



October 2014

Drug Information Update

DRUG INFORMATION UPDATE

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NEW GENERICS TO MARKET

GENERIC DRUG NAME	STRENGTH & DOSAGE FORM	GENERIC MANUFACTURER	BRAND NAME	APPROVAL DATE
OXYCODONE HCL	80 MG TABLET ER 12H	PAR PHARMACEUTICALS	OXYCONTIN	09/30/2014
PNV59/IRON,CARB&FUM/FA/DS S/DHA	27-1-50 MG CAPSULE	ACELLA PHARMACEUTICALS	CITRANATAL HARMONY	09/29/2014
AMLODIPINE/VALSARTAN	5MG-160MG TABLET	PAR PHARMACEUTICALS	EXFORGE	9/30/2014
AMLODIPINE/VALSARTAN 97963	10MG-160MG TABLET	PAR PHARMACEUTICALS	EXFORGE	9/30/2014
AMLODIPINE/VALSARTAN 98579	5MG-320MG TABLET	PAR PHARMACEUTICALS	EXFORGE	9/30/2014
AMLODIPINE/VALSARTAN	10MG-320MG TABLET	PAR PHARMACEUTICALS	EXFORGE	9/30/2014
OXYCODONE HCL	10 MG TABLET ER 12H	SANDOZ	OXYCONTIN	10/08/2014
OXYCODONE HCL	20 MG TABLET ER 12H	SANDOZ	OXYCONTIN	10/08/2014
OXYCODONE HCL	40 MG TABLET ER 12H	SANDOZ	OXYCONTIN	10/08/2014
FLUOROURACIL	0.5% CREAM	SPEAR PHARMACEUTICALS	CARAC	10/10/2014

NEW DRUG ENTITIES

DESCRIPTION	BRAND NAME	GENERIC NAME	STRENGTH	NOTES
ANTIEMETIC/ANTIVERTIGO AGENTS	AKYNZEO	NETUPITANT/PALONOSETRON HCL	300-0.5MG	New Combination
HEP C VIRUS - NS5A & NS5B POLYMERASE INHIB. COMBO.	HARVONI	LEDIPASVIR/SOFOSBUVIR	90MG-400MG	New Combination
DIETARY SUPPLEMENT, MISCELLANEOUS	ARGINAID	ARGININE/ASCORBATE SOD/VITE AC	4.5 G/9.2G	New Combination
CYTOCHROME P450 INHIBITORS	TYBOST	COBICISTAT	150 MG	New Entity
AGENTS TO TREAT MULTIPLE SCLEROSIS	PLEGRIDY	PEGINTERFERON BETA-1A	63-94 MCG	New Entity
AGENTS TO TREAT MULTIPLE SCLEROSIS	PLEGRIDY	PEGINTERFERON BETA-1A	125MCG/0.5	New Entity
AGENTS TO TREAT MULTIPLE SCLEROSIS	PLEGRIDY	PEGINTERFERON BETA-1A	63-94 MCG	New Entity
AGENTS TO TREAT MULTIPLE SCLEROSIS	PLEGRIDY	PEGINTERFERON BETA-1A	125MCG/0.5	New Entity
ANTIMIGRAINE PREPARATIONS	SUMAVEL DOSEPRO	SUMATRIPTAN SUCCINATE	4 MG/0.5ML	New Dosage Form (Solution Jet-injector)
DIRECT FACTOR XA INHIBITORS	XARELTO	RIVAROXABAN	15 MG and 20MG	New Strength
COLCHICINE	MITIGARE	COLCHICINE	0.6 MG	New Dosage Form (capsule)
ANTIHYPENGLY, INCRETIN MIMETIC (GLP-1 RECEPTOR AGONIST)	TRULICITY	DULAGLUTIDE	0.75MG/0.5	PEN INJECTOR
ANTIHYPENGLY, INCRETIN MIMETIC (GLP-1 RECEPTOR AGONIST)	TRULICITY	DULAGLUTIDE	1.5 MG/0.5	PEN INJECTOR

NEW INDICATIONS (EXISTING DRUGS)

RELISTOR®

September 29, 2014

RALEIGH, N.C. & TARRYTOWN, N.Y. –Salix Pharmaceuticals, Ltd. and Progenics Pharmaceuticals, Inc. today announced that the Food and Drug Administration has approved RELISTOR® (methylaltrexone bromide) Subcutaneous Injection, 12 mg/0.6ml, for the treatment of opioid-induced constipation (OIC) in patients taking opioids for chronic non-cancer pain. RELISTOR subcutaneous injection is currently the only available peripherally acting mu opioid receptor antagonist (PAMORA) that is approved for treating OIC at the cause without interfering with the centrally acting analgesic properties of the opioid.

Article link: <http://news.salix.com/press-release/fda-approves-relistor-subcutaneous-injection-treatment-opioid-induced-constipation>

Source: Salix Pharmaceuticals, Inc.

HUMIRA®

October 6, 2014

AbbVie's HUMIRA® (adalimumab) Receives U.S. FDA Approval for Extension of Polyarticular Juvenile Idiopathic Arthritis Indication to Patients Ages 2 and Older

NORTH CHICAGO, Ill.,-- AbbVie today announced that the U.S. Food and Drug Administration (FDA) has approved the extension of the HUMIRA indication for moderately to severely active polyarticular juvenile idiopathic arthritis (JIA) to reducing signs and symptoms in patients ages 2 and older. HUMIRA was approved in the United States in 2008 for polyarticular juvenile idiopathic arthritis (JIA) in patients ages 4 and older.

Article link: <http://abbvie.mediaroom.com/2014-10-06-AbbVies-HUMIRA-adalimumab-Receives-U-S-FDA-Approval-for-Extension-of-Polyarticular-Juvenile-Idiopathic-Arthritis-Indication-to-Patients-Ages-2-and-Older>

Source: AbbVie.mediaroom.com

EYLEA®

October 6, 2014

EYLEA® (aflibercept) Injection Receives FDA Approval for Macular Edema Following Retinal Vein Occlusion (RVO)

EYLEA Now Approved for Wet Age-related Macular Degeneration (AMD), Diabetic Macular Edema (DME), and Macular Edema following RVO

TARRYTOWN, N.Y.,-- Regeneron Pharmaceuticals, Inc. today announced that the U.S. Food and Drug Administration (FDA) has approved EYLEA® (aflibercept) Injection for the treatment of Macular Edema following Retinal Vein Occlusion (RVO), which includes Macular Edema following Branch Retinal Vein Occlusion (BRVO) in addition to the previously-approved

indication of Macular Edema following Central Retinal Vein Occlusion (CRVO).
Therecommended dosage of EYLEA in patients with Macular Edema following RVO is 2 milligrams (mg) every month (4 weeks).

Article link: http://files.shareholder.com/downloads/REGN/3365699376x0x785011/289c9a9e-a261-4750-bbeb-6417a3510b5e/REGN_News_2014_10_6_General_Releases.pdf

Source: Regeneron Pharmaceuticals, Inc.

VELCADE®

October 9, 2014

FDA Approves VELCADE® (bortezomib) for Injection for Previously Untreated Patients with Mantle Cell Lymphoma

This approval extends the benefit of VELCADE for mantle cell lymphoma (MCL) to previously untreated patients in addition to relapsed or refractory patients

First treatment approved by the U.S. Food and Drug Administration for newly diagnosed MCL patients

Cambridge, Mass., – Millennium: The Takeda Oncology Company with its parent company, Takeda Pharmaceutical Company Limited, today announced that the U.S. Food and Drug Administration (FDA) has approved VELCADE® (bortezomib) for injection for use in previously untreated patients with mantle cell lymphoma (MCL). VELCADE is the first treatment in the United States to be approved for use in previously untreated patients with MCL. This approval extends the utility of VELCADE beyond relapsed or refractory mantle cell lymphoma, for which it has been.

Article link: <http://investor.millennium.com/phoenix.zhtml?c=80159&p=irol-newsArticle&ID=1975854&highlight>

Source: Millennium

EMBEDA®

October 17, 2014

FDA Approves Abuse Deterrent Labeling for EMBEDA® (morphine sulfate and naltrexone hydrochloride) Extended-Release (ER) Capsules CII

EMBEDA is the first and only approved ER morphine specifically designed to deter oral and intranasal abuse when crushed Pfizer Inc. (NYSE:PFE) announced today that the United States Food and Drug Administration (FDA) has approved an updated label for EMBEDA® (morphine sulfate and naltrexone hydrochloride) extended-release (ER) capsules, for oral use, CII, to include abuse-deterrence studies. The updated label states that EMBEDA has properties that are expected to reduce abuse via the oral and intranasal (i.e., snorting) routes when crushed. However, abuse of EMBEDA by these routes is still possible. The updated label also includes data from a human abuse potential study of intravenous (IV) morphine and naltrexone to simulate crushed EMBEDA. However, it is unknown whether the results with simulated crushed

EMBEDA predict a reduction in abuse by the IV route until additional postmarketing data are available. EMBEDA is indicated for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate. Pfizer expects EMBEDA will be available in the U.S. in early 2015.

Article link: http://www.pfizer.com/news/press-release/press-release-detail/fda_approves_abuse_deterrent_labeling_for_embeda_morphine_sulfate_and_naltrexone_hydrochloride_extended_release_er_capsules_cii

Source: Pfizer.com

XIAFLEX®

October 20, 2014

AUXILIUM PHARMACEUTICALS, INC. ANNOUNCES XIAFLEX NOW APPROVED FOR THE CONCURRENT TREATMENT OF UP TO TWO AFFECTED JOINTS IN THE SAME HAND IN DUPUYTREN'S CONTRACTURE PATIENTS

Estimated 35-40 Percent of Surgical Procedures to Treat DC Have Been Performed on Multiple Joints

CHESTERBROOK, Pa.,-- Auxilium Pharmaceuticals, Inc., a specialty biopharmaceutical company, today announced that the U.S. Food and Drug Administration (FDA) has approved a supplemental Biologics Application (sBLA) for XIAFLEX® (collagenase clostridium histolyticum or CCH) for the treatment of up to two Dupuytren's contracture (DC) joints in the same hand during a single treatment visit.

Article link: <http://ir.auxilium.com/phoenix.zhtml?c=142125&p=irol-newsArticle&ID=1979556>

Source: Auxilium.com

FDA NEWS/BULLETINS/ADVISORIES/SAFETY ALERTS

Xolair (omalizumab): Drug Safety Communication - Slightly Elevated Risk of Cardiovascular and Cerebrovascular Serious Adverse Events

[Posted 9/26/2014]

ISSUE: An FDA review of safety studies suggests a slightly increased risk of problems involving the heart and blood vessels supplying the brain among patients being treated with the asthma drug Xolair (omalizumab) than in those who were not treated with Xolair. As a result, FDA has added information about these potential risks to the drug label. The review found no difference in the rates of cancer between those patients being treated with Xolair and those who were not being treated with Xolair. However, due to limitations in the 5-year study, FDA cannot rule out a potential risk of cancer with Xolair, so this information was added to the Warnings and Precautions section of the drug label.

BACKGROUND: Xolair is an injectable medicine for patients 12 years of age and older with moderate to severe persistent allergic asthma whose asthma symptoms are not controlled by asthma medicines called inhaled corticosteroids.

RECOMMENDATION: Patients taking Xolair should continue to take the medication as prescribed and discuss any questions or concerns with their health care professionals.

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

Article Link:

<http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm416408.htm>

Ketorolac Tromethamine Injection, USP, 30mg/ml by Sagent Pharmaceuticals: Recall - Incorrect Labeling

[Posted 10/06/2014]

ISSUE: Sagent Pharmaceuticals, Inc. issued a voluntary nationwide recall of three lots (lot numbers: MP5021, MP5024 and MP5025) of Ketorolac Tromethamine Injection, USP, 30mg/mL single-dose vials (NDC numbers 25021-701-01 and 25021-701-02) manufactured by Cadila Healthcare Limited and distributed by Sagent. The affected product was labeled with the incorrect expiration date. The labeled expiration date is longer than the known stability of the product.

BACKGROUND: Ketorolac Tromethamine Injection, USP, 30mg/mL is a nonsteroidal anti-inflammatory drug (NSAID) indicated for short-term management of moderately severe acute pain that requires analgesia at the opioid level, usually in a postoperative setting, and is supplied in a single-dose vial. The lot numbers being recalled - MP5021, MP5024 and MP5025 - were distributed to hospitals, wholesalers and distributors nationwide from September 17, 2014 through October 1, 2014.

RECOMMENDATION: Customers have been instructed to examine their inventory immediately and to quarantine, discontinue distribution of and return the recalled lots of product. Customers who may have further distributed this product have been requested to identify their customers and notify them at once of this product recall. Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this product. Any questions about returning unused product should be directed to the customer call center at (866) 625-1618 M-F 8am-7pm CST. Healthcare workers who have medical questions about Ketorolac Tromethamine Injection, USP may contact Sagent Medical Affairs (866-625-1618, Option 3) M-F 8am-5pm CST.

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

Article link:

<http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm417445.htm>

Vancomycin Hydrochloride for Injection USP, Equivalent to 1 Gram Vancomycin (Sterile Powder) by Hospira, Inc.: Recall - Uncontrolled Storage During Transit [Posted 10/08/2014]

ISSUE: Hospira, Inc. issued a voluntary nationwide user-level recall of one lot of Vancomycin Hydrochloride for Injection, USP, Equivalent to 1 g Vancomycin (Sterile Powder), NDC 0409-01, Lot 35-315-DD with expiration date of 01 NOV 2015. The product may have experienced temperature excursions during shipment to a customer and then was further distributed by the customer.

This recall is being carried out to the medical facility/retail level (both human and veterinary).

BACKGROUND: There have been no adverse events or complaints reported for the affected lot.

RECOMMENDATION: Anyone with an existing inventory of the recalled lot should stop use and distribution and quarantine the product immediately. Please notify all users in your facility. If you have further distributed the recalled product please notify any accounts or additional locations which may have received the recalled product from you and instruct them if they have redistributed the product to notify their accounts, locations or facilities to the medical facility/retail level. In addition, customers should inform potential users of this product in their organizations of this notification. Hospira will be notifying its direct customers via a recall letter and will arrange for impacted product to be returned to Stericycle.

For additional assistance, call Stericycle at 1-844-861-6215 between the hours of 8am to 5pm ET, Monday through Friday.

Article link:

<http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm418065.htm>

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

Assured Brand Naproxen Sodium Tablets by Contract Packaging Resources, Inc.:
Recall - Packaging Mix-Up
[Posted 10/22/2014]

ISSUE: Hospira, Inc. issued a voluntary nationwide user-level recall of one lot of Vancomycin Hydrochloride for Injection, USP, Equivalent to 1 g Vancomycin (Sterile Powder), NDC 0409-01, Lot 35-315-DD with expiration date of 01 NOV 2015. The product may have experienced temperature excursions during shipment to a customer and then was further distributed by the customer.

This recall is being carried out to the medical facility/retail level (both human and veterinary).

BACKGROUND: There have been no adverse events or complaints reported for the affected lot.

RECOMMENDATION: Anyone with an existing inventory of the recalled lot should stop use and distribution and quarantine the product immediately. Please notify all users in your facility. If you have further distributed the recalled product please notify any accounts or additional locations which may have received the recalled product from you and instruct them if they have redistributed the product to notify their accounts, locations or facilities to the medical facility/retail level. In addition, customers should inform potential users of this product in their organizations of this notification. Hospira will be notifying its direct customers via a recall letter and will arrange for impacted product to be returned to Stericycle.

For additional assistance, call Stericycle at 1-844-861-6215 between the hours of 8am to 5pm ET, Monday through Friday.

Article link:

<http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm418065.htm>

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

STUDIES and RECENT TOPICS

Antibiotic Use Before Age 2 Might Raise Obesity Risk, Study Says

September 29, 2014

Children who are given broad-spectrum antibiotics before the age of 2 may face a slightly higher risk of becoming obese during childhood, new research suggests. Broad-spectrum antibiotics target a larger number of organisms than narrow-spectrum ones, according to the study.

Article link: <http://consumer.healthday.com/infectious-disease-information-21/antibiotics-news-30/antibiotic-use-before-age-2-might-raise-obesity-risk-study-692158.html>

Source: healthday.com

AAN Warns Against Opioids in Chronic Noncancer Pain

September 29, 2014

The risks of opioids far outweigh their benefits in chronic pain conditions such as headache, fibromyalgia, and lower back pain, according to a new policy statement from the American Academy of Neurology.

Article link: <http://www.medpagetoday.com/PainManagement/PainManagement/47871>

Source: medpagetoday.com

Bristol immune drug shows strong effect in melanoma study

September 29, 2014

Bristol-Myers Squibb's immunotherapy drug Opdivo produced markedly improved response rates with fewer toxic side effects compared to chemotherapy in a major melanoma study, underscoring its potential as a new treatment option.

