October 2017

Drug Information Update

TABLE OF CONTENTS

NEWLY AVAILABLE GENERICS

GENERIC DRUG NAME	STRENGTH & DOSAGE FORM	GENERIC MANUFACTURER	BRAND NAME
ABACAVIR SULFATE	20 mg/mL SOLUTION	CAMBER PHARMACEUTICALS	ZIAGEN
FOSAMPRENAVIR CALCIUM	700 mg TABLET	MYLAN	LEXIVA
PAROXETINE MESYLATE	7.5 mg CAPSULE	SOLCO HEALTHCARE, PERRIGO CO.	BRISDELLE
SODIUM PHENYLBUTYRATE	500 mg TABLET	PAR PHARM.	BUPHENYL
DEXAMETHASONE	1.5 mg (21 tabs) TAB DS PK	XSPIRE	ZODEX
DICLOFENAC SODIUM	0.01 KIT	STERLING-KNIGHT	DICLOZOR
HYDROCORTISONE/IODOQUIN/ALOE 2	2 %-1 %-1 % GEL	SETON PHARMACEUTICALS	ALCORTIN A
GLATIRAMER ACETATE	40 mg/mL SYRINGE	MYLAN	COPAXONE
LIDOCAINE HCL	3.88% CREAM	PURETEK CORPORATION	LIDOTRAL
DICLOFEN SOD/KINESIOLOGY TAPE	1.50% KIT	PURETEK CORPORATION	XRYLIX
DAPSONE	5% TOPICAL GEL	TARO PHARM USA, PACIFIC	ACZONE

NEW DRUG ENTITIES/COMBINATIONS/STRENGTHS

DESCRIPTION	BRAND NAME	GENERIC NAME	STRENGTH	NOTES
ANTIPARKINSONISM DRUGS,OTHER	GOCOVRI	AMANTADINE HCL	137 mg ER capsule 24H	New Strength and Dosage Form
CALCIUM CHANNEL BLOCKING AGENTS	NYMALIZE	NIMODIPINE	30 mg/10 mL (10 mL) solution	New Strength and Dosage Form
QUINOLONES	BAXDELA	DELAFLOXACIN MEGLUMINE	450 mg tablet	New Entity
ANTINEOPLASTIC SYSTEMIC ENZYME INHIBITORS	VERZENIO	ABEMACICLIB	50 mg tablet	New Entity
ANTINEOPLASTIC SYSTEMIC ENZYME INHIBITORS	VERZENIO	ABEMACICLIB	100 mg tablet	New Entity
ANTINEOPLASTIC SYSTEMIC ENZYME INHIBITORS	VERZENIO	ABEMACICLIB	150 mg tablet	New Entity
ANTINEOPLASTIC SYSTEMIC ENZYME INHIBITORS	VERZENIO	ABEMACICLIB	200 mg tablet	New Entity
TOPICAL LOCAL ANESTHETICS	KAMDOY	LIDOCAINE HCL/PALM OIL	spray	New Combination
GLUCOCORTICOIDS	ZODEX	DEXAMETHASONE	1.5 mg (49 tabs) dose pack	New Dosage Form
EMOLLIENTS	LOYON	DICAPRYLYL CARBONATE/DIMETH	spray	New Combination
SKELETAL MUSCLE RELAXANTS	CYCLOTENS	CYCLOBENZAPRINE/TENS ELECTRODE	10 mg combo package	New Combination
SKELETAL MUSCLE RELAXANTS	CYCLOTENS	CYCLOBENZAPRINE/TENS UNIT/ELEC	10 mg combo package	New Combination
MU-OPIOID RECEPTOR ANTAGONISTS,PERIPHERALLY -ACTING	SYMPROIC	NALDEMEDINE TOSYLATE	0.2 mg tablet	New Entity
INSULINS	FIASP	INSULIN ASPART (NIACINAMIDE)	100 unit/mL	New Entity
INSULINS	FIASP	INSULIN ASPART	100 unit/mL	New Entity

DESCRIPTION	BRAND NAME	GENERIC NAME	STRENGTH	NOTES
	FLEXTOUCH	(NIACINAMIDE)	(3 mL)	
BETA-ADRENERGIC-ANTICHOLINERGIC-GLUCOCORT, INHALED	TRELEGY ELLIPTA	FLUTICASONE/UMECLIDIN/VILANTER	100 mcg-62.5 mcg-25 mcg/actuation	New Combination
NASAL ANTI-INFLAMMATORY STEROIDS	NASAL ANTI-INFLAMMATORY STEROIDS	FLUTICASONE PROPIONATE	93 mcg/actuation	New Strength and Dosage Form
GLUCOCORTICOIDS	ZILRETTA	TRIAMCINOLONE ACETONIDE	32 mg	New Strength and Dosage Form
DRUGS TO TREAT MOVEMENT DISORDERS	INGREZZA	VALBENAZINE TOSYLATE	80 mg	New Entity
XANTHINES	THEOPHYLLINE	TH4EOPHYLLINE ANHYDROUS	80 mg/15 mL (15 mL) solution	New Dosage Form
GLUCOCORTICOIDS, ORALLY INHALED	QVAR REDIHALER	BECLOMETHASONE DIPROPIONATE	80 mcg/actuation	New Dosage Form
GLUCOCORTICOIDS, ORALLY INHALED	QVAR REDIHALER	BECLOMETHASONE DIPROPIONATE	40 mcg/actuation	New Dosage Form
URICOSURIC AND XANTHINE OXIDASE INHIBITOR COMB.	DUZALLO	LESINURAD/ALLOPURINOL	200 MG-200 MG	NEW COMBINATION

NEW INDICATIONS (EXISTING DRUGS)

TRACLEER®

September 6, 2017

SOUTH SAN FRANCISCO, Calif, September 6, 2017 – Actelion Pharmaceuticals US, Inc., one of the Janssen Pharmaceutical Companies of Johnson & Johnson, announced today that the U.S. Food and Drug Administration (FDA) has approved a new 32 mg tablet for oral suspension for TRACLEER® (bosentan) for use in pediatric patients aged three years and older with idiopathic or congenital pulmonary arterial hypertension (PAH), to improve pulmonary vascular resistance (PVR), which is expected to result in an improvement in exercise ability. With this approval, TRACLEER becomes the first FDA-approved medicine for pediatric PAH patients in the United States. PAH is a chronic, life-threatening disorder characterized by abnormally high blood pressure in the arteries between the heart and lungs of an affected person.

Source: Actelion Pharmaceuticals US, Inc.

PRIVIGEN®

September 14, 2017

Global biotherapeutics leader CSL Behring today announced that the U.S. Food and Drug Administration (FDA) has approved Privigen® [Immune Globulin Intravenous (Human), 10% Liquid] for the treatment of adults with chronic inflammatory demyelinating polyneuropathy (CIDP) to improve neuromuscular disability. CIDP is a rare autoimmune disorder that affects the peripheral nerves and may cause permanent nerve damage.

Source: CSL Behring

BRIVIACT®

September 15, 2017

Atlanta, Georgia (U.S.) & Brussels (Belgium), 15 September, 2017 – 0700 (CEST): UCB announced today that the U.S. Food and Drug Administration (FDA) has approved a supplemental new drug application (sNDA) for BRIVIACT® (brivaracetam) CV as monotherapy for partial-onset (focal) seizures (POS) in patients 16 years and older with epilepsy. This is a new indication for BRIVIACT, which is already approved in the U.S. as adjunctive treatment for POS in patients in this age group. As a result, adults and adolescents aged 16 years and older with POS in the U.S. can now be initiated on BRIVIACT as monotherapy or adjunctive therapy.

Source: UCB

SOMATULINE® DEPOT

September 18, 2017

Paris (France), September 18, 2017 – Ipsen (Euronext: IPN; ADR: IPSEY) (Ipsen), today announced that the U.S. Food and Drug Administration (FDA) has approved a supplemental indication for Somatuline® Depot (lanreotide) Injection 120 mg for the treatment of carcinoid syndrome; when used, it reduces the frequency of short-acting somatostatin analogue rescue therapy.

Source: Ipsen

RAPIVAB®

September 21, 2017

RESEARCH TRIANGLE PARK, N.C., Sept. 21, 2017 (GLOBE NEWSWIRE) -- BioCryst Pharmaceuticals, Inc. (NASDAQ:BCRX) a biotechnology company focused on the development and commercialization of treatments for rare and infectious diseases, announced today that the U.S. Food and Drug Administration (FDA) has approved a supplemental New Drug Application for RAPIVAB (peramivir injection), an intravenous (i.v.) neuraminidase inhibitor, extending its availability for the treatment of acute uncomplicated influenza to pediatric patients 2 years and older who have been symptomatic for no more than two days. The pediatric approval was based on the interim analysis of an ongoing pediatric clinical study. Those results will be presented at the upcoming ID Week 2017 meeting in San Diego.

Source: BioCryst Pharmaceuticals, Inc.

KEYTRUDA®

September 22, 2017

KENILWORTH, N.J.--(BUSINESS WIRE)-- Merck (NYSE:MRK), known as MSD outside the United States and Canada, today announced that the U.S. Food and Drug Administration (FDA) has approved KEYTRUDA® (pembrolizumab), the company's anti-PD-1 (programmed death receptor-1) therapy, for the treatment of patients with recurrent locally advanced or metastatic gastric or gastroesophageal junction (GEJ) adenocarcinoma whose tumors express PD-L1 [Combined Positive Score (CPS) ≥1] as determined by an FDA-approved test, with disease progression on or after two or more prior lines of therapy including fluoropyrimidine- and platinum-containing chemotherapy and if appropriate, HER2/neu-targeted therapy. This indication is approved under the FDA's accelerated approval regulations based on tumor response rate and durability of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in the confirmatory trials.

Source: Merck

OPDIVO®

September 22, 2017

PRINCETON, N.J.--(BUSINESS WIRE)--Bristol-Myers Squibb Company (NYSE:BMY) today announced the U.S. Food and Drug Administration (FDA) has approved Opdivo (nivolumab) injection for intravenous use for the treatment of patients with hepatocellular carcinoma (HCC) who have been previously treated with sorafenib. Approval for this indication has been granted under accelerated approval based on tumor response rate and durability of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in the confirmatory trials. In the CheckMate -040 trial, 14.3%* (95% CI: 9.2-20.8; 22/154) of patients responded to treatment with Opdivo. The percentage of patients with a complete response was 1.9% (3/154) and the percentage of patients with a partial response was 12.3% (19/154).1 Among responders (n=22), responses ranged from 3.2 to 38.2+ months; 91% of those patients had responses of six months or longer and 55% had responses of 12 months or longer.

Source: Bristol-Myers Squibb Company

BOTOX® Cosmetic

October 3, 2017

DUBLIN, Oct. 3, 2017 /PRNewswire/ -- Today Allergan plc (NYSE:AGN) announced the FDA approval of BOTOX® Cosmetic for its third indication, the temporary improvement in the appearance of moderate to severe forehead lines associated with frontalis muscle activity in adults. This approval makes the brand the first and only neurotoxin indicated for three facial treatment areas - forehead lines, crow's feet lines and glabellar lines. 1 As the category leader, BOTOX® Cosmetic is also the only neurotoxin brand to receive approval of aesthetic indications beyond glabellar lines in the U.S.

Source: Allergan plc

LYRICA®

October 12, 2017

NEW YORK--(BUSINESS WIRE)--Pfizer Inc. (NYSE: PFE) announced today that the United States Food and Drug Administration (FDA) has approved LYRICA® CR (pregabalin) extended-release tablets CV as once-daily therapy for the management of neuropathic pain associated with diabetic peripheral neuropathy (pDPN) and the management of postherpetic neuralgia (PHN). LYRICA CR did not receive approval for the management of fibromyalgia.

Source: Pfizer Inc.

STELARA®

October 13, 2017

Horsham, Pa., October 13, 2017 — Janssen Biotech, Inc., announced today that the U.S. Food and Drug Administration (FDA) has approved an expanded indication for STELARA® (ustekinumab) for the treatment of adolescents (12 years of age or older) with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy. Today's approval marks a significant milestone for this age group as approximately one-third of individuals who develop plaque psoriasis do so before 20 years of age, and there are limited treatment options for adolescents.[1] Since receiving approval in September 2009 for the treatment of adults living with moderate to severe plaque psoriasis, STELARA® has become a leading therapeutic option for dermatologists and their patients, with only four doses a year after two starter doses.

Source: Janssen Biotech, Inc.

FDA NEWS/BULLETINS/ADVISORIES/SAFETY ALERTS

Ocaliva (obeticholic acid): Drug Safety Communication - Increased Risk of Serious Liver Injury
[Posted 9/21/2017]

ISSUE: FDA is warning that the liver disease medicine Ocaliva (obeticholic acid) is being incorrectly dosed in some patients with moderate to severe decreases in liver function, resulting in an increased risk of serious liver injury and death. These patients are receiving excessive dosing, particularly a higher frequency of dosing than is recommended in the drug label for them. Ocaliva may also be associated with liver injury in some patients with mild disease who are receiving the correct dose. The recommended dosing and monitoring for patients on Ocaliva are described in the current drug label. FDA is working with the drug manufacturer, Intercept Pharmaceuticals, to address these safety concerns.

BACKGROUND: Ocaliva is used to treat a rare, chronic liver disease known as primary biliary cholangitis (PBC). PBC causes the bile ducts in the liver to become inflamed, damaged and destroyed. This causes bile, a fluid that helps in digestion, to build up in the liver. This build-up damages the liver over time, eventually causing it to lose its ability to function. Ocaliva has been shown to improve a certain blood test that measures liver problems.

RECOMMENDATION:
Health care professionals:

- Determine the patient's baseline liver function prior to starting Ocaliva.
- Patients with moderate to severe liver impairment (Child-Pugh B and C) should be started on the approved dosing schedule of 5 mg once weekly, rather than the 5 mg daily dosing used for other PBC patients, and if needed, can be increased up to a maximum approved dose of 10 mg twice weekly.
- Health care professionals should monitor patients frequently for disease progression, and reduce the dosing frequency to once- or twice-weekly for patients who progress to moderate or severe liver impairment.
- In all patients treated with Ocaliva, monitor frequently for liver injury (e.g., worsened liver blood tests and adverse liver-related reactions that may be inconsistent with the patient's extent of disease). If liver injury is suspected, discontinue Ocaliva. After the patient has stabilized, weigh the benefits against the risks when deciding whether to re-initiate treatment.
- Educate patients on the symptoms of potential liver injury.

Patients:

- Contact your health care professional if you have questions or concerns about taking Ocaliva.
- Report new or worsening severe skin itching to your health care professional.
- Contact your health care professional immediately if you develop any of the following symptoms that may be signs of liver injury: new or worsening fatigue, diarrhea, weight loss, abdominal pain, decreased appetite, nausea and vomiting, change in behavior or confusion, vague symptoms such as anxiety or unease, abdominal swelling, yellow eyes or skin, bloody stools

Healthcare professionals and patients are encouraged to report adverse events or side effects related to the use of these products to the FDA's MedWatch Safety Information and Adverse Event

Reporting Program:

- Complete and submit the report Online: www.fda.gov/MedWatch/report
- Download form or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

Source: U.S. Food and Drug Administration (FDA)

Opioid Addiction Medications in Patients Taking Benzodiazepines or CNS Depressants: Drug Safety Communication - Careful Medication Management Can Reduce Risks

[Posted 9/20/2017]

ISSUE: Based on additional review, FDA is advising that the opioid addiction medications buprenorphine and methadone should not be withheld from patients taking benzodiazepines or other drugs that depress the central nervous system (CNS). The combined use of these drugs increases the risk of serious side effects; however, the harm caused by untreated opioid addiction usually outweighs these risks. Careful medication management by health care professionals can reduce these risks. FDA is requiring this information to be added to the buprenorphine and methadone drug labels along with detailed recommendations for minimizing the use of medication-assisted treatment (MAT) drugs and benzodiazepines together.

BACKGROUND: Many patients with opioid dependence may also use benzodiazepines or other CNS depressants, either under a health care professional's direction or illicitly. Although there are serious risks with combining these medicines, excluding patients from MAT or discharging patients from treatment because of use of benzodiazepines or CNS depressants is not likely to stop them from using these drugs together. Instead, the combined use may continue outside the treatment setting, which could result in more severe outcomes.

