NEW DRUGS

Generic Approvals
Seasonale Contraceptive (Jolessa)
Barr Laboratories has launched its generic version of Seasonale extended-cycle oral contraceptive under the trade name Jolessa. This launch followed the final approval by the U.S. Food and Drug Administration (FDA) of Watson Laboratories’ Abbreviated New Drug Application (ANDA) for Seasonale. Watson received approval following the expiration of the company’s three-year new product exclusivity on September 5, 2006.
(Sources: Barr Pharmaceuticals, September 7, 2006; www.seasonique.com.)

Generic Dilantin for Seizures
The FDA has approved Taro’s ANDA for extended-release 100-mg phenytoin capsules for the treatment of seizures related to epilepsy and neurosurgery. The capsules are bioequivalent to Pfizer’s Dilantin Kapseals.
(Source: Taro, September 6, 2006.)

Generic Cipro For Urinary Tract Infections
Several ANDAs for generic versions of Bayer’s Cipro IV have been approved for the treatment of urinary tract infections, lower respiratory tract infections (including pneumonias in hospitalized patients, nosocomial pneumonia), bone and joint infections, complicated intra-abdominal infections, skin and skin structure infections, and therapy of patients with fever and neutropenia.
Ciprofloxacin Injection USP, 10 mg/ml, is packaged in 20- and 40-ml vials and in a 120-ml pharmacy bulk package. The products are made by several companies.
(Sources: FDA, www.fda.gov; September 18, 2006, The Associated Press.)

Posaconazole for Fungal Infections
An antifungal drug has been approved for patients whose weakened immune systems make it difficult for them to fight infection. Posaconazole (Noxafil, Schering-Plough) is indicated for the prevention of infections caused by certain molds and yeast-like fungi such as Aspergillus and Candida. It is intended for patients 13 years of age or older who have received bone marrow transplants or who have decreased white blood cell counts following chemotherapy.
This drug must be taken with a full meal or a nutritional supplement to allow adequate absorption. Posaconazole may interact with several medications, including drugs that suppress the immune system.
(Sources: FDA, www.fda.gov; September 18, 2006, The Associated Press.)

Panitumumab for Colorectal Cancer
The FDA has approved panitumumab (Vectibix, Amgen) for the treatment of patients with colorectal cancer that has metastasized following standard chemotherapy. This monoclonal antibody received an accelerated approval after showing effectiveness in slowing tumor growth and, in some cases, reducing the size of the tumor.
The FDA approved panitumumab on the basis of the results of a randomized, controlled clinical trial of 463 patients with metastatic cancer of the colon and the rectum after undergoing treatment with chemotherapy drugs, fluoropyrimidine, oxaliplatin, and irinotecan. More than 1,200 patients participated in the two phase 3 clinical trials.
Most patients who continued with this regimen achieved a 75% improvement at week 50, the last visit in both studies. More than 1,200 patients participated in the two phase 3 clinical trials.
Psoriasis, a chronic, immune-mediated disease, results when skin cells over-produce and accumulate on the surface, causing red, scaly plaques. This chronic inflammation is driven in part by tumor necrosis factor-alpha, or TNF-α, a cytokine involved in the body’s normal immune response. TNF-α is found at increased levels in psoriatic plaques.
Infliximab also has indications for rheumatoid arthritis, Crohn’s disease in adults and children, ankylosing spondylitis, ulcerative colitis, and psoriatic arthritis.
(Source: Centocor, September 27, 2006.)

NEW INDICATION
Infliximab for Chronic, Severe Plaque Psoriasis
The FDA has approved infliximab (Remicade, Centocor) for the treatment of adults with chronic, severe plaque psoriasis who are candidates for systemic therapy and when other systemic therapies are medically less appropriate.
The recommended dose of infliximab is an infusion of 5 mg/kg, followed by additional doses at two and six weeks after the first infusion and then every eight weeks thereafter. In the Phase 3 European Infliximab for Psoriasis (Remicade) Efficacy and Safety Study (EXPRESS), eight of 10 patients receiving infliximab 5 mg/kg induction therapy achieved a 75% improvement in psoriasis by week 10. Similar results were seen with EXPRESS II, the second phase 3 study. These results were maintained by every-eight-week infliximab 5 mg/kg maintenance infusions at six months.