Article link:

Source: reuters.com

Merck immunotherapy drug shows promise in bladder cancer

September 29, 2014

Merck & Co's new immune system drug Keytruda has produced encouraging results in early tests against bladder cancer, according to a company-sponsored study, prompting the firm to prepare a clinical trial later this year. Keytruda is the first in a new wave of immune-boosting medicines to be approved for treating melanomas in the United States, but it also has potential in a range of other cancers.

Article link: <http://www.reuters.com/article/2014/09/29/us-health-cancer-bristol-myers-idUSKCN0H00HM20140929>

Source: reuters.com

Hundreds of firms join global hunt for copycat biotech drugs

September 29, 2014

Hundreds of companies around the world are chasing an emerging market for cheaper copies of costly biotech drugs, with more than 700 so-called biosimilars now in development or

already approved, according to a major study of the sector. Biotech medicines - made from proteins and other large molecules - account for six of the 10 biggest-selling drugs in the world today, led by AbbVie's \$12 billion-a-year rheumatoid arthritis injection Humira.

Article link: <http://www.reuters.com/article/2014/09/29/health-biotech-biosimilars-idUSL6NORG2MA20140929>

Source: reuters.com

Doubling Up on Blood Thinners May Be Risky

September 29, 2014

Patients with stable coronary artery disease (CAD) seemed to face an increased risk for bleeding when given anti-platelet therapy in addition to a vitamin K antagonist, French researchers reported.

Article link: <http://www.medpagetoday.com/Cardiology/Atherosclerosis/47865>

Source: medpagetoday.com

Experimental Cervical Cancer Vaccine Looks Promising in Trial

October 1, 2014

An experimental vaccine meant to protect against nine types of human papillomavirus (HPV) could prevent 90 percent of all cervical cancers, a new study suggests. Researchers examined data from more than 2,500 women with precancerous cervical lesions and found that nearly all were caused by the nine types of HPV targeted by the vaccine being developed by Merck and Co.

Article link: <http://consumer.healthday.com/sexual-health-information-32/human-papillomavirus-hpv-news-756/more-effective-hpv-vaccine-looks-promising-692190.html>

Source: healthday.com

Drug succeeds in lowering LDL cholesterol –study

October 1, 2014

A new type of experimental cholesterol fighter being developed by Esperion Therapeutics Inc lowered LDL levels significantly more than Merck & Co Inc's Zetia in a midstage clinical trial, the company said on Wednesday.

Article link: <http://consumer.healthday.com/sexual-health-information-32/human-papillomavirus-hpv-news-756/more-effective-hpv-vaccine-looks-promising-692190.html>

Source: reuters.com

2nd Baby 'Cured' of HIV Suffers Relapse

October 2, 2014

An Italian toddler thought cured of HIV with early aggressive treatment following birth has suffered a relapse, his doctor's report. The 3-year-old child's viral levels of HIV rebounded two weeks after doctors took him off antiretroviral medications, according to a case report published Oct. 4 in The Lancet.

Article link: <http://consumer.healthday.com/sexual-health-information-32/childbirth-health-news-126/2nd-baby-thought-cured-of-hiv-shows-signs-of-virus-return-692349.html>

Source: healthday.com

Breast cancer drug sales will almost double by 2023, says IMS

October 2, 2014

Sales of breast cancer treatments are set to increase by an average of 5.8% a year in nine major markets, increasing from a value of \$9.8 billion in 2013 to \$18.2 billion by 2023, according to new forecasts from IMS Health.

Article link: http://www.pharmatimes.com/Article/14-10-02/Breast_cancer_drug_sales_will_almost_double_by_2023_says_IMS.aspx

Source: pharmatimes.com

Cholesterol Drugs Haunted By Ghosts Of Past, Present, And Future

October 2, 2014

The Lancet yesterday published the results of two new studies showing that Amgen's evolocumab was effective in reducing LDL cholesterol in patients with familial hypercholesterolemia (FH), a genetic disposition to high LDL cholesterol levels. In Rutherford-2, injections of evolocumab in people with heterozygous FH resulted in impressive 60% reductions in their LDL levels compared with placebo. In Tesla Part B, people with the more severe and much rarer form of homozygous FH had a 31% reduction in LDL compared with placebo. Patients in both trials were also taking standard lipid-lowering therapies, including statins and ezetimibe.

Article link: <http://www.forbes.com/sites/larryhusten/2014/10/02/cholesterol-drugs-haunted-by-ghosts-of-past-present-and-future/>

Source: forbes.com

Heroin Overdose Deaths Doubled in Much of U.S.: CDC Study

October 2, 2014

Deaths from heroin overdoses doubled from 2010 to 2012, U.S. federal health officials reported Thursday.

The new report included data from 28 states that account for 56 percent of the U.S. population.

Article link: <http://consumer.healthday.com/general-health-information-16/drug-abuse-news-210/prescription-painkiller-abuse-tied-to-upsurge-in-heroin-deaths-692345.html>

Source: healthday.com

Lawmakers Probe 'Staggering' Price Hikes for Generic Drugs.

October 2, 2014

In response to recent reports that the cost of some generic drugs has been unexpectedly rising at a rapid clip, two members of Congress have launched an investigation and asked 14 generic drug makers to providing data about what the lawmakers called the "escalating prices they have been charging" for generic medicines.

Article link: <http://blogs.wsj.com/pharmalot/2014/10/02/lawmakers-probe-staggering-price-hikes-for-generic-drugs/>

Source: wsj.com

New RA biologic ups shingles risk

October 2, 2014

A newly FDA-approved JAK inhibitor is associated with “higher than expected” rates of herpes zoster, according to a review of clinical trials. Researchers looked at the effects of tofacitinib in nearly 4,800 rheumatoid arthritis patients involved in development trials, of whom 240 developed drug-related herpes zoster.

Article link: <http://www.rheumatologyupdate.com.au/latest-news/new-ra-biologic-ups-shingles-risk>

Source: [rheumatologyupdate.com.au](http://www.rheumatologyupdate.com.au)

The FDA gives an Ariad drug candidate ‘breakthrough therapy designation’

October 2, 2014

Ariad Pharmaceuticals Inc. of Cambridge said Thursday that federal regulators have granted “breakthrough therapy designation” to a drug candidate for a form of lung cancer. According to the Food and Drug Administration’s website, a breakthrough therapy designation means that the FDA will expedite the development and review of such drug. The designation is given to drug candidates designed to treat a serious or life threatening disease that have shown great promise based on preliminary clinical evidence.

Article link:

<http://www.bostonglobe.com/business/2014/10/02/ariad/P4k2rSNUF4Vd5A8l4ryu1O/story.html>

Source: [bostonglobe.com](http://www.bostonglobe.com)

Bristol Myers Squibb Getting Close To Lung Cancer Approval For Nivolumab

October 2, 2014

Bristol-Myers Squibb recently announced key developments regarding its immuno-oncology drug nivolumab. The FDA in the U.S. has granted breakthrough status to the drug for advanced melanoma and has agreed to review the license application on priority basis. The review is likely to be completed by the end of March 2015. Additionally, the EMA (European Medicines Agency) is going to accelerate the review and assessment of nivolumab for treatment of advanced melanoma as well. These developments are encouraging for Bristol- Myers Squibb, which earlier had fast tracked clinical trials of nivolumab due to successful results. Merck has already launched a similar drug this year and has first-mover advantage in the market. However, we believe that the market is big enough to accommodate more players, considering that the price for the drug is going to be high.

Article link: <http://www.forbes.com/sites/greatspeculations/2014/10/02/bristol-myers-squibb-getting-close-to-lung-cancer-approval-for-nivolumab/>

Source: [forbes.com](http://www.forbes.com)

Standard Treatment for Underactive Thyroid Gland Still Best: Experts

October 2, 2014

An expert panel reviewing treatments for hypothyroidism has concluded that the drug levothyroxine (L-T4) should remain the standard of care. The updated guidelines from the American Thyroid Association were published recently in the journal *Thyroid*.

Article link: <http://consumer.healthday.com/women-s-health-information-34/misc-hormones-health-news-390/standard-treatment-for-hypothyroidism-still-the-best-treatment-experts-692293.html>

Source: healthday.com

Study Compares Insulin Regimens for Type 1 Diabetes

October 3, 2014

For people with type 1 diabetes, long-acting insulin may be a better treatment choice than intermediate-acting insulin, a new review of the data suggests. "Different types of insulin are used to manage type 1 diabetes with insulin injections," explained one expert not connected to the new study, Dr. Spyros Mezitis.

Article link: <http://consumer.healthday.com/diabetes-information-10/misc-diabetes-news-181/study-compares-insulin-regimens-for-type-1-diabetes-692294.html>

Source: healthday.com

OxyContin, Cialis Makers Dodge Court to Beat Patent Suits

October 3, 2014

Trying to avoid costly legal battles, the makers of blockbuster pharmaceuticals such as painkiller OxyContin and impotence remedy Cialis are trying a new tactic to stay out of court. They're asking the U.S. Patent and Trademark Office to nullify patents on time-release formulas and other inventions that they're accused of violating.

Article link: <http://www.bloomberg.com/news/2014-10-03/oxycontin-cialis-makers-dodge-court-to-beat-patent-suits.html>

Source: bloomberg.com

Hydrocodone Combination Products: New Written Rx Required Starting Today (Mon 10/6)

October 5, 2014

The increased restrictions on hydrocodone combination products that go into effect on Monday, October 6, are having a major impact on chronic pain patients seeking their monthly refill on a currently-valid prescription.

Article link: <http://www.forbes.com/sites/davidkroll/2014/10/05/today-is-the-last-day-for-current-refills-of-hydrocodone-combination-products-sunday-october-5/?ss=pharma-healthcare>

Source: forbes.com

'60 Minutes' Just Attacked High Drug Prices. Here's What You Should Know

October 5, 2014

60 Minutes, the most successful news program in American history, just took aim at the extraordinarily high (\$100,000 per patient per year) prices charged for cancer drugs. The pharmaceutical industry, which only provided canned statements and badly thought-out explanation via the president of its lobbying group, came off looking callous and insensitive.

Article link: <http://www.forbes.com/sites/matthewherper/2014/10/05/60-minutes-just-attacked-high-drug-prices-heres-what-you-should-know/>

Source: forbes.com

Research Suggests Stroke Risk Up With β -Blockers in Select Patients

October 6, 2014

For patients without prior myocardial infarction (MI) with no heart failure, β -blocker use is not associated with lower cardiovascular events, and there may be an increased risk of stroke for patients without previous events but with multiple cardiovascular risk factors, according to a study published online Sept. 30 in *Circulation: Cardiovascular Quality and Outcomes*.

Article link: <http://www.physiciansbriefing.com/Article.asp?AID=692166>

Source: physiciansbriefing.com

Generics Firms Step Up Their Game In Branded Drugs

October 6, 2014

In the past, it was easy to separate the ethical-drug makers that marketed proprietary medicines and the generics makers that specialized in making copies of such branded medicines. Today, however, the line separating the two company types has increasingly blurred.

Article link: <http://news.investors.com/100614-720461-how-to-buy-medical-stocks.htm?ven=yahoocp&src=aurllled&ven=yahoo>

Source: investors.com

Sanofi And Novo Nordisk's Basal-Insulin Battle Continues

October 6, 2014

Sanofi and Novo Nordisk are the two main players in the ongoing race for developing effective basal insulin therapies for the treatment of diabetes. The battle started with the launch of Sanofi's Lantus (insulin glargine) and Novo's Levemir. Both drugs fall under the category of long-acting basal insulin used for controlling the blood glucose levels in diabetic patients.

Article link: <http://www.bidnesstc.com/26794-sanofi-and-novo-nordisks-basalinsulin-battle-continues/>

Source: bidnesstc.com

Why extremely expensive drugs are often worth the cost

October 6, 2014

If you've been wondering why the high cost of a new hepatitis C cure has ignited such a fierce public debate over the past few months, it's because more specialty drugs like Sovaldi are going

to flood the market in coming years. This class of drugs accounted for less than 1 percent of all prescriptions in 2013, but about 25 percent of all prescription drug spending — and spending on specialty drugs is projected to increase 63 percent by 2016, according to Express Scripts.

Article link: <http://www.washingtonpost.com/blogs/wonkblog/wp/2014/10/06/why-extremely-expensive-drugs-are-often-worth-the-cost/>

Source: washingtonpost.com

Docs More Likely to Prescribe Unneeded Antibiotics Later in Day: Study

October 6, 2014

Doctors are more likely to prescribe unnecessary antibiotics for respiratory infections as the day progresses, a new study finds. It appears that doctors "wear down" throughout the day, making them more likely to make inappropriate decisions about antibiotics, according to the researchers from Brigham and Women's Hospital in Boston.

Article link: <http://consumer.healthday.com/infectious-disease-information-21/antibiotics-news-30/early-birds-less-likely-to-get-unneeded-antibiotics-study-says-692386.html>

Source: healthday.com

Cash is not Always King in Pharma Pay-to-Delay Deals, a Judge Rules.

October 6, 2014

Money may talk, but when it comes to pay-to-delay deals, other sorts of payments also have a voice. Yet another federal court judge has ruled that a cash payment is not only the litmus test for determining whether a patent settlement deserves antitrust scrutiny. The ruling was made in a case several insurers brought against AstraZeneca and several drug makers in which a monetary payment was not part of their deal.

Article link: <http://blogs.wsj.com/pharmalot/2014/10/06/cash-is-not-always-king-in-pharma-pay-to-delay-deals-a-judge-rules/>

Source: wsj.com

Drugs Cause Most Fatal Allergic Reactions, Study Finds

October 6, 2014

The most common cause of fatal allergic reactions in the United States are medicines, especially antibiotics and radiocontrast agents used in imaging studies, a new analysis found. Using data from the National Center for Health Statistics, researchers found 2,458 cases of fatal anaphylaxis from 1999 through 2010. Almost 60 percent of the deaths, or 1,446, were caused by reactions to drugs, and in cases where the specific drug was known, half were caused by antibiotics. The rate of drug-induced fatal reactions almost doubled over the period.

Article link: http://well.blogs.nytimes.com/2014/10/06/drugs-cause-most-fatal-allergic-reactions-study-finds/?_php=true&_type=blogs&_php=true&_type=blogs&ref=health&_r=1&

Source: nytimes.com

Nearly half of consumers wary of healthcare costs, insurer finds

October 7, 2014

Health insurer Cigna asked just over 1,847 people about their health and although 54% of consumers told the payer they feel like they've got their health costs and concerns in check, 46% said they are worried about whether their income will be able to keep pace with their healthcare needs.

Article link: <http://www.mmm-online.com/nearly-half-of-consumers-wary-of-healthcare-costs-insurer-finds/article/375916/>

Source: mmm-online.com

Christie announces expansion of prescription drug monitoring program to other states

October 7, 2014

New Jersey is expanding its efforts to combat prescription drug abuse by sharing prescribing records with doctors and pharmacists in Delaware, and soon with New York, to prevent people from "doctor shopping" in surrounding states, Gov. Chris Christie announced today.

Article link:

http://www.nj.com/politics/index.ssf/2014/10/christie_announces_expansion_of_prescription_drug_monitoring_program_to_other_states.html

Source: nj.com

Bristol-Myers Gives Up on Hepatitis C Combination in U.S.

October 7, 2014

Bristol-Myers Squibb Co. won't seek U.S. regulatory approval for its next-generation hepatitis C combination medicine, which would have competed with treatments from Gilead Sciences Inc., Merck & Co. and AbbVie Inc.

Article link: <http://www.bloomberg.com/news/2014-10-07/bristol-myers-gives-up-on-hepatitis-c-combination-in-u-s-.html>

Source: bloomberg.com

Americans Living Longer as Fewer Die From Heart Disease, Cancer

October 7, 2014

A baby born in 2012 will live to a record 78.8 years old on average, as U.S. life expectancy grew and fewer Americans are dying from heart disease, cancer and other chronic illnesses. That's a gain of about one month compared to 2011, according to a report released today by the Centers for Disease Control and Prevention. Average life expectancy for women was 81.2 years. Men will live an average of 76.4 years.

Article link: <http://www.bloomberg.com/news/2014-10-08/americans-living-longer-as-fewer-die-from-heart-disease-cancer.html>

Source: bloomberg.com

Hospitals Profit From Drug Discount Program For Poor Americans

October 8, 2014

A new study by Drs. Rena M. Conti and Peter B. Bach makes a valuable contribution to the growing body of evidence on the harm being done by a federal program that Congress designed to increase poor people's access to prescription drugs, but has been perverted by hospitals to pad their bottom line.

Article link: <http://www.forbes.com/sites/theapothecary/2014/10/08/hospitals-profit-from-drug-discount-program-for-poor-americans/>

Source: forbes.com

NIH to Study More Than 200 Rare Diseases

October 8, 2014

Physician scientists at 22 consortia will collaborate with representatives of 98 patient advocacy groups to advance clinical research and investigate new treatments for patients with rare diseases. The collaborations are made possible through awards by the National Institutes of Health — totaling about \$29 million in fiscal year 2014 funding — to expand the Rare Diseases Clinical Research Network (RDCRN), which is led by NIH's National Center for Advancing Translational Sciences (NCATS).

