**NEW DRUGS**

**Victoza Is a New Contender In the Diabetes Arena**

A drug that helps the pancreas make more insulin has been approved. Liraglutide (Victoza, Novo Nordisk), an incretin mimetic, imitates naturally occurring hormones that encourage insulin production after meals. In comparative trials with exenatide (Byetta, Amylin/Lilly), a twice-daily incretin mimetic already prescribed for initial or stand-alone therapy, once-daily liraglutide was significantly better at reducing hypoglycemia.

Weight loss was another potential benefit; in one study, liraglutide patients lost an average of 3.24 kg, compared with 2.87 kg for the exenatide patients.

In five clinical trials involving nearly 4,000 people, adverse effects were similar to but potentially less severe than those of exenatide. Common side effects from liraglutide were headache, nausea, and diarrhea; other adverse effects included allergy-like reactions such as hives. However, pancreatitis occurred more often with liraglutide than with other diabetes drugs. People with a history of pancreatitis, gallstones, alcoholism, or elevated triglyceride levels may be at higher risk.

In animal studies, liraglutide caused tumors of the thyroid gland; some of these tumors were cancers, although the dose was eight times higher than what humans would receive. Because it isn't known whether liraglutide can cause thyroid tumors or medullary thyroid cancer, the drug should not be used as a first-line treatment until more studies are completed. This agent is not recommended for patients at risk for medullary thyroid cancer or those with multiple endocrine neoplasia syndrome type 2.


**Xiaflex Improves Debilitating Hand Condition**

The FDA has approved Auxilium’s Xiaflex (collagenase *Clostridium histolyticum*) as the first drug to treat a progressive hand disease, Dupuytren’s contracture. Before the approval of Xiaflex, the only effective therapy was surgery.

Patients have an abnormal thickening of the fibrous layer underneath the skin of the palm and fingers. Too much collagen can build up, forming thick, rope-like cords of tissue that can prevent the fingers from being able to relax and straighten normally. The disorder is most common in men older than 50 years of age and in people of northern European descent.

Xiaflex, a biologic agent, breaks up the collagen deposits. It is injected directly into the collagen cord of the hand. This drug should be administered only by a health care professional experienced with injections of the hand, because tendon ruptures may occur.

Although no serious allergic reactions have been observed, introducing this drug, which is a foreign protein, could prompt an immune system reaction.


**NEW INDICATIONS**

**Crestor Reduces Risk Of Cardiovascular Events**

Rosuvastatin calcium (Crestor, AstraZeneca), a cholesterol-lowering drug, is now approved for some patients with an increased risk of heart disease but who have not yet experienced it. The new indication for this statin is intended to reduce the likelihood of a heart attack or stroke or to decrease the need for a procedure to treat blocked arteries in these patients.

The targeted group includes men who are 50 years of age and older and women who are 60 years of age and older with elevated high-sensitivity C-reactive protein (hsCRP) levels and at least one additional cardiovascular risk factor, such as smoking, hypertension, a family history of heart disease, or low levels of high-density lipoprotein-cholesterol (HDL-C). A nonspecific marker of inflammation, hsCRP is associated with the buildup of cholesterol and fatty material in the coronary arteries.

The new indication does not support the drug’s use in individuals with elevated hsCRP levels but who have no traditional cardiovascular risk factors.

Rosuvastatin blocks an enzyme (HMG–CoA reductase) from making cholesterol. High levels of low-density lipoprotein-cholesterol (LDL-C) is a known risk factor for heart attacks, strokes, and heart disease.

In the JUPITER trial, rosuvastatin patients experienced fewer cardiac events and needed fewer procedures such as angioplasties and coronary artery bypass surgeries.

Rosuvastatin is already approved for use in combination with diet and exercise to lower LDL-C levels and triglycerides and to slow the progression of atherosclerosis.

Source: FDA, February 11, 2010

**Rituxan for Leukemia**

The FDA has approved rituximab (Rituxan, Genentech/Roche Group/BioGen Idec) to treat certain patients with chronic lymphocytic leukemia (CLL). CLL primarily affects people older than 50 and arises from a group of white blood cells known as B cells.

