



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 widely available nonprescription drug is the d-isomer of the codeine analog levorphanol (a potent narcotic analgesic)?

hint...one if its abbreviations is the same name as a famous Rapper from Yonkers NY?

In the News

Drug Ads Spur 20 Percent of Consumers to Call Doc

http://story.news.yahoo.com/news?tmpl=story2&cid=594&ncid=594&e=4&u=/nm/20021009/hl_nm/ads_consumers_dc

One in five Americans say direct-to-consumer (DTC) advertising prompted them to call or visit their doctor to discuss an advertised drug, a new consumer tracking study finds. The August PharmTrends survey by market research firm Ipsos-NPD also shows that 50% of consumers recalled seeing advertising for prescription products in the previous 12 months, up from 47% in the first survey conducted in February. "The information is still telling us that consumers are accepting and actually eager to find information about prescription drugs," said Fariba Zamaniyan, director of Ipsos PharmTrends. The percentage of consumers responding to a DTC ad by calling or visiting their doctors actually declined in August--to 20% from 25% six months earlier. Zamaniyan said the numbers might reflect seasonable fluctuation in drugmaker spending on DTC advertising. "I wouldn't necessarily say it's a dip or a drop in the trend. I would say it's actually consistent," she told Reuters Health. Considering that PharmTrends' DTC survey is based on a representative national sample of adults 18 and older, drugmakers have good reason to be encouraged by the 20% "call to action" their ads have provoked. "It's a good sign that they're getting a positive response from the general population," Zamaniyan said. The latest survey also finds that 22% of consumers credit DTC ads with making them aware of potential drug options for their conditions, down from 25% in the February poll. Twelve percent said that they asked their doctor about a drug that they saw advertised, versus 15% in poll 6 months

earlier. These trends may become clearer once the firm has completed the third poll in the tracking series, Zamaniyan said. The February 2003 poll will provide a third snapshot-in-time of consumer behavior and enable year-over-year comparisons. Ipsos NPD is a unit of the Paris, France-based global market research conglomerate Ipsos, which specializes in media, advertising and market research and conducts public opinion polling.

Ore. Considers Universal Health Plan

http://story.news.yahoo.com/news?tmpl=story2&cid=534&ncid=534&e=9&u=/ap/20021009/ap_on_he_me/oregon_health

Every man, woman and child in Oregon would receive full medical insurance - no co-payments, no deductibles - under a measure on the Nov. 5 ballot that would create the first universal health care plan in the nation. The question is whether Oregonians are willing to pay higher taxes for a plan so generous it would cover even acupuncture and massage therapy. "What we are proposing is ambitious and audacious, but we believe the health care system now is in a crisis," said Mark Lindgren, spokesman for the Health Care for All Oregon campaign, sponsor of Measure 23. Under the existing system, he said, an estimated 423,000 of Oregon's 3.3 million residents have no health insurance - about 70,000 of them children. Nationally, the number of uninsured is about 41 million. The Oregon plan would be financed by a new payroll tax of up to 11.5 percent on businesses and an increase in personal income taxes. The top rate would rise from its current 9 percent to as high as 17 percent. No independent polls have been released on the measure, but it is facing strong opposition from business, insurance and health care industry groups, who fear it will lead to runaway spending and wreck the state's economy. "It's the richest benefits package known to man," said J.L. Wilson, head of the Oregon chapter of the National Federation of Independent Business. "Under this bill, you would have to pay for people to go to a massage therapist four days a week because it's deemed `medically necessary.'" Lindgren put the cost \$19 billion a year - more than the entire current state budget of about \$16 billion. About \$7 billion of the cost would be covered by the payroll tax, and \$4.9 billion by higher income taxes. The rest would come from shifting state and federal health care dollars to the new universal system. Oregon has gained a reputation for tackling difficult health-related issues in recent years. Voters in 1996 approved the nation's only law allowing physician-assisted suicide. In 1998 they approved the medicinal use of marijuana. In 1989, the Legislature enacted a groundbreaking health plan that extended insurance to thousands of poor people; the state drew up a master list of hundreds of diseases and treatments, ranking them in order of importance, then drew a cutoff line below which the state would not provide coverage. Measure 23 is backed by the Cleveland-based Universal Health Care Action Network, whose spokeswoman Rachel DeGolia sees the Oregon effort as picking up where

Hillary Rodham Clinton left off a decade ago with her push for universal health care. "It was dead in the water from the beginning" because of opposition from the health care industry, DeGolia said. "That's the reason we think this is going to have to happen at the state level first." "Who is John Galt?" Supporters hope passage of Oregon's measure will lead to similar efforts in other states. People in Oregon would not be required to get rid of their private or group insurance, but most would probably do so since they would be paying for the universal system anyway, Lindgren said. He said that while many people would pay higher taxes, much of that would be offset because they would no longer have to pay premiums, co-payments, deductibles and other out-of-pocket health costs. Opponents say the residency requirement is so loose that seriously ill people without insurance would move to Oregon just to take advantage of the program. New arrivals would merely have to declare their intention to live here. "It would take more to get a hunting license in Oregon than it would take to get access to full health benefits," said the NFIB's Wilson. Opponents also warn that it would cover all treatment deemed "medically necessary" by any state-licensed, certified or registered health-care practitioner. Also, the measure does not contain any limits on coverage and does not spell out whether there would be any exclusions for experimental procedures or devices. Lindgren said those points were deliberately left vague so that a 15-member state board that would be created to oversee the program could make those decisions later. He disputed warnings of runaway costs. Among other things, he said, people who lack insurance are a drain on the system because they often leave minor conditions untreated until they become major problems requiring expensive emergency room treatment. Barney Speight, a former state health administrator, warned that Measure 23 is bad medicine. "It might be able to achieve universal coverage in the short term," he said, "but in the long term it could destroy Oregon's economy."