NEW FORMULATION
Fentanyl Lozenge for Pain
Cephalon has received FDA approval to market a sugar-free fentanyl buccal tablet (Fentora) for the management of breakthrough pain in cancer patients who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain. Break-
through pain is characterized by a rapid onset, intensity, and short duration.

Fentora dissolves in the mouth within minutes. It will be available in dosage strengths of 100, 200, 400, 600, and 800 mcg.

(Sources: FDA, Cephalon, September 25, 2006.)

DRUG NEWS
Florida’s Nonprofit Pharmacies For HIV/AIDS Patients

The AIDS Healthcare Foundation (AHF) has held grand openings of two Positive Healthcare pharmacies in Orlando and Tampa, Florida. Positive Healthcare is a disease-management program that serves more than 10,000 people living with HIV/AIDS who are enrolled in the state’s MediPass (Medicaid) program. The pharmacies serve HIV/AIDS patients primarily, but they are open to all patients.

(Source: PR Newswire, September 13, 2006.)

FDA May Regulate More Diagnostic Tests

The FDA may begin regulating a new category of diagnostic and genetic tests and said that requiring pre-marketing approval could help to ensure that the tests are valid. However, some experts say that this requirement might discourage the development of diagnostics by raising the costs of introducing them.

The agency released draft guidelines for regulating one category of diagnostic tests called “multivariate index assays.” The FDA currently regulates diagnostic tests sold to laboratories, hospitals, and physicians, but it does not regulate diagnostic tests developed and performed by individual laboratories, also known as “home-brew tests.”

The new policy would expand the FDA’s oversight to clinical laboratories.

The FDA says it will regulate tests that measure multiple genes, proteins, or other pieces of information taken from a patient; it will then use an algorithm or software program to analyze the data. For example, Oncotype DX (Genomic Health) analyzes the activities of 21 genes in a sample of breast tumor and computes a score to help predict recurrence and the benefit of chemotherapy.

FDA officials say that such tests should be regulated because the proprietary algorithms make it difficult for doctors to interpret the test results. Some experts have wanted either the FDA or the Centers for Medicare & Medicaid Services to increase regulation because they are concerned about questionable genetic tests that are being sold directly to consumers. However, test developers and testing laboratories say that requiring clinical trials and FDA approval would discourage improvements of tests because each change in a test might require a new regulatory submission.


Grave Threat from Drug-Resistant TB Strain

The World Health Organization is concerned about the emergence of a new drug-resistant strain of tuberculosis (TB). Known as XDR-TB, the strain is practically untreatable and is associated with a high mortality rate. In one recent outbreak in South Africa, 52 of 53 patients died. Most of the victims were positive for HIV infection.

People infected with HIV are particularly susceptible to XDR-TB because of their already weakened immune systems. WHO officials said drug-resistant TB could have a severe impact on mortality in Africa, given the underlying HIV epidemic.

The strain has been found in all regions of the world, most frequently in the countries of the former Soviet Union and in Asia.

(Source: Voice of America, September 6, 2006, www.aegis.org.)

For Resistant S. aureus Infection, Try Daptomycin

The growing problem of bacteremia and endocarditis caused by Staphylococcus aureus resistance to methicillin is magnified by reports of vancomycin failures, say researchers for the S. aureus Endocarditis and Bacteremia Study Group. That’s why they believe that the antimicrobial agent daptomycin (Cubicin, Cubist) is good news.

In their international study, daptomycin competed well with standard therapy in 236 patients with S. aureus bacteremia. Of 120 patients given daptomycin, 53 had a successful outcome within 42 days, as did 48 of 115 patients who received vancomycin or an anti-staphylococcal penicillin.

Creatine kinase levels increased from normal baseline values in 25% of the daptomycin patients, and three patients withdrew from the study for that reason. About 7% had clinically significant daptomycin-associated elevations of creatine kinase.

The researchers advise monitoring patients receiving daptomycin for both creatine kinase and skeletal-muscle dysfunction. Standard therapy was associated with higher rates of clinically significant renal dysfunction (26%, compared with 11% of those receiving daptomycin).

S. aureus infection either persisted or recurred in 16% of patients receiving daptomycin, compared with 10% of those given standard therapy. However, in many cases, treatment failed for reasons other than lack of efficacy.

