



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 laxative, banned from the FDA in 1997, was originally developed as an additive for the identification of artificial wines?

hint?think undergraduate chemistry

In the News

Bristol-Myers says FDA approves new diabetes drug

<http://www.forbes.com/newswire/2002/10/22/rtr760929.html>

Bristol-Myers Squibb Co. on Tuesday said U.S. regulators approved its new type 2 diabetes drug called Metaglip. The U.S. Food and Drug Administration approved the drug, which is a combination of commonly used antidiabetic drugs glipizide and metformin, for use, along with diet and exercise, as initial drug therapy for people with type 2 diabetes. Metaglip was also approved as second-line therapy for patients with type 2 diabetes who are currently taking either metformin or a sulfonylurea with a regimen of diet and exercise, but whose blood sugar levels are inadequately controlled.

Over-The-Counter Drug Labels Lack Detailed Info

http://www.reuters.com/news_article.jhtml?type=search&StoryID=1614854

People who use over-the-counter drugs are not likely to save the packaging that contains detailed warnings and instructions for later use, a new study has found. What's more, the study results indicate that most people wouldn't bother to call a physician to help answer any questions they might have about over-the-counter medications. The findings, according to two researchers from North Carolina State University in Raleigh, suggest that more efforts should be made to give consumers access to all they need to know about over-the-counter medications at the time of use. "Increasingly, consumers are using medications without medical supervision as more drugs that were once available only by prescription are sold over-the-counter, and consumers are relying more on self-care for many medical problems," write Deane B. Cheatham and Michael S. Wogalter. In the study, Cheatham and

Wogalter interviewed 652 people in two separate studies that evaluated how likely people are to save over-the-counter drug packaging or to call a physician if they have a question about the product. Their findings were presented recently in Baltimore, Maryland, at the Human Factors and Ergonomics Society's annual meeting. "One of the most noteworthy findings is the low likelihood that consumers report being willing to contact a physician regarding questions and concerns about over-the-counter medications," the authors write. "This might be due to beliefs that they will rarely actually speak with a physician, if they were to call," they add. Cheatham and Wogalter say this finding is "particularly disconcerting considering that directives on many over-the-counter medications instruct the consumer to call a physician with questions." Such instructions are "sometimes used in lieu of more descriptive warnings due to space constraints on the medication bottle," they add. In addition, the investigators found that consumers tend to throw away packaging material with more detailed instructions and warnings about the medication than labels printed on the drug's container. "This method of conveying hazards assumes that users read and at later times have available the packaging materials," the authors write. As an alternative way to provide consumers with information about over-the-counter drugs, the researchers suggest manufacturers consider printing toll-free phone numbers or Internet addresses on medication containers. "The findings of this study and others demonstrate that common labeling practices do not suffice for conveying this information to many consumers," Cheatham and Wogalter write. "Future research is needed in this area and should focus on identifying methods for effectively presenting over-the-counter medication information given the space limitations and the findings pertaining to consumer behavior reported in this article," they conclude.

FDA Approves Zyrtec for Kids as Young as 6 Months

http://www.reuters.com/news_article.jhtml?type=search&StoryID=1616165

Pfizer's blockbuster antihistamine Zyrtec has gained a supplemental US approval for use in children as young as 6 months old, the US Food and Drug Administration (FDA) said Tuesday. Zyrtec (cetirizine hydrochloride)--which is currently indicated to relieve symptoms of allergic rhinitis, or nasal inflammation, and to treat itching and hives in adults and in children age 2 and older--has now been cleared for those two indications in children 6 months and older, Pfizer confirmed.

As Fall Asthma Season Swings Into Gear, More Than Half-A-Million Asthma Patients Are Learning That Their Medication Has Been Discontinued

http://www.biospace.com/news_story.cfm?StoryID=10437820&full=1

The half-a-million patients using Vancril? (beclomethasone dipropionate

CFC) to control their asthma symptoms are learning that the product is no longer being manufactured. Schering- Plough discontinued the medication recently, but affected users, many of whom are located in California, Pennsylvania, New York, Texas, Illinois and Florida, are not without a alternative. QVAR? (beclomethasone dipropionate) is the only asthma medication on the U.S. market that contains the same active ingredient used in Vanceril, beclomethasone dipropionate (BDP), but in a non-ozone-depleting CFC-free formula. QVAR, indicated for the long-term treatment of asthma in adults and children as young as five years old, offers comparable efficacy at half the dose. "It's important that asthma sufferers maintain regularity in their therapy, especially during the fall and winter seasons when asthma symptoms can be aggravated," said Dennis L. Spangler, M.D., chief medical officer, Atlanta Allergy and Asthma Clinic. "QVAR has fewer side-effects and it is effective at half the dose as compared to Vanceril. This allows the patient to maintain control of asthma, while reducing the amount of steroid that is inhaled."

Early Treatment Of Multiple Sclerosis With Copaxone (Glatiramer Acetate) Delays Accumulation Of Additional Brain Lesions

<http://www.docguide.com/news/content.nsf/news/8525697700573E1885256C5A006C43B0?OpenDocument&c=&count=10&id=48DDE4A73E09A969852568880078C249&abd=yes>

People living with relapsing-remitting multiple sclerosis who delay Copaxone? (glatiramer acetate for injection) treatment for as little as nine months can accumulate additional lesions in their brain, reported a study published in the October 22, 2002 issue of Neurology. The delay in starting therapy resulted in six new enhancing lesions per patient during the first nine study months that could have been prevented, according to the study. The study used magnetic resonance imaging (MRI) to evaluate the brain lesions for patients who were on Copaxone for the entire 18-month period compared to those who switched from placebo to active drug after nine months. There were 29 sites in Europe and Canada. Canadian trial sites involved in the study were located in Montreal, London and Calgary. "This study is significant because it showed that patients who started Copaxone earlier had 35 per cent fewer enhancing lesions over the study period of 18 months," said Dr Douglas Arnold, Director, Clinical Research Unit, Montreal Neurological Institute and Hospital (MNI/H). "Relapse rates for these same patients were 23 per cent lower than for patients who started on Copaxone nine months later and it appeared that delaying treatment with Copaxone resulted in a poorer clinical outcome." The study showed that the benefits gained in the first nine months were sustained through the entire 18 months, indicating a benefit from continuous drug therapy. The two-phase trial began as a nine-month placebo-controlled, double-blind study that showed that Copaxone significantly reduced MRI-measured brain lesions and reduced the relapse rate. The second phase, which is reported in this issue of Neurology, switched placebo patients to Copaxone, evaluating if

those on Copaxone could sustain the benefit shown in the first nine months and whether there was a difference in those who began therapy later. The majority of patients (224 of 239) chose to enter the study continuation, where patients were evaluated clinically and through MRIs on a quarterly basis. "Over the extension, there was a 54-per cent reduction in the mean number of enhanced lesions for those converted from placebo to Copaxone and an additional 24.6 per cent reduction for those always on Copaxone," said Giancarlo Comi, M.D., of the Scientific Institute and University Ospedale San Raffaele, Milan, Italy. "Over the entire study, the accumulated T2 disease burden was less for those always on Copaxone." Copaxone is indicated for the reduction of the frequency of relapses in relapsing-remitting MS. In controlled clinical trials, the most commonly observed adverse events associated with the use of Copaxone which occurred at a higher frequency than in placebo treated patients were: injection site reactions, vasodilation, chest pain, asthenia, infection, pain, nausea, arthralgia, anxiety and hypertonia.

