**NEW DRUG**

**Disposable Growth Hormone Delivery System**

Novo Nordisk, the makers of the first insulin delivery system with a pen-like design and the first liquid human growth hormone (GH) formulation available in a pen system, has announced the Food and Drug Administration’s (FDA’s) approval of Norditropin NordiFlex® (somatropin [rDNA] injection).

The injection is indicated for the long-term treatment of children with growth failure caused by inadequate secretion of endogenous GH.

The new disposable product is pre-filled, and no loading of cartridges is necessary. A total of 100 different dosing options are available.

This product is made of degradable plastic. It is easy for patients and their caregivers to use, and no mixing is needed. However, it should not be used in children who are allergic to phenol or any other ingredients in the medication.

(Source: Novo Nordisk, October 8, 2004.)

**NEW INDICATIONS**

**Duloxetine for Stress Incontinence**

Duloxetine (Yentreve™, Eli Lilly/Boehringer Ingelheim), has been granted marketing approval in the European Union for the treatment of moderate- to-severe stress urinary incontinence. Patients with this condition experience the accidental leakage of urine during physical activity.

Although stress urinary incontinence is common, it is not considered “normal” at any age. Risk factors include obesity, childbirth, chronic coughing, and constipation.

The drug is currently being evaluated by the FDA, which issued an approvable letter in August 2003. Approval from the agency is expected in 2005.

(Source: Eli Lilly/Boehringer Ingelheim, August 13, 2005.)

**Aripiprazole For Acute Bipolar Mania**

Aripiprazole (Abilify®, Bristol-Myers Squibb/Otsuka) has been approved for the treatment of acute bipolar mania, including manic and mixed episodes associated with bipolar disorder. This agent was approved in 2002 for the treatment of schizophrenia.

The FDA’s approval was based on studies in which the drug demonstrated significant improvement in the symptoms of acute manic or mixed episodes. The most common side effects reported in clinical trials were akathisia (an inner sense of restlessness), constipation, and accidental injury. The rate of discontinuation attributable to side effects was low.

Bipolar I disorder affects more than two million Americans. It generally occurs before age 30 years. Even after a diagnosis is made, it is often extremely challenging to convince a person with bipolar I disorder to seek and maintain treatment.

(Sources: Bristol-Myers Squibb/Otsuka Pharmaceutical Co., Ltd., October 1, 2004; www.abilify.com.)

**NEW DRUG APPLICATIONS**

**Flumazenil Reverses Effects of Sedation**

American Pharmaceutical Partners has received the FDA’s approval of its Abbreviated New Drug Application for flumazenil injection, the generic equivalent of Romazicon® Injection (Roche). Flumazenil is indicated for the complete or partial reversal of the sedative effects of benzodiazepines used in general anesthesia, for diagnostic and therapeutic procedures when benzodiazepines have been used for sedation, and for managing benzodiazepine overdose.

(Source: American Pharmaceutical Partners, Inc., October 13, 2004.)

**Alvimopan for Postoperative Ileus**

In findings from a phase 3 clinical study, alvimopan capsules (Entereg™, Adolor/GlaxoSmithKline) accelerated gastrointestinal (GI) recovery in patients undergoing laparotomy for bowel resection or radical hysterectomy. Patients taking 12 mg of the drug were discharged from the hospital about one day earlier than patients taking placebo.

Alvimopan is a peripherally acting mu-opioid receptor antagonist designed to block the negative effects of opioids (e.g., morphine) on the GI system without interfering with the analgesic effects on the central nervous system. It is the first in this new class with a New Drug Application accepted by the FDA for review.

Postoperative ileus is a transient impairment of GI motility and function that often affects patients undergoing abdominal surgery. It contributes to prolonged hospital stays and represents a substantial burden on health care resources. Despite its negative impact, there have been few advances in the treatment of postoperative ileus since the introduction of nasogastric decompression more than 100 years ago. This technique has limited effectiveness and is uncomfortable for patients. Currently, no drugs have been approved for the management of postoperative ileus.

