICHHD

Day care has impact on mother-child bond

A study suggests that the longer a child is in day care, the greater the impact of separation between mother and child becomes.

Researchers working with the National Institute of Child Health and Human Development studied 1274 mothers and their children. They found that children who are placed regularly in day care or another caretaker situation have less positive relations with their mother.

Statistics show that more than 50% of mothers with infants younger than 1 year worked outside the home in the 1990s. Researchers looked at the amount of time the children spent in day care, what type of care they were enrolled in, and the mother-child interactions.

The report can be found in the November issue of Developmental Psychology.

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