**NEW DRUGS**

**Brintellix for Major Depression**

Vortioxetine tablets (Brintellix, Takeda/Lundbeck) have been approved in strengths of 5, 10, 15, and 20 mg to treat adults with major depressive disorder (MDD). As a serotonin modulator and stimulator, vortioxetine enhances levels of the neurotransmitters serotonin, norepinephrine, dopamine, acetylcholine, and histamine in specific areas of the brain.

The medication received FDA approval without deliberation by a science advisory panel. In six studies, vortioxetine was effective in treating depression; in another study, it decreased the likelihood of recurrent depression after treatment of an MDD episode.

A boxed warning cites a risk of suicidal thoughts and behavior in children, adolescents, and young adults 18 to 24 years of age during initial treatment. A medication guide is included for patients.

Vortioxetine is discussed in the Pharmaceutical Approval Update column on page 705.

Sources: FDA and Takeda/Lundbeck, October 1, 2013; Los Angeles Times, September 30, 2013

**Duavee for Hot Flashes**

Duavee (Wyeth/Pfizer/Ligand) has been approved to treat moderate-to-severe hot flashes related to menopause in women who have not had a hysterectomy. The drug, which contains conjugated estrogens and bazedoxifene, is also approved to prevent postmenopausal osteoporosis. This is the first product that combines estrogen with an estrogen agonist/antagonist (bazedoxifene), which reduces the risk of endometrial hyperplasia, a condition that can occur with the estrogen component of Duavee. Bazedoxifene is a third-generation selective estrogen receptor modulator (SERM).

Duavee was approved with the same boxed warning and other warnings that apply to other estrogen products. The drug should be used for the shortest duration possible.

Sources: FDA, Pfizer, and Fierce-Pharma, October 3, 2013

**NovoEight for Hemophilia A**

A Biologics License Application (BLA) has been approved for recombinant coagulation factor VIII, turoctocog alfa (NovoEight, Novo Nordisk), for adults and children with hemophilia A. The product is used to control and prevent bleeding. It will be launched in the U.S. with the new prefilled device, MixPro, shortly after April 2015.

Source: Pharma e-Track, October 16, 2013

**Clinolipid Emulsion For Parenteral Nutrition**

The FDA has approved a lipid injectable emulsion (Clinolipid, Baxter) for intravenous (IV) feeding in adults. Clinolipid provides a source of calories and essential fatty acids for patients who are unable to eat or drink.

The emulsion contains a mixture of refined olive oil and refined soybean oil. The ratio of omega-3 to omega-6 fatty acids in the product was not shown to improve clinical outcomes compared with other lipid emulsion products.

Like other IV lipid emulsions, this product should be prescribed with caution in patients with pre-existing liver disease or liver insufficiency. Clinolipid should not be used in patients with a known hypersensitivity to eggs or soybean proteins or in patients with severe hyperlipidemia.

A warning in the label mentions a risk of death in preterm infants after infusion of IV lipid emulsions. Clinolipid is also not indicated for other pediatric patients, because it is not known whether the amount of essential fatty acids found in the product is enough to meet the nutritional needs of children.

Clinolipid was granted a priority review to help alleviate a drug shortage.

Source: FDA, October 3, 2013

**Two Drugs For Pulmonary Hypertension**

**Adempas**

Riociguat (Adempas, Bayer Healthcare) is used to treat adults with pulmonary arterial hypertension (PAH) of unknown causes and chronic thromboembolic pulmonary hypertension (PH).

PH is a chronic, progressive, debilitating disease, often leading to death or the need for lung transplantation.

Riociguat belongs to a class of drugs called soluble guanylate cyclase stimulators, which help the arteries relax to increase blood flow.

A boxed warning mentions that riociguat should not be used in pregnant women because it can harm the developing fetus. Female patients may receive the drug only through a restricted program, and they must comply with pregnancy testing requirements and be counseled regarding the need for contraception.

