Federal update

From the NIH

Dr Barbara Ross-Lee appointed to NIH committee on women's health

Barbara Ross-Lee, DO, has been selected by the National Institutes of Health to represent the osteopathic medical profession on its Advisory Committee on Research on Women's Health. The committee advises the NIH's Office of Research, ensuring that women's health issues are pursued and supporting the advancement of women in biomedical careers. She joins 17 other committee healthcare professionals and serves an initial appointment of 2 years.

As dean of the Ohio University College of Osteopathic Medicine—the first black woman to serve as dean of a U.S. medical school—Dr Ross-Lee has long been interested in policies related to women, minorities, and osteopathic medical education.

Dr Ross-Lee is also the director of the American Osteopathic Association's National Health Policy Fellowship Program. She formed the fellowship after serving a Robert Wood Johnson Health Policy Fellowship in the capacity of a legislative aide to Bill Bradley, then the senator from New Jersey. She also chairs the AOA's new Minority Health Initiative Advisory Committee and is chairman-elect of the Board of Governors of the American Association of Colleges of Osteopathic Medicine.

From the NHLBI/NIH

Risk of hypertension greater in adults with sleep apnea

A "Sleep Heart Health Study" conducted by the National Heart, Lung, and Blood Institute and involving 6000 people aged 40 years and older has revealed that middle-aged and older adults with sleep apnea have a 45% greater risk of hypertension than people without the sleep condition. Further, the risk of hypertension, or high blood pressure, which is measured at 140/90 mm Hg, increased with the severity of apnea. The risk of hypertension was seen even at moderate levels of apnea.

Sleep apnea, a condition affecting 12 million Americans, is a breathing disorder characterized by 10-second-or-more interruptions of breathing during sleep, accompanied by snoring. Treatment involves wearing a face mask that forces air through the nasal passages.

Because hypertension is a major risk factor for cardiovascular disease, scientists are hopeful that they can reduce cardiovascular mortality in persons with hypertension by diagnosing the apnea.

Portion of high blood pressure study stopped early because of drug performance

The performance of doxazosin, a drug being tested in a large high blood pressure study, caused scientists from the National Heart, Lung, and Blood Institute to stop a part of the study. The alpha-adrenergic blocker was found to be less effective than the traditional treatment, which uses a diuretic called chlorthalidone. Users of doxazosin had 25% more cardiovascular events and were twice as likely to be hospitalized for congestive heart failure as users of chlorthalidone.

The main portion of the study, called the Antihypertensive and Lipid Lowering Treatment to Prevent Heart Attack Trial (ALLHAT), compares newer drug treatments with conventional treatments.

One million of the 24 million who take medication for hypertension use an alpha blocker. Doxazosin, the alpha blocker used in the ALLHAT portion of the study, is sold under the brand name Cardura.

From the NIDA/NIH

Increase in anabolic steroid abuse by teens inspires NIDA education initiative

The results of a Monitoring the Future survey, conducted annually for the past 25 years, has indicated a sharp increase in the number of 8th, 10th, and 12th graders who have taken anabolic steroids at least once. In response, the National Institute on Drug Abuse has announced a national education initiative to draw attention to the abuse of anabolic steroids.

Teen boys concerned about body image and athletic performance who take anabolic steroids, synthetic substances related to testosterone, are in danger of side effects such as reduced sperm production, changes in testicular size, and impotence. Serious problems, such as stunted bone growth and permanent damage to the heart, liver, and kidneys, may also develop.

The education initiative includes launching a new Web site (*www.steroidabuse.org*) and distributing full reports and postcards that describe the dangers of steroid use. A prevention program aimed at girls who use steroids and other body-shaping drugs is in development.

From the NIAMS/NIH

Glucosamine/chondroitin sulfate may be useful in treating patients with osteoarthritis

A study consisting of a review of scientific trials conducted over the past 30 years found that glucosamine/chondroitin sulfate may be useful in treating patients with osteoarthritis.

Fifteen of 37 trials published between 1980 and 1998 met the National Institute of Arthritis and Musculoskeletal and Skin Disease's criteria for further analysis. The

researchers combined data from the studies to determine the compound's "effect size," with 0.2 as the least effect and 0.8 as the most effect. The total effect size for glucosamine was 0.44 and for chondroitin sulfate was 0.78.

Approximately 21 million American adults suffer from this degenerative disease that is caused by the breakdown of cartilage that cushions bones within the joint. Glucosamine and chondroitin sulfate are natural substances that researchers believe may help in the repair and maintenance of the cartilage.

From the HHS

Child abuse and neglect statistics for 1998 reported

The U.S. Department of Health and Human Services reported in April that 1998 national child abuse and neglect statistics indicate a decline, the fifth year in a row of decline of these figures.

The states have reported a decline to just over 900,000 cases of child abuse and neglect in 1998, and the rate of child maltreatment declined to 12.9 per 1000 children. Half (54%) of all victims suffered neglect, 23% suffered physical abuse, and 12% were sexually abused. Child fatalities caused by maltreatment remained at about 1100 annually.

Parents are reported to be the main perpetrators of maltreatment, with the most common scenario (45%) being a child maltreated by a female parent. Male parents are more likely to perpetrate physical and sexual abuse.

HHS officials are hopeful that greater protection for children will result from passage of the Adoption and Safe Families Act and community-based child abuse prevention programs.

HHS issues statement regarding new tobacco product

Donna E. Shalala, Secretary of the U.S. Department of Health and Human Services, announced that her agency is concerned about the marketing plans for Eclipse, a new tobacco product produced by R. J. Reynolds. Stating that it was "not at all clear that a sufficient science base exists to support a bold claim that this tobacco product may reduce the risk of cancer," Shalala said it was also not clear if doctors should support smoking patients switching to this product. Finally, she warns smokers to "be very careful about assuming that products like Eclipse are in any way safer than cigarettes."