This drug is already approved for patients with non-Hodgkin’s lymphoma. The new indication is for patients with CLL who are beginning chemotherapy for the first time and for those who have not responded to other cancer drugs for CLL. Rituximab is given with fludarabine and cyclophosphamide.
Rituximab is a monoclonal antibody that binds to the surface of cancer cells, making it easier for the patient’s immune system to attack the cancer cell as if it were a foreign pathogen.

A boxed warning mentions infusion reactions; rashes and sores in the skin and mouth; progressive multifocal leukoencephalopathy (PML), a brain infection; and tumor lysis syndrome. When tumor cells are killed by the drug, they release toxins into the bloodstream that can cause kidney injury and may increase serum levels of potassium and phosphate.

The role of rituximab in non-Hodgkin’s lymphoma is reviewed on page 148.
Source: FDA, February 18, 2010

**Afluria for Young Children**

Merck’s Afluria inactive seasonal flu vaccine is now approved for use in children six months of age or older. It was originally approved in September 2007 for persons 18 years of age and older against influenza caused by influenza virus subtype A and type B present in the vaccine. This vaccine is not indicated for people with a hypersensitivity to eggs, neomycin, or polymyxin or for anyone who has had a life-threatening reaction to a previous influenza vaccination.

The safety and effectiveness of the product have not been established in children younger than six months of age.
Source: Merck/CSL Ltd., February 18, 2010

**NEW FORMULATION**

**Higher-Dose Urocit-K Helps Prevent Kidney Stones**

Mission Pharmacal Company has introduced an extended-release tablet of potassium citrate (Urocit-K 15 mEq), a maximum-strength alkalinizing agent that has helped to prevent kidney stone recurrence in more than 90% of patients. Urocit-K 15 mEq provides 50% more of the active ingredient, potassium citrate, than Urocit-K 10 mEq.

Potassium citrate helps patients maintain targeted urinary citrate and urinary pH levels, thereby helping reduce stone formation. A slow-release, wax-matrix delivery system enhances a patient’s tolerability of oral potassium citrate. The availability of this new dosage regimen should help patients comply with their treatment regimens.

Urocit-K corrects the pH of the urine and elevates a naturally occurring urinary inhibitor of calcium stone formation (citrate). It also lowers the saturation of calcium oxalate and controls the formation of new stones.
Source: Mission Pharmacal, February 17, 2010; www.urocit-k.com

**DRUG NEWS**

**Label Change For Didanosine (Videx)**

A rare but serious liver disorder has been reported in some HIV-infected patients taking didanosine (Videx/Videx EC, Bristol-Myers Squibb). During an 18-year period, the FDA received reports of 42 cases of non-cirrhotic portal hypertension in patients taking these products. Four patients died as a result of bleeding or liver failure after the condition developed. Non-cirrhotic portal hypertension can lead to severely enlarged veins in the esophagus. These esophageal varices are thin and can break open, resulting in serious and potentially fatal bleeding.

Videx, an antiretroviral drug, was first approved in 1991. Videx EC, a delayed-release version, was approved in 2000. The drugs are used in combination with other antiretroviral agents to treat HIV infection in children and adults.

The labels for both formulations have been revised to mention the risk and the signs of non-cirrhotic portal hypertension. The FDA concluded that the benefits of these drugs in certain patients continue to outweigh potential safety risks. Videx and Videx EC do not cure HIV infection and might not prevent HIV-related illnesses or the spread of the infection to other people.
Source: FDA, February 1, 2010

**Safety Plan to Cover Erythropoiesis-Stimulating Agents**

The FDA has approved a risk-management program for the class of drugs called erythropoiesis-stimulating agents (ESAs).

ESAs, which stimulate bone marrow to make red blood cells, are approved to treat anemia that may occur as a result of kidney failure, chemotherapy, or an HIV drug (AZT); they are also used to treat certain surgical patients with anemia. ESAs include epoetin alfa (e.g., Procrit, Ortho Biotech; Epogen, Amgen Inc.) and darbepoetin alfa (Aranesp, Amgen Inc.).

In April 2008, the FDA required Amgen to establish a program because studies found that ESAs caused tumors to grow faster and resulted in earlier deaths in some cancer patients. Amgen’s Risk Evaluation and Mitigation Strategy (REMS) program requires health care professionals to provide patients with a Medication Guide that contains information on how to use this drug safely.

