**NEW DRUGS**

**Onglyza for Type-2 Diabetes**

Bristol-Myers Squibb and AstraZeneca have announced the FDA’s approval of saxagliptin (Onglyza), a dipeptidyl peptidase-4 (DPP-4) inhibitor, as an adjunct to diet and exercise to improve glycemic control in adults with type-2 diabetes mellitus. DPP-4 inhibitors stimulate the pancreas to make more insulin after meals. Merck’s Januvia is the only other DPP-4 inhibitor on the market.

Taken once daily, saxagliptin can be used alone or with other oral antidiabetic drugs, such as metformin, sulfonylureas, or thiazolidinediones (TZDs). It should not be prescribed for patients with type-1 diabetes or diabetic ketoacidosis.

When saxagliptin is administered with strong cytochrome P450 3A4 and 3A5 inhibitors such as ketoconazole (Nizoral, Janssen), the dose should be limited to 2.5 mg. No dose adjustments are required based on sex, race, weight, or hepatic impairment.

Sources: FDA, July 31, 2009; Fierce-Biotech, August 3, 2009

**New Statin: Livalo For Lipid Disorders**

The FDA has approved the 4-mg maximum dose of pitavastatin (Livalo, Kowa), which is designed to improve blood cholesterol levels. Like other statins, this agent is indicated when diet and exercise fail to lower cholesterol levels.

Pitavastatin was approved on the basis of the primary tumor. It is also used in the treatment of advanced colorectal cancer. Hospira will initially offer the injection in 50-mg and 100-mg single-use vials.

Source: Hospira, August 11, 2009

**Extavia for Relapsing Multiple Sclerosis**

The FDA has approved Extavia (interferon beta-1b) to reduce the frequency of exacerbations in patients with relapsing forms of multiple sclerosis (MS). Developed by Novartis, Extavia is also indicated for patients who have experienced a first clinical episode of MS and who have features consistent with the disease, as shown by magnetic resonance imaging (MRI).

Along with their prescription for Extavia, patients will be given access to a support program, a nurse help line, one-on-one injection training, and an auto-injector from Novartis.

Extavia is the same medicinal product as Betaseron (Bayer/Schering). It is available in January 2010.

Source: Zogenix, August 3, 2009

**Sumavel DosePro For Migraine and Headache**

Zogenix and Astellas US have agreed to co-promote sumatriptan injection (Sumavel DosePro) for the acute treatment of migraine attacks, with or without aura, and the acute treatment of cluster headache episodes. This subcutaneous needle-free delivery system provides relief within 10 minutes for some patients.

Sumavel DosePro is not intended for the prophylactic therapy of migraine or for hemiplegic or basilar migraine, and it should not be given intravenously. If a patient does not respond to the first dose, the diagnosis of migraine or cluster headache should be reconsidered before a second dose is given.

This medication should be used only when a clear diagnosis of migraine or cluster headache has been established, and it is not intended for patients with ischemic heart disease, cerebrovascular syndromes, peripheral vascular disease, or uncontrolled hypertension.

Sumavel DosePro is expected to be available in January 2010.

Source: Zogenix, August 3, 2009

**Eloxatin Injection for Colon Cancer**

Hospira, Inc., has announced the FDA’s approval of oxaliplatin injection in the U.S. The medication is a generic version of Eloxatin (Sanofi-Aventis). This is one of the first generic versions of this drug to be sold in solution form. The brand-name drug is also available as a solution.

Used in combination with infusional 5-fluorouracil/leucovorin, this product is indicated for the adjuvant treatment of stage III colon cancer in patients who have undergone complete resection of the primary tumor. It is also used in the treatment of advanced colorectal cancer.

Source: Hospira, August 11, 2009

**Generic Approvals**

**Toprol XL 25 and 50 mg For Vascular Disease**

Watson Laboratories has received approval for its Abbreviated New Drug Applications (ANDAs) for metoprolol succinate extended-release 25-mg and 50-mg tablets. These are the generic equivalent of AstraZeneca’s Toprol XL tablets. This beta blocker is used to treat angina, heart failure, and hypertension.