In one study, patients who were scheduled for bowel resection or radical total abdominal hysterectomy received 6 mg or 12 mg of alvimopan or placebo two or more hours before surgery, then twice daily until hospital discharge or for up to seven days. The medication did not interfere with opioid analgesia, and it...
appeared to result in decreased hospital readmission rates.

The incidence of nasogastric tube reinsertion after surgery was reported to be lower for the treated patients than for patients in the placebo group. This difference was statistically significant ($P = .004$) for the 12-mg group only.

(Sources: Annals of Surgery, September 2004; www.adolor.com; www.gsk.com.)

**NEW FORMULATION**

**Cefdinir Antibiotic for Children**

Abbott Laboratories has announced that a new FDA-approved dosing option of the antibiotic cefdinir (Omnicef® Oral Suspension) is available for use in children aged six months to 12 years. The more concentrated 250-mg/5-ml formulation allows parents to administer fewer teaspoons per dose.

This drug was originally approved in 1997 at 125 mg/5 ml to treat bacterial infections in children. The new formulation is half the volume of the standard formula (125 mg/5 ml); thus, a 40-pound child would require one teaspoon of cefdinir at 250 mg/5 ml instead of two teaspoons at 125 mg/5 ml.

The new formula has proved effective for treating strep throat as well as mild-to-moderate bacterial infections of the ear, sinus, and skin.

To reduce the development of drug-resistant bacteria and to maintain the effectiveness of cefdinir and other antimicrobial drugs, practitioners should prescribe it only to treat or prevent infections that are thought to be caused by susceptible bacteria.

In pediatric trials, common adverse events were diarrhea, rash, and vomiting.

Cefdinir is contraindicated in patients with known allergy to cephalosporins.

(Sources: Abbott Laboratories, September 28, 2004; www.omnicef.com; www.omnicefforkids.com.)

**DRUG NEWS**

**Long-Term Relief For Restless Legs**

Although levodopa and dopamine agonists have been shown to help relieve restless legs syndrome (RLS), long-term studies have raised concerns about the development of tolerance and dopaminergic-induced augmentation (i.e., a prolonged duration and intensity of RLS symptoms).

Noting the lack of longitudinal studies comparing dopaminergic medications for efficacy and tolerability, researchers from the University of Texas Houston Science Center observed 83 patients who were taking a dopamine agonist for seven to 101 months. Initially, the researchers prescribed pramipexole (Mirapex®, Pfizer) for 52 patients, ropinirole (Requip®, GlaxoSmithKline) for 19 patients, and pergolide (Permax®, Amarin) for 12 patients. Twenty patients switched from one dopamine agonist to another during the study.

More than half the patients reported adverse drug events (ADEs) ranging from rash to daytime sleepiness. Ten patients stopped taking the dopamine agonist altogether after six months because of ADEs, lack of efficacy, increased symptoms, or other problems. Sixteen patients required additional non-dopamine agonists such as opioids.

The efficacy of dopamine agonist therapy was maintained across time but usually with a “modest but significant” dose increase. Only one patient’s symptoms intensified. Overall, the researchers concluded, their results supported the long-term use of dopamine agonists for RLS.

(Source: Arch Neurol 2004;61:1393–1397.)

**Duloxetine and Fibromyalgia**

Eli Lilly’s new antidepressant duloxetine (Cymbalta™) has been found to be effective in reducing pain in women with fibromyalgia.

In a 12-week study, 354 women took either duloxetine once or twice a day; the others took a placebo. More than half of the patients treated with 60 mg of the drug responded to treatment after the 12 weeks, but only one third of those taking placebo responded. Researchers stated that 44% of the patients taking the medication reported a sustained reduction in pain, compared with 19% taking a placebo.

Duloxetine is a dual serotonin–noradrenaline reuptake inhibitor. Some researchers believe that norepinephrine is mainly responsible for the effect on pain. The drug was approved in September for pain related to diabetic neuropathy.

Fibromyalgia affects about six million Americans, most of them women.

(Source: © 2004 Reuters, October 19, 2004.)

