**NEW DRUGS**

**Liquid Vaccine Prevents Rotavirus Gastroenteritis in Infants**

The Food and Drug Administration (FDA) has approved RotaTeq (Merck), a live, oral vaccine for preventing rotavirus gastroenteritis in infants between six and 32 weeks of age. Rotavirus infection often causes diarrhea, vomiting, fever, and dehydration.

In a study of approximately 72,000 healthy infants, RotaTeq prevented 74% of all rotavirus gastroenteritis cases, 98% of severe cases, and 96% of hospitalizations attributed to this infection.

(Source: FDA, February 3, 2006.)

**Generic Flexeril Approved**

Mylan Pharmaceuticals, Inc., has been granted final approval of its supplemental Abbreviated New Drug Application (sANDA) for cyclobenzaprine HCl tablets USP, 5 mg. These tablets are the AB-rated generic equivalent of McNeil’s Flexeril Tablets. This agent is used as a muscle relaxant for patients with painful musculoskeletal conditions.

(Source: Mylan, February 6, 2006.)

**First Generic Version of Flonase**

The FDA has approved Fluticasone Propionate Nasal Spray (Roxane Laboratories), the first generic version of GlaxoSmithKline’s Flonase. The spray is used to treat nasal symptoms of seasonal and nonallergic rhinitis in adults and children four years of age and older. It contains a synthetic, tri-fluorinated corticosteroid with anti-inflammatory activity.

(Source: FDA, February 23, 2006.)

**Lubiprostone for Chronic Constipation in Adults**

Lubiprostone (Amitiza, Sucampo/Takeda), the first drug of its chemical type, has been approved for adults with chronic constipation when the cause is unknown. Chronic idiopathic constipation is marked by infrequent and difficult passage of stool. The drug increases the secretion of intestinal fluid and alleviates symptoms such as abdominal pain and discomfort, bloating, straining, and hard stools.

(Source: FDA, February 1, 2006.)

**Generic Beta Blocker: Coreg**

The FDA has tentatively approved Mylan’s Abbreviated New Drug Application (ANDA) for Carvedilol Tablets in strengths of 3.125 mg, 6.25 mg, 12.5 mg, and 25 mg. The tablets are the generic version of GlaxoSmithKline’s Coreg Tablets.

(Source: Mylan, February 23, 2006.)

**Fixed-Dose Combo Drug For Type-2 Diabetes**

GlaxoSmithKline has announced the availability of a new fixed-dose combination of rosiglitazone maleate and glimepiride (Avandaryl) for patients with type-2 diabetes. This tablet combines a thiazolidinedione (TZD), rosiglitazone maleate (Avandia), with a sulfonylurea, glimepiride (Amaryl), to improve blood glucose control. Rosiglitazone targets insulin resistance and helps the body respond better to its own natural insulin; sulfonylureas help the body release more of its natural insulin.

Avandaryl improved glycosylated hemoglobin and fasting plasma glucose levels better than a sulfonylurea alone.

(Source: GlaxoSmithKline, February 1, 2006.)

**IV Agent for Fungal Infections**

The FDA has approved anidulafungin (Eraxis, Pfizer) to treat candidal infections. The Candida fungus can cause serious infections in hospitalized patients or patients with compromised immune systems.

(Source: FDA, February 21, 2006.)

**Generic Testosterone Gel**

Watson Pharmaceuticals, Inc., has announced the final approval of its ANDA for testosterone gel 1% CIII. This product is the generic equivalent to Solvay’s AndroGel, which is indicated for hormone replacement therapy in men for conditions associated with a deficiency or absence of endogenous testosterone.

(Source: Watson, January 30, 2006.)

**Ranolazine for Chronic Angina**

Ranolazine extended-release tablets (Ranexa, CV Therapeutics), have been approved for the treatment of chronic angina pectoris. This agent prolongs the QT interval and should be reserved for patients who have not achieved an adequate response with other drugs for angina. Because it is a molecular entity that affects electrical conduction in the heart, ranolazine should be used in combination with amlodipine (e.g., Norvasc, Pfizer), beta blockers, or nitrates.

Its beneficial effects appeared to be greater in men than in women.

This approval marks the first new pharmaceutical approach in the U.S. to treat angina in more than 20 years.


**NEW INDICATIONS**

**Bromfenac Ophthalmic Solution for Pain After Cataract Surgery**

The FDA has approved ISTA Pharmaceuticals’ supplemental New Drug Application (sNDA) for bromfenac ophthalmic solution (Xibrom) 0.09%. This approval expands the drug’s indications to include the treatment of pain following cataract surgery. As a topical, twice-daily, nonsteroidal anti-inflammatory (NSAID)
solution, the product was first approved in March 2005 to treat ocular inflammation after cataract surgery.

An oral form of bromfenac (Duract, Wyeth) was withdrawn from the market in the 1990s because of postmarketing reports of rare severe liver failure.

(Source: ISTA, January 30, 2006; FDA.)

