



NEW DRUGS

Generic Wellbutrin XL (Bupropion) for Depression

The FDA has granted final approval of Impax Laboratories' Abbreviated New Drug Application for a generic version of GlaxoSmithKline's Wellbutrin XL 150 mg (bupropion extended-release tablets). An antidepressant, bupropion slows the absorption of dopamine and norepinephrine in the synapses between nerve cells.

Source: Impax, November 28, 2008

Tapentadol for Pain Relief

Tapentadol HCl, a centrally acting synthetic analgesic, has been approved to alleviate moderate-to-severe acute pain. This immediate-release oral tablet is available in strengths of 50 mg, 75 mg, and 100 mg.

Tapentadol acts as an opioid (narcotic) and as a non-opioid. The label warns about the risk of respiratory depression; addictive depressive effects on the central nervous system (CNS) when taken with alcohol and other opioids; and the potential for abuse.

Sources: FDA and Janssen-Ortho/PriCara, November 24, 2008

Extended-Cycle Oral Contraceptive (LoSeasonique)

The FDA has approved Duramed's New Drug Application for LoSeasonique (levonorgestrel/ethinyl estradiol tablets 0.10 mg/0.02 mg and ethinyl estradiol tablets 0.01 mg), the first lower-dose, extended-cycle oral contraceptive.

Women take the tablets for 84 consecutive days, then take 0.01 mg of ethinyl estradiol tablets for seven days. The number of withdrawal bleeding periods is reduced from 13 to four per year.

Source: Drugs.com, October 27, 2008

NEW INDICATIONS

Boostrix Vaccine for Adults

GlaxoSmithKline's Boostrix vaccine

has now been approved for adults 19 to 64 years of age. The product protects against tetanus, diphtheria, and pertussis (whooping cough). Boostrix was previously approved as a booster vaccine for preteens and teenagers.

The approval for adults was based on two clinical trials involving nearly 3,000 participants.

Sources: FDA and GlaxoSmithKline, December 8, 2008

DRUG NEWS

Boxed Warning For Colonoscopy Prep Products

Acute phosphate nephropathy, a type of acute kidney injury, has been associated with the use of oral sodium phosphate products for bowel cleansing preceding colonoscopies. The products include Visicol and OsmoPrep tablets (Salix) as well as over-the-counter laxatives (e.g., Fleet Phospho-soda). It is possible that some patients were dehydrated before they used the product or did not drink sufficient fluids as directed.

The kidney injury is associated with deposits of calcium-phosphate crystals in the renal tubules that can cause permanent renal impairment. The FDA is requiring Salix to add a boxed warning to the label, to implement a risk evaluation and mitigation strategy, and to provide a medication guide.

Source: FDA, December 15, 2008

Thrombosis Risk With Bevacizumab (Avastin)

Cancer patients who receive bevacizumab (Avastin, Genentech), an angiogenesis inhibitor, sometimes have a higher risk of venous thromboembolism (VTE). Anti-angiogenesis medications are widely used in cancer treatment.

Reviewing data from 7,956 patients with advanced solid tumors, researchers at the State University of New York at Stony Brook, found that those receiving

bevacizumab had an increased risk of both all-grade and high-grade VTE.

VTE is a major complication of cancer and an emerging problem with many angiogenesis inhibitors. Identifying the associated risks is a challenge because many randomized, controlled trials are not large enough to reveal the relationship. In this case, 15 studies were analyzed.

Source: *JAMA* 2008;300:2277-2285

Warnings: Suicide and Epilepsy Drugs

The FDA has ordered new warnings to be added to the prescribing information for drugs used to treat epilepsy, migraine, and some psychiatric disorders because of a potentially increased risk of suicidal thoughts and behaviors. A review of clinical studies revealed one additional case of suicidal thoughts or behaviors for every 500 patients who used an antiepileptic agent instead of a placebo.