FDA Approves Subutex (buprenorphine hydrochloride/naloxone hydrochloride) & Suboxone (buprenorphine hydrochloride)

<http://www.docguide.com/news/content.nsf/NewsPrint/8525697700573E1885256C4D0067D24E>

First New Addiction Treatment Products In 30 Years Approved For In-Office Treatment Qualified Physicians Have New Weapon to Treat Addicted Patients With Office-Based, Private Treatment Regimen. Reckitt Benckiser plc (RB.L) announced that the U.S. Food and Drug Administration (FDA) has granted marketing approval for Suboxone? (buprenorphine hydrochloride/naloxone hydrochloride) and Subutex? (buprenorphine hydrochloride), sublingual tablets for the treatment of opioid dependence. Suboxone and Subutex are the first therapies approved for in-office prescribing under the federal Drug Addiction Treatment Act of 2000 (DATA). The new medications and the new in-office model offer a discreet, effective and convenient new

treatment option. "The approval of Suboxone and Subutex is a much anticipated step toward opening up access to treatment for patients with opioid dependence who currently have little or no treatment options," said Herbert D. Kleber, MD, professor of psychiatry and director, Division of Substance Abuse at the College of Physicians and Surgeons of Columbia University and the New York State Psychiatric Institute. "These treatments have potential for tremendous impact in combating opioid dependence, especially in formerly underserved communities." There are up to one million opioid-addicted patients in the U.S., including those who are addicted to heroin and prescription pain medications. The estimated annual cost to society of opioid addiction is more than \$20 billion. The problem affects people in a variety of communities. Only about 15 percent of these heroin-dependent individuals are in treatment, partly because of limited access to treatment centers, which, until now, were among the only places to offer treatment. In addition to lack of access and privacy, current options for treating opioid dependence often have a high rate of relapse and can be fraught with other problems. "People addicted to opioids like heroin and prescription pain medications are faced with a number of obstacles to getting effective treatment," said Dr. Kleber. "We need to change the way we think about addiction. Science has shown that opioid addiction is a chronic, relapsing brain disease, not a character flaw, failure of will or lack of self-control. So we need to stop talking about 'addicts' and start referring to them as 'patients' -- people who have a disease that medication can relieve." Suboxone and Subutex Suboxone is a combination of two proven medications, buprenorphine and naloxone. Buprenorphine, a partial opioid agonist, reduces withdrawal symptoms and blocks the effects of subsequently administered opioids, which suggests that it may help reduce illicit opioid use. Because it contains naloxone, Suboxone is highly likely to produce intense withdrawal symptoms if misused intravenously by opioid-addicted individuals, however, when used as prescribed naloxone has no effect. Suboxone has demonstrated a low treatment dropout rate in clinical trials. Since Suboxone is a partial agonist, withdrawal upon discontinuation is milder than with full agonists. Suboxone also exhibits a "ceiling effect" on respiratory depression, which provides a margin of safety in comparison to other opioids. This "ceiling effect" decreases the danger of overdose. Unlike Suboxone, Subutex contains no naloxone; patients may be prescribed Subutex during a short induction period, which will be closely supervised by their physician, before being switched to Suboxone. Physician Certification DATA enables physicians who meet certain qualifying criteria to prescribe Schedules III, IV, or V narcotic drugs in the privacy of their offices. Under the DATA, qualified physicians can manage a total of 30 patients at one time. Further announcements regarding availability will be provided later. Suboxone Clinical Studies In a comparative study, adverse event profiles were similar for subjects treated with 16 mg Suboxone or 16 mg Subutex. The following adverse events were reported to occur by at least 5% of patients

in a 4-week study. The most common adverse events associated with Suboxone and placebo were respectively: headache (36 percent vs. 22 percent); withdrawal syndrome (25 percent vs. 37 percent); pain (23 percent vs. 19 percent); nausea (15 percent vs. 11 percent); and sweating (14 percent vs. 10 percent). As with other opioid agonists, there is a risk of respiratory depression. Patients should be warned of the potential danger of not using Suboxone or Subutex according to product information labeling and physician instructions. Suboxone and Subutex were developed by Reckitt Benckiser plc, U.K., and Richmond, VA. For more information about Suboxone and Subutex, please see full product information and visit <http://www.Suboxone.com> or call 1-877-Suboxone For more information on Reckitt Benckiser please visit <http://www.reckittbenckiser.com>. Under the Drug Addiction Treatment Act (DATA) of 2000, a physician is qualified to prescribe Schedules III, IV, or V narcotic drugs that are FDA-approved for the treatment of opioid dependence by meeting one or more of the following criteria: * Has been an investigator in one or more clinical trials leading to the approval of a Schedule III, IV, or V narcotic drug indicated for the treatment of opioid dependence * Has been subspecialty board-certified in addiction psychiatry by the American Board of Medical Specialties * Has been subspecialty board-certified in addiction medicine by the American Osteopathic Association * Holds addiction certification from the American Society of Addiction Medicine * Has completed no fewer than 8 hours of approved medical society training in the treatment and management of opioid dependence * Has other such training/experience as the State Medical-licensing Board or Secretary of Health and Human Services deems appropriate