Prescribers must be certified by enrolling in the program. Pharmacies may dispense this drug only to patients who are eligible to receive it.

The FDA evaluated riociguat under its priority review program and granted an orphan drug designation.

Source: FDA, October 8, 2013

**Opsumit**

Actelion’s macitentan (Opsumit) has also been approved for adults with PAH.

In patients with PAH, the right side of the heart must work harder than normal, which can lead to limitations on exercise ability and shortness of breath.

Macitentan is an endothelin receptor blocker, which relaxes the pulmonary arteries, decreasing blood pressure in the lungs. The drug’s safety and effectiveness were established in a long-term clini-
cal trial in which 742 participants were randomly assigned to take macitentan or placebo. The average treatment duration was about two years. In the study, macitentan was effective in delaying disease progression, a finding that included a decline in exercise ability, worsening symptoms of PAH or the need for additional PAH medication.

As with riociguat, macitentan carries a boxed warning alerting patients and health care professionals that the drug should not be used during pregnancy because of potential harm to the fetus. Macitentan is also subject to a restricted distribution program.

Common adverse drug effects have included anemia, nasopharyngitis, sore throat, bronchitis, headache, flu, and urinary tract infection.

Source: FDA, October 18, 2103

**Generic Approvals**

**ER Niacin for Lipid Disorders**

Teva Pharmaceutical Industries has announced the launch of niacin extended-release (ER) tablets in strengths of 500, 700, and 1,000 mg in the U.S. The product is the generic equivalent of AbbVie’s Niaspan.

Niacin ER is used with diet to reduce levels of total cholesterol, low-density lipoprotein-cholesterol, apolipoprotein B, and triglycerides. It is also used to raise levels of high-density lipoprotein-cholesterol in patients with primary hyperlipidemia and mixed dyslipidemia.

Source: Pharma e-Track, September 20, 2013

**Azacitidine**

**For Myelodysplastic Syndromes**

Dr. Reddy’s azacitidine for injection is now approved at a dose of 100 mg per vial. As the bioequivalent generic version of Vidaza (Celgene), azacitidine is a nucleoside metabolic inhibitor. It is indicated for patients with French–American–British subtypes of myelodysplastic syndrome, which encompasses various forms of anemia and chronic myelomonocytic leukemia.

Source: Dr. Reddy’s Laboratories, September 17, 2013

**Adenosine Injection, a Vasodilator**

Teva’s generic equivalent to Astellas Pharma’s Adenoscan (adenosine injection) has been launched in the U.S. Supplied as 20-mL and 30-mL vials, adenosine is indicated as an adjunct to thallium-201 myocardial perfusion scintigraphy in patients who cannot exercise adequately.

Source: Teva, September 24, 2013

**Voriconazole, an Antifungal Agent**

Mylan Pharmaceuticals, Inc., has launched voriconazole for oral suspension, 40 mg/mL. This is the first generic version of Pfizer’s Vfend oral suspension. Voriconazole is a triazole antifungal drug.

Source: Mylan, September 30, 2013

**Paricalcitol for Hyperparathyroidism**

A generic equivalent of AbbVie’s Zemplar (paricalcitol) tablets has been launched by Teva in the U.S. The capsules are an active form of vitamin D and are used to prevent and treat secondary hyperparathyroidism in patients with chronic kidney failure. The drug blocks the formation and release of parathyroid hormone.

Paricalcitol is not indicated for patients with evidence of hypercalcemia or vitamin D toxicity. Chronic hypercalcemia can result in generalized vascular and soft-tissue calcification. Aluminum-containing preparations (e.g., antacids, phosphate binders) should not be administered chronically with paricalcitol. As a Pregnancy Category C product, paricalcitol should be used during pregnancy only if the potential benefits to the mother justify the potential risks to the fetus.

Source: Teva, October 1, 2013

**TOBI in Cystic Fibrosis**

Teva has announced the approval of the generic equivalent to TOBI (Novartis), tobramycin inhalation solution USP, in the U.S. This inhaled antibiotic is used to treat lung infections in patients with cystic fibrosis.

