



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

29-August-2002

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## Question of the Day...

What two drugs were withdrawn from the US market in 1997 after causing primary pulmonary hypertension (PPH) and aortic/mitral regurgitation and what two drugs have since claimed to be there "herbal alternative"?

## In the News

### Insurer Seeks Generic Drug Switch

Illinois' biggest health insurer will start paying pharmacists every time they persuade a customer to switch from a brand-name drug to a generic. Blue Cross and Blue Shield of Illinois saw its drug costs rise 26 percent last year, to \$701 million. Beginning in January, the insurer will pay \$1 for each changed prescription. Generic drugs generally cost much less than brand-name versions. For instance, the generic version of the anti-depressant Prozac is \$70 a month, versus \$96 for Prozac, according to a report Sunday in the Chicago Tribune. Blue Cross and Blue Shield needs to counter the massive marketing efforts of drug makers, said Brad Buxton, senior vice president of health care management for the organization. "We don't want to have all of these commercials driving what everybody is taking," he told the Tribune. "We are simply trying to encourage what is already a healthy relationship between a pharmacist and the patient. If there is a generic drug that is as good as a brand-name, patients could save \$40 to \$60 a prescription." The insurance company projects that some large-volume pharmacies could make as much as \$5,000 to \$10,000 per quarter under the program. But some pharmacists aren't eager. "The only people who would benefit from this is the generic company and the insurance company, and we don't," said Sherman White of 200 Pharmacy in Chicago. "When you are trying to make somebody change, that takes time, and time is money to me. It's not worth it to me anyway." A drug company trade group complained that the insurance company is interfering in the doctor-patient relationship. "We don't think patients will want their insurance company

to play doctors," said Jackie Cottrell, spokeswoman for Pharmaceutical Research and Manufacturers of America. "Patients have the right to know that an insurer has put this kind of program together." Buxton said the pharmacists still will have to check with the doctor before switching a prescription. "We never push a generic over a brand if the brand is the best drug," he said.

### **Expert Panel Publishes New Treatment Recommendations for Middle Ear Infections**

Children's Hospital of Pittsburgh announced today that consensus recommendations for the treatment of acute otitis media (AOM) are published in the current issue of *Clinical Pediatrics*. The guidelines underscore the need for accurate diagnosis of AOM, or middle ear infections, and provide strict criteria that identify patients at risk for resistant bacteria. They also emphasize the need to initiate antibiotics with superior efficacy against resistant bacteria strains for patients who have risk factors for persistent and difficult-to-treat AOM. AOM is the most common bacterial respiratory tract infection in the pediatric population. Three out of four children experience at least one middle ear infection before they are 3 years old, and of these children almost half experience three or more episodes. With a great deal of variability as to the diagnosis and optimal management of AOM, the guidelines recommend that physicians and parents know the factors that put children at high risk for developing AOM with resistant bacteria. The guidelines recommend amoxicillin, especially at higher doses, as first-line treatment for AOM. However, if a patient has a risk factor or has AOM symptoms for more than three days, the guidelines call for treatment with Augmentin ES-600(R) (amoxicillin/clavulanate). As an alternative, patients also can be treated with three injections of Rocephin(R) (ceftriaxone sodium). However, based on limited clinical experience compared to oral agents, it may be advisable to reserve this injectable cephalosporin therapy for use in severe infections only.

### **Weight Loss with Xenical(R) Shown to Significantly Prevent or Delay Onset of Type 2 Diabetes in Obese Patients, According to New Four-Year XENDOS Study**

Xenical(R) (orlistat) plus diet and changes in lifestyle habits significantly prevented obese patients from developing type 2 diabetes, according to a major four-year clinical study presented today at the 9th International Congress on Obesity in Sao Paulo, Brazil. This is the first time that a weight loss medication was shown to prevent or delay the onset of type 2 diabetes in an at-risk patient population. The XENDOS trial studied 3,304 obese Swedish patients over a four-year period who were randomized into two trial arms: Xenical plus diet and lifestyle