FDA Approves Avodart, the First Dual-Acting 5 Alpha-Reductase Inhibitor for Benign Prostatic Hyperplasia (BPH)

<http://www.prnewswire.com/cgi-bin/stories.pl?ACCT=104&STORY=/www/story/10-10-2002/0001815948&EDATE=>

The U.S. Food and Drug Administration (FDA) has approved a supplemental new drug application for Avodart(TM) (dutasteride) for the treatment of symptomatic benign prostatic hyperplasia (BPH) in men with an enlarged prostate to improve urinary symptoms, reduce risk of acute urinary retention (AUR) and reduce the risk of the need for BPH-related surgery. Avodart, a second-generation 5 alpha-reductase inhibitor, is the first and only medicine to inhibit both the type 1 and type 2 enzymes responsible for the conversion of testosterone to DHT (dihydrotestosterone), the primary cause of prostate growth. Avodart's dual inhibition decreases levels of DHT by 90 percent at two weeks and 93 percent at two years. By reducing DHT levels, Avodart reduces the size of an enlarged prostate. In clinical studies, this reduction in prostate volume was seen as early as one month with reductions continuing through treatment. Shrinking the enlarged prostate relieves urinary obstruction and improves urinary flow. Avodart

also improves urinary symptoms and reduces the risk of AUR (the sudden complete inability to urinate) and BPH-related surgery, two potential long-term serious consequences of BPH. The pivotal phase III study data were published in this month's edition of the journal Urology. "With Avodart, we now have a medicine that reduces the production of DHT by more than 90 percent, helping to shrink the prostate," said Claus Roehrborn, MD, a principal trial investigator and professor and chairman of the Department of Urology at the University of Texas Southwestern Medical Center in Dallas, Texas. "By taking Avodart, patients can improve urinary symptoms and reduce their risk of suffering from acute urinary retention -- where you suddenly can't urinate at all -- or needing BPH-related prostate surgery."

Psychiatric Warnings Strengthened for Malaria Drug

http://story.news.yahoo.com/news?tmpl=story2&cid=594&ncid=594&e=4&u=/nm/20021004/hl_nm/malaria_drug_dc

The US Food and Drug Administration (FDA) issued an alert on Friday highlighting strengthened warnings recently added to the labeling for Roche's Lariam (mefloquine), a drug used for prevention and treatment of malaria. Lariam--which Roche sells to the US Army--entered the public eye this summer when the Pentagon said it would investigate whether murders allegedly committed by soldiers in Fort Bragg, North Carolina might be tied to psychological side effects of the drug. The military stressed at the time that there was no direct evidence that Lariam might have triggered the violence. The FDA said on Friday that the Lariam label had been changed to stress that the drug is contraindicated for preventive use in patients with active depression, recent history of depression, generalized anxiety disorder, psychosis, schizophrenia or other major psychiatric disorders. The new label also puts added stress on a contraindication for preventive use in patients with a history of convulsions, the agency noted. The FDA alert adds that if "psychiatric symptoms such as acute anxiety, depression, restlessness or confusion occur," they should be considered a possible warning of a "more serious event. "In these cases, the drug must be discontinued and an alternative medication should be substituted," the FDA states. On the day that the news about the Pentagon investigation broke, rival firm GlaxoSmithKline said that data had been added to the label of its malaria drug, Malarone (atovaquone and proguanil), suggesting that the product causes fewer neuropsychiatric side effects than Lariam does.

Bush's FDA Choice Enjoys Smooth Senate Hearing

http://abcnews.go.com/wire/Living/reuters20021007_578.html

Key senators from both parties lent their support to President Bush's

choice to head the Food and Drug Administration Monday, nearly assuring that the full Senate will approve the nominee. Dr. Mark B. McClellan, already a key advisor to the president on health care issues, gained praise from Democrats and Republicans during confirmation hearings before the Senate Committee on Health, Education, Labor, and Pensions. The HELP committee is expected to vote on McClellan's nomination on Wednesday. Sen. Edward M. Kennedy, the panel's chairman, predicted easy approval for McClellan, possibly before the Senate recesses for the fall elections. If approved by the full Senate, McClellan will fill an FDA commissioner's post that has been vacant for the last 20 months. The Bush Administration has faced growing criticism both from industry and consumers groups, who have complained that the agency has suffered from the lack of a permanent leader. A recent report from the General Accounting Office found that strains on FDA personnel have increased the time it takes the agency to approve new drugs while lowering job satisfaction among FDA experts. Some employees quit the agency at twice the rate that similar workers have quit other federal agencies, the report concluded. "Enhancing the FDA work environment must be a top priority of the commissioner," McClellan told lawmakers. He also said that he supports current efforts in the US Congress to reform the way FDA reviews and approves medical devices. Many lawmakers want to institute a system that charges companies user fees in exchange for the guarantee of faster review and approval times. Prescription drugs already use such a system. "This is the right time for us to move forward on this," McClellan said. McClellan is a physician and economist at Stanford University in California and also serves on the White House council of economic advisors. His brother Scott is the White House deputy press secretary, and his mother is a former mayor of Austin, Texas. The commissioner's post at FDA is often highly controversial. Through its control of drug approvals and food safety, the agency regulates nearly a quarter of all consumer products on US markets. It also has a strong hand in drug approvals and post-market policing that can affect the price of prescription drugs. In past years, the agency has also found itself on the front lines of the abortion debate because of its control of pregnancy termination drugs like mifepristone and the so-called "morning after pill." FDA is also receiving a huge influx of funding from Congress to help it gear up its efforts in vaccine approvals, food inspections, and other counter-bioterrorism operations. "You've got a lot of portfolio to handle," Sen. Judd Gregg (NH), the committee's senior Republican, told McClellan. Senate Democrats led by Kennedy signaled earlier in the year that they would reject several other potential nominees, including FDA acting commissioner Lester B. Crawford, for being too close to industry. McClellan has few industry connections. McClellan declined to say whether he supports moves by Kennedy and others in Congress to give the agency the legal authority it needs to regulate cigarettes and other tobacco products as drugs. The Supreme Court ruled in 2000 that FDA did not have the power under current law to control tobacco, though Health and Human Services

