Dalvance for Skin Infections

The FDA has approved dalbavancin (Dalvance, Durata Therapeutics) to treat adults’ acute bacterial skin and skin-structure infections (ABSSSIs) caused by certain susceptible bacteria, such as Staphylococcus aureus (including methicillin-susceptible and methicillin-resistant strains) and Streptococcus pyogenes.

Administered intravenously, Dalvance is the first drug designated as a qualified infectious disease product (QIDP) to receive FDA approval. As part of its QIDP designation, Dalvance received an expedited review and extended marketing exclusivity.

The safety and efficacy of dalbavancin were evaluated in two phase 3 clinical trials involving 1,289 adults with ABSSSI. Participants were randomly assigned to receive two weeks of treatment with either dalbavancin (1,000 mg followed one week later by 500 mg) or vancomycin (1,000 mg or 15 mg/kg every 12 hours, with the option to switch to oral linezolid after three days).

Based on clinical response rate, dalbavancin was as effective as vancomycin in treating ABSSSI. Responders were defined as patients who had no increase from baseline in lesion area 48 hours after the initiation of therapy and a temperature consistently at or below 37.6 degrees Celsius. The clinical response rates for dalbavancin versus vancomycin/linezolid, respectively, were 83.3% and 81.8% in the first trial and 76.8% and 78.3% in the second trial.

The most common side effects seen in the studies were nausea, headache, and diarrhea. More participants in the dalbavancin group had elevations in liver enzyme tests. The Dalvance drug label recommends dosage adjustments in patients with renal impairment.

Sources: FDA, May 23, 2014; Dalvance prescribing information

Eloctate for Hemophilia A

Antihemophilic factor (recombinant), Fc fusion protein (Elocate, Biogen Idec) has received FDA approval for adults and children with hemophilia A.

Elocate is designed to require less frequent injections to prevent or reduce the frequency of bleeding. It is approved to help control and prevent bleeding episodes, to manage bleeding during surgery, and to prevent or reduce the frequency of bleeding episodes. It consists of the coagulation factor VIII molecule linked to a protein fragment, Fc, that is found in antibodies. This makes the product last longer in patients’ blood.

The recommended starting prophylactic regimen is 50 IU/kg every four days; based on the patient’s clinical response, this can be adjusted in the range of 25 to 65 IU/kg every three to five days.

FDA approval was based on results from the global phase 3 A-LONG trial and interim data from the phase 3 Kids A-LONG study.

The open-label A-LONG trial involving 165 previously treated males 12 years of age and older with severe hemophilia A evaluated individualized and weekly prophylaxis to reduce or prevent bleeding episodes as well as on-demand dosing to treat bleeding episodes. Statistically significant reductions of bleeding episodes were reported in both prophylaxis arms compared with on-demand treatment; 98% of bleeding episodes were controlled with one or two infusions of Elocate. The median projected numbers of bleeding episodes per year were 1.6 for individualized prophylaxis, 3.6 for weekly prophylaxis, and 33.6 on demand.

Interim safety and pharmacokinetic results in 38 boys ages 2 to 11 years in the Kids A-LONG study showed Elocate was generally well tolerated. In children 2 to 5 years old, hemophilic factors have a shorter half-life and higher clearance (adjusted for body weight) than adults and adolescents, so these children may need higher or more frequent doses.

Sources: FDA and Biogen Idec, June 6, 2014

Jublia for Onychomyasis

The FDA has approved efinaconazole 10% topical solution (Jublia, Valeant Pharmaceuticals International/Kaken Pharmaceutical), the first topical triazole antifungal agent indicated for the treatment of distal lateral subungual onychomycosis (onychomycosis of the toenails).

The topical solution is applied daily to the affected nail using a bottle that has a built-in brush applicator. There is no risk of systemic side effects.

Positive results from two 52-week pivotal clinical trials involving 1,655 subjects supported FDA approval. In one study, 17.8% of subjects treated with efinaconazole topical solution were completely cured, compared with 3.3% of subjects treated with vehicle. In the other study, 15.2% of subjects treated with efinaconazole were completely cured, compared with 5.5% of subjects treated with vehicle. A complete cure required that the nail show no clinical involvement and no evidence of fungus by both potassium hydroxide testing and a negative fungal culture.

Adverse events were generally mild and transient. The most common were application-site dermatitis and application-site vesicles.

Source: Valeant Pharmaceuticals, June 9, 2014

Omidria for Eye Surgery

The FDA has approved phenylephrine and ketorolac injection, 1.0%/0.3% (Omidria, Omeros Corporation) for use during cataract surgery or intraocular lens replacement (ILR) to maintain pupil size by preventing intraoperative miosis and to reduce postoperative pain.

Omidria is a proprietary combination of a mydriatic agent (phenylephrine) and...
an anti-inflammatory agent (ketorolac) that is added to irrigation solution customarily used during cataract surgery and other ILR procedures. Collectively, these are the most common surgical procedures performed in the U.S. at nearly four million annually.

In pivotal clinical trials, all patients received standard pupil-dilating and anesthetic agents before surgery. Omidria demonstrated a statistically significant improvement in the prevention of miosis and the reduction of postoperative pain compared with placebo. Ocular adverse events were similar between the Omidria and placebo groups and included eye irritation, posterior capsule opacification, increased intraocular pressure, and anterior chamber inflammation.

A previously agreed-upon postmarketing study of Omidria in pediatric patients, if successfully completed, will make the drug eligible for an additional six months of U.S. marketing exclusivity.

Source: Omeros Corporation, June 2, 2014

**Generic Approvals**

**Celecoxib**

Two companies have FDA permission to sell generic celecoxib, but court settlements and lawsuits may dictate when those generics hit the market.

Teva Pharmaceutical Industries has received FDA approval to market celecoxib capsules in 50-, 100-, 200-, and 400-mg strengths, and has 180-day exclusivity on all but the 50-mg products. Mylan Pharmaceuticals has FDA approval to market 50-mg celecoxib capsules.

Under a settlement of patent litigation with Pfizer, Teva can launch U.S. generic versions of Pfizer’s Celebrex by December 2014 “or earlier under certain circumstances.” A Teva spokesman declined to provide a launch date or detail those circumstances.

Mylan, which has a settlement and license agreement with Pfizer on all four dosage strengths, says it will start sales “at the earliest market formation,” but “not later than December 2014.” Mylan is suing the FDA to challenge Teva’s exclusivity but lost a bid for an injunction in U.S. District Court.

U.S. sales of Celebrex were $2.2 billion in 2013, according to IMS Health. The nonsteroidal anti-inflammatory drug (NSAID) is approved to treat rheumatoid arthritis, osteoarthritis, acute pain, and other conditions. Like all NSAIDs, celecoxib has a boxed warning about the risks of heart attack, stroke, and gastrointestinal bleeding, all potentially life-threatening.

