NEW DRUGS

Teflaro for Bacterial Infections

Ceftaroline fosamil (Teflaro, Forest), an injectable antibiotic, has been approved to treat adults with community-acquired bacterial pneumonia and acute bacterial skin and skin structure infections, including methicillin-resistant *Staphylococcus aureus* (MRSA).

Ceftaroline is a cephalosporin, which acts by interfering with the bacterial cell wall. The drug’s safety and effectiveness were evaluated in four phase 3 clinical trials in patients 18 years of age and older. Adverse effects included diarrhea, nausea, and rash.

Source: FDA, October 29, 2010

KL4, an Orphan Drug For Cystic Fibrosis

An orphan drug designation has been approved for Discovery’s KL4 surfactant for patients with cystic fibrosis (CF). CF is caused by a genetic mutation that can cause life-threatening lung infections and premature death. Previous studies had suggested that a surfactant might improve mucociliary clearance, perhaps with the potential to prevent further compromise of lung function.

Discovery completed a double-blind, randomized crossover phase 2a study in which the aerosol surfactant was generally safe and well tolerated. Patients experienced improved mucociliary clearance, and no associated serious adverse events were reported.

Source: Drug Discovery Dev, November 2, 2010

Latuda Benefits Adults With Schizophrenia

Lurasidone HCl tablets (Latuda, Sunovion) have been approved for the treatment of schizophrenia in adults. Like other atypical antipsychotic agents, lurasidone carries a boxed warning alerting prescribers to an increased risk of death associated with off-label use of these drugs to treat behavioral problems in older adults with dementia-related psychosis. Lurasidone is discussed in this month’s Pharmaceutical Approval Update on page 693.

Source: FDA, October 28, 2010

Egrifta Treats Lipodystrophy In HIV Infection

The FDA has approved tesamorelin injection (Egrifta, Theratechnologies, Inc./EMD Serono) to treat HIV patients with lipodystrophy. This condition, in which excess fat develops around the liver, stomach, and other abdominal organs, is associated with many antiretroviral drugs.

Tesamorelin is a growth hormone–releasing factor that is administered once daily. In two clinical trials, patients receiving tesamorelin experienced greater reductions in abdominal fat, compared with patients receiving placebo. Some patients also reported an improved self-image.

Adverse effects included joint, stomach, and muscle pain; erythema and pruritus at the injection site; swelling; and worsening blood glucose control.

Source: FDA, November 10, 2010

Halaven for Breast Cancer

Eribulin mesylate (Halaven, Eisai) has been approved to treat patients with metastatic breast cancer who have received at least two prior chemotherapy regimens for late-stage disease.

Eribulin, a microtubule inhibitor, is a synthetic form of a compound derived from the sea sponge *Halichondria okadai*. Before therapy, patients should have received prior anthracycline-based and taxane-based chemotherapy for early or late-stage breast cancer.

In a randomized study of 762 women, median overall survival rates were 13.1 months with eribulin and 10.6 months with a different agent. Adverse effects included neutropenia, anemia, leukopenia, hair loss, fatigue, nausea, peripheral neuropathy, and constipation.

Source: FDA, November 15, 2010

Gablofen for Spasticity

CNS Therapeutics has announced the FDA’s approval of Gablofen (baclofen) injection for use in the management of severe spasticity. This movement disorder affects more than 500,000 patients in the U.S. alone and is often brought on by multiple sclerosis, cerebral palsy, spinal cord injury, brain trauma, and stroke.

Originally developed in the 1920s as a potential antiepileptic drug, baclofen was also found to be safe and effective for reducing spasticity. In the early 1980s, the drug was noted to be more effective when delivered intrathecally. Baclofen intrathecal injection was first approved in 1992 as an orphan drug and is now considered the standard of care for patients with severe spasticity of spinal and cerebral origin.

Gablofen is administered in the same standard concentrations as Lioresal Intrathecal (Novartis): 50 mcg/mL, 500 mcg/mL, and 2,000 mcg/mL. It is sold with ready-to-use vials and pre-filled syringes offering clear advantages over glass ampules, including a faster refill preparation time and a lower risk of product contamination.

The company’s research was partly funded by a grant from the Michael J. Fox Foundation.