Secretary Tommy G. Thompson has said that he supports lawmakers' efforts to change the law to give FDA the authority. "That is just not going to be on the table, at least in the short run," McClellan said. Still, Kennedy praised McClellan for his "impressive background," and told reporters that he would push to get McClellan approved before next week's scheduled recess. "I think it's important that he get in the job, that we don't go into recess without him being approved," Kennedy said. Jeff Trehwitt, a spokesman for the Pharmaceutical Research and Manufacturers of America (PhRMA), declined to comment on McClellan's nomination directly, but did say that the lobbying group was pleased that FDA would likely soon have a permanent chief.

CDC Urges Flu, Pneumococcal Shots for Seniors

http://story.news.yahoo.com/news?tmpl=story2&cid=594&ncid=594&e=2&u=/nm/20021007/hl_nm/shots_cdc_dc

All Americans over age 65 should get flu shots as soon as possible, and consider getting a pneumococcal vaccine at the same time if they haven't already had one, government officials said Monday, adding that the shots are part of a new adult vaccination schedule. The adult schedule is meant to encourage higher vaccination rates, said Surgeon General Richard Carmona, noting that \$10 billion is spent each year treating adults for vaccine-preventable illnesses. Immunizations are cost-effective and "are safe and effective," he said at a press briefing with Centers for Disease Control and Prevention (CDC) officials. Dr. Walter Orenstein, director of the CDC's National Immunization Program, discussed the agency's flu and pneumococcal vaccine recommendations. October is the start of flu season in the US. If untreated, the flu can lead to pneumonia, especially in the elderly, the young and people with compromised immunity. Each year, 114,000 people are hospitalized and 20,000 die from the flu, Orenstein said. The vaccine protects 70% to 90% of healthy adults and is 50% to 60% effective in preventing pneumonia in the elderly and the immunocompromised. People can't get the flu from the vaccine, Orenstein emphasized. Beginning now, anyone over age 65, healthcare workers, people aged 6 months to 64 who are at high risk for infectious illness, and healthy children aged 6 months to 23 months should get a flu shot, said Orenstein. All others can wait until November to get a flu shot, he said. This flu season, the CDC included children in its flu shot recommendations for the first time. Jon Abramson of the American Academy of Pediatrics said children are hospitalized as often as the elderly from flu and should be protected. But the Academy is not issuing a mandatory call for vaccination, he said. Safety and efficacy have not been definitively proven, and children must get two shots, not one. For the first time in 2 years, there is an ample supply of flu vaccine, said Orenstein, estimating that there will be 94 million doses--20 million more than last year--with 75 million doses due to

be delivered by the end of October. Orenstein urged Americans to get a flu shot, noting that if there is a lot of unused vaccine, manufacturers might not be so quick to respond to higher demand next season. Last year, even though there was an initial shortage, about 10 million doses were never used, he said. Older people should also get a vaccine against pneumococcus bacteria, which can cause pneumonia and other serious infections, said officials. The vaccine protects against 23 strains of pneumococcus, which sickens 60,000 people a year with severe infections--20,000 over age 65. Another 175,000 contract pneumonia and are hospitalized, and 3,000 to 6,000 get meningitis from the bacteria. The vaccine is 50% to 60% effective, but only 64% of people over age 65 have been immunized, said Orenstein. If given after age 65, the vaccine usually lasts a lifetime. For those given the shot at a younger age, revaccination might be needed, he said. People infected with HIV, or who have a weak immune system or a chronic condition like diabetes should also get a pneumococcal shot. Medicare and Medicaid pay for both flu and pneumococcal vaccines, although they don't usually cover the entire cost, said Sean Tunis, an official with the Center for Medicare and Medicaid Services. But the government is considering raising its reimbursement, which should increase vaccination rates, he said.

Finally, the government will reach out to minority populations, noting that flu and pneumococcal vaccination rates are much lower among African Americans and Hispanics.

