



NSU College of Pharmacy
Drug Information & Resources Center
N e w s l e t t e r

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Question of the Day...

What FDA prescription drug is identical to a product fermented by red yeast rice (*Monascus purpureus*) called monacolin which was widely marketed as a dietary supplement under the Dietary Supplement Health and Education Act of 1994.

hint, first statin approved 1987.

In the News

Gilead wins FDA OK for second once-daily HIV drug

<http://news.moneycentral.msn.com/ticker/article.asp?Feed=RTR&Date=20030702&ID=2678970&Symbol=US:GILD>

Gilead Sciences has announced that the U.S. Food and Drug Administration (FDA) has cleared for marketing EmtrivaT (emtricitabine), a new 200 mg one-capsule, once-daily nucleoside reverse transcriptase inhibitor (NRTI) for the treatment of HIV infection in adults in combination with other antiretroviral medications. Emtriva has been evaluated in clinical trials of both treatment-naïve and treatment-experienced HIV patients. Emtriva attacks HIV by inhibiting reverse transcriptase, the enzyme that copies HIV RNA into new viral DNA. By interfering with this process, which is central to the replication of HIV, Emtriva can help to lower the amount of HIV, or "viral load," in a patient's body and increase the number of immune system cells (called T cells or CD4 cells). Both of these changes are generally associated with improving a patient's health and decreasing the likelihood of AIDS-related illnesses. "The drug's once-daily dosing, side effect profile and long half-life make it an important addition to a new generation of easier-to-use HIV therapies," said Michael Saag, MD, Professor of Medicine and Director of the HIV Clinic at the University of Alabama at Birmingham. "Its activity against the virus, combined with easy dosing, offers patients an effective treatment option that can help reduce the heavy pill burden often associated with combination therapy." Emtriva is Gilead Sciences' second once-daily antiretroviral for the treatment of HIV. The

compound was licensed from Emory University in 1996. Gilead's first anti-HIV medication, Viread® (tenofovir disoproxil fumarate), a one-tablet, once-daily nucleotide reverse transcriptase inhibitor (NtRTI), was cleared for marketing by the FDA in October 2001. The company is developing a fixed-dose co-formulation of Emtriva and Viread, which could potentially be available by early 2005.

FDA Approves New Cancer Drug Bexxar (tositumomab) for Non-Hodgkin's Lymphoma
http://biz.yahoo.com/djus/030630/0715000455_1.html

Corixa Corp. and GlaxoSmithKline PLC received Food and Drug Administration approval for Bexxar as a treatment for follicular non-Hodgkin's lymphoma. In a press release Monday, the drug companies said Bexxar will be sold to patients whose disease relapsed after chemotherapy and didn't respond to the drug rituximab. Corixa said the drug's effectiveness was examined in a single-arm study of 40 patients. A total of 88% of patients enrolled in the study showed no response or a response of less than six months in duration when treated prior to the study with rituximab. Corixa said 63% of these patients had a response to Bexxar, while 29% of patients receiving Bexxar showed no clinical signs of disease after treatment. The most common side effect in the trials included anemia, as well as blood disorders known as neutropenia and thrombocytopenia. The side effects can be both prolonged and severe, Corixa said. Bexxar's original FDA application was submitted by Coulter Pharmaceuticals Inc., which Corixa has since acquired, and GlaxoSmithKline's predecessor, SmithKlineBeecham PLC. Corixa will be ready to start filling orders for the drug in about 30 days. Corixa and GlaxoSmithKline of London plan to co-market Bexxar in the U.S.

More Evidence Chemo During Pregnancy Can Be Safe
<http://www.reuters.com/newsArticle.jhtml?type=topNews&storyID=3021162>

A woman who was diagnosed with cancer and given chemotherapy while she was pregnant has given birth to a healthy child, according to her doctors in Germany. They say the case adds to growing evidence that chemotherapy during pregnancy is safer than many doctors and patients assume. Dr. Holger Stepan, a consultant in the department of gynecology and obstetrics at Leipzig University Clinic, told Reuters Health on Monday that the 24-year-old patient was diagnosed with Hodgkin's disease during her 28th week of pregnancy. "At that point we had to weigh the risk of delivering the baby immediately, with all the risks associated with a premature delivery ... against the risks of starting a course of chemotherapy during pregnancy, but with the advantage for the child of being able to prolong the pregnancy," said Stepan. In her 32nd week of pregnancy, the patient was started on a low dose of chemotherapy with four drugs. "The patient responded well to the therapy," Stepan said. Then at week 34, the baby was delivered by Cesarean section and found to be healthy. The mother then went through a course of

