New USP Standards for Heparin Products
The U.S. Food and Drug Administration (FDA) is alerting health care professionals to a change in heparin manufacturing that is expected to decrease the potency of the common blood-clotting drug. To ensure the quality of heparin and to guard against potential contamination, the United States Pharmacopeia (USP) adopted new manufacturing controls for heparin effective October 1, 2009. These changes include a modification of the reference standard for the drug’s unit dose.

The unit dose of heparin is the measure of the drug’s ability to anticoagulate, and the revised USP reference standard and unit definition for heparin is approximately 10 percent less potent than the former USP unit. U.S. market manufacturers are incorporating the new standard into heparin production and began shipping new product on October 8.

Four companies market heparin in the United States: APP, Hospira, Baxter, and B. Braun. The FDA has asked that all manufacturers identify their new products that meet the new USP manufacturing controls to help pharmacies and health care professionals differentiate it from the former product. Most manufacturers will place an “N” next to the lot number. Products manufactured by Hospira can be identified by the number “82” or higher (e.g., 83, 84) at the start of their lot numbers.

“It is essential that health care professionals be aware of the potential difference in potency between the old and new vials of heparin when administering the drug,” said John Jenkins, M.D., Director of the Office of New Drugs in the FDA’s Center for Drug Evaluation and Research.

Patients who are stabilized on heparin anticoagulation therapy in the inpatient setting and discharged to home on heparin therapy will require careful consideration by home infusion providers to ensure a safe transition of care. Home infusion pharmacists should consider taking the following steps:
• Identify the type of heparin the patient was stabilized on in the hospital: old heparin, or new heparin (approximately 10% less potent)
• Match the heparin (old vs. new) that is used in the home to that which the patient received in the hospital, or be prepared to adjust the dose of heparin the patient is receiving and re-evaluate their coagulation status via lab monitoring
For more information go to www.usp.org/hottopics/heparin.html or www.fda.gov/drugs/drugsafety.

Warning for Promethazine Injection
The FDA is telling manufacturers of promethazine to include a boxed warning regarding the injectable form of the drug in their prescribing information. The black box warning will highlight the risk of serious tissue injury when the drug, used as a sedative and to treat nausea and vomiting, is administered incorrectly.

According to the FDA, promethazine should neither be administered into an artery nor administered under the skin because of the risk of severe tissue injury, including gangrene. There is also a risk of extravasation from the vein into the surrounding tissues during peripheral intravenous administration and continued reports to the FDA of injuries caused by extravasation of this vesicant drug is what ultimately led to the black box warning. As a result of these risks, the preferred route of administration is injecting the drug deep into the muscle, which is the standard of practice among most home infusion providers. A requested revision in the Dosage and Administration section of the label states that if health care professionals choose to administer promethazine intravenously, they should limit the drug’s concentration and rate of administration and ensure a properly functioning intravenous line.
For more information, go to www.fda.gov/Drugs/DrugSafety.

Warning for Iron Dextran Injection
American Regent and the FDA notified health care professionals that anaphylactic-type reactions, including fatalities, have
followed the parenteral administration of iron dextran injection (Dexferrum®). The boxed warning has been modified to recommend observing for signs or symptoms of anaphylactic-type reactions during any administration of the drug in addition to administering a test dose prior to the first therapeutic dose.

Fatal reactions have occurred even in situations where the test dose was tolerated. Patients with a history of drug allergy or multiple drug allergies may be at increased risk of anaphylactic-type reactions. It is recommended that resuscitation equipment and personnel trained in the detection and treatment of anaphylactic-type reactions be readily available during administration.

For more information, go to www.fda.gov/Safety/MedWatch.

**Health IT Strengthens Care in Rural Areas**

Health information technology can improve health care for Americans living in rural communities, according to a report released by the U.S. Department of Health and Human Services (HHS). The report examines how the Columbia Basin Health Association in Othello, Washington uses health information technology to improve health care quality and patient safety as well as promote care coordination and continuity.

Columbia Basin Health Association (CBHA) provides 25,000 patients with access to a variety of medical, dental, prescription, and other services. CBHA was also one of the first health centers in the United States to fully transition from paper-based charts to an electronic health record (EHR) system. Since CBHA implemented EHRs, the community health center has consistently ranked above the 95th percentile nationally in total medical and dental team productivity.

Approximately 65 million Americans live in communities with shortages of primary care providers and nearly 50 million of those Americans live in rural areas. Health information technology, and specifically EHRs, can improve care for patients and assist in clinical decision making and the use of evidence-based
guidelines. Electronic health records can also decrease administrative hassle, increasing workplace satisfaction and productivity.

**College Entrepreneurs Launch IV-Friendly Clothing Line**

Three recent graduates of Miami University in Ohio have created a line of clothing that allows easy access for patients receiving IV treatments. Libre co-founders Megan Stengel, Tess Schuster, and Mandy Eckerman were seniors in the college’s entrepreneurship program.

They started with an idea to help dialysis patients by making outfits with hidden zippers on shirt sleeves that would make treatments easier and more comfortable. Stengel’s mother and Schuster’s grandfather are both on dialysis and talk about how wearing a shirt that allows IV access can sometimes present a challenge keeping warm and comfortable. Next, they put together a business plan—complete with financial data, market research, and prototypes—and began visiting dialysis patients, nurses, and nephrologists to get feedback on the product. Libre eventually won their class competition and a $1,250 prize, which provided a foundation for the business after graduation.

Libre, from the Spanish and French for “free,” launched in October offering activewear and casual styles of clothing. Button-up oxford shirts and quarter-zipped sweatshirts and sweaters are available in a variety of colors. Access zippers are on one sleeve—customers can specify which sleeve when ordering.

Libre will start by marketing its products in dialysis clinics in Ohio, northern Kentucky, and Pennsylvania. However, anyone can order the shirts online at www.libreclothing.com.

**Oley Foundation President Hikes Across Grand Canyon**

Stroke survivor, and Oley Foundation President, Rick Davis, hiked 24 miles across the Grand Canyon in October. Davis who is 66 and disabled did the hike as a fundraiser for

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the non-profit Oley Foundation, which helps thousands of persons with chronic conditions on parenteral and enteral nutrition.

Davis consumed over 4,000 calories of formula, infused through his g-tube, and stayed hydrated by infusing more than two gallons of water during the 14-hour trek. He raised more than $12,000. Donations are still being accepted at www.oley.org.

**New Regulations Designed to Protect Genetic Information**

Patients’ genetic information should have greater protections under new regulations announced on October 1 by the U.S. Departments of Health and Human Services (HHS), Labor, and the Treasury. The interim final rule will help ensure that genetic information is not used adversely in determining health care coverage and will encourage more individuals to participate in genetic testing, which can help better identify and prevent certain illnesses.

Under Title I of the Genetic Information Nondiscrimination Act of 2008 (GINA), group health plans and issuers in the group market cannot: increase premiums for the group based on the results of one enrollee’s genetic information; deny enrollment; impose pre-existing condition exclusions; or do other forms of underwriting based on genetic information.

In the individual health insurance market, GINA prohibits issuers from using genetic information to deny coverage, raise premiums, or impose pre-existing condition exclusions.

In addition, insurers in both the group and individual markets cannot request, require, or buy genetic information for underwriting purposes or prior to and in connection with enrollment and are generally prohibited from asking individuals or family members to undergo a genetic test.

To read a copy of the interim final rule, go to www.federalregister.gov/OFRUpload/OFRData/2009-22504_PI.pdf.