Efficacy of Angiotensin Converting Enzyme Inhibitors Not Altered By Aspirin

<http://www.docguide.com/news/content.nsf/NewsPrint/8525697700573E1885256C47003720B2>

Efficacy of angiotensin-converting-enzyme (ACE) inhibitors are not altered, either positively or negatively, among patients who also take aspirin. This is found in a systematic overview of data of 22,060 patients, in six long-term randomized trials, by Dr. Salim Yusuf and colleagues from McMaster University, Hamilton, Ontario, Canada. "Even though results from the present analyses cannot rule out the possibility of some sort of interaction, they show unequivocally that even if aspirin is given, the addition of ACE inhibitor therapy produced substantial additional benefit in all major vascular outcomes." Clinicians undertook the investigation because of a retrospective analysis in the Studies of Left Ventricular Dysfunction (SOLVD) study suggesting that ACE inhibitors may be less effective in patients receiving aspirin for the treatment of cardiovascular disease. Dr. Yusuf and colleagues assessed whether aspirin altered the effects of ACE inhibitor therapy on major clinical outcomes: a combination of death, myocardial infarction, stroke, hospital admission for congestive heart failure, or coronary artery revascularization. With the exception of one randomised trial, the efficacy of ACE inhibitors was not found to be altered, either positively or negatively, among patients who were also

receiving aspirin. Overall, ACE inhibitor therapy significantly reduced the risk of the major clinical outcomes by 22 percent, with clear reductions in the risk both among those receiving and not receiving aspirin at the start of the randomized trials. "Results from our analyses confirm the benefits of ACE-inhibitor therapy in high-risk patients, with and without CHF or left ventricular dysfunction, on the composite and individual outcomes of total mortality, myocardial infarction, stroke, hospital admission for CHF, and revascularization," the clinicians said. Dr. Yusuf and colleagues conclude: "In the absence of clear contraindications, concomitant use of aspirin and ACE inhibitors should be considered in all patients at high risk of major vascular events."

Incidence of Iris Colour Change in Latanoprost Treated Eyes

<http://www.docguide.com/news/content.nsf/NewsPrint/8525697700573E1885256C39001BEDC0>

Iris pigmentation induced by latanoprost may be more common than previously reported. However, the high number of mixed iris colour among study participants and the fact that they underwent unilateral therapy may explain the finding, say Spanish researchers. Dr MA Teus of the department of ophthalmology, "Principe de Asturias" Hospital, Madrid, and colleagues undertook this study to determine this increase in iris pigmentation. The researchers photographed the anterior segments of both eyes of 43 glaucoma patients after unilateral latanoprost therapy. Two independent masked observers used a stereo viewer to analyse the slides of both eyes and compare iris pigmentation. Results showed that 30 patients had acquired iridial anisochromia, 15 had increased superficial iris pigmentation with a granular appearance, and 15 had an increased "stromal pigmentation." In the latter, the affected iris appeared darker than the fellow eye but without the granular appearance.

FDA Issues Cyber Letter to Yellow Jackets Promoter / Herbal Product

<http://www.fda.gov/bbs/topics/NEWS/2002/NEW00843.html>

FDA announced that it has issued a Cyber Letter (a letter sent via email to notify a company of potential violations) to the operator of an internet web site for promoting and selling Yellow Jackets, an herbal product, as an alternative to illicit street drugs. Yellow Jackets are promoted as a substitute for controlled substances. According to the promoter's web site, they contain ephedra and other herbal ingredients, including kola nut extract (a source of caffeine). There does not appear to be any legitimate drug use for this product, and its sale as a substitute for controlled substances would be illegal. FDA is aware that some street drug alternatives are being marketed as dietary supplements. FDA does not believe that street drug alternatives are intended to be used to supplement

the diet. Accordingly, street drug alternatives do not meet the definition of a dietary supplement. Yellow Jackets, described on the web site as herbal XTC, could pose a serious risk to consumers. "Consumers should not purchase or use these or similar products available through the Internet or elsewhere," said FDA Deputy Commissioner, Dr. Lester M. Crawford. "FDA will continue its efforts to protect American consumers from dangerous and fraudulent internet companies who would sell illegal products that present risks to public health." FDA has issued this "cyber" letter to the internet address of Yellow Jackets promoter, Mr. Xoch Linnebank of the Netherlands and noted that the continued sale of Yellow Jackets and other products as substitutes for controlled substances to U.S. citizens may be illegal. FDA's "cyber" letters provide foreign operators with an explanation of the statutory provisions that govern interstate commerce of drugs in the United States, as well as a warning that future shipments of their products to this country may be detained at the border and subject to refusal of entry. Copies of each "cyber" letter are sent to regulatory officials in the country in which the operator is based and to other individuals and companies involved in the operation of the web site.

AMA to Congress: FDA Should Ban Ephedra Diet Aids

<http://www.prnewswire.com/cgi-bin/stories.pl?ACCT=104&STORY=/www/story/10-08-2002/0001814593&EDATE=>

The American Medical Association (AMA) testified before Congress today on the dangers of the dietary supplement ephedra. "The AMA urges the FDA to remove dietary supplements containing ephedra from the market," said AMA Trustee Ron Davis, MD. "The risk/benefit ratio for these products is unacceptable." "The AMA concurs with the National Institutes of Health guidelines for obesity treatment that say certain prescription drugs may be useful in some obese patients, but diet aids containing ephedra are not recommended for weight loss. And because of ephedra's effects on the cardiovascular and central nervous systems, it may cause cardiac arrhythmias, heart attacks, strokes, seizures and sudden death in both previously healthy people, as well as in those with risk factors for these conditions. "More than 1,000 people have voluntarily submitted Adverse Event Reports (AERs) associated with ephedra to the FDA. Some of these describe events that have resulted in death or serious illness in young, presumably healthy, adults. There are many more actual adverse events. One company recently admitted to having received more than 14,000 AERs for ephedra since 1995. "Obesity is a significant public health problem. Appropriate treatment of obese patients requires a comprehensive approach involving diet and nutrition, regular physical activity, and behavioral change, with an emphasis on long-term weight management, rather than short-term extreme weight reduction. "Because dietary supplements are classified as foods under federal law, they are assumed to be safe and are

subject to limited regulatory oversight. Dietary supplements containing ephedra have significant risks, which may be serious or fatal to people with pre-existing illnesses, as well as those who were previously healthy. They should be removed from the market. "The AMA is very concerned about the quality, safety and efficacy of all dietary supplements and urges Congress to require that dietary supplements be regulated the same way prescription and over-the-counter drugs are," Dr. Davis said.