high-dose chemotherapy and subsequent radiation, and has since fully recovered with no traces of the cancer left. Stepan said this case adds to the growing body of evidence that patients and doctors may overestimate the risks of in-utero exposure to chemotherapy. He said some types of chemotherapy can be given in the second or third trimester without the risk of fetal malformations -- though he pointed out that chemotherapy does pose such a risk in the first trimester. Previous research has suggested that once the fetus is 12 weeks or older, the mother can undergo chemotherapy without an increased risk of birth defects or mental impairment. Hodgkin's disease is the most frequent form of cancer among pregnant women after breast cancer, cervical cancer and the skin tumor melanoma. Stepan said the incidence of cancer among pregnant women might increase because many women are now waiting until later in life to have children.

Single Pill Aims to Cut Heart Disease by 80 Percent

http://story.news.yahoo.com/news?tmpl=story&cid=534&ncid=534&e=5&u=/ap/20030626/ap_on_he_me/single_heart_pill

A single pill combining six medications could prevent more than 80 percent of heart attacks and strokes if heart patients, most diabetics and everyone over 55 took it, British scientists said Thursday. However, the American Heart Association cautioned such a pill might be dangerous for healthy people and not strong enough for those with heart trouble. It could also lull some people into persisting with life-threatening habits. There are massive caveats. We are quite concerned about this," said Heart Association president Dr. Robert Bo now. The concept, outlined Thursday on the Web site of the British Medical Journal, is the brainchild of two University of London doctors, Nicholas Wald and Malcolm Law. Called the "polypill," it would contain aspirin to reduce the stickiness of blood cells involved in clotting; a statin drug to lower cholesterol and folic acid to reduce levels of homocysteine, an amino acid that promotes hardening of the arteries. Three types of blood pressure drugs - an ACE inhibitor, a beta-blocker and a diuretic - would be included at half the standard dose - enough, the doctors say, to lower blood pressure without causing as many side effects as when the drugs are used individually at higher doses. The scientists based their finding on evidence from more than 750 existing studies involving 400,000 participants taking heart medications. By multiplying risk reductions for individual drugs, they estimated the pill would prevent about 88 percent of heart attacks and 80 percent of strokes if taken by people over 55, as well as many people with high blood pressure, heart disease or diabetes. For example, Wald and Law calculated that if 100 people would have had a heart attack without treatment, cholesterol drugs would prevent 61 of the 100 attacks, leaving 39. About 46 percent of those would be prevented with blood pressure drugs, leaving 21 heart attacks. About 16 percent of these would be prevented with folic acid, leaving 18, and 34 percent of the remaining attacks would be averted with aspirin, leaving 12

heart attacks out of the original 100. They estimated that one-third of people over 55 taking the pill would benefit, gaining on average about 11 years of life free from a heart attack or stroke. Side effects, mostly from aspirin, would occur in between 8 and 15 percent of people who take the pill, depending on the formulation, the scientists estimated. "The polypill represents a radical departure from current practice in the prevention of cardiovascular disease. Undoubtedly there will be debate over it, and so there should be," Wald said. Bonow from the American Heart Association urged caution. "There are data already on aspirin that if you give aspirin to a general population, you do not save lives because the people you save by preventing heart disease and stroke is offset by the number of people you kill by causing bleeding," he said. While the risk of a heart attack or stroke increases after the age of 55, age alone is not a strong enough risk factor to warrant treatment, he said. "My concern is one pill may not fit all," he said. Dr. Eric Topol, cardiology chief at the Cleveland Clinic, said the polypill idea runs counter to the way medicine is headed in the future, which is toward personalized medication based on an individual's genetic profile. "There is tremendous promise for the individualization of care in the years ahead," he said. Studies of the "Polypill" are planned to see if the combination is safe and effective. Results are not expected for a few years. Law and Wald have filed a patent application on the formulation of the combined pill they described.