RECOMMENDATION: Health care professionals should take several actions and precautions and develop a treatment plan when buprenorphine or methadone is used in combination with benzodiazepines or other CNS depressants. These include:

- Educating patients about the serious risks of combined use, including overdose and death that can occur with CNS depressants even when used as prescribed, as well as when used illicitly.
- Developing strategies to manage the use of prescribed or illicit benzodiazepines or other CNS depressants when starting MAT.
- Tapering the benzodiazepine or CNS depressant to discontinuation if possible.
- Verifying the diagnosis if a patient is receiving prescribed benzodiazepines or other CNS depressants for anxiety or insomnia, and considering other treatment options for these conditions.
- Recognizing that patients may require MAT medications indefinitely and their use should continue for as long as patients are benefiting and their use contributes to the intended treatment goals.
- Coordinating care to ensure other prescribers are aware of the patient's buprenorphine or methadone treatment.
- Monitoring for illicit drug use, including urine or blood screening.

Patients taking MAT drugs should continue to take these medicines as prescribed. Do not stop taking other prescribed medicines without first talking to your health care professional. Before starting any

new medicines, tell your health care professional that you are taking MAT. Do not take non-prescribed benzodiazepines or other sedatives (See Table 2 in the Drug Safety Communication, List of Benzodiazepines and Other CNS Depressants) or use alcohol when taking MAT because the combined use increases the possibility of harm, including overdose and death.

Health care professionals are encouraged to report any adverse events to FDA's MedWatch Adverse Event Reporting Program:

- Complete and submit the report Online: www.fda.gov/MedWatch/report
- Download form or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178.

Source: U.S. Food and Drug Administration (FDA)

Intraocular Injections of a Compounded Triamcinolone, Moxifloxacin, and Vancomycin (TMV) Formulation: FDA Statement - Case of Hemorrhagic Occlusive Retinal Vasculitis

[Posted 10/4/17]

ISSUE: FDA received an adverse event report on August 14, 2017, from a physician concerning a patient who was diagnosed postoperatively with bilateral hemorrhagic occlusive retinal vasculitis (HORV) after being administered injections of a compounded triamcinolone, moxifloxacin, and vancomycin (TMV) formulation in each eye at the conclusion of cataract surgery procedures that were done two weeks apart. The TMV formulation was compounded by Imprimis Pharmaceuticals, Inc., located in Ledgewood, New Jersey.

HORV is a rare, potentially blinding postoperative complication that has been observed in dozens of patients who have received intraocular injections of vancomycin (anti-infective) formulations toward the end of otherwise uncomplicated cataract surgeries.

BACKGROUND: Many ophthalmologists use intraocular vancomycin during cataract surgery with the intent of preventing postoperative endophthalmitis. FDA is unaware of any adequately controlled studies demonstrating the safety and efficacy of intraocular vancomycin in preventing endophthalmitis. There is no FDA-approved vancomycin formulation for intraocular injection. The formulation is usually prepared at the surgical site or obtained in advance of surgery from a compounding pharmacy.

The use of intraocular vancomycin has recently been associated with the newly described condition HORV. Characteristics of HORV include a delayed onset (up to three weeks) of sudden painless decreased vision, intraocular inflammation, intraretinal hemorrhage (bleeding within the retina), retinal vasculitis (inflammation within retinal vessels), vascular occlusion (blockage of retinal vessels), and retinal ischemia (lack of sufficient blood supply to the retina). If vancomycin is administered to both eyes, legal blindness is a likely consequence of HORV.

No cases of HORV were reported in a retrospective analysis of medical records of 922 patients (1541 eyes) who underwent cataract surgeries with intravitreal injections of compounded TMV formulations from November 2013 to December 2015. However, this chart review of non-controlled data is limited in its ability to identify rare events and may not necessarily be generalizable to a larger population who may undergo cataract surgery. The adverse event being reported here serves as a reminder that

intraocular administration of vancomycin, including when the vancomycin is one of multiple active ingredients in a compounded drug, can result in HORV.

RECOMMENDATION: The prophylactic use of intraocular vancomycin, alone or in a compounded drug combining multiple active ingredients, during cataract surgery is generally not recommended because of the risk of HORV.

Healthcare professionals and patients are encouraged to report adverse events or side effects related to the use of these products to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- Complete and submit the report Online: www.fda.gov/MedWatch/report
- Download form or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

Source: U.S. Food and Drug Administration (FDA)

Intralipid 20 Percent IV Fat Emulsion by Baxter: Recall - One Shipment of Product Exposed to Subfreezing Temperatures

[Posted 10/6/2017]

ISSUE: Baxter International Inc. announced today it is voluntarily recalling one shipment from a single lot of INTRALIPID 20% IV Fat Emulsion, 100 mL, distributed between 8/11/17 and 8/31/17 to hospitals and healthcare providers in the United States, to the user level. The product has been exposed to subfreezing temperatures during transit to a distribution facility. The subfreezing temperature is outside of the acceptable storage range listed on the product labeling. Other shipments of this lot are not affected by this issue. If accidentally frozen, INTRALIPID 20% IV Fat Emulsion should not be used. When subjected to freezing, the emulsion droplets will increase in size, forming aggregates that can block pulmonary circulation and lead to serious adverse health consequences that can be life-threatening.

BACKGROUND: INTRALIPID 20% IV Fat Emulsion is a prescription product indicated as a source of calories and essential fatty acids for patients requiring parenteral nutrition for extended periods of times. The product is packaged in 100 mL bags.

RECOMMENDATION: Baxter has informed customers affected by this particular shipment to locate and remove all affected product. Recalled product should be returned to Baxter for credit by contacting Baxter Healthcare Center for Service at 888-229-0001, Monday through Friday, between 7 a.m. and 6 p.m. Central Time.

Healthcare professionals and patients are encouraged to report adverse events or side effects related to the use of these products to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- Complete and submit the report Online: www.fda.gov/MedWatch/report
- Download form or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178.

Source: U.S. Food and Drug Administration (FDA)

STUDIES AND RECENT TOPICS

Post-Surgical C. difficile Linked to Antibiotic Overuse

September 7, 2017

The overuse of antibiotics following a surgical procedure is associated with an increased risk of Clostridium difficile (C. difficile) infection, according to a new report. Researchers from the University of Wisconsin School of Medicine & Public Health conducted their study at a 592-bed tertiary-care academic center in order to determine the incidence of postoperative C. difficile infection. The investigators examined 4 specific surgery specialties to categorize the risk factor in each: orthopedic surgery, neurosurgery, trauma surgery, and general surgery.

Source: mdmag.com

New Gene-Therapy Treatments Will Carry Whopping Price Tags

September 11, 2017

The first gene therapy treatment in the United States was approved recently by the Food and Drug Administration, heralding a new era in medicine that is coming faster than most realize — and that perhaps few can afford. The treatment, Kymriah, made by Novartis, is spectacularly effective against a rare form of leukemia, bringing remissions when all conventional options have failed. It will cost $475,000.

Source: nytimes.com

Apple is working with Stanford and American Well to test whether its watch can detect heart problems

September 11, 2017

Apple is working with partners to test whether its smartwatch can be used to detect common heart conditions, an effort that would make its device a "must have" for millions of people worldwide. The company is partnering up with a group of clinicians at Stanford, as well as telemedicine vendor American Well, to test whether Apple Watch's heart rate sensor can detect abnormal heart rhythms in a cohort of patients, according to two people familiar. The people requested anonymity as these plans have not yet been made public.

Source: cnbc.com

FDA panel: Teens risk breathing trouble from codeine cough syrup

September 13, 2017

Cough medicines containing codeine or hydrocodone may sometimes help a teen get through a cold, but it’s not worth the dangers, a federal panel advised this week.

The panel's biggest focus wasn't addiction, though addiction is a significant problem with opioids. According to a report in Stat, the panel members expressed greatest concern about the medicine's ability to slow breathing in children.

Source: ajc.com

The FDA just approved the first app for treating substance abuse

September 14, 2017

Federal regulators on Thursday approved the first mobile app to help treat substance use disorders. The app, developed by a start-up called Pear Therapeutics, is designed to be prescribed by clinician and used alongside counseling.

Source: cnbc.com

Antidepressants associated with significantly elevated risk of death, researchers find

September 14, 2017

Antidepressant medications, most commonly prescribed to reduce depression and anxiety, increase the risk of death, according to new findings by a McMaster-led team of researchers.
It's widely known that brain serotonin affects mood, and that most commonly used antidepressant treatment for depression blocks the absorption of serotonin by neurons. It is less widely known, though, that all the major organs of the body—the heart, kidneys, lungs, liver—use serotonin from the bloodstream.

Source: medicalxpress.com

Epilepsy drugs may have damaging effects on children's bones

September 20, 2017

In a study published in Epilepsia, young people taking anti-epileptic drugs experienced elevated rates of bone fractures and had reductions in tibial bone mineral density and lower limb muscle force.
The study included 23 individuals aged 5-18 years who had been taking anti-epileptic drugs for at least 12 months. Each individual was matched to a twin, sibling, or first cousin.

Source: eurekalert.org

FDA warns of death, liver injury risks from Intercept's drug

September 21, 2017

The U.S. Food and Drug Administration (FDA) warned on Thursday that Intercept Pharmaceuticals Inc's drug Ocaliva was being incorrectly dosed in some patients with a rare liver disease, increasing the risk of liver injury and death.

Source: Reuters Health

Hurricane Maria halts crucial drug manufacturing in Puerto Rico, may spur shortages

September 22, 2017

In its latest effort in the war against the opioid epidemic, the US Food and Drug Administration has Puerto Rico's pharmaceutical industry came to a halt after Hurricane Maria devastated the island. Drug companies ranging from Eli Lilly to AstraZeneca rushed to assess damage and braced for the possibility of months of downtime.

Source: usatoday.com

Many adults with diabetes delay insulin therapy

September 27, 2017

Three in ten adults with type 2 diabetes who need to start taking insulin to lower their blood sugar don't begin treatment when their doctors tell them to, a recent study suggests. On average, these patients delay insulin for about two years, researchers report in Diabetic Medicine.

Source: Reuters Health

The Future of Pharmaceuticals is Custom-Printing Drugs

September 28, 2017

Imagine that every time you needed a prescription, you wandered on over to the pharmacy and a pharmacist printed you up your drugs on the spot. On-demand micro manufacturing would allow pharmacists to customize for dosage, for your own personal biology, or even to combine many pills into one dose. It's a vision for the future of pharmaceuticals that a growing number of scientists hope will make drugs cheaper, personalized and more accessible to far-flung places.

Source: gizmodo.com

FDA Makes Side-Effect Database Searchable

September 28, 2017

If you had a bad reaction after taking a medicine, there's now an easy way to find out whether others experienced the same.

The U.S. Food and Drug Administration improved its online database of reports about side effects filed by patients and doctors, making it easily searchable by product, patient age, type of side effect or year it occurred.

Source: bloomberg.com

Statin use appears to reduce risk of serious bacterial bloodstream infection

October 2, 2017

Rochester, MN - Users of statins, widely prescribed for prevention of cardiac disease, have a 27% lower risk of contracting a Staphylococcus aureus (S. aureus) bloodstream infection outside of a hospital, according to a new study in Mayo Clinic Proceedings. Researchers report that statin use, especially among elderly patients with preexisting chronic conditions such as diabetes, kidney, or liver disease, may be protective against this serious bloodstream infection. As the western world's population is aging and more people live with chronic medical conditions, any potential preventive effect of statins could have important clinical implications.

Source: eurekalert.org

The FDA just approved the first mobile device and app to help you quit smoking

October 3, 2017

A start-up called Carrot just got cleared from federal regulators for its digital approach to help millions of people quit smoking. Part of its program includes the first FDA-approved use of a smartphone app to help people quit smoking.

Source: cnbc.com

Risk of Drug Side Effects Rises as You Age

October 5, 2017

Whether it’s an over-the-counter pain reliever or a prescription statin to lower cholesterol, medication has a troubling downside: the risk of side effects. Side effects are the expected (and usually unwanted) reactions you hear rattled off in TV drug ads: constipation, diarrhea, dizziness, drowsiness, dry mouth, nausea, upset stomach, and more. Though some are not serious and are likely to subside over time, some may be especially problematic for older adults.

Source: consumerreports.org

This drug may be able to treat both women's health disorders and prostate cancer

October 13, 2017

If successful, a new drug from the biotech Myovant Sciences Ltd. could treat two women's health disorders, as well as prostate cancer.

The drug, Relugolix, works to reduce estrogen in women and testosterone in men. The hormones are factors in two painful conditions affecting women, uterine fibroids and endometriosis, and in prostate cancer.

Source: marketwatch.com

Flu Season 2017: Medical Supplies Shortage Could Leave U.S. With Deadly Pandemic

October 12, 2017

The flu season is starting, and it could turn deadly due to America's lack of preparation. Healthcare experts believe an influenza pandemic will seriously harm the health of Americans—and not because of the infections themselves.

Source: newsweek.com

'Alexa, order my meds' -- start-up NowRx pioneers prescription refills through Alexa and Google Home

October 14, 2017

NowRx wants to make standing in line at the pharmacy a thing of the past.

This month, its users will have the option to order prescription medications via a virtual home assistant, such as the Amazon Echo or Google Home. A robot then registers to the request and dispenses the medication within minutes, and a car will deliver it within hours.

Source: cnbc.com

RECALLS

Product Type	Product Description	Class	Code Information	Reason for Recall	Recalling Firm
Drugs	Fentanyl Citrate (Preservative Free) 10 mcg per mL (1,000 mcg per 100 mL) 100 mL total volume in a 100 mL LifeCare Bag in Sodium Chloride 0.9% Rx Only, Compounded by PharMEDium Services, LLC, Cleveland, MS 38732, NDC 61553-112-52.	Class II	Lots: 170850012C and 170 850020C Exp. 06/25/17	Labeling: Not Elsewhere Classified- Diluent used to compound product expired prior to the expiration date assigned to the compounded product.	PharMedium Services, Llc12620 W Airport Blvd Ste 130 Sugar Land, TX 77478-6200
Drugs	Fentanyl Citrate (Preservative Free) 20 mcg per mL (2,000 mcg per 100 mL) 100 mL total volume in a 100 mL LifeCare Bag in Sodium Chloride 0.9% Rx Only, Compounded by PharMEDium Services, LLC, Cleveland, MS 38732, NDC 61553-605-52	Class II	Lot: 170850021C Exp. 06/ 25/17	Labeling: Not Elsewhere Classified- Diluent used to compound product expired prior to the expiration date assigned to the compounded product.	PharMedium Services, Llc 12620 W Airport Blvd Ste 130 Sugar Land, TX 77478-6200
Drugs	HYDROmorphone HCl Injection, USP, 2 mg/mL, 1mL Single-use vial, packaged in cartons of 25 vials, Rx only, Hospira, Inc., Lake Forest, IL 60045 USA, NDC 0409-3365-11 (carton) and 0409-3365-01(vial)	Class II	Lot: 760853A	Lack of sterility assurance: resulting from use of a damaged sterilizing filter for nitrogen used in the manufacturing process.	Pfizer Inc.235 E 42nd St New York, NY 10017-5703
Drugs	Levophed (norepinephrine bitartrate) injection, USP, 4 mg/4 mL (1mg/mL), 4mL Fill in 5 mL Single dose Fliptop Vial, Rx only, Hospira, Inc., Lake Forest, IL 60045 USA, NDC 0409-3375-04	Class II	Lot #: 753003A, Exp 9/18; 762153A, 760803A, 76105 3A , Exp 10/18	Lack of sterility assurance: resulting from use of a damaged sterilizing filter for nitrogen used in the manufacturing process.	Pfizer Inc. 235 E 42nd St New York, NY 10017-5703
Drugs	Daytrana (methylphenidate transdermal system) Delivers 10 mg over 9 hours (1.1 mg/hr) Rx Only Contains: 30 Patches Manufactured for: Noven Therapeutics, LLC. Miami, FL 33186 By Noven Pharmaceuticals, Inc., Miami, FL 33186, NDC# 68968-5552-3	Class II	Lot: 80433 Exp. 08/17	Defective Delivery System: Products no longer meet the release liner removal specification and/or z-statistic.	Noven Pharmaceuticals, Inc. 11960 SW 144th St Miami, FL 33186-6109
Drugs	Daytrana (methylphenidate transdermal system) Delivers 20 mg over 9 hours (2.2 mg/hr) Rx Only Contains: 30 Patches Manufactured for: Noven Therapeutics, LLC. Miami, FL 33186 By Noven Pharmaceuticals, Inc., Miami, FL 33186, NDC# 68968-	Class II	Lot: 80431 Exp. 08/17	Defective Delivery System: Products no longer meet the release liner removal specification and/or z-statistic.	Noven Pharmaceuticals, Inc. 11960 SW 144th St Miami, FL 33186-6109