The warnings are required to be added to these products: carbamazepine (Carbatrol, Equetro, Tegretol, Tegretol XR), clonazepam (Klonopin), clorazepate (Tranxene), divalproex (Depakote, Depakote ER, Depakene), ethosuximide (Zarontin), ethotoin (Peganone), felbamate (Felbatol), gabapentin (Neurontin), lamotrigine (Lamictal), lacosamide (Vimpat), levetiracetam (Keppra), mephenytoin (Mesantoin), methsuximide (Celontin), oxcarbazepine (Trileptal), phenytoin (Dilantin Suspension), pregabalin (Lyrica), primidone (Mysoline), tiagabine (Gabitril), topiramate (Topamax), trimethadione (Tridione), and zonisamide (Zonegran).

Drug manufacturers have also been instructed to include a medication guide for patients. The new warning also applies to older epilepsy medications that weren't included in the agency's review. This will not be a black-box warning.

The American Epilepsy Society said



that the analysis was flawed, and it was concerned that the warning would cause patients to stop therapy. It also said that the risk of suicide possibly associated with the drugs is very small.

Sources: FDA; *The Wall Street Journal*, and Bloomberg News, December 17, 2008

PML Risk with Efalizumab (Raptiva) for Psoriasis

Genentech, Inc., has issued a Dear Healthcare Provider letter to inform dermatologists and neurologists of a second case of progressive multifocal leukoencephalopathy (PML), which resulted in the death of a 73-year-old woman who had received efalizumab (Raptiva) for approximately four years to treat chronic plaque psoriasis.

PML, a rare, progressive, demyelinating disease of the central nervous system, usually leads to severe disability or death. PML is caused by activation of the John Cunningham (JC) virus.

In 2003, efalizumab was approved to treat chronic moderate-to-severe plaque psoriasis in adults 18 years of age or older who are candidates for systemic therapy or phototherapy. The prescribing information was updated in October 2008 to include a boxed warning on the risk of serious infections, including PML.

Source: Genentech, November 18, 2008; www.raptiva.com

Statins Protect Against Pneumonia Complications

In vitro studies have suggested that statins have anti-inflammatory properties. Now researchers at the Royal Infirmary of Edinburgh have shown that statins can help reduce the risk of complications and death from community-acquired pneumonia (CAP).

In the study of 1,007 patients with CAP, 30-day mortality was 9.6%. Ten percent of

patients required invasive ventilation or inotropic support, and 6% developed complicated parapneumonic effusion or empyema. Other cardiovascular drugs, such as aspirin, angiotensin-converting enzyme (ACE)-inhibitors, or angiotensin II receptor blockers (ARBs), did not show the same benefits. Moreover, the beneficial effects of statins were independent of the effects of those other cardiovascular drugs.

The researchers believe that their study provides powerful evidence that statins have an anti-inflammatory effect. They found reduced levels of C-reactive protein (CRP) in the study patients independent of pneumonia severity. Having found lower levels of CRP on admission, the researchers performed another analysis looking for any effect of statins on CRP levels at the fourth day. They hypothesized that statins might have ongoing anti-inflammatory properties that could improve outcomes if continued after admission. Statin use was protective against CRP levels that did not fall by 50% or more at the fourth day, a recognized marker of treatment failure and poor outcomes.

Their discovery that statins significantly reduced the incidence of complicated parapneumonic effusion and empyema is a first, as well as an interesting finding that calls for further study.

An unexpected finding was that beta blockers were associated with an increased need for mechanical ventilation or inotropic support; they also increased 30-day mortality. Experimental studies have suggested an important protective effect for endogenous catecholamines in sepsis, septic shock, and pneumonia, which are suppressed by beta blockers. Moreover, in an experimental model of pneumonia, infusion of propranolol, a beta blocker, induced more severe pulmonary inflammation.

Source: *Am J Med* 2008;121:1002-1007

Antibiotics for Pyelonephritis: How Long Is Long Enough?