Florida Rx Law Kicks In: No More Rotten Writing, Or Else

http://www.doh.state.fl.us/Mqa/medical/me_home.html

Section 1. Section 456.42, Florida Statutes, is created to read: 456.42
Written prescriptions for medicinal drugs.--A written prescription for a medicinal drug issued by a health care practitioner licensed by law to prescribe such drug must be legibly printed or typed so as to be capable of being understood by the pharmacist filling the prescription; must contain the name of the prescribing practitioner, the name and strength of the drug prescribed, the quantity of the drug prescribed in both textual and numerical formats, and the directions for use of the drug; must be dated with the month written out in textual letters; and must be signed by the prescribing practitioner on the day when issued.

<http://www.poynter.org/column.asp?id=2&aid=40043>

Florida has a new law this week requiring doctors to write prescriptions legibly. The Florida Department of Health is asking pharmacists to squeal on any doctors who write messy prescriptions. Consumer groups have been asking for national legislation or at least state-by-state adoption of safe script laws for years. Earlier this year, the Institute for Safe Medication practices suggested a national standard for electronic filing of meds. In other words, do away with the old handwritten prescriptions. In December, the Milwaukee Journal Sentinel reported, "Doctors' scrawlings have been linked to thousands of deaths a year from adverse drug reactions. Those

errors add an estimated \$2 billion a year to the cost of health care nationwide as mistakes lengthen hospital stays and require extra care for patients." The paper also said, "Up to 20 percent of medication errors may be related to doctors' illegible handwriting, experts say. Such misinterpreted hieroglyphics, if not caught, can lead to a pharmacist misreading a prescription's dosage, not understanding abbreviations or mixing up drugs that sound alike." "Some medical schools have begun talking about this issue, citing a widely publicized 1999 case in Texas where a jury awarded a woman \$450,000 because her husband died from taking the wrong medication. The pharmacist dispensed the wrong medication because he misread a doctor's handwriting. Science Daily reported a couple of years ago that the famed Cedars-Sinai Hospital offers a three-hour course that is self-instructional and emphasizes a cursive italic handwriting style, with tips on the correct position of the paper, the size of letters, the length of strokes, and how one should hold the writing instrument." This issue has been around for a long time. In 2000, CNN reported, "The nonprofit Institute for Safe Medication Practices (ISMP) calculates that medication errors cause more U.S. deaths each year than workplace injuries. And a recent report from the Institute of Medicine found that some 7,000 of the 98,000 estimated annual deaths from medical errors resulted from improper medication. Because of statistics like those, the ISMP wants to see the end of handwritten prescriptions within the next three years."

So Many Pharmacies; Too Few Pharmacists

<http://www.nacds.org/wmspage.cfm?parm1=3061>

Pharmacist Shortage Continues Unabated, According To Latest NACDS Foundation Chain Pharmacy Employment Survey. The National Association of Chain Drug Stores Foundation latest pharmacist employment survey found 5,499 vacant chain pharmacy positions as of January 2003. With retail pharmacies expected to fill 4 billion prescriptions by 2006, up from 3 billion in 2001, it is clear much work needs to be done to ensure Americans have convenient access to the expertise of their neighborhood pharmacist in the future. The NACDS Foundation Chain Pharmacy Employment Survey is conducted biannually. Results from January 2003 revealed vacancies of 5,499, which is about the same figure compared to last year's figure of 5,475. A total of 90 chain pharmacy companies representing 24,396 stores completed the survey. Respondents represent roughly 70% of the estimated 35,401 pharmacies in the US. Using a scale of 1-5 with one representing a large shortage and five a large oversupply, survey respondents give each of the 50 states plus the District of Columbia and Puerto Rico a shortage ranking. For example, Maine received a 1.27, which means the state has a large shortage while Hawaii received a score of 3.27 signifying it has just the right amount of pharmacists. The survey also identifies specific cities within each state, which are shortage areas. In addition to dispensing more medication than ever before, pharmacists are counseling an ever-growing number of patients,

particularly older patients, on proper medication use. As the US population ages and prescription use continues to surge, the need for pharmacists' services will only increase. Alongside industry efforts to encourage pharmacy as a career, there are several ways this problem can be tackled. NACDS is working with Congress to enact legislation that would help alleviate the pharmacist shortage. The Senate Health, Education, Labor and Pensions (HELP) Committee passed legislation this year to authorize funding for a program of educational loan repayments for pharmacy students and prospective pharmacy school faculty. Peanut. NACDS is advocating for passage by the full Senate, as well as for introduction of similar legislation in the House of Representatives. Pharmacists receive six years of education to become "medication experts". By counseling patients on proper prescription drug use, pharmacists not only improve our health, but also reduce overall healthcare costs. Lawmakers and retailers addressing this industry-wide shortage together will allow pharmacists to continue playing the vital role of trusted, caring healthcare professionals in communities across the country.