Sources: FDA and Teva Pharmaceutical Industries, May 30, 2014; Mylan, June 2, 2014

**Hydromorphone Hydrochloride**

Actavis’ hydromorphone hydrochloride extended-release tablets have received FDA approval in 8-, 12-, and 16-mg dosages—the first generic version of Mallinckrodt’s Exalgo extended-release tablets.

Exalgo is an opioid agonist indicated for management of moderate-to-severe pain in opioid-tolerant patients who require continuous, around-the-clock opioid analgesia for an extended period of time. Hydromorphone is a Schedule II controlled substance. A boxed warning notes the potential risks of fatal respiratory depression and overdose.

Sources: FDA, May 12, 2014; Exalgo prescribing information

**Risedronate Sodium**

The FDA has approved applications by Actavis, Mylan, and Sun Pharma Global to produce the first generic versions of 75-mg and 150-mg risedronate sodium tablets. Actavis now offers Actonel, the brand version of this osteoporosis medication. Teva Pharmaceuticals has produced generic 5-mg, 30-mg, and 35-mg tablets since 2007.

Sources: FDA, June 12, 2014; Actonel prescribing information

**NEW INDICATIONS**

**Vectibix Plus FOLFOX For Colorectal Cancer**

Panitumumab (Vectibix, Amgen) has received FDA approval for use in combination with FOLFOX, an oxaliplatin-based chemotherapy regimen, as first-line treatment in patients with wild-type KRAS (exon 2) metastatic colorectal cancer (mCRC).

Panitumumab is the first biologic agent to offer a survival benefit as first-line treatment with FOLFOX, one of the most common first-line chemotherapy regimens for patients with wild-type KRAS mCRC. The approval also converts the FDA’s accelerated monotherapy approval for the risks of heart attack, stroke, and gastrointestinal bleeding.

Sources: FDA, May 27, 2014; Pennsaid prescribing information

**Budesonide Nasal Spray**

The FDA has approved Apotex’s budesonide nasal spray 32 mcg/inhalation, the first generic version of AstraZeneca’s Rhinocort Aqua 32 mcg/inhalation. Budesonide is an anti-inflammatory synthetic corticosteroid indicated for the management of nasal symptoms of seasonal or perennial allergic rhinitis in adults and children 6 years of age and older.

Sources: FDA, May 12, 2014; Rhinocort Aqua prescribing information
to a full approval for panitumumab. In addition, the agency has approved Qiagen’s therascreen KRAS RGQ PCR kit as a companion diagnostic for panitumumab.

The FDA’s approval was based on results from the phase 3 PRIME and ASPECTT trials. PRIME showed that results from the phase 3 PRIME and ASPECTT demonstrated noninferiority in progression-free survival with panitumumab and FOLFOX compared with FOLFOX alone (9.6 months vs. 8.0 months, respectively; \( P = 0.02 \)) and a significant 4.4-month improvement in overall survival compared with FOLFOX alone (23.8 months vs. 19.4 months, respectively).

ASPECTT demonstrated noninferiority for improving overall survival in patients treated with panitumumab compared with those treated with cetuximab (Erbilux, Bristol-Myers Squibb/Eli Lilly) as a single agent for the treatment of mCRC in patients with wild-type KRAS tumors who responded to chemotherapy.

Panitumumab was approved in the U.S. in September 2006 as monotherapy for patients with epidermal growth factor receptor–expressing mCRC whose disease progressed after treatment with irinotecan-containing chemotherapy. The product labeling for Vectibix includes a boxed warning regarding the potential for dermatological toxicities. Such toxicities occurred in 90% of patients and were severe in 15% of patients receiving Vectibix monotherapy.

Determination of the KRAS mutational status in colorectal tumors using an FDA-approved test is necessary in selecting patients for treatment with Vectibix.

Source: Amgen, May 23, 2014

Azilect Indicated for Use With More Parkinson’s Treatments

The FDA has expanded the indication for rasagiline tablets (Azilect, Teva Pharmaceutical Industries) from monotherapy and adjunct to levodopa to include adjunct to dopamine agonists (DAs).

The approval was supported by data from the 18-week, double-blind, placebo-controlled, randomized ANDANTE (Add ON to Dopamine AgoNists in the TrEatment of Parkinson’s Disease) trial. Patients receiving suboptimal DA monotherapy were randomly assigned to receive add-on treatment with rasagiline (n = 163) or placebo (n = 165). Adding rasagiline 1 mg/day provided a statistically significant improvement (treatment effect –2.4 \( P = 0.012 \)) in the total Unified Parkinson’s Disease Rating Scale score from baseline to week 18.

As a monoamine oxidase B (MAO-B) inhibitor, rasagiline acts by increasing available synaptic dopamine. This mechanism of action provided the rationale for add-on therapy to DAs in the management of Parkinson’s disease.

Sources: Teva Pharmaceutical Industries, June 9, 2014, and March 20, 2013

Aloxi for Nausea, Vomiting in Children During Chemotherapy

The FDA has approved palonosetron HCl injection (Aloxi, Eisai Inc./Helsinn) for the prevention of acute nausea and vomiting associated with initial and repeat courses of emetogenic cancer chemotherapy, including highly emetogenic cancer chemotherapy, in children ages 1 month to less than 17 years.

This is the first approval of a product for prevention of acute chemotherapy-induced nausea and vomiting (CINV) in patients ages 1 month to 6 months. Peak cancer incidence among children occurs within the first year of life. In clinical trials, CINV has been seen in 35% to 80% of pediatric cancer patients.

The approval was based on a randomized, double-blind, noninferiority pivotal trial comparing single-dose intravenous (IV) palonosetron 20 mcg/kg given 30 minutes prior to chemotherapy to a standard-of-care IV ondansetron regimen of 0.15 mg/kg given 30 minutes prior to chemotherapy followed by infusions four and eight hours after the first dose of ondansetron.

Within the first 24 hours after chemotherapy, complete response (defined as no vomiting, retching, or antiemesis rescue medication) was achieved in 59.4% of patients who received palonosetron versus 58.6% of those who received ondansetron. Treatment-emergent adverse events were comparable, with headaches being the most frequently reported in the palonosetron group.

Source: Eisai Inc., May 28, 2014

NEW FORMULATIONS

Bunavail for Opioid Dependence

The FDA has approved buprenorphine and naloxone buccal film (CIII) (Bunavail, BioDelivery Sciences International) for maintenance treatment of opioid dependence as part of a complete treatment plan that includes counseling and psychosocial support.

Bunavail was designed using drug-delivery technology that can potentially overcome some of the administration challenges presented by sublingual dosage forms of buprenorphine.