Source: Watson Pharmaceuticals, August 7, 2009

**Saphris for Schizophrenia And Bipolar Disorder**

Asenapine tablets (Saphris, Schering-Plough) have been approved to treat both schizophrenia and bipolar I disorder in adults.

A boxed warning is included to alert prescribers about an increased risk of death associated with the off-label use of this atypical antipsychotic medication for treating behavioral problems in older people with dementia-related psychosis. Asenapine is not approved for these patients.

In various trials, asenapine showed superior efficacy, compared with placebo, in reducing symptoms of schizophrenia and bipolar disorder.

Source: FDA, August 14, 2009

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Source: FDA, August 14, 2009
Sabril for Infantile Seizures
The FDA has granted two New Drug Application (NDA) approvals for vigabatrin tablets and oral solution (Sabril, H. Lundbeck) to treat infantile spasms in children from one month to two years of age. Sabril is the first drug in the U.S. indicated for this severe type of seizure, which usually appears in the first year of life.

The tablets have been approved for adults in combination with other medications to treat complex partial seizures that have not responded adequately to previous drug therapies.

Damage to vision is an important safety concern. A boxed warning will be included to alert health care professionals to the risk of a progressive loss of peripheral vision with a potential decrease in visual acuity. Even the lowest doses can cause vision damage. The drug will be available only through a restricted distribution program.

Sabril was designated as an orphan drug for use in treating infantile spasms.
Source: FDA, August 21, 2009

Accelerated Approval Of Hiberix Vaccine
The FDA has approved GlaxoSmithKline’s Hiberix vaccine, as a booster dose for children 15 months through 4 years old, to help ensure an adequate supply.

A nationwide shortage of this Haemophilus influenzae type b (Hib) vaccine began in December 2007 because of a voluntary recall of PedvaxHib and Comvax, both made by Merck. This short-age resulted in a recommendation by the Centers for Disease Control and Prevention (CDC) to temporarily defer the Hib vaccine booster dose for children who were not at high risk for infection until the vaccine supply could be restored. This deferral lasted from December 18, 2007, through June 25, 2009.

Although the current vaccine supply is sufficient to reinstate the booster dose and to begin catch-up vaccination, it is not yet ample enough to support a mass vaccination of all children whose boosters were deferred.

Hiberix is available in nearly 100 countries.
Source: FDA, August 19, 2009

NEW FORMULATION
Once-Monthly Invega Injection for Schizophrenia
Paliperidone palmitate (Invega Sustenna) extended-release injectable suspension has been approved for the acute and maintenance treatment of schizophrenia in adults. This is the first once-monthly, long-acting, injectable atypical antipsychotic agent approved in the U.S. for this use. Janssen will market the product in the U.S.

In various studies, Invega Sustenna has been found to be superior to placebo in delaying the time to relapse.

The ready-to-use intramuscular (IM) depot formulation can be administered by health care professionals. Elan’s NanoCrystal technology provides consistent medication coverage for one month and offers the potential to improve compliance for schizophrenic patients. Invega Sustenna is not approved for elderly patients with dementia-related psychosis.

Paliperidone, in the form of once-daily, extended-release tablets (Invega), was approved in 2007.
Sources: The Medical News and Elan Drug Technologies, August 2, 2009

Cancer Warnings Required For Anti-inflammatory Drugs
The FDA is requiring stronger warnings in the prescribing information for tumor necrosis factor (TNF) blockers. An updated boxed warning highlights the increased risk of cancer in children and adolescents who receive these drugs to treat juvenile rheumatoid arthritis, inflammatory bowel disorder, Crohn’s disease, and other inflammatory disorders.

