News Briefs

- The first-ever Surgeon General’s report on bone health, issued in October, stated that pharmacists can help prevent osteoporosis in patients by advising them on calcium and vitamin D supplementation, suggesting the best way to take medications, and averting potential drug interactions. According to the report, osteoporosis affects 10 million Americans older than the age of 50 years, and another 34 million persons are at risk for the bone disease. The 437-page Bone Health and Osteoporosis: A Surgeon General’s Report and other public health reports of the Surgeon General are available at www.surgeongeneral.gov/reportspublications.html.
- The results of the Seventh ACCP Conference on Antithrombotic and Thrombolytic Therapy, convened by the American College of Chest Physicians, were published as the supplement to the September issue of Chest, the organization’s journal. Consisting of 22 articles, the supplement offers evidence-based guidelines on such issues as the use of vitamin K antagonists, prevention of venous thromboembolism, antithrombotic therapy with valvular heart disease, and thrombolysis in acute myocardial infarction.
- To meet the 2005 National Patient Safety Goal to improve the safety of using medications, hospitals, home care organizations, and long-term-care facilities accredited by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) must identify and review at least annually a list of 10 drug combinations that look or sound alike and are used by the health care organization. JCAHO named the specific drug combinations, such as Lantus and Lente insulin products, that a facility may consider for its list. Health care organizations must also act to prevent the erroneous interchange of their selected drug combinations. For more information,

Recent changes to FDA-approved labeling

**Adalimumab** injection (Humira, Abbott): Indications for use in adults with moderately to severely active rheumatoid arthritis were expanded to include improving physical function. The recommended dosage is the same as for the other indications.

**Amphetamine and dextroamphetamine salts** extended-release capsules (Adderall XR, Shire): Indications for use in the treatment of attention-deficit/hyperactivity disorder were expanded to include adults. In adults, the recommended dosage is 20 mg/day with or without food. The boxed warning was expanded to note that the misuse of amphetamine may cause sudden death and serious cardiovascular adverse events. Information was added to the Warnings section concerning an association between sudden death and amphetamine use in children and adolescents.

**Docetaxel** concentrate for injection (Taxotere, Aventis): Indications for use in the treatment of breast cancer were expanded to include combination therapy with doxorubicin and cyclophosphamide in patients after surgery for axillary-node-positive disease. The recommended dosage is 75 mg/m² given as a one-hour i.v. infusion after doxorubicin 50 mg/m² and cyclophosphamide 500 mg/m² every three weeks for six treatment cycles.

**Enoxaparin sodium** injection (Lovenox, Aventis): The dosage in patients with a creatinine clearance of <30 mL/min was decreased; a table details the dosage by indication for use. Information was added to the Clinical Pharmacology section regarding the drug’s pharmacokinetics in patients with severe renal impairment or low body weight or who are undergoing hemodialysis.

**Infliximab** for injection (Remicade, Centocor): A warning on deadly hematologic events was added. Clinicians were advised to consider stopping therapy when significant hematologic abnormalities or central-nervous-system adverse reactions occur. Neutropenia, pericardial effusion, and systemic and cutaneous vasculitis were added to the list of adverse events reported since licensure of the drug.

**Meloxicam** tablets (Mobic, Boehringer Ingelheim): Indications for use were expanded to include the relief of signs and symptoms of rheumatoid arthritis in adults. The recommended starting and maintenance dosages are 7.5 mg daily; the maximum dosage is 15 mg once daily.

**Octreotide acetate** for injectable suspension (Sandostatin LAR Depot, Novartis): A sticker was added to the instruction booklet advising the user that the syringe of diluent is no longer supplied with a cap.

**Pemtrexed** for injection (Alimta, Lilly): Indications for use were expanded to include the second-line treatment of locally advanced or metastatic (stage III or IV) non-small-cell lung cancer in patients who have previously received antineoplastic therapy. The recommended dosage is 500 mg/m² given as a 10-minute i.v. infusion on day 1 of each 21-day treatment cycle, accompanied by pretreatment with a corticosteroid, folic acid, and vitamin B₁₂.

**Somatropin** for injection (Saizen, Serono): Indications for use were expanded to include the replacement of endogenous growth hormone in adults with growth-hormone deficiency. The recommended starting dosage is 0.005 mg/kg per day; after four weeks, the dosage may be increased to a maximum of 0.01 mg/kg per day if the patient tolerates therapy.

**Tegaserod maleate** tablets (Zelnorm, Novartis): Indications for use were expanded to include the treatment of chronic idiopathic constipation in patients younger than age 65 years. The recommended dosage is 6 mg twice daily before meals; information on the efficacy of the treatment beyond 12 weeks is not yet available.

**Ziprasidone hydrochloride** capsules (Geodon, Pfizer): Indications for use were expanded to include the treatment of mania or mixed episodes associated with bipolar disorder. The recommended initial dosage is 40 mg twice daily with food on day 1, 60 or 80 mg twice daily on day 2, and then 40–80 mg twice daily, depending on the patient’s progress and tolerance of the treatment; information on the efficacy of the treatment beyond three weeks is not yet available.
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see www.jcaho.org/accredited+organizations/patient+safety/05+npsg/rlasa.pdf.

- The name of the administrative group overseeing the Office of Pharmacy Affairs (OPA) at the Health Resources and Services Administration has a new name: Healthcare Systems Bureau. OPA, which administers the 340B drug-pricing program, had been moved to the Special Programs Bureau earlier this year (see September 1, 2004, AJHP News). In addition to a new name, the bureau received authority to manage the funds set aside through the Poison Control Center Enhancement and Awareness Act, which had previously been the responsibility of the Maternal and Child Health Bureau (see July 1, 2004, AJHP News).

- The Department of Health and Human Services awarded the prime vendor contract for the 340B drug-pricing program to Texas-based HealthCare Purchasing Partners International, which previously had a subcontract for price negotiation services. This new contract is for two years, with the option for three one-year extensions.

- Use of a tablet splitter or a kitchen knife to break unscored cyclobenzaprine tablets in two produced fragments 69–130% or 50–150%, respectively, of their theoretical weight, according to a study reported in the September/October issue of Journal of the American Pharmacists Association.

- Sanofi-Synthelabo acquired Aventis in August to form Sanofi-Aventis Group and established the U.S. affiliate’s headquarters in Bridgewater, New Jersey. To maintain competition in the market for factor Xa inhibitors used as anticoagulants, the Federal Trade Commission required Sanofi to sell the fondaparinux product line to GlaxoSmithKline.

- Primary care pharmaceutical products owned by Bayer HealthCare will be marketed and distributed in the United States by Schering-Plough Corp., according to an agreement announced in September. The products retain the Bayer brand name but are sold by the Schering-Plough sales force. Bayer also announced that it would create a specialty pharmaceuticals business unit to focus on “high-profit specialty and biotech products,” such as aprotinin, anti-hemophilic factor, and oncology drugs, with specialist physicians.

- Daniel A. Hussar, Ph.D., a professor of pharmacy at the Philadelphia College of Pharmacy, was named the 2004 Pharmacist of the Year by the Pennsylvania Society of Health-System Pharmacists.

- The California Society of Health-System Pharmacists named Michael Gonzales, Sherman Lau, Veda Roshan, and Sandra Sani among the recipients of the 2004 Student Leadership Award.

- Daniel A. Herbert, 61, died September 28 at his home in Richmond, Virginia, after a short illness. Herbert was the president of the American Pharmacists Association. He founded Richmond Apothecaries and, over the years, served as president of the American College of Apothecaries and local and state pharmacy associations.