According to the product’s developer, Bunavail offers twice the bioavailability of buprenorphine compared with buprenorphine and naloxone sublingual film (Suboxone, Reckitt Benckiser). As a result, plasma concentrations of buprenorphine comparable with those of Suboxone can be achieved with half the dose. The ability of Bunavail to stick to the inside of the cheek allows patients to go about daily activities while the buprenorphine and naloxone are absorbed.

Bunavail was assessed in a 12-week phase 3 study of 249 patients that demonstrated favorable safety and efficacy in the maintenance treatment of opioid
dependence, as shown by a high retention rate and a low frequency of patients with positive urine tests for nonprescribed opioids over the study period. Prior to switching from Suboxone to Bunavail, about 40% of patients were experiencing constipation. More than two-thirds of these individuals reported the resolution of symptoms after switching from Suboxone to Bunavail.

Source: BioDelivery Sciences International, June 9, 2014

Natesto for Low Testosterone

The FDA has approved testosterone nasal gel (Natesto, Trimel Pharmaceuticals Corporation) as replacement therapy for conditions associated with a deficiency or absence of endogenous testosterone in men. Such conditions include primary hypogonadism (congenital or acquired) and hypogonadotropic hypogonadism (congenital or acquired).

Natesto is self-administered via a metered-dose nasal applicator, minimizing the risk of secondary exposure of women or children. It was evaluated in a multicenter, open-label, 90-day phase 3 trial. In an evaluation at day 90 of 73 hypogonadal men who had been treated with 33 mg of testosterone daily, 90% had an average serum testosterone level over the 24-hour sampling period within the normal range (300 to 1,050 ng/dL), 10% were below normal, and none exceeded 1,050 ng/dL.

The most common adverse reactions in clinical trials were an increase in prostate-specific antigen, headache, rhinorrhea, epistaxis, nasal discomfort, nasopharyngitis, bronchitis, upper respiratory tract infection, sinusitis, and nasal scab.

Source: Trimel Pharmaceuticals Corporation, May 28, 2014

Nascobal Single-Use Nasal Spray

The FDA has approved a new single-use delivery system for the prescription vitamin B₁₂ nasal spray cyanocobalamin (Nascobal, Strativa Pharmaceuticals) that delivers 500 mcg in once-weekly doses. An existing multi-use glass bottle with actuator pump requires priming.

Nascobal is indicated for the maintenance of normal hematological status in pernicious anemia patients who are in remission following intramuscular vitamin B₁₂ therapy and who have no nervous system involvement. It is also indicated as a supplement for other vitamin B₁₂ deficiencies.

Source: Strativa Pharmaceuticals, June 10, 2014

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Source: Strativa Pharmaceuticals, June 10, 2014

Elotuzumab for Multiple Myeloma

The FDA has granted “breakthrough therapy” designation to elotuzumab (Bristol-Myers Squibb/AbbVie), an investigational humanized monoclonal antibody, for use in combination with lenalidomide and dexamethasone for the treatment of multiple myeloma in patients who have received one or more prior therapies.

The FDA’s decision was based on findings from a randomized, phase 2, open-label study that evaluated two dose levels of elotuzumab—including the 10-mg/kg dose that is being studied in phase 3 trials—in combination with lenalidomide and low-dose dexamethasone in previously treated patients.

In the phase 2 study, patients with relapsed or refractory multiple myeloma were randomly assigned to receive elotuzumab 10 or 20 mg/kg (intravenous infusion on days 1, 8, 15, and 22 of a 28-day cycle in the first two cycles and then days 1 and 15 of subsequent cycles) in combination with oral lenalidomide 25 mg daily on days 1 to 21 and oral dexamethasone 40 mg weekly. The patients were treated until disease progression or unacceptable toxicity occurred.

In 36 patients treated with elotuzumab 10 mg/kg, median progression-free survival (PFS) was 33 months after a median follow-up of 20.8 months, and the objective response rate (ORR) was 92%. The median PFS was 18 months in the 20-mg/kg arm (n = 37) after a median follow-up of 17.1 months, and the ORR was 76%. The most common grade 3 or 4 adverse events were lymphopenia, neutropenia, thrombocytopenia, anemia, continued on page 470

Drug News

‘Breakthrough Therapy’ Designations

CO-1686 for NSCLC

The FDA has granted “breakthrough therapy” designation to the investigational agent CO-1686 (Clovis Oncology) as monotherapy for the treatment of second-line epidermal growth factor receptor (EGFR)–mutant non–small-cell lung cancer (NSCLC) in patients with the T790M mutation.

CO-1686 is an oral, targeted covalent (irreversible) inhibitor of the cancer-causing mutant forms of EGFR. The compound was designed to target selectively both the initial activating EGFR mutations and the T790M resistance mutation while sparing wild-type (normal) EGFR at anticipated therapeutic doses. CO-1686 may have the potential to treat NSCLC patients with EGFR mutations as both a first- and second-line therapy with a reduced toxicity profile compared with current EGFR inhibitors.

The FDA’s decision was based on interim efficacy and safety results from the ongoing phase 1/2 TIGER2 study. Investigators observed an objective response rate in 14 (64%) of 22 evaluable T790M-positive patients. CO-1686 was well tolerated, with one patient discontinuing treatment because of adverse events. There was no evidence of systemic wild-type EGFR inhibition. Subjects are being enrolled in two phase 2 expansion cohorts of the TIGER2 study in EGFR-mutant patients with the T790M mutation.

Source: Clovis Oncology, May 20, 2014

continued on page 470
leukopenia, hyperglycemia, pneumonia, diarrhea, fatigue, and hypokalemia.

Source: Bristol-Myers Squibb, May 19, 2014

Nivolumab for Hodgkin Lymphoma

The FDA has granted a “breakthrough therapy” designation to the investigational programmed-death-1 (PD-1) immune checkpoint inhibitor nivolumab (Bristol-Myers Squibb) for the treatment of Hodgkin lymphoma (HL) after the failure of treatment with autologous stem-cell transplant and brentuximab (Adcetris, Seattle Genetics).

The designation is based on data from HL patients in an ongoing phase 1b study of patients with relapsed and refractory hematological malignancies.

Nivolumab binds to the checkpoint receptor PD-1 expressed on activated T-cells. Research is under way to determine whether, by blocking this pathway, nivolumab would enable the immune system to resume its ability to recognize, attack, and destroy cancer cells.

Source: Bristol-Myers Squibb, May 14, 2014

Orphan Drug Designations

Imatinib for Progressive Multifocal Leuкоencephalopathy

Inhibikase Therapeutics has received FDA orphan drug designation for imatinib to treat progressive multifocal leukoencephalopathy (PML), a rare side effect of small-molecule and antibody drugs given to patients with autoimmune diseases.

Certain drugs used to treat autoimmune diseases suppress patients’ ability to fight infection, particularly for a virus known as JC (for John Cunningham virus). JC lives inside most people, but when the immune system is suppressed, JC occasionally migrates to the brain, where it can cause a debilitating, often fatal loss of cognitive and motor neuron function.