Study Analyzes Nurse Workload

<http://www.washingtonpost.com/wp-dyn/articles/A2319-2002Oct22.html>

Surgery patients had a greater chance of dying after procedures in hospitals where nurses have heavier patient loads, according to a study released yesterday that underscores the importance of the national nurse shortage. For example, there were 31 percent more patient deaths per month after common types of surgeries, such as gall-bladder removal or hip replacement, at hospitals where each nurse cared for eight patients than when each nurse cared for four patients, according to the University of Pennsylvania study, which was published today in the Journal of the American Medical Association. The report follows a study published in May by the New England Journal of Medicine saying that patients who received more hours of care from a registered nurse had a lower risk of health complications and were less likely to die than patients who received fewer hours. The nurse shortage has been attracting the attention of legislators in Washington and in state capitals. Last year about 13 percent of all U.S. nursing jobs went unfilled, in part because of demographic changes. The average hospital nurse is 45 years old, and too few young nurses are entering the pipeline to replace them as they leave the profession. By the year 2020, when many of today's nurses will be retiring, there could be a shortfall of more than 400,000 nurses, according to the Labor Department. Nurse-retention problems are compounding the shortage, said Linda H. Aiken, director of the Center for Health Outcomes and Policy Research at the University of Pennsylvania School of Nursing, which conducted the study. Aiken said that many nurses report constant overwork and understaffing on hospital wards, prompting many to leave the profession each year. "Nurses report greater job dissatisfaction and emotional exhaustion when they're responsible for more patients than they can safely care for," Aiken

said. "Failure to retain nurses contributes to avoidable patient deaths." Aiken said that unlike other industries in which businesses have been compelled by market forces to offer benefits such as flexible hours and child-care assistance to keep valued workers, many hospitals have declined to do so. Instead, they have instituted forced overtime and reduced staffing to cut costs, she said. Richard H. "Rick" Wade, a senior vice president at the American Hospital Association, a trade group representing about 4,600 hospitals nationwide, did not dispute the University of Pennsylvania study, and he described Aiken as a "respected researcher." He said the association's members are acutely aware of the problems posed by inadequate staffing. "Our number one issue today is the workforce shortage, and when you boil it down, it's recruiting and retaining nurses," Wade said. The industry is taking steps to try to solve the problem, he said, referring to a report recently commissioned by the association that outlines ways hospitals can make themselves more attractive employers. Wade said the hospital industry is aware that many nurses are working "harder than they should be" and that it has become apparent that some hospitals "have not maintained as attractive a work environment as they should have." "But it's not the majority," he said. Meanwhile, Labor Secretary Elaine L. Chao, who has called the nursing shortage a "crisis," plans to use federal job programs to steer would-be nurses into the health-care industry. In July, Congress passed the Nurse Reinvestment Act, which is to provide federal money to help pay for nursing training and forgive education loans for trainees who agree to work in areas with acute shortages. President Bush has signed the law, but Congress has not yet appropriated money to fund the program. Sen. Barbara A. Mikulski (D-Md.) co-sponsored the legislation, calling it an effort "to deal with the nursing crisis in a serious way." In Maryland about 2,000 nursing jobs, or more than 15 percent, are unfilled, she said. "For years, they tended to overwork and underpay these women," Mikulski said about the hospital industry. "There was a lack of respect in how they were treated. . . . In some ways, it's a crisis of their own doing." Many nurses have been urging industry leaders to take steps to make work more attractive to today's nurses rather than focusing on recruiting new nurses, saying that bringing in workers who quickly leave fails to solve the problem. About 500,000 registered nurses have left the field in recent years, according to Susan Bianchi-Sand, director of United American Nurses, the labor arm of the American Nurses Association. Nurses have taken their concerns to state legislatures. More than 20 states have enacted or seriously considered laws mandating that hospitals maintain certain patient-to-nurse ratios. California, for example, passed legislation last year establishing fixed nurse-patient ratios for hospitals statewide. Public hearings to discuss implementing the law are scheduled to be held over the next three months. Maine and Oregon have banned mandatory overtime for nurses, according to the nurses association, and nursing trends and patterns are the subject of state study in Florida, Mississippi, North Dakota, Tennessee, Texas, Arkansas and

Pennsylvania.

Pill 'Very Promising' CoQ10 May Arrest Parkinson's Disease

<http://www.washingtonpost.com/wp-dyn/articles/A53533-2002Oct19.html>

Researchers announced last week that a naturally occurring antioxidant called coenzyme Q10, which is sold over-the-counter as a dietary supplement, may help fight Parkinson's disease. At a medical conference in New York, they presented evidence suggesting that a high daily dose of coQ10 slowed the progressive deterioration associated with early stages of the neurological condition. Officials at the National Institute of Neurological Disorders and Stroke (NINDS), which provided \$2 million for the small study, called the research "very promising." But they cautioned Parkinson's patients against taking coQ10 -- an antioxidant often touted for heart health -- until a larger, definitive trial is done. They also warned that because the production of nutritional supplements is not closely regulated, products purporting to contain the compound may not include potentially beneficial amounts of it. The positive coQ10 study runs counter to other recent research into dietary supplements. In those trials, ginkgo biloba, St. John's wort and vitamin E supplements failed to show beneficial effects on, respectively, mental functioning, major depression and Parkinson's disease. According to federal estimates, Parkinson's disease affects 500,000 Americans, but some experts think an equal number have the condition but have not been diagnosed. Primary signs of the disease include tremors that typically begin in one hand or arm and worsen when that part of the body is at rest; muscle rigidity or stiffness; slowness of movement; and difficulty with balance. Most often diagnosed in people in their sixties, Parkinson's progresses at varying rates, but eventually about 30 percent of individuals with the disease experience dementia. While its cause is unknown, the disease is widely thought to result from a combination of genetic susceptibility and environmental causes. Despite the new findings, neurologist Bernard Ravina, a program director for clinical trials at NINDS, said he would consider it premature to recommend coQ10 for Parkinson's. "You could potentially be exposing people to unnecessary risks," Ravina said. "Even though it seems promising, there are many examples of seeming benefits that disappear when studied further." Yet Ravina conceded that the results of a definitive trial on coQ10 are at least three years away: "There's unfortunately no fast way to do it right," he said. Then there is the cost factor. Clifford W. Shults, who has studied coQ10 for a dozen years and led the latest study, estimated that a year's supply of coQ10 at doses used in the trial could easily run \$1,500 to \$2,500, partly because of a labor-intensive manufacturing process in which coQ10 is produced in microorganisms. (People who take the compound merely to maintain their health might spend about \$300 annually on the supplement.) Abraham N. Lieberman, medical director of the National Parkinson Foundation (NPF), put the annual cost figure as high as \$3,600.