NEW INDICATIONS

Vyanse for ADHD in Teenagers

Lisdexamfetamine dimesylate capsules (Vyanse, Shire) have been approved for the treatment of attention deficit hyperactivity disorder (ADHD) in
adolescents 13 to 17 years of age. Vyvanse was previously approved for treating ADHD in adults and children 6 to 12 years of age. The new approval was based on results from a randomized study of 314 adolescents.

Vyvanse is a federally controlled substance (CII) because it can be abused or may lead to dependence. It is available in six once-daily dosage strengths of 20, 30, 40, 50, 60, and 70 mg.

Sources: FDA and Shire, November 15, 2010

Sprycel for Rare Leukemia
Dasatinib (Sprycel, Bristol-Myers Squibb) has been approved for patients with newly diagnosed Philadelphia chromosome-positive (Ph+) chronic myeloid leukemia (CML) in chronic phase. This slowly progressing blood and bone marrow disease is linked to a genetic abnormality.

An oral kinase inhibitor, dasatinib is believed to block the activity of proteins responsible for the growth of cancer cells so that the bone marrow can start reproducing normal red and white blood cells.

In 2006, the FDA granted accelerated approval for dasatinib to treat adults with CP-CML with disease that was resistant to previous therapy, including imatinib (Gleevec, Novartis). In 2009, formal approval was granted.

Bristol-Myers Squibb has launched My Sprycel Support to help patients learn more about the drug. Patients also have access to a care counselor 24 hours every day.

Source: FDA, October 28, 2010

Afinitor for Rare Brain Cancer
Everolimus (Afinitor, Novartis) is now approved to treat subependymal giant cell astrocytoma, a benign brain tumor that is associated with tuberous sclerosis. Tuberous sclerosis is a rare genetic disorder in which tumors grow in the brain, eyes, lungs, liver, heart, skin, and kidneys. Signs may include learning disabilities, skin abnormalities, seizures, and lung and kidney disease.

Everolimus tablets were first approved in March 2009 to treat kidney cancer patients who were not responding to sunitinib (Sutent, Pfizer) or sorafenib (Nexavar, Bayer). Everolimus is also approved as Zortress (Novartis) for preventing organ rejection after kidney transplantation.

Source: FDA, November 1, 2010

Cymbalta for Chronic Pain
The FDA has approved duloxetine HCl (Cymbalta, Eli Lilly) to treat chronic musculoskeletal pain, including discomfort from osteoarthritis and chronic lower back pain. Duloxetine is also indicated for major depressive disorder, diabetic peripheral neuropathy and fibromyalgia, generalized anxiety disorder, and maintenance treatment of major depression.

The FDA assessed the drug’s efficacy in four randomized clinical trials. At the end of the study period, patients taking duloxetine had a significantly greater pain reduction compared with those taking placebo.

The recommended dose is a 60-mg capsule taken once daily without regard to meals.

Source: FDA, November 4, 2010

Herceptin for Stomach Cancer
Trastuzumab has improved outcomes in women with HER-2+ breast cancer. The drug blocks HER-2 protein, which is overexpressed in some stomach cancers. The drug blocks HER-2 and is used to treat early-stage and advanced HER-2+ breast cancer.

The drug was evaluated in the phase 3 ToGA study. Half of the patients received chemotherapy alone, and half received chemotherapy plus trastuzumab. Chemotherapy comprised a fluoropyrimidine (capecitabine [Xeloda, Roche]) or 5-fluorouracil (5-FU) and cisplatin (Platinol, Bristol-Myers Squibb). Overall survival rates were 13.8 months with chemotherapy plus trastuzumab and 11.1 months with chemotherapy alone.

Sources: Reuters and Genentech, October 20, 2010

Herceptin for Stomach Cancer
The FDA has expanded the indication to include the initial treatment of HER-2-positive (HER-2+) metastatic cancer of the stomach or gastroesophageal junction in combination with chemotherapy.

Trastuzumab has improved outcomes in patients with HER-2+ breast cancer. HER-2 protein is also overexpressed in some stomach cancers. The drug blocks HER-2 and is used to treat early-stage and advanced HER-2+ breast cancer.