Imatinib, the active ingredient in Inhibikase’s product IkT-001Pro, is a host-directed protein kinase inhibitor that disrupts the JC virus’ ability to reproduce in the patient. IkT-001Pro delivers imatinib to its targets using a proprietary technology that should reduce the dose and side effects while enhancing imatinib’s ability to suppress the virus.

Source: Inhibikase Therapeutics, May 21, 2014

ADXS-cHER2 for Osteosarcoma

Advaxis has received FDA orphan drug designation for ADXS-cHER2 for the treatment of osteosarcoma.

ADXS-cHER2 is an immunotherapy under investigation for targeting the HER2 receptor. Based on strong preclinical and canine osteosarcoma clinical data, Advaxis plans to initiate a clinical development program with ADXS-cHER2 in pediatric patients with osteosarcoma. Pediatric osteosarcoma affects about 400 U.S. children and teens every year.

Source: Advaxis, May 27, 2014

DCCR for Prader-Willi Syndrome

Diazoxide choline (DCCR, Essentialis) has received FDA orphan drug designation for treatment of Prader-Willi syndrome, a complex neurobehavioral/metabolic disease that afflicts about one in 15,000 to 25,000 people.

DCCR is also in development for the treatment of hypothalamic obesity. Essentialis has evaluated DCCR in more than 200 subjects in double-blind, placebo-controlled studies and is recruiting patients for another recently initiated study.

Source: Essentialis, May 28, 2014

EPI-743 for Leigh Syndrome

The FDA has granted Edison Pharmaceuticals’ EPI-743 (vatiquinone) orphan drug status for Leigh syndrome, an inherited, lethal, progressive, predominately pediatric neuromuscular disorder.

A phase 2B randomized, double-blind, placebo-controlled trial in children with Leigh syndrome is fully enrolled in the U.S., and a phase 2B/3 trial is being conducted in conjunction with Dainippon Sumitomo Pharma Co., Ltd, in Japan. Leigh syndrome is the most common pediatric inherited mitochondrial disease.

Source: Edison Pharmaceuticals, June 9, 2014

Humira for Noninfectious Uveitis

The FDA has granted adalimumab (Humira, AbbVie) orphan drug designation for the treatment of noninfectious intermediate, posterior, or pan-uveitis, or chronic noninfectious anterior uveitis, a group of rare but serious inflammatory eye diseases. AbbVie’s development of Humira for the treatment of noninfectious uveitis is in phase 3.

Source: AbbVie, May 20, 2014

Epidiolex on Fast Track For Dravet Syndrome

The FDA has awarded fast track designation to an investigational cannabidiol product (Epidiolex, GW Pharmaceuticals) for the treatment of Dravet syndrome, a rare, catastrophic, treatment-resistant form of childhood epilepsy.

Epidiolex has already received FDA orphan drug designation. GW is on track to start a phase 2/3 clinical trial for Dravet syndrome in the second half of this year, and also plans to conduct a clinical development program for Epidiolex for the treatment of Lennox-Gastaut syndrome.

Source: GW Pharmaceuticals, June 6, 2014

Pradaxa Cuts Stroke, Death Risk Compared With Warfarin

Among new users of blood-thinning drugs, dabigatran (Pradaxa, Boehringer Ingelheim) is associated with a lower risk of ischemic strokes, bleeding in the brain, and death than warfarin, a new FDA study.
shows. The study also found an increased risk of major gastrointestinal bleeding with use of dabigatran compared with warfarin. The myocardial infarction risk was similar for the two drugs.

The study included information from more than 134,000 Medicare patients 65 years of age or older. The new study is based on a much larger and older patient population than that used in the FDA’s earlier review of postmarket data and employed a more sophisticated analytical method to capture and analyze the events of concern.

As a result of these latest findings, the FDA still considers dabigatran to have a favorable benefit-to-risk profile. The FDA made no changes to the current label or recommendations for use. Both drugs are used to reduce the risk of stroke and blood clots in patients with nonvalvular atrial fibrillation.

Source: FDA, May 13, 2014

**FDA Reduces Starting Dose Of Sleep Drug Lunesta**

The FDA is requiring that the label of the sleep drug eszopiclone (Lunesta, Sunovion Pharmaceuticals) be changed to lower the recommended starting dose. The agency says data show that eszopiclone levels in some patients may be high enough the morning after use to impair activities that require alertness, including driving—even if patients feel wide awake.

Taken at bedtime, the recommended starting dose of eszopiclone has been halved—from 2 mg to 1 mg. The 1-mg dose can be increased to 2 mg or 3 mg if needed, but the higher doses are more likely to result in next-day impairment of driving and other activities that require full alertness. Using lower doses means a smaller amount of the drug will remain in the body in the morning, the FDA says.

The dose change is based partly on findings from a study of 91 healthy adults ages 25 to 40 years. In the study, Lunesta 3 mg (compared with placebo) was associated with severe psychomotor and memory impairment in both men and women 7.5 hours after taking the drug. The study found that recommended doses could impair driving skills, memory, and coordination for as long as 11 hours after the drug was taken. Patients were often unaware that they were impaired.

The FDA approved changes to the Lunesta prescribing information and the patient medication guide to include these new recommendations. The drug labels for generic eszopiclone products must also be updated to include these changes.

Source: FDA, May 15, 2014

**The Cost of Catching Lung Cancer Early**

If Medicare implements new lung cancer screening recommendations for annual low-dose computed tomography (CT) scans of high-risk patients, a lot of lives could be saved—but the price tag could be high, a report suggests.

Researchers projected that about 55,000 more lung cancer cases, many of them early-stage disease, would be detected over a five-year period. But implementing the new U.S. Preventive Services Task Force guidelines could result in a cost increase of $9.3 billion over that period, researchers predicted.

The task force recommended annual low-dose CT screening in healthy people ages 55 to 80 years who have a history of smoking a pack of cigarettes a day for 30 or more years. A large study showed that this strategy might reduce deaths from lung cancer by 20%.

Currently, 57% of lung cancer patients are diagnosed at an advanced stage of disease, when the five-year survival rate is 4%. In contrast, a patient who is diagnosed with localized cancer has a five-year survival rate of 54%.

The task force’s guidelines will be implemented by insurers participating in the Patient Protection and Affordable Care Act. But Medicare hasn’t yet signed on.

If it does, according to the study from the Fred Hutchinson Cancer Research Center, the proportion of cancers diagnosed at an early stage would rise from 15% to 33%. But over five years, about $5.6 billion more would be spent for low-dose imaging, $1.1 billion for diagnostic workups, and $2.6 billion more for cancer care.