JAMA Sounds Warning Regarding Metformin/TZD

<http://www.healthday.com/view.cfm?id=513956>

Patients with diabetes and heart failure seem to be routinely receiving medications that may aggravate one condition even if they help the other. Specifically, metformin (brand name Glucophage) and a class of medications called thiazolidinediones -- both of which help control glucose levels in diabetics -- may cause serious complications in patients with heart failure. The findings are detailed in a study in the July 2 issue of the Journal of the American Medical Association. "The number of patients with diabetes has increased dramatically in the country over the last 10 years and increasingly these medications are being used as part of their therapy," says Dr. Sid Smith, director of the Center for Cardiovascular Science and Medicine at the University of North Carolina. "Because of the observations of fluid retention and weight gain [in the case of thiazolidinediones], it's very important that they not be used in patients with known heart failure or, if necessary, that possible problems be monitored very carefully," adds Smith, who is a past president of the American Heart Association. Part of the problem is that so many patients, especially patients with diabetes, have other health conditions as well. "The typical heart failure patients are patients who have many concurrent illnesses and complications and can end up on a lot of different medications," says study author Dr. Harlan M. Krumholz, a professor of medicine and epidemiology and public health at Yale University School of Medicine. "As people end up going to a specialist, there's often not a lot of cross-talk. We need to pay a lot more attention to the integration of our approaches and taking into account a variety of conditions," Krumholz says. But there's also the issue of whether physicians are paying attention to U.S. Food and Drug Administration (FDA) "black box"

warnings on medications. Such warnings are the most serious category of health side effects. "There's a discordance between what the FDA is saying and what's going on in practice," Krumholz says. "We're potentially undermining the entire system." The black-box warning for metformin indicates the drug could lead to lactic acidosis -- or acid in the blood, a potentially life-threatening problem for people with heart failure. And thiazolidinediones may cause fluid retention, again a serious condition for heart failure patients. "Good care of a chronic condition of heart failure entails getting people into the right balance. And if they're on medications that cause them to retain fluid, it may turn them in the wrong direction and tip them over and cause them to be hospitalized," Krumholz says. For this study, Krumholz and his colleagues pored through the medical records of Medicare beneficiaries who had been hospitalized with heart failure and diabetes from April 1998 to March 1999 and July 2000 to June 2001. The earlier sample consisted of 12,505 patients, 7.1 percent of whom were discharged with a prescription for metformin, 7.2 percent with a prescription for a thiazolidinedione, and 13.5 percent with a prescription for one or the other. In the second sample, which consisted of 13,158 patients, 11.2 percent got metformin, 16.1 percent got a thiazolidinedione, and 24.4 percent one or the other. The study authors did not look at how many people had adverse reactions, simply how many patients were prescribed the drugs. It's not entirely clear why this disconnect is happening, the researchers say. Physicians may simply not be aware of the dangers or they may think the benefits outweigh the risks. Or they may have decided that the risks aren't as high as advertised. "We have a problem when the FDA is saying one thing with respect to the safety of a medication and clinicians are so frequently doing something else," Krumholz says. "We need to determine the best way to treat patients," he says. "It is a problem when the FDA's black-box warning is not being heeded. Either the FDA has overreacted or clinicians are exposing their patients to unnecessary risk, and we [have] to know which it is." And it's not just an issue for heart failure patients with diabetes, although this is a group that warrants more attention. "It raises the issue about the way that we deliver health care in this country," says Dr. Kenneth Hupart, chief of endocrinology, diabetes and metabolism at Nassau University Medical Center in East Meadow, N.Y.