Orphan Medical Announces the Commercial Launch of Xyrem(R) (Sodium Oxybate) Oral Solution Through a Dedicated Specialty Sales Force

<http://www.prnewswire.com/cgi-bin/stories.pl?ACCT=104&STORY=/www/story/10-08-2002/0001814217&EDATE=>

Orphan Medical, Inc. announced the launch of Xyrem(R) (sodium oxybate) oral solution in the United States. Xyrem is being sold through a dedicated specialty sales force to sleep centers and other physicians who treat cataplexy patients. Xyrem is the first and only approved medication for the treatment of cataplexy, a debilitating symptom of narcolepsy. Cataplexy, a sudden loss of muscle tone, is usually triggered by strong emotions such as laughter, anger, or surprise and in its most severe form, can cause a person to collapse. Sixty to ninety percent of the 140,000 Americans with narcolepsy suffer from cataplexy. The U.S. cataplexy market is estimated to be in excess of \$125 million annually. "The creation of an experienced high-caliber specialty sales force that is dedicated to Xyrem is a tremendous advantage for Orphan Medical as we reach out to physicians treating cataplexy. Our new sales force, together with a broad range of marketing and medical education initiatives, represent the key components of a comprehensive strategy to provide physicians the information they need to make the decision to treat their cataplexy patients with Xyrem," said Mark Perrin, Chief Commercial Officer. "The early physician inquiries for Xyrem are encouraging and indicate a high interest and awareness regarding Xyrem in the sleep community." John Bullion, Orphan Medical Chairman and CEO, added "The launch of Xyrem represents years of development and hard work to bring Xyrem to patients who have not had a satisfactory treatment for their cataplexy. It also represents a milestone that will define the future of Orphan Medical. We now have a sales force of over 40 professionals experienced in developing specialty markets, and we have an established presence in the growing market for sleep disorders. We will certainly leverage this presence as we build Orphan Medical into a leading specialty pharmaceutical company."

Forest Made Misleading Claims About Antidepressant, FDA Says

http://quote.bloomberg.com/fgcgi.cgi?T=marketsquote99_news.ht&s=APZ3JBxV3Rm9yZXN0

Forest Laboratories Inc. made misleading statements when comparing its biggest product, the Celexa antidepressant, with GlaxoSmithKline Plc's Paxil medicine, the U.S. Food and Drug Administration said. Forest made claims about Celexa in promotional materials based on a six-month study that were "not adequately substantiated," according to an FDA letter sent to Forest last month and posted on the agency's Web site yesterday. The study lacked a similar control group of patients who are given placebos, the FDA said. A control group helps show how many patients would normally recover without treatment. Doctors say this is especially important in diseases such as depression, which may get better or worse without treatment. The misleading statements were made in a brochure and a visual aid used in Celexa promotions, claiming the antidepressant is similar to Paxil, the agency said. The FDA asked Forest to immediately stop using the materials. Forest officials didn't immediately return phone calls.

'Date-Rape' Drug Detectors Disputed, Local Company Produces

<http://apnews1.iwon.com/article/20021009/D7MI6QL00.html>

Colleges around the country are buying millions of coasters that test for "date-rape" drugs in drinks. But some experts say the coasters are ineffective and could lead to more assaults by creating a false sense of security. The manufacturers - who also make fake snow and party foam - say the 40-cent paper coasters are 95 percent accurate. The coasters have test spots that are supposed to turn dark blue in about 30 seconds if a splash of alcohol contains drugs often used to incapacitate victims. In tests at the Michigan State Police Crime Lab, however, the coasters failed to react clearly to drinks spiked with gamma hydroxybutyrate, a major date-rape drug known as GHB, said forensic scientist Anne Gierlowski. "We tested red wine, cola, whiskey and orange juice and because three out of the four have color already, it was very hard to decipher a color change," she said. "It's a nice idea, but it's probably a nicer idea for the people selling them because they've probably made a lot of money." Plantation, Fla.-based Drink Safe Technologies Inc. has sold about 50 million of the coasters since March, mostly to colleges and convenience stores, said president Francisco Guerra. Guerra likens the coasters to condoms: While not 100 percent safe and effective, they are a good prevention tool. "I've had 100 people say this saved them from getting raped," said Guerra, a former magician. "Before me, there was no way to detect it. It's nice to be able to do something about it." A federal task force recently estimated that college drinking leads to an estimated 70,000 sexual assaults or rapes annually. Yasmine Timberlake, a sophomore at San Jose State University, was grateful for the coasters handed out by the YWCA at a bar near campus. "We're girls, and we've got to be careful," she said, putting a handful in her purse. "That's all we can do." And students are now openly talking