The drug was evaluated in the phase 3 ToGA study. Half of the patients received chemotherapy alone, and half received chemotherapy plus trastuzumab. Chemotherapy comprised a fluoropyrimidine (capecitabine [Xeloda, Roche]) or 5-fluorouracil (5-FU) and cisplatin (Platinol, Bristol-Myers Squibb). Overall survival rates were 13.8 months with chemotherapy plus trastuzumab and 11.1 months with chemotherapy alone.

Sources: Reuters and Genentech, October 20, 2010

Xgeva for Prevention of Skeletal-Related Events
The RANK ligand inhibitor denosumab (Xgeva, Amgen) has been approved to prevent skeletal-related events in patients with bone metastases from solid tumors. Denosumab was approved in the U.S., the European Union, and Canada earlier this year as Prolia for postmenopausal women with osteoporosis who were at a high risk of bone fractures.

The approval of the new indication followed a six-month review based on three pivotal head-to-head trials that compared the drug with zoledronic acid (Zometa, Novartis). Denosumab is given as a single subcutaneous injection every four weeks, whereas zoledronic acid is administered as a monthly infusion and must be dose-adjusted to allow for renal function.

Results showed significant benefits of denosumab therapy over zoledronic acid in preventing skeletal-related events among patients with breast or prostate cancer and bone metastases. Denosumab was also non-inferior to zoledronic acid in patients with bone metastases resulting from other solid tumors or bone lesions caused by multiple myeloma.

Source: Gen Eng Biol News, November 19, 2010
**New Drugs**

**Drug News**

**Lipitor Bottles Recalled**

Pfizer has recalled an additional 38,000 90-count bottles of the 40-mg dose of atorvastatin (Lipitor) because of reports of an uncharacteristic musty, moldy odor related to the product’s packaging. This was the third recall of the drug since August for the same complaint, bringing the total number of bottles to 369,000 at the end of October.

The odor was a result of a chemical called 2,4,6-tribromoanisole, used as a preservative in wood pallets for storing and shipping the drugs. The same chemical was cited in Johnson & Johnson’s recall of Tylenol and other over-the-counter drugs earlier this year. No injuries or illnesses have been reported. Consumers may return the affected bottles to the pharmacy for a replacement.

Sources: Drug Disc Dev and WebMD, October 29, 2010

**Darvon, Darvocet Leaving the Market**

Xanodyne Pharmaceuticals, Inc., has agreed to withdraw the pain medication propoxyphene (Darvon, Darvocet) from the U.S. market at the request of the FDA. The FDA has also informed generic manufacturers of propoxyphene-containing products of Xanodyne’s decision and has requested that they voluntarily remove their products as well.

The FDA sought the withdrawal after receiving data showing that the opioid was putting patients at risk of potentially serious or even fatal heart rhythm abnormalities. As a result, the agency concluded that the risks of the medication outweighed the benefits.

The FDA is advising health care professionals to stop prescribing propoxyphene to patients. Those who are taking the drug should discuss switching to another therapy with their physician.

Propoxyphene is used to treat mild to moderate pain. First approved by the FDA in 1957, the drug has been sold alone (Darvon) or combined with acetaminophen (Darvocet).

Since 1978, the FDA has received two requests to remove propoxyphene from the market. In June 2009, the European Medicines Agency recommended that marketing authorizations for propoxyphene be withdrawn in the European Union.

In July 2009, the FDA required that a new boxed warning be added to alert physicians and patients about the risk of a fatal overdose. A study at that time also showed that even at recommended doses, propoxyphene was affecting the electrical activity of the heart.

Source: FDA, November 19, 2010

**Inspira, a Diuretic, Reduces Deaths From Heart Failure**

The diuretic eplerenone (Inspira, Pfizer) may be able to lower the risk of death and hospitalization in patients with mild heart failure, according to a study from France. The drug, already used to treat advanced heart failure, also has value for people with mild disease.

In a phase 3 trial (EMPHASIS–HF), which included 2,737 patients 55 years of age and older with New York Heart Association class II heart failure, eplerenone reduced the risk of cardiovascular death or heart failure hospitalization by more than one-third, compared with placebo, after two years.