Source: Fred Hutchinson Cancer Research Center, May 14, 2014

**Counseling Could Aid Overweight Adults**

Overweight and obese adults who have at least one risk factor for cardiovascular disease should be offered or referred to behavioral counseling interventions to promote a healthy diet and physical activity for cardiovascular disease prevention, the U.S. Preventive Services Task Force says in a draft recommendation.

Cardiovascular disease, which includes heart disease and stroke, is one of the leading causes of death in the U.S. Nearly half of all adults have at least one risk factor for cardiovascular disease, such as high cholesterol, hypertension, and current smoking. In 2012, approximately 35% of adults were obese, which increases their risk for hypertension, high cholesterol, and diabetes.

For overweight or obese adults who are at increased risk for cardiovascular disease, intensive behavioral counseling interventions, with the goal of improving diet and increasing physical activity, can help reduce the risk of cardiovascular disease. Effective counseling services include education, goal setting, and ongoing monitoring and feedback and are delivered by a trained professional. Effective counseling is delivered over multiple sessions spread over several months to a year.

Source: USPSTF, May 13, 2014
Shortage of Sterrad Cyclesure 24 Biological Indicators

Advanced Sterilization Products (ASP) has notified the FDA of a critical shortage of Sterrad Cyclesure 24 Biological Indicators due to a machine performance issue on its production line. ASP can ship only 30% of its normal capacity but expects to be able to meet demand by August.

The product is used with Sterrad sterilizers to monitor and confirm the effectiveness of the sterilization process for heat-sensitive medical devices that must be sterilized at low temperatures and low moisture. Providers are advised to use an alternative low-temperature sterilizer if available and prioritize use of the Sterrad indicators for sterilization loads that contain the most critical instruments for the most urgent cases.

Source: FDA, May 23, 2014

Cancer Drug Problems Prolong Hospital Stays

In a five-month study involving 973 cancer patients, 12% of 1,299 hospital admissions were due to drug-related problems—and half were deemed preventable, say National Cancer Centre Singapore researchers.

The study was conducted at oncology wards in Singapore’s largest acute tertiary hospital. Patients were screened for drug-related problems (DRPs) that led to admission. DRP cases were classified as minor, moderate, or severe, and nearly all were moderately severe.

Fifty-one DRPs were classified as “probably preventable” and 21 as “definitely preventable.” The researchers note that, due to the complexity of cancer treatment, DRPs—particularly adverse reactions—can happen even when preventive measures are used. Moreover, when an event was classified as preventable, “it remains uncertain whether the event could have actually been prevented even if care had been optimal.”

The DRPs added significantly to hospitalization costs. Length of stay was longer for preventable drug-related admissions than for nonpreventable drug-related admissions. The treatment cost of admissions for preventable DRPs, the researchers found, constituted almost half of the total direct medical costs.

Source: Clin Therapeutics 2014;36:588–592

U.S. Diabetes Prevalence Exceeds 29 Million

More than 29 million people in the U.S. have diabetes, up from 26 million in 2010, according to a report from the Centers for Disease Control and Prevention (CDC). What’s more, one in four people with diabetes doesn’t know they have the disease. Another 86 million adults—more than one in three U.S. adults—have prediabetes, in which their blood sugar levels are higher than normal but not high enough to be classified as type-2 diabetes. Without weight loss and moderate physical activity, 15% to 30% of people with prediabetes will develop type-2 diabetes within five years.

Key findings from the National Diabetes Statistics Report, 2014 (based on health data from 2012) include:

- 29 million people in the U.S. (9.3%) have diabetes.
- 1.7 million people 20 years of age or older were newly diagnosed with diabetes in 2012.
- Non-Hispanic black, Hispanic, and American Indian/Alaska Native adults are approximately twice as likely to have diagnosed diabetes as non-Hispanic white adults.
- 208,000 people younger than 20 years of age have been diagnosed with diabetes (type-1 or type-2).
- 86 million adults 20 years of age or older have prediabetes.

According to the CDC, diabetes and its complications accounted for $245 billion in medical costs, lost work, and lost wages in 2012, up from $174 billion in 2007.

Source: CDC, June 10, 2014

A Delayed Reaction to Long-Term Antidepressants?

Stress-induced cardiomyopathy (SIC) is usually triggered by intense emotional or physical stress, although invasive diagnostic procedures or surgery can play a part. However, Italian clinicians suggest SIC could also be a delayed effect of long-term antidepressants.

In Heart & Lung, they report that a 65-year-old woman developed typical apical SIC two weeks after being weaned from long-lasting antidepressant treatment. The SIC recurred a week later.

The patient was admitted to an emergency department after repeatedly fainting during and after light aerobic exercise. She reported weakness and mild dyspnea. She had a regular heartbeat, mild hypotension, and normal sinus rhythm on an electrocardiogram. She was postmenopausal, had never smoked, and had no history of arterial hypertension, hypercholesterolemia, diabetes, or cardiac or circulatory diseases. Severely depressed for 25 years, she had been treated for the last eight years with a staggeringly complex combination of antidepressants, both tricyclics and serotonin-specific reuptake inhibitors (SSRIs), neuroleptics, antiepileptics, and benzodiazepines. She was taking imipramine, amitriptyline, paroxetine, perphenazine, gabapentin, trazodone, and delorazepam daily.

Her depression had been in remission...
for two years, so her psychiatrist admitted her to the hospital to discontinue most of the drugs. Paroxetine was reduced gradually over three days, gabapentin was continued, and the other drugs were stopped. Diazepam and metadoxine were continuously infused for three days, then hydroxyzine 25 mg was started. The patient tolerated the procedure well and was discharged in good health. Two weeks later, she had the first SIC.

Both SIC episodes were preceded by only a mild stressor; the SIC recurred in a different part of the heart; and the period between stopping the drug and SIC onset was long (symptoms of SSRI discontinuation usually appear within seven days).

Acute withdrawal syndrome from alcohol or opiates can trigger SIC, and rapid interruption of chronic SSRI treatment is known to induce a withdrawal syndrome characterized by psychological and somatic symptoms. The authors single out paroxetine, the SSRI most frequently associated with withdrawal syndrome. Their patient’s symptoms corresponded closely with the most frequent manifestations of this syndrome (dizziness and nausea) at SIC onset. Her delayed reaction may have been due, they say, to extraordinarily long, continuous antidepressant treatment.

Source: Heart & Lung 2014;43:225–230

More People Taking Vitamins and Medicines at the Same Time

Approximately one in three U.S. adults reports using dietary supplements and prescribed medicines concomitantly, say researchers who analyzed data from the 2005–2008 National Health and Nutrition Examination Survey (NHANES).

Prevalence of concomitant use was highest among people with osteoporosis, followed by thyroid, cancer, kidney, arthritis, diabetes, heart/vascular, respiratory, and liver conditions.