**Ziconotide: Another Option For Severe, Chronic Pain**

Patients with severe chronic pain who have exhausted other options, including intrathecal morphine, may benefit from an intrathecal ziconotide infusion (Prialt, Elan). However, researchers from University of California at San Francisco, after reviewing the literature, found that certain risks should be weighed against the benefit of having a different choice.

As the first neuronal-type calcium-channel blocker, ziconotide is delivered via a programmable implanted variable-rate microinfusion device, or an external microinfusion device, along with a catheter.

In three placebo-controlled, double-blind studies, ziconotide significantly improved patients’ perception of pain. However, study periods ranged from only 11 to 21 days. Moreover, in the trial on which FDA approval was based, the final scores for the ziconotide group were only modestly different from those in the placebo groups.

In clinical trials, 40% of patients had serum creatine kinase levels above the upper limit of normal; 11% had levels equal to or greater than three times normal.

Ziconotide also is associated with potentially serious central nervous system and psychiatric adverse drug effects (ADEs), such as depression, cognitive impairment, and hallucinations. Up to 33% of patients had cognitive impairment (confusion, memory and speech problems, and aphasia), although the effects were generally reversed within two weeks of stopping the drug. ADEs were more likely at infusion rates faster than 0.1 mcg/hour or with doses titrated upward more often than every 24 hours.

Serious ADEs were less likely when the upward more often than every 24 hours. Serious ADEs were less likely when the dose was titrated slowly over 21 days.

The researchers also note that the risk of meningitis is higher with external microinfusion devices than with internal devices with a surgically implanted catheter.

Drug–drug interaction studies have not been completed. Current recommendations are to use ziconotide only for chronic pain that is refractory to other therapies, including systemic and adjuvant analgesics.

(Source: *Ann Pharmacother* 2006;40: 1293–1300.)

**Argatroban for Stroke: Early Findings of Benefits**

Preliminary results are in on argatroban (Encysive/GlaxoSmithKline), a direct thrombin inhibitor that augments the benefits of recombinant tissue plasminogen activator (r-tPA) in acute stroke.

In the ongoing t-PA Argatroban Stroke Study (TARTS), low-dose argatroban, combined with intravenous r-tPA, appeared safe and may produce faster, better recanalization than r-tPA alone.

Although the results from this study were not statistically significant, they showed a trend toward improved restoration of the blood vessel’s opening and the formation of new channels. Ten of 14 patients underwent recanalization by two hours (71% compared with 38% with r-tPA alone). Further, the researchers found complete recanalization at two hours in six patients (43%), versus 11 of those patients receiving r-tPA alone (17%). The trend could be clinically important, the researchers say.

One advantage of argatroban over other thrombin inhibitors is its short half-life, which allows rapid offset of action and the ability to adjust monitoring of its antithrombotic effect by means of the activated partial thromboplastin time.

These are the first trials of argatroban in humans. However, the patient group was small, with only 15 patients, and larger trials are needed. The second phase of the study will enroll 50 more patients.

(Source: *Arch Neurol* 2006;63:1057–1062.)

**IV Epinephrine and Severe Asthma**

Is there a wider role for IV epinephrine in treating severe asthma in the emergency department (ED)?

Yes, say researchers from Australia. Moreover, they say, adverse drug effects (ADEs) aren’t a reason *not* to use it. Only a small number of the ADEs were serious, and it was unclear whether they were related to the epinephrine.

The researchers conducted a retrospective study of 220 patients who received epinephrine in the ED. Inhaled albuterol (e.g., Proventil, Schering; Ventolin, GlaxoSmithKline) is standard treatment in Australia for mild-to-moderate asthma, and IV agents are reserved for severe attacks.

The average infusion rate was 1.5 mcg/minute, and the total dose ranged from 15 to 99,551 mcg. Infusions lasted from 10 minutes to 11 days.

In 67 episodes of use, the researchers found 88 ADEs, for an ADE rate per episode of 30.5%. However, most of these were minor, such as uncomplicated sinus tachycardia and hypertension. No clinically significant consequences were found with 30 episodes of hypertension.

Only 3.6% of ADEs were serious. Two patients had myocardial ischemia; two had tachyarrhythmia, and four had hypotension. No patients died. Three of four cases of hypotension that required treatment were related to sedation for endotracheal intubation. Five events consisted of extravasation of the drug or blanching around an IV site, but four of those events occurred in one patient.