ESAs are discussed in this month’s continuing education article on page 165.
Source: FDA, February 16, 2010

**Caution with Asthma Drugs**

The labeling for long-acting beta₂-agonists (LABAs) must now include a warning that they should not be used alone for the treatment of asthma; they are to be used only in combination with an inhaled corticosteroid. These changes reflect the experience with Australia’s guidelines, which have not allowed the stand-alone use of LABAs for more than 15 years.
Concerns over the use of LABAs as a monotherapy first arose in 1996, when the Salmeterol Multicenter Asthma Research Trial (SMART) showed a possible increase in respiratory and asthma-related deaths in an African-American subpopulation. The FDA initially supported the continued use of LABAs with the addition of a warning. However, further reviews noted an increased risk of serious worsening of asthma leading to death and hospitalization for patients using LABAs alone.

Several companies are still developing novel once-daily LABAs, and these would be a major improvement over the currently available twice-daily products. However, it is unlikely that the companies involved will apply for an asthma label; they would rather focus on an approval for chronic obstructive pulmonary disease, in which no adverse events have been recorded with LABA monotherapy.

Preliminary data suggest that the combination of saquinavir (Invirase, Genentech) and ritonavir (Norvir, Abbott) may have potentially adverse effects on the heart. When used together, these anti-retroviral drugs may cause prolonged QT and PR intervals on an electrocardiogram, possibly leading to torsades de pointes, an abnormal heart rhythm. Patients may experience lightheadedness, fainting, or abnormal heart beats. In some cases, torsades de pointes may progress to a life-threatening ventricular fibrillation.

Morphine May Reduce PTSD
Various articles have suggested that opiates, anxiolytics, and beta-adrenergic antagonists may help reduce or prevent the symptoms of post-traumatic stress disorder (PTSD) by impeding memory consolidation and improving the conditioned response of fear. Researchers from the Naval Health Research Center in San Diego have now found that morphine was associated with a significantly reduced risk of PTSD, regardless of dose, severity of injury, or other factors.

Of 696 patients, 243 had PTSD; of those, 61% received morphine. Of the 453 patients who did not have PTSD, 76% received morphine. The use of morphine directly after injury, during resuscitation and early trauma care, was associated with a reduced risk of PTSD. The association remained significant and independent after the authors adjusted for the severity and mechanism of injury, amputation status, and certain injury-related clinical factors.

An earlier study had shown that giving morphine to children with burn injuries protected against PTSD six months after hospitalization. Another study also reported that morphine protected against PTSD in injured adults, but the association pertained only to the severity of symptoms. Although much of the research in this field is speculative, other investigators think that opiates might block the consolidation of memories through a beta-adrenergic mechanism.

The authors found no indication that the protective effect of morphine was dependent on the dose. PTSD was subsequently diagnosed in 40% of patients who received low doses of morphine (2–9 mg), 40% of those who received moderate doses (10–20 mg), and 23% of those who received high doses (more than 20 mg).


Should Patients Take Aspirin With Proton Pump Inhibitors?
The usual protocol for treating patients with peptic ulcer bleeding is to use an endoscopic device with antisecretory therapy and to discontinue aspirin or other antiplatelet agents until the ulcer heals. However, stopping aspirin may put patients at greater risk for cardiovascular and cerebrovascular problems. What happens if patients keep taking aspirin?

Researchers from Hong Kong found that continuous aspirin therapy may increase the risk of recurrent bleeding. However, a prolonged gap in aspirin therapy definitely raises the risk of mortality. Therefore, patients with bleeding ulcers and cardiovascular diseases are advised to resume low-dose aspirin therapy with proton pump inhibitors (PPIs) early.

In the study, 78 patients received aspirin 80 mg/day and 78 received placebo for eight weeks immediately after endoscopic therapy. All patients also received pantoprazole (Protonix, Wyeth). More aspirin recipients had recurrent ulcer bleeding within 30 days (10% vs. 5% of placebo patients). However, despite a higher risk of recurrent bleeding, fewer aspirin recipients died (1%), compared with 13% of patients in the placebo group.

Discontinuing aspirin therapy did not prevent ulcer-related deaths in three patients who received placebo therapy even though they were taking a PPI. The small number of deaths limits further interpretation of the results on mortality; however, the transfusion requirements between the two treatment groups were almost identical. This implies that recurrent bleeding was relatively mild and did not affect the clinical outcomes of those patients.