**Rituximab plus Chemotherapy for Non-Hodgkin’s Lymphoma**

Rituximab (Rituxan, Genentech/Biogen Idec) is now approved for the first-line treatment of patients with diffuse large B-cell, CD20-positive, non-Hodgkin’s lymphoma (NHL), in combination with CHOP (cyclophosphamide, doxorubicin, vincristine and prednisone) or other anthracycline-based chemotherapy regimens.

Rituximab, a therapeutic antibody, was approved in 1997 as a single agent for relapsed or refractory, low-grade or follicular CD20-positive, B-cell NHL. It targets and depletes CD20-positive B cells without affecting stem cells or existing plasma cells. Rituximab is also being studied for other hematological malignancies and autoimmune diseases.

(Source: Genentech/Biogen Idec, www.gene.com.)

**NEW DRUGS**

**Injectable Sumatriptan for Migraine Headaches**

A new injectable form of sumatriptan succinate (Imitrex Injection, Cerenex, GlaxoSmithKline) enables patients to self-administer a 4-mg dose under the skin with the push of a button. This product is indicated for the acute treatment of migraines with or without aura in adults.

The injectable form bypasses the digestive system and enters the bloodstream quickly. It may be more appropriate for morning migraine, migraine accompanied by nausea and vomiting, or rapidly escalating migraine.

(Source: GlaxoSmithKline, February 2, 2006.)

**New Dose and Oral Form Approved for Aripiprazole**

Aripiprazole (Abilify, Bristol-Myers Squibb/Otsuka) is now available as a 2-mg tablet and as a 1-mg/ml non-refrigerated oral solution.

The 2-mg tablet offers a way for physicians to titrate the dose to greatest effect. The non-refrigerated, oral solution is convenient for adults who have difficulty swallowing tablets.

As a dopamine partial agonist, aripiprazole is indicated for the treatment of schizophrenia, for acute manic and mixed episodes associated with Bipolar I Disorder, and for maintaining efficacy in adults with Bipolar I Disorder with a recent manic or mixed episode who had been stabilized and then maintained for at least six weeks.

The tablets are also available in strengths of 5, 10, 15, 20, and 30 mg.

(Source: Bristol-Myers Squibb/Otsuka, February 7, 2006.)

**DRUG NEWS**

**Advisory for Aprotinin**

The FDA has alerted doctors that aprotinin injection (Trasyolol, Bayer) has been linked to an elevated risk of kidney problems, heart attacks, or strokes in their patients undergoing heart bypass surgery.

Aprotinin is the only FDA-approved product for the prevention of perioperative blood loss and for reducing the need for blood transfusions in patients undergoing this surgery. The drug helps to stop bleeding, and it decreases the risk of bleeding.

Physicians should report any adverse events to Bayer or to the FDA Medwatch program. The drug should be prescribed only if the benefits of reduced blood loss outweigh the potential risks.


**Salt Solution Recall: Dangerous Endotoxin Levels**

The FDA has asked Cytosol Laboratories, Inc., to recall of all brands and sizes of its Balanced Salt Solution (BSS). The solution is used to irrigate a patient’s eyes, ears, nose, or throat during surgery, including cataract procedures.

Product lots contained elevated levels of endotoxin, a substance that can cause fever, shock, and changes in blood pressure and circulation. The FDA has received reports of a potentially irreversible eye injury that occurs when a contaminant enters the anterior segment of the eye during surgery.

Three Cytosol products are subject to the recall order: AMO Endosol (distributed by Advanced Medical Optics), Cytosol Ophthalmics (distributed by Cytosol), and Akorn (distributed by Akorn, Inc.).


**Stronger Warnings for Tequin**

Bristol-Myers Squibb has announced labeling changes for the antibiotic gatifloxacin (Tequin), indicated for the treatment of patients with pneumonia, bronchitis, uncomplicated gonorrhea, and other infections such as those of the urinary tract, kidneys, and skin.

The changes are being made because of continuing reports of hypoglycemia and hyperglycemia in patients using this product. Since the approval of Tequin in 1999, life-threatening events have been reported. Most of these events were reversible, but a few had fatal outcomes. Information about these risks was added to the warnings section of the package continued on page 145
Anticoagulant Off the Market

In the interest of patient safety, AstraZeneca is withdrawing the anticoagulant melagatran/ximelagatran (Exanta) from the market and terminating its development because of an association with liver injury. The withdrawal was triggered by new data from the EXTEND trial.

Patients were given the drug to prevent venous thromboembolism following orthopedic surgery. Two ongoing clinical trials involving another 600 patients will be discontinued, and those patients will be switched to other treatments.

AstraZeneca plans to maintain its supply of Exanta during this transition. The company is working on a follow-up compound (AZD837) that it believes will not produce the same liver problems.

(Sources: AstraZeneca, www.exanta.com; Reuters, February 14, 2006.)

Carvedilol Shortages

In January, GlaxoSmithKline (GSK) said that it was experiencing new shortages of the beta blocker carvedilol (Coreg) and a diabetes drug (rosiglitazone maleate/metformin (Avandamet) in the U.S. because of manufacturing problems at a plant in Puerto Rico. More recently, there has been a logjam in distribution.

Doctors are being advised not to initiate carvedilol therapy for patients until further notice. Pharmacists may contact GSK at 1-800-877-1158 to obtain a drop shipment order until normal distribution resumes.