intervention and placebo plus diet and lifestyle intervention alone. XENDOS also is the first large-scale and longest study to examine the efficacy and safety of a weight loss medication. XENDOS Results -- Xenical plus diet is shown to be significantly better than diet alone in preventing or delaying the development of type 2 diabetes -- The risk of developing type 2 diabetes was 37 percent lower in patients treated with Xenical plus diet compared to diet alone -- Xenical-treated patients also showed significant improvements in cardiovascular risk factors such as blood pressure and lipid profiles compared with placebo the placebo treated patients -- Treatment with Xenical for four years was safe and effective and well tolerated. Xenical now is the only weight loss medication available whose safety and efficacy has been studied for this length of time -- Weight loss, both in the short- and long-term, was significantly greater with Xenical plus diet and lifestyle intervention compared with diet and lifestyle intervention alone (-11.4 vs -7.5 kg at one year and -6.9 vs -4.1 kg at four years) -- Weight loss was successfully maintained in the long-term, with almost twice as many Xenical treated patients compared to placebo losing more than 10 percent body weight at the end of four years of treatment (26% vs 16%). Even more patients had lost more than 5 percent body weight after four years (53% vs 37%), an amount that has been shown to have clear health benefits. "Against the background of several studies that show lifestyle intervention in the prevention of diabetes to be successful, it is a significant step forward to be able to show that treatment with Xenical plus diet in combination with lifestyle modification is more effective than diet and lifestyle intervention alone in both diabetes prevention and weight loss," said Professor Lars Sjostrom, Sahlgrenska University Hospital, Gothenburg, Sweden, principal investigator of the XENDOS study. XENDOS in Context The XENDOS study results are consistent with two recently published studies in the New England Journal of Medicine, "Prevention of Type 2 Diabetes Mellitus by Changes in Lifestyle Among Subjects with Impaired Glucose Tolerance," May 3, 2001 and "Reduction in the Incidence of Type 2 Diabetes with Lifestyle Intervention or Metformin," February 7, 2002. These studies, Finnish and U.S. respectively, showed that lifestyle intervention can help prevent the onset of diabetes. The XENDOS study, however, showed that treatment with Xenical plus diet in addition to lifestyle changes, offers benefits beyond diet and lifestyle intervention alone for the prevention of type 2 diabetes.

### **New, Low Dose Formulation of Nation's #1 Prescribed Birth Control Pill Approved by FDA**

The U.S. Food and Drug Administration (FDA) has approved a new oral contraceptive, ORTHO TRI-CYCLEN (R) LO (norgestimate/ethinyl estradiol) Tablets for the prevention of pregnancy. ORTHO TRI-CYCLEN LO will be available by prescription in the fall. Like other oral contraceptives,

ORTHO TRI-CYCLEN LO, is highly effective when taken correctly. It contains a combination of hormones - 25 micrograms (mcg) of estrogen and the progestin, norgestimate - which provides excellent cycle control and tolerability. ORTHO TRI-CYCLEN LO was developed by Ortho-McNeil Pharmaceutical, Inc., the leader in the U.S. contraceptive market and the maker of ORTHO TRI-CYCLEN(R) (norgestimate/ethinyl estradiol) Tablets, the nation's #1 prescribed birth control pill and the first to be FDA-approved to improve moderate acne and help maintain clearer skin.

### **FDA Approves Kytril For The Prevention and Treatment of Post-Operative Nausea and Vomiting**

Roche announced today that the U.S. Food and Drug Administration (FDA) granted approval of its antiemetic, Kytril<sup>®</sup> Injection (granisetron hydrochloride) for both the prevention and treatment of post-operative nausea and vomiting (PONV). When used for prevention, Kytril is given just before or during surgery to prevent PONV from occurring. In the case of treatment, Kytril is given to a patient who experiences PONV after surgery is completed. This approval was based on randomized, double blind clinical trials. Kytril Injection was evaluated in two randomized, double blind, placebo-controlled studies in patients who underwent gynecological surgery or cholecystectomy and received general anesthesia. In one study, patients between the ages of 18 and 88 received a single intravenous dose of Kytril Injection (0.1, 1 or 3 mg) or placebo five minutes before induction of anesthesia. In another study, patients between the ages of 21 and 64 received a single intravenous dose of Kytril Injection (1 or 3 mg) or placebo immediately before the reversal of anesthesia. In both studies, Kytril Injection (1 mg) was significantly more effective ( $p < 0.001$ ) than placebo in preventing postoperative nausea and vomiting. Kytril Injection was evaluated in two randomized, double blind, placebo-controlled studies of adult surgical patients who received general anesthesia and no prophylactic antiemetic treatment, and who experienced nausea and vomiting within four hours after surgery. In one study, patients between the ages of 18 and 86 received a single intravenous dose of Kytril Injection (0.1 mg, 1 mg or 3 mg) or placebo after experiencing postoperative vomiting or severe nausea. This study showed that Kytril Injection given at 0.1 mg, 1 mg and 3 mg doses was significantly more effective ( $p < 0.001$ ) than placebo in preventing further episodes of nausea and vomiting. Furthermore, this study demonstrated efficacy at both time intervals of zero to six hours and zero to 24 hours for the treatment of PONV. The recommended dose of Kytril for prevention and treatment of post-operative nausea and vomiting is 1 mg. The most common adverse events reported in the postoperative nausea and vomiting trials included pain, headache and fever. "The results of these studies are important because there is a need for alternative therapies for