**Not Enough Aspirin After Acute MI?**

Even though aspirin has been shown to reduce mortality in patients who have had acute myocardial infarction (AMI), many patients who could safely be given aspirin are not receiving it, according to the Maximal Individual Therapy in Acute Myocardial Infarction (MITRA) study group in Ludwigshafen, Germany.

Of 4,902 patients in the multicenter registry of AMI patients, 509 (10%) did not receive aspirin at the time of discharge from the hospital, although the rates of absolute contraindications to aspirin were low (2.2%). The mortality rate of these patients after one year of follow-up was twice as high as in the patients who did receive aspirin (16.5% versus 8.3%). The difference in mortality rates remained statistically significant after adjustment for factors such as age, sex, and concomitant diseases.

The reluctance to prescribe aspirin might have resulted from a fear of ADEs

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and a less strong belief in the positive effects of prolonged aspirin therapy, especially for patients who are critically ill after an AMI. However, the researchers suggested that the inadequate treatment of the high-risk patients might have added to the higher mortality rate.

(Source: Am Heart J 2004;148:306–311.)

**HRT: Younger Women and Lower Heart Risk**

Hormone replacement therapy (HRT), taken to reduce the symptoms of menopause, might not be as risky as previously thought, at least for younger women.

New findings, presented at the annual meeting of the North American Menopause Society (NAMS) in early October, suggests that the age at which women start HRT may affect their risk for hormone-related heart problems. Younger women appear to be at lower cardiac risk and might even benefit, according to a review of the two largest hormone studies, the Women’s Health Initiative (WHI) and the Nurses Health Study.

Two years ago, results from the WHI seemed to implicate all hormone use. Many doctors speculated that the data might not apply to the typical 50-year-old patient with menopausal symptoms, but the NAMS report is the first detailed scientific analysis to support the theory.

Both studies reported almost identical increased risks of stroke and blood clots in hormone users compared with nonusers but differences in the risk of heart attack from HRT. The Nurses Health Study, which began in 1976, shows that women who took HRT were 40% less likely to suffer heart attacks than nonusers. The WHI concluded two years ago that HRT increased the risk of a heart attack by 23%.

Although some have assumed that the nurses studied were healthier to begin with than the women in the WHI, the differences cannot be fully explained on that basis. The new analysis suggests that a healthy lifestyle of exercise, diet, and not smoking might be a more powerful predictor of health than HRT use. Because healthy women already showed such a low risk of heart disease and other health problems, whether or not they used HRT did not make a difference. Some think that if women lived a healthy lifestyle, the controversy about HRT might be eliminated.


**Joint Venture to Create Affordable Generic Drugs**

Sigma Medical, in Irving, Texas, a division of Sigma Global Corporation, has announced that it has signed a joint venture agreement with Stason Pharmaceuticals, in Irvine, California, to create its own line of generic pharmaceuticals. Over the next 18 to 24 months, Sigma plans to file for governmental approval to manufacture generic equivalents of eight to 10 of the nation’s most popular agents. Generic pharmaceuticals constitute an increasing proportion of the medications dispensed in the U.S., accounting for 51% of all prescriptions.


**Temporary Heart Saves Lives**

The FDA has approved the first temporary artificial heart for use in patients at risk of dying within 30 days because of irreversible, biventricular failure as they await a heart transplant. The device is not intended to replace the human heart.

The CardioWest Total Artificial Heart (SynCardia Systems) takes over for the patient’s failing heart by restoring normal blood pressure and “shoring up” vital organs like the kidney and liver.

The FDA approved the device for can-
didates who do not respond to other treatments. Patients are typically short of breath, even while resting, because their hearts cannot pump blood efficiently.

Implanted in the chest, the device replaces the bottom half of the heart and is sewn onto the top half of the patient’s original heart. Tubes running through the chest wall connect to a large power-generating console, which operates and monitors the artificial heart.

In March 2004, an FDA advisory committee recommended that the device be approved with caution because of the complex surgery needed to install the heart and the increased potential for infection, bleeding, and stroke.

Of the 2,200 patients who do receive a new heart each year, approximately 500 need temporary assistance to ensure they will still be alive when the donor heart arrives.