Sources: Teva and Philadelphia Business Journal, October 14, 2013

**NEW INDICATIONS**

**Perjeta and Breast Cancer**

Pertuzumab (Perjeta, Roche), a biologic product, is the first neoadjuvant therapy approved for patients with HER-2–positive, locally advanced, inflammatory or early-stage breast cancer at risk for metastasis. It may be used in combination with trastuzumab (Herceptin, Genentech) and other chemotherapy before surgery. After surgery, patients would continue taking trastuzumab for 1 year and may receive chemotherapy after surgery, depending on the regimen used.

Pertuzumab was approved in 2012 in combination with trastuzumab and docetaxel (Taxotere, Sanofi) for women with HER-2–positive metastatic breast cancer who had not previously received anti-HER-2 therapy or chemotherapy.

Source: FDA, September 30, 2013

**Stelara for Psoriatic Arthritis**

Janssen Biotech, Inc., has announced the approval of ustekinumab injection (Stelara) alone or with methotrexate for the treatment of adults 18 years of age or older with active psoriatic arthritis (PsA). This chronic autoimmune disease is characterized by joint inflammation and psoriatic skin lesions. The FDA’s approval was supported by findings from two pivotal phase 3 trials, PSUMMIT I and II. More details are provided on page 705 in the
Pharmaceutical Approval Update column.
Source: Johnson & Johnson, September 23, 2013

Cimzia for Psoriatic Arthritis And Ankylosing Spondylitis

UCB’s certolizumab pegol injection (Cimzia) has received two new indications, one for adults with PsA and one for ankylosing spondylitis. Certolizumab is a humanized, pegylated tumor necrosis factor-α inhibitor.

In the U.S., certolizumab was approved for the treatment of moderate-to-severe rheumatoid arthritis in 2009. The drug was originally approved in 2008 for reducing the signs and symptoms of Crohn’s disease. In October, the FDA announced the additional indication of certolizumab for active ankylosing spondylitis.

Sources: UCB, September 30, 2013; FDA, October 18, 2013

NEW FORMULATION
Lower-Dose Diclofenac for Pain

Iroko Pharmaceuticals, LLC, has announced the FDA’s approval of a lower dosage strength of diclofenac capsules (Zorvolex). Diclofenac is a nonsteroidal anti-inflammatory drug (NSAID) indicated for the treatment of mild-to-moderate acute pain in adults.

The new dosage strengths are 20% lower than those of currently available diclofenac products. The FDA’s approval of the new formulation was supported by data from a phase 3 multicenter, randomized study in which patients reported significant pain relief with diclofenac compared with patients receiving placebo.

The new formulation was developed to address the FDA’s public health advisory recommending that NSAIDs be used at the lowest effective dose for the shortest duration of time consistent with individual patient treatment goals. The risk of serious adverse events, including cardiovascular thrombotic events, myocardial infarction, stroke, gastrointestinal (GI) ulcers, GI bleeding, and renal events (e.g., acute renal failure) associated with NSAIDs is higher among patients receiving higher doses.

The company altered the absorption properties of diclofenac using SoluMatrix fine-particle technology. The medication contains diclofenac as submicron particles that are approximately 20 times smaller than their original size. The reduction in particle size provides an increased surface area, leading to faster dissolution.

The dosage is 18 mg or 35 mg orally three times a day. The capsules are not interchangeable with other formulations of oral diclofenac even if the milligram strength is the same.

A boxed warning mentions the possibility of cardiovascular and GI risks.
Source: Iroko, October 21, 2013

DRUG NEWS
Warning Updates

Risk of Death Added for Tygacil

Tigecycline (Tygacil, Pfizer) should be used only when other treatments are not suitable, according to the FDA, which is requiring a boxed warning to be added to the drug’s label. This intravenous (IV) tetracycline antibiotic is approved for patients with complicated skin and skin-structure infections and community-acquired bacterial pneumonia.