TNF antagonists neutralize TNF-α, a protein that is overproduced in the body as a result of chronic inflammatory disease. TNF-α can cause damage to bones, cartilage, and tissue. The drugs in this class include infliximab (Remicade, Centocor Ortho Biotech Inc.), etanercept (Enbrel, Amgen/Wyeth), adalimumab (Humira, Abbott), certolizumab pegol (Cimzia, UCB), and golimumab (Simponi, Centocor Ortho Biotech Inc.).

The updated prescribing information will also mention reports of psoriasis associated with the use of TNF blockers.
Source: FDA, August 5, 2009

Adverse Effects from Xolair
New preliminary data suggest that the asthma medication omalizumab (Xolair, Genentech/Novartis) might cause heart attacks, strokes, and other serious problems. However, the FDA recommends that patients continue taking the drug as directed.

A study by Genentech tracked the safety of the drug over five years. The FDA suggests that some of the 5,000 patients enrolled might have been predisposed to irregular heart rhythms, hypertension, and other cardiac conditions. Final results are not expected until 2012.

Omalizumab was first approved in the U.S. in 2003 for adults and children older than 12 with moderate-to-severe asthma that is not controlled with inhalers.
Source: Associated Press, July 16, 2009
Treatment Protocol for Patients with Gaucher Disease

Protalix BioTherapeutics, Inc., has announced the approval of a protocol for prGCD, a proprietary plant-cell expressed recombinant form of glucocerebrosidase (GCD) for the treatment of patients with Gaucher disease. This rare and serious lysosomal storage disorder is characterized by debilitating symptoms.

The protocol allows patients to be treated in the U.S. and in other countries while studies of prGCD continue as part of the company’s ongoing pivotal phase 3 clinical trial. The multicenter, open-label trial is designed so that patients can receive prGCD during the expected shortage of Genzyme’s imiglucerase (Cerezyme) and thereafter. Cerezyme is the only enzyme replacement therapy currently approved for Gaucher disease.

Enrolled patients may continue to receive prGCD until it is approved by the FDA. Protalix will provide the drug free of charge to these patients. The company plans to file a New Drug Application by the end of this year.

Source: Protalix, August 18, 2009

Survey: Many Doctors Not Recommending HPV Vaccine For Young Girls

A recent survey shows that more than 50% of Texas physicians are not following the recommendations of the Advisory Committee on Immunization Practices—that all 11- and 12-year-old girls receive the quadrivalent human papillomavirus (HPV) vaccine. The vaccine was approved in 2006.

Of the respondents, 48.5% said that they always recommended the HPV vaccine to girls, 68.4% said they were likely to recommend the vaccine to boys, and 41.7% agreed with mandated vaccination.

Respondents in academic practices and those who considered professional organizations or conferences an important source of information were much more likely to recommend the vaccine.

Although the study population was limited to Texas, these views could be representative of physicians’ viewpoints elsewhere in the U.S. Nationally, vaccine rates for 11- to 12-year-old girls are between 6% and 25%. The researchers suggest that physicians receive further education about the vaccine.

Source: Cancer Epidemiol Biomarkers Prevent 2009;18:2325–2332

Warning Letters: Ibuprofen Topical Drugs

The FDA has warned eight companies about their marketing of unapproved over-the-counter topical agents containing the pain reliever ibuprofen. The letters advise the companies that they may not continue to market their products without FDA approval.

Orally administered ibuprofen has been approved as safe and effective for pain and inflammation, but there are no approved applications for topical ibuprofen. The topical form is often promoted as a safer alternative to oral ibuprofen.

The products are Emuprofen (Progressive Emu), BioEntopic 15% Ibuprofen Crème (BioCentric), IbuNex Topical Ibuprofen (Core), LoPain AF 15% Ibuprofen Crème (Geromatrix), IB-Relief (Mekt), Profen HP (Ridge), IbuPro-10 Plus (Meditrend, Inc., dba Progena Professional Formulations), and Ibu-Relief 12 (Wonder).