Bipolar : Don't D/C Antidepressants When Depression Subsides

<http://www.reuters.com/newsArticle.jhtml?type=topNews&storyID=3020077>

Patients with bipolar disorder should continue taking antidepressants even after their symptoms have eased, researchers suggested on Tuesday, in a break with standard practice. Usual guidelines for treating the chronic disorder, also known as manic depression, recommend discontinuing antidepressants within six months of improvement. But researchers from the University of California at Los Angeles found that patients treated under those guidelines were nearly twice as likely to relapse as those who

continued taking antidepressants along with mood stabilizing medication for the first year after remission of acute bipolar depression. They also found no increased risk of manic relapse among study participants who continued the medication for a year. Manic depression, marked by swings from euphoria to despair, is one of the most common mental illnesses, with some research suggesting it might affect up to 8 million American adults. "Psychiatrists are taught that when someone is depressed you put them on antidepressants, but when the patient is bipolar there was always a risk of inducing mania," said Mark Frye, director of UCLA's Bipolar Disorder Research Program and a co-author of the study. "Maybe we need to be thinking of antidepressants as long-term therapy for bipolar patients who were depressed and did well on medication." The study findings appear in the July issue of the American Journal of Psychiatry. The work was supported by the Stanley Medical Research Institute, a nonprofit organization that supports research on the causes and treatment of schizophrenia and bipolar disorder. Three pharmaceutical companies provided free medication -- including drugs such as Glaxo's Wellbutrin and Pfizer Inc.'s Zoloft -- but no other financial support. "The common clinical practice of discontinuing antidepressant use in bipolar patients soon after remission of depression symptoms may actually increase the risk of relapse," Dr. Lori Altshuler, a professor at the UCLA Neuropsychiatric Institute and the study's lead author, said in a statement. The U.S. Food and Drug Administration last week approved Lamictal, GlaxoSmithKline Plc.'s anti-seizure pill, as the first new maintenance therapy for bipolar disorder since the introduction of lithium in the 1970s. The UCLA study examined 84 individuals with bipolar disorder whose depression symptoms eased with the addition of an antidepressant to an ongoing mood stabilizer, such as lithium or Eli Lilly & Co.'s Zyprexa. At one year after improvement of depression symptoms, 70 percent of the group that discontinued antidepressants had relapsed, compared to 36 percent of the continuation group.

Vitamins may not prevent disease, says US panel

<http://straitstimes.asia1.com.sg/techscience/story/0,4386,197807,00.html>

For years, antioxidants such as vitamins A, C, E, folic acid, and beta-carotene have been touted as having multiple health benefits, including preventing heart disease and cancer. But now a government panel of health experts says there is no clear evidence to support this claim. And for smokers, taking beta-carotene supplements could even increase their risk of lung cancer and death, the panel says. 'We can't say that (people) should or they shouldn't take supplements,' said vice-chairman Janet Allan of the United States Preventive Services Task Force, which conducted the review. 'We can't tell you if it will help or not.' The findings were published in Tuesday's issue of the Annals Of Internal Medicine. Researcher Cynthia Morris of Oregon Health and Sciences University, who compiled and analysed the studies, said that while supplements may have other benefits, they

likely have no effect on cardiovascular health or cancer. Of people who take vitamins for the sole purpose of preventing disease, she says: 'They're basically creating expensive urine.' The task force specifically recommended that people who smoke more than two packs of cigarettes a day should not take beta-carotene, either alone or in a multivitamin combination. But there is no evidence to suggest that beta-carotene is harmful to smokers at the levels that occur naturally in foods. Dr Allan said most people can get all the nutrients they need by eating a healthy diet. Still she acknowledged that many people don't. The elderly, pregnant or lactating women, and people on certain medications have trouble absorbing nutrients from foods. The task force scrutinised more than two dozen studies over two years. They analysed the use of vitamins A, C, or E, multivitamins with folic acid, or antioxidant combinations to reduce the risk of cardiovascular disease, heart attack or sudden cardiac death. They also looked at the effectiveness of antioxidants in preventing several types of cancer. Antioxidant deficiencies have been linked to blood vessel changes that occur in cardiovascular disease and cellular changes that occur in cancer, leading some people to hypothesise that vitamin supplements might help prevent these diseases. But the studies reviewed by the task force did not bear this theory out. But the task force did not rule out the possibility that taking antioxidant supplements may have long-term health benefits.

Schering-Plough adds warning to Zetia label

http://biz.yahoo.com/rc/030630/health_scheringplough_5.html

Schering-Plough Corp. has announced it has altered the label for its cholesterol drug Zetia to include a warning that the drug can cause allergic reactions, including angioedema and rash.