Article link: http://www.dddmag.com/news/2014/10/nih-study-more-200-rare-diseases?et_cid=4197239&et_rid=696418053&type=cta

Source: dddmag.com

Amgen declares a head-to-head PhIII win for Humira biosimilar

October 8, 2014

Amgen has taken a big stride toward gaining regulatory approval for its biosimilar of Humira, AbbVie's megablockbuster anti-inflammatory. The Big Biotech reports today that its knockoff of Humira--dubbed ABP 501--hit its marks on equivalency for efficacy and safety for treating plaque psoriasis.

Article link: http://www.fiercebiotech.com/story/amgen-declares-head-head-phiii-win-humira-biosimilar/2014-10-08?utm_medium=rss&utm_source=rss&utm_campaign=rss

Source: fiercebiotech.com

Satisfaction with EHR systems grows among physicians

October 9, 2014

Considering the dissatisfaction that many physicians have expressed about electronic health records (EHRs), you might think that most doctors hate these systems. But, according to an exclusive Medical Economics survey, 55% of physicians are fairly or very satisfied with their EHRs, and 54% believe they have helped improve the quality of care.

Article link: <http://medicaleconomics.modernmedicine.com/medical-economics/content/tags/2014-ehr-scorecard/satisfaction-ehr-systems-grows-among-physicians>

Source: modernmedicine.com

Pharma Sues Again Over Orphan Drug Discounts to Hospitals

October 9, 2014

An ongoing feud between the pharmaceutical industry and a federal agency over a discount drug program for certain hospitals is back in court. The industry trade group has filed another lawsuit trying to block the U.S. Health Resources and Services Administration from enforcing a rule that allows so-called safety net hospitals and clinics to obtain orphan drugs at a discount. Orphan drugs are used to treat rare diseases.

Article link: <http://blogs.wsj.com/pharmalot/2014/10/09/pharma-sues-again-over-orphan-drug-discounts-to-hospitals/>

Source: wsj.com

Why Cancer Drugs May Work Better While You Sleep

October 9, 2014

The body doesn't process drugs in the same way throughout the day, so it's possible to time your doses to make anti-cancer meds more effective. It's news to no one that your body works differently when you're awake and when you're sleeping. But could the different states also affect how your body processes certain lifesaving drugs? Researchers, reporting Friday in the journal Nature Communications, found that when it comes to cancer drugs, the answer may be yes.

Article link: <http://time.com/3486220/why-cancer-drugs-may-work-better-while-you-sleep/>

Source: time.com

Impotence Drug Might Counter Common Gene Mutation in Type 2 Diabetes: Study

October 9, 2014

In a small study, Swedish researchers found that the impotence drug yohimbine might help people with type 2 diabetes who have a particular gene mutation that lowers their insulin production. Among 50 men and women with type 2 diabetes partially caused by a mutation in a gene called alpha(2A)-AR, those treated with yohimbine showed improved insulin production and lower blood sugar levels, compared with those receiving a placebo.

Article link: <http://consumer.healthday.com/diabetes-information-10/diabetes-drug-news-179/drug-might-counter-a-type-2-diabetes-gene-692569.html>

Source: healthday.com

AMCP Talk Pricing of Specialty Pharma Spurred by Sovaldi

October 9, 2014

Starting off this week's Academy of Managed Care Pharmacy (AMCP) meeting in Boston, experts including patient access advocates, pharma and payer representatives came together for this year's symposium entitled "Specialty Pharmacy and Patient Care: Are We at a Tipping Point?"

Article link: <http://blog.pharmexec.com/2014/10/09/amcp-talk-pricing-of-specialty-pharma-spurred-by-sovaldi/>

Source: pharmexec.com

FDA should play key role in lower drug costs

October 10, 2014

A little known provision of President Obama's signature healthcare law is set to dramatically expand access to life-saving drugs. But some big drug makers – protective of their profits – are fighting tooth and nail to roll back this provision so that these drugs remain astronomically expensive – and inaccessible.

Article link: <http://thehill.com/blogs/congress-blog/healthcare/220159-fda-should-play-key-role-in-lower-drug-costs>

Source: thehill.com

As Pricey Hepatitis Pill Harvoni Joins Sovaldi, States Erect Medicaid Hurdles

October 10, 2014

As Gilead Sciences GILD -3.51% (GILD) launches its next generation Hepatitis C pill, Harvoni, Medicaid programs are bracing for another extraordinary wave of costs, with 70 percent of states implementing coverage restrictions.

Article link: <http://www.forbes.com/sites/brucejapsen/2014/10/10/as-hepatitis-pill-harvoni-joins-sovaldi-states-erect-medicaid-hurdles/>

Source: forbes.com

Are Pricey Specialty Drugs Really Good Value for the Money?

October 10, 2014

As the rising cost of prescription medicines becomes more widely debated, more attention is being focused on what the pharmaceutical industry likes to call the value proposition. Simply put, this refers to the long-run economic benefit that can be gotten from using a particular drug when compared with alternatives. In other words, a high price tag for a drug may not translate into the costliest treatment.

Article link: <http://blogs.wsj.com/pharmalot/2014/06/26/lawmakers-ask-white-house-to-review-fda-rule-for-generic-label-changes/>

Source: wsj.com

FDA fast tracks ALS drug

October 11, 2014

FDA has designated new ALS stem cell therapy from BrainStorm Cell Therapeutics as a fasttrack product. Amyotrophic lateral sclerosis (ALS) also known as Lou Gehrig's Disease, is a neurodegenerative disease that affects the nerves in the brain and spinal cord which leads to progressive paralysis throughout the body. ALS is the most common form of motor neuron disorder affecting adults in the United States and there are approximately 5,000 newly diagnosed cases every year. Currently, treatment for ALS is almost entirely supportive including pain management and speech pathology as well as nutritional support.

Article link: <http://formularyjournal.modernmedicine.com/formulary-journal/content/tags/als/fda-fast-tracks-als-drug>

Source: modernmedicine.com

[A Promising Pill, Not So Hard to Swallow](#)

October 11, 2014

This pill goes down easier if you forget what is in it.

Inside the experimental capsule is human feces — strained, centrifuged and frozen. Taken for just two days, the preparation can cure a dangerous bacterial infection that has defied antibiotics and kills 14,000 Americans each year, researchers said Saturday.

Article link: http://www.nytimes.com/2014/10/12/us/a-promising-pill-not-so-hard-to-swallow.html?_r=1

Source: nytimes.com

[Placebos Help. Just Ask This Health Economist](#)

October 13, 2014

"I bet you \$1,000 that if you just tell me you're putting Demerol in my I.V. but don't actually do it, I would still feel a lot better," I dared the nurse. It was a humid June night in 2013. I had just arrived at the emergency department of Mount Auburn Hospital in Cambridge, Mass., and was in the worst pain of my life. A kidney stone was scraping its way down my right ureter, the narrow tube connecting my right kidney and bladder.

Article link: http://www.nytimes.com/2014/10/14/upshot/placebos-help-just-ask-this-health-economist.html?ref=health&_r=0

Source: nytimes.com

[Got Insurance? You Still May Pay A Steep Price For Prescriptions](#)

October 13, 2014

Sandra Grooms recently got a call from her oncologist's office. The chemotherapy drugs he wanted to use on her metastatic breast cancer were covered by her health plan, with one catch: Her share of the cost would be \$976 for each 14-day supply of the two pills.

Article link: <http://kaiserhealthnews.org/news/got-insurance-you-still-may-pay-a-steep-price-for-prescriptions/>

Source: kaiserhealthnews.org

[PhRMA Launches AccessBetterCoverage.org](#)

October 14, 2014

Today, the Pharmaceutical Research and Manufacturers of America (PhRMA) launched Access Better Coverage.org, a new website designed to educate consumers about the ABCs of health coverage and access to prescription medicines.

Article link: <http://finance.yahoo.com/news/phrma-launches-accessbettercoverage-org-140000251.html>

Source: yahoo.com

[FDA Commissioner in Philadelphia, says drug approval process is making progress](#)

October 14, 2014

Food and Drug Administration Commissioner Dr. Margaret Hamburg dropped by Philadelphia Tuesday for the Pennsylvania Bio's Life Sciences Future conference. She said the federal agency

is making progress with its efforts to accelerate the drug and device approval process — while noting more work needs to be done.

Article link: http://www.bizjournals.com/philadelphia/blog/health-care/2014/10/fda-commissioner-in-philadelphia.html?utm_source=feedburner&utm_medium=feed&utm_campaign=Feed%3A+industry_6+%28Industry+Health+Care%29

Source: bizjournals.com

Will an FDA Policy Shift on Fixed-Dose Drug Approvals Anger Pharma?

October 14, 2014

After months of anticipation, the FDA has issued a so-called final guidance for approving new treatments that contain more than one drug. And the agency decision is likely to stir controversy because untold amounts of money may be at stake.

Article link: <http://blogs.wsj.com/pharmalot/2014/10/14/will-an-fda-policy-shift-on-fixed-dose-drug-approvals-anger-pharma/>

Source: wsj.com

FDA staff recommend Pfizer keep black box warning on anti-smoking drug

October 14, 2014

Pfizer Inc's quit-smoking drug Chantix received its latest setback on Tuesday after U.S. Food and Drug Administration staff recommended that the drugmaker keep a severe warning on the treatment's label. Chantix is one of Pfizer's most controversial drugs and has a number of severe side effects, including suicidal thoughts, erratic behavior and drowsiness.

Article link: <http://www.reuters.com/article/2014/10/14/pfizer-fda-chantix-idUSL3N0S94X920141014>

Source: reuters.com

Oritavancin Shows Similar Safety as Vancomycin

October 14, 2014

The new once-weekly antibiotic oritavancin appears to be as effective as 7-10 days of vancomycin infusion in treating skin and soft tissue infections – and its safety profile was similar to vancomycin, researchers reported here.

Article link: <http://www.medpagetoday.com/MeetingCoverage/IDWeek/48049>

Source: medpagetoday.com

If AbbVie Discounts it's Hep C Drug, Would Pricing Reach a Tipping Point?

October 14, 2014

Can AbbVie ABBV -0.70% make a dent in the burgeoning hepatitis C market? Now that the FDA has approved the Harvoni treatment from Gilead Sciences GILD +2.10% and a \$94,500 price for a 12-week regimen has been established, attention is turning toward AbbVie and the steps the big drug maker must take to win market share. Already, though, some Wall Street prognosticators believe AbbVie may find it daunting.

Article link: <http://blogs.wsj.com/pharmalot/2014/10/14/if-abbvie-discounts-its-hep-c-drug-would-pricing-reach-a-tipping-point/>

Source: wsj.com

Last-resort leukemia treatment produces dramatic remission rate

October 15, 2014

Ninety percent of people facing death because conventional treatments had failed to destroy their leukemia have responded to an experimental therapy that trains their cells to kill out-of-control blood cells, doctors in Philadelphia report. Twenty seven of the 25 children and 5 adults initially responded to the new therapy. Nineteen - including a 9-year-old treated two and a half years ago - have remained cancer-free and 15 of those 19 have not receive any subsequent therapy.

Article link: <http://www.reuters.com/article/2014/10/15/us-health-leukemia-experimental-therapy-idUSKCN0I42P720141015>

Source: reuters.com

A Quick Look at Amgen, Inc.'s Drug Development Pipeline

October 15, 2014

The stock market is always forward-looking, but no sector takes "looking into the horizon" to an extreme more than the healthcare industry. You see, most companies produce a product or offer services that have an immediate and tangible reflection on the success of a business. If a company makes microprocessor chips, you can examine whether or not those chips are selling and making a company profitable, all likely within the first year or two following a company's founding.

Article link: <http://www.fool.com/investing/general/2014/10/15/a-quick-look-at-amgen-incs-drug-development-pipeli.aspx>

Source: fool.com

Painkiller deaths drop for first time since 1999

October 15, 2014

New federal data show deaths from prescription painkillers have decreased for the first time since 1999, while heroin deaths have surged, suggesting some addicts may have turned to illicit drugs as new federal and state restrictions made prescription narcotics harder to get.

Article link: <http://www.usatoday.com/story/news/nation/2014/10/15/painkiller-deaths-drop-for-the-first-time-since-1999/17262383/>

Source: usatoday.com

As Rx deaths dip, heroin overdoses surge

October 15, 2014

Prescription drug deaths declined in 2012 for the first time in more than a decade, but a surge in fatal heroin overdoses wiped out the modest improvement, according to U.S. government statistics released Wednesday.

Article link: <http://www.latimes.com/local/lanow/la-me-in-drug-deaths-20141015-story.html>

Source: latimes.com

Roche, Boehringer Drugs Wins Approval for Lung Disease

October 16, 2014

Roche Holding AG (ROG) and Boehringer Ingelheim GmbH won approval for the first therapies in the U.S. to treat the deadly lung disease idiopathic pulmonary fibrosis. The Food and Drug Administration said it cleared Roche's Esbriet, known chemically as pirfenidone, and Boehringer's Ofev, known as nintedanib, for use in the lung-scarring disease that kills 60 percent to 80 percent of patients within five years and, until now, had no approved drugs in the U.S. Roche acquired Esbriet from InterMune Inc. in a deal that closed last month.

Article link: <http://www.bloomberg.com/news/2014-10-15/roche-boehringer-drugs-wins-approval-for-lung-disease.html>

Source: bloomberg.com

HHS advances third Ebola vaccine development

October 16, 2014

The Department of Health and Human Services will fast-track the development of a third Ebola vaccine that had a 100 percent success rate with non-human primates, the agency said in a release Thursday.

"We are pushing hard to advance the development of multiple products as quickly as possible for clinical evaluation and future use in preventing or treating this deadly disease," said Robin Robinson, the director of the agency's Biomedical Advanced Research and Development Authority.

Article link: <http://thehill.com/policy/healthcare/220991-hhs-accelerates-third-ebola-vaccine-development>

Source: thehill.com

Novartis psoriasis drug benefits outweighs risk-FDA staff

October 16, 2014

The benefits of Novartis AG's anti-inflammation drug outweighed the risks in using it to treat a type of psoriasis, staff reviewers at the U.S. Food and Drug Administration said. The injectable biologic, secukinumab, is part of an eagerly anticipated class of drugs called IL-17 inhibitors that have shown unprecedented success in plaque-psoriasis, the most common form of the painful skin condition.

Article link: <http://www.reuters.com/article/2014/10/16/us-novartis-fda-idUSKCN0I51HS20141016>

Source: reuters.com

No RA Benefit With Remicade Addition

October 16, 2014

Adding infliximab (Remicade) to triple therapy with conventional disease-modifying antirheumatic drugs (DMARDs) for rheumatoid arthritis (RA) did not provide additional benefit, a Finnish study showed. At 5 years, 60% of patients in the triple therapy plus infliximab group

were in strict remission according to the criteria of the American College of Rheumatology (ACR), as were 61% of those given triple therapy plus placebo (P=0.93), according to Vappu Rantalaiho, MD, of Tampere University, and colleagues.

Article link: <http://www.medpagetoday.com/Rheumatology/Arthritis/48114>

Source: medpagetoday.com

Older Antibiotic Still Works Against Staph Infections, Study Finds

October 17, 2014

An older antibiotic called vancomycin is still effective in treating dangerous Staphylococcus aureus bloodstream infections, a new study finds. The findings show that doctors should keep using vancomycin to treat Staphylococcus aureus infections even though there are several newer antibiotics available to do the job, University of Nebraska researchers said.

Article link: <http://consumer.healthday.com/infectious-disease-information-21/antibiotics-news-30/older-antibiotic-still-works-against-staph-bloodstream-infections-study-finds-692768.html>

Source: healthday.com

Many U.S. women use custom-compounded hormones for menopause

October 17, 2014

An estimated 1.4 million U.S. women take custom-compounded bioidentical hormone therapy (CBHT) for menopausal symptoms, and most are unaware that these drugs are not FDA-approved, according to late-breaking research presented this week at the North American Menopause Society (NAMS) annual meeting.

Article link: <http://in.reuters.com/article/2014/10/16/us-compounded-hormone-therapy-idINKCN0I52UT20141016>

Source: reuters.com

Roche, Merck extend immunotherapy fight to breast cancer

October 17, 2014

Swiss drugmaker Roche and U.S. group Merck & Co are to present data on their rival immunotherapy drugs in breast cancer in December, extending the novel approach to fighting tumors to another cancer type.

Article link: <http://www.reuters.com/article/2014/10/17/us-roche-results-cancer-idUSKCN0I60HA20141017>

Source: reuters.com

Regeneron's Eylea works better vs Avastin and Lucentis in study

October 17, 2014

Regeneron Pharmaceuticals Inc said on Friday that a head-to-head study showed that its Eylea treatment for diabetic macular edema created significantly greater improvement in visual acuity compared with Genentech's Avastin and Lucentis.