PONV," states Dr. T. J. Gan, Associate Professor, Director, Clinical Research, Department of Anesthesiology, Duke University Medical Center. Dr. Gan went on to explain that patients who fail treatment with other antiemetics are subjected to extended and unnecessary periods of nausea and vomiting, which can be severe and debilitating. These patients may be successfully managed with Kytril.

### **Ibuprofen Better Fever Reducer for Kids: Report**

The drug ibuprofen, the active ingredient in Motrin, Advil and other over-the-counter drugs, is better at reducing fever in children than acetaminophen, another often-used fever reducer found in Tylenol and other medications, Australian researchers reported at the 10th World Congress on Pain. To reach that conclusion, Tiina Piira, a clinical psychologist, and Dr. G. David Champion, director of the pain research unit at Sydney Children's Hospital, Randwick, and their colleagues conducted a comprehensive analysis of both published and unpublished data. The team performed a meta-analysis of studies in the medical literature and solicited unpublished data. In all, they evaluated 28 studies, with more than 4,000 children, that looked at the use of ibuprofen and acetaminophen for pain and fever, and for their potential for side effects. The children ranged in age from about 18 months to 16 years, Piira said. The general feeling among many doctors as well as parents, Champion said, is that acetaminophen is the better choice for fever reduction in children. But the investigators found that a single dose of ibuprofen was more effective at reducing fever than a single dose of acetaminophen at 2 to 6 hours after the treatment. When it comes to reducing pain, both medicines were fairly equal, the researchers reported. And they are equally safe. However, "you have to conclude that at the doses tested, ibuprofen comes out better for fever," Champion said. In the studies, fever was defined by each research team, Champion said, but normally is considered a temperature of about 101 degrees Fahrenheit (38.3 Celsius) or above. The study was partially funded by Boots Healthcare Australia, a pharmaceutical company. The company makes ibuprofen, among other drugs. But Piira said great care was taken when evaluating the studies to ensure that the investigators did not know details such as the researchers' names or the funding for the studies. "We looked at the scientific merits of each paper," she said.

### **Pharmacia's Pediatric sNDA for ZYVOX Accepted for Review by the FDA**

Pharmacia Corporation announced today that the U.S. Food and Drug Administration (FDA) has accepted for review the supplemental new drug application (sNDA) of ZYVOX™ (linezolid injection, tablets and for oral suspension) for the treatment of Gram-positive infections, including those caused by methicillin-resistant *Staphylococcus aureus* (MRSA) in pediatric

patients. FDA generally acts on pediatric applications within six months of the date of receipt. It approved ZYVOX to be marketed for adult patients in the U.S. in April 2000. "There are limited options available for children and newborns with serious infections, and Pharmacia acknowledged the need to develop a novel anti-MRSA antibiotic available in both IV and oral formulations for people world wide, including the youngest and most vulnerable," said Ferd Massari, vice president of clinical research for infectious diseases at Pharmacia Corporation. "Our clinical development plans have always included pediatric populations, but with ZYVOX we made a special effort to include all pediatric age groups, including newborns where such therapies are desperately needed."