Tigecycline was approved in the U.S. in 2005. In 2010, tigecycline was associated with a greater risk of death when compared with other antibacterial drugs. In the more recent analysis, there was a higher risk of death with tigecycline compared with other antibacterial drugs—2.5% vs. 1.8%, respectively. The risk was greatest in patients with ventilator-associated pneumonia, and tigecycline is not approved for that condition.

Sources: Reuters and MedicalXpress, September 27, 2013

Rituxan and Arzerra

The prescribing information for the immune-suppressing and anticancer drugs ofatumumab (Arzerra, Glaxo-SmithKline) and rituximab (Rituxan, Genentech) is being revised, and new boxed information is being updated regarding a risk of reactivation of hepatitis B virus (HBV) infection.

These two monoclonal antibodies are used to treat chronic lymphocytic leukemia (CLL) in patients with disease progression after receiving fludarabine phosphate (Fludara, Bayer/Berlex) and alemtuzumab (Campath, Bayer/Berlex). Rituximab is also used to treat non-Hodgkin’s lymphoma, rheumatoid arthritis, vasculitis, and other inflammatory conditions.
Source: FDA, September 25, 2013

Biweekly Hizentra

An every-2-week dose has been approved for CSL Behring’s Hizentra 20% subcutaneous, a liquid immune globulin product intended for patients with primary immunodeficiency. The biweekly option enables patients to self-administer treatment less frequently and offers the same level of protection as weekly infusions. Originally approved in 2010, the product is ready to use and can be stored at room temperature.

Source: CSL Behring, September 27, 2013

Statins: Pro and Con

Statins May Help Inflamed Gums

In addition to lowering LDL-cholesterol, a high dose of atorvastatin (Lipitor, Pfizer) may alleviate periodontal disease. In a small randomized study reported from Massachusetts General Hospital, 80 mg of atorvastatin resulted in a greater reduction in periodontal inflammation compared with a 10-mg dose after 12 weeks accompanied by beneficial changes in inflammation in the carotid artery.
Periodontal disease has been associated with atherosclerosis in previous studies, although the American Heart Association last year cast doubt on whether the disease caused heart problems. A possible mechanism underlying the association between gum disease and atherosclerosis may be systemic inflammation stemming from periodontal disease. Statins have been shown to protect against systemic inflammation.

Sources: J Am Coll Cardiol, September 2013; MedPage Today, October 3, 2013

Statins May Raise Risk of Cataracts

It has been suggested that the antioxidant effects of statins might slow the natural aging process of the ocular lens. Yet in some cases, the cholesterol-lowering drugs were protective; in other cases, they increased the risk of cataracts.

In a new observational study, cataracts were about 27% more likely to develop in people who took statins than in those who did not take them. The researchers said that cataract development might be influenced by the effects of the drugs on the oxidation process.

The cholesterol-inhibiting properties of statins might also interfere with cell regeneration in the eye’s lens, which requires cholesterol to maintain transparency. Nevertheless, the authors suggested that the benefits of statins outweighed the risk of cataracts in patients who already have heart disease. However, they recommended that statins be prescribed with caution for use in the primary prevention of cardiovascular disease.

Sources: JAMA Ophthalmology (online); The New York Times, September 25, 2013

Clearer Labeling For Fentanyl Patches

The FDA is requiring color changes to the print on fentanyl transdermal pain patches so that the labels can be seen more easily. This step is part of an effort to prevent accidental exposure to the patches, which can cause serious harm and death in children, pets, and others.

Janssen, as well as manufacturers of generic fentanyl patches, is being required to print the name and strength of the drug on the patch in long-lasting ink and in a color that is clearly visible to patients and caregivers. The current ink color is not always highly visible.

Even after patches have been used, they still contain high amounts of strong narcotic pain medicine and must be properly disposed of after use. Patches that do not stick to the patient’s skin tightly enough may accidentally fall off and stick to someone in close proximity. Patients should make sure that the patch is always sticking to the skin properly.