Supplement and medicine use is significantly more common among people who receive “doctor-informed medical care” (DIMC) versus those who do not (one in two adults versus one in six). Among DIMC recipients, cardiovascular agents were the most common drugs used with supplements. Among people without DIMC, hormones were most common.

The numbers of people using both supplements and medicines have risen steadily. More than 10 years ago, 16% to 18% of prescription medicine users also took supplements, the researchers note. In this study, 69% of prescription medicine users ages 57 and older were using supplements concomitantly.

The researchers say a broad spectrum of patients may benefit from education and guidance on the risks of interactions, particularly the potential of supplements to interfere with the metabolism and potency of prescription medicines. The increasingly complex combinations of ingredients in supplements may require closer evaluation by health care and dietetic practitioners, they add.

Source: J Acad Nutr Diet 2014; article in press

Incretin and the Risk Of Pancreatitis

Is there a link between incretin-based diabetes drugs and pancreatitis? In 2007, the FDA warned of an association based on 30 postmarketing reports of acute pancreatitis in patients taking exenatide.

Because evidence to support a causal relationship is weak, researchers sought to produce a more rigorous assessment. They analyzed data from 60 studies: 55 randomized, controlled trials (all industry funded), ranging from 12 to 234 weeks long and involving 33,350 patients; and five observational studies with 320,289 patients.

Of the randomized trials, 27 stated that no pancreatitis occurred during the study. Overall, 37 events of pancreatitis occurred in 33,227 patients who used at least one drug. The risk did not differ for GLP-1 agonists versus DPP-4 inhibitors.

Four observational studies found no evidence to suggest a greater risk of pancreatitis. The fifth, a case-control study of 1,269 patients, reported a greater risk of admission for acute pancreatitis for patients using sitagliptin or exenatide.

However, the risk of pancreatitis was low, the researchers conclude. In randomized trials, similar numbers of patients (0.11%) developed pancreatitis while taking incretins or in control groups. In cohort studies, the risk of acute pancreatitis was somewhat higher (0.47%), potentially because of a higher incidence of risk factors and longer follow-up.

The researchers caution that many of the randomized trials had small sample sizes and relatively short follow-up. Moreover, trials often recruited patients who had fewer comorbidities than patients in clinical practice. And because pancreatitis is rare in general, the confidence intervals around relative effects are wide, leaving the possibility of an undetected increase in risk. The observational studies had larger samples but were limited, in part, because diagnosis criteria varied.

The researchers say the FDA adverse drug event system has documented 2,327 spontaneously reported cases of pancreatitis in patients taking exenatide, 888 cases in those taking liraglutide, 718 cases in those taking sitagliptin, and 125 in those taking saxagliptin. The number of cases of pancreatitis seemed larger, the researchers say, in patients taking incretins than other anti-diabetic drugs.

Source: BMJ 2014;348:g2366

Recalls

Eight More Lots of Alexion Soliris

Alexion Pharmaceuticals is recalling eight lots of eculizumab (Soliris) 300 mg/30 mL concentrated solution for intravenous infusion that were manufac-
A double-blind, placebo-controlled, randomized clinical trial of 201 patients showed that nearly 38% of those who used the Cerena device when they had a migraine headache were pain-free two hours later compared with approximately 17% of patients in the control group. After 24 hours, approximately 34% of Cerena users were pain-free compared with 10% of the control group. The treatment did not produce any device-related serious adverse events.

Source: eNeura, Inc., May 23, 2014

Pulmonary Artery Pressure Monitor

The FDA has approved the CardioMEMS HF system (CardioMEMS, Inc.), which measures the pulmonary artery (PA) pressures and heart rates of patients with New York Heart Association class III heart failure who have been hospitalized for heart failure in the previous year. The device allows health care professionals to monitor the condition of patients remotely.

The system, used by patients in the home or other remote locations, is the first permanently implantable wireless system intended to provide PA pressure measurements, including systolic, diastolic, and mean PA pressures. Physicians can review the data and adjust therapy to reduce heart failure hospitalizations.

The system consists of a battery-free sensor/monitor implanted permanently in the PA, a delivery system consisting of a transvenous catheter designed to deploy the implantable sensor within the distal PA, and the CardioMEMS hospital and patient electronics system. The electronics system processes signals from the sensor/monitor and transfers measurements to a secure database.

In a pivotal clinical study, 550 participants received the implanted device and were randomly assigned to either the control group or the investigational group. The study showed a clinically and statistically significant reduction in heart failure-related hospitalizations for participants whose physicians had access to PA pressure data. The FDA is requiring a postapproval study to continue to learn about the device’s performance outside the context of a clinical trial.

Source: FDA, May 28, 2014

Kidney Disease Test

The FDA has allowed marketing of the first test that can help determine whether membranous glomerulonephritis (MGN), a chronic kidney disease, is due...
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to the body’s rejection of its own kidney tissue or some other cause.

MGN causes damage to the cluster of blood vessels (glomeruli) in the kidney that filter the blood and begin the process of removing waste and excess fluid from the blood. Once the disease progresses, other areas of the kidney become damaged. Over time (usually 10 to 20 years), some people with MGN progress to kidney failure and require a kidney transplant.

Some cases of MGN are associated with secondary conditions, such as infections, tumors, adverse reactions to drugs, or poisoning. However, approximately 85% of MGN cases are caused by the body’s immune system attacking healthy kidney tissue, a condition called primary MGN (pMGN). The Euroimmune Anti-PLA2R IFA blood test (Euroimmune US, Inc.) detects whether a patient has an antibody that is specific to pMGN.

The FDA reviewed a clinical study of 275 blood samples from patients with presumed pMGN and 285 from patients with other kidney diseases (including secondary MGN) and autoimmune diseases (excluding pMGN) that can damage the kidney. The test detected pMGN in 77% of the presumed pMGN samples, and gave false positive results in less than 1% of the other samples. The test helped distinguish pMGN from secondary MGN in most patients.

The test should not be used alone to diagnose pMGN: Additional information, including symptoms and other lab tests, should be considered. A kidney biopsy is needed to confirm the pMGN diagnosis. A negative result from the test does not rule out pMGN.

Source: FDA, May 29, 2014

Test to Determine Red Blood Cell Types

The FDA has approved the Immucor PreciseType Human Erythrocyte Antigen (HEA) Molecular BeadChip Test (Bio-Array Solutions)—the first FDA-approved molecular assay used in transfusion medicine to assist in determining blood compatibility. The assay can be used to determine donor and patient non-ABO/non-RhD (non-ABO) red blood cell types.

The surfaces of red blood cells display minor blood-group antigens in addition to the major ABO blood group antigens. Some people develop antibodies to non-ABO antigens after transfusion or pregnancy—especially people who receive repeated blood transfusions, such as those with sickle cell disease. The development of such antibodies can destroy red blood cells if cells with the corresponding antigens are later transfused.