Source: FDA, August 20, 2009

Anticoagulation with Warfarin Safe for Some, Not for Others

The American College of Chest Physicians guidelines recommend anticoagulation with warfarin (Coumadin, Bristol-Myers Squibb) for patients with atrial fibrillation who are 75 years of age or older. But as many as 50% of patients might not be getting the anticoagulation they need to prevent a stroke.

Researchers from Montefiore Medical Center say that this low rate might be a result of physicians’ perceptions about bleeding risk, falls, and the need for frequent laboratory monitoring and dosage adjustments. They conducted a retrospective study to determine how war-
farin or acetylsalicylic acid was being used in patients at risk for stroke and hemorrhage, including those with a history of falls or dementia.

Looking at a year’s worth of information on 106 patients, the researchers assessed the prevalence of stroke, hemorrhage, and falls and the possible effects of anticoagulation in dementia. Ninety patients were receiving warfarin, and 16 were taking aspirin.

At 12 months, two of the 90 patients receiving warfarin had a stroke; five patients had major hemorrhage, and 18 had died. Five of 11 patients (45%) with a history of falls and eight of 17 patients (47%) who had dementia died, compared with eight of 65 patients (12%) who had no history of falls or dementia. However, it was unclear whether the higher mortality rate among warfarin patients with falls was a result of risk factors underlying a propensity to fall, atrial fibrillation, or warfarin use. In warfarin patients with falls who survived, the prevalence of stroke and major hemorrhage was not significantly higher compared with that for patients not treated with warfarin. The data suggest that older adults should be carefully screened for falls as part of the decision-making process about anticoagulation.

The coordination and monitoring in the study might have limited the variability in International Normalized Ratio that can result from polypharmacy, drug interactions, and confusion regarding dose alterations. Ultimately, the debate comes down to quality of life versus reducing the risk of stroke and hemorrhage.

Source: Am J Geriatr Pharmacother 2009;7;159–166

Add-on Heparin Therapy: A Risk of Overanticoagulation

Adding unfractionated heparin (UFH) to standard therapy with enoxaparin (Lovenox, Sanofi-Aventis) may lead to excessive anticoagulation and should be avoided, according to the STACKENOX (Stack-on to Enoxaparin) study. An additional intravenous (IV) bolus of UFH resulted in complete inhibition of thrombin generation, even when it was given up to 10 hours after the last enoxaparin dose. Moreover, tests commonly used to monitor UFH anticoagulation, such as activated clotting time (ACT), do not detect the potential overanticoagulation that results from the stack-on therapy.

Seventy-two healthy subjects were given subcutaneous enoxaparin for 2.5 days and were randomly selected to receive a 70-IU/kg UFH bolus four, six, or 10 hours after the final enoxaparin dose. Endogenous thrombin potential levels subsequently dropped by 40%. As expected, anti-Xa and anti-IIa activities increased; however, ACT levels did not indicate any anticoagulation effect. Stack-on UFH at any time point significantly increased anti-Xa and anti-IIa activities to well above accepted therapeutic levels and totally inhibited thrombin generation for more than two hours.

ACT levels remained within the range commonly observed in subjects receiving UFH and poorly predicted the cumulative effects of enoxaparin and UFH, the researchers say. The data suggest that ACT measurements, although commonly used to monitor anticoagulation in patients undergoing percutaneous coronary intervention (PCI), might not be appropriate for evaluating the coadministration of enoxaparin and UFH.

The study results also have important implications for the interpretation of recent trials. In one study, the authors reported that bleeding rates were higher in patients receiving add-on therapy. In light of the STACKENOX study, that might have been the result of prolonged, excessive anticoagulation concentrations in patients who had already received full anticoagulation therapy with enoxaparin.

Source: Am Heart J 2009;158:177–184

Lack of Awareness Of Hypoglycemia In Type-1 Diabetes

Patients with type-1 diabetes who are unaware that they are hypoglycemic may have a five-fold increased risk of severely reduced glucose concentrations. Yet hypoglycemia awareness can be restored if patients can switch to and stick with a different insulin regimen. In general, however, these patients are less adherent to agreed-on changes in insulin therapy, even with more clinic visits, compared with patients who are hypoglycemia-aware.