Article link: <http://www.reuters.com/article/2014/10/17/us-regeneron-pharm-eylea-idUSKCN0I61AK20141017>

Source: reuters.com

GSK says Ebola vaccine development progressing at 'unprecedented rate'

October 18, 2014

Britain's biggest drugmaker GlaxoSmithKline said on Saturday work to develop a vaccine to combat Ebola, which has killed thousands in West Africa, was moving at a rapid pace.

"Development of the vaccine candidate is progressing at an unprecedented rate, with first phase 1 safety trials with the vaccine candidate underway in the USA, UK and Mali, and further trials due to start in the coming weeks," the firm said in a statement posted on its website.

Article link: <http://www.reuters.com/article/2014/10/18/us-health-ebola-vaccine-idUSKCN0I70OC20141018>

Source: reuters.com

Amgen Tests New Way to Make Ebola Drug to Boost Supply

October 18, 2014

Amgen Inc. said it will work with the Bill & Melinda Gates Foundation and other groups to come up with an alternative production method for ZMapp, the promising experimental drug to treat Ebola whose supply ran out in August. Separately, the U.S. government has asked three specialized centers how they can expand manufacturing of the Ebola drug using the current method of tobacco plants.

Article link: <http://www.bloomberg.com/news/2014-10-17/amgen-tests-new-way-to-make-ebola-drug-to-boost-supply.html>

Source: bloomberg.com

Small group of specialty drugs could make up half of total pharmacy spending by 2018

October 20, 2014

Some patients are paying sky-high prices for 'specialty medications' when cheaper options exist, a team of researchers has found. A specialty medication is defined by Medicare as any drug that costs more than \$600 a month. Such drugs typically require special handling like refrigeration or additional supplies like syringes. They represent only a fraction of prescriptions filled, but by 2018, are expected to account for half of total annual pharmacy spending, or \$235 billion, according to a study published in the October issue of Health Affairs.

Article link: <http://www.pbs.org/newshour/updates/can-patients-address-rising-cost-specialty-medication/>

Source: pbs.org

Oral Combo Tx Soars in HCV

October 20, 2014

Oral combination therapy for hepatitis C virus (HCV) infection continues to have striking efficacy, even without additional ribavirin and also in patients with cirrhosis, studies presented here found. In one large international study, 99.3% of patients infected with genotype 1b receiving ABT- 450/r plus ombitasvir and dasabuvir -- the direct-acting 3D regimen -- without ribavirin showed sustained virologic responses at 12 weeks (SVR12), as did 98.7% of those who

were given that regimen plus ribavirin, Andreas Maieron, MD, of Elisabeth Hospital in Linz, Austria, reported during the presidential plenary session at the annual meeting of the American College of Gastroenterology.

Article link: <http://www.medpagetoday.com/MeetingCoverage/ACG/48161>

Source: medpagetoday.com

Parents, Stop Rushing To Give Tylenol To Your Kids: You're Doing It Wrong

October 20, 2014

Every eight minutes, a young child in the United States experiences a medication mistake. Too much Tylenol, say. Maybe an extra tablet of ibuprofen, or an adult dose of Sudafed that's much too strong for a small child. And these mistakes aren't the fault of hospitals or doctors — two groups that have come under close scrutiny for medical errors.

Article link: <http://www.forbes.com/sites/dandiamond/2014/10/20/parents-stop-rushing-to-give-tylenol-to-your-kids-youre-doing-it-wrong/?ss=pharma-healthcare>

Source: forbes.com

Senate Lawmaker Eyes Hearing on the Cost of Hepatitis C Treatments

October 20, 2014

Ed Silverman Responding to the ongoing controversy over the prices for new hepatitis C treatments, U.S. Sen. Bernard Sanders (I-Vt.) will probably hold a hearing — possibly before the year ends — to examine how the cost is affecting the U.S. Department of Veterans Affairs, according to his spokesman. Sanders is chairman of the Senate Committee on Veterans' Affairs.

Article link: <http://blogs.wsj.com/pharmalot/2014/10/20/senate-lawmaker-eyes-hearing-on-the-cost-of-hepatitis-c-treatments/>

Source: wsj.com

FDA panel unanimously backs Novartis' psoriasis drug

October 20, 2014

An advisory panel to the U.S. Food and Drug Administration unanimously recommended the use of Novartis AG's anti-inflammation drug in patients with a type of psoriasis, paving the way for its approval. The panel voted 7-0 in favor of the drug's use in plaque-psoriasis, the most common form of the painful, unsightly skin condition.

Article link: <http://uk.reuters.com/article/2014/10/20/novartis-fda-idUKL3N0SF5RW20141020>

Source: reuters.com

Parkinson's Drugs May Spur Compulsive Behaviors

October 20, 2014

Drugs commonly used to treat Parkinson's disease may raise the risk of so-called impulse control disorders, according to a new review. These disorders include compulsive gambling, compulsive shopping and/or hypersexuality.

Article link: <http://consumer.healthday.com/cognitive-health-information-26/parkinson-s-news-526/more-evidence-that-parkinson-s-drugs-may-spur-compulsive-behaviors-692857.html>

Source: healthday.com

FDA will review Lilly/BI diabetes combo

October 21, 2014

US regulators have agreed to review Eli Lilly/Boehringer Ingelheim's empagliflozin/metformin fixed-dose combination as a potential treatment for patients with type II diabetes. The two components of the therapy have very different modes of action: empagliflozin is a sodium glucose co-transporter-2 (SGLT2) inhibitor that removes excess glucose through the urine by blocking glucose reabsorption in the kidney, while metformin decreases the production of glucose in the liver and its absorption in the intestine and improves the body's ability to utilise glucose.

Article link: http://www.pharmatimes.com/Article/14-10-21/FDA_will_review_Lilly_BI_diabetes_combo.aspx

Source: pharmatimes.com

Oramed's oral insulin succeeds in study, shares jump

October 22, 2014

Oramed Pharmaceuticals Inc said its oral insulin capsule appeared to be safe and was welltolerated by diabetics in a mid-stage trial. The Israeli biotechnology company's shares jumped about 10 percent to \$8.73 before the bell on Wednesday.

Article link: <http://www.reuters.com/article/2014/10/22/us-oramed-study-idUSKCN0IB1HQ20141022>

Source: reuters.com

Nursing Homes Use Too Many Antibiotics, and Residents Are Dying

October 22, 2014

Infections are all-too-common in nursing homes. And all-too-often facilities treat these conditions with large doses of antibiotics. Now the Obama Administration has announced a major initiative aimed at dramatically reducing the use of these drugs. And the effort has the potential to fundamentally change the way nursing homes operate—and the way residents receive care.

Article link: <http://www.forbes.com/sites/howardgleckman/2014/10/22/nursing-homes-use-too-many-antibiotics-and-residents-are-dying/>

Source: forbes.com

Relypsa seeks FDA approval of drug for chronic kidney disease patients

October 22, 2014

Relypsa Inc. asked federal drug regulators Wednesday to approve its experimental treatment for potentially fatal levels of potassium in patients with chronic kidney disease. The Redwood City company— one of the biotech IPO Class of 2013 — filed a new drug application with the Food and Drug Administration to approve Patiromer as a treatment for hyperkalemia.

Article link: <http://www.bizjournals.com/sanfrancisco/blog/biotech/2014/10/relypsa-rlp-hyperkalemia-potassium-kidney-disease.html>

Source: bizjournals.com.

Advair sales slide triggers another \$1.6B in cost cuts at GlaxoSmithKline

October 22, 2014

Brace yourselves for layoffs at GlaxoSmithKline. The saga is familiar: An aging blockbuster loses steam to competing meds, and its maker gets out the cost-cutting ax to compensate. This time, the faltering drug is Advair, which adds some new twists to the story--including a warning to the whole pharma industry about formulary placement.

Article link: <http://www.fiercepharmamarketing.com/story/advair-sales-slide-triggers-another-16-billion-cost-cuts-glaxosmithkline/2014-10-22>

Source: fiercepharmamarketing.com

Biogen Falls After Patient on Top-Selling Drug Dies

October 22, 2014

Shares of Biogen Idec Inc. fell the most in seven months after the company said a patient developed a rare brain infection and died while taking its top-selling multiple sclerosis drug Tecfidera. The patient, who died from pneumonia, is the first using Tecfidera to develop the brain infection known as progressive multifocal leukoencephalopathy, or PML, Chief Executive Officer George Scangos said today. The patient, who had been taking Tecfidera for four years, had low levels of white blood cells, a risk factor for PML outlined in the drug's label.

Article link: <http://www.bloomberg.com/news/2014-10-22/biogen-raises-forecast-as-profit-beats-estimates.html>

Source: bloomberg.com

Novartis reports positive results in spinal inflammation condition

October 23, 2014

Swiss drugmaker Novartis said on Thursday two late-stage trials showed its drug secukinumab improved symptoms of ankylosing spondylitis, a debilitating joint condition of the spine. The trials, which involved a total of approximately 600 patients, found Novartis' drug improved signs and symptoms of the disease as well as physical function and quality of life compared with placebo.

Article link: <http://www.reuters.com/article/2014/10/23/us-novartis-drugs-secukinumab-idUSKCN0ICOGF20141023>

Source: reuters.com

RECALLS*

Product Type	Product Description	Code info.	Class	Reason for Recall	Recalling firm
Drugs	N-Acetyl Cysteine 20% 4 mL Vial Stock Code: 4133	Lot #: 86513, Exp 07/23/2014	Class I	Non-Sterility: One lot of N-Acetyl Cysteine vials tested positive for Herbaspirillum huttiense.	Unique Pharmaceutical ,Ltd
Drugs	Lidocaine HCl Injection, USP, 2%, 20 mg per mL, Preservative-Free, 5 mL Single-Dose Vial, Rx only, For Infiltration and Nerve Block including Epidural and Caudal, NDC 0409-2066-05	Lot Number: 25-550-DD, Exp: 1JAN2015	Class I	Presence of Particulate Matter: The product was discolored and contained visible particulates (iron oxide) in the solution and embedded in the glass vial.	Hospira Inc.
Drugs	Metoprolol Succinate Extended-release Tablets, USP 50mg, 90-count Bottles, Rx only, NDC 0378-4596-77.	Lot 3023805 Exp. 11/15	Class II	Presence of Foreign Tablets/Capsules: A pharmacist reported a rogue tablet of different size and markings in bottle of Metoprolol	Mylan Pharmaceuticals Inc.
Drugs	All sterile products within expiry	All Lots	Class II	Lack of Sterility Assurance: A recent FDA inspection revealed poor aseptic production practices that result in lack of sterility assurance of products intended to be sterile.	Unique Pharmaceutical ,Ltd
Drugs	ZyGenerics ATENOLOL Tablets, USP 25 mg 1000 count bottle, Rx Only NDC 68382-022-01	MP2252 Exp. 01/16	Class II	Superpotent Drug: A complaint was reported by a pharmacist who stated several tablets were noticeably thicker in appearance.	Zybus Pharmaceuticals USA Inc
Drugs	Tarceva (erlotinib) Tablets, 150 mg, 30 count bottle, Rx only, NDC 50242-064-01	Lot 66482CW, Exp 04/16	Class II	Failed Dissolution Specifications: The product did not meet the acceptance	Astellas Pharma US Inc

Product Type	Product Description	Code info.	Class	Reason for Recall	Recalling firm
				criteria for the dissolution test during the 24 month routine stability testing.	
Drugs	METOCLOPRAMIDE ORAL SOLUTION, USP 10 mg/10 mL, (present as the hydrochloride), 10 mL cups, Rx only. NDC 66689-031-01.	Lot #: 283700, Expiry: 11/14; Lot #: 291400, Expiry: 01/15; and Lot #: 303500, Expiry: 04/15.	Class II	Defective Container: Product leaks when inverted.	VistaPharm, Inc.
Drugs	Xarelto (rivaroxaban) Tablets 15 mg per tablet, 5 count bottle, Rx Only, NDC 50458-578-99	Lot 13JG2616 Exp. 07/16	Class II	Microbial Contamination of Non-Sterile Products: Consumer complaint confirmed microbial contamination in sales sample.	Janssen Ortho L.L.C.
Drugs	Amiodarone HCl Injection, 450 mg/9 mL (50 mg per mL), 9 mL Single-Use Vial, Rx only, NDC 67457-153-09.	Lot #140502, Exp 10/31/2015	Class II	Temperature Abuse: One shipment was inadvertently stored refrigerated rather than the labeled room temperature recommendation at McKesson Medical-Surgical Inc., one of the distributing wholesalers.	Mckesson
Drugs	Atorvastatin Calcium 40 MG Tablet, MFG: Apotex NDC# 6050525808	Lot 204751 Exp. 04/15	Class II	Presence of Foreign Tablets/Capsules:179 doses of Valacyclovir HCl 500 mg tablets were repacked in unit dose packs labeled as Atorvastatin Calcium	Unit Dose Solutions Inc
Drugs	Dipyridamole API, NET WT 10 Kg, Rx Only, S.I.M.S. , Chemical Product for Medicines Preparation, NDC 012660-0084	Lot Number: 161600, Exp 03/2016	Class II	cGMP Deviations: GYMA laboratories Inc. has recalled multiple Active Pharmaceutical Ingredients	Gyma Laboratories Of Amer,Inc

Product Type	Product Description	Code info.	Class	Reason for Recall	Recalling firm
				manufactured in Italy upon receipt of a Rapid Alert Notification issued by The Italian Medicines Agency due to lack of good manufacturing practices.	
Drugs	Propranolol HCl, NET WT 1 Kg, Rx Only, S.I.M.S. , Chemical Product for Medicines Preparation, NDC 012660-0004	Lot Number: 154919, Exp 11/2014	Class II	cGMP Deviations: GYMA laboratories Inc. has recalled multiple Active Pharmaceutical Ingredients manufactured in Italy upon receipt of a Rapid Alert Notification issued by The Italian Medicines Agency due to lack of good manufacturing practices.	Gyma Laboratories Of Amer,Inc
Drugs	Clonidine Base Micronized, 55.8 Kg, Rx Only, S.I.M.S. , Chemical Product for Medicines Preparation, NDC 12660-0503-01	Lot Numbers: 166247, 166248, Exp 10/2016	Class II	cGMP Deviations: GYMA laboratories Inc. has recalled multiple Active Pharmaceutical Ingredients manufactured in Italy upon receipt of a Rapid Alert Notification issued by The Italian Medicines Agency due to lack of good manufacturing practices.	Gyma Laboratories Of Amer,Inc
Drugs	Clonidine HCL, 97 Kg, Rx Only, S.I.M.S. , Chemical Product for Medicines Preparation, NDC 012660-0002	Lot Numbers: 167219, 163367, 167220, 167221, Exp 03/2017	Class II	cGMP Deviations: GYMA laboratories Inc. has recalled multiple Active Pharmaceutical Ingredients manufactured in Italy upon receipt of a Rapid Alert	Gyma Laboratories Of Amer,Inc

Product Type	Product Description	Code info.	Class	Reason for Recall	Recalling firm
				Notification issued by The Italian Medicines Agency due to lack of good manufacturing practices.	
Drugs	TOPIRAMATE Tablets 200 mg, 60 Tablet Bottles, Rx Only. NDC 68382-141-14.	Lot #: MN9828, Expiry: Oct 2015.	Class II	Presence of Foreign Tablets: Presence of topiramate 100 mg tablets comingled with 200 mg tablets.	Zydus Pharmaceuticals USA Inc
Drugs	HYDROXYPROGESTERONE CAPROATE 250 MG/ML (IN SESAME OIL), Rx Only 4 mL INJECTABLE IM USE.	Lot# 12-20140207@109; Exp. 12/14 Lot# 12-20142107@82; Exp. 01/15	Class II	Crystallization: Formation of crystals observed in product.	Avella of Deer Valley, Inc.
Drugs	Ketorolac Tromethamine INJECTION, USP, 30 mg per mL, a) 1 mL vial (NDC 25021-701-01) b) 2 mL vial (NDC 25021-701-02), Rx only	Lot MP5021, Exp. 04/16; Lots MP5024, MP5025, Exp. 05/16	Class II	Incorrect or Missing Lot and/or Exp Date: Ketorolac Tromethamine Injection is being recalled as a result of labeling the product with the incorrect expiration date.	Sagent Pharmaceuticals Inc
Drugs	Vaseretic (enalapril maleate/hydrochlorothiazide) 10/25 mg Tablets, NDC 0187-0146-01, 100 ct. bottles	VASERETIC 10-25MG TAB 100CT Lot # 12J022P exp. 9/30/2014 VASERETIC 10-25MG TAB 100CT Lot # 13G047P exp. 07/31/2015	Class III	Labeling: Incorrect or Missing Package Insert: Product is packaged with the incorrect version of the package outset	Valeant Pharmaceuticals North America LLC
Drugs	Vasotec (enalapril maleate) tablets, RX only, NDC 0187-0140-90 5 mg 30 ct - NDC 0187-0141-30 5 mg 90 ct - NDC 0187-0141-90 10 mg 30 ct - NDC 0187-0142-30 10 mg 90 ct - NDC 0187-0142-90 10 mg 1000 ct - NDC	VASOTEC 2.5MG TAB 30CT 12K015P exp. 9/30/2014 VASOTEC 2.5MG TAB 30CT 13G048P exp. 07/31/2015 VASOTEC 2.5MG	Class III	Labeling: Incorrect or Missing Package Insert: Product is packaged with the incorrect version of the package insert.	Valeant Pharmaceuticals North America LLC

Product Type	Product Description	Code info.	Class	Reason for Recall	Recalling firm
	0187-0142-10 20 mg 30 ct - NDC 0187-0143-30 20 mg 90 ct - NDC 0187-0143-90 20 mg 1000 ct - NDC 0187-0143-10 NDC #'s 64455-140, 64455-141, 64455-142 and 64455-143, 30 ct. bottles, 90 ct. bottles and 1000 ct. bottles	TAB 30CT 14A065P exp. 07/31/2015VAS OTEC 2.5MG TAB 90CT 13G020P exp. 07/31/2015VAS OTEC 2.5MG TAB 90CT 12K020Pexp. 9/30/2014 VASOTEC 2.5MG TAB 90CT 13B016P exp. 9/30/2014VASO TEC 5MG TAB 30CT 13B022P exp. 2/28/2015VASO TEC 5MG TAB 30CT 13B023P exp. 2/28/2015VASO TEC 5MG TAB 30CT 13C015P exp. 02/28/2015VAS OTEC 5MG TAB 30CT 13E002P exp. 02/28/2015 VASOTEC 5MG TAB 30CT 14A002P exp. 11/30/2015VAS OTEC 5MG TAB 30CT 13L066P exp. 11/30/2015VAS OTEC 5MG TAB 90CT 13B018P exp. 2/28/2015VASO TEC 5MG TAB 90CT 13G015P exp.			