about date rape at St. Mary's University in Halifax, Nova Scotia, which bought 800 coasters to pass out to freshmen. "That's the purpose: to educate them and to make them more aware," said Donnie Jeffrey, who runs St. Mary's alcohol-awareness program. The coasters' labels promise they will help "identify the presence of illicit drugs in beverages." But in response to questions from The Associated Press, co-inventor Brian Glover, a New York dentist who dabbles in chemistry, acknowledged that the coasters can identify just two of the many date-rape drugs - GHB and ketamine. There are 36 drugs on the street classified as date-rape drugs, too many for police field tests to detect, said Trinka Porrata, a retired Los Angeles detective who is an authority on GHB. "I'm horrified to think people are actually buying it and passing it out. I think it will do more damage than it will ever do good," said Porrata, a board member of Project GHB, a prevention and education organization. "If it was that simple, we could shut down all of our crime labs." Porrata tested different varieties of drugs on the coasters. Some test spots turned a slight shade of blue within 30 minutes; others did not change color until hours later, she said. The Drug Enforcement Administration also advises against putting faith in tests that cannot keep up with the constantly changing chemistry of illegal drugs. "In cases where there are scientific advances, the bad guys get around it faster than the good guys can," DEA spokeswoman Rogene Waite said. "I would urge people to be really, really, really careful. It's so dangerous, I wouldn't want them to rely on one thing."

New Bill Would Ban Steroid-Like Muscle Builders

http://story.news.yahoo.com/news?tmpl=story2&cid=594&ncid=594&e=3&u=/nm/20021009/hl_nm/steroid_bill_dc

A bill introduced in the US Congress Wednesday seeks to ban over-the-counter sales of steroid-like performance enhancers available in many health-food stores. The measure would reclassify steroid precursors like androstenedione and androstenediol as schedule III controlled substances, making them available only with a doctor's prescription. The compounds, collectively known in gyms and locker rooms as "andro," become indistinguishable from anabolic steroids once metabolized in the body. As many as one fifth of gym-going US men in a January survey conducted in Boston acknowledged using "andro" over the previous 3 years. Lawmakers said they were moving to ban store sales of the compounds because of their widespread use among teens and the associated health risks. Anabolic steroid use is linked to an increased risk of heart disease, liver damage and stunted growth in children. "What 16-year-old doesn't want to knock the ball out of the park just a little bit further," said Rep. John Sweeney (D-NY), who is sponsoring the bill with Rep. Tom Osborn (R-NE), a former coach of the University of Nebraska football team. "These drugs are obtained too easily by youngsters," Sweeney said. The US Anti-Doping Agency already lists androstenedione as a banned substance for competing

athletes. The US Olympic Committee (USOC) also endorsed the proposal, which is not expected to get a vote in Congress until next year. "It's about the creation of fair play on the field of competition," said Lloyd Ward, the USOC's chairman. By law, schedule III classification is reserved for substances with some medical applications but also the potential for abuse. Anabolic steroids, some barbiturates, and codeine are all listed under schedule III. The Council on Responsible Nutrition, a dietary supplements industry group, had no comment on the substance of the new legislation. "We are reviewing the bill," lobbyist Mike Greene said.

Kaletra(R) (lopinavir/ritonavir) Attains Status As Most-Prescribed Protease Inhibitor for the Treatment of HIV

<http://www.prnewswire.com/cgi-bin/stories.pl?ACCT=104&STORY=/www/story/10-02-2002/0001810892&EDATE=>

Abbott Laboratories' Kaletra(R) (lopinavir/ritonavir) has become the most-prescribed protease inhibitor (PI) as part of a treatment regimen for HIV in the United States, the company announced today. Based on the number of patients receiving therapy, Kaletra also has become the PI market share leader in Europe with a 29.5 percent share. Kaletra, which now holds a 28.6 percent share in the U.S. PI market, received accelerated approval in the U.S. in September 2000, based on ongoing clinical studies. "Abbott Laboratories has been committed to HIV since the early 1980s to help improve the lives of those impacted by HIV," said Jeff Leiden, M.D., Ph.D., president and chief operating officer, Pharmaceutical Products Group, and chief scientific officer, Abbott Laboratories. "We are pleased Kaletra-based regimens have helped some patients maintain undetectable viral levels. Abbott will continue to research and develop new therapeutic options for patients with HIV." According to UNAIDS figures, approximately 40 million adults and children worldwide now are living with HIV/AIDS.

New Insulin Analog Formulation With Disposable Prefilled Doser From Novo Nordisk is Now Available

<http://www.prnewswire.com/cgi-bin/stories.pl?ACCT=104&STORY=/www/story/09-30-2002/0001808834&EDATE=>

Novo Nordisk announced today that NovoLog(R) Mix 70/30 (70% insulin aspart [rDNA origin] protamine suspension and 30% insulin aspart [rDNA origin] injection), a new dual-action insulin analog, along with the new NovoLog Mix 70/30 FlexPen(R) prefilled syringe, is now available nationwide for the treatment of diabetes. NovoLog Mix 70/30 has a rapid onset and intermediate duration of action, so insulin needs immediately after a meal and between meals can be met through a single injection rather than separate injections of these types of insulins. NovoLog Mix 70/30 is typically dosed twice a

day, immediately before breakfast and dinner

Reuse of Needle at Hospital Infects 50 With Hepatitis C

<http://www.nytimes.com/2002/10/10/health/10HEPA.html>

More than 50 people at an Oklahoma hospital have been infected with hepatitis C after a nurse repeatedly used the same needle and syringe to give drugs, area health officials say. Officials of the hospital, Norman Regional Hospital in Norman, have contacted hundreds of patients treated since 1999 at the hospital clinic where the nurse worked and have urged them to be tested for blood-borne diseases. "By my understanding, this is the biggest outbreak of hepatitis C that has taken place as a result of transmission within a health care facility," Dr. Michael Crutcher, state epidemiologist at the Oklahoma Department of Health, said yesterday.