"If I knew this arrested disease, I would say it's worth the money," Lieberman said, but the evidence is not yet conclusive, and it is unknown whether there are harmful interactions between coQ10 and medications. An NPF spokeswoman said Wednesday that the group had received a 30 percent increase in phone calls in the first days after the study's release.

Shults, a professor of neurosciences at the University of California at San Diego School of Medicine and chief of the neurology service at the VA San Diego Healthcare System, acknowledged that, as a co-inventor of a product containing the compound, he could gain financially from an increase in coQ10 sales. But he said his involvement with the company making the supplement is to ensure product purity. "I'm not a salesman," he said.

People with Parkinson's may choose from an array of prescription drugs, such as levodopa, at a cost Lieberman estimated at \$1,500 to \$2,000 yearly. These medications help control symptoms, but they do not slow the neurological damage done by the disease. Because stress worsens symptoms,

some patients practice relaxation techniques involving acupuncture, aromatherapy, massage, tai chi and yoga, though these alternative therapies have not undergone rigorous scientific testing. Given the limited options for treating Parkinson's, some clinicians find coQ10 promising enough to recommend without delay.

"If I have a patient tomorrow with Parkinson's, I will offer coQ10 at a high dose. It may do good and it won't do harm," said Raul N. Mandler, a professor of neurology at the George Washington University School of Medicine. "This is a good study," Mandler said. "I think there's a lot of promise, not just for Parkinson's, but also for ALS (amyotrophic lateral sclerosis, also known as Lou Gehrig's disease) and other neurodegenerative disorders." He noted that he has recommended coQ10 to patients with ALS, Parkinson's, multiple sclerosis and Alzheimer's disease. "I don't think the ALS patients feel any difference [from coQ10].

It's like vitamin C. Is it working? We don't know, but there's potential for good without harm," Mandler said. NINDS's Ravina disagrees. The dose of coQ10 found most effective in the new study -- 1,200 milligrams a day -- is at least five times higher than people would ordinarily take, he said. He also noted that previous coQ10 studies used around 300 milligrams to treat congestive heart failure and 600 to treat Huntington's disease. "We don't know the right dose yet [for Parkinson's]," Ravina said. "Even higher doses may be better, and we don't know the long-term safety profile for 1,200 milligrams a day," or the safety of using higher doses. Ravina said there is also uncertainty over whether the benefits shown in the new study were caused by coQ10. "If patients are better, they're better," he said. "But you have to be sure they're better. This was a very small study, 20 patients per group, so the statistics are more likely [than those from a larger study] to be due to chance." Shults and other investigators hypothesize that coQ10 helps to improve energy-producing reactions within cells' mitochondria, and helps rid the body's cells of potentially harmful chemicals generated during metabolism. Animal studies have found that coQ10 protects the substantia nigra, a part of the brain damaged by Parkinson's;

other trials have shown that people with Parkinson's have impaired mitochondrial function and reduced levels of coQ10 in the mitochondria. An earlier pilot study by Shults' team showed that coQ10 doses of up to 800 milligrams a day significantly raised the level of the compound in people with Parkinson's. In the new study, which was presented at the American Neurological Association's conference last week and published in the Oct. 15 issue of the Archives of Neurology, Shults and his colleagues randomly put 80 people with mild symptoms of Parkinson's into four groups. Three groups received daily doses of 300, 600 or 1,200 milligrams of coQ10, while the fourth group got a matching placebo. Each participant was clinically evaluated a month after the study began, then every four months up to 16 months or until the patient was found to need treatment with levodopa. "The placebo group did the worst, 300 milligrams a day and 600 milligrams a day about the same, and the 1,200-milligram-a-day group was substantially better," Shults said. By the end of the study, the people getting the highest daily dose had 44 percent less functional decline than those in the placebo group. While they had less decline in motor and mental functions, Shults said, "the greatest benefit was seen in activities of daily living: dressing, bathing, eating and walking." Researchers also found significant increases in coQ10 levels in the non-placebo groups and a significant rise in energy-producing reactions within mitochondria. Shults said he and his colleagues expect to propose a follow-up trial of perhaps 400 patients, some of whom may be assigned to take more than 1,200 milligrams. In evaluating study findings, it is important to remember that research "doesn't move in a straight line," said John Hathcock, vice president for nutritional and regulatory science at the Council for Responsible Nutrition, a trade association representing the dietary supplement industry. "My view is [that] we have to assess the current state of knowledge based on everything we know rather than on one study." Donald Brown, Sr., 66, a retired railroad worker in Baltimore, said his wife encouraged him to get a physical when he retired in 1998 and to ask the doctor about a tremor in his hand. He had written it off as a muscle spasm, although once in a while he stuttered or felt unsteady on his feet. After the exam, he was diagnosed with Parkinson's and later volunteered to join Shults' study. Brown said he doesn't know whether he took a placebo or coQ10. All he knows is that while he exercises and watches his diet, he is not taking any medication for Parkinson's and his symptoms remain mild. "My doctors, they say, 'Everything is as it was.' I kind of prayed a lot, and right now I'm just accepting it for what it is. Who knows? It could pop up [again as] something worse, or not at all."

Senate Confirms New FDA Commissioner

http://story.news.yahoo.com/news?tmpl=story2&cid=594&ncid=594&e=10&u=/nm/20021018/hl_nm/senate_fda_dc