Mortality rates were higher when aspirin therapy was discontinued until ulcers healed. Most deaths were related to cardiovascular events. Deaths related to gastrointestinal (GI) bleeding usually occurred within the first three to five days after index bleeding. By contrast, patients in the placebo group died throughout...
The phenomenon might be related to the fact that despite rapid clearance of aspirin from the circulation, the antiplatelet effects last for at least a few days. The researchers recommend that aspirin be discontinued for three to five days after the index bleeding episode and that it be resumed after the patient is stabilized, minimizing the risks of bleeding and vascular ischemia.

Source: Ann Intern Med 2010;152:1–9

**Pneumonia May Be More Likely After Acid-Suppressive Drugs**

Acid-suppressive medications, such as proton pump inhibitors (PPIs) and histamine-2 receptor antagonists (H2RAs), have been observed to raise the likelihood of recurrent community-acquired pneumonia (CAP) in some elderly patients by 51%, according to a Canadian study. New users of these drugs, in particular, may have the highest risk.

During five years of follow-up, 71 of 608 patients taking PPIs or H2RAs (12%) had recurrent pneumonia, compared with 130 of 1,487 non-users of these agents (8%). When the researchers classified the current users according to when PPI or H2RA therapy was started, they found that current users bore the highest risk: 15% developed pneumonia, in contrast to previous studies, in which patients’ overall risk of CAP was considerably lower.

Source: Am J Med 2010;123:47–53

**Online Pain Relief Program**

PainBalance, an educational initiative supported by King Pharmaceuticals, offers information for health care professionals that enables them to provide appropriate care for patients with pain. Chronic pain costs an estimated $100 billion in the U.S. each year.

A Web site, www.painbalance.org, includes guidelines about categories of pain; its management, prevalence, and pathophysiology; and recommendations for assessing pain. The Opioid Risk Tool is a calculator that helps to quantify a patient’s risk of potential opioid abuse. Three-dimensional instructional animation is also included.

Source: King, February 3, 2010

**Timing and Dosage of Beta Blockers Make a Difference**

Studies have been conflicting on the benefits, if any, of giving beta blockers in the perioperative period to patients at risk for cardiovascular complications. The PeriOperative Ischemic Evaluation (POISE) trial was started in 2002 to try to resolve the inconsistencies.

In this study, 8,351 patients received extended-release metoprolol succinate or placebo. At 30 days, the number of cardiac events was decreased, but that reduction came with a significant increase in the incidence of total mortality and stroke.

The high incidence of stroke led researchers at Leiden University in the Netherlands to question the liberal use of perioperative beta blockers. They decided to combine the results from several Dutch Echocardiographic Cardiac Risk Evaluation Applying Stress echo-cardiography (DECREASE) trials to assess the incidence, risk factors, and use of beta blockers associated with postoperative stroke.

At 30 days, 18 of 3,884 patients (0.46%) had strokes; of those, 12 patients had been given beta blockers perioperatively. All strokes were ischemic. Patients with a history of stroke were the most at risk. The researchers found no association with statins, anticoagulants, or bisoprolol (e.g., Zebeta, Duramed).

Timing might be the key, they suggest. In the DECREASE studies, low-dose bisoprolol was started 30 days or more before surgery. The team noted that when beta-blocker therapy was started within hours of surgery, any adverse effects from the drug could be overlooked and an overdose was a risk. They cited studies in which beta blockers were started only hours before surgery; the incidence of postoperative stroke was greater when beta blockers were started at least one week before surgery.

The dose is also a clue to solving the mystery. In POISE, 50% to 100% of the maximum recommended therapeutic dose of metoprolol was used and a high dose was given right before surgery; in the DECREASE trials, 10% to 20% was used and therapy was also titrated for a prolonged period.

Thus, the protocol in the DECREASE studies—low-dose, long-acting agents continued on page 139
titrated to effect well in advance of surgery—was associated with an overall benefit, but high-dose therapy, started in the morning of surgery, was related to greater risk.