Development of antibodies to non-ABO antigens can be prevented by selecting blood that is better matched to the patient’s non-ABO antigens. In addition, when a potential transfusion recipient has a known antibody that causes red blood cell destruction, red blood cells that are negative for the corresponding antigen must be found.

The identification of red blood cell antigens has traditionally been performed by serological typing. The Immucor test provides a new method that detects genes governing the expression of 36 antigens that can appear on the surface of red blood cells. A study comparing the new test with licensed serological reagents and DNA sequencing found comparable performance among the three methods.

Source: FDA, May 21, 2014

Relaxis for Restless Leg Syndrome

Relaxis, the first nonpharmacological approach to help improve the quality of sleep in patients with primary restless leg syndrome (RLS), has received FDA clearance. Developed by Sensory Medical Inc., Relaxis was designed to provide physical relief of RLS while enabling the patient to remain in bed.

During an RLS episode, the patient places the low-profile Relaxis pad at the site of the discomfort and chooses a vibration intensity. The device provides 30 minutes of vibratory counterstimulation, gradually ramping down and shutting off without waking the patient.

Results from two randomized, multi-center, controlled, double-blind, prospective clinical research studies found the device superior to placebo pads for improving sleep quality in patients with primary RLS. An estimated 12 million Americans may suffer from RLS, a neurological condition that causes discomfort, pain, and sleep deprivation.

Source: Sensory Medical Inc., May 29, 2014
Gel-Syn for Knee Osteoarthritis
The FDA has approved marketing of Gel-Syn to relieve pain from osteoarthritis and function as a lubricant and shock absorber in the knee.

Marketed by Institut Biochimique S.A., Gel-Syn is an artificial material that contains sodium hyaluronate and is injected into the knee joint in patients with moderate osteoarthritis who have failed conservative treatments from physical therapy and simple pain medicines such as acetaminophen. It is similar to hyaluronic acid found in the knee joint. Treatment consists of three weekly injections.

Gel-Syn relieves pain associated with osteoarthritis for up to 26 weeks. Side effects may include injection-site pain, swelling, or joint pain.

In a clinical study, pain scores were used to compare the effectiveness of the Gel-Syn injections to commercial hyaluronate. Patients receiving Gel-Syn experienced the same amount of improvement in knee pain over 26 weeks as those who received the commercially available hyaluronate.

Source: FDA, May 21, 2014

ClearShield Craniofacial Implant
The FDA has given 510(k) clearance to OsteoSymbionics’ ClearShield craniofacial implant, used to restore protective and cosmetic features for patients who have suffered trauma to the skull.

Using digital technology and custom software, OsteoSymbionics’ biomedical engineering experts work with sculptors and artisans to create implants that match the surgeon’s plan and the patient’s needs. Made from polymethyl methacrylate, ClearShield uses a room-temperature peracetic acid/hydrogen peroxide vacuum vapor sterilization process offered by Revox Sterilization Solutions, a subsidiary of Cantel Medical Corp.

Source: Cantel Medical Corp. and OsteoSymbionics, May 28, 2014

FDA Turns Up Heat on Sunlamps
The FDA has reclassified sunlamp products and ultraviolet (UV) lamps intended for use in sunlamps from low-risk (class I) to moderate-risk (class II) devices. The agency is also requiring that sunlamps carry a boxed warning explicitly stating that they should not be used on persons under the age of 18 years.

In addition, certain marketing materials for sunlamp products and UV lamps must include additional and specific warning statements and contraindications.

Sunlamp products, which include tanning beds and tanning booths, emit UV radiation that may cause skin cancer. According to the American Academy of Dermatology, people who have been exposed to UV radiation from indoor tanning experience a 59% increase in the risk of melanoma. This risk increases each time they use a sunlamp product. The risk peaks in persons under age 18 and people with a family history of skin cancer.

Based on the FDA’s action, manufacturers will now have to submit a 510(k) premarket notification to the FDA—and obtain agency clearance—prior to marketing these devices, which until now were exempt from premarket review. Manufacturers will have to show that their products meet performance testing requirements, address product design characteristics, and include warnings and contraindications. The FDA’s order for the reclassification of sunlamp products and UV lamps follows recommendations from a meeting of outside experts convened in March 2010.

Source: FDA, May 29, 2014

Recalls
Fisher & Paykel Infant CPAP Prongs
Fisher & Paykel Healthcare has recalled nasal continuous positive airway pressure (CPAP) prongs used for infants with its FlexiTrunk Patient Interface in hospital or clinical settings.

The prongs deliver CPAP through infants’ nostrils. The firm received 24 reports of prongs detaching from the tubing during use, especially when mucus or moisture are present. This may cause hypoxemia, and the detached prongs may present a choking hazard.

Affected model numbers (with lot numbers in parentheses) are: BC3020-10 (13060603XX–14032503XX), BC3520-10 (13082003XX–14032503XX), BC4030-10 (13091903XX–14032503XX), BC4540-10 (13082603XX–14032503XX), BC5040-10 (13091903XX–14032503XX), BC5050-10 (14022603XX–14032503XX), BC5550-10 (14022603XX–14032503XX), BC5560-10 (14031203XX–14032503XX), BC6060-10 (14031203XX–14032503XX), BC6070-10 (14031203XX–14032503XX), BC6570-10 (14031203XX–14032503XX), as well as Bubble CPAP Starter Kits BC461-SK (131007–140325), BC471-SK (131007–140325), BC490-SK (131007–140325), BC491-SK (131007–140325), and BC492-SK (131007–140325).

Customers are advised to destroy the prongs and contact their FPH representative for replacements.

Source: FDA, May 23, 2014

Baxter ABACUS Parenteral Software
Baxter Corporation Englewood recalled its ABACUS Total Parenteral Nutrition (TPN) Calculation Software, versions 3.1, 3.0, 2.1, and 2.0, after receiving reports of malfunctions.

Pharmacists use the Windows-based application to calculate or order TPN to meet the nutritional needs of patients who cannot eat or drink by mouth. ABACUS may also be used in other calculations. The firm identified software issues that could cause toxic or overdose symptoms.

17, 2014. Health care professionals with questions can contact Baxter at 1-800-678-2292, Monday through Friday, 6 a.m. to 5 p.m. Mountain time.

Source: FDA, May 22, 2014

**Alaris Pump**

CareFusion is recalling its Alaris Pump model 8100, version 9.1.18. Because of a software problem, the pump module may not properly delay an infusion when the “Delay Until” option or “Multidose” feature is used. The pump may also fail to properly deliver a multidose infusion under some conditions.

The pumps were distributed from February 7, 2014, through April 7, 2014. For serial numbers, visit www.carefusion.com and click on “Product Alerts.” CareFusion will contact customers to schedule installation of replacement software.