The US Senate late on Thursday confirmed Bush administration health advisor

Dr. Mark B. McClellan as the next commissioner of the US Food and Drug Administration (FDA), filling a top federal post that had been vacant for almost two years. McClellan, 39, will take the helm of an agency that employs over 10,000 people and oversees over \$1 trillion in annual sales of pharmaceuticals, medical devices, foods and other products. He is a Harvard-educated physician with a doctorate in economics from the Massachusetts Institute of Technology (news <http://rd.yahoo.com/dailynews/nm/hl_nm/inlinks/*http://rd.yahoo.com/DailyNews/manual/*http://search.news.yahoo.com/search/news?p=%22Massachusetts%20Institute%20of%20Technology%22&c=&n=20&yn=c&c=news&cs=nw> - web sites <http://rd.yahoo.com/dailynews/nm/hl_nm/inlinks/*http://rd.yahoo.com/DailyNews/manual/*http://search.yahoo.com/bin/search?cs=nw&p=Massachusetts%20Institute%20of%20Technology>). Before joining the Bush administration, he was an associate professor of medicine and economics at Stanford University and worked as a deputy assistant treasury secretary for economic policy during the Clinton administration. McClellan, who currently serves on Bush's three-member Council of Economic Advisors, also helped formulate the Bush administration's position on a Medicare prescription drug benefit. The Senate confirmed McClellan by voice vote on Thursday night before adjourning for the November elections. As a candidate for the FDA post, McClellan enjoyed support from both sides of the aisle and sailed through his confirmation hearing. He will take his post at a challenging time for the agency. "It would seem that there are staff-retention issues throughout the organization, especially in the drug review office," noted Neil Grubert, a London-based analyst with the research firm Decision Resources. Grubert told Reuters Health that McClellan also faces hurdles related to the FDA's authority, including First Amendment challenges to its jurisdiction over drug and dietary supplement promotions. "They have had a number of knocks in recent times," he said. Grubert noted that the appointment of a commissioner is unlikely to have much effect on drug review times. "It's difficult to see how much further he can reduce review times anyway, bearing in mind that this needs to be a thorough process," he said. He pointed out that US review times already have decreased considerably in recent history. Ira Loss of Washington Analysis, a Washington, DC-based analyst firm that specializes in regulatory and policy matters, echoed the sentiment. "The installment of McClellan and his impressive, industry-free resume as FDA Commissioner is a welcome move...but it doesn't mean that companies will no longer find fault with the agency for slow reviews, approvable letters and the like," Loss said. "The appointment merely eliminates the excuse that the lack of a commissioner is to blame for FDA action or inaction, and will force critics to direct blame somewhere else." Still, McClellan can play a significant role in terms of providing the agency with leadership, Pharmaceutical Research and Manufacturers of America (PhRMA) spokesman Jeff Trewhitt told Reuters Health. "It is important to have a nominated and confirmed candidate to deal with a wide range of issues," he said. "We are pleased

the Senate has acted to fill this vital position, and we look forward to Dr. McClellan's leadership at the FDA," added PhRMA spokeswoman Jackie Cottrell. Similar sentiments were expressed by the Biotechnology Industry Organization (BIO). McClellan "appears exceptionally well qualified to lead the agency and tackle issues related to the recently enacted Prescription Drug User Fee Act, food labeling, and the judicious reorganization of the biologics approval process," said BIO President Carl B. Feldbaum. McClellan, who comes from a prominent Texas political family and whose brother is a spokesman for the White House, was not available for immediate comment.

FDA Posts Generic Drug Change Proposed by Bush

http://www.reuters.com/news_article.jhtml?type=search&StoryID=1616173

Following President Bush's announcement Monday that the administration was proposing new rules that would help speed the path of generic drugs to the market, the US Food and Drug Administration (FDA) has published a 70-page document spelling out the changes. The FDA has made the proposed rule available on its Web site and it will publish it in the October 24th issue of the Federal Register. The agency will accept comments on the rule changes until December 24. The proposed rule would amend a 1984 law called the Hatch-Waxman Act, which had sought to balance competition between brand-name and generic drug manufacturers while encouraging continued research on new medicines. But critics of the act have noted that brand-name drugmakers have exploited a loophole in the law, enabling them to delay or stifle generic competition--a view echoed by the US Federal Trade Commission (FTC) in a report released this past July. The FTC recommended new laws aimed at tightening companies' ability to exclude generics from the market and to force financial disclosure of marketing deals between brand-name and generic manufacturers. Those changes formed the core of a generic drug bill, co-sponsored by Sens. John McCain (R-AZ) and Charles Schumer (D-NY), that passed the Senate in September but saw no action in the House of Representatives. The new regulations would limit brand-name drugmakers' use of lawsuits to keep generic competitors off the market. "Who is John Galt?" The proposal would also prohibit brand-name companies from filing controversial "frivolous" patents, which can use trivial changes in a drug's look or packaging to extend its market exclusivity. Administration officials estimated that the changes could save US consumers \$3.5 billion per year in drug costs. They could also give the Republicans credibility on the rising cost of prescription drugs heading into elections where party control over the US Congress is at stake. "Generic drugs make America's healthcare more affordable," Bush said during a Rose Garden ceremony at the White House on Monday. He quoted statistics stating that the average price for a generic drug is about \$17 per prescription compared with \$72 for the average brand-name medication. The president said that the move was designed to protect profit potential

and innovation within the brand-name pharmaceutical industry while preventing potential legal abuses that can add to the cost of medications for consumers. Sen. Schumer said in a statement that the White House announcement "sounds like an election-day conversion." He added, "There are so many holes in this that it's not going to do much good." The McCain-Schumer proposal would have prohibited brand-name companies from filing for stays on any patents but those listed when a drug is first approved. In contrast, the administration's rule would still permit stays on late-filed patents but limit them to one per generic drug.

Low-Carb Diet Deemed Safe over Short Term

http://story.news.yahoo.com/news?tmpl=story2&cid=594&ncid=594&e=19&u=/nm/20021021/hl_nm/diet_carbohydrates_dc

People who follow a low-carbohydrate, high-protein diet for 6 months may lose more weight than those on a standard low-fat diet, and they appear to experience no cardiovascular problems as a result. However, study author Dr. Bonnie J. Brehm of the University of Cincinnati in Ohio told Reuters Health that despite the apparent short-term benefits of the low-carbohydrate, high-protein (LCHP) diet, this option may not be healthy in the long run. Following the diet for 3 or 4 months may be fine, Brehm said. "But long-term? We don't know," she added. One example of a LCHP diet is the Atkins Diet, which first gained popularity during the 1970s. Limited evidence suggests it may help people lose weight, but many experts remain concerned about the long-term health effects of the diet, which can contain high levels of fat and cholesterol. The current study is based on results from 53 obese women, half of whom were asked to follow the LCHP diet, in which less than 10% of their calories came from carbohydrates. The rest of the women followed a standard low-fat diet, in which fat made up only 30% of their total calories. Both groups consumed the same number of calories each day. After 6 months, Brehm and her colleagues found that women on the LCHP diet lost 10 more pounds of body weight and 6 more pounds of body fat than did those following the low-fat diet. Blood pressure and blood sugar levels--which can indicate increased risk for cardiovascular disease--were within normal ranges for both groups. However, as the authors reported here on Sunday at the 85th Annual Meeting of the American Dietetic Association (ADA), those on the LCHP diet ate less carbohydrate and fiber and more protein, fat and cholesterol than did the low-fat diet followers. The ADA is a professional organization representing the nation's licensed nutritionists and dietitians. So why did a seemingly unhealthy diet not affect indicators of cardiovascular risk? In an interview with Reuters Health, Brehm suggested that the benefits of losing more weight may offset the disadvantages associated with high fat and cholesterol. "Perhaps it's weight loss that causes the positive results (in cardiovascular risk factors)...and it isn't dependent on the diet," she said. Although the LCHP diet helped dieters shed more pounds than the low-fat regimen, Brehm

cautioned that much more research is needed before consumers can consider this program to be safe and effective. "More research does need to be done before I think you can make any kind of recommendation as to what you should follow," she said. The study was supported by funds from the American Heart Association In an interview with Reuters Health, Dr. Meir Stampfer of Harvard University said that the current study was well conducted, but he agreed that 6 months is not long enough to determine if the LCHP diet is safe over the long term. However, he added that low-fat diets are often unsatisfying for dieters, because many carbohydrateshe added that-faw