Product Type	Product Description	Code info.	Class	Reason for Recall	Recalling firm
		06/30/2015VAS OTEC 10MG TAB 90CT 12M017P exp. 11/30/2014 VASOTEC 10MG TAB 1000CT 12L105P exp. 11/30/2014VAS OTEC 10MG TAB 30CT 12M016P exp. 11/30/2014VAS OTEC 10MG TAB 30CT 13G013P exp. 06/30/2015VAS OTEC 10MG TAB 30CT 13J081Pexp. 9/30/2015VASO TEC 10MG TAB 90CT 12M025P exp. 11/30/2014VAS OTEC 10MG TAB 90CT 13J082P exp. 0/2015VASOTEC 10MG TAB 90CT 13J085P exp. 0/2015VASOTEC 10MG TAB 90CT 13J094P exp. 09/30/2015VAS OTEC 10MG TAB 1000CT 13J098P exp. 09/30/2015VAS OTEC 10MG TAB 1000CT 13G011P exp. 06/30/2015VAS OTEC 10MG TAB 1000CT 13J097P exp.			

Product Type	Product Description	Code info.	Class	Reason for Recall	Recalling firm
		09/30/2015VAS OTEC 20MG TAB 30CT 12J017P exp. 5/31/2014VASO TEC 20MG TAB 30CT 13C016P exp. 2/28/2015VASO TEC 20MG TAB 30CT 13E003P exp. 02/28/2015VAS OTEC 20MG TAB 30CT 13L068P exp. 09/30/2015VAS OTEC 20MG TAB 90CT 13J086P exp. 09/30/2015VAS OTEC 20MG TAB 90CT 13J087P exp. 09/30/2015VAS OTEC 20MG TAB 90CT 12M029P exp. 11/30/2014 VASOTEC 20MG TAB 90CT 12M030P exp. 11/30/2014VAS OTEC 20MG TAB 1000CT 12J023P exp. 5/31/2014VASO TEC 20MG TAB 1000CT 12L108P exp. 11/30/2014VAS OTEC 20MG TAB 1000CT 13C088P exp. 02/28/2015VAS OTEC 20MG TAB			

Product Type	Product Description	Code info.	Class	Reason for Recall	Recalling firm
		1000CT 13J099P exp. 09/30/2015VAS OTEC 20MG TAB 1000CT 13M054P exp. 09/30/2015VAS OTEC 20MG TAB 1000CT 13M055P exp. 12/31/2015VAS OTEC 20MG TAB 1000CT 14B054P exp. 12/31/2015			
Drugs	Hydrocortisone Butyrate Cream 0.1%, Net Wt. 15 gm tubes, Rx only, NDC 43478-270-15	Lot numbers 13052C, exp 03/2015 and 13156A, exp 08/2015, NDC 43478-270-15	Class III	Subpotent Drug; for the active, HCB, and preservatives, Propylparaben and Butylparaben at the 18 month stability test point	Valeant Pharmaceuticals International
Drugs	Locoid (hydrocortisone butyrate 0.1%), Cream, Net Wt. 15 gm tubes, Rx only, NDC 16781-382-15	Lot number 13052B, Exp. 03/2015, NDC16781-382-15	Class III	Subpotent Drug; for the active, HCB, and preservatives, Propylparaben and Butylparaben at the 18 month stability test point	Valeant Pharmaceuticals International
Drugs	E-Z- GAS II EFFERVESCENT GRANULES Antacid/Antiflatulent ,4 g (0.14 oz), 50 -count box, Rx Only, NDC 10361-793-01	Lot # F12C01; Exp. 02/15	Class III	Subpotent Drug: Out of Specification (OOS) result during routine stability testing at 24 months.	Bracco Diagnostic Inc
Drugs	Truvada (200 mg emtricitabine and 300 mg tenofovir disoproxil fumarate) tablets, 30 count bottles, Rx only, NDC 61958-0701-1	TRUVADA (NDA 21-752; NDC 61958-0701-1) Lot# 002808, Expiration Date: 31 December 2017	Class III	Presence of Foreign Substance: Truvada was found to contain small red silicone rubber particulates.	Gilead Sciences, Inc.

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

CURRENT DRUG SHORTAGES[†]

Zinc Injection

October 7, 2014

Reason for the Shortage

- Hospira states the shortage of zinc chloride injection is due to manufacturing delays.
- Hospira is the only manufacturer of zinc chloride injection.
- American Regent states the shortage of zinc sulfate injection is due to manufacturing delays.
- FDA is allowing temporary importation of zinc gluconate trihydrate 1 mg/mL 10 mL vials from Aguetant Laboratories in France. This product is being distributed through Baxter Healthcare. The labeling will come in the original container which is in French. Information translated into English along with a table comparing the US and French products can be found in the Dear Healthcare Professional Letter.

Article link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=777><http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=915>

Source link: <http://www.ashp.org>

Sodium Chloride Concentrated Solution for Injection

October 7, 2014

Reason for the Shortage

- American Regent discontinued 23.4% sodium chloride 30 mL and 100 mL presentations in 2012.
- Baxter discontinued their sodium chloride 250 mL presentation in 2008.
- Fresenius Kabi (formerly APP) has sodium chloride concentrated solution on shortage due to increased demand. Fresenius Kabi discontinued 14.6% sodium chloride 20 mL vials in February 2013.
- Hospira has 14.6% and 23.4% sodium chloride solutions for injection on shortage due to manufacturing delays. Hospira discontinued sodium chloride 14.6% solution 250 mL vials in February 2011.

Article link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=724>

Source link: <http://www.ashp.org>

Selenium Injection

October 7, 2014

Reason for the Shortage

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

Article link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=784>

Source link: <http://www.ashp.org>

Papaverine Injection

October 7, 2014

Reason for the Shortage

- Bedford and Sandoz have discontinued their papaverine presentations.
- American Regent has papaverine on shortage due to manufacturing delays.
- American Regent is the sole supplier of papaverine.

Article link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=781>

Source link: <http://www.ashp.org>

Oxycodone/Acetaminophen Oral Solution

October 7, 2014

Reason for the Shortage

- Roxane states that the reason for the shortage is that they are validating a new source for raw materials.
- Roxane discontinued oxycodone/acetaminophen 5 mL unit-dose cups in July 2014.
- Oxycodone/acetaminophen oral solution is not available from other manufacturers or in other concentrations.
- This shortage does not affect single-ingredient oxycodone solutions or oxycodone/acetaminophen solid oral dosage forms.

Article link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1117>

Source link: <http://www.ashp.org>

Mitomycin Injection

October 7, 2014

Reason for the Shortage

- Ben Venue stopped production in its plant in Bedford, Ohio and closed in July 2014.

Article link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=433>

Source link: <http://www.ashp.org>

Cisplatin Injection

October 7, 2014

Reason for the Shortage

- Fresenius states the shortage was due to increased demand and manufacturing delays.
- Teva is allocating cisplatin to prevent stockpiling.
- WG Critical Care is allocating product due to increased demand.

Article link: <http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=57>

Source link: <http://www.ashp.org>

Cisatracurium Injection

October 7, 2014

Reason for the Shortage

- Sandoz could not provide a reason for the shortage.
- Nimbex injection is on shortage due to increased demand.

Article link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1072>

Source link: <http://www.ashp.org>

Chloroprocaine Injection

October 7, 2014

Reason for the Shortage

- West-Ward Pharmaceuticals' parent company, Hikma Pharmaceuticals, acquired several products from Bedford Laboratories in July 2014 including chloroprocaine injection. West-Ward is not actively marketing chloroprocaine injection.
- Hospira discontinued chloroprocaine injection in January, 2012 due to inability to obtain raw materials. All supply was depleted in January.

- Fresenius Kabi (formerly APP) has transitioned from 1 count presentations to 25 count sizes. All 1 count presentations were depleted in early 2012.
- Fresenius Kabi (formerly APP) had Nesacaine on shortage from depletion of raw materials due increased demand for the product.

Article link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=849>

Source link: <http://www.ashp.org>

Cefotaxime Injection

October 7, 2014

Reason for the Shortage

- Fresenius Kabi discontinued all cefotaxime presentations in April 2011.
- Hospira has Claforan on shortage due to manufacturing delays.

Article link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=826>

Source link: <http://www.ashp.org>

Caffeine and Sodium Benzoate Injection

October 7, 2014

Reason for the Shortage

- American Regent had temporarily suspended manufacture of multiple drug products including caffeine and sodium benzoate injection in April, 2011.
- American Regent resumed manufacturing in Shirley, New York in early-May, 2011.
- American Regent is the sole manufacturer of caffeine and sodium benzoate injection.
- Caffeine citrate injection is not affected by this shortage.

Article link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=817>

Source link: <http://www.ashp.org>

Sincalide Injection

October 8, 2014

Reason for the Shortage

- Bracco Diagnostics has Kinevac on shortage due to manufacturing delays.
- There are no approved alternatives to Kinevac for the labeled indications.

Article link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1032>

Source link: <http://www.ashp.org>

Phenylephrine 2.5% and 10% Ophthalmic Solution

October 8, 2014

Reason for the Shortage

- Akorn stopped manufacturing phenylephrine ophthalmic solution in April 2014 and stopped distributing product on June 30, 2014.
- Alcon discontinued phenylephrine 2.5% ophthalmic solution with the Sandoz label in April 2014.
- Alcon discontinued Mydrin 2.5% ophthalmic solution in 2014.
- Hub discontinued phenylephrine 2.5% and 10% ophthalmic solution in 2013.
- Phenylephrine 2.5% and 10% from Paragon BioTeck is the only FDA-approved phenylephrine ophthalmic product. Paragon BioTeck supplies phenylephrine ophthalmic solution 2.5% and 10% and this is distributed by Bausch & Lomb (a division of Valeant).

Article link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1105>

Source link: <http://www.ashp.org>

Epinephrine Injection

October 8, 2014

Reason for the Shortage

- American Regent has epinephrine on shortage due to manufacturing delays.
- Hospira had epinephrine syringes on shortage due to manufacturing delays.
- Amphastar states the shortage is due to increased demand.

Article link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=685>

Source link: <http://www.ashp.org>

Citric acid and potassium citrate

October 8, 2014

Reason for the Shortage

- Cypress Pharmaceuticals has Cytra-K crystals on back order due to a raw material supply issue.

Article link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1080>

Source link: <http://www.ashp.org>

Azithromycin Injection

October 8, 2014

Reason for the Shortage

- Fresenius Kabi could not provide a reason for the shortage.
- Hospira has azithromycin injection on shortage due to increased demand.
- Sagent has azithromycin injection on shortage due to increased demand.
- Pfizer discontinued Zithromax 500 mg vial with Vial-Mate Adaptor in January 2013.

Article link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=936>

Source link: <http://www.ashp.org>

Amifostine Injection

October 8, 2014

Reason for the Shortage

- West-Ward Pharmaceuticals' parent company, Hikma Pharmaceuticals, acquired amifostine injection from Bedford in July 2014. West-Ward is actively marketing amifostine injection.
- Caraco could not provide a reason for the shortage.
- Medimmune discontinued brand name Ethyol 500 mg injection in August, 2009.

Article link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=980>

Source link: <http://www.ashp.org>

70% Dextrose Injection Large Volume Bags

October 8, 2014

Reason for the Shortage

- Baxter, BBraun, and Hospira state the reason for the shortage is increased demand for product.

Article link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1133>

Source link: <http://www.ashp.org>

Sufentanil Injection

October 9, 2014

Reason for the Shortage

- West-Ward had sufentanil on shortage due to manufacturing delays.
- Hospira has sufentanil on shortage due to manufacturing delays.
- Akorn could not provide a reason for the shortage.

Article link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=823>

Source link: <http://www.ashp.org>

Sodium Chloride 0.45% Injection Bags

October 9, 2014

Reason for the Shortage

- Baxter has 0.45% sodium chloride on shortage due to increased demand.
- BBraun had 0.45% sodium chloride on allocation due to increased demand.
- Hospira cited increased demand as the reason for the shortage.

Article link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1083>

Source link: <http://www.ashp.org>

Methylprednisolone Sodium succinate injection

October 9, 2014

Reason for the Shortage

- Hospira discontinued all methylprednisolone sodium succinate products in January 2013 due to raw material issues.
- Bedford discontinued methylprednisolone in May, 2011 to concentrate on the manufacturing of other products.
- Pfizer had Solu-Medrol on shortage due to manufacturing delays.
- Fresenius Kabi (formerly APP) has methylprednisolone sodium succinate on shortage due to priority of other medications.

Article link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1077>

Source link: <http://www.ashp.org>

Dextrose 5% Injection Large volume bags

October 9, 2014

Reason for the Shortage

- Baxter states the shortage is due to increased demand.
- BBraun had 5% dextrose on allocation due to increased demand.
- Hospira states the shortage is due to increased demand and manufacturing delays.

Article link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1081>

Source link: <http://www.ashp.org>

Ceftriaxone Sodium injection

October 9, 2014

Reason for the Shortage

- Ben Venue stopped production in its plant in Bedford, Ohio and closed in July 2014.
- Fresenius Kabi states the reason for the shortage is increased demand.
- Hospira states the reason for the shortage is manufacturing delay.
- Sagent states the reason for the shortage is increased demand.
- Sandoz cannot provide a reason for the shortage.
- WG Critical Care states the reason for the shortage was increased demand.

Article link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1101>

Source link: <http://www.ashp.org>

Caffeine Citrate Injection and Oral solution

October 9, 2014

Reason for the Shortage

- American Regent has caffeine citrate on shortage due to manufacturing delays.
- Caraco cannot provide a reason for the shortage.
- Paddock discontinued caffeine citrate injection and oral solution in May 2014.
- Sagent states the reason for the shortage is increased demand.

- West-Ward Pharmaceuticals' parent company, Hikma Pharmaceuticals, acquired Cafcit from Bedford in July 2014. West-Ward is actively marketing Cafcit injection.

Article link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=862>

Source link: <http://www.ashp.org>

Phosphorus Oral Supplements

October 10, 2014

Reason for the Shortage

- Cypress Pharmaceuticals had Phos-Nak Powder on back order due to manufacturing delays.

Article link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1102>

Source link: <http://www.ashp.org>

Paclitaxel Injection

October 10, 2014

Reason for the Shortage

- Fresenius Kabi (formerly APP) has paclitaxel on shortage due to increase demand for the product.
- West-Ward Pharmaceuticals' parent company, Hikma Pharmaceuticals, acquired paclitaxel injection from Bedford in July 2014. West-Ward is not actively marketing paclitaxel.
- Teva has paclitaxel on shortage due to manufacturing delays.
- Sandoz has paclitaxel on back order due to a raw material shortage.
- Hospira had paclitaxel on shortage due to increased demand.
- Sagent has paclitaxel on shortage due to increased demand.
- Pfizer launched paclitaxel 100 mg and 300 mg vials in March, 2012 and launched the 30 mg vials in April, 2012.
- Mylan Institutional acquired paclitaxel injection from Pfizer on December 7, 2013.
- WG Critical Care launched paclitaxel injection in September 2014.