(Sources: Reuters, January 11, 2006; Philadelphia Inquirer, January 29, 2006; www.fda.gov/cder/drug/shortages/default.htm, February 17, 2006.)

NEW MEDICAL DEVICES

Marvin M. Goldenberg, PhD, RPh, MS

Name: Victory Pacemaker Family
Manufacturer: St. Jude Medical, Inc., St. Paul, MN
Approval Date: February 7, 2006
Use Classification: The Victory pacemaker is used to reduce abnormal heart rhythms. It minimizes the time needed to implant the pacemaker. Its pre-programmed settings enhance the efficiency and success of implantation.
Description: Models 5810 and 5816 offer a suite of algorithms that make it easier for physicians to treat patients with atrial fibrillation. This arrhythmia results in a fast, un-
controlled heartbeat in which the heart’s upper chambers (atria) quiver instead of beating.

**Purpose:** The advanced technology promotes a more natural heart function and minimizes ventricular pacing. Studies such as St. Jude Medical’s Dual-Chamber and VVI Implantable Defibrillator (DAVID) trial have shown that excessive ventricular pacing may contribute to heart failure in some patients.

**Benefit:** The device helps to decrease in-clinic follow-up time without compromising patient care. The pacemaker measures thresholds and displays the results with electrograms for quick verification. In-clinic testing can be performed more rapidly than before with a summary screen so that clinicians can spend more time with patients and less time programming the device.

**Source:** www.pharmacyonesource.com

**Name:** Niobe Magnetic Navigation System/Carto RMT Steerable Tip Catheter

**Manufacturer:** Stereotaxis, Inc., Maple Grove, MN/Biosense Webster, Diamond Bar, CA (Johnson & Johnson)

**Approval Date:** February 7, 2006

**Use Classification:** This combination of technologies is indicated for restoring normal heart rhythms during cardiac radiofrequency ablation.

**Description:** A magnetic navigation system with catheters is integrated with stereotactical automated technology. The device enables electrophysiologists to steer a catheter remotely, map the heart’s electrical activity, and ablate targeted arrhythmic areas to be treated.

**Purpose:** During the nonsurgical procedure, a catheter delivers energy to damaged heart tissue to re-establish normal rhythm.

**Benefit:** Physicians can treat a broad range of patients with arrhythmias.

**Sources:** www.pharmacyonesource.com; www.jnj.com/news/jnj_news/20060207_141150.htm

**Name:** bcr–abl Mutation Analysis Test

**Manufacturer:** Genzyme Corporation, Cambridge MA

**Approval Date:** February 9, 2006

**Use Classification:** This test monitors drug resistance in patients with chronic myeloid leukemia (CML) who are taking imatinib mesylate (Gleevec, Novartis) and can help determine whether the patient will be resistant to the drug’s anticancer effects.

**Description:** In relapsed patients, most secondary mutations in the abl portion of the gene are associated with treatment failure. The test can detect all secondary bcr–abl mutations.

**Purpose:** Despite high efficacy response rates to imatinib, about 4% to 5% of patients who initially respond successfully develop resistance during therapy. The bcr–abl mutation is the specific target of imatinib and is found in 95% of patients with CML. The test can help physicians evaluate resistance to therapy so that they can adjust treatment.

**Benefit:** This predictive test helps oncologists personalize treatment.

**Source:** www.genzyme.ie.corp/news/recent_news/GENZ%20PR-020906.asp

**In the News**

**Stents**

In a prospective, randomized clinical trial (Intracoronary Stenting or Angioplasty for Restenosis Reduction in Small Arteries [ISAR-SMART]) of small coronary vessels, the paclitaxel-eluting stent (Cypher, Johnson & Johnson/Cordis) was superior to the sirolimus-eluting stent (Taxus, Boston Scientific) in three key endpoints used to assess efficacy: in-stent late lumen loss (the amount that the open artery has closed from the time of the immediate post-stenting measurement and the measurement at the nine-month angiographic follow-up), restenosis on angiography, and the need for revascularization of the targeted blockage. The study intended to show that the paclitaxel stent was not inferior to the sirolimus-eluting stent with respect to the primary endpoint.


**Tumor Detection**

A navigation technology is being used in hospitals in the U.S. to help physicians detect lung cancer in its earliest stages, when the disease is more treatable. The SuperDimension/Bronchus image-guiding system (Super Dimension, Herliya, Israel/Minneapolis) operates like a global positioning system, allowing physicians to navigate to suspicious-looking masses throughout the lungs in real time.

In this minimally invasive procedure, a bronchoscope and a bronchial tool are guided to a target in or next to the bronchial tree on a path, indicated by computed tomography, and the target and interior of the tree are visualized.

By creating a three-dimensional lung image, the device offers a low-risk means of obtaining biopsies in the lungs and lymph nodes. This technology combines the strengths of each method into a single step and provides access to the lymph nodes so that doctors can determine the stage of malignancy.

Standard bronchoscopy, the most common method of detecting lung cancer, carries little risk, but it cannot reach the lung periphery, where most masses are located. This makes it difficult to determine whether a mass is benign or malignant.