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one-third as likely to have bowel damage from blood clots. "If my mother were going into surgery now, there's no question she would get aspirin postoperatively," said the lead researcher, Dr. Dennis Mangano, founder of the ischemia foundation, a nonprofit research group in San Francisco. The study was conducted from 1996 through 2001. The heart association and the American College of Cardiology in 1999 recommended giving patients 100 mg to 325 mg of aspirin within 24 hours of bypasses using grafts from leg veins. The guidelines do not cover grafts using chest arteries or both veins and arteries, but Mangano said that in the study, aspirin benefited patients getting every graft type. In another surprise, the study also found patients who stopped taking aspirin before surgery were more likely to die than those who kept on taking it. That, too, goes against the conventional wisdom; in fact, American Heart Association guidelines call for taking many heart patients off aspirin 7 to 10 days before bypass surgery. Dr. Daniel Shindler, associate professor of medicine and anesthesiology at Robert Wood Johnson Medical School in New Brunswick, N.J., said the new study could change that practice, too. "This paper allays the fear of giving aspirin preoperatively," he said. Cardiac bypass surgery is becoming more common as the world's population gets older and heavier. Despite improved surgical techniques, major complications hover around 15 percent. Patients in the study were not randomly chosen for each treatment, as is done in many experiments; the doctors decided who got aspirin, which could have influenced results. But Mangano said that limitation is far outweighed by the uniform findings and the comprehensive data on each patient.

Bayer CEO Says 3,500 Baycol Suits Pending

http://story.news.yahoo.com/news?tmpl=story2&cid=594&ncid=594&e=7&u=/nm/20021021/hl_nm/bayer_suits_dc

German drugs and chemicals group Bayer AG faces 3,500 damages suits in the United States following the recall last year of its Baycol cholesterol drug, the group's chief executive told a newspaper on Monday. Bayer withdrew Baycol, which was sold under the name Lipobay in countries outside the United States, in August 2001 after it was linked with more than 50 deaths worldwide. The number of deaths linked to the drug has since risen to more than 100. Baycol belongs to a class of drugs called statins, all of which have the potential to cause muscle damage. This damage can lead to a fatal condition in which all the muscle breaks down. Chief Executive Officer Werner Wenning told the Financial Times Deutschland that the number of suits had risen to 3,500. The company had already said there were well over 2,000 cases worldwide, most in the United States. "We expect the first case in the first quarter of 2003," Wenning said. A spokeswoman confirmed the report. Wenning said the company had already reached out-of-court settlements in 100 cases and reiterated that Bayer had made no special provisions for the Baycol litigation as it was insured for such possible

cases

Busy ER Leads to Prescribing Errors in Children

http://story.news.yahoo.com/news?tmpl=story2&cid=594&ncid=594&e=6&u=/nm/20021018/hl_nm/children_emergencies_dc

Children treated in busy urban emergency departments run the risk of being prescribed the wrong dose of medication, leading, potentially, to severe adverse outcomes, according to a study conducted at one emergency room. Many mistakes seem to occur when doctors have to calculate proper dosage based on a child's weight. The findings are from a study conducted at Albany Medical Center in New York and presented Friday at the American Academy of Pediatrics conference. Dr. Renee E. Rasmus and colleagues reviewed more than 56,000 pediatric drug orders originating from the emergency department over a 48-month period. They found that a total of 176 "clinically significant" pediatric prescribing errors had been made during this time frame. The incidence of detected errors was 3.1 per 1,000 admissions. This discovery was "surprising, but expected," Rasmus told Reuters Health. "Albany Medical is a busy ER. We have resident doctors and academics writing orders in a very busy environment," she explained. The most common errors were underdosing (50%) and overdosing (32%) followed by drug allergy, wrong formulation, and wrong drug (roughly 4% each). Of note, according to Rasmus, 33% of errors had the potential to cause "serious" adverse patient outcomes and 6% could have led to "potentially life-threatening" situations. The errors most often involved antibiotics (74%). "With pediatric patients, you need to prescribe the medication based on weight," Rasmus said. "And while weight was taken into account in the errors detected, for one reason or another, the math was done improperly or the weight was wrong." She added, "I don't think Albany Medical is unique. I think that every ER that is seeing children that is busy is making these sorts of errors." Rasmus hopes a "calculation worksheet" she developed for use in the emergency department will help. "The doctor puts in the weight of the child and follows the calculations so there is less room for error," she said. Rasmus is now with Crow/Northern Cheyenne Hospital in Montana.

BMS, GSK Reinstate Discount Card For Needy Seniors

http://www.reuters.com/news_article.jhtml?type=search&StoryID=1623124

Two large pharmaceutical manufacturers said on Wednesday they would be restoring the original level of discounts provided through a drug card program for seniors and sending refunds to members who bought medications after those discounts were reduced. GlaxoSmithKline and Bristol-Myers Squibb Co. decided to reinstate the larger discounts in light of the federal government's finding that the discounted prices offer to members of the "Together Rx" program won't trigger a Medicaid rule that could cost them big bucks. Medicaid Chief Tom Scully said in the letter on Tuesday

that his agency does not believe the discounts will subject drugmakers to Medicaid's "best price" requirement. The new guidance is based on a review of how the Together Rx program operates. In most cases, drugmakers are required by law to give Medicaid their best price. Scully reiterated the requirement in a letter to the drug industry dated June 24. Some companies feared they would be forced to absorb millions of dollars in additional price concessions to the entire Medicaid program if the savings offered to Medicare beneficiaries through Together Rx exceeded what Medicaid gets. Citing that rigid interpretation, Bristol and Glaxo, two of the seven drugmakers that participate in Together Rx, trimmed the average discount offered to seniors earlier this month. Together Rx sponsors subsequently met with officials of the Centers for Medicare and Medicaid Services (CMS) and provided additional data to bolster their case for an exception from Medicaid's best price requirement. Scully's latest guidance "means that the discounted prices will not be considered in the calculations for best price," said Doug Arbesfeld, a Together Rx spokesman. Both Glaxo and Bristol are working to reinstate the original savings levels under the program as quickly as possible. The average discount on Glaxo drugs purchased through Together Rx, for example, will jump to 30% from 25%. Glaxo is still working with federal health officials "to clarify discounts" provided through its "Orange Card" senior discount program, said spokeswoman Patty Seif. The company hopes to reinstate the higher discounts under that program as well, she said. Meanwhile, the two companies are preparing to send refund checks to seniors affected by the Together Rx discount reduction. In Bristol's case, that's about 20,000 seniors, said spokesman Rob Hutchison. The companies are still calculating the total refunds to seniors. Scully's earlier warning to drugmakers caused some industry observers to question the agency's motivations. While the Bush administration has applauded private efforts to make prescription drugs more affordable for seniors, its own effort to create a discount program for seniors was blocked by a federal judge after pharmacy groups sued. Together Rx has enrolled 334,000 members to date, savings seniors a total of \$10.5 million on purchases of sponsoring companies prescription medications since the program's launch this past spring. Low-income seniors who have no prescription drug coverage can save 20% to 40% on medications under the program. "We're just happy that the thing has resolved itself amicably," said Crystal Wright, a spokeswoman for the National Association of Chain Drug Stores. Through its Pharmacy Care Alliance, chain druggists help promote Together Rx as a way for seniors cut their medication costs. "In the absence of Congress being able to get any traction on this issue this year, why would anyone want to undermine a program like Together Rx?" she wondered.