Article link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=790>

Source link: <http://www.ashp.org>

Methylphenidate Hydrochloride

October 10, 2014

Reason for the Shortage

- Mallinckrodt states the shortage was due to delay in obtaining raw materials. The company has stopped using the trade name Methylin and all products are now marketed as methylphenidate immediate-release or extended-release tablets with new NDC numbers.
- Sandoz states that the shortage is due to delay in obtaining raw materials.
- Teva introduced generic methylphenidate extended release capsules (CD) in late-September 2012, and these capsules are AB-rated to Metadate CD capsules.
- UCB states methylphenidate IR tablets were on shortage due to supply and demand.
- Actavis says the methylphenidate IR tablets were on shortage due to supply constraints.
- Noven cannot provide a reason for the shortage of Daytrana patches.

Article link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=752>

Source link: <http://www.ashp.org>

Hydroxychloroquine sulfate

October 10, 2014

Reason for the Shortage

- Ranbaxy and Sandoz state the hydroxychloroquine shortage is due to increased demand.
- Zydus could not provide a reason for hydroxychloroquine shortage.
- West-Ward discontinued hydroxychloroquine tablets in September 2014

Article link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1126>

Source link: <http://www.ashp.org>

Doxycycline capsules and tablets

October 10, 2014

Reason for the Shortage

- Actavis states the reason for the shortage is supply and demand.
- Aqua and Mylan could not provide a reason for the shortage.

- Teva discontinued their doxycycline presentations in May 2013.
- Major discontinued most doxycycline presentations in February 2013. The company could not provide a reason for the discontinuation.

Article link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=977>

Source link: <http://www.ashp.org>

Ciprofloxacin Injection

October 10, 2014

Reason for the Shortage

- Claris, Sagent, and Sandoz could not provide a reason for the shortage.
- Hospira has ciprofloxacin injection on back order due to manufacturing delays.

Article link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=944>

Source link: <http://www.ashp.org>

Atorvastatin

October 10, 2014

Reason for the Shortage

- In November 2012, Ranbaxy voluntarily recalled 41 lots of atorvastatin tablets due to possible contamination with very small glass particles. Ranbaxy resumed supply of atorvastatin tablets in late-March 2013.
- Ranbaxy has atorvastatin on shortage due to manufacturing delay.
- Sandoz could not provide a reason for the shortage.
- Watson discontinued all atorvastatin presentations in February 2013.

Article link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=989>

Source link: <http://www.ashp.org>

Ticarcillin Clavulanate

October 13, 2014

Reason for the Shortage

- GlaxoSmithKline could not provide a reason for the shortage.
- GlaxoSmithKline discontinued Timentin 3.1 gram ADD-Vantage vials in late-2012.

Article link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=802>

Source link: <http://www.ashp.org>

Ranitidine Injection

October 13, 2014

Reason for the Shortage

- West-Ward Pharmaceuticals' parent company, Hikma Pharmaceuticals, acquired ranitidine injection from Bedford in July 2014. West-Ward is not actively marketing ranitidine injection.
- Covis has Zantac on shortage due to capacity issues at the manufacturer.
- Oral ranitidine products are not affected by this shortage.

Article link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=820>

Source link: <http://www.ashp.org>

Propranolol Injection

October 13, 2014

Reason for the Shortage

- Ben Venue closed its plant in Bedford, Ohio in July 2014.
- Fresenius Kabi has propranolol injection on back order due to shortage of raw materials.
- Sandoz cannot provide a reason for the shortage.
- West-Ward had propranolol injection on shortage due to manufacturing delays.

Article link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1091>

Source link: <http://www.ashp.org>

Ocreotide Injection

October 13, 2014

Reason for the Shortage

- Caraco cannot provide a reason for the shortage.
- Fresenius Kabi (formerly APP) reports that the shortage was due to increased demand for the product.
- Sandoz discontinued octreotide injection in 2nd quarter 2013.

- Sagent has octreotide on shortage due to increased demand for the product.
- Teva has octreotide on shortage due to manufacturing delays.
- West-Ward Pharmaceuticals' parent company, Hikma Pharmaceuticals, acquired octreotide injection from Bedford in July 2014. West-Ward is not actively marketing octreotide injection except available 1000 mcg/mL, 5 mL vial (NDC 55390-0164-01) short-dated inventory with May 2015 expiry.
- Wockhardt has octreotide on back order due to an import ban.
- Sandostatin LAR presentations from Novartis are not affected by this shortage

Article link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=803>

Source link: <http://www.ashp.org>

Haemophilus B Conjugate

October 13, 2014

Reason for the Shortage

- Sanofi Pasteur had ActHIB in short supply due to the shortage of other combination vaccines (eg, Pentacel®).
- GlaxoSmithKline cannot provide a reason for the shortage of Hiberix but it has not been manufactured since 2011.
- Merck announced in March 2014 plans to discontinue Comvax vaccine. Product will no longer be available directly from Merck after December 31, 2014.

Article link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1052>

Source link: <http://www.ashp.org>

Fluconazole Injection

October 13, 2014

Reason for the Shortage

- Teva has fluconazole injection on shortage due to manufacturing delays.
- Pfizer had fluconazole injection on shortage due to manufacturing delays related to labeling changes.
- West-Ward has fluconazole injection on shortage due to manufacturing delays.
- Ben Venue has stopped production in its plant in Bedford, Ohio and closed in July 2014.

Article link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=644>

Source link: <http://www.ashp.org>

Famotidine Injection

October 13, 2014

Reason for the Shortage

- Ben Venue stopped production in its plant in Bedford, Ohio and closed in July 2014.
- West-Ward states the shortage is 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.

Article link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=810>

Source link: <http://www.ashp.org>

Ephedrine Injection

October 13, 2014

Reason for the Shortage

- Hospira discontinued ephedrine in March, 2011

Article link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=351>

Source link: <http://www.ashp.org>

Digoxin Injection

October 13, 2014

Reason for the Shortage

- West-Ward states the shortage is due to manufacturing delays

Article link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=748>

Source link: <http://www.ashp.org>

Dexrazoxane Injection

October 13, 2014

Reason for the Shortage

- West-Ward Pharmaceuticals' parent company, Hikma Pharmaceuticals, acquired dexrazoxane injection from Bedford in July 2014. West-Ward is not actively marketing dexrazoxane injection at this time.
- Biocodex USA acquired Totect from Apricus Pharmaceuticals in April 2013.
- Apricus Pharmaceuticals acquired Topotarget USA in late 2011.
- Topotarget worked with FDA to extend the expiration date of specific batch numbers of Totect to 36 months. Information regarding this extension and the batch numbers can be found in four Dear Healthcare Customer letters available online.

Article link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=415>

Source link: <http://www.ashp.org>

Daunorubicin Hydrochloride

October 13, 2014

Reason for the Shortage

- West-Ward Pharmaceuticals' parent company, Hikma Pharmaceuticals, acquired daunorubicin injection and Cerubidine injection from Bedford in July 2014. West-Ward is not actively marketing daunorubicin injection or Cerubidine injection at this time.
- Teva states daunorubicin was on back order due to manufacturing delays.

Article link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1007>

Source link: <http://www.ashp.org>

Cidofovir Injection

October 13, 2014

Reason for the Shortage

- Gilead recalled one lot of Vistide on February 4, 2013, due to particulate matter in some vials.
- Gilead discontinued Vistide injection in July 2014.
- Mylan Institutional launched cidofovir injection in mid-March 2013.

Article link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=994>

Source link: <http://www.ashp.org>

Cefuroxime Sodium Injection

October 13, 2014

Reason for the Shortage

- Sagent states manufacture of cefuroxime 1.5 gram was suspended in March, 2013. No further production is planned.
- Hospira discontinued cefuroxime 1.5 gram and 7.5 gram vials in January, 2013.
- Covis launched the new NDC numbers in August 2013.
- BBraun discontinued their cefuroxime solution in December 2013.
- Fresenius Kabi discontinued manufacturing cefuroxime in 2013.

Article link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=990>

Source link: <http://www.ashp.org>

Calcium gluconate injection

October 13, 2014

Reason for the Shortage

- American Regent has calcium gluconate on shortage due to manufacturing delays.
- Fresenius Kabi had calcium gluconate on shortage due to increase demand for the product.
- 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.

Article link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=48>

Source link: <http://www.ashp.org>

Butorphanol Injection

October 13, 2014

Reason for the Shortage

- Apotex discontinued butorphanol injection in 2008.
- Ben Venue closed its plant in Bedford, Ohio in July 2014.
- Hospira states the shortage was due to manufacturing delays.

- West-Ward discontinued butorphanol injection in early 2012.
- Sandoz discontinued Stadol injection in 2010.

Article link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=939>

Source link: <http://www.ashp.org>

Black Widow Antivenin (*Latrodectus Mactans*)

October 13, 2014

Reason for the Shortage

- Merck has low inventory of Antivenin *Latrodectus Mactans*.
- Merck, working in combination with FDA, announced on July 3, 2014 that the expiration date for Antivenin lot H019984 was extended to January 3, 2015. The packaged Antivenin lot H019984 contains one vial of Antivenin lot 0672105, one vial of sterile diluent lot 0671078, and a 1 mL vial of horse serum for sensitivity testing. The expiration dating for the sterile diluent has not been extended. Discard the sterile diluent and reconstitute the Antivenin vial with 2.5 mL of sterile water for injection.

Article link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=670>

Source link: <http://www.ashp.org>

BCG Vaccine Live Intravesical

October 13, 2014

Reason for the Shortage

- Sanofi Pasteur states the reason for the shortage is manufacturing delay.
- Merck states the reason for the shortage is manufacturing delay.
- Merck states Tice BCG vaccine percutaneous for tuberculosis (Merck, NDC 00052-0603-02) is also affected because this product is manufactured at the same facility.

Article link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=915>

Source link: <http://www.ashp.org>

Ampicillin Sulbactam

October 13, 2014

Reason for the Shortage

- AuroMedics Pharma launched new product in mid-June, 2012.
- Hospira states that ampicillin sulbactam vials are on back order due to manufacturing delay.
- Mylan Institutional discontinued ampicillin sulbactam injection in late 2013.
- Sagent has ampicillin sulbactam vials on allocation due to increased demand for the product.
- WG Critical Care states the shortage is due to increased demand.
- Pfizer and Sandoz cannot provide a reason for the shortage.
- WG Critical Care launched ampicillin sulbactam 1.5 gram vials in March 2014.
- West-Ward acquired several Baxter products in early 2011.

Article link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=805>

Source link: <http://www.ashp.org>

Aminohippurate Sodium

October 13, 2014

Reason for the Shortage

- Merck cannot provide a reason for the shortage.

Article link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1135>

Source link: <http://www.ashp.org>

Vancomycin Hydrochloride Injection

October 14, 2014

Reason for the Shortage

- Hospira has vancomycin on shortage due to increased demand.
- Fresenius Kabi (formerly APP) has vancomycin injection on shortage due to increased demand.
- Sagent has vancomycin on shortage due to increased demand.
- Akorn has sold their vancomycin products to Pfizer and stopped distributing on April 29, 2011.3
- Mylan Institutional acquired vancomycin injection from Pfizer on December 6, 2013.
- Mylan Institutional (formerly Bioniche) has acquired multiple products from Generamedix, including vancomycin hydrochloride.

- Mylan Institutional discontinued two vancomycin presentations in September 2013.
- Pfizer acquired multiple products from Akorn, including vancomycin hydrochloride in early-May, 2011.

Article link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=132>

Source link: <http://www.ashp.org>

Oxacillin Sodium Injection

October 14, 2014

Reason for the Shortage

- Auromedics states the reason for the shortage is increased demand.
- Sagent states the reason for the shortage is manufacturing delay.
- Sandoz states the reason for the shortage is difficulty obtaining the active pharmaceutical ingredient.

Article link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1121>

Source link: <http://www.ashp.org>

Lidocaine with Epinephrine Injection

October 14, 2014

Reason for the Shortage

- Hospira has lidocaine with epinephrine presentations on shortage due to manufacturing delays.
- Fresenius Kabi (formerly APP) has Xylocaine with epinephrine presentations on shortage due to increased demand for the product.

Article link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=860>

Source link: <http://www.ashp.org>

Leucovorin Calcium Injection

October 14, 2014

Reason for the Shortage

- West-Ward Pharmaceuticals' parent company, Hikma Pharmaceuticals, acquired leucovorin calcium injection from Bedford in July 2014. West-Ward is not actively marketing leucovorin calcium injection at this time.
- Teva has leucovorin on shortage due to manufacturing delays. Teva imported leucovorin calcium (calcium folinate solution) 30 mL vials available; however, all product expired in July 2014. Teva will not be importing any additional calcium folinate solution.
- Fresenius Kabi (formerly APP) has leucovorin on shortage due to increase demand.
- Fusilev (levoleucovorin) and leucovorin oral tablets are not affected by the shortage.

Article link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=488>

Source link: <http://www.ashp.org>

Bupivacaine with epinephrine injection

October 14, 2014

Reason for the Shortage

- Fresenius Kabi (formerly APP) has Sensorcaine with epinephrine on shortage due to increased demand for the product.
- Hospira has bupivacaine with epinephrine and Marcaine with epinephrine on shortage due to manufacturing delays.

Article link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=937>

Source link: <http://www.ashp.org>

Amikacin Injection

October 14, 2014

Reason for the Shortage

- West-Ward Pharmaceuticals' parent company, Hikma Pharmaceuticals, acquired amikacin injection from Bedford in July 2014. West-Ward is not actively marketing amikacin 250 mg/mL 4 mL vials at this time.
- Hospira discontinued amikacin in May, 2010 due to a raw material shortage.
- Teva's product was unavailable due to manufacturing delays.
- Sandoz discontinued Amikin injection in 2006.
- Heritage launched amikacin injection in March 2014.

Article link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=501>

Source link: <http://www.ashp.org>

Vecuronium Bromide Injection

October 15, 2014

Reason for the Shortage

- Hospira states the shortage is due to manufacturing delays.
- Teva states the shortage is due to manufacturing delays.
- Pfizer sold vecuronium injection to Mylan Institutional in December 2013.
- Ben Venue has stopped production in its plant in Bedford, Ohio and closed in 2014.
- Sagent temporarily suspended the manufacture of vecuronium 10 mg and 20 mg vials.

Article link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=490>

Source link: <http://www.ashp.org>

Pantoprazole Tablets

October 15, 2014

Reason for the Shortage

- Actavis, Aurobindo, Mylan, Teva, and Torrent could not provide a reason for the shortage.
- Actavis discontinued pantoprazole 20 mg tablets in October 2014.
- Kremers Urban state the shortage is due to increased demand.
- FDA imposed an import ban in mid-2013 on several Wockhardt products including pantoprazole.

Article link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=979>

Source link: <http://www.ashp.org>

Multiple Vitamins for Infusion

October 15, 2014

Reason for the Shortage

- Hospira states the shortage is due to manufacturing delays.
- Baxter states the reason for the shortage is manufacturing delays.

Article link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=831>

Source link: <http://www.ashp.org>

Dexamethasone Sodium phosphate

October 15, 2014

Reason for the Shortage

- American Regent has dexamethasone sodium phosphate on shortage due to manufacturing delays.
- Fresenius Kabi states the dexamethasone sodium phosphate shortage was due to supply and demand issues.
- Baxter could not provide a reason for the shortage. Baxter sold several products to West-Ward in mid-2011.
- West-Ward had dexamethasone sodium phosphate injection on shortage due to increased demand.
- Pfizer divested all dexamethasone presentation to Mylan Institutional on December 6, 2013.

Article link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=751>

Source link: <http://www.ashp.org>

Cytarabine Injection

October 15, 2014

Reason for the Shortage

- Fresenius Kabi (formerly APP) had cytarabine on shortage due to increased demand.
- West-Ward Pharmaceuticals' parent company, Hikma Pharmaceuticals, acquired several products from Bedford Laboratories in July 2014 including cytarabine injection.
- Mylan Institutional acquired cytarabine injection from Pfizer on December 6, 2013. Mylan discontinued cytarabine 20 mg/mL 25 mL vials in 2014.
- Mylan Institutional has cytarabine on shortage due to increased demand and manufacturing delays.

Article link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=413>

Source link: <http://www.ashp.org>

Fluorescein Sodium Injection

October 16, 2014

Reason for the Shortage

- Altaire Pharmaceuticals temporarily discontinued fluorescein and fluorescein lite products. Altaire Pharmaceuticals could not provide a reason for the temporary discontinuation.
- Alcon could not provide a reason for the shortage.

Article link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1104>

Source link: <http://www.ashp.org>

Droperidol Injection

October 16, 2014

Reason for the Shortage

- American Regent has droperidol injection on back order due to manufacturing delays.
- Hospira has droperidol on back order due to shortage of raw material.