In a study of 90 patients, investigators from King’s College London School of Medicine identified 31 patients as aware of their hypoglycemia and 19 patients as hypoglycemia-unaware. Only 50% of the hypoglycemia-unaware patients were adherent to therapy, compared with 87% of hypoglycemia-aware patients.

Failure to perceive a situation as unpleasant or dangerous undermines motivation and the ability to change behavior. In this study, about half of the patients with hypoglycemia unawareness had been in a structured education program that both reduced severe hypoglycemia rates and restored hypoglycemia awareness. The researchers concluded that it might be a good idea to include behavioral strategies that address habitual behavior.

Source: Diabetes Care 2009;32:1196–1198

Alcohol, Ethnicity, And HIV Treatment

Alcohol, race, and ethnicity all play complicated roles in lipid-profile changes in patients taking highly active antiretroviral therapy (HAART), according to researchers from Florida International University in Miami. HAART is already continued on page 479
continued from page 472

known to cause dyslipidemia in 40% to 80% of patients.

A longitudinal study of 88 “hazardous” and 76 “nonhazardous” drinkers reveals some differences that underscore the importance of tailoring treatment.

At a baseline evaluation, Caucasian and Hispanic patients had the most adverse lipid profiles, whereas African-American patients had the fewest atherogenic factors. Cholesterol levels increased more in the Caucasian patients (by 11%) and in Hispanic patients (by 6%), as did triglycerides (by 40% in Caucasians and by 24% in Hispanic patients). The rise in LDL was highest in the Hispanic hazardous drinkers and at least double that of any other group.

After the researchers adjusted for age, CD4 cell count, and dietary intake, Hispanic patients who were drinkers and who were receiving HAART had a doubled risk of hypertriglyceridemia; Caucasian drinkers had 1.5 times the risk. Heavy drinkers (having more than 30 drinks per week) had the highest risk.

The authors concluded that race and alcohol were independent risk factors for lipoprotein disturbances in HIV-infected patients, and they urged caution when prescribing HAART regimens containing protease inhibitors for certain Hispanic and Caucasian hazardous alcohol users.

The Urban Ministry defines hazardous drinking as consuming 21 or more drinks per week for men and 14 or more drinks per week for women (amounts that place individuals at risk for adverse health effects). The World Health Organization and the American Medical Association define hazardous drinking as any alcohol consumption that confers the risk of physical or psychological harm. “Harmful” drinking results in adverse events.

Sources: J Assoc Nurses AIDS Care 2009;20(3):176–183; About.com: Alco-

holism; Arch Intern Med, http://arch-
inte.ama-assn.org; www.urbanministry.

org

RESEARCH NEWS
Slow ing Ovarian Tumor Growth
With Diphtheria Toxin DNA

A new technique for reducing the burden of ovarian tumors in mice might be available for testing in humans within 18 to 24 months.

Although early-stage ovarian cancer sometimes responds to surgery followed by chemotherapy, there are no effective treatments for advanced ovarian cancer that has recurred after surgery and primary chemotherapy. Therefore, most treated early-stage cancers recur.

Colleagues at the Massachusetts Institute of Technology evaluated the efficacy of a polymer as a vector for the nanoparticle delivery of a DNA-encoding diphtheria toxin suicide gene. These nanoparticles were injected into mice with primary or metastatic ovarian tumors.

Measuring tumor volume before and after treatment, the researchers found that although treated tumors increased in size by two-fold, the control mice experienced a 4.1-fold to six-fold increase.

Four of the treated tumors did not grow at all, but all control tumors increased in size. Giving nanoparticles to three different ovarian cancer mouse models prolonged life spans by almost four weeks and suppressed tumor growth more effectively, and with minimal non-specific cytotoxicity, compared with mice receiving clinically relevant doses of cisplatin (Platinol) and paclitaxel (Taxol, Bristol-Myers Squibb).

