



NSU College of Pharmacy
Drug Information & Resources Center
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Happy Thanksgiving to all!

In the News

FDA OKs Over-the-Counter Claritin Sales

The government approved over-the-counter sales of the popular allergy remedy Claritin on Wednesday, a long-anticipated move that will save uninsured allergy sufferers money but prove more costly to those with prescription drug insurance plans. The decision comes four years after a prominent insurance company petitioned the Food and Drug Administration to force Claritin's maker to sell it without a prescription here just like it long has in Canada. Money aside, proponents of the switch argued that nondrowsy Claritin is safer than today's over-the-counter antihistamines that make people sleepy, very dangerous if they're driving. Manufacturer Schering-Plough Corp. vehemently fought the switch at first, saying the insurance industry pushed the change because it doesn't pay for over-the-counter medicines - meaning insurers will save billions in drug costs as well as doctor fees. But Claritin's patent expires in December, opening the drug to generic competition - so earlier this year, Schering grudgingly changed course and asked the FDA to allow Claritin to be sold next to the aspirin and cough syrup after all. Today's prescription-only Claritin costs about \$60 a month, plus the cost of a doctor's visit to get a prescription. Schering didn't immediately say what the over-the-counter version will cost, but in Canada, a month's supply of nonprescription Claritin is about \$17. "Who is John Galt?" For people without insurance that covers medications, that's a boon. But allergy sufferers used to a \$10 or so insurance co-payment for their drugs would start paying more. The FDA's action also means that when generic versions of Claritin debut next year, they, too, will sell without a prescription - and generic drugs usually are significantly cheaper than their brand-name counterparts. Not clear is how soon Claritin competitors Allegra and Zyrtec could sell without a prescription as well. Last year, FDA's advisers recommended the agency take that step, ruling that all three of the non-sedating antihistamines were equally safe for over-the-counter sales. The FDA still is debating the fate

of Allegra and Zyrtec, said Dr. Robert Meyer, the agency's nonprescription drugs chief. Schering in January also began selling a prescription-only successor to Claritin called Clarinex. But Clarinex isn't considered much of an improvement over the older drug, so insurance companies may not reimburse patients for the more expensive prescription remedy. Analysts predict the Claritin switch will mean revenue from the company's top-selling drug will shrivel, from worldwide sales of \$3.1 billion last year to likely under half a billion next year. Some 40 million Americans have allergies, and half of them are estimated to use over-the-counter remedies. Claritin's main advantage over the other nonprescription choices is that it's not sedating - it won't carry that warning against driving or operating heavy machinery that's so common on over-the-counter drugs. But anyone who takes higher-than-recommended doses of Claritin, or has kidney or liver disease that slows metabolism of the drug, can experience some drowsiness, Meyer cautioned.

FDA Approves Teriparatide First Drug to Build Bone

A new drug approved by the Food and Drug Administration is the first to combat osteoporosis, the brittle-bone disease, by causing the body to form new, healthy bone tissue. Approved Tuesday, the drug works by stimulating osteoblasts, the body's bone-building cells, which often are inactive among the 10 million Americans with osteoporosis. Active osteoblasts increase bone density and its resistance to fractures. The chemical name of the new drug is teriparatide. It will be marketed by Eli Lilly and Co. of Indianapolis under the brand name Forteo. FDA officials said the drug, given by injection daily, will carry a special warning because in laboratory tests teriparatide caused cancerous bone tumors in rats. Such tumors have not been seen in 2,000 people who tested the drug in clinical trials, officials said. "We feel this is an important drug," said Dr. Eric Colman, a team leader in the FDA division of metabolic and endocrine drug products. "It is the first approved that stimulates bone formation instead of slowing the breakdown of bone." As people age, their risk for osteoporosis increases. Over a person's lifetime, bone is built up and broken down by special cells. The osteoblast cell forms new bone, while osteoclast dissolves old, worn-out bone tissue. So long as this process remains in balance, bones stay strong and dense. But in many women after menopause and in some men, age brings an imbalance of action by the two bone-sculpting cells. Osteoclasts tend to become more active, dissolving old bone faster than osteoblasts can build new bone. The result is that bones become thin and brittle, leading to fractures, particularly of the spine. Since 1995, drugs like Fosamax have attacked this problem by slowing the action of osteoclasts, thus helping bones retain density. The new drug takes a different approach by stimulating the osteoblasts and restoring the body's ability to build new bone. Colman said that to bolster the effect, patients may use teriparatide with the older approved drugs because the drugs work by different mechanisms in the body.

Labels and instructions issued with teriparatide will carry a "black box" warning, Colman said the warning will discuss rat studies that showed some animals injected with teriparatide developed osteosarcomas, a rare and serious cancer of the bone. However, he said that teriparatide was testing for 19 months in 1,637 women and for 10 months in 437 men. None of those patients developed bone cancer. In the test patients there were significant increases in bone density at the spine and hip when compared with patients who took only calcium pills and vitamin D. The studies also found in women a reduction in bone fractures among patients taking teriparatide when compared to a placebo. The effect on fracture risk in men was not studied, according to an FDA statement. The FDA said that in teriparatide clinical trials some patients developed mild side effects, including nausea, dizziness and leg cramps. Robert Marcus, a medical adviser for Lilly, said the cancer that occurred in the rats would be highly unlikely in humans for several reasons, including that rat skeletons are significantly different from human skeletons. To lower the risk of cancer, Marcus said, Lilly is recommending the drug not be prescribed for patients with an increased risk of osteosarcoma, including those with Paget's disease or unexplained elevations of alkaline phosphate. Also, he said, children, growing adults and those who have had radiation therapy involving the skeleton should not receive the drug. Osteoporosis affects around 10 million Americans, 80 percent of them women. Brittle bones can lead to small fractures of the vertebrae and a gradual slumping, leading to the distinctive hump frequently seen in elderly women and in some men. The fractures can also cause pain and crippling.

FDA Approves Eli Lilly Drug for ADHD Atomoxetine

The first non-stimulant drug designed to treat attention-deficit/hyperactivity disorder won approval Tuesday from the Food and Drug Administration. Indianapolis-based Eli Lilly and Co. expects Strattera to be available in pharmacies in January. Lilly has tested Strattera on more than 4,000 patients, some for as long as 2 1/2 years. It has not been tested in children under 6.

Strattera is the first drug to be approved for ADHD that is not a stimulant under the federal Controlled Substances Act. The drug comes in a capsule and can be taken once or twice a day. Lilly said it provides full-day relief from the symptoms of ADHD. ADHD is one of the most common behavioral disorders of childhood. Although not widely recognized in adults, experts estimate that 4 percent, more than 8 million people, have the disorder, Lilly said. Scientists believe it works by blocking or slowing reabsorption of norepinephrine, a brain chemical considered important in regulating attention, impulsiveness and activity levels. The most common side effects of the drug are decreased appetite, nausea and vomiting. Expect to see it on shelves in January.