Article link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=818>

Source link: <http://www.ashp.org>

Doxorubicin liposomal injection

October 16, 2014

Reason for the Shortage

- Janssen Products, LP states the shortage is due to manufacturing issues. Janssen Products, LP has updates with information about the shortage on the Doxil website that is updated regularly.
- Janssen is working to transition Doxil manufacturing to additional suppliers. A temporary solution to this shortage was to use areas of the Ben Venue Laboratories facility available for production and other partners to complete the manufacturing process. FDA exercised regulatory discretion and approved an additional lot of 2 mg/mL 10 mL (20 mg) vials.
- Ben Venue has stopped production in its plant in Bedford, Ohio and will close in early 2014. Ben Venue supplies multiple sterile injectable products for Bedford Laboratories. Supplies of product that has already been manufactured will continue to be released

until inventory is depleted. Bedford Laboratories has a small number of products manufactured elsewhere that are not affected by this closure.

- Ben Venue has stopped production in its plant in Bedford, Ohio and closed in 2014.
- Caraco launched generic doxorubicin liposomal injection in mid-March 2013 and can supply the market with their presentations.

Article link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=806>

Source link: <http://www.ashp.org>

Diphtheria, tetanus toxoid, and acellular pertussis vaccine (DTaP)

October 16, 2014

Reason for the Shortage

- Sanofi Pasteur states the reason for the Daptacel shortage is manufacturing delay.
- Sanofi Pasteur discontinued Tripedia in 2011.

Article link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=922>

Source link: <http://www.ashp.org>

Diphtheria, tetanus toxoid, and acellular pertussis and inactivated poliovirus and Haemophilus B conjugate vaccine (DTaP-IPV/Hib)

October 16, 2014

Reason for the Shortage

- Sanofi Pasteur states the reason for the shortage is manufacturing delay, which will reduce supplies below current demand.

Article link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=921>

Source link: <http://www.ashp.org>

Diltiazem Injection

October 16, 2014

Reason for the Shortage

- Ben Venue stopped product in its plant in Bedford, Ohio and closed in July 2014.
- Hospira states the reasons for the shortage are manufacturing delays and increases in demand.

- West-Ward had diltiazem injection on shortage due to manufacturing delays caused by increased demand due to current market conditions.
- Akorn states the reason for the shortage is increased demand due to market conditions.
- Teva discontinued all diltiazem presentations in March, 2011.
- Biovail discontinued Cardizem Lyo-Ject in 2007 due to business reasons.

Article link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=217>

Source link: <http://www.ashp.org>

Dextran Low Molecular Weight (Dextran 40), 10% Injection

October 16, 2014

Reason for the Shortage

- Hospira states the reason for the shortage is manufacturing delay.

Article link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1108>

Source link: <http://www.ashp.org>

Dexpanthenol Injection

October 16, 2014

Reason for the Shortage

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

Article link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1103>

Source link: <http://www.ashp.org>

Cefazolin Injection

October 16, 2014

Reason for the Shortage

- Fresenius Kabi, BBraun, West-Ward, and WG Critical Care have cefazolin on shortage due to increased demand.
- Apotex and Sandoz have cefazolin on shortage due to manufacturing delays.
- Hospira has cefazolin on shortage due to manufacturing delays and increased demand.
- Sagent has cefazolin on shortage due to increased demand and shipping delays.

Article link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=987>

Source link: <http://www.ashp.org>

Bupropion Hydrochloride 24 hour ER Tablets

October 16, 2014

Reason for the Shortage

- Global, Mylan, and Par state the reason for the shortage is increased demand of product.

Article link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1106>

Source link: <http://www.ashp.org>

Retepase Injection

October 17, 2014

Reason for the Shortage

- Cornerstone Therapeutics acquired EKR Therapeutics in June 2012. EKR Therapeutics had previously purchased Retavase from PDL BioPharma.
- [Cornerstone is seeking FDA approval of a new supplier of the active pharmaceutical ingredient for Retevase.](#)

Article link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=569>

Source link: <http://www.ashp.org>

Polymyxin B Sulfate Injection

October 17, 2014

Reason for the Shortage

- Fresenius Kabi (formerly APP) could not provide a reason for the shortage.
- Sagent suspended manufacturing of Polymyxin B sulfate injection in October, 2012.
- West-Ward Pharmaceuticals' parent company, Hikma Pharmaceuticals, acquired several products from Bedford Laboratories in July 2014 including polymyxin B sulfate injection. West-Ward is not actively marketing polymyxin B sulfate injection.

Article link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=974>

Source link: <http://www.ashp.org>

Nebivolol Tablets

October 17, 2014

Reason for the Shortage

- Actavis could not provide a reason for the shortage.

Article link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1137>

Source link: <http://www.ashp.org>

Morphine Injections

October 17, 2014

Reason for the Shortage

- Fresenius Kabi (formerly APP) states the shortage is due to a change in manufacturing sites.
- Hospira states the shortage is due to manufacturing delays.
- Hospira discontinued preservative-containing Carpuject syringes in August, 2012 and replaced them with preservative-free Carpuject syringes.
- West-Ward states the shortage was due to increased demand for product. West-Ward changed old Baxter to new West-Ward NDC codes in early 2012.
- IMS (Amphastar) discontinued morphine 1 mg/mL 10 mL Luer-lock syringes in March, 2012 due to low demand for the product.

Article link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=664>

Source link: <http://www.ashp.org>

Methazolamide Tablets

October 17, 2014

Reason for the Shortage

- Sandoz cannot provide a reason for the shortage.

- Perrigo acquired Neptazane tablets and methazolamide tablets from Fera

Article link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=901>

Source link: <http://www.ashp.org>

Hydromorphone Hydrochloride Injection

October 17, 2014

Reason for the Shortage

- Hospira has hydromorphone injection on shortage due to manufacturing delays.

Article link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=856>

Source link: <http://www.ashp.org>

Heparin Sodium Injection

October 17, 2014

Reason for the Shortage

- FDA has issued import bans against 22 Chinese manufacturers of heparin due to inadequate good manufacturing practices (GMPs).¹
- West-Ward obtained five presentations of the heparin sodium injection from Baxter in September, 2011. Baxter only retained two large volume heparin presentations. All other Baxter presentations have been discontinued.^{2,3}
- Fresenius Kabi (formerly APP) reports that heparin products are on back order due to increased demand for the product.⁴
- Hospira states the shortage of heparin vials is due to manufacturing delays.⁵
- Covidien and B. Braun could not provide a reason for the shortage.^{9,11}
- Sagent had heparin on shortage due to increased demand for the product.⁶

Article link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=387>

Source link: <http://www.ashp.org>

Empty Evacuated Containers

October 17, 2014

Reason for the Shortage

- Baxter had empty evacuated containers on shortage due to supply constraints.
- B. Braun had evacuated glass containers on shortage due to increased demand for the product and raw material constraints.

Article link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=983>

Source link: <http://www.ashp.org>

Atenolol Tablets

October 17, 2014

Reason for the Shortage

- Avkare and Pack Pharmaceuticals could not provide a reason for the shortage.
- Ranbaxy has atenolol tablets on shortage due to manufacturing delays.
- Zydus has atenolol tablets on allocation due to increased demand.
- Aurobindo and Caraco have discontinued atenolol tablets.

Article link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1127>

Source link: <http://www.ashp.org>

Sodium Acetate Injection

October 20, 2014

Reason for the Shortage

- American Regent has sodium acetate on shortage due to manufacturing delays.
- American Regent has discontinued sodium acetate 2 mEq/mL 100 mL vials.
- Fresenius Kabi has sodium acetate on shortage due to increased demand.
- Hospira had sodium acetate on shortage due to increased demand.
- Baxter discontinued sodium acetate in June, 2008.

Article link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=762>

Source link: <http://www.ashp.org>

Oxytocin Injection

October 20, 2014

Reason for the Shortage

- Fresenius Kabi, USA (formerly APP) states the shortage is due to increased demand.
- Par Sterile Products (formerly JHP) discontinued generic oxytocin injection in July 2014.
- West-Ward states the shortage is due to stock becoming short-dated.

Article link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=876>

Source link: <http://www.ashp.org>

Nafcillin Sodium

October 20, 2014

Reason for the Shortage

- Auromedics and Fresenius Kabi state the reason for the shortage is increased demand.
- Sagent states the reason for the shortage is manufacturing delay.
- Sandoz states the reason for the shortage is internal issues.

Article link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1136>

Source link: <http://www.ashp.org>

Morrhuate Sodium Injection

October 20, 2014

Reason for the Shortage

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

Article link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=903>

Source link: <http://www.ashp.org>

Lidocaine Topical 4% Solution

October 20, 2014

Reason for the Shortage

- Hospira discontinued LTA Syringes kits on August 5, 2014 due to a business decision.
- Amphastar IMS has Laryng-O-Jets on shortage due to increased demand.

Article link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1128>

Source link: <http://www.ashp.org>

Lactated Ringer's Injection Bags

October 20, 2014

Reason for the Shortage

- Baxter has lactated ringer's on shortage due to increased demand.¹
- BBraun has lactated ringer's on allocation due to increased demand.²
- Hospira cites increased demand as the reason for the shortage.³

Article link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1078>

Source link: <http://www.ashp.org>

Fluorouracil Injection

October 20, 2014

Reason for the Shortage

- Fresenius Kabi (formerly APP) states fluorouracil was on allocation to prevent excessive purchases.¹
- Teva has fluorouracil on back order due to manufacturing issues.²
- Mylan Institutional discontinued their fluorouracil injection in Fall 2014.³
- Mylan Institutional acquired fluorouracil injection from Pfizer on December 6, 2013, but is not marketing these products.³

Article link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=798>

Source link: <http://www.ashp.org>

Fenoldopam Mesylate Injection

October 20, 2014

Reason for the Shortage

- Hospira has Corlopam ampules on shortage due to manufacturing delays.

Article link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1031>

Source link: <http://www.ashp.org>

Electrolyte Concentrate

October 20, 2014

Reason for the Shortage

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

Article link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1054>

Source link: <http://www.ashp.org>

Doxorubicin Injection

October 20, 2014

Reason for the Shortage

- West-Ward Pharmaceuticals' parent company, Hikma Pharmaceuticals, acquired Adriamycin injection from Bedford in July 2014. West-Ward is not actively marketing Adriamycin injection at this time.¹
- Pfizer had doxorubicin solution for injection on shortage due to shipping delays.⁵
- Sagent introduced doxorubicin injection in November 2013.⁶
- Mylan Institutional acquired doxorubicin lyophilized powder from Pfizer on December 6, 2013.⁷
- Teva could not provide a reason for the shortage.²

Article link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=464>

Source link: <http://www.ashp.org>

Divalproex Sodium Delayed Release Tablets

October 20, 2014

Reason for the Shortage

- Caraco, Mylan, Teva and Unichem Laboratories cannot provide a reason for the shortage.
- Aurobindo, Dr. Reddy's Laboratories, Lupin, and Qualitest discontinued divalproex sodium delayed release tablets.

- Upsher-Smith had divalproex sodium on long-term back order due to manufacturing delay. Product has recently become available but is being allocated to wholesalers.
- Zydus has divalproex sodium delayed-release tablets on allocation due to increased demand.

Article link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1124>

Source link: <http://www.ashp.org>

Dipyridamole Injection

October 20, 2014

Reason for the Shortage

- Bedford discontinued dipyridamole injection in May, 2011 to concentrate on the manufacturing of other products.
- Teva has temporarily discontinued their 2 mL and 10 mL products in order to increase the package sizes.

Article link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=465>

Source link: <http://www.ashp.org>

Dihydroergotamine Mesylate Injection

October 20, 2014

Reason for the Shortage

- Ben Venue has stopped production in its plant in Bedford, Ohio and closed in 2014.
- Valeant cannot provide a reason for the shortage of dihydroergotamine mesylate injection.

Article link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1050>

Source link: <http://www.ashp.org>

Cefpodoxime

October 20, 2014

Reason for the Shortage

- Ranbaxy has an import ban on all solid medications including cefpodoxime.
- Aurobindo could not provide a reason for the shortage.
- Pfizer has discontinued Vantin.
- Sandoz could not provide a reason for the shortage.

Article link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=793>

Source link: <http://www.ashp.org>

Azathioprine Injection

October 20, 2014

Reason for the Shortage

- West-Ward Pharmaceuticals' parent company, Hikma Pharmaceuticals, acquired azathioprine injection from Bedford in July 2014. West-Ward is not actively marketing azathioprine injection.
- There are no other manufacturers of azathioprine injection.
- The oral presentations are not affected by this shortage.

Article link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=935>

Source link: <http://www.ashp.org>

Albuterol Sulfate 0.5% Inhalation Solution

October 20, 2014

Reason for the Shortage

- Enterovirus D68 can cause mild to severe respiratory illness. In 2014, hospitals are seeing more children than usual with severe respiratory illness from enterovirus D68. This is leading to an increased demand for albuterol solution.
- Hi-Tech has albuterol 0.5% solution on back order due to increased demand.
- Albuterol sulfate 0.083% solution and albuterol HFA inhalers supplies remain available.

Article link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1130>

Source link: <http://www.ashp.org>

Torsemid Injection

October 21, 2014

Reason for the Shortage

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

Article link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=344>

Source link: <http://www.ashp.org>

Sodium Phosphate Injection

October 21, 2014

Reason for the Shortage

- American Regent has sodium phosphate injection on back order due to manufacturing delays.1,2
- [American Regent](#) has issued a statement that all lots of sodium phosphate have potential for crystallization. Do not use if any particles are present.3,4
- Hospira had sodium phosphate injection on shortage due to manufacturing delays.5
- In cooperation with FDA, Fresenius Kabi USA is providing Glycophos (sodium glycerophosphate) injection to the US market to help alleviate the shortage. Glycophos is manufactured in an FDA-approved facility in Norway by Fresenius Kabi AG.6
- Fresenius Kabi launched sodium phosphate injection in mid-January 2014.7

Article link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=770>

Source link: <http://www.ashp.org>

Phytonadione (Vitamin K) Injection

October 21, 2014

Reason for the Shortage

- Amphastar has vitamin K injection on shortage due to increased demand for the product.
- Hospira has vitamin K injection on shortage due to increased demand for the product.
- Oral vitamin K is not affected by this shortage.

Article link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=852>

Source link: <http://www.ashp.org>

Olanzapine Injection

October 21, 2014

Reason for the Shortage

- American Regent states the reason for the shortage is manufacturing delay.
- Sandoz states the reason for the shortage is increased demand.

Article link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1093>

Source link: <http://www.ashp.org>

Nitroglycerin Injection

October 21, 2014

Reason for the Shortage

- American Regent has recently upgraded their manufacturing plant. Product will become available in stages as production resumes.¹
- Hospira states the shortage is due to manufacturing delays.²
- Hospira discontinued nitroglycerin in Dextrose 5%, 40 mg/100 mL, 500 mL glass bottles (NDC 00409-1484-03) in 2010.²
- Baxter had nitroglycerin premixes on shortage due to a raw material supply issue.³
- In cooperation with FDA, Arbor Pharmaceuticals is importing glyceryl trinitrate (Nitronal) injection to the US market to help alleviate the national shortage. This glyceryl trinitrate is manufactured in an FDA-approved facility in Germany by Pohl Boskamp. Glyceryl trinitrate is another name for nitroglycerin.⁴

Article link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=786>

Source link: <http://www.ashp.org>

Methylprednisolone Acetate Injection

October 21, 2014

Reason for the Shortage

- Sandoz and Teva could not provide a reason for the shortage.
- Pfizer had Depo-Medrol injection on shortage due to manufacturing delay.

Article link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=923>

Source link: <http://www.ashp.org>

Indigo Carmine Injection

October 21, 2014

Reason for the Shortage

- American Regent has indigo carmine on back order due to manufacturing delays.¹
- Akorn has discontinued production of indigo carmine due to shortage of raw material. Akorn is looking for a new raw material supplier.²

Article link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=861>

Source link: <http://www.ashp.org>

Hydroxyzine Injection

October 21, 2014

Reason for the Shortage

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

Article link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=829>

Source link: <http://www.ashp.org>

Furosemide Injection

October 21, 2014

Reason for the Shortage

- Fresenius Kabi (formerly APP) has furosemide injection on shortage due to increased demand for the product.1
- American Regent has furosemide injection on shortage due to manufacturing delays.3
- Hospira states the shortage was due to manufacturing delays.5
- Wockhardt has discontinued all furosemide injection presentations.6

Article link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=636>

Source link: <http://www.ashp.org>

Fosphenytoin Injection

October 21, 2014

Reason for the Shortage

- Akorn discontinued fosphenytoin injection in 2011.1
- Fresenius Kabi recalled numerous lots of fosphenytoin due to particulate matter potentially from glass delamination and consistent with glass particulates observed in samples. Fresenius Kabi has a [letter](#) discussing the lot numbers and what to do with affected product.2
- American Regent discontinued fosphenytoin injection in late-2010.3
- Bedford discontinued fosphenytoin in May, 2011 to concentrate on the manufacturing of other products.4
- Hospira states the shortage is due to manufacturing delays.5,6
- Pfizer discontinued the Cerebyx 500 mg presentation in September, 2009 and the 1 gram presentation in early-February, 2010.7
- Pfizer launched Cerebyx 2 mL and 10 mL vials in October 2013.7
- Teva, Apotex, Baxter, GeneraMedix, and Wockhardt have discontinued their fosphenytoin presentations.8-12

Article link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=127>

Source link: <http://www.ashp.org>

Atropine Sulfate Injection

October 21, 2014

Reason for the Shortage

- American Regent states the shortage is due to manufacturing delays.
- Hospira states the shortage is due to manufacturing delays.
- Amphastar has atropine on shortage due to increased demand.