Which is better—short-term or long-term antibiotics for acute pyelonephritis? Researchers from Greece and the U.S. say it might not matter. When they compared short-course antibiotic treatment (one to two weeks) with long-course treatment (two to six weeks) in four randomized, controlled trials, they found no significant differences between the therapies in terms of clinical success, bacteriologic efficacy, relapses, adverse events, or withdrawals from the study.

Guidelines from the Infectious Diseases Society of America recommend 10 to 14 days of treatment for women with acute pyelonephritis and a two-week course for uncomplicated urinary tract infection. All things being equal, shorter is probably better to help reduce the risk of antibiotic resistance.

Source: *Clin Ther* 2008;30:1859-1868

Clopidogrel (Plavix) After Coronary Bypass

Recent studies have touted the effectiveness of clopidogrel (Plavix, Bristol-Myers Squibb/Sanofi-Aventis) when used with aspirin, antithrombin therapy, and invasive procedures, for reducing death and ischemic complications in patients with acute coronary syndrome (ACS)—a benefit that appears early after therapy begins and persists into the extended follow-up period.

Despite the demonstrated effectiveness, many centers don't use clopidogrel because of concerns about coronary artery bypass graft (CABG) surgery-related bleeding or delays to surgery if CABG is indicated after a patient receives clopidogrel. However, those concerns might not be warranted, say researchers from Stanford and Duke Universities.

Of 4,794 CABG patients, 332 (7%) received clopidogrel for five days or less before CABG; 127 (3%) had reoperation

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for bleeding, 3,277 (68%) received red blood cell transfusions, and 4,387 (92%) had the composite outcome. After an adjustment, early clopidogrel use was not significantly associated with reoperation or with the composite endpoint. It was modestly associated with red blood cell transfusion, but more weakly than other factors, including which surgeon performed the procedure.

The upshot: the impact of withholding clopidogrel in patients with ACS and the impact of delaying CABG (especially by more than two days) to prevent bleeding complications should be viewed in the context of other, stronger determinants of bleeding.

Source: *Am Heart J* 2008;156:886–892

Missing the Target With Beta Blockers

Although national guidelines recommend that physicians make every effort to achieve the target doses of the beta blockers that are considered effective in major clinical trials, real-world evidence from a study of patients with heart failure (HF) reveals a substantial “titration gap.”

The Organized Program to Initiate Lifesaving Treatment in Hospitalized Patients with Heart Failure (OPTIMIZE-HF) enrolled 5,791 patients at 91 academic and community hospitals across the U.S. Of 2,373 patients with systolic HF eligible for beta blockers at discharge, 1,350 (57%) who were receiving beta blockers continued with that treatment, and 632 (27%) were newly started. Of the 1,537 patients who were using beta blockers before admission, 1,350 (88%) continued therapy.

The mean total daily dose before admission was less than half the recommended target dose, with infrequent up-titration or down-titration during the hospitalization. More than two-thirds of patients had no change in their beta

blocker doses in the first 60 to 90 days after discharge. At follow-up, only 18% taking carvedilol and 8% taking metoprolol succinate were receiving the recommended doses.

Source: *Am J Cardiol* 2008;102:1524–1529

New Guidelines For Congenital Heart Disease

Many children born with congenital heart disease can live well into adulthood, thanks to new surgical and medical treatments. To assist cardiologists in making clinical decisions for this challenging group of patients, the American College of Cardiology and the American Heart Association have released practice guidelines. Some of the guidelines address coordinating patient care, counseling, helping patients switch from a pediatric to an adult cardiologist, and educating patients about the risks of infection to the heart lining or heart valves posed by dental procedures, tattoos, piercings, or surgery.

The guidelines were developed by the American Society of Echocardiography, the Canadian Cardiovascular Society, the Heart Rhythm Society, the International Society for Adult Congenital Cardiac Disease, the Society for Cardiovascular Angiography and Interventions, and the Society of Thoracic Surgeons.