Source: FDA, April 23, 2014

**Ventlab Resuscitator Bags**

Ventlab LLC initiated a “medical device removal” of some Ventlab Resuscitator Bags based on complaints that a sticking valve resulted in failure to deliver air to patients. Lot numbers are available at www.fda.gov/Safety/Recalls/ucm397682.htm. Users with bags in those lots should stop using them and contact Ventlab for instructions at 1-844-635-5326, Monday through Friday, 8:30 a.m. to 5 p.m. Eastern time.

Source: Ventlab LLC, May 14, 2014

**Portex Low Dead Space Connector**

Smiths Medical is recalling lot 2553426 of its Portex Low Dead Space Connector with Sideport, 3.5 mm, because this lot, although labeled 3.5 mm, actually consists of 3.0-mm connectors. The products were distributed in November 2013.

Used to attach an endotracheal tube to the patient breathing circuit for respiratory support, the low dead space connector is designed to decrease mechanical dead space and subsequent carbon dioxide rebreathing. Customers can reach Smiths’ Customer Service Department at 1-800-258-5361.

Source: FDA, June 12, 2014

**Blood Glucose Test Strips**

Diabetic Supply of Suncoast recalled all BMB-BA006A Advocate Redi-Code+ blood glucose test strip lots due to a labeling error that could cause confusion about which meter models the test strips should be used with. Using the strips with the wrong meters could yield incorrect results. Customers who want to know if their strips are being used correctly or should be replaced can contact the company at 561-296-0488, Monday through Friday, 9 a.m. to 5 p.m. Eastern time.

Source: Diabetic Supply of Suncoast, June 6, 2014

**NEW MEDICAL DEVICES**

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

Name: Dynagen Mini and Inogen Mini Implantable Cardioverter Defibrillators (ICDs) and Dynagen X4 and Inogen X4 Cardiac Resynchronization Therapy Defibrillators (CRT-Ds).

Manufacturer: Boston Scientific, Natick, Massachusetts

Approval Date: April 15, 2014

Purpose: The Dynagen Mini and Inogen Mini ICDs and the Dynagen X4 and Inogen X4 CRT-Ds are designed to treat patients who are at risk for sudden cardiac death or who suffer from heart failure by shocking racing heartbeats back into normal rhythm. It is thought that these devices offer more options to improve outcomes, reduce complications, and lower the costs of treating patients.

Description: Extending the company's portfolio of defibrillators, the ICDs in the Mini family are the world’s smallest and thinnest devices and are designed for patient comfort. The Mini ICDs are up to 20% smaller by volume and up to 24% thinner than competitive devices from other manufacturers.

The CRT-Ds are also used to protect against sudden cardiac death due to abnormal heart rhythms in patients suffering from heart failure, in which the heart is unable to pump blood sufficiently.

Benefit: The tiny size of the Mini ICD provides a real benefit to some patients, in particular those with a smaller frame.

The X4 line of quadripolar CRT-Ds offers 70% more pacing options to address high capture thresholds and phrenic nerve stimulation effectively, along with the largest battery capacity in the industry.

ICDs and CRT-Ds are designed to treat patients suffering from heart failure and/or to protect patients at risk of sudden cardiac death. Heart failure is a chronic, progressive condition in which the heart muscle is unable to pump enough blood to meet the body’s need for blood and oxygen. Sudden cardiac death is a swift, unexpected death caused by loss of heart function and is a leading cause of death. Nearly 400,000 out-of-hospital cardiac arrests occur annually in the United States.

With these new devices and the current line of long-lasting ICDs and CRT-Ds, including the world’s only subcutaneous ICD, there is now an excellent range of options for patients at risk of sudden cardiac arrest with or without the need for cardiac resynchronization therapy.

Source: www.bostonscientific.com

Name: Cobas HPV (human papillomavirus) Test

Manufacturer: Roche Molecular Systems, Inc., Pleasanton, California

Approval Date: April 24, 2014

Purpose: This is the first FDA-approved HPV DNA test for women 25 years old and older that can be used alone to help a health care professional assess the need for a woman to undergo continued on page 518
additional diagnostic testing for cervical cancer. The test also can provide information about the patient's risk for developing cervical cancer in the future.

The FDA initially approved the molecular test in 2011 for use in conjunction with or as a follow-up to a Pap test. The new approval gives health care professionals the option to use the HPV test alone or as a co-test with cervical cytology.

**Description:** Employing a sample of cervical cells, the cobas HPV test detects DNA from 14 high-risk HPV types. The test specifically identifies HPV 16 and HPV 18, while concurrently detecting 12 other types of high-risk HPVs.

Based on results of the cobas HPV test, women who test positive for HPV 16 or HPV 18 should have a colposcopy, an exam using a device that illuminates and magnifies the cervix so a physician can directly observe the cervical cells. Women testing positive for one or more of the 12 other high-risk HPV types should have a Pap test to determine the need for a colposcopy.

**Benefit:** The FDA has approved a molecular test for HPV DNA as a first-line, stand-alone screen for cervical cancer (first HPV test for primary cervical cancer screening). Health care professionals should use the cobas HPV test results together with other information, such as the patient screening history and risk factors, and current professional guidelines.

The agency approved the cobas HPV test to screen women at least 25 years of age for infection with 14 high-risk HPV strains, including HPV 16 and 18, which account for most cases of cervical cancer in the U.S. and worldwide. The approval offers women and physicians a new option for cervical cancer screening.

In most cases, a high-risk HPV infection goes away on its own and does not cause any health problems. However, about 10% of women infected with high-risk HPV develop a persistent infection that may put them at risk of cancer.

**Source:** www.medpagetoday.com

**Name:** SonoSure Sonohysterography and Endometrial Sampling Device

**Manufacturer:** CrossBay Medical Inc. and Norgenix Pharmaceuticals LLC (marketing), San Rafael, California, and Spartanburg, South Carolina

**Approval Date:** April 25, 2014

**Purpose:** The device is indicated to access the uterine cavity for saline infusion sonohysterography and to obtain an endometrial biopsy.

**Description:** The single-use, disposable product contains a low-profile, flexible insertion catheter and a built-in endometrial sampling brush and comes with a 50-cc refillable fluid injection bag. Its sealing mechanism can be repositioned so as not to obscure the lower uterine segment.

**Benefit:** Acute uterine bleeding (AUB) occurs in 20% of women between the ages of 19 and 55 years. Saline infusion sonohysterography and endometrial biopsy are routinely used in the workup for AUB. Many providers perform these procedures at the same setting, using separate instrumentation for each procedure.

SonoSure combines saline infusion hysterography and endometrial biopsy capabilities into one device, streamlining workups for abnormal uterine bleeding or heavy menstrual periods. The device eliminates the requirement to insert a cannula into the cervix twice or schedule separate appointments for procedures that utilize different instrumentation.

**Sources:** www.marketwatch.com, www.onlinetmd.com