Sources: FDA, September 24, 2013; Reuters, September 23, 2013

Drug Shortages Persist: Egrifta for Lipodystrophy

In September, EMD Serono, a subsidiary of Merck, notified the FDA to expect a shortage of tesamorelin injection (Egrifta) in the U.S. that could begin in mid-October, with a complete lack of stock by mid-November. This human growth hormone-releasing factor analogue is used to treat HIV-infected adults with lipodystrophy.

Earlier this year, production of tesamorelin was halted to correct problems related to the consistency of the lyophilization cycle. Corrective measures were implemented, and production was resumed in May 2013. However, problems in product quality ensued, and it was decided that more developmental work was needed.

Sources: Pharma e-Track, September 18, 2013; MedLine Plus

Doxil in Cancer Treatment

Problems at a Ben Venue Laboratories unit warned doctors to expect further shortages of its cancer drug, Doxil, for which Boehringer Ingelheim’s Ben Venue is the sole supplier.

Janssen suggested that physicians could try its competitor, Sun Pharma, which is producing an FDA-approved generic version of the drug.

Manufacturing and sterility problems forced Ben Venue to suspend operations in November 2011. FDA Commissioner Margaret Hamburg turned to Sun Pharma to temporarily import Lipodox, a Doxil substitute that the FDA had not approved. Earlier this year, the FDA approved a version from Sun Pharma to help ease the shortage.

Janssen advised physicians that no new patients should start treatment with Doxil until a continuous supply of the drug could be confirmed and stated that if a patient was using conventional doxorubicin HCl, Doxil should not be substituted on a milligram-per-milligram basis with that drug. Accidental substitution of Doxil for doxorubicin HCl has resulted in severe adverse effects.

To complicate matters, Ben Venue said it planned to end all operations starting in October, eliminating 1,100 jobs, thereby exacerbating the shortages. In June, Ben Venue had announced that it was curbing production but would still keep 800 employees.

Sources: Janssen, September 25, 2013 (letter); FiercePharma and Fierce PharmaManufacturing, September 26, 2013; The Wall Street Journal, October 3, 2013

Orphan Drug Designations: LUM001 for Liver Diseases

LUM001 (Lumena Pharmaceuticals) is being tested for the treatment of four rare cholestatic liver diseases: Alagille syndrome, progressive familial intrahepatic cholestasis, primary biliary cirrhosis, and...
primary sclerosing cholangitis. These diseases result in the impaired flow of bile acids and the retention of these acids in the liver, leading to liver damage that can cause liver failure. LUM001 inhibits the apical sodium-dependent bile acid transporter, which recycles intestinal bile acids back into the circulation.

Source: Lumena, September 26, 2013

OMS824 for Huntington’s Disease

Omeros Corporation’s phosphodiesterase 10 (PDE_{10}) inhibitor, OMS824, is used in the treatment of Huntington’s disease. OMS824 inhibits PDE_{10}, an enzyme expressed in areas of the brain and linked to various diseases that affect cognition.

In a phase 1 study, the drug was well tolerated in healthy subjects and appeared to have a better safety factor than other PDE_{10} inhibitors in development.

The only other approved treatment is tetrabenazine (Xenazine, Valeant/Lundbeck), which is indicated for movement disorders related to Huntington’s disease.

Source: Omeros, September 30, 2013

CPI-613 for Myelodysplastic Syndrome

CPI-613 is Cornerstone’s drug candidate for the treatment of myelodysplastic syndrome (MDS), a form of cancer resulting from damaged blood-forming cells in the bone marrow. In about one-third of MDS cases, the disease progresses to acute myeloid leukemia (AML).

The company recently launched a phase 2 MDS clinical trial and previously received an orphan drug designation for CPI-613 for the treatment of AML and pancreatic carcinoma.