Approximately 13% of patients receiving eplerenone died, compared with 16% of patients given placebo. Further, 12% of patients taking eplerenone were hospitalized for heart failure, compared with almost 19% of those taking a placebo.

The study was stopped early because of eplerenone’s benefits. However, this medication can raise potassium levels, which must be monitored.


**Contraception Compliance Is Low in Women Taking Category X Drugs**

Many women who are taking teratogenic medications, which pose risks in pregnancy, might not be adhering to their prescribed oral contraceptive regimen.

Researchers from Medco Health Solutions evaluated prescription medication claims and refill patterns for more than six million women 18 to 44 years of age. Of the 2,355,790 women who were taking one or more long-term medications to treat a chronic disease, 146,758 (6%) were taking one classified as Category X and 26,136 were also taking an oral contraceptive. Nearly all of the Category X prescriptions (97%) were sedative-hypnotics, antineoplastics, retinoids, or statins. More than two-thirds of the women were receiving five or more medications during the study period.

About 40% of the women who received prescriptions for Category X agents and oral contraception had refill patterns suggesting suboptimal adherence to their birth control drugs—a percentage that was no better than that of the general population.

The greater the number of prescriptions, the less likely the women were to use the contraceptive. Adherence rates were highest among women taking statins and women whose contraceptive had been prescribed by a primary care provider. Women whose prescribers were obstetrician/gynecologists were about as adherent as the general population; those whose prescribers were dermatologists were the least adherent. Older, better-educated women were more adherent than single and lower-income patients.

As for why adherence rates might...
have been low, the Centers for Disease Control and Prevention found that only 20% of women correctly interpreted the teratogen warning symbol to mean that they should not become pregnant while taking the drug; however, it’s possible that women receiving Category X drugs were not advised about risks to the fetus. Research suggests that physicians do not routinely counsel patients who are taking certain agents about the need for contraception. In one study, 50% of women who filled a Category X drug prescription had no documentation of counseling.

The researchers suggest improving compliance by including electronic reminders for physicians at the time of prescribing and alerts for pharmacists when women are late in filling their oral contraceptive prescription.


**Heated Patches Reduce Pain**

In a pilot study of 88 patients, heating topical anesthesia patches helped lower pain intensity scores by 37%. The findings spurred a larger study of 250 healthy adults, with a similar reduction of 31%. The patches, which have an air-activated heating element, warm the skin and make it easier to deliver local anesthetics.

Researchers randomly assigned participants to eight groups, some receiving a heated patch and some receiving an unheated patch. The duration of application also varied (20 minutes vs. 30 minutes), as did catheter size (16 gauge, or 5 French vs. 18 gauge, or 3.8 French).

In the larger study, the aim was to test the impact of controlled heat on local dermal analgesia prior to vascular access. Using the pilot study findings, the researchers randomly assigned subjects to eight groups, some receiving an heated patch and some receiving an unheated patch. The duration of application also varied (20 minutes vs. 30 minutes), as did catheter size (16 gauge, or 5 French vs. 18 gauge, or 3.8 French).

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In the study, 140 of 195 older patients had positive results on the carbon-13 (13C)-urea breath test. The incidence of erosive or micro-erosive gastritis, duodenitis, and gastroduodenitis; gastric or duodenal ulcer; and reflux esophagitis was similar among subjects with and without dyspeptic symptoms. The symptoms were not linked to any specific organic pathology. Micro-erosive and peptic lesions were associated with both nonspecific symptoms and various combinations of symptoms. Symptoms were also variable and nonspecific in patients without any lesion at gastric endoscopic exploration.

It was not possible to formulate an accurate differential diagnosis between organic pathology and functional disorders of the upper gastrointestinal (GI) tract based only on symptoms in older patients. None of the patients with specific symptoms, with or without organic pathology, responded differently to *H. pylori*-eradicating treatment. Even the asymptomatic group had a high rate of organic pathology, similar to that of the symptomatic group. Thus, *H. pylori* positivity may indicate cellular damage even in the absence of clinical manifestations.