Product Type	Product Description	Class	Code Information	Reason for Recall	Recalling Firm
	5554-3				
Drugs	Daytrana (methylphenidate transdermal system) Delivers 30 mg over 9 hours (3.3 mg/hr) Rx Only Contains: 30 Patches Manufactured for: Noven Therapeutics, LLC. Miami, FL 33186 By Noven Pharmaceuticals, Inc., Miami, FL 33186, NDC# 68968-5555-3	Class II	Lot: 80442 Exp. 10/17 Lot: 80439 Exp. 08/17 Lot: 80438 Exp. 08/17	Defective Delivery System: Products no longer meet the release liner removal specification and/or z-statistic.	Noven Pharmaceuticals, Inc. 11960 SW 144th St Miami, FL 33186-6109
Drugs	Daytrana (methylphenidate transdermal system) Delivers 15 mg over 9 hours (1.6 mg/hr) Rx Only Contains: 30 Patches Manufactured for: Noven Therapeutics, LLC. Miami, FL 33186 By Noven Pharmaceuticals, Inc., Miami, FL 33186, NDC# 68968-5553-3	Class II	Lot: 80426 Exp. 10/17	Defective Delivery System: Products no longer meet the release liner removal specification and/or z-statistic.	Noven Pharmaceuticals, Inc. 11960 SW 144th St Miami, FL 33186-6109
Drugs	Procrit (epoetin alfa), 10,000 units/mL, packaged in a) box of 6 single use 1 mL vials (NDC 59676-310-01), b) box of 25 single use 1 mL vials (NDC 59676-310-02), Rx Only, Manufactured by: Amgen, Inc. Thousand Oaks, CA 91320, Manufactured for: Janssen Products, LP Horsham, PA 19044	Class II	Lot #: a) G290530A, Exp 07/18; b) G290531A, Exp 07/18	Presence of particulate matter: glass flakes identified as lamellae observed during a routine quality inspection.	Amgen, Inc. 1 Amgen Center Dr Thousand Oaks, CA 91320-1730
Drugs	Sterile Water for Injection, USP Single Dose 100 mL vials, Rx only, Manufactured by Hospira, Inc., Lake Forest, IL 60045 USA for Genentech, Inc., South San Francisco, CA 94080-4990. NDC 50242-901-24	Class II	Lot: 63-075-DK Exp. FEB 2019	Non-Sterility: cracked or chipped glass at the neck of Sterile Water for Injection vials.	Pfizer Inc. 235 E 42nd St New York, NY 10017-5703
Drugs	Acarbose Tablets, 25 mg, 100-count bottle, Rx only, Manufactured by: Arrow Pharm (Malta) Ltd., Birzebbugia BBG3000, Malta; Distributed by: Actavis Pharma, Inc., Parsippany, NJ 07054; NDC 16252-523-01.	Class II	Lot #: 1082710A, Exp 07/18	Labeling: Incorrect or Missing Lot and/or Exp Date: An incorrect expiration date of July 2018 is printed on the product labeling rather than the correct expiration date of July 2017.	Teva Pharmaceuticals USA 1090 Horsham Rd North Wales, PA 19454-1505
Drugs	Ketorolac Trom 30 mg/mL Injection, packaged in a) 1 mL vials, NDC 61786-0741-01 (Orig: 00548-9021-00), Ref: 33631 and b) 10 x 1 mL vials per tray, NDC 61786-0741-08 (Orig: 00548-9021-00), Ref: 33632, Rx only,	Class II	Lot #: a) B0158730-060816 (Mfg: XI002A6), Exp: 12/2017 ; and b) B0160669-061516 (Mfg: XI003A6), Exp	Crystallization: Product is being recalled due to the manufacturer's recall due to the presence of visible particulate in vials that has been identified as crystalline	RemedyRepack Inc. 625 Kolter Dr Ste 4 Indiana, PA 15701-3571

Product Type	Product Description	Class	Code Information	Reason for Recall	Recalling Firm
	Packaged by: RemedyRepack Inc, Indiana, PA 15704; Mfg by: Amphastar, Rancho Cucamonga, CA 91730.		12/2017	ketorolac calcium salt.	
Drugs	Option Systems Antibacterial Foaming Hand Wash, 0.3% P.C.M.X., 8 fl oz and 18 fl oz. bottles and 500, mL 800 mL, and 1000 mL pouches, ALSO labeled as STYLE Antibacterial Hand Soap, Inopak Ltd Ringwood, NJ --- NDC 5031-431-02	Class II	Batch Numbers 6718, 6730, 6744, 6754, 6760, 6773, 6784, 6793, 6804, 6812, 6819, 6838, 6846, 6862, 6877, 6890, 6902, 6910, 6919, 6838, 6846, 6862, 6877, 6890, 6902, 6910, 6919, 6938, 6944, Style Batch Numbers 6725, 6732, 6735, 6742, 6756, 6762, 6766, 6770, 6777, 6792,6798, 6807, 6813, 6816, 6829, 6839, 6868, 6872, 6875, 6891, 6904, 6906, 6914, 6916, 6923, 6932, 6939, 6820	GMP Deviations; potential bacterial contamination may have been introduced to products through a contaminated diaphragm pump	Inopak Ltd 24 Executive Pkwy Ringwood, NJ 07456-1430
Drugs	Mild Healthcare Antibacterial Hand Soap, 6% P.C.M.X., 1000 mL and 2000 mL Disc Pump, 800 mL Universal Valve, and 1 gallon bottles, Inopak. Ltd, Ringwood, NJ 07456	Class II	Batch Numbers 6749, 6909	GMP Deviations; potential bacterial contamination may have been introduced to products through a contaminated diaphragm pump.	Inopak Ltd 24 Executive Pkwy Ringwood, NJ 07456-1430
Drugs	Choice Antibacterial Hand Soap, (ethyl alcohol 61%) 800 ml/ 27 fl oz, Universal Valve, Inopak LTD, Ringwood, NJ	Class II	All lots within expiry	GMP Deviations; potential bacterial contamination may have been introduced to products through a contaminated diaphragm pump.	Inopak Ltd 24 Executive Pkwy Ringwood, NJ 07456-1430
Drugs	Deferoxamine Mesylate for injection, USP, Single-use Vial, 500 mg/vial, 10 mL vial. Intravenous, Intramuscular, Subcutaneous Use, Rx Only, Hospira, Inc., Lake Forest IL USA, NDC 0406-2336-10.	Class II	Lot: 51275DD; Exp. 09/01/17	CGMP Deviations: Firm failed to control impurity for color change at the API stage	Pfizer Inc. 235 E 42nd St New York, NY 10017-5703
Drugs	Glutamine, Arginine and Carnitine, 10/100/200mg/mL, 30 mL (Multi Dose Vial), Rx Only, For Injection, United Pharmacy Compounded, 13951 N. Haverhill Rd Ste. 120-121 West Palm Beach, FL 33417	Class II	Lot: GAC-12 BUD 11/10/17; Lot: GAC-13 BUD: 01/14/18	CGMP Deviations; FDA analysis determined that the product does not contain glutamine and two unknown impurities were observed	United Pharmacy 3951 Haverhill Rd N West Palm Beach, FL 33417-8154
Drugs	Quillivant XR methylphenidate HCl, for extended-release oral	Class	Lot # 03216048A, Exp. 05/	Failed Dissolution	Pfizer Inc. 235 E 42nd St New York,

Product Type	Product Description	Class	Code Information	Reason for Recall	Recalling Firm
	suspension, 600 mg/120 mL total volume (When constituted with 105 mL of water, 25 mg/5 mL (5 mg/mL) when reconstituted, Rx Only, Distributed by Nextwave Pharmaceuticals, Inc. A subsidiary of Pfizer Inc., New York, NY 10017, Manufactured by Tris Pharma, Inc., Monmouth Junction, NJ 08852, NDC 24478-200-20	III	18	Specifications	NY 10017-5703 United States
Drugs	Quillivant XR methylphenidate HCl, for extended-release oral suspension, 750mg/150 mL total volume (When constituted with 131 mL of water, 25 mg/5 mL (5 mg/mL) when reconstituted, Rx Only, Distributed by Nextwave Pharmaceuticals, Inc. A subsidiary of Pfizer Inc., New York, NY 10017, Manufactured by Tris Pharma, Inc., Monmouth Junction, NJ 08852, NDC 24478-200-25	Class III	Lot # 03216047A Exp. 02/ 18	Failed Dissolution Specifications	Pfizer Inc. 235 E 42nd St New York, NY 10017-5703 United States
Drugs	Ampicillin for Injection, USP, 500 mg per vial, single vial (NDC 0781-3407-78) packaged in 10-count shrink wrap packs (NDC 0781-3407-95), Rx only, Manufactured in Austria by Sandoz GmbH or Sandoz Inc., Princeton, NJ 08540.	Class III	Lot: GH8254, Exp 06/19	Labeling: Missing Label: customer complaint that some vials of ampicillin within the shrink wrap pack are missing labels.	Sandoz Inc 100 College Rd W Princeton, NJ 08540-6604
Drugs	Deferoxamine Mesylate for injection, USP, Single-use Vial, 500 mg/vial, 10 mL vial. Intravenous, Intramuscular, Subcutaneous Use, Rx Only, Hospira, Inc., Lake Forest IL USA, NDC 0406-2336-10.	Class III	Lot: 51275DD; Exp. 09/01/ 17	CGMP Deviations: Firm failed to control impurity for color change at the API stage.	Pfizer Inc. 235 E 42nd St New York, NY 10017-5703
Drugs	Magnesium Citrate Oral Solution Lemon Flavor, 1.745g per fl oz, packaged in 10 fl. oz. (296 mL) bottles, Labeled as a) CVS Health, Distributed by: CVS Pharmacy, Inc. One CVS Drive, Woonsocket, RI 02895; NDC 59779-667-38, UPC 05042842790; b) Swan Citroma, Distributed by: Vi-Jon One Swan Drive Smyrna, TN 37167, NDC 0869066738, UPC 308690667382; c) GoodSense, Distributed By: Geiss, Destin & Dunn, Inc. Peachtree City, GA 30269, NDC 50804-667-38, UPC 846036007374; d) Leader, Distributed By: Cardinal Health,	Class III	Lot #: a) 0326166 Exp. 07/ 2018; b) 0326164, Exp. 07 /2018; 0326730, Exp. 08/2 018; c) 0326183, Exp. 07/ 2018; 0326730 Exp. 08/20 18; d) 0326183, Exp. 07/2 018, e) 0326183, Exp. 07/ 2018, f) 0326730 Exp. 08/ 2018,g) 0326736, Exp. 08/ 2018, 0341351 Exp. 11/20 18, h) 0326736, Exp. 08/2 018.	Failed Impurities/Degradation Specifications.	Vi-Jon, Inc. 1 Swan Dr Smyrna, TN 37167-2099 United States

Product Type	Product Description	Class	Code Information	Reason for Recall	Recalling Firm
	Dublin, Ohio, 43017, NDC 3720511038, UPC 096295382433; e) Signature Care, Distributed By: Better Living Brands, LLC. P.O. Box 99, Pleasanton, CA 94566-0009, NDC 21130-667-38, UPC 321130779155; f) Discount Drug Mart Food Fair, Distributed By: Drug Mart-Food Fair Medina, Ohio 44256, NDC 5394301077, UPC 093351100383; g) Sunmark, Distributed By McKesson One Post Street San Francisco, CA 94104, NDC 4934869649, UPC 010939112330, h) Major, Distributed By: Major Pharmaceuticals 31778 Enterprise Drive Livonia, MI 48150 USA, NDC 0904630477, UPC 309046304777				
Drugs	Magnesium Citrate Oral Solution Cherry Flavor, 1.745 g per fl oz, packaged in 10 fl. oz (296 mL) bottles, Labeled as a) CVS Health, Distributed by: CVS Pharmacy, Inc. One CVS Drive, Woonsocket, RI 02895; NDC 6984238038, UPC 050428418321, b) Meijer, Dist. By Meijer Distribution, Inc. Grand Rapids, MI 49544, NDC 4125038038, UPC 708820824294, c) Life Brand, Manufactured for: Shoppers Drug Mark/Pharmaprix Toronto, UPC 057800856405	Class III	Lot #: 0323439 Exp. 07/2018	Failed Impurities/Degradation Specifications.	Vi-Jon, Inc. 1 Swan Dr Smyrna, TN 37167-2099 United States
Drugs	Mobic (meloxicam) tablets, 15 mg, package in 100-count bottle, Rx only, Dist. by: Boehringer Ingelheim (BI) Pharmaceuticals, Inc., Ridgefield, CT 06877 USA, Lic. from: BI Int'l GmbH, Made in Italy, NDC 0597-0030-01	Class III	Lot 754037	Labeling: Incorrect or missing package insert. One lot of Mobic Tablets is packaged with an incorrect insert.	Boehringer Ingelheim Pharmaceuticals, Inc. 39 Briar Ridge Rd. Danbury, CT 06810
Biologics	Bexsero Meningitis Vaccine, 0.5 mL single-dose pre-filled syringes, 60 vials/ 1 each per box	Class III	Lot # 159001	Bexsero Meningitis Vaccine, lacking assurance of proper temperature maintenance during storage, was distributed.	MCKESSON MEDICAL 9954 Mayland Dr Rm 4000 Richmond, VA 23233-1464

*Please refer to FDA website for further information; http://www.fda.gov/Safety/Recalls/EnforcementReports/default.htm

CURRENT DRUG SHORTAGES

5% Lidocaine and 7.5% Dextrose Injection

August 7, 2017

Reason for the Shortage

- Pfizer has 5% lidocaine and 7.5% dextrose 2 mL ampules on shortage due to manufacturing delays.
- Pfizer is the sole supplier of this combination.

Estimated Resupply Dates

- Pfizer has 5% lidocaine and 7.5% dextrose 2 mL ampules on long-term back order and the company estimates a release date of 2nd quarter 2018.

Ciprofloxacin Oral Suspension

August 8, 2017

Reason for the Shortage

- Lupin did not provide a reason for the shortage.
- Bayer has Cipro oral suspension available.

Estimated Resupply Dates

- Lupin has ciprofloxacin oral suspension on long-term back order and the company cannot estimate a release date.

Flurbiprofen Sodium Ophthalmic Solution

August 16, 2017

Reason for the Shortage

- Allergan discontinued Ocufen ophthalmic solution in February 2017.
- Valeant has flurbiprofen sodium on shortage due to manufacturing delay.

Estimated Resupply Date

- Valeant has flurbiprofen sodium on back order and the company estimates a release in November 2017.

Ceftazidime Injection

August 22, 2017

Reason for the Shortage

- Pfizer has Tazicef available.
- Sagent has ceftazidime injection on shortage due to manufacturing delays.
- Sandoz discontinued ceftazidime 1 gram and 2 gram vials in 2015.
- BBraun had ceftazidime on allocation due to increased demand.

- WG Critical Care has ceftazidime on shortage due to manufacturing delays.

Estimated Resupply Date

- Teligent has Fortaz 2 gram and 6 gram vials on back order and the company cannot estimate a release date.
- WG Critical Care has ceftazidime 1 gram vials on back order and the company estimates a release date of late-October 2017.

Hepatitis B Vaccine Recombinant

August 25, 2017

Reason for the Shortage

- Merck has Recombivax HB on shortage due to increase in global demand.

Estimated Resupply Date

- Merck has Recombivax HB adult formulation vials and syringes on back order and the company estimates this will continue through 2018.
- Merck has Recombivax HB pediatric/adolescent formulation syringes and pediatric/adolescent vials on back order and the company does not anticipate these products will be available in 2017.