Of prime importance is the need for the therapy to be able to reach the target. A major accomplishment of this research is the delivery of diphtheria toxin genes to the actual tumor site (the peritoneum).

Source: Cancer Res, August 1, 2009

NIH NEWS
New NIH Director:
Dr. Francis S. Collins

Francis S. Collins, MD, PhD, has become the 16th director of the National Institutes of Health (NIH). Nominated by President Barack Obama on July 8, he was unanimously confirmed by the Senate on August 7. Raynard S. Kington, MD, PhD, who was acting NIH director since mid-October, will return to his role as NIH principal deputy director.

Dr. Collins, 59, is a physician–geneticist noted for his landmark discoveries of disease genes and his leadership of the Human Genome Project. He served as director of NIH’s National Human Genome Research Institute from 1993 to 2008, which culminated in April 2003 with the completion of a finished sequence of the human DNA instruction book. His own laboratory discovered genes responsible for cystic fibrosis, neurofibromatosis, Huntington’s disease, a familial endocrine cancer syndrome, and genes for type-2 diabetes and the gene that causes Hutchinson–Gilford progeria syndrome.

Awarded the Presidential Medal of Freedom in November 2007, he is an elected member of the Institute of Medicine and the National Academy of Sciences. His books include The Language of God: A Scientist Presents Evidence for Belief and The Language of Life: DNA and the Revolution in Personalized Medicine (to be published in early 2010).

Source: www.nih.gov, August 17, 2009

Pulmonary Hypertension Study Halted

On July 7, the National Heart, Lung, and Blood Institute stopped a clinical trial that was testing a drug treatment for pulmonary hypertension (PH) in adults with sickle cell disease. The trial was discontinued almost one year early.

Compared with participants receiving placebo, participants taking sildenafil
(Revatio, Pfizer) were more likely to have serious medical problems, namely episodes of severe pain (sickle cell crises), which resulted in hospitalization. No deaths were associated with sildenafil in the clinical trial.

Sildenafil is approved for patients with PH. The drug helps to relax the blood vessels in the lungs to allow blood to flow more easily.

The walk-PHaSST study was the first multicenter, randomized clinical trial to test the safety and effectiveness of sildenafil for PH in patients with sickle cell disease. PH is a debilitating condition that can lead to heart failure and death. Approximately 30% of patients with sickle cell disease develop PH, and even mild levels of PH have been associated with sudden death in people with sickle cell disease.

The medical problems experienced in this trial were complications that were specific to sickle cell disease. Participants have been instructed to taper sildenafil treatment over a period of three to seven days to minimize problems associated with immediate withdrawal from the drug, such as worsening of symptoms of PH.

Researchers will continue to monitor participants.

Source: NIH, July 28, 2009

NEW MEDICAL DEVICES

Marvin M. Goldenberg, PhD, RPh, MS

Name: Taxus Liberté Atom (2.25 mm) Paclitaxel-Eluting Coronary Stent System (Monorail and Over-the-Wire Delivery Systems)

Manufacturer: Boston Scientific Corp., Maple Grove, Minn.

Approval Date: June 29, 2009

Use Classification: This drug-coated stent is used in patients with narrowed coronary arteries resulting from atherosclerosis.

Description: The Taxus stent contains paclitaxel (Taxol, Bristol-Myers Squibb) within a thin polymer coating on its surface. With the stent remaining permanently implanted within the coronary artery, the medication is released into the artery wall around the stent to help prevent restenosis.

Purpose: Expansion of the stent within the narrowed coronary artery allows more blood flow to the heart. After stent implantation, restenosis of the artery can occur as a result of overgrowth of normal tissue during the healing process. Paclitaxel is added to limit the overgrowth of normal tissue.

Benefit: The stent helps to prevent restenosis in the coronary arteries.

Contraindications: This stent is not indicated for patients who cannot take aspirin or anticoagulants; who are allergic to the metal in the stent, paclitaxel, or the polymers coating the stent; or who have a blocked coronary artery that prevents proper stent placement.