Sources: *J Am Coll Cardiol* 2008;52:e1–e121; *Circulation* 2008;118:e714–e833.

ADHD Drugs Not Linked To Genetic Damage in Children

In contrast to recent findings, two common medications used to treat attention-deficit/hyperactivity disorder (ADHD) do not appear to cause genetic damage in children who take them as prescribed.

Researchers at the National Institutes of Health (NIH) and Duke University Medical Center evaluated three meas-

ures of cytogenetic damage in the white blood cells of each child in the study, such as chromosome breaks, and found no changes after three months of continuous treatment. The study was funded through the Best Pharmaceuticals for Children Act.

The study included 63 children from 6 to 12 years of age who had not previously used stimulants. The children were divided into two groups and were treated either with methylphenidate HCl (Ritalin LA, Novartis; Concerta, McNeil) or with mixed amphetamine salts (Adderall and Adderall XR, Shire). The researchers found no significant differences between the two groups in age, sex, race, body weight, height, or ADHD subtype.

A previous paper had reported that methylphenidate induced chromosomal changes in children with ADHD, but the current study was not able to replicate those findings. The researchers emphasize that these results should not be interpreted as final proof of the long-term safety of stimulant drugs.

Sources: *J Am Acad Child Adolesc Psychiatry*, November 2008, online; www.nih.gov

Adenosine: Best Choice for Supraventricular Tachycardia?

For some patients, adenosine may be the optimal drug for treating paroxysmal supraventricular tachycardias, say researchers in Italy. A retrospective study of 454 patients found that 331 (73%) responded immediately to the 6-mg dose, 68 (15%) responded after the second 12-mg dose, and five patients (1%) responded to another 12-mg dose. The remaining 50 patients (11%) were unresponsive.

Adenosine has a half-life of less than one minute, and the time needed to reverse tachycardia ranges from seconds to a few minutes after the bolus is given. Adverse events are generally short-lived,



but they can be unpleasant. Some of the patients reported minor side effects, including chest tightness, flushing, shortness of breath, headache, and nausea, and some patients had a sense of impending death. A second dose of adenosine accelerated the ventricular rate in one woman, who had an undiagnosed atrial flutter.

Adenosine offers prompt efficacy, few major side effects or contraindications, and a high success rate. Verapamil (Calan, Pfizer), although less expensive, takes a longer time to reverse tachycardia, and is contraindicated in some emergency situations such as acute heart failure. Good patient selection and limiting the use of adenosine to patients with narrow QRS complex tachycardia should help in preventing major side effects.

Source: *Am J Emerg Med* 2008;26:879-882

Resuming Antiretroviral Therapy in HIV Infection

The multinational Strategies for Management of Anti-Retroviral Therapy (SMART) trial of 5,472 patients with HIV infection compared the episodic use of antiretroviral therapy, based on CD4+ cell counts, with the continuous use of antiretroviral therapy. The study clearly showed that episodic treatment raised the risk for opportunistic diseases, death, and serious non-opportunistic diseases.

Episodic treatment was discontinued in January 2006, and patients resumed antiretroviral therapy for another 18 months. Re-initiating antiretroviral therapy reduced the rate of opportunistic disease or death by 38% but did not eliminate the excess risk. During the follow-up period, the patients who had been receiving episodic treatment were three times as likely to have CD4+ cell counts below 0.350×10^9 cells/L and were twice as likely to have continuing HIV-RNA

levels above 400 copies/mL.

Although the researchers attributed the residual and ongoing excess risk for opportunistic disease or death to the lower CD4+ cell counts and the higher HIV-RNA levels, they noted that the follow-up period was too short to observe a full reversal of risk.

Source: *Ann Intern Med* 2008;149:289-299

High-Dose Atorvastatin (Lipitor): More Effective And Less Costly

High-dose atorvastatin (Lipitor, Pfizer) not only reduces cardiovascular events in patients with stable coronary artery disease but also does so enough to pay for almost all of its extra cost.