Reteplase Injection

August 29, 2017

Reason for the Shortage

- Chiesi USA acquired Cornerstone Therapeutics in March 2014.
- Cornerstone Therapeutics acquired EKR Therapeutics in June 2012. EKR Therapeutics had previously purchased Retavase from PDL BioPharma.
- Cornerstone Therapeutics was seeking FDA approval of a new supplier of the active pharmaceutical ingredient for Retevase.

Estimated Resupply Date

- Chiesi USA has Retavase on long-term back order and the company cannot estimate a release date.

Penicillin G Procaine Injection, Penicillin G Benzathine

August 29, 2017

Reason for the Shortage

- Pfizer states the shortage is due to a delay in the manufacturing process.
- Pfizer is the sole supplier of penicillin G procaine.

Estimated Resupply Date

- Pfizer has penicillin G procaine 600,000 unit/mL 1 mL and 2 mL vials on back order and the company estimates a release date of 4th quarter 2017.

- Pfizer has Bicillin L-A 600,000 unit/ 1 mL syringes, 1,200,000 unit/ 2 mL syringes, and 2,400,000 unit/ 4 mL syringes on allocation.
- Pfizer has Bicillin C-R 1,200,000 units/2 mL prefilled syringes and 1,200,000 units/2 mL pediatric prefilled syringes on allocation.
- Pfizer has Bicillin C-R 900/300 2 mL pediatric prefilled syringes on allocation.

Yellow Fever Vaccine Injection

September 6, 2017

Reason for the Shortage

- Sanofi Pasteur states the shortage is due to production delays.
- There are no other suppliers of yellow fever vaccine.

Estimated Resupply Date

- Sanofi Pasteur has YF-Vax multi-dose vials and single dose vials on back order and the company cannot estimate a release date.1
- FDA accepted an investigational new drug application in October 2016. This is for the importation of another yellow fever vaccine from France. The trade name of the imported product is Stamaril.

Torsemide Injection

September 6, 2017

Reason for the Shortage

- Roche discontinued Demadex injection for business reasons. Demadex tablets are not affected by this shortage.
- American Regent has torsemide on shortage due to manufacturing delays.

Estimated Resupply Date

- American Regent has torsemide injection on long-term back order and the company cannot estimate a release date.

Tobramycin Injection

September 6, 2017

Reason for the Shortage

- Akorn has tobramycin injection on shortage due to manufacturing delays.
- Pfizer did not provide a reason for the shortage.

Estimated Resupply Date

- Akorn has tobramycin 40 mg/mL 2 mL vials on back order and the company cannot estimate a release date.
- Fresenius Kabi has tobramycin 1.2 gram preservative-free powder 50 mL vials on back order and the company estimates a release date of mid-October 2017.

- Mylan Institutional has tobramycin 40 mg/mL 2 mL vials on intermittent back order and the company is releasing product as it becomes available.
- X-Gen has tobramycin 1.2 gram preservative-free powder 50 mL vials in 1 count on back order and the company estimates a release date of mid-October 2017.

Ofloxacin Ophthalmic Solution

September 6, 2017

Reason for the Shortage

- Allergan has Ocuflox ophthalmic solution available.
- Akorn did not provide a reason for the shortage.
- Rising has ofloxacin ophthalmic solution available.
- Valeant did not provide a reason for the shortage.

Estimated Resupply Date

- Valeant has temporarily discontinued ofloxacin ophthalmic solution in 5 mL and 10 mL bottles and the company cannot estimate a release date.
- Akorn has ofloxacin ophthalmic solution in 5 mL vials on allocation.

Methylene Blue Injection

September 6, 2017

Reason for the Shortage

- Akorn has methylene blue on shortage due to manufacturing delays.
- American Regent has recently launched an FDA approved presentation, ProvayBlue and product is available.

Estimated Resupply Date

- Akorn has methylene blue 10 mg/mL 1 mL vials on back order and the company cannot estimate a release date.

Carboplatin Solution for Injection

September 8, 2017

Reason for the Shortage

- Bedford discontinued carboplatin in May, 2011 to concentrate on the manufacturing of other products.
- Fresenius Kabi has carboplatin available.
- Mylan Institutional cannot provide a reason for the shortage.
- Pfizer has carboplatin injection on shortage due to manufacturing delays.
- Sagent states the reason for the shortage is increased demand for the product and manufacturing delays.
- Sandoz has discontinued carboplatin injection.
- Teva has carboplatin on allocation due to increased demand.

Estimated Resupply Date

- Mylan Institutional has all carboplatin injection on back order and the company cannot estimate a release date.
- Sagent has carboplatin 10 mg/mL 5 mL and 15 mL vials on back order and the company cannot estimate a release date.
- Teva has carboplatin 10 mg/mL 15 mL, 45 mL, and 60 mL vials on allocation. Please check wholesaler for inventory.

Liotrix Tablets

September 13, 2017

Reason for the Shortage

- Thyrolar tablets from Actavis (formerly Forest) are on shortage due to manufacturing changes.

Estimated Resupply Date

- Actavis (formerly Forest) has all Thyrolar presentations on long-term back order and the company cannot estimate a release date.

Dipyridamole Injection

September 13, 2017

Reason for the Shortage

- West-Ward did not provide a reason for the shortage.

Estimated Resupply Date

- West-Ward has dipyridamole 5 mg/mL 10 mL vials on back order and the company cannot estimate a release date.

Trace Elements Injection

September 18, 2017

Reason for the Shortage

- American Regent did not provide a reason for the shortage.

Estimated Resupply Date

- American Regent has trace elements-4 pediatric vials and Multitrace-4 Pediatric 3 mL vials on back order and the company cannot estimate a release date. The Multitrace-5 Concentrate 1 mL and 10 mL vials and Multitrace-5 regular 10 mL vials are available in limited supply.

Hydroxyzine Hydrochloride Injection

September 18, 2017

Reason for the Shortage

- American Regent would not provide a reason for the shortage. They are the sole supplier of hydroxyzine injection.

Estimated Resupply Date

- American Regent has hydroxyzine 50 mg/mL 10 mL vials on back order and the company cannot estimate a release date. The 25 mg/mL 1 mL vials and 50 mg/mL 1 mL vials are available in limited supply.

Electrolyte Concentrate

September 18, 2017

Reason for the Shortage

- American Regent has Nutrilyte and Nutrilyte II on back order due to manufacturing delays.

Estimated Resupply Date

- American Regent has Nutrilyte and Nutrilyte II presentations on long-term back order and the company cannot estimate a release date.

Dexamethasone Sodium Phosphate

September 18, 2017

Reason for the Shortage

- American Regent has dexamethasone sodium phosphate on shortage due to manufacturing delays.
- AuroMedics has dexamethasone sodium phosphate on intermittent back order.
- Fresenius Kabi has dexamethasone sodium phosphate presentations available.
- Mylan Institutional did not provide a reason for the shortage.
- West-Ward has dexamethasone sodium phosphate available.

Estimated Resupply Date

- American Regent has dexamethasone sodium phosphate 4 mg/mL products on back order and the company cannot estimate a release date.
- AuroMedics has dexamethasone sodium phosphate 4 mg/mL 1 mL and 30 mL vials on intermittent back order and the company is releasing product as it becomes available.
- West-Ward has dexamethasone sodium phosphate 4 mg/mL 1 mL and 5 mL vials on back order and the company cannot estimate a release date.

Ammonium Molybdate Injection

September 18, 2017

Reason for the Shortage

- American Regent has ammonium molybdate injection on shortage due to manufacturing delays.
- American Regent is the sole supplier of ammonium molybdate injection.

Estimated Resupply Date

- American Regent has ammonium molybdate injection on back order and the company cannot estimate a release date.

Mitoxantrone Hydrochloride Injection

September 19, 2017

Reason for the Shortage

- Fresenius Kabi has mitoxantrone available.
- Pfizer has mitoxantrone injection on shortage due to manufacturing delays.
- Teva has mitoxantrone injection available except for the 10 mL vials which are temporarily discontinued.

Estimated Resupply Date

- Fresenius Kabi has mitoxantrone 2 mg/mL 15 mL vials available with an expiration date of <9 months.
- Pfizer has all mitoxantrone presentations on long-term back order and the company estimates a release date of early-4th quarter 2017.
- Teva has temporarily discontinued mitoxantrone 10 mL vials and the company cannot estimate a release date.

Haloperidol Lactate Injection

September 20, 2017

Reason for the Shortage

- Mylan Institutional has haloperidol lactate injection available.
- Patriot Pharmaceuticals has haloperidol lactate available.
- Sagent has haloperidol lactate on shortage due to manufacturing delays.
- Teva is not currently marketing haloperidol lactate.
- West-Ward is not actively marketing haloperidol lactate at this time.
- Janssen has Haldol injection available.

Estimated Resupply Date

- Sagent has haloperidol lactate 5 mg/mL 10 mL vials on back order and the company cannot estimate a release date.

Folic Acid Injection

September 20, 2017

Reason for the Shortage

- Fresenius Kabi has folic acid on shortage due to a delay in getting the active ingredient.

Estimated Resupply Date

- Fresenius Kabi has folic acid 5 mg/mL 10 mL vials available with an expiration date of <4 months. The next estimated release date is November 2017.

Belatacept Injection
September 20, 2017

Reason for the Shortage
- Bristol-Myers Squibb has Nulojix in short supply due to manufacturing delays.

Estimated Resupply Date
- Bristol-Myers Squibb has limited the distribution of Nulojix. They have product only for existing patients available through the US Nulojix Distribution Program. They have no estimated recovery date, but do not expect full recovery before the end of 2017. Nulojix is distributed by McKesson Plasma Biologics.

Aminocaproic Acid Injection
September 20, 2017

Reason for the Shortage
- Pfizer has aminocaproic acid on shortage due to manufacturing delays.

Estimated Resupply Date
- Pfizer has aminocaproic acid 250 mg/mL 20 mL vials on back order and the company estimates a release date of December 2017.

Leuprolide Acetate 14-Day Kit
September 22, 2017

Reason for the Shortage
- Caraco will not provide availability information.
- Sandoz states the reason for the shortage was increased demand.
- Teva states the shortage is due to manufacturing delays.

Estimated Resupply Date
- Teva has leuprolide acetate injection on long-term back order and the company cannot estimate a release date.

Indomethacin Capsules
September 22, 2017

Reason for the Shortage
- Glenmark had indomethacin 25 mg 100 count on shortage due to manufacturing delays.

- Heritage did not provide a reason for the shortage. Heritage discontinued indomethacin 50 mg capsule presentations.
- Mylan did not provide a reason for the shortage.
- Sandoz discontinued indomethacin in mid-2016.
- Teva did not provide a reason for the shortage.

Estimated Resupply Date

- Glenmark has indomethacin 50 mg capsules in 500 count on back order and the company estimates a release date of late-September 2017.
- Heritage has indomethacin 25 mg capsules in 100 count and 1,000 count bottles on long-term back order, and the company cannot estimate a release date.
- Mylan has indomethacin 25 mg capsules are on back order and the company estimates a release date of late-November 2017 for the 100 count bottles and early-November 2017 for the 1,000 count bottles. The 50 mg capsules in 100 count bottles are on back order and the company estimates a release date of mid-October 2017. The 50 mg capsules in 500 count are available with an expiration date of June 2018. The 50 mg capsules in 100 count and 300 count unit-dose presentations are on back order and the company cannot estimate a release date.
- Teva has all indomethacin presentations temporarily unavailable and the company cannot estimate a release date.

Morrhuate Sodium Injection

September 25, 2017

Reason for the Shortage

- American Regent has morrhuate sodium injection on shortage due to manufacturing delays.

Estimated Resupply Date

- American Regent has morrhuate sodium 50 mg/mL 30 mL vials on long-term back order and the company cannot estimate a release date.

Methyldopate Injection

September 25, 2017

Reason for the Shortage

- American Regent has methyldopate injection on shortage due to manufacturing delays.
- There are no other suppliers of methyldopate injection.

Estimated Resupply Date

- American Regent has methyldopate injection on long-term back order and the company cannot estimate a release date.

Multiple Vitamins for Infusion

September 26, 2017

Reason for the Shortage

- Pfizer states the shortage is due to manufacturing delays.
- Baxter has all presentations fully available at this time.

Estimated Resupply Date

- Pfizer has M.V.I. adult 50 mL Dual vials on back order and the company estimates a release date of mid-November 2017.
- Pfizer has M.V.I. pediatric 5 mL vials on back order and the company estimates a release date of October 2017.

Cefotaxime Injection

September 26, 2017

Reason for the Shortage

- Hospira has discontinued Claforan. Sanofi-Aventis manufactured Claforan for Hospira and is no longer making the product.
- Baxter discontinued Claforan in late-2015.
- West-Ward has cefotaxime on shortage due to manufacturing and issues with raw material.

Estimated Resupply Date

- West-Ward has cefotaxime 500 mg, 1 gram, 2 gram, and 10 gram vials on long-term back order and the company cannot estimate a release date.

Desiccated Thyroid Tablets

September 28, 2017

Reason for the Shortage

- Acella has NP Thyroid available.
- Allergan has Armour Thyroid available.
- RLC states the reason for the shortage is increased demand.

Estimated Resupply Date

- RLC has Nature-Throid and Westhroid presentations on back order and the company cannot estimate a release date.

Carbidopa and Levodopa Extended-Release Tablets

September 28, 2017

Reason for the Shortage

- Accord has discontinued carbidopa and levodopa 25 mg/100 mg extended-release tablets due to problems obtaining active ingredient. The 50 mg/ 200 mg tablets remain available.
- Caraco refuses to provide availability information. However, per FDA, Caraco has carbidopa and levodopa extended-release tablets available.
- Merck could not provide a reason for the Sinemet CR shortage.

- Mylan could not provide a reason for the shortage.

Estimated Resupply Date

- Merck has Sinemet CR 25 mg/100 mg and 50 mg/200 mg tablets on back order and the company estimates a release date in late-October 2017.
- Mylan has carbidopa and levodopa 25 mg/ 100 mg and 50 mg/200 mg extended-release tablets on back order and the company estimates a release date in mid-October 2017.
- Mylan Institutional has carbidopa and levodopa 25 mg/100 mg and 50 mg/200 mg extended-release tablets on back order and the company estimates a release date in early-January 2018 for the 25 mg/100 mg and late-November to early-December 2017 for the 50 mg/200 mg.

Asparaginase Erwinia chrysanthemi

September 28, 2017

Reason for the Shortage

- Jazz Pharmaceuticals has Erwinaze on shortage due to manufacturing issues.

Estimated Resupply Date

- Jazz Pharmaceuticals has Erwinaze unavailable. The company estimates a release date in mid-September 2017. The company requests that Erwinaze only be ordered for patients who are currently undergoing treatment or initiating treatment.

Sodium Acetate Injection

September 30, 2017

Reason for the Shortage

- American Regent has had sodium acetate on long-term back order for several years.
- Fresenius Kabi has sodium acetate on shortage due to increased demand.
- Pfizer has sodium acetate on shortage due to manufacturing delays.

Estimated Resupply Date

- Fresenius Kabi has sodium acetate 4 meq/mL 100 mL vials on intermittent back order and the company is releasing product as it becomes available.
- Pfizer has sodium acetate 2 meq/mL 20 mL vials on intermittent back order and the company is releasing product as it becomes available. The 50 mL vials are available in limited supply.

Promethazine Injection

September 30, 2017

Reason for the Shortage

- Teva is not marketing promethazine injection at this time.
- West-Ward states the shortage is due to manufacturing delays.
- Hospira discontinued promethazine in 2016.
- X-Gen has promethazine available.

Estimated Resupply Date

- West-Ward has promethazine 50 mg/mL 1 mL ampules on back order and the company cannot estimate a release date.

Lidocaine with Epinephrine Injection

September 30, 2017

Reason for the Shortage

- Fresenius Kabi has Xylocaine with epinephrine presentations on shortage due to increased demand for the product and manufacturing delays.
- Pfizer has lidocaine with epinephrine presentations on shortage due to manufacturing delays.