### **Sankyo Pharma and Cygnus Announce FDA Approval For Pediatric Use of GlucoWatch(R) G2(TM) Biographer**

Sankyo Pharma and Cygnus announced today that Cygnus has received a supplemental pre-market approval (PMA) from the Food and Drug Administration (FDA) for use of the GlucoWatch(R) G2(TM) Biographer in children and adolescents (ages 7 to 17). The GlucoWatch G2 Biographer (which will be available September 2002) is the second-generation model of the GlucoWatch(R) Biographer system, the first and only monitoring system that provides glucose readings continuously, automatically and non-invasively. In April 2002, Cygnus received notification from the FDA that the GlucoWatch G2 Biographer was approved for use with adults. The device consists of two main parts: the durable Biographer, a watch-like device, is worn on a person's wrist, and the AutoSensor, a disposable component (attached to the back of the device) that allows for glucose monitoring for up to 13 hours. It detects trends and tracks patterns in patient glucose levels. The GlucoWatch G2 Biographer is intended for use by adults (age 18 and older) and now for children and adolescents (ages 7 to 17). It is for prescription use only. The Biographer is not intended to replace the common "finger-stick" testing method, but is indicated as an adjunctive device to supplement blood glucose testing to provide more complete, ongoing information about glucose levels. It is indicated for detection and assessment of episodes of hyperglycemia and hypoglycemia, facilitating both acute and long-term therapy adjustments, which may minimize these excursions. Interpretation of Biographer results should be based on the trends and patterns seen within several sequential readings over time. The GlucoWatch(R) G2(TM) Biographer differs from conventional blood glucose monitoring devices in several important ways: \* It measures and displays glucose levels automatically, continuously up to every 10 minutes, non-invasively collecting glucose through the skin, not from blood. \* It also creates an "electronic diary," storing up to 8,500 glucose values that can be reviewed at the touch of a button, or uploaded into a software program, helping detect trends and track patterns in glucose

levels. \* In addition, users can set personal glucose alert levels so that an alarm sounds if readings are too high or too low, or if readings decline rapidly. The GlucoWatch(R) G2(TM) Biographer differs from conventional blood glucose monitoring devices in several important ways: \* It measures and displays glucose levels automatically, continuously up to every 10 minutes, non-invasively collecting glucose through the skin, not from blood. \* It also creates an "electronic diary," storing up to 8,500 glucose values that can be reviewed at the touch of a button, or uploaded into a software program, helping detect trends and track patterns in glucose levels. \* In addition, users can set personal glucose alert levels so that an alarm sounds if readings are too high or too low, or if readings decline rapidly.

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### **Judge Bans Some Anti-Depressant Ads**

A federal judge ordered the maker of the popular anti-depressant Paxil to halt all television commercials nationwide that claim the drug is not habit-forming. The ruling against GlaxoSmithKline comes about a year after a class-action lawsuit was filed on behalf of 35 patients who claimed they suffered withdrawal symptoms such as nausea, fever, and "electric zaps" to their bodies. U.S. District Judge Mariana Pfaelzer found that in other countries, labels on the drug warn of adverse reactions when use of the drug is discontinued.

### **..While a 2nd Judge Lifts Ad Ban**

GlaxoSmithKline Plc, the second-largest drugmaker, won't have to pull ads for the antidepressant Paxil that call the drug "non-habit forming" for at least three weeks after a federal judge lifted a ban on them. U.S. District Judge Mariana Pfaelzer in Los Angeles stayed her order after the U.S. Justice Department on Tuesday argued that only the Food and Drug Administration, which approved the television commercials, has authority to regulate prescription-drug advertising and labeling. Paxil is one of Brentford, England-based GlaxoSmithKline's most prescribed drugs, with sales of \$2.67 billion last year. Users claim in a lawsuit that the ads for the antidepressant are false and deceptive and that some users experience withdrawals when they stop using the medicine. GlaxoSmithKline is "pleased" with the stay, said Michael Fleming, a spokesman for the company. "We're very strongly in agreement with the FDA's position." Pfaelzer last week sided with lawyers for the Paxil users and placed a ban on advertisements that referred to the drug as non-habit forming through the end of a trial that is set for next year. Pfaelzer allowed the FDA two weeks to submit arguments concerning what evidence the agency considered when it approved the commercials. Lawyers for the Paxil users will then have one week to respond. Her earlier order would have taken effect Sept. 1. Paxil, introduced in 1992, competes with Eli Lilly & Co.'s Prozac and Pfizer Inc.'s Zoloft. New York-based Pfizer is the world's largest drugmaker. About 35 Paxil users last year sued GlaxoSmithKline, claiming