In a randomized study from Duke Clinical Research Institute in Durham, North Carolina, a regimen of atorvastatin at 80 mg/day decreased the risk of death from coronary artery disease, myocardial infarction, cardiac arrest, and stroke by 22% compared with 10 mg/day, and it cost only \$1 more per day.

During the five-year study, patients in the high-dose group had fewer cardiovascular hospitalizations and revascularization procedures and also spent fewer days in the hospital.

Source: *Am Heart J* 2008;156:698-705

Why Doesn't Donepezil (Aricept) Work Better?

In a year-long study of 168 elderly adults with memory problems but without dementia, 10 mg of donepezil (Aricept, Eisai/Pfizer) did not improve cognitive function in most patients with or without cognitive training.

Stanford University and Palo Alto Veterans Affairs researchers gave volunteers either 5 mg of donepezil or placebo daily for six weeks, then 10 mg/day for another six weeks, followed by two weeks of cognitive training. The 10-mg

dose was maintained for the rest of the year.

To determine whether the dosage was a factor in performance on memory tests, the researchers also assessed another cohort of 30 patients whose dosage was adjusted to 2.5, 5, or 7.5 mg. However, optimally adjusted dosages did not improve outcomes in this study or in the larger one. These findings were consistent with those indicating that the level of red blood cell acetylcholinesterase (AChE) inhibition with 5- and 10-mg dosages was virtually identical in the main study.

Physiological tolerance was also evaluated; AChE levels may increase with chronic treatment, reducing the potential for a long-term clinical benefit. The literature is not consistent, the investigators say, but tolerance might explain why AChE-inhibitors have shown short-term benefits that do not continue over time. The researchers also cite studies suggesting that around-the-clock dosing has adverse effects on sleep and other parameters that interfere with consolidation of memory. Those studies propose more frequent treatment with AChE-inhibitors with a short half-life instead of with donepezil, which has a long half-life.

The fact that there was no index of central cholinergic function, combined with the wide range of interindividual AChE inhibition, makes it challenging to determine the proper dosage of donepezil in patients without dementia. It is unlikely that a fixed dosage of an AChE inhibitor would work for everyone. Until those challenges are met, using donepezil to augment memory in patients without dementia is not warranted.

Source: *J Gerontology* 2008;63B(5):288-294

Too Much Heparin After Heart Attacks

Approximately 50% of patients with ST-segment elevation myocardial infarction



tion (STEMI) who are treated with heparin and fibrinolytic agents have received an excess dose of unfractionated heparin (UFH), according to researchers at Duke University and the University of Cincinnati.

Of 964 patients treated with fibrinolytic agents, 758 (79%) received adjunctive UFH therapy. Although practice guidelines recommend a maximum bolus dose of 4,000 units and a maximum infusion dose of 1,000 units/hour, 336 patients (44%) received excess bolus doses and 129 patients (17%) received excess infusion doses. Among those who received excess dosing, more than one-third (137 patients) were given bolus or infusion doses far above the recommended levels. An excess dose was defined as more than a 60-unit/kg bolus or more than a 12-unit/kg-per-hour infusion; major excess was defined as a bolus dose of more than 70 units/kg or an infusion of more than 15 units/kg per hour.

Women, older patients, and patients with low body weight were more likely to receive excess dosing.

Proper dosing of fibrinolytic and anti-thrombotic drugs is crucial for patients with STEMI because small deviations in the intensity of anticoagulation can influence bleeding complications and outcomes. Adherence to dosing guidelines is far from ideal.

These results are of concern because patients with STEMI—who are more likely to receive excess heparin dosing—are already at risk of bleeding. One factor might be the lack of weight-based dosing, as evidenced by the preponderance of patients who received the combination dose of a 5,000-unit bolus per 1,000-unit-per-hour infusion. However, more than one-third of patients did receive an excess dose based on body weight.