Estimated Resupply Date

- Pfizer has 1% lidocaine with epinephrine (1:100,000) 20 mL on back order and the company estimates a release date of 2nd quarter 2018. The 1% lidocaine with epinephrine (1:100,000) 30 mL vials are on intermittent back order and the company is releasing product as it becomes available. The 1% lidocaine with epinephrine (1:100,000) 50 mL vials are on back order and the company cannot estimate a release date. The 0.5% lidocaine with epinephrine (1:200,000) 50 mL vials are on back order and the company estimates a release date of 1st quarter 2018. The 1.5% lidocaine with epinephrine (1:200,000) 30 mL vials and 5 mL ampules are on back order and the company estimates a release date of October 2017. The 2% lidocaine with epinephrine (1:200,000) 20 mL vials are on intermittent back order and the company is releasing product as it becomes available. The 2% lidocaine with epinephrine (1:100,000) 20 mL, 30 mL, and 50 mL vials are on back order and the company estimates a release date of October 2017 for the 20 mL and 50 mL vials and 1st quarter 2018 for the 30 mL vials.
- Fresenius Kabi has 0.5% Xylocaine with epinephrine (1:200,000) 50 mL vials on intermittent back order and the company is releasing product as it becomes available. The 1% Xylocaine with epinephrine (1:200,000) 10 mL, 20 mL, and 50 mL vials are on intermittent back order and the company is releasing product as it becomes available. The 1% Xylocaine-MPF with epinephrine (1:200,000) 30 mL vials are on intermittent back order and the company is releasing product as it becomes available. The 1% Xylocaine-MPF with epinephrine (1:200,000) 10 mL vials are on back order and the company cannot estimate a release date. The 1% Xylocaine-MPF with epinephrine (1:200,000) 30 mL vials in sterile packs are on intermittent back order and the company is releasing product as it becomes available. The 1.5% Xylocaine-MPF with epinephrine (1:200,000) 10 mL and 30 mL vials are on back order and the company cannot estimate a release date. The 2% Xylocaine with epinephrine (1:200,000) 20 mL and 50 mL vials are on intermittent back order and the company is releasing product as it becomes available. The 2% Xylocaine-MPF with epinephrine (1:200,000) 10 mL vials are on back order and the company cannot estimate a release date. The 2% Xylocaine-MPF with epinephrine (1:200,000) 20 mL vials are on intermittent back order and the company is releasing product as it becomes available. The 2% Xylocaine-MPF with epinephrine (1:200,000) 20 mL vials in sterile packs are on back order and the company cannot estimate a release date.

Labetalol Injection
September 30, 2017

Reason for the Shortage

- Akorn has labetalol injection available.
- Pfizer has labetalol injection on shortage due to manufacturing delays.
- West-Ward has labetalol injection available.

Estimated Resupply Date

- Pfizer has labetalol 5 mg/mL 20 mL and 40 mL vials on intermittent back order and the company is releasing product as it becomes available. The 5 mg/mL 4 mL syringes are on back order and the company estimates a release date of 1st quarter 2018.

Gentamicin injection
September 30, 2017

Reason for the Shortage

- Pfizer has discontinued all premixed bags.
- Baxter did not provide a reason for the shortage.

Estimated Resupply Date

- Fresenius Kabi has gentamicin 40 mg/mL 2 mL vials on intermittent back order and the company is releasing product as it becomes available.

Furosemide Injection
September 30, 2017

Reason for the Shortage

- American Regent is not actively marketing furosemide injection.
- Pfizer has furosemide injection on shortage due to manufacturing delays and increased demand.
- Claris has furosemide injection available.
- Fresenius Kabi has furosemide injection available.

Estimated Resupply Date

- Claris has furosemide 10 mg/mL 10 mL vials in 5 count and 25 count on back order and the company cannot estimate a release date.
- Fresenius Kabi has furosemide 10 mg/mL 10 mL vials on back order and the company estimates a release date of 4th quarter 2017.
- Pfizer has furosemide 10 mg/mL 10 mL syringes available in limited supply. The 10 mg/mL 10 mL vials are on back order and the company estimates a release date of early-November 2017. The 10 mg/mL 4 mL syringes are available in limited supply.

Fluconazole Injection

September 30, 2017

Reason for the Shortage

- Baxter, Claris Lifesciences, and West-Ward did not provide a reason for the fluconazole injection shortage.
- Pfizer has fluconazole injection on shortage due to manufacturing delays.

Estimated Resupply Date

- Baxter has 200 mg/100 mL and 400 mg/200 mL in 0.9% sodium chloride premixed bags on back order and the company cannot estimate a release date.
- Claris Lifesciences has fluconazole injection 100 mg/50 mL in 0.9% sodium chloride in 6 count, 400 mg/200 mL in 0.9% sodium chloride in 6 count, 200 mg/100 mL in 5% dextrose in 6 count, and 400 mg/200 mL in 5% dextrose in 6 count on back order and the company cannot estimate a release date. Fluconazole injection 400 mg/200 mL in 5% dextrose in 10 count is available in limited supply.
- Pfizer has fluconazole injection 400 mg/200 mL in 0.9% sodium chloride premixed bags on back order and the company estimates a release date of early-November 2017. The fluconazole injection 400 mg/200 mL in 5% dextrose premixed bags are on back order and the company estimates a release date of October 2017.
- West-Ward has all presentations on back order. The company cannot estimate a release date for any of the presentations except for the 200 mg/100 mL in 5% dextrose premixed bags which have an estimated release date of November to December 2017.

Etomidate Injection

September 30, 2017

Reason for the Shortage

- Pfizer has Amidate on shortage due to manufacturing delays. Pfizer discontinued etomidate ampules in October 2016.
- Mylan has etomidate available.
- Par Sterile Products discontinued etomidate in early 2015.
- Sagent is no longer marketing etomidate.
- Zydus had etomidate on shortage due to an increase in demand.
- AuroMedics launched etomidate in mid-2017 and product is available.

Estimated Resupply Date

- American Regent has etomidate 2 mg/mL 10 mL and 20 mL vials available with an expiration date of November 2017.
- Mylan Institutional has etomidate 2 mg/mL 10 mL and 20 mL vials available with an expiration date of March 2018.
- Pfizer has Amidate 2 mg/mL 20 mL LifeShield syringes on back order and the company cannot estimate a release date. The 2 mg/mL 10 mL vials are on intermittent back order and the company is releasing product as it becomes available.

Dexrazoxane Injection
September 30, 2017

Reason for the Shortage
- Cumberland Pharmaceuticals relaunched Totect in late-July 2017.
- Mylan Institutional did not provide a reason for the shortage.
- Pfizer states manufacturing delay as the reason for the shortage.
- West-Ward is not actively marketing dexrazoxane injection at this time.

Estimated Resupply Date
- Pfizer has Zinecard 250 mg and 500 mg vials on back order and the company estimates a release date of 1st quarter 2018 for the 250 mg vials and 3rd quarter 2018 for the 500 mg vials.
- Mylan has dexrazoxane 250 mg and 500 mg vials available by drop shipment only.

Cefuroxime Sodium Injection
September 30, 2017

Reason for the Shortage
- Teligent has Zinacef on shortage due to increased demand.
- West-Ward did not provide a reason for the cefuroxime injection shortage.

Estimated Resupply Date
- Sagent has cefuroxime 1.5 gram and 7.5 gram vials on back order and the company cannot estimate a release date.
- Teligent has Zinacef 750 mg vials, 750 mg ADD-Vantage vials, 1.5 gram vials, and 7.5 gram vials on long-term back order and the company cannot estimate a release date.
- West-Ward has cefuroxime 750 mg vials and 7.5 gram vials on allocation.

Calcium Gluconate Injection
September 30, 2017

Reason for the Shortage
- American Regent has calcium gluconate on shortage due to manufacturing delays.
- Fresenius Kabi has calcium gluconate available with alternating short-dating due to manufacturing process of the vials.
- American Regent has issued a statement that all lots of calcium gluconate may contain glass particles and filters must be used. Do not use if there are visible glass particles and filter all other product.

Estimated Resupply Date
- American Regent has calcium gluconate 100 mg/mL 50 mL and 100 mL vials on back order and the company cannot estimate a release date.
- Fresenius Kabi has calcium gluconate 100 mg/mL 10 mL, 50 mL, and 100 mL vials on intermittent back order and the company is releasing product as it becomes available. Check wholesalers for inventory.

Bupivacaine with epinephrine Injection

September 30, 2017

Reason for the Shortage

- Fresenius Kabi has bupivacaine and epinephrine on shortage due to increased demand and manufacturing delays.
- Pfizer has bupivacaine with epinephrine on shortage due to manufacturing delays.

Estimated Resupply Date

- Fresenius Kabi has 0.25% Sensorcaine-MPF with epinephrine 10 mL and 30 mL vials on intermittent back order and the company is releasing product as it becomes available. The 0.25% Sensorcaine with epinephrine 50 mL vials are on intermittent back order and the company is releasing product as it becomes available. The 0.5% Sensorcaine-MPF with epinephrine 30 mL vials are on intermittent back order and the company is releasing product as it becomes available. The 0.5% Sensorcaine-MPF with epinephrine 10 mL vials are on back order and the company cannot estimate a release date. The 0.5% Sensorcaine-MPF with epinephrine 30 mL vials and 30 mL sterile packs are on intermittent back order and the company is releasing product as it becomes available. The 0.5% Sensorcaine with epinephrine 50 mL vials are on back order and the company cannot estimate a release date. The 0.75% Sensorcaine with epinephrine 30 mL vials are on back order and the company cannot estimate a release date.
- Pfizer has 0.25% bupivacaine with epinephrine 10 mL and 30 mL preservative-free vials on back order and the company estimates a release date of October 2017. The 0.25% bupivacaine with epinephrine 50 mL vials are on back order and the company estimates a release date of October 2017. The 0.5% bupivacaine with epinephrine 10 mL and 30 mL preservative-free vials are on back order and the company estimates a release date of October 2017. The 0.5% bupivacaine with epinephrine 50 mL vials are on back order and the company estimates a release date of October 2017.
- Pfizer has 0.25% Marcaine with epinephrine 10 mL and 30 mL preservative-free vials on intermittent back order and the company is releasing product as it becomes available. The 0.25% Marcaine with epinephrine 50 mL vials are on back order and the company estimates a release date of 1st quarter 2018. The 0.5% Marcaine with epinephrine 10 mL and 30 mL preservative-free vials are on back order and the company estimates a release date of 1st quarter 2018 for the 10 mL vials and October 2017 for the 30 mL vials. The 0.5% Marcaine with epinephrine 50 mL vials are on back order and the company estimates a release date of 1st quarter 2018.

Succinylcholine Injection

October 2, 2017

Reason for the Shortage

- Pfizer has Quelicin on shortage due to manufacturing delays.

Estimated Resupply Date

- Pfizer has Quelicin 20 mg/mL 10 mL vials available in limited supply.

Sodium Bicarbonate Injection

October 2, 2017

Reason for the Shortage

- Amphastar has sodium bicarbonate injection on shortage due to increased demand.
- Pfizer has sodium bicarbonate injection on shortage due to manufacturing delays.
- Fresenius Kabi has reintroduced sodium bicarbonate injection in response to the shortage.

Estimated Resupply Date

- Amphastar has 8.4 % sodium bicarbonate 50 mL syringes on allocation.
- Fresenius Kabi has 8.4% bicarbonate 50 mL vials on intermittent back order and the company is releasing product as it becomes available. Check wholesalers for inventory
- Pfizer has 8.4 % sodium bicarbonate 50 mL syringes and 50 mL vials available in limited supply. The 8.4% sodium bicarbonate 10 mL syringes are available in limited supply. The 4.2% sodium bicarbonate 10 mL syringes are available in limited supply. The 7.5% sodium bicarbonate 50 mL syringes are available in limited supply
- Pfizer has Neut 4% additive solution in 5 mL vials on back order and the company estimates a release date of October 2017.
- To help alleviate the shortage, FDA is granting Athenex Pharmaceutical Division (APD) the ability to import 10 mL vials of sodium bicarbonate from Phebra, an Australian company. Supplies are limited and only available via direct orders. Orders may be placed by contacting customer service at 855-273-0154 or apdorders@dlss.com.

Norepinephrine Bitartrate Injection

October 2, 2017

Reason for the Shortage

- Claris has norepinephrine injection available.
- Pfizer has Levophed on shortage due to manufacturing delays.
- Teva has norepinephrine injection available.

Estimated Resupply Date

- Pfizer has Levophed 1 mg/mL 4 mL ampules and vials on allocation.

Nitroglycerin Injection

October 2, 2017

Reason for the Shortage

- American Regent did not provide a reason for the shortage.
- The premixed bags are not affected by this shortage.

Estimated Resupply Date

- American Regent has nitroglycerin 50 mg/mL 10 mL vials available.

Metoclopramide Injection

October 2, 2017

Reason for the Shortage

- Fresenius Kabi has metoclopramide 2 mL syringes available.
- Pfizer has metoclopramide injection on shortage due to manufacturing delays.
- Teva has metoclopramide injection on shortage.

Estimated Resupply Date

- Pfizer has metoclopramide 5 mg/mL 2 mL vials on back order and the company estimates a release date of late-October 2017.
- Teva has metoclopramide 5 mg/mL 2 mL vials on intermittent back order and the company is allocating product upon release.

Methotrexate Injection

October 2, 2017

Reason for the Shortage

- Accord did not provide a reason for the shortage.
- Fresenius Kabi has methotrexate injection on shortage due to increased demand.
- Mylan did not provide a reason for the shortage.
- Pfizer had methotrexate injection on shortage due to increased demand.
- Teva has methotrexate injection on shortage due to increased demand.

Estimated Resupply Date

- Accord has methotrexate 25 mg/mL 2 mL, 10 mL, and 40 mL vials on back order and the company cannot estimate a release date.
- Mylan Institutional has methotrexate injection temporarily unavailable and the company cannot estimate a release date.
- Teva has methotrexate 25 mg/mL 2 mL, 10 mL, and 40 mL preservative-free vials on allocation. Please check wholesaler for inventory.

Mepivacaine Injection

October 2, 2017

Reason for the Shortage

- Pfizer said the reason for the back order is manufacturing delays.

Estimated Resupply Date

- Pfizer has Carbocaine 1% in 50 mL multiple-dose vials on back order and the company estimates a release date of late-November 2017. Carbocaine 1% 30 mL preservative-free vials are on intermittent back order and the company is releasing product as it becomes available. Carbocaine 1.5% in 30 mL preservative-free vials are on intermittent back order and the company is releasing product as it becomes available. Carbocaine 2% in 20 mL preservative-free vials are on intermittent back order and the company is releasing product as it becomes

available. Carbocaine 2% in 50 mL multiple-dose vials are back order and the company estimates a release date of late-October 2017.

Meperidine Hydrochloride Injection

October 2, 2017

Reason for the Shortage

- Pfizer has Demerol injection on shortage due to manufacturing delays.

Estimated Resupply Date

- Pfizer has Demerol 50 mg/mL 0.5 mL ampules on intermittent back order and the company is releasing product as it becomes available. The 100 mg/mL 20 mL vials are on back order and the company estimates a release date of 1st quarter 2018. The 100 mg/mL 1 mL Carpuject syringes are on back order and the company estimates a release date of 3rd quarter 2018. The 25 mg/mL 1 mL Carpuject syringes and 75 mg/mL 1 mL Carpuject syringes are on back order and the company estimates a release date of 2019. The 50 mg/mL 30 mL vials are on back order and the company cannot estimate a release date.

Mannitol Injection

October 2, 2017

Reason for the Shortage

- American Regent did not provide a reason for the mannitol shortage.
- Baxter did not provide a reason for the mannitol shortage.
- Fresenius Kabi did not provide a reason for the mannitol shortage.
- Pfizer has mannitol on shortage due to manufacturing delays.

Estimated Resupply Date

- American Regent has mannitol 250 mg/mL 50 mL vials on back order and the company cannot estimate a release date.
- Baxter has Osmitrol 50 mg/mL 1000 mL premixed bags on back order and the company cannot estimate a release date. The 200 mg/mL 250 mL and 500 mL premixed bags are available in limited supply.
- Fresenius Kabi has mannitol 250 mg/mL 50 mL vials on intermittent back order and the company is releasing product as it becomes available.
- Pfizer has mannitol 250 mg/mL 50 mL vials on intermittent back order and the company is releasing product as it becomes available.

Magnesium Sulfate Injection

October 2, 2017

Reason for the Shortage

- American Regent has had magnesium sulfate unavailable since late 2012.