Presented at the 42nd Interscience Conference on Antimicrobial Agents and Chemotherapy (ICAAC).

Calcium-Fortified Orange Juice May Interfere with Fluoroquinolone Absorption

<http://www.docguide.com/news/content.nsf/news/8525697700573E1885256C4400724113?OpenDocument&c=&count=10&id=48DDE4A73E09A969852568880078C249>

Bacteroides fragilis Resistance Rising Quickly to New Fluoroquinolones

<http://www.docguide.com/news/content.nsf/news/8525697700573E1885256C4700627A1E?OpenDocument&c=&count=10&id=48DDE4A73E09A969852568880078C249>

Prophylactic Antiviral Therapy Helps Prevent Spread of Herpes Gladiatorum in High Risk Group

<http://www.docguide.com/news/content.nsf/news/8525697700573E1885256C470063D9FF?OpenDocument&c=&count=10&id=48DDE4A73E09A969852568880078C249>

"Closed" Formularies Linked To Higher Rates Of Resistance To Antibiotics

<http://www.docguide.com/news/content.nsf/news/8525697700573E1885256C46006F8BE2?OpenDocument&c=&count=10&id=48DDE4A73E09A969852568880078C249>

Short-course Telithromycin As Effective As 10 Days Of Clarithromycin For Community-acquired Pneumonia

<http://www.docguide.com/news/content.nsf/news/8525697700573E1885256C4600712B37?OpenDocument&c=&count=10&id=48DDE4A73E09A969852568880078C249>

Caspofungin Appears Effective In Treating Aspergillosis And Candidiasis

<http://www.docguide.com/news/content.nsf/news/8525697700573E1885256C46004B1ABA?OpenDocument&c=&count=10&id=48DDE4A73E09A969852568880078C249>

Investigational Antifungal Micafungin Outperforms Fluconazole In Stem Cell Transplant Patients

<http://www.docguide.com/news/content.nsf/news/8525697700573E1885256C44007022E3?OpenDocument&c=&count=10&id=48DDE4A73E09A969852568880078C249>

Kaletra Sustains Undetectable Viral Loads During Four Years of Treatment

<http://www.docguide.com/news/content.nsf/news/8525697700573E1885256C45005BFCB6?OpenDocument&c=&count=10&id=48DDE4A73E09A969852568880078C249>

Atazanavir Matches Efavirenz in Reducing Viral Loads in HIV-Infected Patients

<http://www.docguide.com/news/content.nsf/news/8525697700573E1885256C440064BC4C?OpenDocument&c=&count=10&id=48DDE4A73E09A969852568880078C249>

Once-a-Day Dosing for HIV Equivalent to Twice-a-Day Regimens

<http://www.docguide.com/news/content.nsf/news/8525697700573E1885256C44005F542B?OpenDocument&c=&count=10&id=48DDE4A73E09A969852568880078C249>

Recombinant Human Growth Hormone Reduces Fat Redistribution in HIV+ Patients

<http://www.docguide.com/news/content.nsf/news/8525697700573E1885256C4800710533?OpenDocument&c=&count=10&id=48DDE4A73E09A969852568880078C249>

Boosted Saquinavir Has Better Lipid Safety, Comparable Efficacy to Boosted Indinavir in Adult HIV-1 Infection

<http://www.docguide.com/news/content.nsf/news/8525697700573E1885256C4600704573?OpenDocument&c=&count=10&id=48DDE4A73E09A969852568880078C249>

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A Decline in the U.S. Share of Research Articles

Website of the Day

Pharmacoethics.com

<http://www.pharmacoethics.com/articles.html>

A site dedicated to the "exploration of ethical issues related to the development, promotion, sales, prescription, and use of pharmaceuticals".

Pretty neat stuff.

Answer of the Day

Dextromethorphan (DMX, DXM, Robo, Red Devis, Dex, C-C-C), widely available in a variety of cough and cold remedies, is the d-isomer of the codeine analog levorphanol, a potent narcotic analgesic. Dextromethorphan acts a cough suppressant via a centrally acting mechanism on the cough center in the medulla oblongata like codeine and also suppresses the overactivity of the glutamate center, noncompetitively antagonizes NMDA receptors, and possibly effects 5-HT1A receptors. Additionally, its metabolite, dextrorphan, has action similar to PCP

The drug is supposed to lack addictive, sedative, and analgesic properties and many claim, falsely, that it is a nonopioid agent. However, the drug has been abused since the 1960's to "get high" due to its pharmacology and potential for physical dependence. Dextromethorphan has the potential for abuse via different mechanisms. It can be mixed with heroine and other drugs to increase their pharmacologic effect via a competitive pathway and in high doses it can cause hallucinations, euphoria, and altered perception. To complicate the issue, Dextromethorphan is widely available via the Internet in large doses that are easily abused, and with instructions on making illicit substances and how to ingest huge quantities without nausea or vomiting.