Source: Pharma e-Track, October 3, 2013

Fast-Track Status For ALKS 5461 In Depression

The FDA has granted fast-track status to ALKS 5461, made by Alkermes, for the adjunctive treatment of major depressive disorder (MDD) in patients with an inadequate response to standard therapies.

ALKS 5461’s mechanism of action is based on the use of a balanced combination of agonism and antagonism of opioid receptors. The product consists of buprenorphine, a partial agonist, and ALKS 33, a potent mu-opioid antagonist.

The drug is designed to be non-addictive. Early clinical development of ALKS 5461 was funded through a grant from the National Institute on Drug Abuse.

Source: Alkermes, October 10, 2013

Benefits of Intravenous Iron Therapy

Adverse outcomes associated with allogeneic red blood cell (RBC) blood transfusions and oral iron have focused attention on intravenous (IV) iron therapy. The earlier risk of anaphylaxis with IV iron has been reduced, but little was known about the theoretical risk of infection.

Researchers from Australia suggest that IV iron may have broad benefits in hospitalized patients with anemia and may be able to reduce the need for allogeneic RBC transfusions.

The team conducted a meta-analysis of 75 studies involving 10,879 participants to evaluate the safety and effectiveness of IV iron. Patients receiving IV iron therapy experienced a significant increase in mean hemoglobin levels, compared with those receiving oral iron or no iron supplementation. IV iron was also associated with a reduced need for allogeneic RBCs, thereby also decreasing the risk of serious adverse events, including death.

The researchers found no significant difference in mortality rates or in adverse events with the use of IV iron and oral iron or no iron. In the 32 studies that included reporting on anaphylaxis, eight patients of 2,186 receiving IV iron experienced anaphylaxis.

These findings are in keeping with recent advances in the understanding of iron metabolism, the researchers say. IV iron is more effective than oral iron, particularly in acute or chronic inflammation, as a result of bypassing the effects of hepcidin, a liver hormone that inhibits gastrointestinal iron absorption.

IV iron was associated with a higher risk of all-cause infection. No interactions were found between baseline ferritin, transferrin saturation, iron per dose, or erythroid-stimulating agents and the risk of infection. The researchers say that infection was not a predefined endpoint in many pooled studies, and it is possible that missing data could have created unmeasured bias in their analysis.

Although free iron potentiates bacterial growth in vitro, clinical evidence regarding a link between IV iron therapy and infection has been inconclusive. Until randomized controlled trials are adequately powered for patient-centered outcomes, the researchers conclude, it might be preferable to use IV iron preparations with relatively low free iron concentrations.

Source: BMJ 2013;347:f4822

NEW MEDICAL DEVICES

Marvin M. Goldenberg, PhD, RPh, MS

Name: Crosstrees Pod System for Percutaneous Vertebral Augmentation (PVA)

Manufacturer: Crosstrees Medical, Inc., Boulder, Colo.

Approval Date: September 19, 2013

Purpose: The Crosstrees Pod technology was designed to address the need for improved devices for vertebral fracture repair. The device provides surgeons with a percutaneous means of delivering bone cement to patients with painful pathological compression fractures of the vertebral body.

Description: Compression (spinal) fractures can result from osteoporosis or trauma; the vertebrae weaken and collapse, causing severe pain. They usually occur in the middle and lower sections of...
the spine and can lead to loss of height, postural deformity, and pulmonary complications such as pulmonary embolism and nerve root compression.

Previously, surgeons could treat vertebral compression fractures only by vertebroplasty (the direct injection of liquid bone cement into the fractured vertebral body) and by kyphoplasty (a balloon is used to create a cavity in the vertebral body before the cement is injected). In both procedures, the bone cement hardens, providing stabilization and pain relief.

The Crosstrees method provides physicians with excellent control of cement placement. A soft woven fabric pod allows the physician to control the flow of bone cement as it is injected into the vertebral body. This reduces the risk of complications caused by the leakage of the polymethyl methacrylate (PMMA).