Angioedema is characterized by swelling of one or all of the hands, feet, eyelids and lips. Sometimes the membranes lining the mouth, throat and airways swell, making breathing difficult. In severe cases, it can prove fatal. Schering-Plough said it decided to update the label following routine monitoring of reports of adverse events. The company declined to reveal the number of people affected by the allergic reactions. It said only that none of the cases were life-threatening. An official from the U.S. Food and Drug Administration (News - Websites) was unable to immediately answer the question. Schering-Plough, which is marketing the drug with Merck & Co. (NYSE:MRK - News), said it submitted its new label to the FDA in April, and that it will be in the market in July. Zetia was approved last October and had sales of \$46 million in the first quarter. The companies expect to combine Zetia with Merck's blockbuster cholesterol drug Zocor to form a new multibillion-dollar treatment. Depending on how many people are affected, angioedema can be a serious side effect.

Ranbaxy Gains FDA Approval to Exclusively Market Generic Alternative to Cytovene(R)

http://www.ranbaxy.com/newsroom/pressrelease_det.asp?sno=112

Ranbaxy Laboratories Limited (Ranbaxy), announced today that the Company has received approval from the US Food and Drug Administration to manufacture and commercialize Ganciclovir Capsules in 250 mg and 500 mg strengths. The Division of Bioequivalence has determined Ranbaxy's Ganciclovir Capsules, 250 mg and 500 mg, to be bioequivalent and therefore, therapeutically equivalent to the listed drug Cytovene® Capsules, 250 mg and 500 mg, respectively, of Roche Palo Alto, LLC. In 2002, sales for Ganciclovir Capsules totaled \$31.9 million. Ganciclovir Capsules are indicated for the prevention of Cytomegalovirus (CMV) disease in solid organ transplant recipients and in individuals with advanced HIV infection at risk for developing CMV disease. Cytovene® Capsules are also indicated as an alternative to the intravenous formulation for maintenance treatment of CMV retinitis in immuno-compromised patients, including patients with AIDS, in whom retinitis is stable following appropriate induction therapy and for whom the risk of more rapid progression is balanced by the benefit associated with avoiding daily IV infusions.

Wyeth's low-dose Prempro 0.45 mg/1.5 mg - Now Available

<http://main.pslgroup.com/news/industrynews.nsf/IndustryNewsId/8960D43D269B45CF85256D550073CAC2?opendocument&id=>

A new low-dose hormone pill for post-menopausal women from Wyeth hit pharmacies this week, six months after the Food and Drug Administration warned women should only take hormone therapy in low doses for short amounts of time. Wyeth's lower-dose Prempro, a combination of the hormones estrogen and progestin, won FDA approval in March and an even-lower dose set for release at year's end. The Prempro that will be available Tuesday contains 28% less estrogen, at 0.45 milligram, and 40% less progestin, at 1.5 milligrams, when compared with the currently available pill. The drug has been struggling since last summer, when a huge government-funded study found so-called hormone-replacement therapy slightly elevated a woman's risk for heart attack, stroke and breast cancer -- the very things many women and their doctors thought the hormones prevented.

One third of the 15 million U.S. women who were taking hormones have since quit. The number of women taking Prempro plunged 65% to 1.2 million from 3.4 million after the release of the study, Wyeth said. No one knows if a lower dose will revive the brand. "The whole trend has been so weird," said independent pharmaceutical analyst Hemant Shah. "With all the concerns about risks, it is very difficult to predict. Under normal circumstances (the lower-dose Prempro) would have been a very big contributor for Wyeth. In this new environment it is very difficult to say." It also isn't clear if the lower dose will be free from the same small increase in health risks because it hasn't been tested in the same type of very large, long-term study and Wyeth isn't planning one. Following the study release last year,

Wyeth, the FDA and several medical groups have since said hormone treatment should only be prescribed for treating a very short list of symptoms -- hot flashes, vaginal dryness and osteoporosis. The controversy about how hormone therapy should be prescribed jumped into the foreground after a 16,000-woman National Institutes of Health study stopped earlier than planned last summer. Per 10,000 women, those on Prempro had fewer than 10 more cases of breast cancer, stroke and heart attack. However small, those numbers represented a 20% increase over those taking a placebo sugar pill. Dr. Valerie Montgomery Rice, who has led studies of Prempro and is head of the obstetrics and gynecology department at Meharry Medical College in Nashville, Tenn., said most of her patients have been confused by the data but are interested in lower doses of Prempro. "For most women in my practice it is prescribed for hot flashes," said Dr. Rice, who is also a member of Wyeth's visiting speakers bureau. Mary Alice Williams, a woman's health advocate and Wyeth consultant, said women now need to realize hormone therapy isn't for everyone. She noted women need to check into their family history of heart disease, breast cancer, osteoporosis and other ailments to figure out if they are already at elevated risks for these diseases. Peanut "You have to know where you come from," said Ms. Williams. She added women should also realize there are other ways to combat some symptoms of menopause -- including avoiding caffeine, alcohol and spicy foods. The new low-dose Prempro will cost the same as the current drug, with a wholesale cost of \$1.13 a day, and come in packs of 28 pills. Natalie DeVane, a Wyeth spokeswoman said the company is considering a consumer-education campaign, but no full-scale advertising program is planned now.