It was not clear whether the “one-dose-fits-all” approach was related to under-

recognition of STEMI dosing guidelines or was a response to the intense time pressure of rapid reperfusion, which might deter clinicians from taking time to consider a patient’s body weight.

Source: *Am J Med* 2008;121:805–810

Megestrol Acetate (Megace) And Adrenal Insufficiency

Malnourished older patients who are given megestrol acetate (Megace, Bristol-Myers Squibb) could be at risk for adrenal insufficiency, but it might be difficult to detect because the signs and symptoms are subtle.

In Kansas City, Missouri, an 80-year-old woman with dyspnea was being treated for major depression with psychotic features. Her physical functioning had declined, and because she was losing weight, megestrol acetate was prescribed to stimulate her appetite.

During hospitalization, however, her dyspnea worsened. She was transferred to the intensive-care unit, where she was intubated. Her blood pressure dropped. After infectious, cardiac, and neurological causes of hypotension were ruled out, a cosyntropin stimulation test, which was performed to exclude adrenal insufficiency, indicated a suboptimal response.

The medication was discontinued, and steroid replacement was initiated. Blood pressure returned to normal, and the patient slowly improved. She was weaned from the ventilator several weeks later. Two months later, her respiratory function improved, and cosyntropin stimulation test findings were normal.

Chronically ill, malnourished elderly patients with adrenal insufficiency may experience depression and reduced appetite, making the diagnosis difficult. In this case, adrenal insufficiency was not suspected at first because the presentation was unusual, the patient’s clinical history was complicated by other illnesses, and she had not been using

megestrol for a long time.

For patients who need more than 12 weeks of treatment with megestrol, free cortisol levels should be checked at 12 weeks and biweekly thereafter. The researchers recommend empirical therapy with stress doses of corticosteroids during periods of illness in patients receiving megestrol and tapering the drug gradually.

Source: *Am J Geriatr Pharmacother* 2008;6:167–172

Is Caffeine a Gateway Drug?

The abuse of caffeine might be a clue to the abuse of other pharmaceutical products.

In a retrospective review of all cases reported to the Chicago Poison Center between January 2002 and January 2004, the number of phone calls regarding caffeine had increased yearly. The trend may reflect the growing number of caffeine-enhanced products on the market; for instance, more than 500 energy drinks were launched worldwide in 2007. In one study, 31% of teenagers reported using energy drinks.

The researchers studied 254 patients ranging from 10 to 64 years of age. In most cases (79%), caffeine was abused in the form of a nondietary drug, a caffeine-enhanced beverage, or a dietary supplement. Thirty-two patients abused more than one form of caffeine, 64 patients abused caffeine for energy, and 12 patients used it to get high. Although 174 patients (68%) reported abusing only a caffeine product, 74 (29%) abused other pharmaceutical products as well; seven patients abused alcohol, and six patients were taking illegal drugs.

The abuse of supplemental caffeine (e.g., an energy drink), in combination with any other drug, increased the need for hospitalization. No patients died, but a 13% rise in hospitalization was associated with supplemental caffeine.



Although caffeine might not be harmful, patients should be asked how much caffeine they are using, especially because over-the-counter products containing caffeine are inexpensive and easily obtained. Other agents, such as antidepressants and sedative hypnotics, might also be legitimately prescribed.

Source: *Am J Emerg Med* 2008;26:799-802

The Best Reason to Quit Smoking: Longer Life

Patients who stop smoking after coronary artery bypass graft surgery gained three years of life, according to a 30-year study. Researchers in Rotterdam analyzed the clinical outcomes for 1,041 patients who underwent bypass surgery between 1971 and 1980. The study included 551 smokers, 43% of whom stopped smoking in the first year.

The study revealed a 38% reduction in mortality—a much better rate than that offered by secondary prevention therapies, such as the use of aspirin (a 15% reduction), statins (a 29% reduction), and angiotensin-converting enzyme inhibitors (a 23% reduction).

