Recalls, warnings and label changes
A labeling change for all extended-release and long-acting (ER/LA) opioid analgesics to combat misuse and abuse of the drugs. The updated indication states that ER/LA opioids are indicated for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate, and it further clarifies that, because of the risks of addiction, abuse, and misuse, even at recommended doses, and because of the greater risks of overdose and death, these drugs should be reserved for patients for whom alternative treatment options are ineffective, not tolerated, or would be otherwise inadequate to provide sufficient management of pain. A new boxed warning will caution that chronic maternal use during pregnancy can result in neonatal opioid withdrawal syndrome. The FDA is also adding new postmarket study requirements to further assess the risks of misuse, abuse, hyperalgesia, addiction, overdose, and death.

A labeling change on fluoroquinolone drugs to better describe the serious side effect of peripheral neuropathy. The risk of peripheral neuropathy occurs only with fluoroquinolones that are taken by mouth or by injection and may occur soon after these drugs are taken and be permanent. If a patient develops symptoms of peripheral neuropathy, he or she should be switched to another antibacterial drug, unless the benefit of continued treatment with a fluoroquinolone outweighs the risk.

A recall of Iradimed Corporation, MBidium 360+ infusion systems equipped with MBidium 1145 Dose Error Reduction System (DER) Drug Library Kit because the DERs can potentially give an incorrect recommended value for the pump infusion rate during the initial infusion setup, which can result in over-infusion or under-infusion and serious adverse health consequences, including death.

A recall of certain Hospira blood sets due to customer reports of the outer wall of blood bags being punctured with the piercing pin during insertion of the pin, which may result in spillage of the blood and blood products stored in the bag and a delay or interruption in therapy. This issue has been identified as a contributing factor in one patient death.

A recall of Siemens MicroScan Synergies Plus and MicroScan RapidS/P Plus negative panels because they may report false susceptible and false intermediate results for imipenem and meropenem antimicrobial susceptibility testing when used with the MicroScan WalkAway System. This error may lead to treatment with an inappropriate antibiotic or a delay in appropriate therapy.

A recall of Hospira bupivacaine HCl injection due to reports of foreign particulates, which were identified as stainless steel and iron oxide.

A product labeling update on the Cordis Optease retrievable inferior vena cava filter to clarify a previous recall and minimize likelihood of implanting the filter backwards.

A recall of one lot of Hospira’s aminosyn II 10%, sulfate-free, 500 mL, due to 1 report of a foreign particle, which was identified as human hair.

A recall of repackaged products sent by Aidapak Services LLC to hospitals in Washington, Oregon, California and Arizona, due to possible incorrect labeling of over-the-counter, prescription and dietary supplement products. This could result in patients receiving drugs that were not prescribed, which may pose serious or life-threatening risks to a patient’s health.

A recall of certain lots of Covidien Monocent prefill flush syringes due to the risk that a number of the syringes were filled with water but not subjected to the autoclave sterilization process. These products are labeled as either sodium chloride flush or heparin lock flush and some but not all syringes have mismatched syringe tip cap, syringe label, filled volume and wrapper. This issue poses a risk of life-threatening infection or clotting.

A recall of 9 lots of carbamylmethylcellulose sodium 0.5% ophthalmic solution, 30 mL, by Altaire Pharmaceuticals, Inc., due to complaints of mold found in the bottles after use.

A recall of all lots of unexpired sterile products from Specialty Compounding, LLC, after reports of bacterial infections affecting 15 patients at two Texas hospitals. There is a potential association between the infections and the medication.

A number of recalls due to a recent unsatisfactory FDA inspection of Front Range Laboratories, which performed testing for compounding pharmacies, including:

- 2 lots of methylcobalamin 5 mg/mL, 30 mL and Multitrace-S Concentrate 10 mL for injection and 1 lot of testosterone cypionate (sesame oil) from Park Pharmacy & Compounding Center,
- 2 lots of bevacizumab and 1 lot of lidocaine/phenylephrine from Leiter’s Compounding Pharmacy,
- 6 lots of dialysis drug products from JCB Laboratories,
- certain lots of dextanephenol 250 mg/mL, magnesium sulfate 50%, methylcobalamin 0.5 mg/mL and sodium phosphate 200 mg/mL, R.L. glutathione 100 mg/mL, and ascorbic acid (ascavas) 500 mg/mL from Wellness Pharmacy,
- compounded bevacizumab 1.25 mg/mL, 0.5 mL PF and vancomycin PF (BSS) 1% from Avella Specialty Pharmacy,
- and certain sterile products from Medusa Pharmacy and University Compounding Pharmacy.

Approvals
The UroLift system, the first permanent implant to relieve low or blocked urine flow in men age 50 and older with an enlarged prostate. Approval was based on data from 2 studies of men with benign prostatic hyperplasia implanted with 2 or more UroLift sutures, in which physicians successfully inserted the device in 98% of participants, resulting in a 35% increase in urine flow, a decrease in symptoms, and an increase in quality of life. Adverse events include pain or burning during urination, blood in the urine, frequent or urgent need to urinate, incomplete emptying of the bladder, and decreased urine flow.

The Alera Determine HIV-1/2 (Ag/Ab Confirmation) test, the first rapid test for simultaneous detection of both HIV-1 antigen and HIV-1/2 antibodies in human serum, plasma, or venous or fingerstick whole blood specimens. Approved for use as an aid in the diagnosis of HIV-1 and HIV-2 infection, it is also the first FDA-approved test that independently distinguishes results for HIV-1 p24 antigen and HIV antibodies in a single test.

Dolonguvir (Tivicay) to treat HIV-1 infection. A daily pill taken with other antiretrovirals, dolonguvir is an integrase strand transfer inhibitor that interferes with one of the enzymes necessary for HIV to multiply. It is approved for use in a broad population of adult HIV patients, both treatment-naïve and treatment-experienced, including those who have been treated with other integrase strand transfer inhibitors, as well as children ages 12 years and older weighing at least 40 kg who have not previously taken other integrase strand transfer inhibitors. Common side effects include insomnia and headache. Serious side effects include hypersensitivity reactions and abnormal liver function in participants co-infected with hepatitis B or C.