From the NIAID/NIH

Research reveals reason for inability to recover from chronic hepatitis C

A long-term study of patients who contracted the hepatitis C virus from blood transfusions indicates that their outcomes, ranging from short-term infection to chronic disease, depend on changes in surface proteins that allowed the virus to avoid an immune system response.

Researchers from the National Institute of Allergy and Infectious Diseases and the National Institutes of Health conducted the study to see if the hepatitis C virus changes during infection. They looked for changes in the genes that encode special proteins coating the viral surface and immune system changes in response to hepatitis C infection.

Where the virus remained unchanged after immune response, patients were able to eliminate hepatitis C in a short time, but in the 85% who failed to recover, an early immune response resulted in viral variants that resulted in chronic infection.

Four million Americans have been infected with the hepatitis C virus, which can result in chronic liver disease, cirrhosis, and liver cancer. The virus causes approximately 10,000 deaths annually.

The report can be found in the April issue of *Science*.

From the FDA

FDA approves Visudyne for wet macular degeneration

The FDA approved verteporfin for injection (Visudyne) to slow vision loss in people with wet age-related macular degeneration.

While the majority of people with macular degeneration have the dry form, the 10% who have the wet form are in greater danger of losing their vision more quickly, and, if untreated, the condition may lead to blindness within 2 years.

Visudyne therapy consists of an intravenous injection into the patient's arm which reaches the blood vessels of the eye. Laser light then activates the drug. Following treatment, patients must avoid sunlight and bright indoor light for 5 days.

Treatment does not stop or reverse vision loss. Though it is well tolerated by most, side effects do include increased sensitivity to light, vision disturbances, and, in 1% to 4% of patients, severe vision decrease.

Age-related macular degeneration, a major cause of blindness in people over 60 years of age, affects the central field of vision, while peripheral vision is preserved.

FDA approves recombinant human insulin analog with once-daily administration for patients with diabetes

The FDA has approved Lantus (insulin glargine [rDNA origin] injection), the first long-acting recombinant human insulin analog, for the treatment of patients with type 2 and type 1 diabetes.

Adult patients with type 2 diabetes mellitus who require basal insulin for the control of hyperglycemia and patients with type 1 diabetes mellitus are provided a constant concentration/time profile with the administration of a once-daily injection at bedtime.

Lantus performed similarly as NPH human insulin in trials that tested for metabolic control. Side effects associated with human insulin therapy include hypoglycemia, the most common problem, and increased diabetic retinopathy, lipodystrophy, and allergic and skin reactions.

Rezulin to be withdrawn from the market

The FDA has requested that the manufacturers of Rezulin (troglitazone), Parke-Davis/Warner-Lambert, remove the product from the market.

Rezulin, a drug used to treat patients with type 2 diabetes millitus, was found to be more toxic to the liver than two other approved drugs used for the same condition, rosiglitazone (Avandia) and pioglitazone (Actos).

Parke-Davis had altered its labeling of Rezulin several times since the discovery of its toxicity in 1997.

Rezulin will continue to be available for select patients whose diabetes is not controlled by other drugs.

Heartburn drug, Propulsid, to be pulled

Following talks with the FDA, Janssen Pharmaceutica, a subsidiary of Johnson & Johnson, has decided to pull the nighttime heartburn drug, Propulsid, off the market because of its association with fatal heart rhythm abnormalities.

Since its introduction in 1993, Propulsid has been associated with 341 reports of heart rhythm abnormalities, including 80 deaths. Janssen has initiated education programs and changed the drug's labeling several times to reduce inappropriate use.

The FDA was planning a public advisory committee meeting where the possibility of pulling Propulsid off the market would have been discussed.

FDA approves new anti-epilepsy drug

The FDA has approved Zonegran (zonisamide) capsules for the treatment of adults with partial (focal) epileptic seizures.

As part of an adjunctive therapy, Zonegran will be used to treat the population of people with epilepsy who suffer from partial seizures that are not controlled with a single-drug regime.

Since 1989, Zonegran has been marketed as Excegran in Japan.

Zyvox approved by the FDA

The FDA has approved Zyvox (linezolid) to treat infections often found in immunocompromised patients and especially in patients who are institutionalized. This is the first antibacterial drug in a new class of synthetic drugs, the oxazolidinone class, approved to treat infections associated with vancomycin-resistant *Enterococcus faecium* (VREF). This includes cases of bloodstream infection; hospital-acquired pneumonia; complicated skin and skin structure infections, such as methicillin-resistant *Staphylococcus aureus* (MRSA); community-acquired pneumonia; and uncomplicated skin and skin structure infections.

Controlled clinical studies involved more than 4000 patients. A dose-comparison study was conducted for approval of the use of Zyvox for VREF infections. It was reported that the cure rate was 67% in the group receiving 600 mg every 12 hours and 52% in the group receiving 200 mg every 12 hours.

The study, developed to test Zyvox's effectiveness compared to vancomycin, found it to be equally effective for the treatment of hospital-acquired pneumonia, including cases with MRSA.

The study that compared linezolid with oxacillin/dicloxacillin gained approval for Zyvox's use for complicated skin and soft tissue infections.

Reported side effects included headaches, nausea, diarrhea, and vomiting. A decrease in platelets in laboratory tests may occur, and Zyvox may interact with certain other drugs, particularly cold remedies containing pseudoephedrine or phenylpropanolamine, to cause an increase in blood pressure.

The first case of VREF in the United States was reported in 1989. Sharp increases in both VREF and MRSA infections have occurred since then. ◆