There is a sound rationale for using IV epinephrine rather than albuterol, the researchers say. Because epinephrine has both an alpha-agonist and a beta-
agonist effect, it can target both airway resistance and airway edema.

(Source: Ann Emerg Med 2006;47:559–563.)

Early Combination Hepatitis C Therapy Effective for HIV

A combination of pegylated interferon alfa-2a (Pegasys, Roche), and ribavirin (e.g., Copegus, Roche; Rebetol, Schering) showed “excellent efficacy” in acute hepatitis C (HCV) in patients with human immunodeficiency virus (HIV) infection, according to a pilot study at Hôpital Pitié-Salpêtrière in Paris. The researchers suggest that their timing—early, but not too early—was the key to success.

About 80% of HIV-infected patients develop chronic HCV infection, which can rapidly progress to fibrosis and cirrhosis. However, patients co-infected with HIV generally respond less well to combined treatment with pegylated interferon and ribavirin.

In other research, sustained virological response appeared to be more frequent when therapy began in the acute phase of HCV infection, but it is not known whether this also applies to HIV co-infected patients.

In this study, approximately half of the patients with symptomatic infection spontaneously cleared the virus, often within 16 weeks. The researchers began treatment no earlier than at 12 weeks to avoid treating patients who might not need it.

At the baseline evaluation, 23 of 25 men were receiving highly active retroviral treatment (HAART). Nineteen started anti-HCV therapy, a median of 14 weeks after HCV was diagnosed. Of the 14 men who were included in post-treatment follow-up at 24 weeks, 10 (71%) had a sustained virological response. As of this writing, the remaining five patients were still being treated.

The anti-HCV treatment was well tolerated, and no dose adjustments were needed. One patient was lost to follow-up after three weeks because of psychiatric disorders possibly caused by interferon.

(Source: AIDS 2006;20:1157–1161.)

Primary Bone Lymphoma: Finding the Best Treatment

In perhaps the largest study of the current treatment of primary bone lymphoma, researchers from Memorial Sloan-Kettering Cancer Center examined 40 years’ worth of data from 82 patients.

Eleven patients received radiation therapy alone, and 24 received chemotherapy alone. The remaining 46 patients received combined modalities: either vincristine/cyclophosphamide/doxorubicin (Adriamycin)/prednisone (VCAP) or VCAP plus rituximab (Rituxan, Genentech).

The researchers were encouraged by an excellent prognosis, with an overall survival rate of 88%, but combined-modality treatment further boosted survival: Overall survival rates were 95% (combined therapy) and 78% (single-modality therapy); freedom-from-treatment-failure rates were 90% (combined modality) and 67% (single-agent therapy); and cause-specific survival rates were 95% (combined therapy) and 83% (single-agent therapy).

(Source: Cancer 2006;106:2652–2656.)

Perioperative Beta Blockade: Is It Needed?

Perioperative beta blockade is recommended for patients at cardiac risk who undergo major noncardiac surgery. But it might be pointless for some patients, say researchers from the multicenter Diabetes Postoperative Mortality and Morbidity Trial Group.

In the randomized study, which involved nine hospitals in Copenhagen, Denmark, 462 patients with diabetes received metoprolol succinate (Toprol, AstraZeneca) and 459 received placebo.

The intervention lasted up to eight days in each group. The follow-up phase lasted from six to 30 months.

Metoprolol significantly reduced the mean heart rate by 11% and mean blood pressure by 3%, but it had no significant effect on mortality and cardiac morbidity: 74 patients in the metoprolol group and 72 in the placebo group died. In the metoprolol group, 46 had a cardiac event, compared with 45 in the placebo group.

The researchers suggest that the evidence is insufficient to recommend perioperative beta blockers for patients at risk for cardiac morbidity. Moreover, it might be premature for policy-making organizations to use treatment with perioperative beta blockers as a measure of hospital quality.

(Source: BMJ [online first bmj.com], 2006;332:1482.)

Adding Ciclesonide to Reduce Prednisone in Asthma Patients

Substituting twice-daily ciclesonide (Alvesco, Sanofi-Aventis/Altana Pharma) for high doses of other forms of inhaled corticosteroids could mean much less prednisone (e.g., Deltasone, Pfizer) for patients with severe asthma, according to a phase 3, 12-week multicenter study from South Africa; Long Island, New York; Omaha, Nebraska; and Denver.