In clinical trials conducted by SynCardia, 79% of patients lived long enough after receiving the device to receive a donor heart. The average patient lived for 79 days, and the longest survival was 400 days before heart transplantation. The device malfunctioned in 18% of recipients, and 17 patients died before a donor heart could be found.

Infection was the most common complication, affecting 72% of participants in the study. Bleeding occurred in 42% of patients, and 25% suffered neurological events such as major or minor stroke.

It is expected that the device will be an option for perhaps only 100 patients per year in the U.S.


Identity Chip Approved
A Florida company has been granted FDA approval to market implantable identity (ID) chips that would provide easy access to people’s medical records.

Applied Digital Solutions, in Delray Beach, Fla., believes that its VeriChip, the size of a grain of rice, will be able to save lives and limit injuries from medical errors. The chip is inserted under the skin of the arm or hand with a syringe.

The company foresees that patients will receive more effective care because doctors, emergency-room personnel, and ambulance crews equipped with a handheld radio scanner would be able to read a unique 16-digit number on the chip. The chip does not contain any records, but with the number, care providers would be able to retrieve medical information about blood type, drug history, and other crucial data stored in computers.

Applied Digital claims that the implantation of chips is voluntary and that the only records linked to a chip would be those authorized by the person with the implant. However, critics say that if the technology gains a foothold, employers and government authorities might be able to dictate how it is used.

Although passive tags like VeriChip do not broadcast radio waves and cannot be used to track one’s movements, design advances might make tracking possible.

Approval of the chip is expected to provoke much debate, especially in the area of privacy concerns and civil liberties. Surveys have shown that 14% to 22% of people would consider having the implant, but more than 80% said they would consider it if the survey questions were framed to show a medical benefit.


NEW MEDICAL DEVICES
Marvin M. Goldenberg, PhD, RPh, MS

Name: Uni-Gold™ Recombigen® HIV Test

Manufacturer: Trinity Biotech PLC, Bray, Ireland

Approval Date: September 29, 2004

Use Classification: Detection of antibodies to human immunodeficiency virus (HIV) in human serum, plasma, venous blood, fingerstick blood, and whole blood.

Description: A fingerstick whole-blood sample is normally a drop of blood taken from the finger or thumb with a lancet. This is the simplest and fastest procedure for producing a sample for HIV testing.

Purpose: Detection of HIV antibodies.

Benefits: The test is easy to use and provides results in 10 minutes. It is 100% sensitive and 99.7% specific. It is the first device to be approved for use with all four blood types (A, B, AB, and O). The test can be used in hospitals, reference laboratories, physician’s offices, clinics for sexually transmitted diseases, and community-based organizations. It is patient-friendly, particularly because its rapid results may allay anxiety in patients and because of its sensitivity.

Source: www.infectioncontroltoday.com/hotnews/49h291293.html.

Name: Sprint Fidelis™ Defibrillation Leads

Manufacturer: Medtronic, Inc., Minneapolis, MN

Approval Date: October 3, 2004

Use Classification: Defibrillation leads for the prevention of sudden death from cardiac arrest.

Description: Leads are thin, insulated wires that connect an implantable cardioverter–defibrillator (ICD) directly to the heart. With a size of 6.6 French in diameter, these right-ventricular defibrillation leads are the smallest ones available, allowing for compatibility with introducers measuring 7 French. An Isoglide™ polyurethane overlay is fabricated for smoother venous entry. The product is designed to reduce lead-to-lead interactions for improved passage.
**Purpose:** Prevention of potentially lethal heart rhythms in patients who are at risk for sudden cardiac arrest. Approximately 3 million people worldwide have rapid heartbeats that can eventually deteriorate into a life-threatening condition called ventricular fibrillation, the major cause of sudden cardiac arrest. Heart seizure (massive heart attack) kills 450,000 Americans each year, more than lung cancer, breast cancer, acquired immunodeficiency syndrome, and stroke combined. However, ICDs have proved 98% effective in treating the rapid rhythms, and rapid defibrillation is a very effective treatment.