- Fresenius Kabi had magnesium sulfate injection on shortage due to increased demand for the product.
- Pfizer has magnesium sulfate injection on shortage due to manufacturing delays.
- X-Gen has magnesium sulfate injection available.

Estimated Resupply Date

- Pfizer has magnesium sulfate 500 mg/mL 20 mL vials on back order and the company estimates a release date of 2nd quarter 2018. The 500 mg/mL 10 mL Ansyr syringes are available in limited supply.

Hydromorphone Hydrochloride Injection

October 2, 2017

Reason for the Shortage

- Pfizer did not provide a reason for the shortage.
- Purdue discontinued Dilaudid and Dilaudid HP in May 2017 for marketing reasons.
- Teva did not provide a reason for the shortage.
- West-Ward did not provide a reason for the shortage.

Estimated Resupply Date

- Fresenius Kabi has Dilaudid 1 mg/mL 1 mL syringes on intermittent back order and the company is releasing product as it becomes available. The 2 mg/mL 1 mL syringes are on back order and the company estimates a release date of October 2017.
- Pfizer has hydromorphone 0.5 mg/0.5 mL 0.5 mL iSecure syringes available in limited supply. The 1 mg/mL 1 mL Carpuject syringes, 2 mg/mL 1 mL vials, and 10 mg/mL 5 mL vials are on intermittent back order and the company is releasing product as it becomes available. The 1 mg/mL 1 mL iSecure syringes, 2 mg/mL 1 mL iSecure syringes, and 4 mg/mL 1 mL Carpuject syringes are on back order and the company estimates a release date of 3rd quarter 2018.
- Teva has hydromorphone 10 mg/mL 1 mL and 5 mL vials on allocation.
- West-Ward has hydromorphone 2 mg/mL 1 mL and 20 mL vials on allocation.

Erythromycin Lactobionate Injection

October 2, 2017

Reason for the Shortage

- Pfizer has Erythrocin on shortage due to manufacturing delays.

Estimated Resupply Date

- Pfizer has Erythrocin 500 mg ADD-Vantage vials and regular vials on back order and the company estimates a release date of 4th quarter 2017.

Epinephrine Injection
October 2, 2017

Reason for the Shortage
- Amphastar stopped distributing epinephrine 1 mg/mL 30 mL vials on May 10, 2017. They are continuing to supply 0.1 mg/mL 10 mL syringes. These are on shortage due to increased demand.
- Pfizer stopped distributing epinephrine 1 mg/mL presentations on May 10, 2017.
- BPI has epinephrine 1 mg/mL 2 mL ampules available.
- Par has Adrenalin 1 mg/mL 1 mL and 30 mL vials available.

Estimated Resupply Date
- Amphastar has epinephrine 0.1 mg/mL 10 mL syringes on allocation.
- Pfizer has epinephrine 0.1 mg/mL 10 mL syringes available in limited supply.

Disopyramide Phosphate Controlled-release Capsules
October 2, 2017

Reason for the Shortage
- Pfizer has disopyramide controlled-release capsules on shortage due to manufacturing delays.

Estimated Resupply Date
- Pfizer has Norpace CR 150 mg capsules in 100 count available with an expiration date of July 2018. The 100 mg capsules in 100 count and 500 count and 150 mg capsules in 500 count are on back order and the company estimates a release date of March 2018.

Dextrose (50%) Injection
Dextrose (25%) Injection
October 2, 2017

Reason for the Shortage
- Amphastar has 50% dextrose injection on shortage due to increased demand.
- Pfizer has 50% dextrose injection on shortage due to manufacturing delays.
- Pfizer has 25% dextrose injection on shortage due to manufacturing delays.

Estimated Resupply Date
- Amphastar has 50% dextrose 50 mL syringes on allocation and is regularly releasing product.
- Pfizer has 50% dextrose 50 mL LifeShield syringes and 50 mL Ansyr II syringes available in limited supply. The 50% dextrose 50 mL vials are on back order and the company estimates a release date of October 2017.
- Pfizer has 25% dextrose 10 mL Ansyr syringes available in limited supply.

Dexpanthenol Injection
October 2, 2017

Reason for the Shortage
- American Regent has dexpanthenol injection on shortage due to manufacturing delays.
- There are no other suppliers of dexpanthenol injection.

Estimated Resupply Date
- American Regent has dexpanthenol injection on long-term back order and the company cannot estimate a release date.

Acetylcysteine Oral and Inhalation Solution
October 2, 2017

Reason for the Shortage
- American Regent has acetylcysteine oral and inhalation solution on shortage due to manufacturing delays.
- Fresenius Kabi has acetylcysteine oral and inhalation solution available.
- Pfizer has acetylcysteine oral and inhalation solution on shortage due to manufacturing delays.
- Roxane Labs discontinued acetylcysteine oral and inhalation solution in April 2014.

Estimated Resupply Date
- American Regent has acetylcysteine solution 100 mg/mL 10 mL vials, and 200 mg/mL 10 mL and 30 mL vials on back order and the company cannot estimate a release date. Acetylcysteine 200 mg/mL 4 mL in 25 count is available in limited quantities.
- Fresenius Kabi has acetylcysteine solution 200 mg/mL 30 mL vials on back order and the company estimates a release date of late-November 2017.
- Pfizer has acetylcysteine solution 200 mg/mL 30 mL vials on back order and the company estimates a release date in December 2017.

23.4% Sodium Chloride Injection
0.9% Sodium Chloride 10 mL, 20 mL, and 50 mL Preservative Free Vials
October 2, 2017

Reason for the Shortage
- Fresenius Kabi has 23.4% sodium chloride injection on shortage due to increased demand.
- Pfizer has 23.4% sodium chloride injection on shortage due to increased demand.
- Fresenius Kabi has 0.9% sodium chloride preservative free vials available.
- Pfizer could not provide a reason for the shortage.

Estimated Resupply Date
- Fresenius Kabi has 23.4% sodium chloride 30 mL on back order and the company estimates a release date of late-October to early-November 2017. The 200 mL vials are on intermittent back order and the company is releasing product as it becomes available.

- Pfizer has 23.4% sodium chloride 200 mL vials on back order and the company estimates a release date of late-October 2017.
- Pfizer has 0.9% sodium chloride preservative free Life Shield vials on intermittent back order and the company is releasing product as it becomes available.

Sincalide Injection

October 4, 2017

Reason for the Shortage

- Bracco Diagnostics has Kinevac injection on shortage due to a supply disruption.
- There are no approved alternatives to Kinevac for the labeled indications.

Estimated Resupply Date

- Bracco has Kinevac on back order and the company cannot estimate a release date.

Potassium Phosphate Injection

October 4, 2017

Reason for the Shortage

- American Regent has not had potassium phosphate injection available since 2012. It is unclear if and when product will return to market.
- Fresenius Kabi has potassium phosphate injection on shortage due to increased demand.
- Pfizer had potassium phosphate injection on shortage due to manufacturing delays.

Estimated Resupply Date

- Fresenius Kabi has potassium phosphate 3 mmol/mL 15 mL and 50 mL vials on intermittent back order and the company is releasing product as it becomes available.

Potassium Chloride Injection

October 4, 2017

Reason for the Shortage

- Baxter has their highly concentrated potassium chloride in sterile water on shortage because a manufacturing facility has been affected by Hurricane Maria. Baxter has removed these products from distribution and they can be purchased directly if they are in stock. Baxter is also adjusting the allocation of these products. Baxter did not provide a reason for the shortage of their other potassium chloride products.
- Pfizer has potassium chloride injection on shortage due to increase demand and manufacturing delays.

Estimated Resupply Date

- Baxter has potassium chloride 10 mEq/1000 mL in 5% dextrose and 0.45% sodium chloride, potassium chloride 20 mEq/1000 mL in 5% dextrose and 0.2% sodium chloride, and potassium chloride 20 mEq/1000 mL in 0.45% sodium chloride available in limited quantities. Potassium

chloride 20 mEq/1000 mL in 5% dextrose and 0.9% sodium chloride and potassium chloride 40 mEq/1000 mL in 5% dextrose and 0.9% sodium chloride on back order and the company cannot estimate a release date.

- Baxter has potassium chloride 10 mEq/50 mL in sterile water and 10 mEq/100 mL in sterile water available for direct purchase. Baxter has 20 mEq/100 mL in sterile water, 40 mEq/100 mL in sterile water, and 20 mEq/50 mL in sterile water on back order and the company cannot estimate a release date.
- Fresenius Kabi has potassium chloride 10 mEq/ 5 mL and 20 mEq/10 mL on back order and the company estimates a release date of mid-October 2017.
- Pfizer has potassium chloride 2 mEq/mL 10 mL vials on back order and the company estimates resupply in late-October 2017. The 10 mEq/100 mL sterile water, 20 mEq/100 mL in sterile water, and 20 mEq/50 mL sterile water are on back order and the company estimates a release date in mid-October 2017. Potassium chloride 10 mEq/500 mL in 5% dextrose and 0.225% sodium chloride premixed bags are on long-term back order.

Potassium Acetate Injection

October 4, 2017

Reason for the Shortage

- American Regent has not had product available for several years. It is unclear if they will market potassium acetate again in the future.
- Pfizer has potassium acetate on shortage due to manufacturing delays.

Estimated Resupply Date

- Pfizer has potassium acetate 2 mEq/mL 20 mL vials on back order and the company estimates a release date of early-December 2017. The potassium acetate 50 mL vials are available in limited supply.

Pantoprazole Injection

October 4, 2017

Reason for the Shortage

- Pfizer did not provide a reason for the back order.
- AuroMedics did not provide a reason for the back order.

Estimated Resupply Date

- Pfizer has Protonix 40 mg vials in 10 count and 25 count packs on back order and the company estimates a release date of October 2017.
- AuroMedics has pantoprazole 40 mg vials on intermittent back order and the company and the company is releasing product as it becomes available.

Morphine Injections

October 4, 2017

Reason for the Shortage

- Astramorph injection has been unavailable since 2012. Fresenius Kabi changed manufacturing sites and cannot estimate if Astramorph will return.
- Pfizer states the shortage is due to manufacturing delays. Pfizer discontinued morphine ADD-Vantage vials in January 2017.
- Pfizer anticipates a shortage of several prefilled syringe products, including morphine, starting in late-July 2017 due to issues at a manufacturing facility. To minimize the impact of the shortage, Pfizer is prioritizing production of certain morphine Carpuject syringes. Pfizer expects the shortage of prefilled syringe products to recover by late-first quarter 2018.
- West-Ward launched several new morphine sulfate products in late-September 2015. They are not actively marketing the 15 mg/mL 1 mL vials or the 8 mg/mL 1 mL vials (NDC 00641-6075-25). They are still marketing the 8 mg/mL 1 mL vials with NDC 00641-6126-25.

Estimated Resupply Date

- Fresenius Kabi has morphine 2 mg/mL 1 mL syringes and 4 mg/mL 1 mL syringes on back order and the company estimates a release date of October 2017.
- Pfizer has morphine 2 mg/mL 1 mL Carpuject syringes and 4 mg/mL 1 mL Carpuject syringes on back order and the company estimates a release date of October 2017 for the 2 mg/mL syringes and December 2017 for the 4 mg/mL syringes. The 50 mg/mL 50 mL vials are on back order and the company estimates a release date of late-October 2017. The 25 mg/mL 1 mL preservative-free vials are on back order and the company estimates a release date of late-October 2017. The 2 mg/mL 1 mL iSecure syringes, 4 mg/mL 1 mL iSecure syringes, 8 mg/mL 1 mL Carpuject syringes, and 10 mg/mL 1 mL Carpuject syringes are on back order and the company estimates a release date of 3rd quarter 2018.
- West-Ward has Duramorph 0.5 mg/mL 10 mL ampules and 1 mg/mL 10 mL ampules on a weekly allocation. Morphine 4 mg/mL 1 mL vials and 10 mg/mL 1 mL vials are on back order and the company estimates a release date of October 2017.

Lidocaine Injection

October 4, 2017

Reason for the Shortage

- Amphastar had lidocaine 2% emergency syringes on shortage due to increase demand for the product.
- AuroMedics introduced lidocaine injection in February 2014.
- Fresenius Kabi had generic lidocaine presentations on shortage due to a supply interruption of raw ingredients.
- Pfizer has lidocaine presentations on shortage due to manufacturing delays.

Estimated Resupply Date

- AuroMedics has 1% lidocaine 5 mL ampules on intermittent back order and the company is releasing product as it becomes available. AuroMedics has 2% lidocaine 2 mL ampules on intermittent back order and the company is releasing product as it becomes available.

- Fresenius Kabi has 1% Xylocaine 20 mL and50 mL vials on intermittent back order and the company is releasing product as it becomes available. The 1% Xylocaine-MPF 30 mL vial sterile packs are on intermittent back order and the company is releasing product as it becomes available. The 2% Xylocaine 20 mL and 50 mL vials are on intermittent back order and the company is releasing product as it becomes available. The 2% Xylocaine-MPF 5 mL vials are on intermittent back order and the company is releasing product as it becomes available.
- Pfizer has 1% lidocaine 50 mL vials available in limited supply. The 0.5% lidocaine 50 mL tear drop vials are on back order and the company cannot estimate a release date. The 1% lidocaine 2 mL preservative-free ampules are on back order and the company estimates a release date of late-November 2017. The 1% lidocaine 5 mL preservative-free ampules are available in limited supply. The 1% lidocaine 5 mL Ansyr syringes and 5 mL LifeShield syringes are available in limited supply. The 2% lidocaine 5 mL vials are on back order and the company estimates a release date of 1st quarter 2018. The 2% lidocaine 10 mL ampules and 2% lidocaine 5 mL LifeShield syringes are on back order and the company estimates release dates of early-November 2017 for the ampules and October 2017 for the syringes. The 2% lidocaine 5 mL Ansyr syringes are available in limited supply.

Diltiazem Hydrochloride Injection

October 4, 2017

Reason for the Shortage

- Akorn states the reason for the shortage was increased demand due to market conditions.
- Pfizer states the reasons for the shortage is manufacturing delays and increases in demand.
- West-Ward has diltiazem injection on shortage due to manufacturing delays caused by increased demand due to current market conditions.

Estimated Resupply Date

- Pfizer has 100 mg ADD-Vantage vials on intermittent back order and the company is releasing product as it becomes available. The 5 mg/mL 5 mL and 10 mL vials are on back order and the company estimates a release date of 2018.
- West-Ward has diltiazem 5 mg/mL 10 mL and 25 mL vials on a weekly allocation.

Diazepam Injection

October 4, 2017

Reason for the Shortage

- Pfizer has diazepam on shortage due manufacturing delays.

Estimated Resupply Date

- Pfizer has diazepam 5 mg/mL 2 mL Carpuject syringes on back order and the company estimates a release date of December 2017.

Calcium Chloride Injection

October 4, 2017

Reason for the Shortage

- American Regent had calcium chloride on shortage due to manufacturing delays.
- Amphastar has calcium chloride on shortage due to increased demand.
- Pfizer has calcium chloride on shortage due to manufacturing delays.
- Mylan Institutional has withdrawn calcium chloride syringes from the market. The company recalled the syringes in April 2015 due to incompatibility of the syringes and some needless adaptors.

Estimated Resupply Date

- Amphastar has calcium chloride 100 mg/mL 10 mL syringes on intermittent back order with regular releases.
- Pfizer has calcium chloride 100 mg/mL 10 mL Ansyr syringes available in limited supply. The 100 mg/mL 10 mL LifeShield syringes are on back order and the company estimates a release date of late-October 2017.

Bupivacaine Injection

October 4, 2017

Reason for the Shortage

- AuroMedics has not provided a reason for the shortage.
- Fresenius Kabi had Sensorcaine on shortage due to increased demand for the product.
- Pfizer has bupivacaine on shortage due to manufacturing delays.