Source: Am J Cardiol 2010;105:43–47

Some Flu Drugs Might Be Ineffective

Despite the widespread use of neuraminidase inhibitors against influenza, they probably aren’t right for the job, say researchers for the Cochrane Acute Respiratory Infections Group. In updating a 2005 Cochrane review, they found that antiviral agents such as oseltamivir (Tamiflu, Roche) and zanamivir (Relenza, GlaxoSmithKline) had only a modest effect and that the evidence for their benefits and risks was limited.

The data did suggest that neuraminidase inhibitors could reduce the symptoms of influenza by approximately one day when they were taken within 48 hours of flu onset. However, their effectiveness against complications of influenza remains unclear. Moreover, because these medications do not prevent infection or stop nasal viral excretion, they could be considered a suboptimal means of interrupting viral spread in a pandemic and should be considered as only part of a strategy.

Evidence of serious adverse events is also lacking, the researchers say. They focused their analysis on oseltamivir because of their considerably greater global experience with the drug. Oseltamivir mainly causes nausea, but there have been rare reports of more serious effects, including hallucinations.

Source: BMJ 2009;339:b5106

Ivabradine Improves Diabetes and Angina

Patients with diabetes and stable angina pectoris who have been relying on beta blockers may have another choice: ivabradine, a selective I(f) inhibitor. Drawing on data from eight multicenter trials involving 535 patients with diabetes and 2,372 without, researchers found that the pharmacokinetics of ivabradine did not differ between the two groups.

Both groups experienced similar reductions in the heart rate at rest—a decrease of 15% in diabetic patients and a decrease of 15.7% in nondiabetic patients. Improvements in most exercise tolerance measures were also similar.

The researchers noted no special safety concerns for patients with diabetes. The patients did not have higher rates of sinus bradycardia or visual disturbances, which are known to be related to the action of ivabradine, and ivabradine was not associated with adverse effects on glucose metabolism.

Beta-blocker therapy can reduce both insulin secretion and sensitivity to insulin and may raise blood glucose and glycosylated hemoglobin (HbA1c) levels, even though those adverse effects might be less severe or absent with some adrenergic blockers such as carvedilol (Coreg, GlaxoSmithKline).

Source: Am J Cardiol 2010;105:29–35

RESEARCH NEWS

More Evidence Shows That HRT Raises Risk Of Heart Disease

A re-analysis of the Women’s Health Initiative (WHI) has confirmed that estrogen/progestin combination hormone replacement therapy (HRT) increases the risk of heart disease in healthy postmenopausal women, especially during the first two years of treatment.

The trend was noted among patients who began therapy within 10 years of menopause and among those who began HRT more than 10 years after menopause.

Overall, the risk more than doubled within the first two years of taking HRT. The difference in the initial level of risk did not appear to be related to age. The new findings do not apply to women who have had a hysterectomy and who take estrogen-only HRT.

Most women who take HRT for menopausal symptoms begin treatment shortly after menopause, but even these women appeared to be at increased risk of heart disease for several years after starting the therapy. These findings continue to support the FDA’s recommendations that postmenopausal HRT not be used to prevent heart disease.

Researchers from Harvard and the National Institutes of Health re-analyzed data from the landmark WHI trial involving postmenopausal women with an intact uterus and compared findings with similar analyses in the Nurses Health Study.

The new analyses showed women who started HRT less than 10 years after menopause remained at an increased risk of heart disease for about six years. After this point, they appeared to have a lower risk compared with similar women not receiving HRT. In the Nurses study, the initially higher risk with combination HRT changed toward a lower risk after about three years.

Women who started HRT 10 years or more after menopause were nearly three times more likely to develop heart disease within the first two years of therapy than women receiving placebo. They remained at increased risk throughout the eight years of follow-up.

It is not clear why the risk seemed to be higher for patients who began HRT a decade after menopause than for patients who began HRT within 10 years after menopause. The risk may depend on when women start HRT and how long they continue.


Sources:

“Ivabradine Improves Diabetes and Angina”

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Amyloid May Predict Alzheimer’s Disease in People With Normal Cognition

Abnormal deposits of a sticky protein called beta-amyloid appear to be associated with an increased risk of Alzheimer’s disease (AD). Researchers at Washington University in St. Louis have found a link between higher amounts of protein deposits, a greater risk of AD, loss of brain volume, and a decline in cognitive ability—even for people without cognitive impairment.