Lay People Underestimate Dangers Of OTC Analgesics

http://biz.yahoo.com/rc/021023/health_painkillers_1.html

Many Americans are unaware of potentially serious side effects from commonly used over-the-counter pain medicines, a consumer group said Wednesday. The National Consumers League is launching a campaign to educate people about the risks of stomach bleeding and other problems linked to nonprescription painkillers. Millions of people take the drugs without incident. But a 1999 report in the New England Journal of Medicine estimated that 16,500 people die in the United States annually from aspirin, ibuprofen and other nonsteroidal anti-inflammatory drugs, typically from gastrointestinal bleeding and ulcers. Sixty-four percent of people who answered the consumer group's national survey said they were unconcerned about the possibility of serious side effects, including stomach bleeding and ulcers, from over-the-counter painkillers. "People mistakenly assume that if a prescription is not required for a medication that is sold in a drugstore or a supermarket, then it must be safe," said Linda Golodner, president of the consumer group. The Food and Drug Administration is considering an advisory panel's recommendations to require stronger warnings on over-the-counter pain medicines.

Update from our Friend in KC

Judge Mulls Over Diluted Drug Case

http://story.news.yahoo.com/news?tmpl=story2&cid=534&ncid=534&e=2&u=/ap/20021018/ap_on_re_us/diluted_drugs

With perhaps tens of millions of dollars at stake, a judge in the case of the pharmacist who watered down cancer drugs must decide how to divide the compensation among as many as 4,200 patients. U.S. District Judge Ortrie Smith's dilemma is whether to give a lot of money to a few victims, or a little money to many victims, law clerk Steve Wolfe said. "I imagine that he'll want to give something to as many people as possible," Wolfe said. Robert R. Courtney faces up to 30 years in federal prison after pleading guilty to diluting the chemotherapy drugs to make extra money. Sentencing was set for Dec. 5. Although the guilty plea in February involved 34 patients, the judge could decide to allow restitution for a wider group. More than 400 lawsuits have been filed against the former pharmacist. Federal prosecutors have moved to seize a house valued at \$285,000 to add to Courtney's other assets, insurance and drug company money that could be used to compensate people. Private attorneys are after some of the \$71 million in insurance that Courtney and his pharmacy had carried. "I don't think there will be a whole lot," said Donna Bair of Warsaw, Mo., whose husband died of lung cancer in 1999 after getting chemotherapy drugs from Courtney's pharmacy. "I think a lot of it will go for the federal fines and things like that." Bair said she and several other plaintiffs said they don't yet know how much they'll get from last week's settlement with drug makers Eli Lilly & Co. and Bristol-Myers Squibb over allegations they should have done more to stop Courtney. Cancer patient Georgia Hayes won a

\$2.25 billion jury verdict against Courtney last week. She has promised to share whatever money she gets with other victims. But her lawyers acknowledged that the money will likely come from his insurance company, which is fighting the claims, saying Courtney committed crimes, not just malpractice or negligence.

In the Pipeline

GlaxoSmithKline Announces License Agreement with Kissei for Selective Inhibitors of Renal Glucose Transport for Diabetes

<http://www.prnewswire.com/cgi-bin/stories.pl?ACCT=104&STORY=/www/story/10-23-2002/0001825378&EDATE=>

GlaxoSmithKline (GSK) today announced that it has entered into an exclusive license agreement for Kissei's novel selective inhibitors of the sodium-dependent renal glucose transporter type 2 (SGLT2). These compounds represent a potential new class of oral antidiabetic agents, which would act by suppressing glucose reabsorption in the kidney, and thus increasing the excretion of excess glucose from the body. This mechanism may help relieve hyperglycemia without placing additional stress on pancreatic beta cells, which fail over time with the onset of type 2 diabetes to produce enough insulin to adequately absorb excess blood sugar. Under the agreement, Kissei has granted GlaxoSmithKline the exclusive rights to develop and market these compounds worldwide, excluding Japan, Korea, China and Taiwan. Kissei will receive upfront fees, royalties, and milestone payments related to development and commercialisation success from GlaxoSmithKline. Kissei has almost completed preclinical studies with the most advanced agent in this series, which is planned to enter Phase I in the first quarter of 2003. GlaxoSmithKline will undertake the further development of the lead compound and guide commercialisation in all territories excluding Japan, China, Korea and Taiwan.

Table of Contents

JAMA

Table of Contents - October 23/30, 2002

Vol 288, No 16, pp 1937-2070

<http://jama.ama-assn.org/issues/v288n16/toc.html>

This Week in JAMA

Highlights of selected articles

<http://jama.ama-assn.org/issues/v288n16/full/jtw20036.html>

Original Contributions

Hospital Nurse Staffing and Patient Mortality, Nurse Burnout, and Job Dissatisfaction

<http://jama.ama-assn.org/issues/v288n16/abs/joc20547.html>

Exercise Type and Intensity in Relation to Coronary Heart Disease in Men

<http://jama.ama-assn.org/issues/v288n16/abs/joc20649.html>

Risk Factors for Traumatic and Bloody Lumbar Puncture in Children With Acute

Lymphoblastic Leukemia

<http://jama.ama-assn.org/issues/v288n16/abs/joc11632.html>

Clinical Investigation

Platelet Activation in Obese Women: Role of Inflammation and Oxidant Stress

<http://jama.ama-assn.org/issues/v288n16/abs/jci20017.html>

Reviews

Homocysteine and Risk of Ischemic Heart Disease and Stroke: A Meta-analysis

<http://jama.ama-assn.org/issues/v288n16/abs/jma20003.html>

MTHFR 677C -> T Polymorphism and Risk of Coronary Heart Disease: A Meta-analysis

<http://jama.ama-assn.org/issues/v288n16/abs/jma20025.html>

Clinical Crossroads

Clinician's Corner

A 54-Year-Old Man With Obstructive Sleep Apnea

<http://jama.ama-assn.org/issues/v288n16/rfull/jxr20009.html>

Editorials

Meeting the Challenge of Nursing and the Nation's Health

<http://jama.ama-assn.org/issues/v288n16/ffull/jed20059.html>

Homocysteine and Coronary Heart Disease: How Great Is the Hazard?