Estimated Resupply Date

- Pfizer has 0.25% Marcaine 10 mL and 30 mL preservative-free vials on back order and the company estimates a release date of 2nd quarter 2018 for the 10 mL vials and cannot estimate a release date for the 30 mL vials. The 0.25 Marcaine 50 mL vials are on back order and the company cannot estimate a release date. The 0.5% Marcaine 10 mL and 30 mL preservative-free vials are on back order and the company estimates a release date of 2nd quarter 2018. The 0.75% Marcaine 10 mL preservative-free vials are on back order and the company estimates a release date of 1st quarter 2018.
- Pfizer has 0.25% bupivacaine 30 mL preservative-free vials on back order and the company estimates a release date of early-November 2017. The 0.5% bupivacaine 30 mL preservative-free vials are on back order and the company estimates a release date of mid-November 2017.

Bumetanide Injection

October 4, 2017

Reason for the Shortage

- Pfizer has bumetanide injection on shortage due to manufacturing delays.
- West-Ward did not provide a reason for the shortage.

Estimated Resupply Date

- Pfizer has bumetanide 0.25 mg/mL 4 mL and 10 mL vials on back order and the company estimates a release date of early-April 2018.
- West-Ward has bumetanide 0.25 mg/mL 4 mL and 10 mL vials on a weekly allocation.

Atenolol Tablets

October 4, 2017

Reason for the Shortage

- Mylan, Sandoz, and Teva did not provide a reason for the back order.
- Zydus states increased demand as the reason for the back order.
- Ranbaxy refuses to provide us with any information regarding drug availability.

Estimated Resupply Date

- Major has atenolol 25 mg tablets on back order and the company cannot estimate a release date.
- Mylan has all atenolol in bottles on back order and the company cannot estimate a release date.
- Sandoz has all atenolol tablets temporarily unavailable and the company cannot estimate a release date.
- Teva has all presentations of atenolol 50 mg and 100 mg tablets on back order and the company cannot estimate a release date.
- Zydus has all presentations of atenolol 25 mg, 50 mg, and 100 mg tablets on allocation.
- Almatica has Tenormin 100 mg tablets on back order and the company cannot estimate a release date. The 25 mg and 50 mg tablets are on allocation.

Vancomycin Hydrochloride Injection

October 5, 2017

Reason for the Shortage

- Pfizer has vancomycin vials on back order due to manufacturing delays.
- Fresenius Kabi has vancomycin injection on shortage due to increased demand.
- Mylan Institutional has vancomycin injection available.
- Sagent has vancomycin injection on shortage due to manufacturing delays.
- Baxter has vancomycin injection available.
- Samson Medical Technologies has vancomycin injection available.

Estimated Resupply Date

- Fresenius Kabi has vancomycin 500 mg, 1 gram, 5 gram and 10 gram vials on intermittent back order with regular releases.
- Pfizer has vancomycin lyophilized powder 750 mg vials on back order and the company estimates a release date of January 2018. The 500 mg, 1 gram, 5 gram, and 10 gram vials are available in limited supply. The 500 mg and 750 mg ADD-vantage vials are on back order and the company estimates a release date of October 2017. The 1 gram ADD-Vantage vials are available in limited supply.

- Sagent has vancomycin 5 gram and 10 gram vials on back order and the company estimates a release date of October 2017.

Theophylline Extended-Release Tablets

October 5, 2017

Reason for the Shortage

- Major has discontinued theophylline extended-release tablets.
- Teva cannot provide a reason for the shortage.

Estimated Resupply Date

- Teva has theophylline extended-release tablets temporarily unavailable and the company cannot estimate a release date.

Talc, Sterile

October 5, 2017

Reason for the Shortage

- Lymol has Sclerosol and talc powder on shortage due to manufacturing delays.
- Novatech SA is launching Steritalc powder and the company estimates a release date in September 2017.

Estimated Resupply Date

- Lymol has Sclerosol and talc powder on long-term back order and the company cannot estimate a release date.
- Novatech SA is launching Steritalc powder and the company did not estimate a release date for the 2 gram/50 mL and 3 gram/10 mL vials.

Rocuronium Injection

October 5, 2017

Reason for the Shortage

- Fresenius Kabi has rocuronium on shortage due to delay of raw materials.
- Pfizer has rocuronium on shortage due to manufacturing delays.
- Sagent has rocuronium on shortage due to increased demand.
- X-Gen has rocuronium on shortage due to increased demand.
- AuroMedics launched rocuronium in mid-2017.

Estimated Resupply Date

- Pfizer has rocuronium 10 mg/mL 5 mL and 10 mL vials on back order and the company estimates a release date of mid-October 2017 for both presentations.
- Sagent has rocuronium 10 mg/mL 5 mL vials on back order and the company estimates a release date of November 2017. The 10 mL vials are on allocation.

- Auromedics has rocuronium 10 mg/mL 5 mL and 10 mL vials available with intermittent releases.
- Sandoz has rocuronium 10 mg/mL 5 mL vials available in limited quantities.
- X-Gen has rocuronium 10 mg/mL 5 mL and 10 mL vials on back order and the company estimates a release date of mid-October 2017.

Piperacillin Tazobactam Injection

October 5, 2017

Reason for the Shortage

- Apotex has piperacillin/tazobactam on shortage due to regulatory delays.
- AuroMedics and Sandoz could not provide a reason for the shortage.
- Fresenius Kabi has piperacillin/tazobactam on shortage due to increased demand.
- Mylan Institutional launched piperacillin/tazobactam 3.375 gram and 4.5 gram vials in early-June 2016.
- Pfizer has Zosyn single dose vials and piperacillin/tazobactam on shortage due to manufacturing delays.
- Sagent has piperacillin/tazobactam on shortage due to increased demand.
- Sandoz has piperacillin/tazobactam available for contracted customers.
- WG Critical Care states the reason for the shortage is increased demand.
- FDA in conjunction with SteriMax was allowing temporary importation of piperacillin/tazobactam 3.375 gram, 4.5 gram, and 40.5 gram vials from Canada. This was being distributed through X-Gen Pharmaceuticals. These are no longer being imported with the launch of the products from X-Gen. The product codes on these items will not be recognized by U.S. systems so institutions will need to implement alternative plans to assure the dose is being given correctly. More information can be found here on the FDA site.
- Wockhardt has piperacillin/tazobactam injection available.
- X-Gen has piperacillin/tazobactam injection available.

Estimated Resupply Date

- Apotex has piperacillin/tazobactam 3.375 gram and 40.5 gram vials on back order and the company estimates a release date of late-October 2017.
- AuroMedics has piperacillin/tazobactam 3.375 gram vials on intermittent back order and the company is releasing product as it becomes available. Check wholesalers for inventory.
- Pfizer has Zosyn 2.25 gram vials, 3.375 gram vials, 4.5 gram vials, and 40.5 gram vials on back order and the company estimates a release date of January 2018. Pfizer has piperacillin/tazobactam 4.5 gram ADD-Vantage vials on back order and the company estimates a release date of mid-December 2017.
- Sandoz has piperacillin/tazobactam 2.25 gram (NDC 00781-3110-85) and 4.5 gram (NDC 00781-3114-95) temporarily unavailable and the company cannot estimate a release date.
- WG Critical Care has piperacillin/tazobactam 40.5 gram vials on back order and the company cannot estimate a release date.
- Mylan has piperacillin/tazobactam 4.5 gram vials on back order and the company estimates a resupply date of early-November 2017.

Octreotide Injection

October 5, 2017

Reason for the Shortage

- Fresenius Kabi did not provide a reason for the shortage.
- Mylan Institutional has octreotide available.
- Sagent has octreotide on shortage due to manufacturing delays.
- Sun Pharma refuses to provide availability information for any of their products including octreotide.
- Teva has octreotide available.
- Novartis has Sandostatin available.

Estimated Resupply Date

- Fresenius Kabi has octreotide 50 mcg/mL 1 mL vials on back order and the company estimates a release date of 1st quarter 2018. Octreotide 100 mcg/mL and 500 mcg/mL 1 mL vials are on back order and the company estimates a release date of October 2017.
- Sagent has octreotide 50 mcg/mL 1 mL vials on allocation. The 500 mcg/mL 1 mL vials and 1000 mcg/mL 5 mL vials are on back order and the company estimates a release date of October 2017. There are short-dated octreotide 1000 mcg/mL 5 mL vials available.

Lorazepam Injection

October 5, 2017

Reason for the Shortage

- Bedford discontinued lorazepam injection in May, 2011.
- West-Ward has product on shortage due to manufacturing delays.
- Pfizer has product on shortage due to increased demand and manufacturing delays.
- Akorn has not provided a reason for the shortage.
- Amphastar has product available.

Estimated Resupply Date

- Pfizer has lorazepam 2 mg/mL 1 mL Carpuject syringes available in limited quantities. The 2 mg/mL 10 mL vials are on back order and the company estimates a release date of 1st quarter 2018. The 4 mg/mL 1 mL vials are on back order and the company estimates a release date of late-October 2017. The 4 mg/mL 1 mL Carpuject syringes are on back order and the company estimates a release date of 3rd quarter 2018.
- West-Ward has lorazepam 2 mg/mL 1 mL vials on allocation.
- West-Ward has Ativan 2 mg/mL 10 mL vials available with an expiration date of August 2018. The 2 mg/mL 1 mL vials are on back order and the company estimates release date of October or November 2017.

Furosemide Tablets

October 5, 2017

Reason for the Shortage

- Major states the shortage is due to supply and demand issues.
- Mylan and Teva did not provide a reason for the shortage.
- West-Ward states the shortage is due to manufacturing delays.
- Sandoz discontinued furosemide tablets in late-August 2017.

Estimated Resupply Date

- Mylan has furosemide 20 mg and 40 mg tablets in 100 count and 1000 count bottles on back order and the company estimates a release date of October 2017. The furosemide 80 mg tablets in 1000 count bottles are on back order and the company estimates a release date of late-November 2017.
- Teva has furosemide 20 mg and 40 mg tablets in 100 and 1000 count bottles on back order and the company cannot estimate a release date.
- West-Ward has furosemide 20 mg 100 count unit-dose blister packs on back order and the company cannot estimate a release date. The 20 mg tablets in 100 count bottles are on allocation. The 40 mg tablets in 100 count and 1000 count bottles and 100 count unit-dose blister packs are on allocation. The 80 mg tablets in 100 count bottles and 100 count unit-dose blister packs are on allocation.

Famotidine Injection

October 5, 2017

Reason for the Shortage

- Ben Venue stopped production in its plant in Bedford, Ohio and closed in July 2014.
- West-Ward stated the shortage was due to manufacturing delays.
- Oral famotidine products are not affected by this shortage.
- Pfizer launched famotidine injections in March 2012.
- Mylan Institutional acquired famotidine injections from Pfizer on December 6, 2013.
- Baxter has famotidine premixed bags available.
- Fresenius Kabi has famotidine vials available.

Estimated Resupply Date

- Mylan Institutional has famotidine 10 mg/mL 4 mL vials on back order and the company estimates a release date of October 2017.
- West-Ward has famotidine 10 mg/mL 20 mL vials on back order and the company estimates a release date of October 2017.

Cisplatin Injection

October 5, 2017

Reason for the Shortage

- Fresenius Kabi did not provide a reason for the shortage.
- Mylan Institutional could not provide a reason for the shortage.
- Teva has cisplatin on allocation due to increased demand.
- WG Critical Care has cisplatin available.

Estimated Resupply Date

- Fresenius Kabi has cisplatin 200 mL vials on back order and the company estimates a release date of mid-October 2017.
- Mylan Institutional has cisplatin 50 mL and 100 mL vials temporarily unavailable and the company cannot estimate a release date.

Ampicillin Sulbactam

October 5, 2017

Reason for the Shortage

- Pfizer has discontinued generic ampicillin sulbactam.
- Sandoz cannot provide a reason for the shortage.
- Sagent has ampicillin sulbactam vials on allocation due to manufacturing delays.
- WG Critical Care states the shortage was due to increased demand.

Estimated Resupply Date

- AuroMedics has ampicillin sulbactam 1.5 gram and 3 gram vials on intermittent back order and the company is releasing product as it becomes available.
- Fresenius Kabi has ampicillin sulbactam 1.5 gram, 3 gram, and 15 gram vials on long-term back order and the company cannot estimate a release date.
- Sagent has ampicillin sulbactam 1.5 gram, 3 gram, and 15 gram vials on back order and the company estimates a release date of October 2017. Short-dated product is available.
- Sandoz has ampicillin sulbactam 1.5 gram, 3 gram, and 15 gram vials temporarily unavailable and the company cannot estimate a release date.

Indigo Carmine Injection

October 6, 2017

Reason for the Shortage

- American Regent launched indigo carmine in July 2017.
- Akorn has discontinued production of indigo carmine due to shortage of raw material.

Estimated Resupply Date

- American Regent has indigo carmine 8 mg/mL 5 mL ampules available.

Sodium Phosphate Injection

October 8, 2017

Reason for the Shortage

- American Regent has sodium phosphate injection on shortage due to manufacturing delay.
- Fresenius Kabi states the reason for the shortage is increased demand.
- Pfizer has sodium phosphate injection on shortage due to manufacturing delay.

Estimated Resupply Date

- American Regent has sodium phosphate 3 mmol/mL 5 mL, 15 mL, and 50 mL vials on back order and the company cannot estimate a release date.
- Fresenius Kabi has sodium phosphate 3mmol/mL 5 mL and 15 mL vials on back order and the company estimates a release date of early-December 2017.
- Pfizer has sodium phosphate 3 mmol/mL 15 mL vials available in limited supply.

Selenium Injection

October 8, 2017

Reason for the Shortage

- American Regent did not provide a reason for the shortage.

Estimated Resupply Date

- American Regent has selenium 40 mcg/mL 10 mL vials available in limited supply.

Levetiracetam Injection

October 8, 2017

Reason for the Shortage

- American Regent has product available.
- AuroMedics did not provide a reason for the shortage.
- Caraco will not provide availability information on levetiracetam.
- Fresenius Kabi had levetiracetam injection on shortage due to manufacturing delays.
- Mylan has product available.
- Pfizer has product available.
- Sagent had levetiracetam injection on shortage due to manufacturing delays.
- UCB has product available.
- West-Ward has product available.
- X-Gen has product available.

Estimated Resupply Date

- AuroMedics has levetiracetam 100 mg/mL 5 mL vials on intermittent back order and the company is releasing product as it becomes available.
- Fresenius Kabi has levetiracetam 100 mg/mL 5 mL vials on back order and the company estimates a release date of mid-October 2017.

Leucovorin Calcium Injection

October 8, 2017

Reason for the Shortage

- Fresenius Kabi has leucovorin available.
- Sagent has leucovorin on shortage due to manufacturing delay.
- Teva has leucovorin available.
- West-Ward did not provide a reason for the current shortage.

Estimated Resupply Date

- Fresenius Kabi has leucovorin 500 mg vials on back order and the company estimates a release date of mid-November 2017.
- Sagent has leucovorin 50 mg, 200 mg, and 350 mg vials on back order and the company estimates a release date of October 2017.
- West-Ward has leucovorin 350 mg vials on allocation. The 100 mg vials are on back order and the company cannot estimate a release date.

Isosorbide Dinitrate Extended-Release Tablets

October 8, 2017

Reason for the Shortage

- Sun Pharma is not currently manufacturing isosorbide dinitrate 40 mg extended-release tablets.

Estimated Resupply Date

- Sun Pharma refuses to provide estimated resupply dates.

Fentanyl Citrate Injection

October 8, 2017

Reason for the Shortage

- Akorn had fentanyl injection on shortage due to increased demand.
- West-Ward has fentanyl injection on shortage due to supply and demand issues.
- Pfizer has fentanyl injection on shortage due to manufacturing delays.

Estimated Resupply Date

- Pfizer has fentanyl 50 mcg/mL 5 mL ampules on intermittent back order and the company is releasing product as it becomes available. The 20 mL ampules are on back order and the company cannot estimate a release date. The 2 mL Carpuject syringes are on back order and the company estimates a release date of 3rd quarter 2018. The 10 mL, 20 mL, and 50 mL vials are on intermittent back order and the company is releasing product as it becomes available.
- West-Ward has fentanyl 50 mcg/mL 2 mL, 5 mL, and 50 mL vials on allocation. The 20 mL vials are on back order and the company estimates a release date of October 2017. The 2 mL, 5 mL, and 20 mL ampules are on back order and the company cannot estimate a release date.