The reduced need for oral corticosteroids was apparent by the second week and continued during the study. By the end of the study, almost one third of the patients receiving ciclesonide were able to stop using prednisone entirely, in contrast to 11% of the placebo patients.

The 141 patients received ciclesonide, either 640 mcg/day (80 mcg x four puffs twice daily) or 1,280 mcg/day (160 mcg x four puffs twice daily) or placebo. The lower dose reduced the need for prednisone by 47%; the higher dose reduced the need by 63%. By contrast, the need for prednisone increased by 4% in the
**Easier Emergency Endoscopy**

Acute upper GI bleeding can make emergency endoscopy a challenge, and gastric lavage might not be effective. Two studies have suggested that an erythromycin infusion can help by accelerating gastric emptying. However, say researchers from Hôpital Saint-Antoine in Paris, one study did not compare the erythromycin infusion with gastric lavage, and the other was not placebo-controlled.

The researchers thus performed a double-blind trial, randomly assigning 100 patients admitted for upper GI bleeding to receive either gastric lavage plus IV erythromycin or gastric lavage plus placebo before endoscopy.

The endoscopist was able to visualize the gastric mucosa entirely in 65% of patients receiving erythromycin but in only 44% of those receiving placebo. The quality of the examination of the upper GI tract was also better in the erythromycin group. The endoscopic examination revealed clots in 30% of the erythromycin patients and in 52% of the placebo group.

Although the IV erythromycin infusion improved gastric cleansing, the clinical benefit is doubtful, the researchers say, because the ability to identify the source of bleeding, the mean duration of the endoscopy, the effectiveness of hemostatic treatments, and the need for a second-look endoscopy within 48 hours did not differ between the two groups.

(Source: *Am J Gastroenterol* 2006;101:1211–1215.)

**New Smallpox Vaccine**

Bavarian Nordic, with operations in the U.S. and Denmark, is ready to produce and deliver its new Imvamune smallpox vaccine to the national emergency stockpile.

Congress and the Department of Health and Human Services (DHHS) are implementing Project BioShield, which is speeding up the process for new bioterrorism countermeasures to protect the public, including the new highly attenuated modified vaccinia virus Ankara (MVA) smallpox vaccine, currently in the acquisition process.

In response to the government’s critical need for quick and large-scale manufacturing capacity, Bavarian Nordic started a $60 million investment program two years ago to build a new manufacturing plant in Denmark. Last month, Danish and European regulatory authorities approved the plant for large-scale commercial production.

Imvamune vaccine is being developed for immune-compromised persons who may experience serious side effects from the traditional vaccine, such as children and the elderly, patients with eczema, and those with compromised immune systems resulting from HIV/AIDS.

Imvamune offers protection in three to four days after exposure to the smallpox virus, whereas protection from current vaccines takes 10 to 14 days.


**Revised Bevacizumab Label**

Genentech and the FDA have notified health care professionals about revisions to the Warnings and Adverse Reactions sections of the prescribing information for bevacizumab (Avastin). The alert concerns cases of a rare brain–capillary leak syndrome (reversible posterior leukoencephalopathy syndrome [RPLS]) and postmarketing reports of nasal septum perforation.

RPLS, a neurological disorder, is associated with hypertension, fluid retention, and cytotoxic effects of immunosuppressive drugs on the vascular endothelium. Patients may experience headache, seizure, lethargy, confusion, blindness, and other visual and neurologic disturbances. Hypertension may be present. Magnetic resonance imaging is necessary to confirm a diagnosis of RPLS.

(Source: FDA, September 25, 2006.)

**Botulinum Toxin and Wound Healing**

Botulinum toxin is most famous for smoothing out celebrities’ wrinkles, but it can also help wounds heal with less scarring than prior treatments, according to a prospective study conducted at the Mayo Clinics.

Researchers evaluated 31 patients who had traumatic forehead lacerations or who were undergoing elective excisions of forehead masses. Using a Visual Analogue Scale to rate the appearance of scarring in the 16 patients who completed the study, the researchers scored the botulinum results at 8.9, compared with 7.2 for the placebo, a statistically significant difference.