All patients who tested positive for *H. pylori* received 20 mg of omeprazole (Prilosec, AstraZeneca) twice daily, 500 mg of clarithromycin (Biaxin, Abbott) twice daily, and 1 g of amoxicillin (Amoxil, GlaxoSmithKline) twice daily for one week. After four weeks, the 13C-urea breath test was given again. In both the symptomatic and asymptomatic groups, *H. pylori* infection was eradicated in 88% of patients with minimal secondary effects. Seven patients withdrew from the study for nonmedical reasons.

These findings suggest that this well-tolerated treatment, with its high rate of *H. pylori* eradication, can be initiated promptly and safely in older patients, regardless of the endoscopic diagnosis.

Source: *Arch Gerontol Geriatr* 2010; 51:237–240

**MRSA Is More Prevalent In the U.S. Than in the U.K.**

Methicillin-resistant *Staphylococcus aureus* (MRSA) bacteria seem to be thriving to a greater extent in the U.S. than in the United Kingdom. Americans appear to be more than six times as likely as Britons to contract the infection in the community, but rates of hospital infections are about the same—even though MRSA was first discovered in the U.K.

Almost 29 per 100,000 people in the U.S. contract a MRSA bloodstream in-
**New Drugs**

**Antibiotics of Limited Benefit in Otitis Media**

The benefits of using antibiotics to treat newly diagnosed ear infections in children might not always outweigh the costs in adverse effects and dollars spent, suggests a new study.

Researchers from the Southern California Evidence-Based Practice Center examined published data about the diagnosis and treatment of acute ear infections among children. The American Academy of Pediatrics had requested the review as part of its effort to update practice guidelines on otitis media treatment.

Children in the U.S. receive antibiotics for acute ear infections more often than for any other illness, costing almost $2.8 billion dollars, or $350 per child, spent each year to treat the condition.

In the study, antibiotics offered a modest benefit in treating the infection, were somewhat more effective than no treatment, and worked quickly; however, they were also associated with an increased risk of side effects, such as rash and diarrhea, in 4% to 10% of the children.

No evidence was found that using newer, name-brand products to treat uncomplicated acute ear infections in normal-risk children offered an advantage over generic antibiotics, namely amoxicillin, even though higher-priced antibiotics are often prescribed for these infections.

The investigators concluded that a less aggressive approach to prescribing antibiotics, such as using amoxicillin, might lead to considerable cost savings.

Sources: *JAMA* 2010;304(19):2161–2169; Rand Corp., November 17, 2010, retrieved from ScienceDaily

**RESEARCH NEWS**

**A New Use for Forteo: Building Dental Bone**

A six-week treatment with teriparatide injections (Forteo, Eli Lilly), which stimulate bone remodeling, improved alveolar bone formation in patients undergoing periodontal surgery. The findings, from the University of Michigan, are important, as gum disease is the leading cause of tooth loss in adults.

Bone gain in the osseous defects of the 20 patients who received daily teriparatide was detectable early after treatment began and continued to improve during 12 months of follow-up. These patients also had better periodontal probing depth and attachment.

Teriparatide, a recombinant agent, contains the first 34 amino acids of parathyroid hormone (PTH), which stimulates the formation of pre-osteoblast cells, which form bone. Treated patients also experienced better resolution of periodontal bone defects at six, nine, and 12 months, compared with patients receiving placebo. Teriparatide is approved only for treating osteoporosis but scientists hope that it might also be used to grow bone around dental implants.


**Genetic Test For Heart Disease**

Some day a simple blood test may be able to detect clogged arteries. Until now, angiograms, usually performed in hospitals, have been used. Angiograms, however, involve radiation, are often inconclusive, and can cost more than $30,000.

The Corus CAD test (CardioDx) costs about $1,200, and it is covered by some insurers. Results take three days. The goal is to determine whether a patient has heart disease. The test does not look for heart disease but for signs of artery blockage.

Sources: P&T® Vol. 35 No. 12 ? December 2010 ? P&T® 661
for genes or mutations; it measures how active 23 key genes are. In one study comparing Corus CAD with the leading method, the test improved diagnoses for 16% more patients.

One drawback of the test is the high rate of false-positive and false-negative results. Physicians hope that as the test is perfected, it might enable them to order fewer angiograms as “defensive medicine.”