Source: *Am Heart J* 2008;156:473-476

Hiding Medications at Home

Health care providers do not always have a complete picture of medications that elderly patients are taking, say researchers from West Virginia and Georgia. In a retrospective study, nearly 70% of 121 patients who were admitted to an internal medicine service had one or more unspecified drugs in the admission note. Medications were considered unspecified if an indicated disease state or condition for the drug was not reported.

Patients with unspecified medications were taking more home medications (10.2 vs. 7.5 drugs for patients without unspecified medications); some were receiving proton pump inhibitors or hista-

mine type-2 antagonists without a clear indication, and others were receiving selective serotonin reuptake inhibitors without a clear indication. The investigators advocated a rigorous program to re-evaluate the need for continuing medications at hospital admission and at discharge to home.

Source: *Am J Geriatr Pharmacother* 2008;6:161-166

Combining Hormones May Raise Heart Risk

Women who take hormone replacement therapy (HRT) might not have a higher risk of heart attacks if they avoid daily doses of both estrogen and progesterone. In a Danish study of almost 700,000 patients, those who took progesterone only periodically or who used topical drugs had a lower chance of heart attacks. Women who took daily tablets that combined the two hormones, such as Prempro (Wyeth), had a higher heart risk.

These findings may allow women and their doctors to tailor treatment of menopause to avoid dangerous side effects. HRT has been available since the 1950s and was widely prescribed until 2002. Preliminary results from the Women's Health Initiative showed an increased risk of breast cancer, stroke, and heart attacks. The FDA recommends that HRT for menopausal symptoms be taken at the smallest dose and for the shortest time possible.

Wyeth claimed that the Danish study findings were based on products and doses used in Denmark and that it was difficult to determine whether the product, dose, or route of administration was responsible for the result. The Danish study did not include data on weight, body fat distribution, alcohol intake, physical activity, or smoking.

Doctors sometimes prescribe estrogen to combat menopausal symptoms

along with progesterone to avoid uterine cancer, which may result from taking estrogen alone. In the Danish study, women who did not take HRT were 8% more likely to have heart attacks than those who took estrogen regularly and progesterone periodically and were 20% more likely to have an attack than those who used estrogen creams, gels, and patches. Earlier research from France had shown that estrogen patches posed no additional risk of blood clots forming in veins.

Sources: *Eur Heart J* and Bloomberg News, October 1, 2008

DEVICE APPROVALS

Keeping Warm or Cool With RapidBlue

Cardium Therapeutics and its operating unit, InnerCool Therapies, Inc., have received approval to market the RapidBlue System, which automatically cools or warms patients to achieve and maintain a desired body temperature.

Source: Cardium, October 20, 2008, www.cardiumthx.com

Lung Valve Repairs Air Leaks

An implantable and removable valve system is now approved to control pulmonary air leaks that occur after some lung operations. Although most air leaks heal themselves, leaks that persist for seven days after surgery make breathing difficult and can prolong hospital stays. The IBV Valve System (Spiration, Inc.) was approved under the Humanitarian Device Exemption program. Patients who cannot tolerate bronchoscopy should not be treated with the device.

Source: FDA, October 27, 2008

NEW MEDICAL DEVICES

Marvin M. Goldenberg, PhD, RPh, MS

Name: Align 360 Total Knee System
Manufacturer: Cardo Medical, Los Angeles, Calif.



Approval Date: November 5, 2008

Use Classification: The system is the flagship product within the Align 360 platform, which includes unicompartmental and patello-femoral systems.

Description: With this advanced knee platform, the femoral component features a funnel-shaped patella track that accommodates the quadriceps angle anatomy for both men and women, thus saving inventory costs for operating rooms.

Purpose: Unicompartmental, bi-compartmental, and tricompartmental arthritis can be treated surgically.