Article link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=814>

Source link: <http://www.ashp.org>

Tamsulosin Hydrochloride Capsules

October 22, 2014

Reason for the Shortage

- Boehringer Ingelheim could not provide a reason for the shortage.
- Actavis and Zydus state the reason for the shortage is increased demand.
- Aurobindo is not marketing the 100 count size.
- Caraco cannot provide a reason for the shortage.
- Teva discontinued tamsulosin 0.4 mg capsules in April 2014.
- Par discontinued tamsulosin 0.4 mg capsules.

Article link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1112>

Source link: <http://www.ashp.org>

Tamoxifen Tablets

October 22, 2014

Reason for the Shortage

- Teva and Mylan could not provide a reason for the shortage.
- Actavis could not provide a reason for the shortage.

Article link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1071>

Source link: <http://www.ashp.org>

Radium Ra 223 Dichloride Injection

October 22, 2014

Reason for the Shortage

- Bayer states the reason for the shortage is manufacturing delay.
- A Dear [Healthcare Professional Letter](#), which describes the shortage and dosing delays.

Article link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1138>

Source link: <http://www.ashp.org>

Dexmethylphenidate Hydrochloride

October 22, 2014

Reason for the Shortage

- Teva has product on allocation and shortage is due to DEA quotas that are projected annually.
- Mylan could not provide a reason for the shortage.
- Novartis stated the reason for the shortage was increased demand.

Article link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1079>

Source link: <http://www.ashp.org>

Calcitriol Injection

October 22, 2014

Reason for the Shortage

- Akorn had calcitriol injection on shortage due to increased demand for the product.
- American Regent has calcitriol on back order due to manufacturing delays.
- Abbott discontinued Calcijex in April 2012.
- West-Ward discontinued their calcitriol injection in May, 2011.
- Calcitriol capsule and oral solution presentations are available from multiple manufacturers.
- Fresenius Kabi (formerly APP) discontinued calcitriol injection in January 2014.

Article link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=940>

Source link: <http://www.ashp.org>

Bacitracin Topical Ointment

October 22, 2014

Reason for the Shortage

- Altaire, Sandoz, and Qualitest cannot provide a reason for the shortage.

Article link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=677>

Source link: <http://www.ashp.org>

Amphetamine Mixed Salts, Immediate-Release Tablets

October 22, 2014

Reason for the Shortage

- Teva has product on allocation and shortage is due to DEA quotas that are projected annually.

Article link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=836>

Source link: <http://www.ashp.org>

Acyclovir Suspension

October 22, 2014

Reason for the Shortage

- Actavis could not provide a reason for the shortage.

Article link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1018>

Source link: <http://www.ashp.org>

Trace Elements Injection

October 23, 2014

Reason for the Shortage

- American Regent has trace element injection on back order due to manufacturing delays.^{1,2}
- American Regent is the sole supplier of FDA-approved combined trace elements.
- In cooperation with FDA, Fresenius Kabi USA is providing Addamel N (adult trace element injection) and Peditrace (pediatric trace element injection) to the US market to help alleviate the shortage. Addamel N and Peditrace are manufactured in an FDA-approved facility in Norway by Fresenius Kabi AG, the parent company of Fresenius Kabi, USA.³

Article link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=785>

Source link: <http://www.ashp.org>

Rabies Immune Globulin

October 23, 2014

Reason for the Shortage

- Sanofi Pasteur states the reason for the shortage is increased demand and manufacturing delay.¹

Article link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=331>

Source link: <http://www.ashp.org>

Prednisone Tablets

October 23, 2014

Reason for the Shortage

- Cadista states the shortage was due to a raw materials shortage.
- Perrigo discontinued prednisone tablets in 2013.
- Roxane and Watson could not provide a reason for the shortage.
- Qualitest discontinued prednisone 20 mg tablets in August 2013.
- West-Ward states the reason for the shortage is manufacturing delays.

Article link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=930>

Source link: <http://www.ashp.org>

Pramipexole Dihydrochloride Tablets

October 23, 2014

Reason for the Shortage

- Avkare, Aurobindo, Mylan, Sandoz, and Torrent cannot provide a reason for the shortage.
- Zydus has pramipexole on allocation due to increased demand.

Article link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1131>

Source link: <http://www.ashp.org>

Potassium Chloride Injection

October 23, 2014

Reason for the Shortage

- Hospira states the reason for the shortage is manufacturing delays.
- Fresenius Kabi and Baxter could not provide a reason for the shortage.

Article link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=696>

Source link: <http://www.ashp.org>

Phentolamine Mesylate for Injection

October 23, 2014

Reason for the Shortage

- West-Ward Pharmaceuticals' parent company, Hikma Pharmaceuticals, acquired phentolamine injection from Bedford in July 2014. West-Ward is actively marketing phentolamine injection.

Article link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=349>

Source link: <http://www.ashp.org>

Pancuronium Injection

October 23, 2014

Reason for the Shortage

- Teva discontinued their pancuronium presentations in May, 2010.1
- Hospira's product is on back order due to manufacturing delays and retesting of raw material. Hospira is the only manufacturer of pancuronium.2

Article link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=851>

Source link: <http://www.ashp.org>

Mupirocin Calcium 2% Nasal Ointment

October 23, 2014

Reason for the Shortage

- GlaxoSmithKline could not provide a reason for the shortage.
- Mupirocin cream is not affected by this shortage.
- Mupirocin 22 gram tubes are not affected by this shortage.

Article link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1094>

Source link: <http://www.ashp.org>

Hydrocortisone Sodium Succinate Injection

October 23, 2014

Reason for the Shortage

- Hospira has A-Hydrocort on shortage due to requirements related to good manufacturing practices.
- Pfizer had Solu-Cortef on shortage due to manufacturing delays.

Article link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=925>

Source link: <http://www.ashp.org>

Haloperidol Decanoate Injection

October 23, 2014

Reason for the Shortage

- Teva products are on shortage due to manufacturing delays.
- Fresenius Kabi could not provide a reason for the shortage.
- West-Ward Pharmaceuticals' parent company, Hikma Pharmaceuticals, acquired haloperidol decanoate injection from Bedford in July 2014. West-Ward is not actively marketing haloperidol decanoate injection at this time.

Article link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=526>

Source link: <http://www.ashp.org>

Fludarabine Injection

October 23, 2014

Reason for the Shortage

- Fresenius Kabi, USA (formerly APP) had fludarabine lyophilized powder for injection on shortage due to focus on supplying solution for injection.1
- Fresenius Kabi, USA had fludarabine solution for injection on shortage due to increased demand.1
- Teva had fludarabine on shortage due to manufacturing delays.2
- Sagent had fludarabine on shortage due to manufacturing delays.3
- Hospira had fludarabine on shortage due to manufacturing delays.4,5
- Sandoz had fludarabine on back order due to manufacturing delays.6
- Mylan Institutional temporarily discontinued fludarabine injection in late-April 2013.7
- Genzyme discontinued Fludara in July, 2012.8

Article link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=648>

Source link: <http://www.ashp.org>

Dacarbazine Injection

October 23, 2014

Reason for the Shortage

- Fresenius states the reason for the shortage is increased demand.4
- Teva had dacarbazine on back order due to manufacturing delays.1

- West-Ward Pharmaceuticals' parent company, Hikma Pharmaceuticals, acquired dacarbazine injection from Bedford in July 2014. West-Ward is not actively marketing dacarbazine injection at this time.^{2,5}

Article link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=949>

Source link: <http://www.ashp.org>

Cyanocobalamin Injection

October 23, 2014

Reason for the Shortage

- American Regent has cyanocobalamin injection on shortage due to manufacturing delays.¹
- Fresenius Kabi has cyanocobalamin injection on shortage due to increased demand for the product.²

Article link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=947>

Source link: <http://www.ashp.org>

Clindamycin Injection

October 23, 2014

Reason for the Shortage

- Pfizer states the Cleocin Add-Vantage vials are on shortage due to manufacturing delays.
- Hospira has clindamycin injection on shortage due to manufacturing delays.
- Akorn launched clindamycin injection in June 2013.
- Sandoz had clindamycin injection on shortage due to increased demand.
- Sagent has clindamycin injection on shortage due to manufacturing delays.

Article link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1029>

Source link: <http://www.ashp.org>

Calcium Chloride Injection

October 23, 2014

Reason for the Shortage

- American Regent has calcium chloride on shortage due to manufacturing delays.
- Amphastar has calcium chloride on shortage due to increased demand.
- Hospira has calcium chloride on shortage due to manufacturing delays.

Article link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=941>

Source link: <http://www.ashp.org>

Acetylcysteine Inhalation Solution

October 23, 2014

Reason for the Shortage

- American Regent has acetylcysteine inhalation on shortage due to manufacturing delays.
- Roxane Labs discontinued acetylcysteine inhalation solution in April 2014. The product had previously been on shortage due to manufacturing delays.
- Hospira has acetylcysteine inhalation solution on shortage due to manufacturing delay.
- Fresenius Kabi (formerly APP) states the reason for the shortage was increased demand.

Article link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=932>

Source link: <http://www.ashp.org>

Tobramycin Injection

October 24, 2014

Reason for the Shortage

- Teva has tobramycin solution for injection on shortage due to manufacturing delays.
- Hospira has tobramycin on shortage due to manufacturing delays.
- Fresenius Kabi has tobramycin solution for injection on shortage due to increased demand.
- Pfizer acquired tobramycin injection from Akorn in early-May, 2011.
- Pfizer divested tobramycin injection to Mylan Institutional on December 6, 2013.
- Mylan Institutional could not provide a reason for the shortage.

Article link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=701>

Source link: <http://www.ashp.org>

Piperacillin Tazobactam Injection

October 24, 2014

Reason for the Shortage

- Apotex has piperacillin/tazobactam on shortage due to regulatory delays.
- Aurobindo and Sandoz could not provide a reason for the shortage.
- Hospira and Sagent have piperacillin/tazobactam on shortage due to increased demand.
- Pfizer has Zosyn on shortage due to shipping delays
- WG Critical Care states the reason for the shortage was increased demand.

Article link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1075>

Source link: <http://www.ashp.org>

Magnesium Sulfate Injection

October 24, 2014

Reason for the Shortage

- American Regent has magnesium sulfate on shortage due to manufacturing delays.
- Fresenius Kabi (formerly APP) had magnesium sulfate injection on shortage due to increased demand for the product.
- Hospira has magnesium sulfate injection on shortage due to manufacturing delays.

Article link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=757>

Source link: <http://www.ashp.org>

Ketorolac Tromethamine Injection

October 24, 2014

Reason for the Shortage

- American Regent discontinued all ketorolac injection presentations in 2010.

- Fresenius Kabi (formerly APP) states the shortage is due to manufacturing delays.
- Cura filed for bankruptcy in 2010.
- Hospira has ketorolac on shortage due to manufacturing delays for quality improvement activities and increased demand for the product.
- Ben Venue closed its plant in Bedford, Ohio in July 2014.
- West-Ward has ketorolac injection on shortage due to manufacturing delays.
- FDA imposed an import ban in mid-2013 on several Wockhardt products including ketorolac.

Article link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=593>

Source link: <http://www.ashp.org>

Dopamine Injection

October 24, 2014

Reason for the Shortage

- B Braun discontinued their dopamine premix in November 2012 due to raw material supply issues.
- Hospira states the shortage is due to manufacturing delays.
- American Regent has recently upgraded their manufacturing plant. Product will become available in stages as production resumes.
- Baxter had dopamine on allocation due to increased demand.

Article link: <http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=88>

Source link: <http://www.ashp.org>

Deferoxamine Mesylate Injection

October 24, 2014

Reason for the Shortage

- Fresenius Kabi states the shortage is due to increased demand.
- Hospira has deferoxamine on shortage due to manufacturing delays.
- Teva discontinued all deferoxamine presentations in 2013.
- Watson discontinued all deferoxamine presentations.

- West-Ward Pharmaceuticals' parent company, Hikma Pharmaceuticals, acquired deferoxamine injection from Bedford in July 2014. West-Ward is not actively marketing deferoxamine injection at this time.

Article link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1008>

Source link: <http://www.ashp.org>

Bupivacaine Injection

October 24, 2014

Reason for the Shortage

- Fresenius Kabi (formerly APP) has Sensorcaine on shortage due to increased demand for the product.
- Hospira has Marcaine and bupivacaine on shortage due to manufacturing delays.
- AuroMedics introduced bupivacaine injection in February 2014.

‡ Please refer to ASHP website for more information

NEW DRUGS COMING TO MARKET

PRODUCT	MFR	ROUTE	INDICATION	PHARMACOLOGY	MARKET RELEASE
Lumigan® (Bimatoprost)	Allergan	Ophthalmic	Glaucoma	A prostaglandin analog with hypotensive activity	Patent Extended until March 2025
Nasonex® (mometasone furoate monohydrate)	Merck	Inhaled insulin	Nasal symptoms of allergic rhinitis, nasal congestions associated with seasonal allergic rhinitis, treatment of nasal polyps	Metered, nasal spray of corticosteroid demonstrating potent anti-inflammatory properties.	Patent extended until October 3, 2017 or April 3, 2018
Renagel® (sevelamer hydrochloride)	Genzyme	PO	Hyperphosphatemia in chronic kidney disease on dialysis	Phosphate binder to control serum phosphorus	Impax Lab granted license to sell oral suspension 9/16/2014
Celebrex® (celecoxib)	Pfizer	PO	Anti-inflammatory drug for osteoarthritis, rheumatoid arthritis, juvenile rheumatoid arthritis, ankylosing spondylitis, acute pain, and primary dysmenorrhea	Nonsteroidal anti-inflammatory drug that inhibits prostaglandin synthesis primarily via COX-2 resulting in anti-inflammatory, analgesic, and antipyretic activities.	Teva and Mylan received approval to market 5/30/2014
Intuniv® (guanfacine hydrochloride)	Shire	PO	Attention Deficit Hyperactivity Disorder (ADHD)	Central α -2 adrenergic receptor agonist used as monotherapy or adjunctive therapy for ADHD.	FDA granted Actavis' ANDA 180 days market exclusivity. Actavis can launch 12/1/2014
Invega® (paliperidone)	Janssen	PO	Schizophrenia and schizoaffective disorder	Proposed central dopamine type 2 (D ₂) and serotonin type 2 (5HT _{2A}) receptor antagonism	Patent expires October 6, 2014 but no known generic release date
Travatan Z® (travoprost)	Alcon	Ophthalmic	Open-angle glaucoma or ocular hypertension	Prostaglandin analog that binds to prostanoid receptor thus reducing intraocular pressure by increasing uveoscleral	Patent doesn't expire until October 13, 2029.

PRODUCT	MFR	ROUTE	INDICATION	PHARMACOLOGY	MARKET RELEASE
				outflow.	
Copaxone® (glatiramer acetate)	Teva pharma	INJ (SQ)	Relapsing-forms of multiple sclerosis	Modifies the immune processes that are believed to be responsible for the pathogenesis of MS	Patent expired May 2014; Teva appeal 10/15/2014 for validity of patent.
Nexium® (esomeprazole)	AstraZeneca	PO	Gastroesophageal reflux disease (GERD)	Proton pump inhibitor (PPI)	AstraZeneca made a patent settlement with Ranbaxy to launch a generic on 5/27/2014. Due to quality concerns, FDA hasn't approved the company's generic. Pfizer launched OTC 5/2014
Restasis® (cyclosporine)	Allergan, Inc.	Ophthalmic	Increase tear production for chronic dry eye	Immunosuppressive agent presumed to suppress inflammation that may be preventing tear production	Unknown
Viracept® (nelfinavir mesylate)	ViiV Healthcare	PO	HIV	Protease inhibitor for HIV-1 infection as combination therapy with other antiretrovirals agents.	Unknown
Vivelle Dot® (estradiol transdermal system)	Novartis	Transdermal patch	Moderate to severe vasomotor symptoms, vulvar, and vaginal atrophy due to menopause	Transdermal component contains estradiol which is delivered throughout the day	12-16-2013