**Cancer Cells Can ‘Hide Out’ After Chemotherapy**

After chemotherapy, many patients experience remissions that can last for months or years. In some cases, however, tumors grow back and may be resistant to the drugs that had worked earlier.

In a study of mice with lymphoma, biologists at Massachusetts Institute of Technology (MIT) discovered that some cancer cells are not affected by chemotherapy; they can “hide out” in the thymus, where immune cells mature. In the thymus, these cancer cells are bathed in growth factors that protect them from the drugs’ effects. These cells are likely to be the source of relapse.

The researchers plan to test mice with drugs that interfere with one of these protective factors. These drugs were originally developed to treat arthritis.

For cancer therapy to succeed, a component that kills tumor cells as well as a component that blocks pro-survival signals must be present. Current therapies have not been able to target this survival response. In the new study, mice were given doxorubicin (Adriamycin). During treatment, cells that line the blood vessels release cytokines, small proteins that affect immune responses and cell development.

The researchers think that chemotherapy-induced DNA damage provokes these blood-vessel cells to launch a stress response that is normally intended to protect progenitor cells (immature cells that can evolve into different types of blood cells). That response includes the release of cytokines such as interleukin-6 (IL-6), which promotes cell survival.

It is unclear whether the results can be applied to humans. This protective effect was seen only in the thymus, but there might be other protected areas where tumor cells hide, such as bone marrow.

Sources: MIT, http://web.mit.edu; Cell, October 29, 2010

**Updates: Progress In Neurodegenerative Diseases Reducing Tau Protein Avoids ‘Traffic Jams’ in the Brain**

Amyloid beta proteins, which are thought to cause Alzheimer’s disease (AD), block the transport of vital cargoes inside brain cells. Scientists at the Gladstone Institute of Neurological Disease have discovered that reducing the level of tau protein can prevent amyloid beta from causing such “traffic jams.”

Suppressing tau can prevent amyloid beta from causing memory deficits and other abnormalities in mice. The scientists explored whether this rescue might be caused by improvements in axonal transport.

Neurons from normal mice or from mice lacking one or both tau genes were exposed to human amyloid beta, which slowed down axonal transport of mitochondria and growth factor receptors—but only in neurons that produced tau and not in neurons that lacked tau. In the absence of the amyloid beta challenge, reducing tau had no effect on axonal transport.

Tau reduction looks promising, but more work is needed before such an approach can be explored in humans.

Sources: Science Daily, September 9, 2010, retrieved October 15; Gladstone Institutes via EurekAlert!

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Diazoxide Improves Memory

A vasodilator that was used in the 1970s and 1980s to treat hypertension may improve learning in mouse models of AD. Diazoxide stabilizes nerve cells in the mouse brain and slows the development of the neurodegenerative disorder.

Researchers observed that diazoxide prevented a biological cascade in the mice that could cause the destruction of nerve cells. The drug also improved blood flow in the brain and prevented the harmful accumulation of beta-amyloid and tau proteins. Diazoxide is now used to treat patients with hypoglycemia.

The scientists studied two groups of mice with AD. The brain tissue of the treated group showed fewer amyloid and tau deposits, less damage resulting from oxidative stress, and better blood flow. Diazoxide activated and opened channels in the cell that enhanced potassium movement, thereby calming the electrical activity of nerve cells in parts of the brain involved in learning and memory. The drug also lowered the excessive calcium often found in nerve cells in brains affected by AD.

The dose of diazoxide is low enough to prevent a major decrease in blood pressure.

Sources: NIH and J Alz Dis, November 15, 2010

Actos May Help Slow Parkinson’s Disease

A medication that has been used for diabetes may be able to be used to treat patients with Parkinson’s disease (PD) and some inflammatory conditions. Pioglitazone (Actos, Eli Lilly) decreases inflammation associated with neurological diseases, and unlike steroids, it carries few side effects. It does not lower glucose levels if diabetes is not present.

Scientists now think that PD may stem from an “energy crisis” in the brain, years before symptoms appear, and that mal-

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functioning mitochondria play a role in degenerative brain disease. Ten sets of genes work at abnormally low levels in PD, and they are sluggish in people with presymptomatic PD. Each gene set is controlled by a master regulator gene named PGC_1 alpha. Pioglitazone is known to activate part of that PGC_1 alpha pathway.