<http://jama.ama-assn.org/issues/v288n16/ffull/jed20061.html>

Letters

Health Risks of Latino Children

<http://jama.ama-assn.org/issues/v288n16/ffull/jlt1023-1.html>

A Patient Requesting Physician-Assisted Suicide
<http://jama.ama-assn.org/issues/v288n16/ffull/jlt1023-2.html>

Notifying Participants of Clinical Trial Results
P. Periman; A. Partridge, E. Winer
<http://jama.ama-assn.org/issues/v288n16/ffull/jlt1023-3.html>

Research Letter

Cellulitis and Sepsis Due to Sphingobacterium
<http://jama.ama-assn.org/issues/v288n16/ffull/jlt1023-4.html>

News and Analysis

Medical News & Perspectives

Researchers Identify Anti-HIV Proteins
<http://jama.ama-assn.org/issues/v288n16/ffull/jmn1023-1.html>

Seeking a Way to Alleviate Sickle Cell Disease
<http://jama.ama-assn.org/issues/v288n16/ffull/jmn1023-2.html>

New Focus on Research Participant Protection
<http://jama.ama-assn.org/issues/v288n16/ffull/jmn1023-3.html>

>From the World Health Organization

Reducing Risks to Health, Promoting Healthy Life
<http://jama.ama-assn.org/issues/v288n16/rfull/jwh20004-1.html>

>From the Centers for Disease Control and Prevention

West Nile Virus Activity--United States, September 26-October 2, 2002, and
Investigations of West Nile Virus Infections in Recipients of Blood
Transfusion
and Organ Transplantation
<http://jama.ama-assn.org/issues/v288n16/ffull/jwr1023-1.html>

Possible West Nile Virus Transmission to an Infant Through Breast-Feeding--
Michigan, 2002
<http://jama.ama-assn.org/issues/v288n16/ffull/jwr1023-2.html>

Nonfatal Sports- and Recreation-Related Injuries Treated in Emergency
Departments--United States, July 2000-June 2001
<http://jama.ama-assn.org/issues/v288n16/ffull/jwr1023-3.html>

Update: Influenza Activity--United States and Worldwide, June-September, 2002

<http://jama.ama-assn.org/issues/v288n16/ffull/jwr1023-4.html>

The Cover

Model of a Boat

<http://jama.ama-assn.org/issues/v288n16/ffull/jcs1023-1.html>

Poetry and Medicine

Congestive Heart Failure

<http://jama.ama-assn.org/issues/v288n16/ffull/jpm20186-1.html>

JAMA 100 Years Ago

The Psychologic Moment in Surgery

<http://jama.ama-assn.org/issues/v288n16/ffull/jjy20033-1.html>

Prevention of Germ Diseases

<http://jama.ama-assn.org/issues/v288n16/ffull/jjy20033-2.html>

Contempo Updates: Linking Evidence and Experience

Medical Informatics: Improving Health Care Through Information

<http://jama.ama-assn.org/issues/v288n16/rfull/jct10034.html>

On Call: Issues in Graduate Medical Education

What Is an Academic General Internist? Career Options and Training Pathways

<http://jama.ama-assn.org/issues/v288n16/abs/jrf20000.html>

Books, Journals, New Media

Protecting American Health Care Consumers (Kinney)

<http://jama.ama-assn.org/issues/v288n16/ffull/jbk1023-1.html>

The Practice of Clinical Echocardiography (Otto, ed)

<http://jama.ama-assn.org/issues/v288n16/ffull/jbk1023-2.html>

Ethical Issues in Neurology (Bernat)

<http://jama.ama-assn.org/issues/v288n16/ffull/jbk1023-3.html>

Five Hundred Years of Medicine in Art: An Illustrated Catalogue of Prints and
and

Drawings From the Clements C. Fry Collection in the Harvey Cushing/John Hay

Whitney Medical Library at Yale University (Wheeler)
<http://jama.ama-assn.org/issues/v288n16/ffull/jbk1023-4.html>

Goodman and Gilman's The Pharmacological Basis of Therapeutics (Hardman et al, eds)
<http://jama.ama-assn.org/issues/v288n16/ffull/jbk1023-5.html>

Books, Journals, New Media Received
<http://jama.ama-assn.org/issues/v288n16/ffull/jbk1023-6.html>

JAMA Patient Page

Lumbar Puncture
<http://jama.ama-assn.org/issues/v288n16/fpdf/jpg1023.pdf>

BMJ Table of contents for 19 October 2002; Vol. 325, No. 7369

Editor's Choice

BMJ on speed
<http://bmj.com/cgi/content/full/325/7369/0/g>

This Week in the BMJ

High work stress doubles risk of cardiovascular death
<http://bmj.com/cgi/content/full/325/7369/0>

Guidelines supported by case learning improved lipid management
<http://bmj.com/cgi/content/full/325/7369/0/a>

Patients make balanced decisions whether to take drugs
<http://bmj.com/cgi/content/full/325/7369/0/b>

Erysipelas can be treated with oral pristinamycin
<http://bmj.com/cgi/content/full/325/7369/0/c>

{pound}100m a year could greatly improve diabetes care in England
<http://bmj.com/cgi/content/full/325/7369/0/d>

GPs do not recommend screening for excessive alcohol use
<http://bmj.com/cgi/content/full/325/7369/0/e>

Too few lessons learnt from inquiries
<http://bmj.com/cgi/content/full/325/7369/0/f>

Editorials

Diagnosis of infective endocarditis

BMJ 2002;325 845-846

<http://bmj.com/cgi/content/full/325/7369/845>

The world's first international tobacco control treaty

BMJ 2002;325 846-847

<http://bmj.com/cgi/content/full/325/7369/846>

Electronic tagging of people with dementia who wander

BMJ 2002;325 847-848

<http://bmj.com/cgi/content/full/325/7369/847>

The I in the new CHAI

BMJ 2002;325 848-850

<http://bmj.com/cgi/content/full/325/7369/848>

Electronic books

BMJ 2002;325 850

<http://bmj.com/cgi/content/full/325/7369/850>

Papers

Work stress and risk of cardiovascular mortality: prospective cohort study of industrial employees

BMJ 2002;325 857

<http://bmj.com/cgi/content/abstract/325/7369/857>

Implementing intensive control of blood glucose concentration and blood pressure in type 2 diabetes in England: cost analysis (UKPDS 63)

BMJ 2002;325 860

<http://bmj.com/cgi/content/abstract/325/7369/860>

Oral pristinamycin versus standard penicillin regimen to treat erysipelas in adults: randomised, non-inferiority, open trial

BMJ 2002;325 864

<http://bmj.com/cgi/content/abstract/325/7369/864>

Effect of general hospital management on repeat episodes of deliberate self poisoning: cohort study

BMJ 2002;325 866-867

<http://bmj.com/cgi/content/full/325/7369/866>

Mortality after admission to hospital with fractured neck of femur:

database study

BMJ 2002;325 868-869

<http://bmj.com/cgi/content/full/325/7369/868>

Drug points: Tonic-clonic seizures in patients taking sildenafil

BMJ 2002;325 869

<http://bmj.com/cgi/content/full/325/7369/869>

Primary care

Screening and brief intervention for excessive alcohol use: qualitative interview study of the experiences of general practitioners