Benefit: Surgeons are able to treat the various stages of a degenerative knee using a minimally invasive approach. Anteromedial overhang of the femoral component, a cause of postoperative knee pain, is reduced.

Source: www.cardomedical.com

Name: Curois Port Protector

Manufacturer: Ivera Medical Corporation, San Diego, Calif.

Approval Date: November 13, 2008

Use Classification: The Corus Port Protector is used to decontaminate needle-less intravenous (IV) access ports and to prevent contamination resulting from physical contact and airborne sources. The device reduces the bacterial count of two selected gram-positive bacteria and two selected gram-negative bacteria.

Description: This nonsterile device contains 70% isopropyl alcohol and is used to decontaminate needle-less Luer-activated valves. When left in place for 5 to 15 minutes, the port protector decontaminates the injection port and provides a physical barrier during its intended use.

Purpose: In view of the increasing incidence and associated costs of hospital-acquired bloodstream infections, the device should help decrease patient

exposure to infectious bacteria.

Benefit: Bloodstream infections acquired in hospitals dramatically increase the patient's length of stay, potential mortality, and overall cost of care—more than \$5 billion every year in the U.S. alone. At a time when health care systems are reducing payments for treating bloodstream infections, it is hoped that this device will change infection control practices and improve patient care.

Sources: www.pharmacyonesource.com; www.fda.gov; www.ivteam.com

Name: Apex PTCA Dilatation Catheter

Manufacturer: Boston Scientific Corp., Natick, Mass.

Approval Date: November 10, 2008

Use Classification: The Apex high-performance pre-dilatation balloon catheter enables physicians to treat challenging atherosclerotic lesions.

Description: The device is sold with both Monorail and Over-The-Wire catheter platforms. An inner shaft improves pushability and flexibility. A redesigned tip provides excellent turning and wire tracking.

The catheter is available in various balloon diameters ranging from 1.5 mm to 5 mm. Balloon lengths range from 8 mm to 40 mm. Both catheters come in two 1.5-mm designs: the Apex Push Catheter enhances pushability for tight lesions, and the Apex Flex Catheter enhances trackability for tortuous arteries.

Purpose. Percutaneous transluminal coronary angioplasty (PTCA) is used to treat coronary artery disease, and the catheter is used to open arteries blocked by atherosclerosis.

Benefit: Complex lesions can be dilated with this advanced technology.

Sources: www.pharmacyonesource.com; www.bostonscientific.com

Devices in the News

Faulty lead. Thoratec Corporation has

notified health care professionals of a correction of the HeartMate II Left Ventricular Assist System of all serial numbers (Catalogue No. 1355 or 102139) distributed since November 2003. Over time, wear and fatigue of the percutaneous lead connecting the blood pump with the system controller may cause damage that could interrupt pump function, potentially causing serious injury or death.

Source: FDA, October 28, 2008

Recalls

Field generator. The FDA has issued a class I recall of the Vibrational Integrated Bio-photonic Energizer Machine Multi-Frequency Field Generator (Vibe Technologies). The FDA has not approved this device. The company has not submitted any evidence to the FDA to support claims that the product can treat or cure cancer, depression, infection, or pain. The device should not be used, and it should be returned to Vibe.

Source: FDA, October 1, 2008

Battery caps. Animas battery caps, used with the OneTouch Ping System, the 2020 Insulin Pump, the IR1200 Insulin Pump, and the IR1250 Insulin Pump, have been recalled. The caps were manufactured from June 1, 2008, through July 31, 2008, and were distributed from June 16, 2008 through August 1, 2008.

The caps were recalled because of a possible intermittent loss of contact between the battery cap and the battery compartment in the pump, causing the device to reset. This failure can prevent the appropriate administration of insulin, which can cause an excess of glucose in the blood. Patients can become confused about the amount of insulin administered, and this can contribute to errors in future doses, resulting in suboptimal levels of blood glucose.

Source: FDA, November 11, 2008 ■