**Benefits:** The small size of the defibrillator lead enables passage into a patient’s venous system for an easier implant and minimizes venous obstruction. The leads are available in both quadrupolar and tripolar configurations, with active and passive fixation options.

**Sources:** [http://biz.yahoo.com/bw/040902/25049_1.html](http://biz.yahoo.com/bw/040902/25049_1.html); [www.medtronic.com/tachy2/leads/fidelis.html](http://www.medtronic.com/tachy2/leads/fidelis.html)

**Name:** Cook Spectrum® Glide™ Minocycline/Rifampin Impregnated Catheters

**Manufacturer:** Cook Critical Care, Bloomington, IN

**Approval Date:** September 1, 2004

**Use Classification:** Antibiotic-coated central venous catheters for reducing infection.

**Description:** This device helps to reduce the risks of catheter-related infections, sparing hospitals the enormous cost of treating patients. A patented process protects the internal and external surfaces of the antibiotic-coated central venous catheter.

**Purpose:** Reduction of catheter-related bloodstream infections.

**Benefits:** These catheters are up to 12 times more likely than chlorhexidine/silver sulfadiazine-coated catheters to resist life-threatening infections. The highly lubricous hydrophilic surface combines patient safety and ease of placement by the critical-care physician.


**Name:** Zenith Flex™ AAA Endovascular Graft and H&L-B One Shot™ Introduction System

**Manufacturer:** Cook Critical Care, Bloomington, IN

**Approval Date:** October 4, 2004

**Use Classification:** Endograft system for treating abdominal aortic aneurysms (AAAs). AAAs occur in 90% of all aortic aneurysms in the U.S. If an aneurysm ruptures, the patient is at high risk of dying as a result of internal bleeding. This system is designed to create the most stable and accurate endograft available to save and extend the lives of patients with AAAs.

**Description:** Widely spaced stent bodies allow the device to conform to tortuous anatomy and to bend around tighter turns in the aorta with less chance of kinking.

**Purpose:** Treatment of patients with AAAs.

**Benefits:** This is the only handmade device with a wide array of components and sizes that can be tailored to fit the unique aortic anatomy of each patient. The system is minimally invasive.

**Sources:** [www.insideindianabusiness.com](http://www.insideindianabusiness.com); [www.pharmacyonesource.com](http://www.pharmacyonesource.com)

**Name:** Allura Coronary Angiography 3D-CA

**Supplier:** Philips Medical Systems, Andover, MA

**Approval Date:** September 28, 2004

**Use Classification:** Three-dimensional (3D) images of the coronary arteries.

**Description:** The system takes images of the coronary vessels from multiple viewpoints and angles.

**Purpose:** Obtaining a detailed representation of the condition of the heart’s coronary vessels.

**Benefits:** The system enables cardiologists to make quick decisions, to arrive at clinically confident diagnoses, to design effective treatment-panning methods, and to obtain detailed 3D images of the coronary arteries for accurate stent placement. These advantages can result in enhanced care, potentially shorter procedure times, the need for less contrast medium, and less radiation exposure for patients.

**Sources:** [www.pharmacyonesource.com](http://www.pharmacyonesource.com); [www.forbes.com](http://www.forbes.com)

**Over-the-Counter Defibrillator**

The FDA has granted marketing clearance for the first time for the over-the-counter sale of an automatic external defibrillator designed specifically for the public. The device shocks the heart to restore rhythm in people who are experiencing cardiac arrest. The HeartStart Home Defibrillator (Philips Medical Systems) is available for use at home.

**Recall**

The FDA and Medtronic, Inc., have announced a Class I recall of all Medtronic Model 8870 software application cards, Version AAA 02, used in conjunction with the Model 8840 N’Vision Clinician Programmer. This card is used to control the administration of medication of SynchroMed® and SynchroMed® EL implantable infusion pumps. Several pump infusion modes require the entry of a time duration or interval. Medtronic has received reports of the entry of hours into the minutes field, which has resulted in deaths and injuries as a result of drug overdose.

**Sources:** [www.fda.gov/medwatch/safety/2004/safety04.htm#med8870](http://www.fda.gov/medwatch/safety/2004/safety04.htm#med8870)