Teamster Pharmacists at Osco Overwhelmingly Authorize Strike

<http://www.prnewswire.com/cgi-bin/stories.pl?ACCT=104&STORY=/www/story/06-26-2003/0001972322&EDATE=>

After 12 Weeks of Negotiations Pharmacists Still Without New Contract. Teamster represented pharmacists at Osco Drug stores, an arm of the Albertsons Corporation voted Sunday, June 22 to authorize a strike if a contract between them and the company could not be reached. Teamsters Local 714 represents 630 pharmacists at 185 stores in Cook, Lake, Dupage and McHenry counties. "The public, particularly our senior citizens feel confident that when they go to Osco their prescriptions will be filled correctly. Osco pharmacists deserve to be compensated properly to ensure that the company continues to attract the best pharmacists in the area," said Robert A. Hogan, Local 714 Secretary-Treasurer. "We've been negotiating since April, and Albertsons has forced us to take the extraordinary step of taking a strike vote." Teamster pharmacists first rejected the company's offer June 1 by a margin of 10-1. The Teamsters have successfully reached agreements with Osco or its parent nine times since 1972, when the pharmacists affiliated the ir association with Local 714. Osco is currently owned by the Albertsons,

which operates 2,287 stores in the 31 states. Teamster pharmacists reached a three-year agreement with Albertsons shortly after the retail giant bought Jewel-Osco in 2000. "Contracts are more than wages, they're about your rights on the job, so it's not surprising that a national company would come into Chicago and try to impose its model on our community," Hogan said. "Unfortunately, the company's national model doesn't meet with the standards we've built here in Chicago. This strike vote shows our members determination to protect their families and community." Local 714 represents more than 9,000 hardworking men and women in various industries and in the public sector. It is an affiliate of the International Brotherhood of Teamsters.

Ex-Rite Aid executive Sorkin pleads guilty

http://biz.yahoo.com/rc/030626/crime_riteaid_sorkin_4.html

A former Rite Aid Corp. vice president on Thursday became the third executive from the drugstore chain to plead guilty to conspiracy in one of the largest corporate accounting scandals in U.S. history. Eric Sorkin, Rite Aid's former vice president of pharmacy services, pleaded guilty to a single felony count of conspiracy to obstruct justice during a hearing in U.S. District Court in Harrisburg. "Who is John Galt?" Under a plea bargain with federal prosecutors, he could spend up to five years in prison, pay a \$250,000 fine and face a maximum of three years on parole for his role in a \$1.6 billion overstatement of company profits during the 1990s. The 10-page plea agreement, dated June 19, also stated that Sorkin could receive leniency if he can demonstrate to the court that he accepted responsibility for his misdeeds by aiding the investigation against him. With tears in his eyes at Thursday's hearing, Sorkin apologized in a wavering voice to the federal government, his family and friends, and Rite Aid. "I'm so sorry for what I did," the bespectacled former executive told Judge Sylvia Rambo while flanked by two attorneys. Rambo accepted Sorkin's plea and will impose a penalty after reviewing a pre-sentencing report on the case. Sorkin, 54, was one of four ex-Rite Aid executives named in a 37-count fraud indictment handed up by a federal grand jury last summer. Former Chief Executive Martin Grass, 49, faces up to eight years in prison and payment of \$3.5 million after pleading guilty to two conspiracy counts last week. Former Chief Financial Officer Frank Bergonzi, 57, pleaded guilty early in June, and faces the same maximum sentence as Sorkin. The fourth and final defendant named in the indictment, ex-vice chairman and chief legal counsel Franklin Brown, was also scheduled to plead guilty to conspiracy on Thursday. But Judge Rambo cancelled Brown's hearing at the request of his attorneys and gave the 75-year-old defendant until July 14 to decide whether to proceed with a guilty plea or opt for a trial. She also disbanded a 12-member jury impaneled for trial proceedings that had been set to get under way in Brown's case on June 30. A three-year probe by the FBI and the U.S. Securities and Exchange Commission (News - Websites) showed that Grass,