Source: www.fda.gov

Name: Calmare Therapy Treatment (Calmare TT)

Manufacturer: Competitive Technologies, Inc., Fairfield, Conn.

Approval Date: July 1, 2009

Use Classification: Calmare TT provides noninvasive pain relief.

Description: A biophysical, rather than a biochemical, approach is used to decrease pain. Surface electrodes are applied to the skin to provide electronic nerve stimulation. A passive means is used to convey a message of “normality” to the central nervous system (CNS). The procedure scrambles this information to the CNS, which can then modify the reflex adaptive response.

Purpose: This device offers quick relief to patients with extreme pain who have not responded to standard therapeutic protocols, including potent opioids.

Benefit: This therapy is used to treat intense pain without the harmful side effects of narcotic medications. Unlike most drugs, Calmare TT can be used on a continuing basis to steadily diminish the intensity of the pain.

Sources: www.calmare.competitive tech.net; http://biz.yahoo.com

Name: Xpert C. difficile Test

Manufacturer: Cepheid, Sunnyvale, Calif.

FDA Approval Date: July 13, 2009

Use Classification: This molecular diagnostic test is used to detect the bacterium that causes Clostridium difficile infection. A spore-forming bacterium, C. difficile is now challenging methicillin-resistant Staphylococcus aureus (MRSA) as the most prevalent health care–associated infection in the U.S. Each day, more than 7,000 patients in the U.S. have this infection, and approximately 300 patients with C. difficile infection die each day. The disease, which can cause mild to severe diarrhea, pseudomembranous colitis, toxic megacolon, sepsis, and death, is costing health care institutions up to $51.5 million daily.

Description: This test is designed to purify, concentrate, and detect nucleic acid sequences, delivering results directly from unprocessed samples. The closed, self-contained, automated platform can produce accurate results with a minimal risk of contamination.

Purpose: The Xpert test identifies the organism that causes C. difficile infection. Toxigenic culture offers high sensitivity, but laboratories find it burdensome and too slow for practical diagnostic use. Instead, many use less labor-intensive toxin enzyme immunoassay and glutamate dehydrogenase tests, which fail to detect 20% to 50% of cases of C. difficile infection. Thus, proper isolation procedures that could curtail transmission of the organism are lacking for many patients.

Sources: www.calmare.competitive tech.net; http://biz.yahoo.com
**Benefit**: Results are delivered in just 45 minutes, and repetitive steps are eliminated. This advance should aid physicians in implementing appropriate treatment and infection-control measures.

**Sources**: www.cepheid.com

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**Device Recalls**

**Infusion sets.** Medtronic has initiated a recall of specific lots of Quick-set infusion sets that are used with MiniMed Paradigm insulin pumps. The infusion set is used to deliver insulin and is typically replaced by the patient every three days. Affected sets include MMT-396, MMT-397, MMT-398, and MMT-399. Approximately 2% of Lot 8 sets (about 60,000 of three million sets currently with customers) might not allow the insulin pump to vent air pressure properly. This defect can result in the delivery of too much or too little insulin and may lead to serious injury or death.

Patients should stop using these Lot 8 Quick-set sets. Customers should return any affected infusion sets to the company, which is providing replacement Quick-set infusion sets at no additional charge. The sets were distributed in the U.S. and in limited quantities in a few countries outside of the U.S.

**Sources**: www.medtronicdiabetes.com/lot8; www.fda.gov/Safety/Recalls/ucm171588.htm, July 10, 2009

**Catheters.** Abbott Laboratories and the FDA have notified health care professionals of a Class 1 recall of three lots of Powersail Coronary Dilatation Catheters from distribution in the U.S. and one lot from international distribution. There were four complaints that the distal shaft of the catheter was damaged. This type of damage has the potential to cause a leak of contrast material during use, which could lead to air embolism or myocardial infarction.

**Source**: www.fda.gov, July 30, 2009