**Benefit:** This approach reduces new vertebral fractures after treatment by 23% to 48%. The pod eliminates the balloon-inflation step and reduces the need for repeated device exchanges. Improved PMMA control also helps to decrease complications of leakage.

**Precautions:** Because the bone cement is injected directly into the vertebral body, vertebroplasty and kyphoplasty carry a risk that the bone might leak from the vertebral body before it hardens. Cement leaks can result in neurological complications, emboli, or death.

Risks may include fracture of a spinal pedical, the sternum, or the rib; injury to vertebral body endplates, veins, arteries, or spinal nerve tissue; recurrent disk herniation; spinal fluid leak; and the need for re-operation.

**Sources:** www.crosstreesmedical.com; www.pharmalive.com

**Name:** Complete SE (Self-Expanding) Vascular Stent

**Manufacturer:** Medtronic, Inc., Minneapolis, Minn.

**Approval Date:** September 24, 2013

**Purpose:** The stent is used in the lower extremities, namely in the superficial femoral artery and proximal popliteal artery, which carry blood through the upper legs.

**Description:** A dual-deployment handle and a triaxial catheter enable physicians to place the stent with accuracy while minimizing unexpected stent jumping (migration).

**Benefit:** In a clinical study, more than 90% of study subjects did not require any follow-up procedures after 1 year. The SE stent demonstrated the smallest amount of repeated interventions in the superficial femoral artery compared with studies of competitor devices. There were no stent fractures at 12 months.

**Source:** www.peripheral.medtronicendovascular.com

**Name:** MiniMed 530G System Plus Enlite Sensor

**Manufacturer:** Medtronic, Inc., Minneapolis, Minn.

**Approval Date:** September 27, 2013

**Purpose:** This “artificial pancreas” mimics the human pancreas and was approved for diabetic patients 16 years of age and older. This is the first system approved under a new product classification, “OZO: Artificial Pancreas Device System, Threshold Suspend,” created by the FDA.

**Description:** Insulin delivery is automatically stopped if glucose levels reach a certain level, between 60 and 90 mg/dL. If the patient is sleeping or unconscious, or unable to react, the system suspends delivery for 2 hours. Delivery can be resumed at any time.

The pump is worn externally and communicates wirelessly with the glucose monitor to deliver the optimal amount of insulin. The device helps to alleviate a fear among diabetic patients that their glucose levels might drop precipitously while they sleep, possibly leading to a coma.

**Benefit:** This device stops delivery of insulin if the patient is not responding to the Threshold Suspend alarm. The continuous glucose sensor can detect up to 93% of hypoglycemia episodes when the alerts are turned on. It is 69% smaller than the previous-generation Medtronic sensor and is easier to insert with a hidden introducer needle. It can be worn for 6 days.

The FDA is requiring Medtronic to conduct patient follow-up evaluations. The company plans to conduct a post-approval study that will enroll children 2 years of age and older.

**Sources:** www.fiercemedicaldevices.com; www.medtronicdiabetes.com; www.startribune.com/business/225601262.html

**Device Recall**

**Microbiology Testing Panels**

In August, Siemens recalled more than 78,000 units of its MicroScan microbiology testing panels over concerns that the devices are reporting false results. The FDA has labeled this recall as Class I.

The devices are used to determine antimicrobial susceptibility or identification for gram-negative bacteria. False-susceptible and false-intermediate results were being reported for imipenem (e.g., Primaxin) and meropenem (e.g., Merrem) when the MicroScan WalkAway System was used. This defect may lead to treatment with an inappropriate antibiotic or may cause a delay in starting therapy. The following panels were affected:

- Urine Combo 1: 10444745/B1025-106
- Combo 2: 10444747/B1025-108
- Breakpoint Combo 7: 10444748/B1025-109
- Urine Combo 2: 10444749/B1025-112
- Urine Combo 5: 10483101/B1025-115

**Sources:** www.fda.gov; www.reuters.com, September 4, 2013