Brown and Bergonzi hatched well over a dozen fraud schemes to create the impression that Rite Aid was a profitable company. Federal authorities say further indictments could still emerge from the ongoing investigation. Sorkin was named last year in two counts of an indictment that charged him with helping to obstruct the FBI, SEC and grand jury investigations, and lying to grand jurors about a bogus severance letter he received from Grass. On Thursday, Sorkin admitted lying to investigators between November 1999 and July 2001 about the legitimacy of his severance letter, which sought to award him \$800,000 to \$1.5 million over a three-year period. The letter, written by Grass and allegedly delivered to Sorkin by Brown, was dated April 2, 1999. But Sorkin said he realized the letter had actually been written after Grass resigned as CEO in October 1999 and had been back-dated on Grass' computer. Sorkin also admitted to Rambo that he discussed ways to mislead investigators about the severance document with Brown.

In the Pipeline

Crestor (SuperStatin): Big Vote Set Next Week

http://www.fdaadvisorycommittee.com/FDC/AdvisoryCommittee/Committees/Endocrinologic+and+Metabolic+Drugs/070903_crestor/070903_CrestorA.htm

AstraZeneca's statin Crestor (rosuvastatin) will be reviewed July 9 by FDA's Endocrinologic & Metabolic Drugs Advisory Committee for treatment of hypercholesterolemia and mixed dyslipidemia. In response to a May 2002 "approvable" letter, AstraZeneca submitted data Feb. 12 on the 10 mg, 20 mg and 40 mg doses, giving the NDA a mid-August user fee goal. Development of an 80 mg dose was discontinued due to findings of rhabdomyolysis and renal impairment. The decision followed Bayer's August 2001 withdrawal of Baycol (cerivastatin) due to rhabdomyolysis-related deaths. While rhabdomyolysis has not been associated with the lower Crestor doses, AstraZeneca has reported some cases of myopathy (less than 0.01%). Crestor gained Canadian approval Feb. 18 in 10 mg, 20 mg and 40 mg dosage forms for familial and primary hypercholesterolemia, as well as for mixed dyslipidemia. The firm, however, has been focusing marketing on the 10 mg dose. Crestor investigators have been describing the 10 mg dose as achieving target cholesterol levels without requiring dose increases. Avoiding titration, investigators pointed out, provides both convenience and psychological benefits, as well as a safety advantage.

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Website of the Day

Overnight Prescriptions

<http://www.overnightprescriptions.com>

The future of Pharmacy or the demise of a profession?

This website asks three very poignant questions relating to its service...

Why wait in line at your local pharmacy?

Why wait at your local Doctors Office?

With the price of gas why drive?

My answer...because you idiot its better than this garbage. This being "an online medical consultation for prescription medications". Basically you answer a (loose) set of questions online and then receive, via mail, Viagra, Ambien, Sonata, Adipex, Phentermine, Cyclobenzaprine, Paxil and other

(risky) medications. But on the flip side, they do ship to all 50 states...Thanks for saving me on the gas money though bud.

Answer of the Day

Lovastatin is identical in structure to monacolin, a by-product of fermented red yeast rice (*Monascus purpureus*). Red yeast rice, made by fermenting red yeast (*Monascus purpureus*) on rice, duh! has been used for centuries in Chinese food and Medicine. When carefully fermented, *Monascus purpureus*, yields, in essence, lovastatin, an HMG-CoA reductase inhibitor effective in reducing cholesterol (estimates are that four grams of red yeast rice contain about 10 milligrams of statin). (sidenote: uncontrolled fermentation of red yeast yields citrinin, a hepatotoxic substance, so beware) Since red yeast rice is considered "natural" in the US it was originally regulated under the Dietary Supplement Health Education Act of 1994 and was widely available without a prescription. However, after numerous court battles (Pharmanex vs Shalala) the FDA finally closed the DSHEA loophole in this case and categorized Red Yeast Rice as a Drug and not a dietary supplement and outlawed any marketing of the product as such. Good thing for Merck as Lovastatin has been a huge seller for years and profited billions and for the company. oh...by the way red yeast rice is the yummy red border on those Chinese spare-ribs. See, maybe good for the cholesterol.