Dopamine Hydrochloride Injection

October 8, 2017

Reason for the Shortage

- American Regent has dopamine on shortage due to manufacturing delays.
- Baxter has all dopamine presentations on shortage due to manufacturing delays.
- Pfizer states the shortage is due to manufacturing delays. The dopamine 200 mg/250 mL and 400 mg/500 mL premixed bags were discontinued in August 2017.

Estimated Resupply Date

- American Regent has all dopamine presentations on back order and the company cannot estimate a release date.
- Baxter has all dopamine premixed bags on allocation only through direct orders. Product is not available through wholesalers.
- Pfizer has dopamine 40 mg/mL 10 mL vials on back order and the company estimates a release date of 2018. The 400 mg/250 mL bags are on back order and the company estimates a release date of October 2017. The 800 mg/500 mL premixed bags are on back order and the company estimates a release date of October 2017. The 800 mg/250 mL premixed bags are on back order and the company estimates a release date of October 2017.

Dobutamine Injection

October 8, 2017

Reason for the Shortage

- Baxter has dobutamine on shortage due to manufacturing delays.
- Pfizer has dobutamine on shortage due to manufacturing delays.

Estimated Resupply Date

- Baxter has all dobutamine premixed bags on allocation only through direct orders. Product is not available through wholesalers.
- Pfizer has dobutamine 12.5 mg/mL 20 mL and 40 mL latex-free vials on back order with an estimated release date of 2018. The 12.5 mg/mL 20 mL regular vials in single count are on back order and the company cannot estimate a release date.
- Pfizer has dobutamine 1 mg/mL in 250 mL bags on intermittent back order and the company is releasing product as it becomes available. The dobutamine 2 mg/mL 250 mL bags are on back order and the company estimates a release date of late-November 2017.

Clindamycin Injection

October 8, 2017

Reason for the Shortage

- Akorn did not provide a reason for the shortage.
- Alvogen did not provide a reason for the shortage.
- Fresenius Kabi did not provide a reason for the shortage.
- Pfizer has Cleocin available.
- Sagent has clindamycin on shortage due to manufacturing delays.
- Sandoz has clindamycin injection available.

Estimated Resupply Date

- Alvogen has clindamycin 150 mg/mL 2 mL, 4 mL, and 6 mL ADD-Vantage vials on back order and the company cannot estimate a release date.
- Fresenius Kabi has clindamycin 150 mg/mL 2 mL, 6 mL, and 60 mL vials on back order and the company estimates a release date in mid-October 2017.

- Sagent has clindamycin 150 mg/mL 2 mL vials on back order and the company estimates a release date of September 2017. The clindamycin 150 mg/mL 4 mL vials are on back order and the company cannot estimate a release date.
- Pfizer has Cleocin 150 mg/mL 2 mL ADD-Vantage vials available in limited supply. The 150 mg/mL 6 mL vials are on back order and the company cannot estimate a release date.

Cefoxitin Sodium Injection

October 8, 2017

Reason for the Shortage

- Fresenius Kabi and West-Ward did not provide a reason for the shortage.
- Sagent has cefoxitin on shortage due to manufacturing delays.
- BBraun has cefoxitin on allocation due to increased demand.

Estimated Resupply Date

- West-Ward has cefoxitin 10 gram vials on back order and the company cannot estimate a release date. The 2 gram vials are on allocation.

Cefepime Injection

October 8, 2017

Reason for the Shortage

- Apotex could not provide a reason for the shortage.
- Baxter had cefepime on shortage due to increased demand.
- BBraun has cefepime on shortage due to increased demand.
- Fresenius Kabi has cefepime injection on shortage due to manufacturing delays.
- Pfizer has Maxipime on shortage due to manufacturing delays.
- Sagent has cefepime injection on shortage due to manufacturing delays.
- Sandoz discontinued cefepime injection in early-2016.
- WG Critical Care had cefepime injection on shortage due to increased demand

Estimated Resupply Date

- BBraun has cefepime 1 gram and 2 gram premixed bags on allocation.
- Pfizer has Maxipime 1 gram ADD-Vantage vials on intermittent back order and the company is releasing product as it becomes available. The 2 gram ADD-Vantage vials are on back order and the company estimates a release date of mid-November 2017. The 1 gram vials are on back order and the company cannot estimate a release date. The 2 gram vials are available in limited supply.
- Sagent has cefepime 1 gram vials on allocation.

Atropine Sulfate Injection

October 8, 2017

Reason for the Shortage

- American Regent has atropine injection on shortage due to market demand.
- Pfizer has atropine injection on shortage due to manufacturing delays.

Estimated Resupply Date

- American Regent has atropine 0.4 mg/mL 1 mL ampules and 1 mg/mL 1 mL vials on back order and the company cannot estimate a release date.
- Pfizer has atropine 0.1 mg/mL 10 mL Ansyr syringes, 0.1 mg/mL 5 mL LifeShield syringes, and 0.1 mg/mL 10 mL LifeShield syringes available in limited supply.

Alcohol Dehydrated Injection (Ethanol)

October 8, 2017

Reason for the Shortage

- Akorn states the back order was due to manufacturing delays.

Estimated Resupply Date

- American Regent has dehydrated alcohol 1 mL and 5 mL ampules on back order and the company cannot estimate a release date.

Tolmetin Capsules and Tablets

October 9, 2017

Reason for the Shortage

- Mylan did not provide a reason for the shortage.
- Sun Pharma has not had tolmetin available since 2015. They refuse to provide availability information on any product.

Estimated Resupply Date

- Mylan has tolmetin 600 mg tablets on back order and the company estimates a release date of late-January to early-February 2018.

Ethiodized Oil

October 9, 2017

Reason for the Shortage

- Guerbet states their Lipiodol product is in short supply due to manufacturing problems at Jubliant HollisterStier, the manufacturing site in Canada that supplies Lipiodol for Guerbet. The company estimates the shortage will last at least one year.

Estimated Resupply Date

- Guerbet is shipping supplies of Lipiodol Ultra-Fluide.2 Lipiodol Ultra-Fluide is not FDA approved. In order to prevent a drug shortage, FDA is allowing Guerbet to import Lipiodol Ultra-Fluide, a product manufactured for Guerbet in France by Delpharm Tours.2

- Customers must order Lipiodol Ultra-Fluide directly from Guerbet by calling 1-877-729-6679. Lipiodol Ultra-Fluide is non-refundable and may not be resold.2

5% Dextrose Injection (PVC-free and DEHP-free)

October 10, 2017

Reason for the Shortage

- ICU Medical states the shortage is due to increased demand and manufacturing delays. ICU Medical discontinued the 500 mL VisIV bags in 2011 due to leaking around the administration and medications ports.
- ICU Medical is now the IV fluid business of Pfizer after the acquisition of Hospira.
- Baxter is not currently marketing 5% dextrose PVC/DEHP-free bags.
- BBraun has 250 mL, 500 mL, and 1,000 mL PVC/DEHP-free bags on back order due to manufacturing delays.

Estimated Resupply Date

- BBraun has 5% dextrose 250 mL, 500 mL, and 1,000 mL PVC/DEHP-free bags on back order and the company cannot estimate a release date.

Metronidazole Hydrochloride Injection

October 10, 2017

Reason for the Shortage

- Pfizer has metronidazole injection on shortage due to manufacturing delay.
- Baxter, BBraun, and Claris did not provide a reason for the metronidazole injection shortage.

Estimated Resupply Date

- BBraun has metronidazole 100 mL bags on intermittent back order and the company is releasing supplies regularly.
- Claris has metronidazole 100 mL bags on long-term back order and the company cannot estimate a release date.
- Pfizer has metronidazole 100 mL bags in 24 count and 80 count on back order and the company estimates a release date of mid-November 2017.

Ketorolac Tromethamine Injection

October 11, 2017

Reason for the Shortage

- Amphastar did not provide a reason for the shortage.
- BD RX is now part of Fresenius Kabi.
- Fresenius Kabi did not provide a reason for the shortage.
- Pfizer has ketorolac injection on back order due to manufacturing delays.
- Sagent states the reason for the shortage is manufacturing delay.
- West-Ward is not actively marketing ketorolac injection.

- Ben Venue closed its plant in Bedford, Ohio in July 2014.
- FDA imposed an import ban in mid-2013 on several Wockhardt products including ketorolac.
- Sprix Nasal Spray is not affected by this shortage.

Estimated Resupply Date

- Amphastar has ketorolac 30 mg/mL 1 mL vials on back order and the company cannot estimate a release date.
- Fresenius Kabi has ketorolac 30 mg/mL 1 mL prefilled syringes on back order and the company estimates a release date of mid-January 2018.
- Sagent has ketorolac 15 mg/mL 1 mL vials, 30 mg/mL 1 mL vials, and 30 mg/mL 2 mL vials for intramuscular injection on back order and the company cannot estimate a release date.
- Pfizer has ketorolac 30 mg/mL 1 mL and 2 mL Carpuject syringes and 1 mL iSecure syringes on back order and the company estimates a release date of 3rd quarter 2018. The 30 mg/mL 2 mL vials are on back order and the company estimates a release date of late-October 2017.

C1-Esterase Inhibitor (Human) Injection

October 11, 2017

Reason for the Shortage

- CSL Behring has Berinert on shortage due to increased demand.
- Shire has resumed manufacturing of Cinryze and certain lots are available.
- The subcutaneous dosage form of C1-esterase inhibitor (human) is unaffected by this shortage.

Estimated Resupply Date

- CSL Behring is shipping limited supplies of Berinert to specialty distributers.
- Shire has certain lots of Cinryze available.

5% Dextrose Injection

October 11, 2017

Reason for the Shortage

- ICU Medical states the shortage was due to increased demand.
- ICU Medical is now the IV fluid business of Pfizer after the acquisition of Hospira.
- Baxter did not provide a reason for the shortage.
- 5% dextrose 1,000-mL bags are not affected at this time.

Estimated Resupply Date

- Baxter has 5% dextrose 250 mL bags on back order and the company cannot estimate a release date.

0.9% Sodium Chloride Large Volume Bags Injection Bags

October 11, 2017

Reason for the Shortage

- Baxter discontinued 0.9% sodium chloride 250 mL and 500 mL AVIVA bags. The 250 mL Viaflex bags are available in limited supply. All other presentations are available.
- BBraun did not provide a reason for the shortage.
- Pfizer cited increased demand as the reason for the shortage.
- Fresenius Kabi is no longer importing product.
- Baxter has received FDA approval for 0.9% sodium chloride in Viaflo containers manufactured in an FDA-approved facility in Spain.

Estimated Resupply Date

- BBraun has 0.9% sodium chloride 250 mL, 500 mL, and 1,000 mL PVC/DEHP-free bags on back order and the company cannot estimate a release date.
- Baxter has 0.9% sodium chloride 250 mL bags available in limited quantities.
- Pfizer has 0.9% sodium chloride 500 mL and 1,000 mL bags on back order and the company estimates a release date of mid-October 2017. The 250 mL and 250 mL PVC/DEHP-free bags are on back order and the company estimates a release date of mid-October 2017. The 250 mL 2-port bags are on back order and the company estimates a release date of early-November 2017. The 500 mL 2-port bags are on back order and the company cannot estimate a release date. All product will be allocated upon release.

Heparin Injection

October 13, 2017

Reason for the Shortage

- Fresenius Kabi did not provide a reason for the shortage.
- Pfizer did not provide a reason for the shortage.
- Sagent has all heparin presentations available.
- West-Ward did not provide a reason for the shortage.

Estimated Resupply Date

- Fresenius Kabi has 1,000 unit/mL 2 mL vials on back order and the company estimates a release date in late-October 2017. The 1,000 unit/mL 10 mL multi-dose vials are on back order and the company estimates a release date in mid- to late-October 2017.
- West-Ward has 1,000 mL 30 mL vials and 5,000 unit/mL 10 mL vials are on back order and the company cannot estimate a release date.
- Pfizer has 10,000 unit/mL 0.5 mL preservative-free Carpuject syringes on back order and the company estimates a release date in mid-October 2017. The 5,000 unit/mL 10 mL vials are on back order and the company estimates a release date in February 2017. The 1,000 unit/mL 10 mL glass vials and 30 mL glass vials are on back order and the company estimates a release date of early-December 2017 for the 10 mL vials and December 2017 for the 30 mL vials. The 1,000 unit/mL 10 mL vials are on back order and the company estimates a release date of first quarter 2018. The 10,000 unit/mL 1 mL vials are on back order and the company cannot estimate a release date.

Ceftriaxone Sodium Injection

October 13, 2017

Reason for the Shortage

- Apotex states the reason for the shortage is manufacturing delays. Apotex has updated the NDC numbers for ceftriaxone 500 mg and 1 gram vials.
- Fresenius Kabi states the reason for the shortage is increased demand.
- Pfizer has ceftriaxone injection available.
- Sagent states the reason for the shortage is manufacturing delay.
- Sandoz has most ceftriaxone available.
- West-Ward states the reason for the shortage is manufacturing delay.
- WG Critical Care states the reason for the shortage is increased demand.
- Wockhardt relaunched their ceftriaxone presentations in October 2017.

Estimated Resupply Date

- Apotex has ceftriaxone 10 gram vials on back order and the company estimates a release date of early-November 2017. The 2 gram vials are available in limited supply. The 250 mg, 500 mg, and 1 gram vials are on back order and the company cannot estimate a release date.
- Fresenius Kabi has ceftriaxone 500 mg vials on back order and the company cannot estimate a release date.
- Lupin has all ceftriaxone presentations on allocation.
- Sagent has ceftriaxone 2 gram vials on allocation.
- Sandoz has ceftriaxone 2 gram vials on back order and the company estimates a release date of November 2017.

Amino Acid Products

October 13, 2017

Reason for the Shortage

- Baxter has most amino acid products on allocation due to delays because of the hurricane in Puerto Rico.
- BBraun has all amino acid products available.
- Pfizer has Aminosyn on back order due to an ingredient shortage which has caused a supply disruption. Pfizer has obtained the ingredient, but does not yet have an estimated date as to when manufacturing will resume.

Estimated Resupply Date

- Pfizer has all Aminosyn presentations on back order and the company cannot estimate a release date.
- Baxter has most amino acid products on allocation.

0.9% Sodium Chloride Small Volume Bags (<150 mL)

October 13, 2017

Reason for the Shortage

- Baxter has 0.9% sodium chloride small volume bags on shortage due to manufacturing delays.
- BBraun has 0.9% sodium chloride small volume bags on shortage due to increased demand.
- ICU Medical has 0.9% sodium chloride small volume bags on shortage due to increased demand.

Estimated Resupply Date

- Baxter has all 0.9% sodium chloride small volume bags on allocation.
- BBraun has all 0.9% sodium chloride small volume bags on allocation.
- ICU Medical has all 0.9% sodium chloride small volume bags on allocation.

Hepatitis A Virus Vaccine Inactivated

October 16, 2017

Reason for the Shortage

- Merck did not provide a reason for the Vaqta shortage.
- GlaxoSmithKline has Havrix available.

Estimated Resupply Date

- Merck has Vaqta pediatric/adolescent formulation 25 U/0.5 mL prefilled syringes in 10 count on back order and the company estimates a release date of 1st quarter 2018.
- Merck has Vaqta adult formulation 50 U/1 mL and 10 mL vials in 1 count on back order and the company cannot estimate a release date. Vaqta 50 U/1 mL prefilled syringes are on back order and the company estimates a release date of 1st quarter 2018.
- GlaxoSmithKline has Havrix adult formulation 1440 EL.U. prefilled syringes on back order and the company estimates a release date of January 2018. Havrix adult formulation 1440 EL.U. vials are on allocation.

Amino Acids in Dextrose
Amino Acid Products with Electrolytes in Dextrose with Calcium (Clinimix E)

October 17, 2017

Reason for the Shortage

- Baxter has all Clinimix presentations on allocation due to delays because of the hurricane in Puerto Rico.

Estimated Resupply Date

- Baxter has all Clinimix presentations on allocation.
- Baxter has all amino acid products with electrolytes plus calcium on allocation.

Procainamide Hydrochloride Injection

October 17, 2017

Reason for the Shortage

- Pfizer did not provide a reason for the shortage.
- Nexus Pharmaceuticals launched procainamide injection in October 2017.

Estimated Resupply Date

- Pfizer has procainamide 100 mg/mL 10 mL vials on back order and the company estimates a release date of late-January 2018.

*Please refer to ASHP website for more information at:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/