Previous studies had suggested that the pathology of AD, a progressive brain disorder, causes changes to the brain many years before memory loss, confusion, and other symptoms are apparent. New evidence suggests that the beta-amyloid, if present in the brains of cognitively normal persons, might be a preclinical sign of disease and that it might be present in the brain even in people without symptoms of AD. Previously, the link between beta-amyloid load and AD could be confirmed only at autopsy.

The investigators used positron emission tomography with a radioactive form of Pittsburgh compound B (PiB), an agent developed to detect levels of beta-amyloid protein in the living brain. Magnetic resonance imaging was used to measure brain volume, and tests of memory and thinking were conducted.

Between 2004 and 2008, researchers used PiB scans to track 159 volunteers, who started the study with no signs of cognitive impairment. Over time, 23 participants experienced mild impairment, and AD was eventually diagnosed in nine patients. Compared with participants who remained cognitively normal, the nine patients with AD had high levels of PiB binding in the brain and experienced cognitive decline as well as volume loss in the parahippocampal gyrus, which controls memory. However, not every person with beta-amyloid deposits experienced cognitive impairment. Beta-amyloid deposition may be a risk factor for AD, but its presence is not diagnostic.

In 135 cognitively normal older adults ranging from 65 to 88 years of age, the level of beta-amyloid, as measured by PiB binding, correlated with atrophy in many parts of the brain and to declines in memory and thinking over many years. More study is needed in larger groups of patients for longer periods, but these trials seem to confirm the value of detecting and measuring amyloid early.

Sources: Arch Neurol online and NIH, December 14, 2009

DEVICES IN THE NEWS

Recalls

Cracked Catheters

ev3 Endovascular, Inc., and the FDA have notified health care professionals of a class I recall of the Trailblazer Support Catheter. If the catheter cracks near the radiopaque marker band, serious patient injury may result, including an insufficient oxygen supply to the tissues, damage to blood vessels, heart attacks, limb amputation, unplanned surgery, or death. The device was manufactured from September 11, 2009, through September 29, 2009, and was distributed from September 21, 2009, through October 27, 2009.

Affected model numbers start with SC- and end in 014-135, 018-090, 035-065, 035-135, 014-150, 018-150, 035-090, and 035-150. Lot numbers include 828282, 7792290, 7792584, 7805570, 7805797, 7806392, 7820252, 7790666, 7791887, 7800327, 7835331, 7822490, 7822593, 7800446, 7800555, 7800756, 7800779, 7800809, 7801822, 7801875, 7803305, 7803306, 7820273, 7834779, 7834845, 7824905, and 7832205.

Sources: FDA, January 5, 2010

Luer and Nexiva Devices

Becton Dickinson and Co. has expanded its recall of catheters because of a manufacturing problem that might cause potentially fatal embolisms or blood leakage. The company is recalling lots of its Q-Syte Luer Access Devices and Nexiva Closed IV Catheter Systems. The initial recall started October 28, 2009, and the original cause of the problem has been corrected.

Source: FDA, February 8, 2010; Associated Press.

Update: Excess CT Exposure

In December 2009, P&T reported on the problem of overexposure to radiation from computed tomography (CT) perfusion scans. The FDA has identified at least 50 additional patients who were exposed to excess radiation of up to eight times the expected level during their scan. So far, a few manufacturers of CT scanners are involved. Some patients reported hair loss or skin redness following the procedure. High doses of radiation can cause cataracts and may increase the risk of some forms of cancer.

The FDA is recommending that if more than one study is performed for a patient during one imaging session, the dose should be adjusted for each study.

Source: FDA, December 8, 2010

Reducing Exposure From Medical Imaging

The FDA has announced a program to reduce unnecessary radiation exposure from CT scans, nuclear medicine studies, and fluoroscopy. These procedures are the greatest contributors to total radiation exposure within the U.S., and they emit much higher radiation doses compared with standard x-rays, dental x-rays, and mammography. As an example, the radiation dose associated with a CT abdominal scan is the same as the dose from 400 chest x-rays. A dental X-ray contains approximately 50% of the radiation dose of a chest x-ray.
Imaging has led to early diagnosis of disease and improved treatment planning. However, ionizing radiation can increase a person’s lifetime cancer risk. Accidental exposure to high amounts of radiation also can cause skin burns, hair loss, and cataracts. Over the past 20 years, the amount of radiation that Americans receive from medical imaging has dramatically increased. Experts may disagree about the extent of the cancer risk from imaging, but most agree that steps should be taken to reduce unnecessary radiation exposure.