the drug causes withdrawal symptoms such as shaking, nausea and insomnia that are often misdiagnosed by doctors as a relapse into depression. They sought the injunction on the television ads on behalf of the estimated 3,000 to 5,000 people in the U.S. who start taking Paxil each day. "These procedural delays are delaying the removal of an ad that is continuing to cause harm," said Karen Barth, a lawyer for the Paxil users. The suit, which seeks class-action status on behalf of thousands of Paxil users, asks the court to force GlaxoSmithKline to give up profits from Paxil and establish a medical monitoring program to help patients stop taking the drug. The company denies that the drug is addictive and says the symptoms that some patients experience are encountered with almost all antidepressants. In December, it added a cautionary note to Paxil's packaging about stopping use of the drug too suddenly. The commercials were "misleading and created inaccurate expectations about the ease of withdrawal from the drug," Pfaelzer ruled Monday. Company attorneys are appealing. "The U.S. Food and Drug Administration ( news - web sites ) - and not the courts - has the expertise and responsibility for reviewing and regulating pharmaceutical ads," David Stout, president of U.S. Pharmaceuticals at Paxil's producers, GlaxoSmithKline, said in a statement. "The Paxil television ad was submitted for FDA review prior to use, and the agency raised no objections to the language at issue," Stout said. The plaintiffs' lead attorney, Karen Barth, said GlaxoSmithKline changed its labeling on Dec. 14 but continued to run commercials and distribute brochures saying Paxil "may cause mild, usually temporary side effects in some individuals." Plaintiffs' attorneys said a hearing was set for Oct. 7 to decide whether the lawsuit should be converted to a nationwide class-action. The ads also said "Paxil has been studied both in short-term and long-term use and is not associated with dependence and addiction." Surging U.S. sales of Paxil and the asthma drug Advair led a 15 percent increase in second-quarter profits for London-based GlaxoSmithKline PLC. Global sales of Paxil grew 29 percent.

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### **Pros and Cons of yo Ma (Ma Huang)**

Statement from FDA Deputy Commissioner Crawford Regarding Metabolife  
Three weeks ago, we asked the Department of Justice to pursue a criminal investigation of Metabolife - whether they made false statements to FDA regarding the existence of adverse event reports. Since at least 1997, the FDA has tried to get these adverse event reports from industry. We also unsuccessfully sought these reports through litigation. Metabolife has refused and resisted us every step of the way. Given their long history of being uncooperative, we view their offer to make these reports available now to be disingenuous. We are greatly disturbed that Metabolife has repeatedly refused to cooperate with the FDA, and news that so many reports exist greatly heightens our concern. Once we get these reports, the FDA will have a special task force review them. Remember, Congress placed the

burden on the Secretary of Health and Human Services to prove that these products are unsafe. Thus, the Secretary called for an extensive scientific review of ephedra in June to establish a scientific base for addressing health concerns around ephedra. The Rand Corporation is conducting a comprehensive review of the existing science on ephedra, and the NIH will use this information to guide an expanded research effort on the safety of the product.

### **FDA Charges Unfounded, Supplement Maker Says**

The lead attorney for dietary supplement maker Metabolife International challenged the US Food and Drug Administration (FDA) on Friday to produce "one shred" of evidence that the company's products are unsafe or that it withheld information about adverse event reports from the agency. The FDA has asked the US Justice Department to launch a criminal investigation to determine whether Metabolife knowingly made false statements to the agency regarding adverse events associated with its weight-loss pill, a dietary supplement containing ephedra. Metabolife lead attorney Lanny J. Davis, of the firm Patton Boggs, responded that although there is no law requiring the company to report adverse events or even keep records on them, it has in fact voluntarily recorded the reports and offered them to the FDA. "Any suggestion or innuendo that we didn't turn these reports over are completely false," Davis said, adding that he believes the FDA is kowtowing to consumer groups by targeting the firm. Davis said the company would welcome stricter regulation of the dietary supplement industry by the FDA and was even willing to provide up to \$500,000 a year to help pay for a dietary supplement adverse event reporting system. He added that Metabolife was also willing to defray the costs of a so-called blue-ribbon panel to review the firm's adverse event reports. But the FDA called the company's offers "disingenuous," maintaining that the agency has pressured Metabolife for its adverse event reports for some time and that the firm "has refused and resisted...every step of the way." Metabolife says it received about 13,000 calls between 1997 and 2001 reporting health-related issues. Of those, 80 mentioned the side effects that are under investigation by the FDA, according to the firm. The FDA said it finds those numbers worrisome. "[N]ews that so many reports exist greatly heightens our concern," the agency said in its statement on Thursday. The agency acknowledged, however, that under dietary supplement regulations, the burden falls on the government to prove that a product is dangerous, rather than on the company to prove it is safe. Secretary of Health and Human Services Tommy Thompson called earlier this summer for a major scientific review of health concerns potentially related to ephedra. The existing science is being reviewed by the Rand Corporation, and the National Institutes of Health

will use the results of that review to conduct further research into the ingredient's safety, the FDA said. Davis said the science would prove that ephedra products are safe and effective if taken according to the label. He added that Metabolife was willing to fund a national consumer education campaign to ensure that the supplements are used as directed. In related news, US Senator Dick Durbin (D-IL) renewed on Friday his call for Thompson to take immediate action against ephedra. "If we are serious about protecting the health of our citizens, the Secretary must pull this product from the shelves until we are sure it is safe," Durbin said. Durbin made a similar statement last month at a Senate hearing on weight-loss supplements.