A major factor that determines the appearance of any scar is the tension that acts on the wound edges during the healing phase. Surgical techniques reduce rather than eliminate muscle tension. The repeated microtrauma caused by continuous muscle activity around a wound induces a prolonged inflammatory response, leading ultimately to hypertrophic and hyperpigmented scars. Immobilizing aids in healing, and botulinum excels in this activity, effectively paralyzing the muscles adjacent to the wounds.

After monitoring the patients for six months, the researchers noted that the resulting scars appeared mature and that
the forehead wounds healed with a “superior cosmetic appearance.”


**Morphine plus Ketorolac For Pain: Advantages and Drawbacks**

Morphine and the nonsteroidal anti-inflammatory agent ketorolac tromethamine (Toradol, Roche) work better together than either agent alone, and with the fewest adverse effects, for treating acute renal colic, according to researchers from Yale University, Mount Sinai Hospital, and Hospital of Saint Raphael in Connecticut. On its own, ketorolac has an analgesic ceiling, which morphine does not; on the other hand, morphine is associated with more ADEs.

The randomized, double-blind study is the first to compare intravenous (IV) ketorolac with IV morphine. Researchers assigned 130 emergency-department patients to receive morphine 5 mg at 0 (zero) and 20 minutes, ketorolac 15 mg at 0 and 20 minutes, or morphine plus ketorolac.

The primary outcome measurements were reduced pain and the need for rescue analgesia at 40 minutes. Mean pain scores on a Visual Analogue Scale were 3.7 cm for morphine, 4.1 cm for ketorolac, and 2.0 cm for the combination. One third of patients receiving combination therapy reported nausea or vomiting. The researchers found no significant difference between the groups with regard to changes in blood pressure, pulse rate, respiratory rate, or oxygen saturation.

(Keto)torolac-treated patients were pain-free after the first dose. Can a local anesthetic help reduce perineal pain during delivery?

Researchers from the United Kingdom compared the effectiveness of lidocaine with a placebo spray in 185 women during spontaneous vaginal delivery. Although all of the women, who were in the second stage of labor, found the lidocaine spray acceptable, it was not associated with any reduction in perineal pain. Mean pain scores were similar in both groups of patients. In fact, the trend suggested worse pain with the study agent.

However, the spray may have longer-term benefits; women who received the spray were less likely to have second-degree perineal trauma and to experience dyspareunia during the two months after delivery. The researchers suggest that the spray might allow a more controlled delivery of the fetal head, thus preventing trauma.

(Source: BMJ 2006;333:117.)

**Preventing Eptifibatide-Related Bleeding**

Advanced age is a main risk factor for increased bleeding in patients treated with eptifibatide (Integrilin, Cor) during and after percutaneous coronary intervention, according to findings from the Randomized Trial to Evaluate the Relative PROTECTION against Post-PCI Microvascular Dysfunction and Post-PCI Ischemia among Antiplatelet Agents—Thrombosis In Myocardial Infarction (PROTECT-TIMI-30) trial.

The researchers discovered a common problem: giving a full-dose eptifibatide infusion to patients with reduced creatinine clearance (CrCl). Among the 33 patients with a CrCl of 50 ml/minute or less, and who thus met criteria for a reduced dose, 15 patients received the full dose. Using serum Cr alone may yield inadequate dose reductions; the researchers recommend using CrCl or the glomerular filtration rate instead.

More than 50% of the bleeding events occurred more than six hours after the initiation of eptifibatide. However, it was unclear whether early termination of the infusion would preserve or reduce the ischemia-related efficacy of the drug. The researchers advise prospective, randomized trials of shorter infusions.

(Source: J Am Coll Cardiol 2006;47: 2374–2379.)

**NEW MEDICAL DEVICES**

**Marvin M. Goldenberg, PhD, RPh, MS**

**Name:** Integrated Off-Pump Cannula

**Manufacturer:** Abiomed, Danvers, MA

**Approval Date:** August 14, 2006

**Use Classification:** The cannula is designed to work with the company’s AB5000 and BVS 5000 circulatory support systems for use in off-pump (“beating-heart”) procedures for patients with acute heart failure.

**Description:** A 42 French cannula, a surgical sewing cuff, and an inline connector are provided for precise implantation and reduced blood loss. During surgery, the surgical felt patch is trimmed to size and sutured to the heart wall at the desired location. A special proprietary tool makes an incision at the heart wall through the center of the graft. Bleeding is controlled while the cannula is introduced into the graft, across the incision site. The base of the graft is secured to the cannula with umbilical tape or heavy gauge silk ties. During explanation, the tapes or ties are removed, the cannula is withdrawn, and the graft is sewn over or stapled to seal the site.