If blocking a “brain energy drain” is to succeed, presymptomatic PD must be detected early in the process.

Sources: Translat Med 2010;2:52ra73; Nature online, October 6, 2010; Associated Press, November 2, 1010

DEVICE NEWS

New Uses for Defibrillators

Three cardiac resynchronization therapy defibrillators, made by Boston Scientific Corp., have new indications. The devices are used to treat left bundle branch block in patients who have either mild heart failure or heart failure with no apparent symptoms.

Implantable defibrillators sense arrhythmias and attempt to shock the heart back into a normal rhythm, enabling blood to be pumped more effectively. The devices are used with, but do not replace, drug therapy.

Source: FDA, September 16, 2010

NEW MEDICAL DEVICES

Marvin M. Goldenberg, PhD, RPh, MS

Name: Advanix Biliary Plastic Stents
FDA Approval Date: October 21, 2010
Purpose: The stent is used to treat biliary stone disease, benign biliary strictures, and suspected and confirmed malignancies in the biliary system. Endoscopic therapy, specifically with stent placement, has gained acceptance as a first-line therapy for biliary strictures and is less invasive than surgery.

Description: The stent accommodates variations in anatomy. The NaviFlex RX Delivery System offers physicians the flexibility of using both long and short guide wires during access and stent placement. The visible guide wire exit port allows for easier manipulation during the stenting procedure.

Benefit: In a study of patients with postoperative benign bile duct strictures, stenting was associated with long-term success rates and lower early complication rates. The design offers precise control for surgeons when they must navigate tight strictures in the bile ducts, and it facilitates stent placement and removal. The stent’s thin wall and increased inner diameter increase duct patency, resulting in improved outcomes.

Sources: www.medicalnewstoday.com/articles/205569.php; www.news-medical.net

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Name: Zerona Low-Level Body-Sculpting Laser  
Manufacturer: Erchonia Medical, Inc., McKinney, Tex.  
FDA Approval Date: September 9, 2010  
Purpose: This noninvasive aesthetic device is used to reduce the circumference of the patient’s waist, hips, and thighs.  
Description: An Erchonia laser scanner targets fat cells with cold energy, emulsifying adipose tissue. The tissue is then released into the interstitial space and passed naturally through the body. Treatment consists of 40-minute sessions three times per week. The laser is applied to the front and back of target areas on the waist, hips, or thighs. Because no heat is applied to cause discomfort, patients can resume normal activities immediately.  
Benefit: The FDA’s approval of the low-level laser was based on data from a placebo-controlled, randomized, double-blind, multicenter study of 67 patients. The cold laser decreased the total circumference of the waist, hips, and thighs by 3.64 inches in as little as two weeks, compared with 0.5 inch in patients receiving a placebo treatment. The trial set a precedent for evaluating aesthetic devices, because there were no dietary restrictions or exercise requirements. No equivalent device had previously been granted clearance by the FDA.  

Name: Talent Thoracic Stent Graft with Captivia Delivery System  
Manufacturer: Medtronic, Inc., Minneapolis, Minn.  
FDA Approval Date: November 3, 2010  
Purpose: Approximately 60,000 people in the U.S. have a thoracic aortic aneurysm (TAA), but only about 50% of these are diagnosed because patients have no symptoms. The Talent system is used to repair TAA’s, which can rupture and cause death if left untreated. The device is used in the endovascular repair of fusiform aneurysms, saccular aneurysms, and penetrating ulcers of the descending thoracic aorta in patients with the appropriate anatomy.  
Description: A tip-capture mechanism enables precise placement of the implantable stent graft. The device is inserted into the femoral artery in the patient’s groin and is moved up through blood vessels to the aorta. With the device at the site of the aneurysm, the physician expands the stent graft within the aorta, creating a new path for blood flow, reducing pressure on the bulge and decreasing the risk of rupture.  
Benefit: The clinician has excellent control of the device during deployment to ensure that blood flow isn’t occluded into the nearby arteries, and the surgery is minimally invasive.  
Sources: www.medtronic.com; www.ptca.org