BMJ 2002;325 870

<http://bmj.com/cgi/content/abstract/325/7369/870>

Patients' decisions about whether or not to take antihypertensive drugs: qualitative study

BMJ 2002;325 873

<http://bmj.com/cgi/content/abstract/325/7369/873>

Learning in practice

Efficacy of case method learning in general practice for secondary prevention in patients with coronary artery disease: randomised controlled study

BMJ 2002;325 877-880

<http://bmj.com/cgi/content/abstract/325/7369/877>

Clinical Review

Headache * Commentary: Headache in South America

BMJ 2002;325 881-886

<http://bmj.com/cgi/content/full/325/7369/881>

ABC of antithrombotic therapy: Venous thromboembolism: pathophysiology, clinical features, and prevention

BMJ 2002;325 887-890

<http://bmj.com/cgi/content/full/325/7369/887>

Education and Debate

Cost effectiveness analysis in health care: contraindications

BMJ 2002;325 891-894

<http://bmj.com/cgi/content/full/325/7369/891>

The use and impact of inquiries in the NHS

BMJ 2002;325 895-900
<http://bmj.com/cgi/content/full/325/7369/895>

Letters

When is an emergency department not an emergency department?
BMJ 2002;325 901
<http://bmj.com/cgi/content/full/325/7369/901>

Focus on emergency departments to reduce delays in thrombolysis
BMJ 2002;325 901
<http://bmj.com/cgi/content/full/325/7369/901/a>

Probiotics and antibiotic associated diarrhoea
BMJ 2002;325 901
<http://bmj.com/cgi/content/full/325/7369/901/b>

Metronidazole is used for antibiotic associated diarrhoea in pregnancy in UK
BMJ 2002;325 903
<http://bmj.com/cgi/content/full/325/7369/903>

Heterogeneity among Indians, Pakistanis, and Bangladeshis is key to racial inequities
BMJ 2002;325 903
<http://bmj.com/cgi/content/full/325/7369/903/a>

Sex differences in occupation may affect height associations
Geoff Der
BMJ 2002;325 903
<http://bmj.com/cgi/content/full/325/7369/903/b>

Alcohol and death: the New Zealand experience
BMJ 2002;325 904
<http://bmj.com/cgi/content/full/325/7369/904>

Surveillance of whooping cough should continue
BMJ 2002;325 904
<http://bmj.com/cgi/content/full/325/7369/904/a>

Adverse events with medical devices may go unreported
BMJ 2002;325 905
<http://bmj.com/cgi/content/full/325/7369/905>

Bad bugs travel as well as happy holidaymakers
BMJ 2002;325 905

<http://bmj.com/cgi/content/full/325/7369/905/a>

=====

THE NEW ENGLAND JOURNAL OF MEDICINE

Volume 347, Issue 17: October 24, 2002

<<http://content.nejm.org/content/vol347/issue17/index.shtml?query=TOC>>

=====

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THIS WEEK IN THE JOURNAL

=====

Article Summaries:

<http://content.nejm.org/this_week/347/17/index.shtml?query=TOC>

Perspective: Hypertrophic Cardiomyopathy -- The Benefits of a
Multidisciplinary
Approach

<<http://content.nejm.org/cgi/content/short/347/17/1306?query=TOC>>

=====

ORIGINAL ARTICLES

=====

Aspirin and Mortality from Coronary Bypass Surgery

<<http://content.nejm.org/cgi/content/short/347/17/1309?query=TOC>>

Outcomes after Total versus Subtotal Abdominal Hysterectomy

<<http://content.nejm.org/cgi/content/short/347/17/1318?query=TOC>>

Nonsurgical Reduction of the Interventricular Septum in Patients with
Hypertrophic Cardiomyopathy

<<http://content.nejm.org/cgi/content/short/347/17/1326?query=TOC>>

=====

IMAGES IN CLINICAL MEDICINE

=====

Ventricular Septal Rupture after Myocardial Infarction

<<http://content.nejm.org/cgi/content/short/347/17/1334?query=TOC>>

=====

SPECIAL ARTICLE

=====

A National Survey of Provisions in Clinical-Trial Agreements between

Medical Schools and Industry Sponsors

<<http://content.nejm.org/cgi/content/short/347/17/1335?query=TOC>>

=====
CLINICAL PRACTICE

Initial Management of Glycemia in Type 2 Diabetes Mellitus

<<http://content.nejm.org/cgi/content/short/347/17/1342?query=TOC>>

=====
CASE RECORDS OF THE MASSACHUSETTS GENERAL HOSPITAL

Weekly Clinicopathological Exercises: Case 33-2002: A 28-Year-Old Woman with Ocular Inflammation, Fever, and Headache

<<http://content.nejm.org/cgi/content/short/347/17/1350?query=TOC>>

=====
EDITORIALS

Aspirin with Bypass Surgery -- From Taboo to New Standard of Care

<<http://content.nejm.org/cgi/content/short/347/17/1359?query=TOC>>

Hysterectomy -- Still a Useful Operation

<<http://content.nejm.org/cgi/content/short/347/17/1360?query=TOC>>

Institutions, Contracts, and Academic Freedom

<<http://content.nejm.org/cgi/content/short/347/17/1362?query=TOC>>

=====
CLINICAL IMPLICATIONS OF BASIC RESEARCH

RNA Interference -- A New Weapon against HIV and Beyond

<<http://content.nejm.org/cgi/content/short/347/17/1364?query=TOC>>

=====
SOUNDING BOARD

Academic Freedom in Clinical Research

<<http://content.nejm.org/cgi/content/short/347/17/1368?query=TOC>>

Collaborating with Industry -- Choices for the Academic Medical Center

<<http://content.nejm.org/cgi/content/short/347/17/1371?query=TOC>>

=====
CORRESPONDENCE
=====

<<http://content.nejm.org/cgi/content/short/347/17/1376?query=TOC>>

Molecular Profiling of Lymphoma

Cardiac Syndrome X

Weight Loss and Plasma Ghrelin Levels

Fumagillin for Intestinal Microsporidiosis

Head Lice

Ethical Incentives -- Not Payment -- for Organ Donation

Treatment of Asymptomatic Intestinal Entamoeba histolytica Infection

Website of the Day

Facts and Comparisons Online

"eFacts brings you online access to drug, interaction, herbal, and patient information"

<http://www.drugfacts.com>

Drug Facts is an amalgamated (KC) site containing top drug-news headlines and drug news updates, a free database to check for drug interactions, access to monograph type information, and a whole lot more. A scintilla of marketing and commercial information, but worthy of some time.

Answer of the Day

Phenolphthalein

Phenolphthalein was widely used in laxatives until being banned from the FDA in August 1997 due to its potential as a carcinogen. The agent was first developed to test acidity in the identification of artificial wines.

Professional magicians even use phenolphthalein turning water into wine.

The magician taps the edge of a glass of water with a wand and quickly pours it into an empty wine glass, and voila! The water is instantly changed into red wine. Pouring the wine into a third container changes it back into water. Classic acid-base titrations. Is knowledge great?