**Purpose:** The system is expected to standardize surgical procedures for patients with acute heart failure by offering cardiovascular surgeons standardized, efficient circulatory support.

*continued on page 576*
Benefit: Patients do not need a second sternotomy during explantations. Off-pump techniques provide the potential advantages of a shorter hospital stay and recovery time as well as less bleeding, less potential for infection, and less trauma. Off-pump implantations are easier to perform, and damage to the heart muscle is minimized.

Sources: www.pharmacyonesource.com; www.abiomed.com

Name: Aptima Combo 2 Assay, Tigris System
Manufacturer: Gen-Probe, San Diego, CA
Approval Date: August 22, 2006
Use Classification: The assay has been approved to test two additional kinds of patient samples for *Chlamydia trachomatis* and *Neisseria gonorrhoeae*, sexually transmitted organisms, on the Tigris system.

Description: The system allows the testing of liquid Pap specimens and vaginal swab specimens.

Purpose: The assay is cleared to detect *Chlamydia* infections and gonorrhea from a wide variety of sample types. In addition to liquid-based ThinPrep Pap Tests and vaginal swabs, these types include endocervical and urethral swab specimens and female and male urine specimens.

Tigris is a fully automated, high-throughput testing instrument for molecular diagnostics. The system automates all phases of nucleic acid testing, including sample preparation, amplification, detection, and reporting results. One operator can test 500 samples with this assay in approximately 8.5 hours or 1,000 samples in approximately 13.5 hours. One operator can also run two Tigris systems simultaneously.

Benefit: Intercepting organisms that cause sexually transmitted diseases in conjunction with ThinPrep Pap Tests or with noninvasive vaginal swabs can help physicians prevent serious medical complications and avoid unnecessary health care costs.

Sources: www.pharmacyonesource.com; www.gen-probe.com

Name: AbioCor Implantable Replacement Heart
Manufacturer: Abiomed, Danvers, MA
Approval Date: September 5, 2006
Use Classification: This is the first totally implanted artificial heart for patients with advanced heart failure that involves both pumping chambers of the heart.

Description: A two-pound mechanical heart takes over the pumping function of the diseased heart, which is removed during the implantation procedure. A power transfer coil powers the system across the skin and recharges the internal battery from the outside. A controller and an internal battery are implanted in the patient’s abdomen.

The controller monitors and controls the functions of the device, including the pumping rate of the heart. The internal battery allows the patient to be free from all external connections for up to one hour. Two external batteries allow free movement for up to two hours.

While the patient sleeps and while the batteries are being recharged, the system can be plugged into an electrical outlet.

Purpose: This device is indicated for patients who are not eligible for a heart transplant, whose pumping heart chambers are failing, who are younger than 75 years of age, who have end-stage heart disease, and who are not likely to live more than a month without intervention. To receive the heart, patients must undergo screening to determine whether their chest volume is large enough to hold the device.

The FDA approved the heart under the Humanitarian Device Exemption Program. It is allowing Abiomed to sell up to 4,000 devices a year. The number might be much smaller, perhaps 25 to 50 devices, in part because relatively few patients will be eligible. It is unclear whether health insurers will cover the cost of the heart ($250,000).

Benefit: In a small clinical study of 14 patients, the device was found to be safe and had probable benefit for patients with severe heart failure. In some cases, it extended survival by several months.


Device Alert Update: Bare-Metal or Drug-Eluting Stents?

The benefits of switching from bare-metal stents to drug-eluting stents to reopen blocked coronary arteries may be less important than previous trials indicated, according to a study published in the August 2006 issue of *Clinical Cardiology* and data provided by Goodroe Healthcare Solutions. The study appears amid recent news that drug-eluting stents may contribute to potentially deadly blood clots.

The early stents, which were first used in the 1990s, were composed of bare metal, but often treatment was required to combat restenosis (the formation of new blockages). The newer stents, which are more expensive, are coated with drugs.

Goodroe examined clinical data from 17,000 patients who received bare-metal stents from December 1998 through March 2003. This information was collected from 17 hospitals in the U.S.

This study raised the possibility that bare-metal stents might be more effective than earlier trials had suggested.