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THE NEW ENGLAND JOURNAL OF MEDICINE

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IMAGES IN CLINICAL MEDICINE

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Coronary-Stent Fracture

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Experiences of Oregon Nurses and Social Workers with Hospice Patients  
Who Requested Assistance with Suicide

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Mechanisms of Disease: Thrombotic Microangiopathies

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CASE RECORDS OF THE MASSACHUSETTS GENERAL HOSPITAL  
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Weekly Clinicopathological Exercises: Case 26-2002: An 87-Year-Old  
Woman with Abdominal Pain, Vomiting, Bloody Diarrhea, and an  
Abdominal Mass

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Escherichia coli O157:H7 -- Piecing Together the Jigsaw Puzzle

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Another Surprise from the Mitochondrial Genome

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Gene Therapy for Severe Combined Immunodeficiency Disease

Erythromycin-Resistant Group A Streptococci

Sulindac in Familial Adenomatous Polyposis

Transplantation of the Right Hepatic Lobe

Luxury Primary Care

Botulinum Toxin, Sweating, and Body Odor

Bradykinin-Mediated Angioedema

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BOOK REVIEWS

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The Cure: A Story of Cancer and Politics from the Annals of the Cold War

Brain Cancer

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THIS WEEK IN THE JOURNAL

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Article Summaries:  
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Perspective: Ventilation with Small Tidal Volumes  
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ORIGINAL ARTICLES

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High-Frequency Oscillatory Ventilation for the Prevention of Chronic

Lung Disease of Prematurity

<<http://content.nejm.org/cgi/content/short/347/9/633?query=TOC>>

High-Frequency Oscillatory Ventilation versus Conventional Mechanical Ventilation for Very-Low-Birth-Weight Infants

<<http://content.nejm.org/cgi/content/short/347/9/643?query=TOC>>

Derivation of Nephrogenic Adenomas from Renal Tubular Cells in Kidney-Transplant Recipients

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Neonatal Rash Due to Herpes Gestationis

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Insurance Coverage and Outcomes of in Vitro Fertilization

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Adolescent Depression

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CASE RECORDS OF THE MASSACHUSETTS GENERAL HOSPITAL  
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Weekly Clinicopathological Exercises: Case 27-2002: A 5 1/2-Year-Old Boy with Seizures and Progressive Deterioration of Cognitive and Motor Function

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High-Frequency Oscillatory Ventilation to Prevent Bronchopulmonary  
Dysplasia -- Are We There Yet?

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Nephrogenic Adenomas as Renal Tubular Outposts

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Should Insurance Coverage for in Vitro Fertilization Be Mandated?

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Responses to Smallpox Vaccine

Diagnosis of Smallpox

Smallpox and Smallpox Vaccination

Clinical Investigation in the 18th Century

Brachytherapy and Saphenous-Vein Grafts

Volume and Outcome

Bronchial Cast

Combined Blood Substitute and Erythropoietin Therapy in a Severely  
Injured Jehovah's Witness

Acute Babesiosis Caused by Babesia divergens in a Resident of Kentucky

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Hepatitis B: The Hunt for a Killer Virus

## Proteins of Iron Metabolism

### Thrombosis and Thromboembolism

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#### Answer of the Day

Fenfluramine (Pondimin) and dexfenfluramine (Redux) were removed from the US market in 1997.

The FDA started becoming increasingly concerned with anti-obesity agents after a 1996 study published in The New England Journal of Medicine found a twenty-three-fold increase in the risk of developing PPH when using fenfluramine and phentermine (fen phen) for more than three months.

Subsequently, the FDA requested that both fenfluramine and dexfenfluramine be removed from the market following increasing reports of cardiac valvular abnormalities when being used in combination with phentermine (Ionamin).

In 1996 alone there were 20.6 million prescriptions written for the appetite suppressant fen phen, and in the U.S. there are estimates that between 6 million and 7 million people took fen phen.

So..."herbal fen phen" became all the rage. The combination of ephedra (ma huang) and St. John's Wort (herbal prozac) (herbal fen phen) became increasingly used as for weight loss.

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