The FDA wants to require manufacturers of CT and fluoroscopic devices to justify each procedure, use the most appropriate radiation doses, incorporate safeguards into the design of their machines, and provide appropriate training to support safe use by practitioners. The agency is scheduled to hold a public meeting on March 30 and 31, 2010.

Source: FDA, February 11, 2010

### NEW MEDICAL DEVICES

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

**Name:** Assure Platinum Blood Glucose Monitoring System  
**Manufacturer:** Arkray, Inc., Edina, Minn.  
**Approval Date:** December 14, 2009  
**Purpose:** This blood glucose meter is designed for diabetic patients in long-term care and multiresident use settings. They are backed by the Assure Brilliance program, which provides customer service, on-site training, guidance for quality assurance and quality control, diabetes advice, a quarterly newsletter, and online continuing education programs. The meters should help facilities meet state regulatory standards and provide improved resident care.

**Description:** As the first auto-code Assure brand blood glucose meter, this product exceeds newly approved heightened standards proposed by the FDA. The glucose oxidase strip chemistry is not subject to interference than can affect glucose dehydrogenase–pyrroloquinoline quinone (GDH–PQQ) systems. Such interference might cause falsely high results in patients with diabetes who are exposed to peritoneal dialysis solutions that contain icodextrin or maltose.

**Benefit:** Auto-coding eliminates the need for manual coding, thus helping to reduce user errors and provide more consistent, accurate results.

**Source:** www.assureusa.com

**Name:** Aromahaler Nasal SoftStrips  
**Manufacturer:** Clerisy Corp., Rochester, N.Y.  
**Approval Date:** December 22, 2009  
**Use Classification:** Initially, two types of SoftStrips will be available: a peppermint blend to curb appetite and a lavender blend to promote relaxation and provide relief from stress and tension.

**Purpose:** This FDA-approved medical delivery device is designed to provide an effective and natural means to improve health and well-being. As the product is peeled from the pad, it begins to curl in the shape of the letter U. The U-shaped strip is then fit around the septum of the nose. The patient squeezes the strip lightly so that it will stay in place, then breathes deeply through the nose for two minutes or longer.

**Description:** Vapors are released from the distilled oils and concentrated extracts that are infused on the Nasal SoftStrips. The vapors rapidly interact with the proper receptors in the patient’s nasal cavity, triggering nerve signals to the brain.

**Benefit:** The nasal strips are easy to apply, and no adhesives are needed for the strip to stay in place. Both products contain blends of natural ingredients that help to promote satiety and relaxation.

**Source:** http://nasalsoftstrips.com/products_appetite_control.html

### NEW DRUGS

**Name:** Melody Transcatheter Pulmonary Valve  
**Manufacturer:** Medtronic Corp., Minneapolis, Minn.  
**Approval Date:** January 27, 2010  
**Purpose:** The Melody valve replaces the pulmonary valve in patients born with a heart defect. The defect causes disruption of the blood flow from the heart’s right ventricle to the pulmonary artery. Patients with this defect typically require several open-heart surgical procedures to replace the cardiac valves.

**Description:** The device is implanted through a small catheter. The heart valve is attached to a stent that functions as an artificial pulmonary valve for patients with pulmonary valve conduits that have failed. The Melody valve was specifically designed for delivery to the cardiovascular system in a catheter. In clinical studies from the U.S. and Europe, the valve improved heart function and most participants noted improvements in their symptoms.

The valve was approved under the FDA’s Humanitarian Device Exemption program and is expected to be implanted in fewer than 1,000 patients in the U.S. each year. Medtronic will be required to conduct post-approval studies to assess the product’s long-term risks and benefits. The company must also evaluate a physician-training program and maintain a database of Melody valve recipients.

**Benefit:** This is the first heart valve approved in the U.S. that can be implanted without open-heart surgery. The valve may be able to delay the need for open-heart surgery, reduce the number of operations, and permit a less invasive procedure. However, it does not completely eliminate the need for open-heart surgery and does not cure the heart condition. Over time, it may need to be replaced.

**Sources:** The Wall Street Journal, January 26, 2010; www.medtronic.com/melody/index.html